SELF-ASSESSMENT OF THE NATIONAL REGULATORY INFRASTRUCTURE FOR SAFETY

Finland

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IAEA SAFETY STANDARDS (the basis of the SARIS self-assessment questionnaires)

Under the terms of Article III of its Statute, the IAEA is authorized to establish standards of safety for protection against ionizing radiation and to provide for the application of these standards to peaceful nuclear activities.

The regulatory related publications by means of which the IAEA establishes safety standards and measures are issued in the **IAEA Safety Standards Series**. This series covers nuclear safety, radiation safety, transport safety and waste safety, and also general safety (that is, of relevance in two or more of the four areas), and the categories within it are **Safety Fundamentals, Safety Requirements and Safety Guides**:

Safety Fundamentals (blue lettering) present basic objectives, concepts and principles of safety and protection in the development and application of nuclear energy for peaceful purposes.

Safety Requirements (red lettering) establish the requirements that must be met to ensure safety. These requirements, which are expressed as 'shall' statements, are governed by the objectives and principles presented in the Safety Fundamentals.

Safety Guides (green lettering) recommend actions, conditions or procedures for meeting safety requirements. Recommendations in Safety Guides are expressed as 'should' statements, with the implication that it is necessary to take the measures recommended or equivalent alternative measures to comply with the requirements.

The IAEA's safety standards are not legally binding on Member States but may be adopted by them, at their own discretion, for use in national regulations in respect of their own activities. The standards are binding on the IAEA in relation to its own operations and on States in relation to operations assisted by the IAEA.

Information on the IAEA's safety standards programme (including editions in languages other than English) is available at the IAEA Internet site:

https://www-ns.iaea.org/standards/

Or on request to the Safety and Security Coordination Section, IAEA, P.O. Box 100, A-1400 Vienna, Austria.

OTHER RELEVANT SAFETY RELATED PUBLICATIONS

Under the terms of Articles III and VIII.C of its Statute, the IAEA makes available and fosters the exchange of information relating to peaceful nuclear activities and serves as an intermediary among its Member States for this purpose.

Reports on safety and protection in nuclear activities are issued in other series, in particular **the IAEA Safety Reports Series**, as informational publications. Safety Reports may describe good practices and give practical examples and detailed methods that can be used to meet safety requirements. They do not establish requirements or make recommendations.

Other IAEA series that include safety related publications are the **Technical Reports Series**, the **Radiological Assessment Reports Series**, the **INSAG Series**, the **TECDOC Series**, the **Provisional Safety Standards Series**, the **Training Course Series**, the **IAEA Services Series**, the **Computer Manual Series**, and **Practical Radiation Safety Manuals** and **Practical Radiation Technical Manuals**. The IAEA also issues reports on radiological accidents and other special publications.

SELF-ASSESSMENT OF THE NATIONAL REGULATORY INFRASTRUCTURE FOR SAFETY

BACKGROUND

The International Atomic Energy Agency (IAEA) is responsible for the development of standards for the safety and protection of health, environment and property against ionizing radiation and for assisting their application in States through appropriate mechanisms such as peer review, appraisal and training. The IAEA applies the standards to its own operations and wherever it is supporting Member States. In addition, at the request of third parties, the IAEA applies the standards to operations under bilateral or multilateral arrangements or, at the request of a State, to any of that State's activities concerning nuclear energy.

IAEA standards and guidance are based on the presumption that a national infrastructure is in place to enable a government to discharge its responsibilities for radiation protection, safety and the security of radioactive sources.

A national infrastructure for nuclear and radiation safety includes all persons, organizations, qualified experts, systems, documents, facilities and equipment, and technical services that are, in whole or in part, dedicated to nuclear and radiation safety.

The IAEA offers a range of reviews, appraisals and advisory services to help States' verify that standards and international undertakings are adequately applied at the national level and to evaluate the effectiveness and sustainability of State regulatory infrastructure. In particular, the IAEA offers the *Integrated Regulatory Review Service* (IRRS) covering all aspects of nuclear, radiation, transport and waste safety and emergency planning. The IRRS is a comprehensive and modular service addressing all components of a national regulatory infrastructure for safety. It comprises an *internal* self-assessment phase, followed by an *external* expert team review.

To facilitate States' regular and routine self-assessment of national regulatory infrastructure for nuclear and radiation safety, the Agency has developed the IAEA Self-Assessment Methodology and its associated software, the Self-Assessment of Regulatory Infrastructure for Safety (SARIS). The SARIS is a stand-alone system; however, it is fully compatible with the IRRS Guidelines and may also be used in preparation for IRRS.

This Report contains factual answers to the SARIS questions (themselves derived from the IAEA standards and international undertakings). In addition, it incorporates appended documentary evidence to support the answers given and an analysis of the responses, both by SARIS Module and collectively for all Modules addressed in this self-assessment cycle. Within this report there is also an electronically generated 'Priority Assignment' (PA) value for each Module and for the whole self-assessment, providing an indication of where the most immediate needs for improvement may lie. The SARIS and this report are structured in such a way to facilitate action planning for the continuous improvement of regulatory infrastructure in accordance with identified priorities and realistically achievable objectives.

The Report is freely editable, but once agreed as a complete and accurate record, it can be archived in unchangeable form, thus serving as an important record of the status of the regulatory infrastructure at a particular point in time.

The Self-Assessment Report for
Finland

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REPORT FOR Finland

Introduction

This electronically-generated SARIS Report documents findings against each completed SARIS Module, together with an overview and the basis for any findings. It also provides a Priority Assignment (PA) value for each completed Module and for the national regulatory infrastructure as a whole. Both the electronically-generated report and the PA values are for guidance only. In the analysis phase of a self-assessment cycle (performed in accordance with the IAEA methodology) it is expected that the content of the SARIS Report will be modified manually to reflect extensive internal discussion and consensus on the findings, conclusions and recommendations for improvement.

The SARIS Report and the PA values contained within it are not an alternative to a properly conducted peer review or appraisal. The IAEA self-assessment methodology and the SARIS provide a comprehensive process of self-assessment and indicate priority areas for improvement. It is recommended that the outcomes of any such internal assessment are occasionally verified by an external review process (such as the IRRS).

The SARIS report and PA values may be used to objectively inform discussions with IAEA and other organisations with regard to advice, guidance, support and assistance as appropriate, in all areas addressed during a self-assessment.

FINDINGS

This section presents your responses to the questionnaire, which is arranged in a number of core and thematic SARIS Modules. An electronically-generated conclusion and PA value is provided for each completed SARIS Module.

ANALYSIS

When the question-answering (response phase) for each SARIS Module is completed, the analysis phase begins for that Module. The SARIS is structured to enable the SARIS questionnaire responses to be reviewed and analysed. The Analysis Team's output for each Module and for the overall scope of the self-assessment, are presented in terms of the regulatory infrastructure's identified strengths, weaknesses, opportunities and threats, culminating in the Analysis Team's overall conclusions and recommendations, as incorporated in this SARIS Report.

Table of Contents

OUTCOMES OF THE SELF-ASSESSMENT FOR CORE QUESTIONS (CORE IRRS MODULES)

Module: 01. Responsibilities and Functions of the Government

Findings

Question 1 Has the Government established a national policy and strategy for safety?

Answer: Yes

Response:

In Finland, the policies and strategies for radiation and nuclear safety are mainly expressed through legislation. The fundamental safety objectives are set out in the Nuclear Energy Act (hereafter YEL) and in Radiation Act (hereafter SätL):

- According to Sections 5 and 6 of YEL the use of nuclear energy shall be in line with the overall good of society, and in particular shall ensure that the use of nuclear energy is safe for man and the environment and does not promote the proliferation of nuclear weapons. Basic safety principles are provided in Chapter 2 A of YEL. The Act lays down general principles for the use of nuclear energy, the implementation of nuclear waste management, the licensing and control of the use of nuclear energy, and the competent authorities.

- The purpose of the SätL is to protect human health against detriments caused by exposure to radiation. The Act also aims to prevent and reduce environmental and other detriments of radiation (Section 1). General principles of radiation protection are provided in Chapter 2, the responsibility for safety in Section 22, the general principles regarding radioactive waste are addressed in Sections 78 and 82 and the prohibitions on the use radioactive substances in Section 68. The SätL covers the use of radiation and other radiation practices, emergency exposure situations and existing exposure situations.

YEL (Sections 4-6 b) includes e.g. the following safety principles:

- Nuclear explosives: Import of nuclear explosives as well as their manufacture, possession and detonation in Finland are prohibited.
- Overall good of society: The use of nuclear energy, taking into account its various effects, shall be in line with the overall good of society.
- Safety: The use of nuclear energy must be safe; it shall not cause injury to people, or damage to the environment or property. The license holder or a party with waste management obligations are responsible for safety. This obligations cannot be transferred to another.

- Management of nuclear waste generated in Finland: Nuclear waste generated in connection with or as a result of use of nuclear energy in Finland shall be handled, stored and permanently disposed of in Finland.
- Provisions concerning nuclear waste not generated in Finland: Nuclear waste generated in connection with or as a result of the use of nuclear energy elsewhere than in Finland, shall not be handled, stored or permanently disposed of in Finland.
- Physical protection and emergency planning and other comparable arrangements: Sufficient physical protection and emergency planning as well as other arrangements for limiting nuclear damage and for protecting nuclear energy against illegal activities shall be a prerequisite for the use of nuclear energy.

More detailed principles are given in Chapter 2 A of YEL.

SätL (Sections 5 – 7, 22, 68, 78 and 82) include the following principles:

- General principles of radiation protection: Principle of justification, Principle of optimization, Principle of limitation
- Responsibility for safety: The undertaking is responsible for the radiation safety of the practice. This responsibility cannot be transferred to another.
- Prohibition of the use of radioactive substances in foodstuffs, animal feed, cosmetic products, jewelry and other equivalent personal accessories, toys and tracers tests carried out in water supply systems the water of which is used as household water.
- Radiation practices shall be organized in such a way that they generate as little radioactive waste as practically possible without compromising the practice's accordance with the principle of justification, optimization and limitation.
- Radioactive waste generated in radiation practices may not be deliberately diluted for the purpose of releasing it from regulatory control.
- A radiation source manufactured outside Finland may not be imported or transferred to Finland as radioactive waste.

In the following it is described how the principles of IAEA Safety Fundamentals have been covered in the Finnish legislation. More detailed requirements related also to Safety Fundamentals are presented in STUK regulations and YVL Guides.

Principle 1: Responsibility for safety

- YEL Chapter 2, 2 A and Sections 6 and 9; "The use of nuclear energy must be safe and it shall not cause harm to people or damage to the environment or property.". "The licence holder shall be under an obligation to ensure the safe use of nuclear energy. This obligation may not be delegated to another party."

- SätL Section 22 states that: “The undertaking is responsible for the radiation safety of the practice. This responsibility cannot be transferred to another.” and further specifies that: “The obligations imposed on undertakings are not diminished by the appointment of a radiation safety officer or some other person in charge or by the use of experts in the operations.”

Principle 2: Role of government

According to The Constitution of Finland (731/1999) section 3 the legislative powers are exercised by the Parliament. The proposal for the enactment of an Act is initiated in the Parliament through a government proposal submitted by the Government or through a legislative motion submitted by a Representative. (section 70) The President of the Republic, the Government and a Ministry may issue Decrees on the basis of authorisation given to them in this Constitution or in another Act. However, the principles governing the rights and obligations of private individuals and the other matters that under this Constitution are of a legislative nature shall be governed by Acts. If there is no specific provision on who shall issue a Decree, it is issued by the Government. Moreover, other authorities may be authorised by an Act to lay down legal rules on given matters, if there is a special reason pertinent to the subject matter and if the material significance of the rules does not require that they be laid down by an Act or a Decree. The scope of such an authorisation shall be precisely circumscribed. (section 80).

The Government and Ministries may issue Decrees and STUK legal rules (regulation) on the basis of authorisation given to them in YEL and SätL.

The YEL and SätL adopted by the Parliament on the Government's proposal establishes the legal and governmental framework for the regulation of facilities and activities. The regulatory framework enables to fulfil all national responsibilities and international obligations effectively. The Ministry of Social Affairs and Health has supreme authority and highest directing power in supervising compliance with the SätL. The Ministry of Economic Affairs and Employment has supreme authority and highest directing power in supervising compliance with the SätL in matters concerning the use of nuclear energy as referred to in the Nuclear Energy Act (Section 13 of SätL). The relation of SätL to other legislation has been clearly defined in the Section 3 of SätL.

The regulatory framework enables the establishment of an independent regulatory body (Act on STUK, SätL Section 14), which is described in details in the Module 3.

Government has ensured that arrangements are made for preparing programmes of actions to reduce radiation risks. A national programme for the waste management of radioactive waste outlining the general goals and principles of the waste management of radioactive waste as well as the amounts and locations of the waste, and an estimate of the costs and schedules of the waste management has to be established according to the Section 89 of SätL. State's subsidiary duties on ensuring that the radioactive waste is rendered harmless is stipulated in the Section 80 of SätL. Control of orphan sources is stipulated in the Section 86 of SätL.

Preparation of national action plans have been stipulated for identifying existing exposure situations and for the implementation of the measures referred to in the plan (Section 142 of SätL) and for the prevention of long term risks arising from radon (Section 159 of SätL). According to the Section 139 of SätL, in existing exposure situations the State takes care of the cleaning the areas, facilities, structures and the environment of radioactive substances to the extent that: 1) the undertaking or holder of the area does not within a reasonable period of time meet or cannot be expected to meet its duty of care specified in section 138; or 2) the undertaking responsible cannot be identified.

Principle 3: Leadership and management for safety

- YEL Section 7 k and Section 7 j; STUK Regulation on the Safety of Nuclear Power Plants 1/Y/2018 Chapter 6; STUK Regulation on the Safety of Disposal of Nuclear Waste Chapter 9; SätL Section 12, 29. "The licence holder shall appoint a responsible manager and his or her deputy. A nuclear facility shall have a management system. The management system of the nuclear facility shall take into account in particular the impact of the safety perceptions and attitudes of management and personnel on maintaining and development of safety, as well as systematic practices and their regular assessment and development. When designing, constructing, operating and decommissioning a nuclear facility, a good safety culture shall be maintained."

The organization's management shall ensure leadership for the management of safety (SätL Section 12). In practices subject to a safety licence, the undertaking must have a written management system for the radiation practice according to the Section 29 of SätL. The management of an organization shall ensure that the organization's activities maintain and develop a good safety culture (Section 12).

Principle 4: Justification of facilities and activities

According to YEL section 5, the use of nuclear energy, taking into account its various effects, shall be in line with the overall good of society. In addition the general provision of the Radiation Act section 5 applies to the use of nuclear energy (YEL section 2 a).

Radiation practices and protective actions are justified if the overall benefits achieved exceed the detriment caused (SätL Section 5). The undertaking shall demonstrate that a new type of radiation practice subject to a safety licence is justified. The same applies to existing radiation practices if new important information on the efficiency, possible consequences or alternative methods or techniques of the practice is obtained (SätL Section 24). Individual examination, procedure or treatment resulting in medical exposure which is not generally justified may be considered justified with respect to a single individual due to a special need related to them (SätL Section 110).

Principle 5: Optimization of protection

According to YEL section 7a the safety of nuclear energy use shall be maintained at as high a level as practically possible. For the further development of safety, measures shall be implemented that can be considered justified considering operating experience and safety research and advances in science and technology. The safety requirements and measures for ensuring safety shall be graded and targeted so as to be commensurate with the risks in the use of nuclear energy. In addition, the general provision of the Radiation Act section 6 applies to the use of nuclear energy (YEL section 2 a).

To optimize radiation protection, occupational exposure and public exposure to ionizing radiation shall be kept as low as is reasonably achievable, and medical exposure shall be limited to what is necessary to achieve the intended examination or treatment result and performance of the procedure (SätL Section 6). Further provisions, including factors to be considered in the optimization of protection, are prescribed in Sections 2 and 8–11 of VnA 1034/2018. Use of dose constraints in the optimization is stipulated in the Section 9 of SätL and further provisions on dose constraints for members of the public, workers and potential exposure are in the Chapter 3 of STUK Regulation S/6/2019.

Principle 6: Limitation of risks to individuals

In nuclear and radiation practices the radiation dose of workers and members of the public during normal operation may not exceed the dose limit (SätL Section 7). Dose limits are stipulated in the Chapter 3 of the VnA 1034/2018.

YEL Section 7 c lays down further requirements for the works at the nuclear facilities and individuals in the public. Section 7d requires preparation for the operational occurrences and accident in the nuclear facilities. The dose limits for the individual in the public in different types of events are set in

the YEA Section 22b for nuclear power plants, in Section 22c for mining and enrichment facilities and in Section 22d for nuclear waste management facilities and final disposal facilities.

Principle 7: Protection of present and future generations

According to YEL Section 6 The use of nuclear energy must be safe and it shall not cause harm to people or damage to the environment or property. The guiding principle is that the safety of nuclear energy use shall be maintained at as high a level as practically possible (YEL Section 7a). The principles apply both to nuclear facilities in operation or under decommissioning, and to facilities disposing of nuclear waste. The present generation is protected by means of design of facilities with sufficient levels of independent protection (YEL Section 7b) and preparation for operational occurrences and accidents (YEL Section 7d). Future generations are protected with the requirements set for radioactive waste management. Nuclear facilities shall be designed with decommissioning in mind (YEL Section 7g), and the dismantling of the facility and other measures for the decommissioning may not be postponed without due cause. Nuclear waste shall be managed so that after disposal of the waste no radiation exposure is caused which would exceed the level considered acceptable at the time the disposal is implemented.

The disposal of nuclear waste in a manner intended as permanent shall be planned in a way that gives priority to safety and so that ensuring long-term safety does not require the surveillance of the disposal site (YEL Section 7h).

The releases from facilities shall be restricted in compliance with the optimization principle of radiation protection (YEL Section 7c). The dose limits for the use of nuclear energy, including safety of disposal facilities after closure, have been set in YEA Chapter 3 a. The radiological criteria a set so that no harm is caused to people, environment, or property. The long-term safety has been considered when setting the criteria.

The purpose of the Radiation Act is to protect human health against detriments caused by exposure to radiation (SätL Section 1). According to the motivation (HE 28/2018 vp) protection of present and future generations can be considered to be included in the wording of the purpose of the law, as the prevention and limitation of adverse health effects is of direct concern to current and indirect generations.

Principle 8: Prevention of accidents

According to YEL Chapter 2, Section 6 “The use of nuclear energy must be safe and it shall not cause harm to people or damage to the environment or property.” And Section 7d (Preparation for operational occurrences and accidents) states “The design of a nuclear facility shall provide for the possibility of operational occurrences and accidents. The probability of an accident must be lower, the more severe the consequences of such an accident would prove for people, the environment or property. The primary objective shall be the prevention of accidents. Any practical measures required shall be taken to manage accidents and mitigate the consequences thereof.

Maximum values for radiation exposure, to be used as a basis for safety design in case of operational occurrences and accidents, will be provided by a YEA.

SätL 23 states that “The undertaking shall implement the organization of the practice in such a way that radiation safety deviations are prevented with adequate effectiveness and that their consequences are as insignificant as possible.” Further, Section 26 requires, as part of carrying out a safety assessment, the licensee shall identify ways in which ways the practice can cause radiation exposure, considering any possible radiation safety deviations, and to present measures to prevent and prepare for identified radiation safety deviations. STUK S/5/2019 Section 6, requires that facilities with radiation sources use structural solutions that allow the organisation of activities in such a way, among others, the potential exposure and the probability of its occurrence are as low as practicable and do not exceed the constraint for potential exposure and that the radiological safety deviation can be controlled and the sources can be made safe for workers and the public.

Principle 9: Emergency preparedness and response

According to YEL, Section 7i: The licence holder shall appoint the persons responsible for ensuring the emergency arrangements. STUK Regulation 2/Y/2018 applies to the emergency arrangements of a nuclear power plants and to other nuclear facilities as required by the danger they pose.

SätL Section 26, as part of carrying out a safety assessment, requires the licensee to identify ways in which ways the practice can cause radiation exposure, considering any possible radiation safety deviations. Section 129 requires the undertaking to prepare for radiation safety deviations and to have an up-to-date plan of action for radiation safety deviations. Sections 130 -131 set requirements on the measures to be taken by the undertaking during and after a radiation safety deviation.

Principle 10: Protective actions to reduce existing or unregulated radiation risks

The scope of the SätL covers all exposure situations i.e. also existing or unregulated exposures. The most common exposures to natural radiation are regulated under the Chapter 18 on Natural Radiation. These include exposures arising from radon in workplaces, other premises with public access, and dwellings, processing of materials containing natural radionuclides, radioactivity in construction products, natural radionuclides in household water and cosmic radiation in aviation. All other existing exposure situations are regulated under Chapter 17 Existing Exposure Situations. Both Chapters provide for the identification of the situations, establishment of reference levels and measures to reduce exposures. If occupational or public exposure cannot be reduced below the relevant reference level, the operations leading to the exposure are considered as a radiation practice subject to a safety licence (exception: not in the case of radon in dwellings).

SätL Section 86 states that “Practices which repeatedly handle, or store orphan sources are subject to a safety licence.” and that “The undertaking shall immediately notify STUK if it suspects or knows of the finding or melting of an orphan source or any significant contamination caused by such an orphan source.”

(GSR Part 1, Req. 1 Para 2.3. b) Binding international legal instruments, such as conventions and other relevant international instruments;

Finland does participate in the relevant international treaties and conventions and other relevant international arrangements considering nuclear and radiation safety. See module 2.

(GSR Part 1, Req. 1 Para 2.3. c) The specification of the scope of the governmental, legal and regulatory framework for safety;

The scope of governmental, legal and regulatory framework for safety are defined for different type of activities considered under the use of nuclear energy in YEL.

Defined by the Radiation Act. The scope of the act includes on all exposure situations: planned (radiation practices), existing and emergency exposure situations.

(GSR Part 1, Req. 1 Para 2.3. d) The need and provision for human and financial resources;

Nuclear Energy Act defines as a condition for granting a construction or operating licence that the applicant has sufficient financial resources, necessary expertise and, in particular, that the operating organisation and the competence of the operating staff are appropriate. According to the Nuclear Energy Act, the licensee shall also have adequate financial resources to take care of the safety of the plant. In addition, Nuclear Energy Act provides detailed regulations for the financial arrangements for taking care of nuclear waste management and decommissioning (see Question 7). The Act on Third Party Liability provides regulations on financial arrangements for nuclear accidents, taking into account that Finland is a party to the Paris and Brussels conventions.

The financial preconditions are primarily assessed by authorities other than STUK (mainly by the Ministry of Economic Affairs and Employment). The financial position and business environment of the licensee also affect the safety of plants, and STUK therefore follows licensees' plans to improve safety of nuclear power plants, as well as organisational reforms, safety research conducted by licensees, the number of employees and the competence of personnel. The annual reports of Fortum Corporation and Teollisuuden Voima Oyj provide financial information on the utilities. Both utilities have annually invested typically about 40–50 M€ for maintaining the plant and improving safety. For example, When TVO started to renew all emergency diesel generators the overall investment was more than 100 M€.

Regarding radiation practices, section 23 of SätL states that "The undertaking shall ensure that it has the expertise necessary in terms of the nature and extent of the practice at its disposal and sufficient financial and human resources for the safe implementation of the practice."

Human and financial resources of STUK, see 3.2.

(GSR Part 1, Req. 1 Para 2.3. e) The provision and framework for research and development;

Nuclear Safety Research

The national infrastructure comprise several universities and research organizations that carry out nuclear safety research. In Finland, VTT Technical Research Centre of Finland Ltd is the largest

research organisation in the field of nuclear energy. At VTT, about 200 experts are working in the field of nuclear energy, about half of them full-time. The total volume of the nuclear energy research in Finland in the year 2014 was 90 million € (estimate of the Ministry of Economic Affairs and Employment). This figure includes research related to use of nuclear energy conducted in all the stakeholder organisations. Two thirds of the research is focused on the disposal of the spent fuel. The largest individual organizations are VTT, LUT (Lappeenranta University of Technology), GTK (Geological Survey of Finland), and Aalto University (former Helsinki University of Technology, HUT). Research is funded by forementioned organizations, Business Finland, Academy of Finland and Nuclear Waste management Fund (VYR). Finland takes actively part into international co-operation in research especially in contest of Euratom, OECD/NEA and IAEA. The Finnish share of the Jules Horowitz Research Reactor under construction in France is 2 %.

YEL was amended in 2003 to ensure funding for a long-term nuclear safety and nuclear waste management research in Finland. Funds are collected annually from the license holders to a special fund. Regarding nuclear safety research the amount of money is proportional to the actual thermal power of the licensed power plants or the thermal power presented in the Decision-in-Principle. For the nuclear waste research, the annual funding payments are proportional to the current fund holdings for the future waste management activities.

YEL Section 53a § to 53e§ “Ensuring expertise” establish legal framework for national nuclear safety and national nuclear waste management programmes. According to the justification of the YEL anyone who is licensed to operate a nuclear facility of considerable general significance shall participate in the financing of research activity and infrastructure aiming at ensuring that if new factors concerning the safe use of nuclear facilities emerge that could not have been foreseen, the authorities have, at their disposal, such adequate and comprehensive nuclear engineering expertise and other facilities as can be used, where necessary, to analyse the significance of such factors without delay. The amendment of the YEL in 2021 emphasizes the development of national capability that serves in addition to the authority license holders and those responsible for nuclear waste management.

The main purpose of the programmes is to develop national capability in assessing nuclear safety so that TSO support is available for STUK whenever needed. All the relevant stakeholders such as STUK, licensees and research organizations participate in the steering of the research. STUK is chairing the management board of the research programmes and it has leading role in the defining the content of the research programmes, the funding of the projects and steering the research.

In 2016 the Nuclear Energy Act was amended, and a temporary increase of the payments collected to the nuclear safety research fund was introduced. The purpose of the temporary increase of the research funding is to renew the ageing infrastructure for the nuclear safety related research. The increased funding is collected in between the years 2016 and 2025. At the first stage the additional funding has

been allocated for the hot cells at VTT Centre of Nuclear Safety (CNS) and at the second stage it will be allocated for the thermohydraulic laboratory at Lappeenranta University of Technology. The investment for the VTT CNS hot cells capacity has been about 18 million €. In 2021 the Nuclear Energy Act was manded with the goal of combined research programme for nuclear safety and waste management safety from the beginning of 2023. Also, the level or funding was checked, and the administration was made more flexible.

The research projects are selected so that they support and develop the competences in nuclear safety and to create preparedness for the regulator to be able to respond on emerging and urgent safety issues. These national safety research programs are called SAFIR and KYT. The structure for SAFIR2022 (2019–2022) enhanced multidisciplinary co-operation within the research program. Research areas were 1) Plant Safety and Systemic Approach to Safety, 2) Reactor Safety and 3) Structural Safety and Material. The key topics of the recent nuclear safety research program (SAFIR2022) were automation, organisation and human factors, severe accidents and risk analysis, fuel and reactor physics, thermal hydraulics, structural integrity and development of research infrastructure. The amount of money collected from the licensees since year 2016 has been about 9 million € for nuclear safety research. Out of this 4 million € is used to research projects and the rest is for the enhancement of the infrastructure. The research projects have also additional funding from other sources. The total volume of the program has been about 7 million € each year. An international evaluation of the previous SAFIR2018 program was performed at the beginning of the year 2018. The scientific level and performance of the program was found very good. The international evaluation of the running program SAFIR2022 will be made at the beginning of the year 2022.

The new period for the national publicly funded nuclear safety research programme SAFIR2022 was planned and initiated in 2018. The research issues of the new programme continue the main areas of previous SAFIR2018 research programme. However, new research issues concerning the changes in the operating environment are integrated into the programme such as use of 3D-printing for components important to safety, small modular reactors, machine learning etc.

The objective of KYT (Finnish Research Programme on Nuclear Waste Management) is to ensure the sufficient and comprehensive availability of the nuclear technological expertise and other capabilities required by the authorities when comparing different nuclear waste management ways and implementation methods. KYT2018 was divided into three main categories:

- new and alternative technologies in nuclear waste management
- safety research in nuclear waste management and
- social science studies related to nuclear waste management.

The main emphasis in the research programme will continue to be devoted to safety related research. The funding of the research programme is provided mainly by the State Nuclear Waste Management

Fund (VYR) into which those responsible for nuclear waste management pay annually 0.13% of their respective assessed liability. The current level of annual funding is 1.9 million €.

Similar to SAFIR, the new period for the Finnish Research Programme on Nuclear Waste Management, KYT2022, was planned and initiated in year 2018. The program continues the traditions of previous periods with the main research areas of:

- safety research in spent nuclear fuel management
- near-surface disposal
- low and intermediate nuclear waste management
- decommissioning
- new and alternative technologies in nuclear waste management and
- social science studies related to nuclear waste management.

SAFIR2022 and KYT2022 safety research programs held an international virtual interim seminar in March 2021. In the KYT2022 and SAFIR2022 programs, a total of million 30 euro was used for research and infrastructure development in 2019–2020. The development of the next program has been started already. The A new six-year program SAFER2028 will be launched in 2023. This program will integrate the national research on nuclear safety and nuclear waste management into one research program.

http://safir2022.vtt.fi/framework.htm

http://kyt2022.vtt.fi/index_en.htm

Radiation Safety Research

STUK participates in radiation safety research mainly thorough a consortium with universities, co-operation agreements and European research programmes. The main goal for STUK of the safety research is to retain and develop oversight capabilities and staff competence. Co-operation with universities strengthen to ensure these capabilities and competence also in future in parallel with other aims of education in universities.

Cores is a consortium established by Radiation and Nuclear Safety Authority (STUK) and nine Finnish universities or research institutes. The purpose of Cores is to coordinate and strengthen the radiation safety research in Finland. At present Cores has 12 members. STUK is responsible for the overall coordination of the consortium's activities (steering group meetings, seminar arrangements, national program coordination, communication).

The report National Programme for Radiation Safety Research 2018-2022 (STUK-A 262/December 2018):

https://www.julkari.fi/bitstream/handle/10024/137346/STUK_A262_12_2018.pdf?sequence=5&isAllowed=y)

provides an update on the national radiation safety research programme and the activities of the Consortium for Radiation Safety Research (Cores), giving more detail on radiation safety research carried out by the consortium members. While there has been long-standing cooperation between STUK and universities, such ties were further strengthened and formalised after the government decided to introduce a comprehensive reform of the Finnish research and innovation system in 2013. This subsequently led to the setting up of the national Consortium for Radiation Safety Research (Cores) and the formulation of a national programme on radiation safety research in Finland.

The main goal of the government reform was to strengthen multidisciplinary, high-level research of social significance. One line of action was to deepen cooperation between research institutes and universities. To achieve this goal, the Resolution envisaged a step-by-step integration process leading to centres of competence (agreement-based consortia). According to the government policy, such agreement-based consortia must have common research equipment, laboratories and information resources (e.g. follow-up material, sample material, statistical and register material) as well as engage in close cooperation in research and education (e.g. sharing of mutually complementary competencies, joint professorships and duties, and shared staff).

Based on the Government Resolution, a process was initiated to strengthen the cooperation between STUK and universities and to create a national research consortium that would carry out research on various aspects of ionising and non-ionising radiation safety. The agreement to set up the Consortium was signed between STUK and nine universities by 2015. In addition to STUK, the following universities signed the Consortium Agreement forming the Finnish Consortium for Radiation Safety Research (Cores), and contributed to the national programme: Aalto University, Lappeenranta University of Technology, Tampere University of Technology, the University of Helsinki, the University of Eastern Finland, the University of Jyväskylä, the University of Oulu, the University of Tampere and the University of Turku. More recently, Åbo Akademi University and Technology Research Centre VTT Oy also joined Cores.

In addition to CORES, STUK's participation in the Helsinki Institute of Physics has been important in developing new analysis and detection methods. Continuation of this cooperation requires basic funding that should be guaranteed. Moreover, Euratom partnership program is crucial for international cooperation in radiation protection research. Support from ministries (MSAH, MEAE, Ministry of Education and Culture) is needed to ensure participation in the program. This support includes the nomination of a national program manager and owner as well as reserving sufficient funding for possible third parties participating in the program research calls.

(GSR Part 1, Req. 1 Para 2.3. f) Adequate mechanisms for taking account of social and economic developments;

In Finland radiation and nuclear safety has been an important issue over 70 years. Accordingly, strict safety requirements have been developed taken into account both of international and of national needs and development. STUK has been intensively involved in this development work.

The risks inherent in the use of nuclear energy require a more comprehensive and intensive regulatory oversight than any other form of energy. The oversight aims to ensure the safety of the use of nuclear power and appropriate handling of nuclear waste, and that the use of nuclear energy does not lead to development of nuclear weapons. The final disposal of low and medium active radioactive waste has already been started in Finland, and a Decision in Principle approved by Parliament on the final disposal of spent fuel in Finnish bedrock has also been made and the application for the operating license is expected at the beginning of the year 2022.

The objectives and framework of the regulatory oversight functions are determined by YEL. Its underlying principle is that the use of nuclear energy must be in the overall interest of the society. The major mechanism for taking account of social and economic development is the System of licensing (see module 5).

The guiding principle of the Nuclear Energy Act Section 7 also states "The safety of nuclear energy use shall be maintained at as high a level as practically possible. For the further development of safety, measures shall be implemented that can be considered justified considering operating experience and safety research and advances in science and technology."

Nuclear energy is considered in the development of national infrastructure that is developed systematically from national level to municipal level. Nuclear power plays currently a major role in the

implementation of the Finnish national climate and energy strategy (Long term climate and energy strategy, 2021).

Ministry of Social Affairs and Health has assessed the current situation in the process of preparing the Radiation Act (HE 28/2018 vp, Chapter 2.3). For example, new technology in health care has been taken into account (HE 28/2018 vp., pages 38–39) and development of occupational doses has been described (pages 18–20).

The undertaking shall demonstrate that a new type of radiation practice subject to a safety licence is justified. The same applies to existing radiation practices if new important information on the efficiency, possible consequences or alternative methods or techniques of the practice is obtained (SätL Section 24). Non-medical imaging exposure shall be assessed at least every five years by the undertaking whether the practice is still justified (SätL Section 121).

(GSR Part 1, Req. 1 Para 2.3. g) The promotion of leadership and management for safety, including safety culture.

The guiding principle of the Nuclear Energy Act Section 7 a states “The safety of nuclear energy use shall be maintained at as high a level as practically possible. For the further development of safety, measures shall be implemented that can be considered justified considering operating experience and safety research and advances in science and technology.” The following section stipulate on priority of safety in each lifecycle phase of the nuclear facility or nuclear installation and on the elements for the management for safety such as management system and culture for safety, competence of personnel etc.

The priority of safety is emphasised in the Nuclear Energy Act and in the STUK Regulation (STUK Y/1/2018) Section 25 and in the STUK Regulation (STUK Y/4/2018) Section 38. The STUK regulations set a binding requirement for the licensees to maintain a good safety culture where safety shall be a priority. It states that when designing, constructing, operating and decommissioning a nuclear power plant or any waste management facility, a good safety culture shall be maintained by making sure that the decisions and activities of the entire organisation reflect commitment to operational practices and solutions that promote safety. An open working atmosphere must be promoted to encourage identification, reporting and elimination of factors endangering safety, and the personnel must be given opportunity to contribute to the continuous enhancement of safety. The licensees have to ensure that these requirements are applied in all organisations that participate in safety significant activities.

According to the Nuclear Energy Act Section 7 k, a responsible manager has to be appointed for the construction, operation and decommissioning of a nuclear power plant. The appointment is subject to approval by STUK. The responsible manager has a duty to ensure the safe use of nuclear energy and to see that the arrangements for physical protection and emergency preparedness and the safeguards control are complied with.

STUK has revised the STUK's Guide YVL A.3 that sets requirements for management systems. The new guide YVL A.3, published in March 2019, is based on IAEA GSR Part 2 and it includes detailed requirements for promoting good safety culture. The revised guide also describes what the good safety culture includes, e.g. that safety is the overriding priority in decision making and that safety is considered comprehensively. The YVL A.3 requires that the management must demonstrate its commitment to safety. Safety culture expertise must be available for developing the safety culture. The development of the safety culture must be target oriented and systematic. The licensee has to also establish a process to measure, assess and improve its safety culture.

STUK has revised also the Guide YVL A.5 concerning nuclear facility construction, commissioning and modifications. The safety culture requirements from the previous version has been moved to the Guide YVL A.3 to clarify and ease the usability of the guide documents. Still during construction and modification projects the licensee must ensure that the contributing parties are able to perform according to safety requirements and there must be training on safety culture issues for the personnel taking part in the activities. The licensee must have procedures for evaluating and developing the safety culture of the contributing parties according to Guide YVL A.3.

TEPCO Fukushima Dai-ichi accident has highlighted the importance of safety culture and its continuous assessment and improvement. The Diet report in 2012 concluded that "fundamental causes of the accident are to be found in the ingrained conventions of Japanese culture; our reflexive obedience; our reluctance to question authority; our devotion to 'sticking with the program'; our groupism; and our insularity". These ingrained conventions were seen as factors preventing necessary stakeholders (Licensee, Regulatory Body and Government) to take needed actions to ensure safety and therefore also contradicting with good safety culture. The influence of ingrained conventions in national culture was considered in Finland to be one of the key messages in the Diet report. To better understand the ingrained conventions in the Finnish culture and their possible positive and/or negative impacts on safety culture, STUK has continued to explore the sociological factors influencing safety culture in the Finnish nuclear community within the Finnish nuclear research program SAFIR 2018 (the ORSAC and ORSAPP project). Furthermore, in March 2019 STUK hosted the OECD NEA and WANO managed Country-Specific Safety Culture Forum in Helsinki, were personnel from the Finnish nuclear utilities and STUK discussed the country specific culture traits and their possible influences on the nuclear safety culture. A report is being prepared by the NEA.

Reports ORSAC (LUT report ORSAC final report, SAHA #2037076), VTT report Overall safety and organizations SAHA #1768394) and ORSAP (VTT Technology 349: SAFIR 2018 Final Report (vttresearch.com), https://www.vttresearch.com/sites/default/files/pdf/technology/2019/T364.pdf

OECD NEA and WANO Country-Specific Safety Culture Forum: Finland https://www.oecd-nea.org/jcms/pl_15146/country-specific-safety-culture-forum-finland?details=true

Safety culture and safety management are also stipulated in the Section 12 of SätL. The management of an organization responsible for compliance with the oblications laid down in the Act shall ensure that the organization's activities maintain and develop a good safety culture, and that persons working at all levels of the organization, in accordance with their tasks:

1) are aware of the radiation risks involved in the practice and the protective actions and understand their relevance for safety;

2) follow safe operating methods;

3) participate in the continuous development of safety.

In addition, the organization's management shall ensure that the safety management combines procedures, operating methods and leadership for the management of safety.

STUK's safety and quality policy set the targets and guidance for STUK's internal management activities (STUK 1.1). STUK has developed a safety culture program, within which it develops its own safety culture (e.g. according to GSR Part 2). See more in Module 4.

Question 1.1 How does the implementation of the policy and strategy for safety take into account a graded approach?

Response:

The graded approach has been considered in the legislation in such a way that the risks associated to different type of facilities and activities have been taken into account in licensing and other regulation. The principle of graded approach was explicitly included in the Nuclear Energy Act in the year 2013 (499/2013), where Section 7a states now that "Safety requirements and measures to ensure the safety

shall be sized and allocated proportionate to the use of nuclear energy risks." The Nuclear Energy Act Section 60 a stipulates the inspections of the pressure equipment, mechanical components, and structures so that the equipment most important to safety are inspected by STUK and the other safety related items are inspected by authorized inspection organizations.

At the STUK regulations and YVL Guide level graded approach in reflected in the nuclear facility or installation specific regulations and grading the safety requirements based on safety classification of the items important to safety.

The implementation of the strategy is discussed more in Module 3.

The graded approach has been onsidered in the SätL by using a categorization of radiation practices (Section 27). Based on the results of the safety assessment (Section SätL 26) the undertaking shall categorize the radiation practices based on the radiation exposure caused by the practices and the radiation sources used in the practices. The categorization criteria is established in VnA 1034, Section 16 and Annex 4 and include categorization in respect of (when ever applicable in the practice in question):

- occupational exposure
- public exposure
- medical exposure
- unsealed radiation sources used
- sealed sources used
- waste to be disposed of as landfill

The categorization is reflected e.g. in the requirements set in STUK regulations, in the level of assessments and demonstration of safety needed in licence applications and in targeting regulatory activities such as establishing inspection programmes (SätL Section 182).

SätL Section 11 sets specific requirement for the regulatory authority to account risks in regulatory control. The VnA 134/2018, Section 57 § specifies that the inspection programme established by the regulatory authority shall take into account the risks involved.

Question 2 Has the Government established an appropriate governmental, legal and regulatory framework for safety, with clearly allocated responsibilities?

Answer: Yes

Response:

The Finnish Constitution is the cornerstone of all legislation and exercise of public power. It contains provisions on governmental organization, checks and balances between the top government branches and fundamental civil rights. The new Constitution of Finland entered into force in March 2000. The Constitution stipulates, how and by whom the acts and decrees as well as delegation of legislative powers can be issued. The Ministry of Economy Affairs and Employment the (MEAE) is responsible for the legislation in the nuclear energy field and the Ministry of Social Affairs and Health (MSAH) for the use of radiation (acts and decrees).

Nuclear energy regulation

The current nuclear energy legislation in Finland (see Annex 1) is based on the Nuclear Energy Act originally from 1987. The Act has been amended over twenty times during the years it has been in force: most changes are minor and originate from changes to EU or other Finnish legislation. In 2008, nuclear energy legislation was updated to correspond to current level of safety requirements and the new Finnish Constitution. Together with a supporting Nuclear Energy Decree originally from 1988, the scope of this legislation covers e.g.

- the construction, commissioning, operation and decommissioning of nuclear facilities;
- nuclear facilities refer to facilities for producing nuclear energy, including research reactors, facilities for extensive disposal of nuclear wastes, and facilities used for extensive fabrication, production, use, handling or storage of nuclear materials or nuclear wastes
- the possession, fabrication, production, transfer, handling, use, storage, transport, export and import of nuclear materials and nuclear wastes as well as the export and import of ores and ore concentrates containing uranium or thorium.

The licensing process for a nuclear facility includes the following phases: Decision in Principle, Construction license, Operating license and Decommissioning license. The Decision in Principle is done and licenses for the construction and operation are granted by the Government. In addition to safety, many other essential issues are considered, and therefore the licensing decisions are made in Finland at the governmental level. However, safety review by STUK is needed before the Decision in Principle is done and the Construction license, Operating licenses and Decommissioning licenses are granted. The Decommissioning license in its current form was introduces to the Nuclear Energy Act Chapter 5 Section 16 and Section 20 a in 2017.

Decision in Principle is required for a nuclear facility having considerable general significance. This is essentially a political decision: the government decides whether the construction project is in line with

the overall good of society. The decision can be applied for one or more sites, the host municipality has a veto right and the parliament has the choice of ratifying or not ratifying the decision.

In 2013 the requirements concerning the Environmental Impact Assessment (EIA) process and submission of the EIA report were clarified in YEL. The requirement states that DiP application shall include EIA report as well as the Statement of the Contact Authority (Nuclear Energy Degree 755/2013). The consistency between YEL and the EIA law (252/2017) has been further enhanced as the EIA law was updated due to implementation of the European directive (2014/52/EU). The contact authority for facilities and activities related to the Nuclear Energy Act is MEAE. However, in 2021 EIA law update (559/2021) clarifies among other things Section 10 and stipulates the contact authority for mining and milling operations aimed at producing uranium or thorium (YEL section 2 para.1 2)) is the Centre for Economic Development, Transport and the Environment due to the different nature of these activities.

In 2012, the Finnish regulatory framework for nuclear and radiation safety was reviewed in the IRRS (Integrated Regulatory Review Service) peer review process. According to the IRRS recommendations, some amendments were made to the legislation aimed to increase the independence of STUK and to extend its authorities. The Nuclear Energy Act was amended in 2015. The Government, when making a decision in principle, and the licensing authority as giving a license, were obligated to take into account STUK's proposals given in the preliminary safety assessment and safety proposals given by STUK in its license application statement. Regulations were added expanding STUK's mandate in radiation monitoring in the immediate vicinity of nuclear facilities and giving STUK a mandate to issue binding regulations.

STUK Regulations concerning the areas of previous Government Decrees; the safety of nuclear power plants, safety of the disposal of nuclear waste as well as emergency and security arrangements of nuclear facilities, and a new area concerning mining and milling operations aimed to produce uranium or thorium. STUK issued the regulations on 1st January 2016. Updates were published and came into force on 15th December 2018.

- STUK Regulation on the Safety of Nuclear Power Plants (STUK Y/1/2018)
- STUK Regulation on Emergency Arrangements of a Nuclear Power Plant (STUK Y/2/201
- STUK Regulation on the Security in the Use of Nuclear Energy (STUK Y/3/2016)
- STUK Regulation on the Safety of Disposal of Nuclear Waste (STUK Y/4/2018)
- STUK Regulation on the Safety of Mining and Milling Operations aimed at Producing Uranium or Thorium (STUK Y/5/2016).

STUK Regulations and their explanatory memorandums are published in Finnish and Swedish which are official. English translations are also published but their status is unofficial.

The Nuclear Energy Act was amended in 2017 for implementation of the Council Directive 2014/87/ Euratom amending Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations. The amendment of the Nuclear Energy Act entered into force on 1st January 2018 and supplemented also the former implementation (2013) of the Spent Fuel and Radioactive Waste Directive (2011/70/Euratom) due to the additional questions by the Commission. The most significant changes caused by the directives concerned transparency of activities, licensee's obligation to provide information and responsibility for subcontractors, involvement of the population in decision-making concerning the nuclear facility licensing and international peer reviews. At the same time, the provisions of the act regarding pressure equipment were updated due to the new Pressure Equipment Act (1144/2016) that entered into force on 1st January 2017. In addition, national legislation was deemed to require disambiguation on matters related to the decommissioning of nuclear facilities and nuclear waste management, which is why further specifications were entered in the act regarding these matters, and the decommissioning license was added as a new licensing phase for nuclear facilities, and changes were made regarding waste management.

The Nuclear Energy Act amendment proposals concerning security arrangements in the use of nuclear energy were started in conjunction with the preparation for the amendment that entered into force in the beginning of 2018, but were separated from the Nuclear Energy Act amendment bill based on the feedback received during the circulation for comments. Preparation of the bill was continued by the Ministry of Economic Affairs and Employment, STUK, the Ministry of the Interior and the Ministry of Justice separately, and the government bill for amending the act was sent for comments on 15 November 2018 and statements were requested by mid-January 2019. The amendment proposal concerns e.g. authorities of security personnel and the temporal dimension of the use of security personnel, specially the point of time when security organization has to be established in new plant projects. Provisions on health examinations for security and control room personnel and the right to report of the doctor or other medical professional in relation to the health examinations are proposed to be added to the act as completely new items. New items also include rules of jurisdiction concerning defense against drones and unmanned aerial vehicles at nuclear power plant sites. This amendment of the Act entered into force in December 2020.

The amendments to the Nuclear Energy Act due to the amendment (2014/52/EU) of Directive 2011/92/EU on the assessment of the effects of certain public and private projects on the environment came into force on 1st May 2017. The new requirements in the Act concerned the Environmental Impact Assessment (EIA) responsibilities of the license applicant, informing about a pending application and measures that the license shall include for preventing or reducing significant detrimental environmental impacts.

The Nuclear Energy Decree (161/1988) was amended in 2017 and the amendment entered into force on 1st January 2018. Due to the amendments made to the Nuclear Energy Act provisions further specifying the licensing procedure regarding decommissioning of nuclear facilities and oversight by STUK were added to the decree. Provisions regarding the minimum contents of the national nuclear

waste management program were also added to the decree. Due to the new Environmental Impact Assessment Act (252/2017) the references to the EIA procedure were updated. Furthermore, provisions regarding the phases of and documents related to the procedure were amended for compliance with the new act. Some minor technical corrections and specifications were also made to the Nuclear Energy Decree.

By virtue of the Radiation Act and the Nuclear Energy Act, STUK also issued on 15 December 2018 a new common regulation on the exemption values for radioactive substances and the clearance levels of radioactive materials. However, the exemption values are not applied to the use of nuclear energy.

At the same time with the international negotiations to update the Paris and Brussels Conventions on Nuclear Liability also the Finnish Nuclear Liability Act was reviewed by a special governmental committee already in 2002. The financial provisions to cover the possible damage and resulting costs caused by a nuclear accident have been arranged according to the Paris and Brussels Conventions. A remarkable increase in the sum available for compensation of nuclear damages is expected in the future since international negotiations about the revision of the Paris/Brussels agreements on nuclear liability were successfully completed in 2004. In addition to the revised agreements, Finland decided to enact unlimited licensee liability by law. This means, that insurance coverage will be required for a minimum amount of EUR 700 million and the liability of Finnish operators shall be unlimited in cases where nuclear damage has occurred in Finland and also the third tier of the Brussels Supplementary Convention (providing cover up to EUR 1500 million) has been exhausted. The revised law will also have some other improvements, like extending the claiming period up to 30 years for victims of nuclear accidents (personal injuries). The law amendment (2005) has not taken effect yet. It will enter into force at a later date as determined by Government Decree. The entering into force of the amending act will take place as the 2004 Protocols amending the Paris and Brussels Conventions will enter into force.

As the ratification of the 2004 Protocols has been delayed, Finland made a temporary amendment in the Finnish Nuclear Liability Act in 2012, implementing the provision on unlimited liability and requirement of insurance coverage for a minimum amount of EUR 700 million by the operator. The temporary law came into force in January 2012 and will be repealed when the 2005 law amendment takes effect. In Finland, the finishing off the international ratification process of the convention amendments without any undue delay is considered to be extremely important. Now the international ratification has been proceeded however Nuclear Energy Act needs to be changed due to changes in the environment and the amendment of the act is in the Parliamentary for review and decision at the time of writing this report.

Based on Section 7r of the Nuclear Energy Act STUK has been authorized to issue the detailed safety requirements YVL Guides.

The latest amendment of the Act in 2021 concerns the changes in the managing the Nuclear Waste Funds (VYR) and the funding of safety research through VYR to ensure expertise in Finland so that there will expertise availed for the regulatory if any safety issues occur at the Finnish nuclear facilities. The changes were needed to allow flexible investment of VYR Funds and integration of current safety research and nuclear waste management research programs into a common research program from the beginning of year 2023.

The preparation of the total revision of the nuclear energy act, underlying legislation and regulations has started. Binding requirements will be presented in the Nuclear Energy Act, Nuclear Energy Decree and in STUK Regulations according to the principles laid down in Finnish Constitution. The revision of the act would consider more flexible licensing of the nuclear reactors foreseen in the future. The public consultation of the draft act is expected to take place in 2024. The review by the Government and the Parliament will be in 2025-2026. The enactment of the act is expected in 2027.

Implementation of STUK's new strategy includes developing the regulations and guides to support the strategy. STUK has started the evaluation of needed modifications. In the same context, STUK evaluates if there are any needs to modify the present licensing model presented in the Nuclear Energy Act and Nuclear Energy Decree (Decision in Principle – Construction License – Operating License – Decommissioning License), for example considering the applicability of the present models to SMRs.

Radiation regulation

The radiation legislation was fully reformed on 15 December 2018, when the SätL, the VnA 1034/2018 and the STMA 1044/2018) entered into force. The reformation was motivated by the need to bring it in line with the Constitution of 2000 and as to implement the EU BSS Directive.

As part of brining the radiation legislation in line with the Constitution, the statutory levels of all requirements were checked. In practice, this meant that requirements that were previously included in radiation safety guides (ST Guides) and decisions issued by the Radiation and Nuclear Safety Authority are now presented as binding provisions in acts, decrees and STUK Regulations issued by virtue of the Radiation Act. In addition, within this process many of the detailed requirements of the ST guides were reformulated to become more general and performance oriented, instead of the prescriptive formulation of the ST guides. Therefore, the over number of requirements in the STUK Regulations is significantly reduced compared to the ST Guides. Some of the detailed material of the ST guides are being

transformed into non-legally guidance to serve as possible examples for the practical implementation of the new performance based requirements.

The first regulations issued by virtue of the Radiation Act by the end of December 2018 concerned work-related radiation exposure, radiation safety deviations, security arrangements for radiation sources, and ionising radiation measurements relating to work-related exposure, public exposure and medical exposure. In 2019 – 2020, further regulations were issued concerning radiation waste and releases in the use of unsealed sources, practices causing exposure to natural radiation, justification and optimization in medical exposure, in-service safety of radiation sources and decommissioning of radiation sources and facilities, and on practices requiring a safety license.

The various elements included in the new radiation legislation are discussed separately in below under the titles referring to the elements listed in paragraph 2.5 of GSR Part 1.

Regulatory framework of nuclear energy and radiation safety

The legislation provides the regulatory framework for the use of nuclear energy and radiation safety (including use of radiation and other radiation practices). According to Section 55 of the Nuclear Energy Act and Section 14 of the Radiation Act, STUK is responsible for the regulatory oversight of nuclear energy and of radiation practices.

Other authorities have also responsibilities related to use of nuclear energy and radiation practices. Typical areas relate to environmental issues, security arrangements as well as emergency preparedness. In the areas of rescue services and security the Ministry of the Interior (MI) is the overall authority.

According to the Nuclear Energy Act (Section 54) the overall authority in the field of nuclear energy is the Ministry of the Economy Affairs and Employment. It prepares license decisions for the Government. The Ministry also steers the general planning and implementation of nuclear waste management originating from nuclear facilities. The Nuclear Waste Management Fund is operated in connection with the Ministry. Furthermore, the Nuclear Waste Management Fund grants funding to research to ensure expertise in Finland (Section 53). The research supports the regulatory oversight of the use of nuclear energy. Furthermore, the Ministry grants a small amount of funding for research in international co-operations.

The Environmental Impact Analysis is needed for a nuclear facility. The EIA process involves two stages: the preparation of an EIA programme and, at the second stage, draw up the EIA report. The contact authority for both stages is the Ministry of the Economy Affairs and Employment. As regards EIA process for mining and milling activities the contact authority is the regional Centre for Economic Development, Transport and the Environment (ELY).

According to the Radiation Act (Section 13) the overall authority in the field of the use of radiation and other radiation practices is the Ministry of Social affairs and Health and for the Ministry of the Economy Affairs and Employment in matters related to use of nuclear energy defined in Nuclear Energy Act.

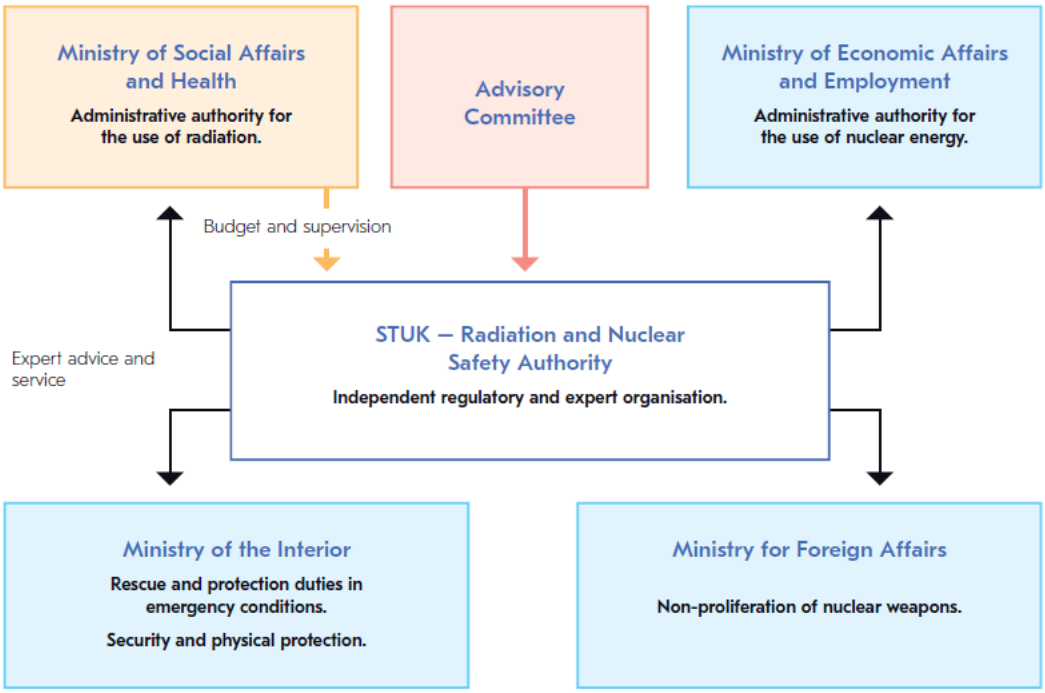

FIGURE 9. Co-operation and interfaces between STUK and Ministries and other organisations.

FIGURE 1. Co-operation and interfaces between STUK and Ministries and other organisations

As regards emergency preparedness for nuclear facilities, in addition to the on-site emergency plans established by the licensees, off-site emergency plans required by the rescue legislation are prepared by regional authorities. The requirements for off-site plans and activities in a radiation emergency are provided in the Decree of the Ministry of the Interior (407/2011).

During emergency response in case of nuclear or radiological accident, STUK is an expert body supporting ministries and other authorities involved with recommendations for protective actions and information about the radiological situation. Depending on the situation, ministries most likely involved are Ministry of the Interior, Ministry of Social Affairs and Health, and Ministry of Agriculture and Forestry. The arrangements are tested in off-site emergency exercises conducted at routine intervals.

Many other governmental and local organizations, as well as the municipalities, have their own functions based on separate legislation as regards the construction and operation of facilities and conducting activities. The roles of organizations are defined in the Nuclear Energy Act Chapter 9. Other legislation and cooperation between authorities".

Regarding radiation safety, the regulatory duties of the municipality's health protection authority, customs and other authorities are prescribed in Sections 15 -17 of SätL.

(1) The safety principles for protecting people — individually and collectively — society and the environment from radiation risks, both at present and in the future;

The main principles for protecting people and the environment from radiation risks are set in the legislation. They cover also the risks related to waste management activities to be carried out in the future. In the developing of the legislation relevant international principles have been taken into account, such as those issued by the International Commission on Radiological Protection (ICRP) and IAEA.

As member of EU Finland also implements all the EU legislation.

The safety principles are discussed in more detail under the Primary Question 1 above.

(2) The types of facilities and activities that are included within the scope of the framework for safety;

The Nuclear Energy Act Section 1 and 2 define the facilities and activities that are regulated. This Act applies to:

1) the construction, operation and decommissioning of a nuclear facility; (905/2017)

2) mining and milling operations aimed at producing uranium or thorium; (269/2011)

3) the possession, manufacture, production, transfer, handling, use, storage, transport and import of nuclear material; (342/2008)

4) the possession, manufacture, production, transfer, handling, use, storage, transport, export and import of nuclear waste; (342/2008)

4a) disposal of nuclear waste that is of a lesser extent than large-scale disposal of nuclear waste; (905/2017)

5) in cases to be provided for by a Government decree, the possession, manufacture, assembly, transfer and import of the following material, devices, equipment, or information, should they prove pertinent to the proliferation of nuclear weapons or should the obligations under Finland's international treaties in the field of nuclear energy have a bearing on them:

a) non-nuclear material, in cases where its properties are particularly suited for obtaining nuclear energy;

b) devices and equipment intended or otherwise particularly suited for use in nuclear facilities; c) devices and equipment intended or otherwise particularly suited for use in the manufacture of nuclear material or material referred to in subparagraph a;

d) such equipment that is essential to the manufacture of devices or equipment referred to in subparagraphs a and b; and

e) nuclear information that is in written or other tangible form and not generally available; and (342/2008)

6) export and import of uranium-containing or thorium-containing ores, to be specified under a Government decree. (342/2008)

SätL applies to radiation practices, emergency exposure situations, and existing exposure situations (Section 2 Scope).

Radiation practices include (SätL, Section, point 25): a) the use of radiation; b) practices or circumstances in which exposure to natural radiation exceeds the reference level despite remedial measures; c) protective actions carried out in an existing exposure situation in which the occupational exposure exceeds the reference level.

The use of radiation means (Section 4, point 23): a) the use and manufacture of, trade in, installation, maintenance and remediation of radiation sources; b) the possession, safekeeping, import, export, transfer and storage of radiation sources and radioactive waste; c) the transport of radioactive substances and radioactive waste; d) rendering radioactive waste harmless.

Radiation source means (Section 4, point 22) a radiation appliance and a radioactive substance used because of its radioactivity. A radiation appliance means (SätL, Section 4, point 20) means device which produces radiation electrically or in which a radioactive substance is used due to its radioactivity.

(3) The type of authorizations that is required for the operation of facilities and for the conduct of activities, in accordance with a graded approach;

The basic authorisation requirements for nuclear facilities are set in Sections 11-15 and 18-20 of YEL. Authorisation of activities requiring authorization that do not exceed the criteria of nuclear facilities is set in YEL Section 21. More detailed requirements are presented in Sections 23-38 of YEA. The authorisation requirements for activities in the use of nuclear energy are given in Sections 21-23 of YEL and in Sections 41-73 of YEA. The exempted activities from licensing are described in Section 10-22 of YEA.

A safety license is required for the use of radiation (SätL, Section 48) and other radiation practices (SätL, Sections 141 and 148). Practices exempted from a safety license are defined in SätL (Section 49) and VnA 1034/2018 (Section 27). SätL (Section 50) provides for an exemption from a safety license under the decision of STUK provided that the exemption criteria specified in SätL (Section 50) and VnA 1034/2018 (Section 28) are met. Safety license is the only form of authorization (i.e. registration is not used), however, the graded approach is built in within the system of licensing through categorization of radiation practices (SätL, Section 27 and VnA 1034/2018, Section 16 §) and accordingly based requirements for obtaining a license.

The current YEL and SätL do not provide specific mechanisms for transferring radioactive materials from practices licensed under YEL to be regulated as radioactive sources under SätL, nor for transferring radioactive waste generated from practices licensed under SätL to long term storage or disposal facility licensed under YEL.

(4) The rationale for the authorization of new facilities and activities, as well as the applicable decision making process;

In the following the Decision in Principle procedures are described for a nuclear facility of considerable general significance. According to Section 11 of YEL the

construction of such a nuclear facility shall require a Government Decision in Principle on that the construction project is in line with the overall good of society. Such facilities are

1. facilities operated for the generation of nuclear energy having a thermal power higher than 50 megawatts;
2. facilities serving as repositories for nuclear waste; and
3. facilities operated for purposes other than the generation of nuclear energy and the possession at any given time, of an amount of nuclear material or waste or involving a radiation risk, as defined by Government decree, that shall be deemed comparable with nuclear facilities as defined in 1) above.

According to Section 12 a Decision in Principle is applied for by submitting an application to the Government, on which MEAE must obtain a preliminary safety assessment from STUK and a statement from ME as well as from the municipal council of the municipality intended to be the site of the facility and from its neighbouring municipalities.

According to Section 13 MEAE shall reserve the residents and municipalities in the immediate vicinity of the nuclear facility, the authorities and the public the possibility to express their opinions on the project in writing before making the Decision-in-Principle. The Ministry shall also arrange a public event in the municipality of the intended site of the facility, at which oral or written opinions may be expressed on the issue. The opinions expressed shall be communicated to the Government prior to the making of the Decision-in-Principle.

In Section 14 it is stated that before making the Decision in Principle the Government shall ascertain that the municipality where the nuclear facility is planned to be located in its statement referred to in Section 12, is in favour of the facility and that no facts indicating a lack of sufficient prerequisites for constructing a nuclear facility, as required in Section 6, have arisen. Should the Government find that the prerequisites have been met, it shall, in reaching its Decision in Principle, consider the issue from the perspective of the overall good of society, and take into account the benefits and drawbacks arising from the nuclear facility, paying particular attention to:

1. the need for the nuclear facility project with respect to the country’s energy supply;
2. the suitability of the intended site of the nuclear facility and its effects on the environment; and
3. arrangements for the nuclear fuel and waste management.

According to Section 15 the Government Decision in Principle, made under Section 11, in which the construction of the nuclear facility is judged to be in line with the overall good of society, shall be forwarded, without delay, to Parliament for perusal. Parliament may reverse the decision-in-principle as such or may decide that it remains in force as such.

Prior to Parliament arriving at its decision thereon, the applicant may not engage in any measures to be laid down by Government decree which, due to their economic significance, might impede Parliament's, and the Government's, possibilities to determine the issue at their own discretion.

The authorisation and decision-making processes for other facilities and activities are described also in the legislation referred to in licensing process (module 5 on authorization).

The licensing of facilities not exceeding the criteria of a nuclear facility are authorized according to YEL 21 §. The approach is graded from the nuclear facility authorization and consists of a single license and STUK's verification. It is stated that

- the use of nuclear energy meets the safety requirements laid down in this Act, and appropriate account has been taken of the safety of workers and the population, and environmental protection
- nuclear waste management has been arranged appropriately and provision for the cost of nuclear waste management has been made in accordance with the provisions of chapter 7 of YEL;
- the applicant is considered to have the financial and other prerequisites to engage in operations safely and in accordance with Finland's international contractual obligations

The licensing system for radiation practices is prescribed in Chapter 7 of the SätL. The use of radiation and other radiation practices requires a safety licence. STUK grants a safety licence upon application until further notice or, for a special reason, for a fixed period of time. The licence may also be granted separately for different stages of the practice. The licence may include conditions necessary for ensuring safety. A safety licence is granted provided that:

1. the radiation practice complies with the principles of justification, optimization and limitation;
2. a safety assessment has been drawn up for the radiation practice;
3. the practice can be carried out safely;
4. the undertaking has the right to engage in a trade in Finland.

Based on Section 24 of the SätL, the undertaking shall demonstrate that a new type of radiation practice subject to a safety licence is justified. STUK confirms the practice as justified either as part of granting the safety licence or separately.

Further provisions on the procedures to be followed in the justification assessment are given in the VnA1034/2018, Sections 2–7. However, justification need not be demonstrated by the applicant if the practice is included in the list of justified practices maintained by STUK on its website (https://www.stuk.fi/stuk-valvoo/sateilyn-kayttajalle/hae-turvallisuuslupaa-tai-ilmoita-muutoksesta/oikeutettu-ja-oikeuttamaton-sateilyn-kaytto). Compliance with the principles of optimization and limitation are demonstrated through the safety assessment (Section 26 of the SätL).

Requirements on the application for a safety license are given in Section 51 of the SätL and Section 23 and Annex 5 of the VnA 1034/2018. Furnishing of a security for the costs arising from rendering radioactive waste harmless and any possible environmental clean-up measures for certain types of practices are provided for in Sections 54 – 55 of the SätL and Section 29 of the VnA 1034/2018.

(5) Provision for the involvement of interested parties and for their input to decision making;

Section 13 of YEL states that before the Decision in Principle is made, the applicant shall compile according to instructions by MEAE an overall description of the facility, the environmental effects it is expected to have and it's safety, and make it generally available to the public after a check by the Ministry. In 2017 the Section 13 has been enlarged to consider public in general not limiting the participation process for public in the vicinity of the facilities. In 2017 the public hearing was added also the Section 23 a concerning other licensing phases e.g. construction, operation and decommissioning of the nuclear facilities.

MEAE shall provide residents and municipalities as well as local authorities an opportunity to present their opinions in writing before the Decision in Principle is made. Furthermore, in a way the Ministry may specify in more detail, the Ministry shall arrange a public hearing in the municipality where the planned site of the facility is located and during this hearing the public shall have the opportunity to give their opinions either orally or in writing. Opinions that have been presented shall be made known to the Government.

The Environmental Impact Analysis is also required for mining activities to produce uranium and thorium. The process includes also opportunities needed for a nuclear facility. The EIA process involves two stages: the preparation of an EIA program and, at the second stage, draw up the EIA report. The contact authority for both stages is MEAE for the facilities and activities related to YEL except for mining and milling operations aimed at producing uranium or thorium (YEL section 2 para.1 2) the contact authority is the the Centre for Economic Development, Transport and the Environment. EIA is for residents and municipalities to present their opinions.

Section 199 of Radiation Act states that prior to issuing regulations under this Act, STUK provides the Ministry of Social Affairs and Health, the Ministry of Economic Affairs and Employment, the Advisory Committee on Radiation Safety and, to the extent necessary, undertakings and other authorities a chance to be heard. Section 7 of Government Decree on Ionizing Radiation stipulates on statements that STUK has to request from the Advisory Committee on Radiation Safety, Data Protection Ombudsman and other relevant stakeholders as appropriate on new types of practices in the process of justification.

Hearing of the views of parties is obligatory according to the Administrative Procedure Act (434/2003), section 34 subparagraph 1. Before a matter is decided, each party shall be provided with an opportunity to express an opinion on the matter and to submit an explanation of claims and of evidence which may influence the decision. A matter may be decided without hearing according to subparagraph 2, for example if a claim which does not concern any other parties is approved, or the hearing of views is manifestly unnecessary for another reason.

In addition governmental guidelines for involvement of all interested parties are followed in preparation of laws, regulations and guides. Guidelines are as follows:

https://oikeusministerio.fi/kuuleminen

http://kuulemisopas.finlex.fi/ohje/kuulemisohje/

https://valtioneuvosto.fi/paatokset/paatos?decisionId=0900908f804a9259

An example of involvement of interested parties was the preparation of the Radiation Act in 2015–2018. The Ministry of Social Affairs established a steering group that consisted of representatives from other ministries, regulatory bodies and professional societies. The preparation of the Act was conducted in 8 thematic subgroups that consisted mainly of representatives from licensees, professional societies and education and training organizations. Other ministries were actively consulted in relevant issues and guidance was received for example from Ministry of Education and Culture in preparation of requirements on radiation protection education and training.

The Ministry of Justice has a web based transparent platform that has been used since 2017 for consultation of STUK regulations: www.Lausuntopalvelu.fi. The system is public and open even to

each citizen to give comments on regulations. The system requires a registration. All comments that are given are visible to anyone and summaries of grouped comments can be achieved automatically.

(6) Provision for assigning legal responsibility for safety to the persons or organizations responsible for the facilities and activities, and for ensuring the continuity of responsibility where activities are carried out by several persons or organizations successively;

According to Section 8 of YEL the use of nuclear energy without the licence is prohibited (except some minor activities).

Section 9 sets that it is the licensee's obligation to assure safe use of nuclear energy. In 2017 the responsibility of the licensee on the work of subcontractors was added to the Nuclear Energy Act to emphasize licensee's prime responsibility on safety.

Further, the licensee is also responsible for assuring such physical protection and emergency planning and other arrangements, necessary to ensure limitation of nuclear damage, which do not rest with the authorities. A licensee whose operations generate or have generated nuclear waste (licensee under a waste management obligation) shall be responsible for all nuclear waste management measures and their appropriate preparation, as well as for their costs (waste management obligation).

According to Section 7 k the licensee shall appoint a responsible manager and his or her deputy:

1. for the construction of a nuclear facility;

2. for the operation of a nuclear facility;

2a) for the decommissioning of a nuclear facility;

3. for mining and enrichment operations aimed at producing uranium or thorium;

4. for the possession, manufacture, production, handling, use, storage and transport of nuclear materials and nuclear waste, if a separate licence is required for these operations.

A person who has consented to occupy the position and who has been approved for the role by STUK can be appointed as responsible manager. The appointment of the responsible manager shall be proposed when applying for a licence. It is the responsible manager's task to ensure that the provisions, licence conditions and regulations issued by STUK concerning the safe use of nuclear energy, the arrangements for security and emergencies, and the control of nuclear materials are complied with.

The licensee shall ensure that the responsible manager occupies the position required by the task and possesses adequate authority and the actual prerequisites required for bearing the responsibility vested in him or her.

According to Section 7 i of YEL the holder of the licence granting the right to use nuclear energy (licensee) shall have a sufficient number of qualified personnel suitable for the related tasks.

Further, only a person approved by STUK for the position in question may act as a nuclear facility operator in the control room of the facility. The licensee shall appoint persons responsible for ensuring emergency response arrangements, security and the control of nuclear material. Only persons approved by STUK specifically for each position can be appointed. The licensee shall ensure that the persons referred to above occupy the positions required for the task, while possessing adequate authority and the genuine prerequisites for bearing the responsibility vested in them.

According to Section 7 j of YEL the management system of a nuclear facility shall pay particular attention to the impact of safety related opinions and the attitudes of the management and personnel towards the maintenance and development of safety, alongside systematic operating methods and their regular assessment and development. In Section 25 of the STUK Regulation (Y/1/2018) and Section 38 of the STUK Regulation (Y/4/2018), more detailed requirements are provided for the management for safety and quality.

SätL (Section 22) defines that the undertaking is responsible for the radiation safety of the practice and this responsibility cannot be transferred to another. The obligations imposed on undertakings are not diminished by the appointment of a radiation safety officer or some other person in charge or by the use of experts in the operations. The undertaking is relieved from its responsibility only when the safety license is withdrawn which is possible when the practice is discontinued and the licensee has demonstrated in an acceptable manner that it has relinquished or rendered harmless the radiation sources specified in the licence and the radioactive waste generated in the practice. If the practice is transferred to another undertaking (e.g. selling of business operations which includes a radiation practice), the other undertaking shall obtain a license and the license of the transferor will be

withdrawn when the other undertaking obtains a safety license. Regarding transferring a radiation source instead of the whole practice, the transferor is obligated to ensure that the recipient has the required safety license (SäL, Section 72).

(7) The establishment of a regulatory body, as addressed in Requirements 3 and 4;

YEL and SätL establishes STUK as an independent governmental organization for the regulatory control of radiation and nuclear safety as well as nuclear security and nuclear materials. The mission and duties of STUK are based on Act on STUK (1069/1983) and the Decree on STUK (618/1997). The establishment of STUK is prescribed in more detail in Question 3.

(8) Provision for the review and assessment of facilities and activities, in accordance with a graded approach;

The basic safety requirements are given in YEL and SätL. More detailed requirements are given in YEA, VnA 1034/2018 and STUK regulations. The graded approach has been taken into account in the legislation (YEL Section 7a) and in subsequent regulations and guides.

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The requirements for the safety evaluation of nuclear facilities are set in Sections 11-15 and 18-20a of YEL. More detailed requirements are presented in Sections 23-38 of YEA.

The requirements for a safety assessment of radiation practices are presented in Section 26 of the SätL and Sections 13 – 17 of STUK S/6/2019. When reviewing the safety assessment for compliance with the provisions of the SätL, STUK shall consider 1) the nature and extent of the exposure situation; 2) the risks associated with radiation exposure and radiation sources; 3) the impact that the regulatory control may have in the reduction of risks and the improvement of radiation safety (Section 11 of the SätL).

STUK's Management System addresses implementation of graded approach in all regulatory activities. In the oversight of nuclear facilities this is largely based on the application of safety classification also in regulatory activities (review and assessment) as well as on the use and information provided by both deterministic and probabilistic tools. Guide YTV 6.c describes the

application of graded approach for the oversight of nuclear power plants. All of the regulatory functions from licensing to enforcement are covered by the procedure Guide YTV 6.c. The process of reviewing a license application for radiation practices is prescribed in SKV 3.2.

Furthermore, the ongoing VALKE and RIVAKKA development projects at the Nuclear Safety Department in planned to enhance risk informed oversight and application of graded approach. Also the Radiation Practices Regulation Department has an ongoing project to develop regulatory processes similarly. More detailed information on application of graded approach can be seen in Modules 5-8.

(9) The authority and responsibility of the regulatory body for promulgating (or preparing for the enactment of) regulations and preparing guidance for their implementation;

All governmental authorities are entitled to promulgate regulations and prepare guidance and therefore this is not usually regulated in legislation. According to Decree on the Radiation and Nuclear Safety Authority (section 1), STUK is entitled to making proposals for developing legislation in its field of activity and for issuing general guides concerning radiation and nuclear safety STUK has used different methods: information sheets and letters to lisences, e-letters, social media, training activities and the SAMMIO.

According to YEL section 7 q the Radiation and Nuclear Safety Authority shall issue further regulations on the technical details of the principles and requirements laid down in the chapter YEL 2 a (Requirements concerning safety). According to Section 7 r of YEL, STUK shall specify detailed safety requirements concerning the implementation of safety level in accordance with the Act. These requirements are presented in YVL Guides. STUK shall specify the safety requirements it sets in accordance with the safety sectors involved in the use of nuclear energy and publish them as part of the regulations issued by the STUK.

The responsibilities of regulatory bodies to issue more detailed regulations is stated in connection to each requirement of the SätL. For example, the Article 59 on the reliability of radiation measurements states that “STUK issues more detailed regulations on verifying the reliability of measurements and on the radiation meters’ and measuring equipments’ calibration, accuracy, use and suitability for a particular purpose.” STUK has issued the STUK regulation on ionizing radiation measurements (S/7/2021).

(10) Provision for the inspection of facilities and activities, and for the enforcement of regulations, in accordance with a graded approach;

STUK has the legal authority to carry out regulatory control of radiation practices and nuclear energy. The responsibilities and rights of STUK are provided in YEL and SätL. They cover the regulatory control of the construction, operation and decommissioning of a nuclear facility and of activities.

The functions and authority of STUK as a regulatory body for nuclear are set in Sections 55 and 63-68 of YEL. The inspection programmes are described in YVL and in detail in internal YTV Guides. The graded approach is taken into account in the Guides. The regulatory oversight of nuclear power plants is described in Guides YVL A.1. The consideration of the graded approach in the regulatory requirements and guides is discusses in primary question 1.

STUK's has the right to inspect radiation practices (SätL Section 176). STUK shall draw up an inspection programme (Section 182 of SätL) which shall consider, among other things, the categorization of radiation practices referred to in Section 27 of the SätL and the experience gained from the findings of previous inspections (Section 58 of VnA 1034/2018). The basis for establishing the inspection programme is prescribed in SKV 3.4 and the annual inspection programme is worked out as part of establishing annual overall workplan for regulatory control. Sections 177 – 178 and 180 of the SätL provide for the mechanisms to enforce requirements of the SälL and subsequent legislation and regulations. The basis and processes for their implementation are prescribed SKV 3.7. The SKV 3.4 and 3.7 implement a graded approach as required by Section 11 of the SätL on accounting for risks in regulatory control.

(11) Provision for appeals against decisions of the regulatory body;

The basic provisions for appeal against regulatory decisions in the field of nuclear energy are given in YEL (section 75 and 75 a). Decisions in Principle made by the Council of State under Section 11 and decisions under Section 46 (Waste Fund) are not subject to appeal. Decision of an inspection organisation and a decision ment in YEL section 53 section be subject to rectification from the regulatory authority as provided in the Administrative Procedure Act (434/2003). Decisions other than referred to above, are appealed in the order laid down in the Administrative Juridical Procedure Act (808/2019), unless otherwise provided by the Euratom Treaty.

According to Radiation Act section 196 a decision made by an inspector pursuant to section 177 as well as a decision concerning a regulatory certain may be subject to rectification from the regulatory authority as provided in the Administrative Procedure Act. Any other decision made pursuant to Radiation Act and a decision made to a claim for rectification may be appealed as provided in the Administrative Judicial Procedure Act (586/1996). The decision of an Administrative Court may be appealed only if the Supreme Administrative Court grants the leave to appeal. A decision by STUK in a matter referred to in section 96, subsection 3 may not be appealed. Nor may a decision by an inspector in a matter referred to in section 178, subsection 2 be appealed. Any regulatory charge shall be paid within the prescribed period of time despite an appeal. Any other charge imposed by a State authority may be appealed as provided in the Act on Criteria for Charges Payable to the State.

According to Administrative Juridical Procedure Act (808/2019), appeals against the decision of an authority shall be made to a regional administrative court. (section 8) Appeals against the decision of a government plenary session shall be made to the Supreme Administrative Court. Person whom a decision concerns, or whose right, obligation or interest is directly affected by the decision, and a person whose right of appeal is separately provided by law may request a judicial review of an administrative decision by way of appeal. An authority may also request a judicial review by appeal if this is necessary because of a public interest overseen by the authority. Only a person who has requested an administrative review may appeal against the decision issued on the request. If an administrative decision has been amended or reversed in an administrative review procedure, then a person with the right of appeal in the matter according to subsection 1 may nevertheless also request a judicial review by appeal. (section 7) The appeal shall be filed in writing within 30 days of receipt of the decision. (section 13).

SätL section 188 and YEL section 196, subsection 7 state that decision made pursuant certain sections may stipulate that the decision is to be complied with despite an appeal. If a stipulation has been given, the appeal official shall process the appeal as urgent.

(12) Provision for preparedness for, and response to, a nuclear or radiological emergency;

According to Section 7 of YEL a prerequisite for using nuclear energy is that emergency response arrangements for limiting nuclear damages are adequate. Basic provisions for emergency arrangements are set in Section 7 p. Emergency preparedness plans have to be included in the license application for nuclear facilities (Sections 35 and 36 of YEA).

According to Section 55 of YEL STUK is responsible for the regulatory control of emergency preparedness arrangements for nuclear facilities.

STUK Regulation on Emergency Response Arrangements at Nuclear Power Plants 2/Y/2018 lays down further provisions on emergency response arrangements at a nuclear power plant. The STUK Regulation applies, as necessary, to other nuclear facilities equipped with a nuclear reactor. The STUK Regulation covers e.g. requirements on design basis, emergency response organisation, preparedness and emergency plans. More detailed requirements are provided in Guide YVL 7.4.

According to Section 129 of SätL, practices subject to safety license, the undertaking must prepare for radiation safety deviations. Section 130 describes the responsibilities of the undertaking in case of actual safety deviation, and Section 131 of the responsibilities after the deviation. Further details on the required planning and actions during any safety deviation are set in STUK Regulation S/2/2018. According to Section 14 of SätL, STUK is responsible for the regulatory control of these arrangements.

In case of accident that causes emergency exposure situation, Sections 132 – 137 provide general requirements for protective actions, protection of emergency workers and helpers, and transition from emergency exposure situation to existing exposure situation. These requirements apply whether the situation is caused by facility controlled by YEL or SätL. Further details on these requirements are described in Sections 45 – 48 of VnA 1034/2018.

Responsibilities for different organizations during emergencies, including nuclear and radiological emergencies, are provided in the Rescue Act (379/2011).

(13) Provision for an interface with nuclear security;

According to Section 7 of YEL a prerequisite for using nuclear energy is that security arrangements for limiting nuclear damages and for protecting the use of nuclear energy from illegal actions are adequate. Basic provisions for security arrangements are set in Sections 7 l - 7 o. Security plans have to be included in the license application for nuclear facilities (Sections 35 and 36 of YEA).

STUK Regulation on the Security in the Use of Nuclear Energy (Y/3/2016) lays down further provisions on the security related to the use of nuclear energy. The STUK Regulation concerns the security of nuclear facilities, and, as necessary, the security of nuclear materials and nuclear waste, and the transportation thereof. The STUK Regulation covers requirements for design basis, general planning of a nuclear facility, personal security as well as implementation and maintenance of security arrangements.

According to Section 55 of YEL STUK is responsible for the regulatory oversight of security arrangements.

According to Section 67 of SätL “The undertaking shall protect radiation sources subject to a safety licence against illegal operation or loss or otherwise falling into the hands of third parties at their use and storage facilities. These security arrangements shall be adequate in terms of the risks related to the practice and the radiation sources and they must form a whole compatible with the measures concerning radiation safety.” The same section prescribes the possible security arrangements and more detailed provisions on their application in accordance with the radiation sources are given in STUK S/3/2018. STUK is responsible for the regulatory oversight of security arrangements for radiation sources.

(14) Provision for an interface with the system of accounting for, and control of, nuclear material;

According to Section 4 of YEL import of nuclear explosives as well as their manufacture, possession and detonation in Finland are prohibited.

According to Section 55 of YEL STUK is responsible for the necessary control of the use of nuclear energy to prevent proliferation of nuclear weapons. STUK maintains a control system of nuclear materials with the purpose of carrying out the safeguards control of the use of nuclear energy that is necessary for the non-proliferation of nuclear weapons as well as the safeguards control that is related to the international agreements on nuclear energy to which Finland is a party. STUK sees to it that the licensee has the necessary expertise and preparedness to arrange the supervision and that the licensee for his own part implements the above-mentioned supervision in accordance with the pertinent regulations (Section 118 of YEA).

When maintaining the safeguards system, STUK shall take account of the obligations of Commission Regulation (Euratom) No. 302/2005 on the application of the provisions on Euratom safeguards. STUK shall act as the site representative, as referred to in the Regulation, for all sites (Section 118 of YEA).

Detailed requirements for nuclear materials are given in YVL Guides D.1.

(15) Provision for acquiring and maintaining the necessary competence nationally for ensuring safety;

According to Section 7 a of YEL the safety of nuclear energy use shall be maintained at as high a level as practically possible. For the further development of safety, measures shall be implemented that can be considered justified considering operating experience and safety research and advances in science and technology.

According to Section 7 k of YEL the licensee shall appoint a responsible manager and his or her deputy:

1. for the construction of a nuclear facility;

2. for the operation of a nuclear facility;

2a) for the decommissioning of a nuclear facility;

3. for mining and enrichment operations aimed at producing uranium or thorium;

4. for the possession, manufacture, production, handling, use, storage and transport of nuclear materials and nuclear waste, if a separate licence is required for these operations.

A person who has consented to occupy the position and who has been approved for the role by STUK can be appointed as responsible manager. Section 7 i of YEL provides that the licensee shall have a sufficient number of qualified personnel suitable for the related tasks. Only a person approved by STUK for the position in question may act as a nuclear facility operator in the control room of the facility.

The licensee shall appoint persons responsible for ensuring emergency response arrangements, security and the control of nuclear material. Only persons approved by STUK specifically for each position can be appointed.

The licensee shall ensure that the persons referred to above occupy the positions required for the task, while possessing adequate authority and the genuine prerequisites for bearing the responsibility vested in them.

Further, the licensee shall arrange adequate training for maintaining and developing the competence and skills of its personnel engaged to nuclear safety related tasks.

The applications for the construction and operating licenses need to include also adequate documentation on the organisation and the competence of the applicant (Sections 32 and 34 of YEA).

Nuclear safety research is discussed in answer to question on human and financial resources.

The basic professional education and basic research are done in Finnish universities and government centers, for example in VTT Technical Research Centre of Finland. Government has established together with parties involved in the use of nuclear energy specific training program for nuclear safety (YK-course) and nuclear waste management (YJH-course). A specific group established by MEAE has recently analyzed the present and future competence related to use of nuclear energy.

Qualification requirements and radiation protection competence are stipulated in the Chapter 6 of Radiation Act. Qualifications of a radiation safety expert are stipulated in the Section 37 and fields of expertise in the Section 36. Qualification of a medical physics expert and a radiation safety officer are stipulated in the Section 38 and 41, respectively. Language proficiency and other practical requirements for experts and radiation safety officers are stipulated in the Section 44. As stipulated in the Section 47, the undertaking is responsible for ensuring that workers engaged in medical use of radiation are in possession of the applicable qualifications, including radiation protection skills.

Detailed requirements on qualifications and radiation protection competence are given by a decree of the Ministry of Social Affairs and Health on ionizing radiation (1044/2018) in Sections 2–6.

It is stipulated in the Section 46 of the Radiation Act that STUK approves, on the basis of an application, the radiation protection training for a radiation safety officer organized by a training organization other than a university. At the request of a university organizing training, STUK issues a statement on the radiation protection training of a radiation safety expert and radiation safety officer or any material changes thereto to ensure that the training provides the necessary knowledge and the radiation protection skills required for the task as stipulated in the Section 45.

The radiation safety research and needs for ensuring of its' funding are discussed in Q1. The research activities support acquiring and maintaining the necessary competence nationally for ensuring safety.

(16) Responsibilities and obligations in respect of financial provision for the management of radioactive waste and of spent fuel, and for decommissioning of facilities and termination of activities;

According to Section 9 of YEL a licensee whose operations generate or have generated nuclear waste (*licensee under a waste management obligation*) shall be responsible for all nuclear waste management measures and their appropriate preparation, as well as for their costs (*waste management obligation*).

Chapter 7 (Sections 35-53) of YEL sets down the more detailed regulations for the provision for costs of waste management. The establishment of the State Fund for nuclear waste management is enacted in Section 38.

Furnishing of a security for the costs arising from rendering radioactive waste harmless and any possible environmental clean-up measures for certain types of practices are provided for in Sections 54 – 55 of the SätL and Section 29 of the VnA. A security shall be furnished if a safety license is granted for:

1. the use, manufacture, trade, possession, safekeeping, import, export, transfer or storage of a high-activity sealed source;
2. the use, manufacture, trade, possession, safekeeping, import, export, transfer or storage of a radioactive substance or a radiation source containing such a substance, provided that the combined nuclide-specific activity of the radioactive substance being held at any one time is greater than the activity of an equivalent high-activity sealed source;
3. the maintenance, remediation or rendering harmless of radiation appliances containing sealed sources, provided that sealed sources are being removed from their fixed container and the combined nuclide-specific activity of the sealed sources to be removed annually is greater than the activity of an equivalent high-activity sealed source;
4. a practice which generates or may generate radioactive waste, or the waste specified in section 78, subsection 3, provided that the costs arising from rendering it harmless are substantial.

However, a security need not be furnished if the practice concerns a radioactive substance with a shorter half-life than 150 days. The State, a municipality or a joint municipal authority is not required to furnish a security.

(17) The criteria for release from regulatory control;

The restrictions on the application of YEL are set down in Chapter 2 (Sections 8, 9 and 9 a) and 2 A of YEA. License-free activities of the use of nuclear energy are covered in Chapter 3 (Sections 10-20) of YEA. The requirements for releasing nuclear waste from regulatory control are set in YEL 27 c and d §. The clearance level values are given in SY/1/2018.

Radiation practices exempted from a safety license are prescribed in SätL Section 49. Practices exempted on the basis of complying with the exemption criteria (see below) are given in VnA 134/2018, Section 27 §. In addition, STUK may exempt an individual practice from a safety license provided that the exemption criteria are met. The exemption criteria are prescribed in Section 50 § of the SätL and Section 28 § of the VnA 134/2021. The exemption levels are given in SY/1/2018.

The requirements for decommissioning of facilities for radiation practices including their releasing to other use after decontamination are prescribed in Section 83 of the SätL. Prequisites for reuse, recycling, utilization and disposal of materials and waste arising from radiation practices are prescribed in Section 84 of the SätL. The clearance levels are established in Section 85 of the SätL and their values are given in SY/1/2018.

(18) The specification of offences and the corresponding penalties;

YEL defines the enforcement system and rules for suspension, modification or revocation of a licence. The enforcement system includes provisions for executive assistance if needed and for sanctions in case the law is violated.

The offences and penalties for the use of nuclear energy are covered in Section 69 of YEL, referring to the Penalty Code (39/1889), as follows:

- Sections 4, 5, 7 and 8 of Chapter 34 of the Penal Code provide a sanction for the use of nuclear energy in a way that endangers life or is hazardous to public health.
- Sections 6–8 of Chapter 34 of the Penal Code provide a sanction for activities that are in violation of Section 4 of this Act.
- Section 9 of Chapter 34 of the Penal Code provides a sanction for the acquisition of equipment or material, or of formulae or drawings required in the making of nuclear explosives with the purpose of committing a nuclear energy offence.

- Sections 1–4 of Chapter 48 of the Penal Code provide a sanction for acts harmful to the environment that are in violation of this Act or of the provisions or regulations issued by virtue of this Act.
- Section 10 of Chapter 44 of the Penal Code provides a sanction for an offence involving use of nuclear energy that is in violation of this Act or of the provisions or regulations issued by virtue of this Act.

Section 185 of SätL defines Radiation violations subject to a fine, unless the act is insignificant in consideration of the circumstances or unless a more severe punishment is laid down elsewhere in the law. A Radiation violation occurs if a party intentionally or through negligence:

- engages in a practice subject to a safety licence without a safety licence or violates the conditions of a safety licence
- violates a prohibition to manufacture, import, export, transfer, place on the market, offer, keep for sale, sell or otherwise hand over of a product that is not safe
- violates the prohibition to use, import or transfer an unidentified sealed source to Finland,
- neglects the record-keeping or notification obligation concerning radiation sources
- hands over a radiation source to a party who does not hold the necessary safety licence
- neglects the duty to provide information related to the transfer of a radiation source
- violates the prohibition to import or transfer a radiation source manufactured somewhere else than in Finland to Finland as radioactive waste
- reuses, recycles, utilizes or disposes of radioactive waste or some other radioactive material without an appropriate approval
- neglects the obligation to report an established or suspected radiation dose exceeding the dose limit
- neglects the record-keeping duty concerning discharges or the duty to provide information on the discharges
- violates a decision concerning obtaining information
- violates a decision concerning the discontinuation or restriction of a practice

Section 186 of SätL Reference provisions concerning punishments are given in Section 186 of the SätL. These are:

- the punishment for the endangerment of health is laid down in chapter 34, section 4 and 5 and for negligent endangerment in section 7 and 8 of the Criminal Code of Finland.
- the punishment for a health offence is laid down in chapter 44, section 1, and for careless handling in section 12, and for the possession of radioactive material offence in section 12a of the Criminal Code of Finland.
- the punishment for a work safety offence is laid down in chapter 47, section 1 of the Criminal Code of Finland.
- the punishment for an impairment of the environment is laid down in chapter 48, section 1, 2 and 4 and for an environmental infraction in section 3 of the Criminal Code of Finland.

(19) Provision for controls on the import and export of nuclear material and radioactive material, as well as for their tracking within, and to the extent possible outside, national boundaries, such as tracking of the authorized export of radioactive sources.

A license to import nuclear materials and ore containing uranium or thorium is needed according to Section 2 of YEL. The license is granted by STUK according to Section 53 a of YEA.

Provisions on the export of nuclear material are laid down in Council Regulation (EC) No 428/2009, setting up a Community regime for the control of exports of dual-use items and technology, and in the Act on the Control of Exports of Dual-Use Goods (562/1996).

A license for the export of ore containing uranium or thorium is needed according to Section 2 of YEL. The license is granted by STUK according to Section 54 a of YEA.

A license for the import and export of nuclear waste is needed according to Section 2 of YEL. The license in granted by STUK according to Section 55 of YEA.

A safety license (SätL Section 48) is required for the import and export (from and to outside of the EU) of radiation sources except for the export of a radiation source which does not contain a radioactive substance. The Finnish Customs supervises, for its part, the import and export of radiation sources and radioactive waste and the transit of radioactive waste through Finland's territory. In addition, Customs supervises, for its part, international shipments of radiation sources and radioactive waste and international traffic (SätL Section 16).

The transfer of radioactive substances within the EU is regulated by the Council regulation 1493/93/Euratom which provides mechanisms to track transfers of sealed and unsealed radioactive sources between the member states including the verification from the regulatory authority in the recipient Member State that the receiver of the source is appropriately authorized.

SätL Section 72 states that a radiation source the holding of which is subject to a safety licence may be handed over only to an undertaking with the necessary safety licence. The transferor shall ensure that the recipient has the required safety licence. The recipient shall provide the transferor with a certificate

on the reception of the radiation source. The party which transports the radiation source shall notify STUK of the transportation subject to a safety licence (means high activity sealed sources) prior to the start of the transport or the radiation source's arrival to Finland.

According to VnA 1034/2018, before granting a safety license for the export of a Category 1 or 2 high-activity sealed source, STUK verifies with the relevant supervisory authority of the country of destination that there is no obstacle to the export from the country of destination and that the recipient is authorised to receive the source.

Question 2.1 How does the Government maintain the framework for Safety ?

Response:

In Finland the Ministries are responsible for the development and maintenance of the legislation. Considering legislation on nuclear safety (YEL etc) the responsible Ministry is MEAE. Radiation safety legislation (SätL etc) belongs to MASAH. The Ministry of Justice monitors the quality of the legislation and requests total revision of the acts when several updating into individual Sections has been made.

STUK is responsible for making proposals for developing legislation on nuclear and radiation safety. (Decree on STUK, section 1). STUK has also legislative power given in YEL and SätL. STUK issues regulations on the technical details of the principles and requirements laid down in YEL and specify detailed safety requirements concerning the implementation of safety level in accordance with YEL. (YEL sections 7q and 7r.) STUK also issues regulation based on Radiation Act.

In order to maintain and develop the national framework for safety Finland also hosts regularly international prereviews to have an independent review of the framework for safety.

<u>YEL and YEA</u>

The Nuclear Energy Act and related acts and decrees are updated as necessary.

T

he Constitutional Law Committee of Parliament of Finland drew attention to the need to reform the Nuclear Energy Act already in 2008. The parliament requested review of the current Nuclear Energy Act and needed for changes in respect to overall licensing process of nuclear facilities. In 2020 the Constitutional Law Committee stated that YEL has been amended several times and the system of the law has become confusing. The Committee emphasized the urgent need for an overall legislation reformation. It stated, the regulation of the Nuclear Energy Act must be assessed in its entirety in the light of the current Constitution.

https://www.eduskunta.fi/FI/vaski/Lausunto/Sivut/PeVL_22+2020.aspx

MEAE started a project for developing the Nuclear Energy legislation in 2019. (TEM080:00/2019).

https://tem.fi/hankesivu?tunnus=TEM080:00/2019

As a part of this work, a multilateral working group, including members from STUK, was nominated by the MEAE in 2019. In August 2020, the working group released its assessment. According to the published assessment a comprehensive reform of the Nuclear Energy Act is necessary due to major changes in the operating environment of nuclear energy use since the legislation's entry into force in 1988.

According to the report, the key principles of the comprehensive legislative reform would be as follows:

- Finland will continue to ensure compliance with international agreements, commitments and best practices related to the use of nuclear energy,
- the existing licensing scheme covering the life cycle of a nuclear facility should be continued, respecting democratic decision-making in a transparent and effective manner, but at the same time it requires several improvements (e.g. identification of appropriate stage for detailed assessment, increasing the certainty for acceptable solutions in advance, best way to address the decommissioning stage in the licensing scheme),
- requirements and expectations for nuclear safety and technology need to be clear at different stages of the life cycle of a nuclear plant or other nuclear installation and take into account the potential risk to people, environment and the society,
- the definitions need to be concise and facilitate the understanding of provisions.

The assessment is available on MEAE web site in Finnish.

https://julkaisut.valtioneuvosto.fi/handle/10024/162396

After the assessment MEAE has continued discussions with STUK and stakeholders on various topics, e.g. reactor and reactor site pre-assessments, safeguards of nuclear materials, licenses to operate and to decommission a nuclear power plant, activities of the supervising authority, devices and systems used in nuclear power plants, and new approaches needed for new concepts, e.g. SMR development. The first results of these discussions are expected to be available by early 2022. The upcoming National Climate and Energy strategy will be expected to contain a statement to boost the renewal process. The renewal of the legislation on nuclear energy will take many years. The preparation of the total revision of the nuclear energy act, underlying legislation and regulations has started. Binding requirements will be presented in the Nuclear Energy Act, Nuclear Energy Decree and in STUK Regulations according to the principles laid down in Finnish Constitution. The revision of the act would consider more flexible licensing of the nuclear reactors foreseen in the future. The public consultation of the draft act is expected to take place in 2024. The review by the Government and the Parliament will be in 2025-2026. The enactment of the act is expected in 2027.

YVL Regulation and Guides

STUK regulations and YVL guide are reviewed and updated in a systematic manner described in the STUK management system guide STUK 3.6. The review of the status of STUK regulations and guides is made during annual planning process.

On October 2020 STUK adopted the decision to begin the preparation of the structural and substantive renewal of the safety regulation on the use of nuclear energy. The reform seeks to effect changes in the oversight of nuclear safety and related operating culture. No changes will be made to the level of safety presently required of nuclear facilities and other uses of nuclear energy. The new provisions will emphasize the operators' responsibility for safety. Recommendatory guidelines and binding requirements will be clearly distinguished from one another. The new, technology-neutral safety requirements will specify the target outcomes instead of dictating the acceptable solutions. Target-oriented requirements will provide the license holders with an opportunity to seek the solutions best suited for meeting the demands. Technology neutrality, in turn, enables a more flexible authorization of new technologies, such as small modular reactors (SMR), than is possible under the provisions presently in force. More detailed schedule of the reform will be specified by the beginning of 2022.

STUK made a press release 4 Nov 2020 about launching of the renewal of STUKs safety regulation on the use of nuclear energy. In the press release STUK stated, that since YEL and the regulations and guidelines issued under it are so closely interconnected, it would be advantageous to amend them at the same time. In connection with the upcoming reform, the regulations and guidelines will also be analyzed to determine whether, due to constitutional considerations, any requirements specified in them should be provided for in legislation or a decree. Thus, a comprehensive examination of all parts would therefore ensure the best outcome in terms of preparations and the end result.

Radiation legislation

The Radiation legislation was reformed in 2018, see question 1. The implementation of the new legislation revealed some immediate needs to correct/clarify/change some of the provisions of the SätL These are foreseen to be adopted by the Parliament in 2022 in conjunction with the adoption of a new Act on STUK. Also further needs for improvement have been identified. Like for all new legislation in Finland, an overall assessment on its effectives and functionality will take place some years after its adoption. The findings of this assessment and those of the IRRS mission, as well as, the issues already identified will form the basis for the next revision of the legislation.

Question 3 Has the government, through its legal system, established a regulatory body for safety?

Answer: Yes

Response:

STUK is an independent governmental organization for the regulatory control of radiation and nuclear safety as well as nuclear security and nuclear materials as provided for in the Radiation Act (SätL) and the Nuclear Energy Act. (YEL) The mission and duties of STUK are based on Act on STUK (1069/1983) and the Decree on STUK (618/1997). According to Act on STUK (section 1) STUK is administratively under the Ministry of Social Affairs and Health.

The Ministry of Social Affairs and Health has supreme authority and highest directing power in supervising compliance with Radiation Act. However the Ministry of Economic Affairs and Employment has supreme authority and highest directing power in supervising compliance with Radiation Act in matters concerning the use of nuclear energy as referred to in the Nuclear Energy Act. According to YEL the overall authority in the field of nuclear energy is the Ministry of Economic Affairs and Employment who also prepares matters concerning nuclear energy to the Government for decision-making. Among other duties, the Ministry of Economic Affairs and Employment is responsible for the formulation of a national energy policy whereas STUK is a safety regulator without no such duties. Interfaces to ministries and governmental organizations are described in Figure 9.

According to the Decree on STUK, STUK has the following duties:

In accordance with YEL, SätL, the Act on STUK as well as other regulations and international agreements, STUK shall be responsible for:

1. regulatory control of the safety of the use of nuclear energy, and regulatory control of physical protection, emergency preparedness and nuclear materials;

2. regulatory control of the use of radiation and of other radiation practices;

3. monitoring the radiation situation in Finland, and for maintaining preparedness for abnormal radiation situations;

4. maintaining national metrological standards in its field of activity;

5. pursuing research and promoting development to enhance radiation and nuclear safety;

6. providing information on radiation and nuclear safety issues, and for participating in training activities in the field;

7. producing expert services applicable in its field of activity;

8. making proposals for developing legislation in its field of activity, and for issuing general guides concerning radiation and nuclear safety; as well as

9. contributing to international co-operation in its field of activity, and for taking care of international control, contact and reporting activities, as enacted or prescribed.

According to Section 55 of the Nuclear Energy Act STUK is responsible for the regulatory oversight of the safe use of nuclear energy. In addition, STUK is responsible for the regulatory oversight of security and emergency preparedness arrangements as well as regulatory oversight for the non-proliferation of nuclear weapons (safeguards). The special functions of STUK are listed in Section 55. They cover the safety review and assessment of licence applications, and the regulatory oversight of the construction, operation and decommissioning of a nuclear facility. The regulatory oversight of nuclear power plants is described in detail in the Guide YVL A.1. The rights and authorities of STUK are provided in Chapter 10 (Sections 63-68). The responsibilities and rights of STUK, as regards the regulation of the use of nuclear energy, are provided in the Nuclear Energy Act. STUK has e.g. legal rights to require modifications to nuclear power plants, to limit the power of plants and to require shutdown of a plant when necessary for safety reasons.

STUK does not grant construction or operating licences for nuclear facilities. However, in practice no such licence would be issued without STUK's statement where the fulfillment of the safety regulations is confirmed as described in Article 7.

According to Section 14 of the Radiation Act STUK supervises compliance with Radiation Act, unless otherwise provided elsewhere. The rights and authorities of STUK are provided in Chapter 20 (for example Section 176 Right to inspection, information and investigation.)

In addition STUK issues further regulations on the technical details of the

principles and requirements laid down in YEL and specify detailed safety requirements concerning the implementation of safety level in accordance with YEL. (YEL sections 7q and 7r.) STUK also issues regulation based on Radiation Act.

Question 3.1 What legal authority has been assigned to the Regulatory Body to enable it to fulfil its regulatory obligations for the control of facilities and activities?

Response:

According to Section 55 of YEL STUK is responsible for the regulatory control of safe use of nuclear energy. In addition, STUK is responsible for the control of physical protection and emergency planning, and for the necessary control of the use of nuclear energy to prevent proliferation of nuclear weapons.

In order to carry out the tasks mentioned above the STUK shall, according to Section 55 of YEL, in particular:

1. participate in the processing of license applications pursuant to this Act;

2. control the observance of license conditions as well as set detailed requirements concerning the operations referred to in the license;

3. issue proposals for general safety regulations as referred to in Section 7q, and specify the detailed safety requirements as referred to in Section 7 r;

4. issue detailed regulations, if necessary, and control compliance therewith;

5. set qualification requirements for persons involved in the use of nuclear energy and control that the requirements are met;

6. provide expertise for other authorities;

6a. act as the competent authority required in the Directive referred to in paragraph 7 of Section 21 subsection 1;

7. carry out research and development activities necessary for regulatory control and participate in international co-operation in the field; and

8) make proposals and issue statements required by the regulatory task;

9) engage in cooperative activities on the nuclear safety of nuclear facilities with the regulatory authorities of other States;

10) attend to the arrangement of a national self-assessment based on a specific topic related to the nuclear safety of nuclear facilities once every 6 years.

STUK shall also be in charge of deciding on such license applications pursuant to this Act as have been provided to be determined by STUK, and of control that indemnification regarding liability in case of a nuclear damage has been arranged as provided.

STUK may, upon request by anyone planning to use nuclear energy, check the plan drawn up by them and issue preliminary instructions on what should be taken into account with respect to safety, physical protection and emergency planning.

According to Section 14 of SätL, STUK supervises compliance with the SätL.SätL also specifically empowers STUK, among others, to (Section number in brackets refer to the relevant Section of the SätL):

- establish (Section 10) or approve (Section 25) dose constraints and constraints for potential exposure to be used in a radiation practice
- maintain registers for the purposes of carrying its tasks (Section 19)
- confirm the justification of a practice (Section 24)
- confirm the safety assessment of a radiation practice (Section 26)
- confirm the categorizations concerning the radiation practice (section 27)
- grant a safety license for the use of radiation and other radiation practices (Section 48)
- exempt a practice from a safety license (under conditions defined by the SätL) (Section 50)
- amend a safety license and its conditions (Section 52)
- withdraw a safety license (Section 53)

- approve dose measurement service (Section 60) and other radiation measurements (Section 64)
- approve the reuse, recycling, utilization and disposal of waste and other material deriving from a radiation practice if the clearance levels are exceeded (Section 84)
- authorize a discharge exceeding the limit value for a minor discharge (Section 127)
- inspect and observe a practice and to access the facility and to make tests and to take samples, photographs etc. (Section 176)
- obtain information necessary for supervision (Section 176)
- investigate a radiation safety deviation and to hear also other persons and parties aware of the deviation (Section 176)
- obligate an undertaking to remedy the practice to comply with the SätL (Section 177)
- discontinue or restrict a practice (Section 178)
- obtain information from another regulatory authority and to use samples acquired by another regulatory authority (Section 179)
- receive official assistance from the customs and the police (Section 180)
- use the assistance of an outside expert for the performance of inspections, investigations studies and measurements to clarify a matter relevant to the regulatory control (Section 181)
- enforce a decision with a notice of condition fine, enforced compliance and suspension (Section 184)

SätL authorizes STUK to issue regulations as specified in Sections 10, 12, 23, 26, 28, 29, 30, 33, 49, 59, 63, 66, 67, 70, 71, 72, 73, 74, 75, 78, 83, 85, 88, 89, 92, 101, 109, 112, 119, 127, 128, 129, 130, 131, 136, 138 and 160 of the SätL.

By its mandate as the regulatory authority supervising compliance with the SätL, STUK may issue Guides on any matters which are within the scope of the SätL.

Question 3.2 What processes does the Government use to ensure that the Regulatory Body always has sufficient competence and resources to fulfil its statutory obligations?

Response:

Funding

At the moment STUK has access to sufficient financial resources for the proper and timely discharge of its assigned responsibilities. The main funding channels for STUK are the annual Governmental budget allocation to the Agency in the budget and the payments received by STUK from its clients (public and commercial payments). Budget funding accounted for 41% of the agency's total funding in 2020.

Governmental budget allocation. The focus of budget funding is on STUK's other statutory obligations / tasks than nuclear safety supervision, such as research and development, preparedness and security arrangements, environmental radiation monitoring and communications. It also secures the participation of Finnish experts in multilateral nuclear and radiation safety cooperation. In addition, the radiation safety supervision is mainly funded from the government budget since 15.12.2018.

Nuclear Safety Supervision is net budgeted and the cost-effectiveness ratio in 2020 was 100%, when the share of budget-funded funding in Nuclear Safety Supervision was 0%. The goal of nuclear safety supervision is that the revenues of supervision cover 100% of the costs, which is achieved by invoicing the supervision work during the year at an estimated hourly rate, and correcting the invoicing with an equalization invoice after cost calculation. The fee for nuclear safety supervision is based on the State Payment Basis Act (150/1992) and Decree (211/1992) and the decision of the Ministry of Trade and Industry on the payment and payment bases of the Radiation and Nuclear Safety Authority's services subject to nuclear safety supervision (1285/1993, section 3).

Radiation safety supervision was previously net budgeted. Previously STUK collected separate annual fees and inspection fees for planned inspections from lisencees. This meant that the supervision fees were paid to STUK.

Currently STUK collects an annual regulatory charge from an undertaking engaged in a practice subject to a safety licence and a licence referred to section 165 to cover the costs arising from supervision compliance with the Radiation Act (SätL, Section 189). The regulatory charge comprises a practice-specific basic charge and a radiation source-specific surcharge. Currently tax-like supervision fees charged by STUK (in 2020, EUR 2.6 million) revenue to the state and, correspondingly, an increase in the operating expenses of STUK is budgeted by the estimated revenue accrual from the control fees charged. Because the control fee is referred to as tax-related, the current price list of STUK is substantially revised less frequently to match the cost level. Previously, the price list of the STUK has been revised almost annually.

Because of this development STUK is currently more dependent on the state budget and governmental guidance. The existing legislation and related practices may jeopardize STUKs access to sufficient financial resources for the proper and timely discharge of its assigned responsibilities.

Competence

STUK has currently adequate and competent human resources to fulfill its responsibilities.

However, STUK in depth competence building in the field of radiation protection and emergency preparedness rest on radiation and emergency safety research. As regards the years 2015-2021 STUK's financial resources from the Governmental budget are being cut. The decision was related mainly to the Governmental decision to reorganize research institutes and research programmes and their funding. This means that STUK resources especially in the area of radiation research were decreased. However, STUK provided international expert services which profits were used to develop current radiation safety research program for STUK. For the years 2018 to 2025 STUK uses annually for research 2 million euros that are not coved by STUK budget. This means that in practice the radiation safety research needed by STUK rely on extra income from expert services. This is posing high risk for the continuity of the radiation safety research at STUK and sustainable development of the expertise in the area at STUK.

STUK is administratively under the Ministry of Social Affairs and Health. It is emphasized that the regulatory oversight of the safe use of radiation and nuclear energy is independently carried out by STUK. However, in regard to budgeting the Ministry of Social Affairs and Health has no obligations to present STUK proposal for adequate financing forwards to discussions on Government Budget. STUK is discussing the means for funding radiation protection and emergency preparedness research with the ministries. STUK has proposed to increase the research funding in Government Budget for STUK. However, so far no solutions have been found for sustainable funding of national radiation safety research and ensuring in-depth expertise on the field.

Current budgetary situation poses a risk for independence of the regulatory oversight of radiation practices and sustainability of radiation safety expertise for regulatory decision making. As a result of the budget cuts and reorganization of the radiation safety research STUK may not have its own expertise in the field of radiation safety and it may no longer be able to obtain external applied research support in radiation safety that it may consider necessary to support its regulatory duties. Because of this development STUK is currently more dependent on the state budget and governmental guidance. The existing legislation and related practices may jeopardize STUKs access to sufficient financial resources for the proper and timely discharge of its assigned responsibilities and sufficient competent staff.

There are also several areas where STUK's competence relies on only one or few competent experts. STUK's competences on oversight of nuclear waste management are thin. When Posiva's spent fuel disposal programme enters operation in late 2020's, new challenges arise for maintaining STUK's competence especially in the post-closure safety area.

The total revision of the nuclear energy act, underlying legislation and regulations results in significant workload to STUK for which no additional budget funding has been allocated. In addition, STUK has a challenge to develop competencies for new areas/technologies (e.g. SMRs). For example, there is a following objective stated in the annual performance agreement between STUK and the Ministry of Social Affairs and Health: “STUK is significantly enhancing its competencies related to SMRs”. STUK asked more money for that task for its budget but the request was rejected by the Government/parliament.

The government should ensure that STUK's funding remains sufficient for radiation safety oversight and radiation safety research in order to retain and develop oversight capabilities and staff competence. Moreover, the future competence for oversight of long-term nuclear waste management in Finland should be ensured. Further more, appropriate arrangements should be made to ensure STUK preparation for the foreseen future use of nuclear energy in Finland.

Staffing and training

There are provisions for staffing and training. See question 8.

Question 3.3 How does the Government ensure that the regulatory body remains effectively independent in its safety related decision making, and that it is able to perform its functions without undue pressure or constraint?

Response:

Evidences:

2.8. To be effectively independent from undue influences on its decision making, the regulatory body:

(a) S*ufficient authority and sufficient competent staff*

STUK is an independent governmental organization for the regulatory control of radiation and nuclear safety as well as nuclear security and nuclear materials as provided for in the Radiation Act (SätL) and the Nuclear Energy Act. (YEL) The mission and duties of STUK are based on Act on STUK (1069/1983) and the Decree on STUK (618/1997). See also question 3.

Sufficient competent staff, see question 3.2 and 8.

(b) *Sufficient financial resources*

See 3.2

(c) *independent safety related decision making (d) pressure free*

STUK is independent in its decision making in all stages in the lifetime of facilities and the duration of activities, under operational states and accidents. No Ministry or other party can take for its decision-making a matter that has been defined by law to be on the responsibility of STUK.

STUK has an independent and strong role in the nuclear safety related proposals. The Government must take into account the proposals included in the STUK's statements when considering the conditions of the Decision in Principles and licenses for nuclear facilities (YEL 12 a Section) The licensing authority shall also observe the proposals relating to safety presented in the statement of the Radiation and Nuclear Safety Authority referred to in section 23. (YEL 25 section) In addition a statement shall be obtained from the Radiation and Nuclear Safety Authority prior to its settlement when a matter to be settled by the authorities may affect the safe use of nuclear energy. (YEL section 62).

At present, the independent role of the STUK in decision-making is not explicitly provided in the Act on STUK. The independency is currently based on general constitutional and public law rules, such as the provisions of the Constitution and general administrative laws. In addition, independence is achieved partly through laws concerning the legal powers of the Centre's supervisory activities (YEL, SätL) and the present organizational legislation (Act and Decree on STUK).

The Act on STUK (section 1 subsection 2) is about to be amended so that the fundamental premise of effective independence in decision-making would be clearly expressed in the Act. According to the proposal, the Radiation and Nuclear Safety Authority would have an independent position in its positions/statements and supervisory activities related to its field of activity.

Supervision activities would be understood to mean oversight carried out by STUK as an authority, and it would include the related administrative decisions and other administrative actions, such as inspections. This provision would cover not only the oversight function, but also the independence of STUK in taking positions/statements in its field of activity. In addition to safety assessments, such opinions would include a range of other management activities closely related to STUK, such as opinions and initiatives, advice and communication.

The proposed amendment aims at clarifying the implementation of the Amended Nuclear Safety Directive (2014/87/Euratom) and commitment to international requirements and recommendations considering independency of regulatory body. The proposed regulation would also partly mean the national implementation of this directive. It would not be a question of changing STUK's status, but of expressing and confirming the situation actually taking place at the organization Act.

The new provision is proposed to be added to the Act to implement more clearly the independence regulation required by international obligations and recommendations and EU directives. In part, the proposed regulation would therefore constitute a national implementation of the Amended Nuclear Safety Directive (2014/87/Euratom) and concerned. Article 5(2) of the Nuclear Safety Directive and Article 76(1) of the Radiation Safety Directive (2013/59/Euratom) which also require the competent supervisory authority to be independent in carrying out its supervisory role. It would not be a question of changing the status of STUK, but of expressing and establishing the actual situation in law.

The purpose of the new legislation would also be to protect STUK and its personnel from inappropriate influence or pressure. The purpose of providing for independent status would be to protect the Radiation and Nuclear Safety Authority and its staff from possible undue influence and attempts to influence (including pressures from other parties).

In addition STUK has legislative power and responsibilities given in YEL and SätL. STUK issues further regulations on the technical details of the principles and requirements laid down in YEL and specify detailed safety requirements concerning the implementation of safety level in accordance with YEL. (YEL sections 7q and 7r.) STUK also issues regulation based on Radiation Act. STUK is also responsible for making proposals for developing legislation in its field of activity. (Decree on STUK,

section 1) *The government, should ensure STUK the access to sufficient financial resources and competent staff for the maintenance and development of STUK regulation and making proposals for developing the legislation.* This is important especially at the moment and in the near future when YEL and related STUK regulation are under major development or reform. See 2.1.(e) *independent advice and reports* and

STUK is responsible for issuing general guides concerning radiation and nuclear safety. STUK is responsible for providing information on radiation and nuclear safety issues. (Decree on STUK, section 1).

(f) *international co-operation*

STUK is responsible for r participating in training activities in the field and contributing to international co-operation in its field of activity, and for taking care of international control, contact and reporting activities, as enacted or prescribed (Decree on STUK, section 1)

2.9. No responsibilities shall be assigned to the regulatory body that might compromise or conflict with its discharging of its responsibility for regulating the safety of facilities and activities.

STUK has no responsibilities or duties which would be in conflict with regulatory control. STUK has separated commercial service activities (e.g. radon measurement services) from the supervision activities. See Module 3.

2.10. *Interest conflicts*

Personnel-related independence is based on the qualification requirements for STUK's personnel and is mainly based on the Act on Public Officials in Central Government (750/1994).

When considering an appointment, the authority shall take into account the integrity of the person to be appointed or appointed and shall ensure that he or she has no interests which might be prejudicial to the proper performance of the duties of the post and that he or she is otherwise able to perform his or her duties independently and with integrity. In assessing the above obligation of the public authority,

account shall be taken of the nature of the post or function to be filled, the previous employment relationship of the person to be appointed with the State and the proper performance of that relationship, and the means at the disposal of the public authority to ascertain the background of the person to be appointed. (Section 8 c) The appointment to a post shall be subject to the condition, if so provided by Government Decree, that the appointee holds a valid personal security clearance certificate as referred to in the Security Clearance Act (726/2014). In addition decree on STUK (Section 8) includes certain qualification requirements for directors of STUK.

According to The Act on Public Officials in Central Government secondary activities are subject to authorisation or notification to a government official. An official may not be prevented from performing his or her duties by reason of a secondary activity. Nor may the secondary activity undermine confidence in the impartiality of the exercise of the function or otherwise prejudice the proper performance of the function or, as a competing activity, manifestly prejudice the employer. (section 18) The Act also provides that the Authority may conclude a written agreement restricting an official's right to transfer to another employer or to take up a trade, business, profession or similar activity (quarantine agreement, section 44 a).

Administrative Procedure Act (434/2003) includes provisions of disqualification (Section 27 and 28). According to the Act public official shall not participate in the consideration of a matter or be present during such consideration if he or she is disqualified. (Section 27).

2.11. In the event that a department or agency of government is itself an authorized party operating an authorized facility or facilities, or conducting authorized activities, the regulatory body shall be separate from, and effectively independent of, the authorized party.

STUK itself uses radiation sources in some of its activities including dosimetry laboratory, training and as test sources for measuring instruments. The Radiation Practices Regulation Department supervises the uses of radiation within the other departments in the same ways as for any licensee. A dedicated inspector from the Nuclear Safety Department supervises similarly the use of radiation sources within the Radiation Practices Department.

Question 4 Has the government expressly assigned prime responsibility for safety to the person or organisation responsible for the facility or the activity?

Answer: Yes

Response:

According to the Nuclear Energy Act Section 7 k, a responsible manager has to be appointed for the construction, operation and decommissioning of a nuclear facility, mining and milling of uranium and thorium, and for activities where a license is needed due to nuclear safeguards reasons. The appointment is subject to approval by STUK. The responsible manager has a duty to ensure the safe use of nuclear energy and to see that the arrangements for physical protection and emergency preparedness and the safeguards control are complied with.

According to YEL Section 9 the responsibility can not be transferred and According to Section 7 f safety shall take priority during the construction and operation of a nuclear facility.

Section 22 of SätL states that "The undertaking is responsible for the radiation safety of the practice. This responsibility cannot be transferred to another. The obligations imposed on undertakings are not diminished by the appointment of a radiation safety officer or some other person in charge or by the use of experts in the operations." By definition an undertaking means the holder of a safety licence, enterprise, corporation, foundation or institution as well as any employer or private entrepreneur conducting a radiation practice (Section 4, point 34 of the SätL).

Question 4.1 How is the regulatory body empowered to require persons or organisations having prime responsibility for safety of facilities and activities, to comply with regulatory requirements and to demonstrate such compliance?

Response:

YEL Chapter 10 "Supervision and coercive measures" defines the enforcement system and rules for suspension, modification or revocation of a licence. The enforcement system includes provisions for executive assistance if needed and for sanctions in case the law is violated. The enforcement tools and procedures of the regulator are considered to fully meet the needs.

In practice, STUK's enforcement tools include: oral notice or written request for action by the inspector, order for actions by STUK. Actions can include stopping the plant operation immediately or decrease of reactor power for unlimited time. Legally stronger instruments would be 1) setting a conditional imposition of a fine, 2) threatening with interruption or limiting the operation and, 3) threatening that STUK enforces the neglected action to be made at the licensee's expense.

The repertoire of these tools together with some practical examples for implementing them has been presented in an internal policy document as part of STUK's Quality System.

The use of radiation and other radiation practices are subject to a safety license (SätL, Section 48). A condition for obtaining the license is a safety assessment (Section 26) which is reviewed by STUK before issuing the license. Later, STUK may amend the license and its conditions (Section 52) and to withdraw it (Section 53). A radiation practice is subject to STUK's inspections (SätL Sections 176 and 182).

STUK is empowered to enforce compliance with regulatory requirements by various means, STUK may, among others (Section in brackets refer to SätL):

- obligate an undertaking to remedy the practice to comply with the SätL (Section 177)
- discontinue or restrict a practice (Section 178)
- obtain information from another regulatory authority and to use samples acquired by another regulatory authority (Section 179)
- receive official assistance from the customs and the police (Section 180)
- enforce a decision with a notice of conditional fine, enforced compliance and suspension (Section 184)

Question 4.2 How does the government stipulate that compliance with regulations and requirements does not relieve the person or organisation responsible for a facility or activity of its prime responsibility for safety?

Response:

According to YEL Section 7a the safety of nuclear energy use shall be maintained at as high a level as practically possible. For the further development of safety, measures shall be implemented that can be considered justified considering operating experience and safety research and advances in science and technology. More detailed requirements of the continuous improvement of safety are presented in STUK regulations:

- STUK Regulation on the Safety of Nuclear Power Plants (STUK Y/1/2018), (3 § (1) and 25 § (1))
- STUK Regulation on Emergency Arrangements of a Nuclear Power Plant (STUK Y/2/2018) (3 § (8.), 4 § (10.) ja 8 §)
- STUK Regulation on the Security in the Use of Nuclear Energy (STUK Y/3/2016) (6 § (4))
- STUK Regulation on the Safety of Disposal of Nuclear Waste (STUK Y/4/2018), (4 § (2.))

Furthermore, the periodic safety reviews are made according to YEL Section 7 e§ every 10 years for nuclear power plants and every 15 years for other nuclear facilities. According to YEL Section 54a § in the event of an accident the consequences of which are significant from the point of view of nuclear safety or radiation protection a self-assessment shall be made.

The undertaking shall actively identify and make safety improvements. The main requirements in this respect are Sections 26 (Safety assessment) and 23 (Criteria for organizing practices) of SätL.

According to SätL, Section 26, the undertaking shall carry out a safety assessment concerning the radiation practice, which: 1) identifies ways in which the practice can cause radiation exposure, considering any possible radiation safety deviations; 2) assesses the magnitude of the occupational, public and medical exposure arising from the practices as well as the probability and magnitude of the potential exposure; 3) presents measures to ensure radiation safety and the optimization of radiation protection; 4) presents measures to prevent and prepare for identified radiation safety deviations.

The safety assessment shall be kept up to date. STUK S/6/2019, Section 14 requires reviewing it regularly (every 2 – 5 year, depending on the exposure category), but also in the event of a change of the practice, after a radiation deviations, and in the light of experience gained from other similar activities, the results of the safety research and technical progress.

SätL, Section 23 states that ”…. The undertaking shall implement such measures to improve radiation safety as can be considered justified in terms of their quality and costs as well as their improving impact.”

In case of a radiation deviation (emergency exposure situation), the undertaking shall assess the situation and take the measures necessary to ensure radiation safety. If rescue operations or protective actions from an authority are required, the undertaking shall take part in them (SätL, Section 130).

Question 5 Has the government provided for effective coordination of the regulatory functions of the various authorities having responsibilities for safety within the regulatory framework?

Answer: Yes

Response:

Cooperation between authorities is based on legislation. According to the administrative procedure act section 11, an authority shall, within its competence and to the extent required by the matter, assist another authority, at its request, in performing an administrative duty and shall also otherwise seek to promote cooperation between authorities.

In the use of nuclear energy MEAE has supreme command and control (YEL Section 54). MI is responsible for security and emergency response functions in general. MSAH and MAF steer

environmental health and ME environmental authorities in case of a radiation fallout and other nuclear or radiological incident. MFA is responsible for nuclear non-proliferation policy.

According to Section 55 of the Nuclear Energy Act and Section 14 of the Radiation Act, STUK is responsible for the regulatory oversight of nuclear energy and of radiation practices. Provisions are laid down on executive assistance given by one authority to another (SätL section 180, YEL sections 68 and 68 a). Authorities' right to obtain and disclose information is provided for by law (SätL sections 179 and 180, Act on the Openness of Government Activities Section 29 etc). Other authorities have also responsibilities defined in the Nuclear Energy Act and Radiation Act related to the radiation practice and nuclear energy. Duties of customs authorities in controlling the import and export of nuclear and other radioactive materials are specified Section 115a of YEA and Section 17 of SätL. Police are responsible for controlling transports of radioactive and nuclear materials on the roads.

Also many other governmental and local organizations, as well as the municipalities, have their own functions based on separate legislation as regards the construction and operation of facilities and conducting activities.

In addition STUK has done documented arrangements for example with Finnish Customs, Finnish Defense Forces and Finnish Meteorological Institute.

YEL

STUK is responsible for the regulatory control of safe use of nuclear energy. In addition, STUK is responsible for attending to the regulatory control of physical protection and emergency planning, and for the necessary control of the use of nuclear energy to prevent proliferation of nuclear weapons (YEL Section 55). The rights of STUK in nuclear field are in YEL Section 63. Functions of STUK are more detailed prescribed in the Law and Decree on STUK.

YEL chapter 9 "Other legislation and cooperation between authorities" defines the interface in relation to safety and security of the use of nuclear energy between STUK and other authorities. The issues cover the construction and planning of the use of land, work safety, pressure equipment, enacted laws concerning Radiation protection, transport of nuclear material and liability for nuclear damage. YEL Section 62 "Cooperation among authorities" states that "When a matter to be settled by the authorities may affect the safe use of nuclear energy, a statement shall be obtained from the Radiation and Nuclear Safety Authority prior to its settlement." See also Module Interface with Security Question 1.3.

SätL

The Chapter 3 of Radiation Act stipulates on regulatory authorities and other regulatory duties. The Section 13 states that The Ministry of Social Affairs and Health has supreme authority and highest directing power in supervising compliance with this Act. The Ministry of Economic Affairs and Employment has supreme authority and highest directing power in supervising compliance with this Act in matters concerning the use of nuclear energy as referred to in the Nuclear Energy Act.

The Section 14 states that STUK supervises compliance with this Act, unless otherwise provided elsewhere. STUK acts as the supervisory facility referred to in Article 35 of the treaty establishing the European Atomic Energy Community and carries out the regulatory duties, liaising duties and reporting duties falling under the scope of the radiation safety supervision to be implemented pursuant to the treaty, unless otherwise provided elsewhere. STUK acts as the competent authority referred to in Council Directive 2006/117/Euratom, on the supervision and control of shipments of radioactive waste and spent fuel, hereinafter referred to as the Waste Shipment Directive. STUK prepares and implements an environmental radiation monitoring programme representing all members of the public to monitor the amounts of radioactive substances in the environment and the magnitude of the public exposure resulting from them. STUK compiles and publishes nationwide assessments on exposures arising from medical use of radiation and their development. STUK maintains the national metrological standards necessary to ensure the reliability of radiation measurements. STUK acts as the competent authority referred to in the Act on the Recognition of Professional Qualifications (1384/2015) for the purposes of deciding on the qualifications of a radiation safety expert and a radiation safety officer. The Act on Health Care Professionals (559/1994) contains provisions on the recognition of the professional qualifications of health care professionals.

The Section 15 states that a municipality’s health protection authority supervises compliance with the reference levels of the radioactivity in household water referred to in section 154 and the radon concentration in dwellings and other premises used by people referred to in section 158, as well as the investigation obligation referred to in section 146, subsection 1, with regard to household water, dwellings and other spaces with public access. The supervision carried out by a municipality’s health protection authority referred to in subsection 1 is subject to the Health Protection Act. A municipality’s health protection authority furthermore carries out the surveys of sunbeds in accordance with section 173 and 174.

The Section 16 states that Finnish Customs supervises, for its part, the import and export of radiation sources and radioactive waste and the consumer goods referred to in section 69 as well as the transit of

radioactive waste through Finland's territory. In addition, Customs supervises, for its part, international shipments of radiation sources and radioactive waste and international traffic. Customs supervises, for its part, compliance with the import and export prohibition of products falling under the scope of the prohibition to use radioactive substances referred to in section 68. The supervision carried out by Customs is subject to the Customs Act (304/2016).

Responsibilities of other authorities are stipulated in the Section 17. Compliance with the action level applicable to foodstuffs and animal feed and the prohibition to use radioactive substances referred to in section 68 is supervised by the authorities referred to in chapter 4 of the Food Act (23/2006) and the authorities referred to in chapter 4 of the Feed Act (86/2008) in terms of their respective branches of activity. The Finnish Safety and Chemicals Agency (Tukes) supervises the prohibition referred to in section 68 in terms of cosmetics and toys. The authorities referred to in this section comply with the relevant laws applicable to their respective branches of activity in their supervision.

Cooperation areas

Typical areas calling for coordination are occupational exposure, environmental issues, security arrangements as well as emergency preparedness.

Radon has been identified as an interface between the powers of several supervisory authorities. STUK and the municipality's health protection authority have partly overlapping control competences in relation to radon in workplaces and other premises used by people. In addition, occupational health and safety inspectors are also involved in the radon supervision process. The process has been agreed between STUK and MSAH. On the other hand the municipal building authority is responsible for health surveillance of construction, but the process does not detect radon. Therefore, a working group has been established to develop regulation, practices and communication in the area of radon-cooperation. The same working group also work as a steering committee of National Radon Action Plan. It involves members from Ministry of Social Affairs and Health (MSAH), National Supervisory Authority for Welfare and Health (Valvira), Ministry of the Environment (EM), STUK, Regional State Administrative Agency (AVI), Building Control Authority, Association of Finnish Local and Regional Authorities (Kuntaliitto) etc.

Question 6 Has the government established an effective system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural and artificial origin) and contamination from past activities or events?

Answer: Yes

Response:

Radiation risks arising from most common types of exposures to natural radiation (radon in workplaces and homes, NORM industries, radioactivity in construction products and drinking water and cosmic radiation in aviation) are regulated under Chapter 18 on Natural radiation of SätL. The Chapter provides for the identification of these situations and establishment of reference levels, as well as, sets requirements of the undertaking to investigate the level of exposure and to take remedial action if the exposure exceeds the relevant reference level. A common feature to all these activities is that if measures to reduce the exposure below the reference level is not successful, a safety license is required, and it is then regulated as a practice. Implementation of Chapter 18 is discussed in more detail under Module 5.

Apart from activities falling under Chapter 18 of SätL, existing exposure situations are regulated through Chapter 17 of SätL. Section 142 of the SätL states that STM draws up a national action plan for identifying existing exposure situations and for the implementation of the measured referred to in the plan. This plan is currently under preparation (November 2021). Further provisions on the scope (types pf existing exposure situations to be considered) of the plan are given in section 49 of the VnA 1034/2018. Section 139 of the SätL defines roles and duties of the different authorities once an existing exposure situation has been identified. STUK is responsible for assessing the radiation exposure arising from the existing exposure situation and for the determination of the required measures, should there be a reason to suspect exposure higher than the reference level. Then the National Supervisory Authority for Welfare and Health draws up a plan on the protective actions and the provision of guidance for individuals living or working in the area; more detailed provisions on this plan and its implementation are given in Section 50 – 51 of the VnA 1034/2018.

Question 6.1 To what extent are the principles of justification and optimization applied within the system for protective actions?

Response:

The principle of justification is applied to protective actions. Section 5 of SätL states that “Radiation practices and protective actions are justified if the overall benefits achieved exceed the detriment caused.” Sections 2 and 3 of VnA 1034/2018 specify the exposures, benefits and detriments to be considered in assessment of justification of protective actions. Similarly, the principle of optimization is applied to protective actions (Section 6 of the SätL). Justification of protective actions is also referred to in Section 139 of SätL stating that “Unless otherwise determined by the principle of justification, the National Supervisory Authority for Welfare and Health may decide that the existing exposure situation does not require measures.”

Section 2 of VnA 1034/2018 states that “ In the event of a radiological emergency and in the existing exposure situation, the assessment of the justification for protective actions and the optimisation of radiation protection shall take into account occupational exposure and the population's exposure of the population before, during and after protective actions” and continues by stating that “the assessment of

justification and the optimization of radiation protection must also take into account the waste generated and the radiation exposure resulting from its management".

Question 6.2 How does the regulatory body provide any necessary input for protective actions, including advising government or exercising regulatory control over the protective action?

Response:

Once an existing exposure situation has been identified, assessed and a plan for protective action has been drawn up, as prescribed under the primary question 6, a safety license shall be applied for taking the protective action if the radiation dose arising from occupational exposure is expected to be higher than the reference level. The value of the reference level for occupational exposure in existing exposure situations, 1 mSv per year, is established in Section 16 of STMA 1044/2018.

Section 86 of SätL states that practices which repeatedly handle, or store orphan sources are subject to a safety licence. Further, any undertaking shall immediately notify STUK if it suspects or knows of the finding or melting of an orphan source or any significant contamination caused by such an orphan source. As a consequence of such an event, the contaminated products, waste and other materials are subject to Section 84 of the SätL (Prequisites for reuse, recycling, utilization and disposal). There are no legal requirements for monitoring for the purpose of detecting orphan sources as the metal recycling industry have arranged such monitoring for their own commercial interests. In addition, the Finnish Customs conducts monitoring at the boarders based on its responsibility to supervise imports and exports of goods. However, STUK provides guidance for metal recycling industry (especially the small companies collecting the metal from individuals and enterprises), for example, in forms of leaflets and posters to be placed in their facilities. See following links on STUK's webpages:

https://www.stuk.fi/documents/12547/522963/Varo_sateilylahteita_metallinkierratyksessa_juliste_A3.pdf/9825ec08-7c4e-f77d-6405-ea2277dbf926?t=1543311889801

https://www.stuk.fi/documents/12547/522963/Varo_sateilylahteita_metallinkierratyksessa_esite.pdf/98b2ae2b-d517-5dea-233c-f4457fac8989?t=1543311892144

Question 7 Has the government made provision for the safe decommissioning of facilities, the safe management and disposal of radioactive waste, and the safe management of spent fuel?

Answer: Yes

Response:

The Finnish Government decided on the first principles of arranging nuclear waste management in 1978. According to this decision, each producer of nuclear waste is responsible for the management of spent fuel and other radioactive waste generated in connection with their operations and for the costs incurred. In 1983, the Finnish Government enacted a law on Radiation and Nuclear Safety Authority (STUK) and made a general decision on the objectives and schedules of the Research and Development (R&D) activities concerning nuclear waste management at the existing nuclear power plants. For the first time, the 1983 decision presented an option that power companies had to consider disposal of spent fuel in Finland. Later in 1991, decision by a predecessor to MEAE lauched more serious research and evaluation of the spent fuel disposal option within Finnish territory. The nuclear waste management policy has been described in detail in the updated Finnish National Programme (reference).

The Nuclear Energy Act (Section 9) prescribes that the generators of nuclear waste are responsible for all nuclear waste management measures and their appropriate preparation, and for their cost. The State has the secondary responsibility in case any producer of nuclear waste is incapable of fulfilling its nuclear waste management obligations (Nuclear Energy Act, Sections 31 and 32). When the licensee's waste management obligations have ceased as the disposal of the nuclear waste has been carried out in an approved manner, the ownership of the waste is transferred to the State, which shall be responsible thereafter for the nuclear waste (the Nuclear Energy Act, Sections 32–34).

The Radiation Act (Section 79) provides that the organization engaged in a radiation practice shall take the measures necessary to render harmless any radioactive waste arising from its operations. Rendering radioactive waste harmless means any measure needed to treat, isolate, or dispose of the waste, or to restrict its use so that it does not endanger human health or the environment. This applies also to undertakings utilizing natural resources containing radioactive substances. The State has the secondary responsibility in case a producer of radioactive waste is incapable of fulfilling its management obligations (the Radiation Act, Section 80).

According to the Nuclear Energy Act (Section 6 a), nuclear waste generated in Finland must be handled, stored, and permanently disposed of in Finland. Respectively, nuclear waste generated elsewhere than in Finland, shall not be handled, stored, or permanently disposed of in Finland. There are only minor exemptions to these principles, notably concerning the nuclear waste arising from the use of a research reactor in Finland (Section 6 a of the Nuclear Energy Act). As stipulated in Section 7 b of the Nuclear Energy Decree, the spent fuel from a research reactor in Finland may be handled, stored, and disposed of outside Finland, if justified on grounds of safety or due to a significant economic or other cogent reason.

Non-nuclear radioactive waste is regulated in Finnish legislation within the framework of the Radiation Act. According to the Radiation Act (Section 83), the operator is responsible to return the disused

sources subject to safety license to the manufacturer or supplier or to surrender them to an operator holding safety license. The Radiation Act (Section 80) specifies that the State shall discharge the function of rendering radioactive waste harmless where there is no operator of the kind. In that case the operator is responsible to compensate the costs to the State. STUK takes care of the rendering waste harmless on behalf of the State (Section 32 of the Government Decree on the Ionizing Radiation).

The Nuclear Energy Act (Section 7 g) requires that provisions for the decommissioning of a nuclear facility must be considered in its design. The decommissioning plan must be updated regularly as prescribed in the Act (Section 28). After the permanent shut-down of the facility, it must be decommissioned in accordance with the plan approved by STUK. The dismantling of the facility and other actions related to decommissioning may not be unjustifiably postponed. A decommissioning license is required for facilities (YEL Section 20a).

Nuclear facilities shall have premises, equipment and other arrangements to ensure the safe handling and storage of nuclear material required by the facility as well any nuclear waste generated during operation and decommissioning. (YEL Section 7h)

Nuclear waste shall be managed so that after disposal of the waste no radiation exposure is caused which would exceed the level considered acceptable at the time the disposal is implemented. (YEL Section 7h)

The disposal of nuclear waste in a manner intended as permanent shall be planned in a way that gives priority to safety and so that ensuring long-term safety does not require the surveillance of the disposal site. (YEL Section 7h) Detailed nuclear waste management requirements are set in Chapter 6 of YEL: waste minimization, national programme, release from regulatory control, clearance levels, prohibition of dilution, and procedures for the endpoints of waste management obligations. After a facility is decommissioned and all nuclear waste has been disposed, and the closure of the disposal facility has been approved, the responsibilities are transferred to the State (YEL Sections 32, 33, 34).

The main provisions for decommissioning of radiation sources and facilities and for the management of radioactive waste derived from radiation practices are (Section in brackets refer to the corresponding section of the SätL unless otherwise specified):

- General principle: Radiation practices shall be organized in such a way that they generate as little radioactive waste as practically possible without compromising the practice’s accordance with the principle of justification, optimization and limitation (Section 78)

- Consideration of radioactive waste as part of the whole practice: the assessment of justification and the optimization of radiation protection must also take into account the waste generated and the radiation exposure resulting from its management (Section 2 of VnA 1034/2018)
- Undertaking's duty of care: The undertaking shall ensure that the radioactive waste generated in its practice is rendered harmless (Section 79)
- Decommissioning of radiation sources and facilities: The undertaking must manage used radiation sources and radioactive waste generated by the practice as well as clean the facilities used in the practice from radioactive substances (Section 83)
- Furnishing security: The undertaking shall furnish a security for the costs arising from rendering radioactive waste harmless and any possible environmental clean-up measures if the licence is granted for a practice specified in Section 54 of the SätL (Section 54)
- Subsidiary duty of care: State ensures that radioactive waste is rendered harmless in case the undertaking cannot be expected to MEAEt it's duty of care or if the origin of the waste is unknown or if the undertaking responsible for the duty of care is not found (Section 80). STUK shall ensure that these tasks of the State are carried out (Section 32 of VnA 1034)

A financing system for the costs of future waste management and decommissioning exists to ensure that the producers of nuclear waste bear their full financial liability on the coverage of those costs and that the costs can be covered even in case of insolvency of the waste generator. The pertinent lienholders submit every three years for regulatory review the technical plans and cost calculations on which the liability estimates are based. After confirmation of the financial liabilities, the licensees pay fees to a State controlled Nuclear Waste Management Fund and provide securities for the liability not yet covered by the funded money. At the end of 2020, the fund contained 2621 million euros.

The provisions and regulations for nuclear waste management and decommissioning are well developed. Nuclear waste generated in connection with or as a result of the use of nuclear energy elsewhere than in Finland, shall not be handled, stored or permanently disposed of in Finland (YEL Section 6). All general principles of safe use of nuclear energy (YEL Chapter 2) are applied to waste management, including decommissioning of facilities and disposal. Spent nuclear fuel is considered nuclear waste (YEA Section 4). The Finnish national policy has been described in a separate document. (Management of spent fuel and radioactive waste in Finland –national programme in accordance with Article 12 of the Council Directive 2011/70/Euratom)

Question 7.1 How is the responsibility assigned for the maintenance of institutional control of a disposal facility after it is closed?

Response:

When the licence holder's waste management obligation has ceased, the ownership right to the nuclear waste is transferred to the State, which shall be responsible thereafter for the nuclear waste. The waste management obligation has ceased when the licenced facility has been decommissioned, all nuclear

waste has been disposed of, and the closure of the disposal facility has approved. (YEL Sections 32, 33, 34)

Should it become necessary after the disposal, the State has the right, at the disposal site, to take all measures required for the monitoring and control of the nuclear waste and for ensuring the safety of the repository.

Question 7.2 How is financial provision assured for decommissioning of facilities, management of radioactive waste, disused sources and spent fuel?

Response:

A financing system for the costs of future waste management and decommissioning exists and is set in YEL Chapter 7 and YEA Chapter 13 to ensure that the producers of nuclear waste bear their full financial liability on the coverage of those costs and that the costs can be covered even in case of insolvency of the waste generator. The mechanism is set so that the full waste managements costs including costs of decommissioning of facilities and disposal of any nuclear waste shall at any year be covered by funds and collateral security given to the Nuclear Waste Management Fund (VYR).

The liabilities for a new facility are determined by the MEAE before activities where waste is produced is started (YEA Section 88). The pertinent licenseholders submit every three years for regulatory review the technical plans and cost calculations on which the liability estimates are further based. After confirmation of the financial liabilities, the licensees pay fees to a State controlled Nuclear Waste Management Fund and provide securities for the liability not yet covered by the funded money. At the end of 2020, the fund contained 2621 million euros.

Financial provision is assured for decommissioning of radiation sources and facilities and of the management of radioactive waste derived from radiation practices through furnishing security (Section 54 of SätL) and a subsidiary duty of care of the State (Section 80 of SätL).

The undertaking shall furnish a security for the costs arising from rendering radioactive waste harmless and any possible environmental clean-up measures if the licence is granted for:

- the use, manufacture, trade, possession, safekeeping, import, export, transfer or storage of a high-activity sealed source;
- the use, manufacture, trade, possession, safekeeping, import, export, transfer or storage of a radioactive substance or a radiation source containing such a substance, provided that the combined nuclide-specific activity of the radioactive substance being held at any one time is greater than the activity of an equivalent high-activity sealed source;

- the maintenance, remediation or rendering harmless of radiation appliances containing sealed sources, provided that sealed sources are being removed from their fixed container and the combined nuclide-specific activity of the sealed sources to be removed annually is greater than the activity of an equivalent high-activity sealed source;
- a practice which generates or may generate radioactive waste, provided that the costs arising from rendering it harmless are substantial.

State ensures that radioactive waste is rendered harmless in case the undertaking cannot be expected to meet it's duty of care or if the origin of the waste is unknown or if the undertaking responsible for the duty of care is not found (Section 80 of the SätL).

Question 8 Has the government made provision for building and maintaining the competence of all parties having responsibilities relating to the safety of facilities and activities?

Answer: Yes

Response:

The basic professional education and basic research are done in Finnish universities and government centers, for example in Technical research centre of Finland (VTT).

Nuclear safety

Government provision related to use of nuclear energy are given in YEL. The general safety provisions describe requirements concerning nuclear energy use licensees. According to nuclear energy act the holder of the license granting the right to use nuclear energy (licensee) shall have a sufficient number of qualified personnel suitable for the related tasks. (YEL 7i).

Nuclear facility licensees are also obligated by YEL to finance research related to nuclear safety and nuclear waste management. One aim of the research is to ensure that the authorities, license holders of nuclear facilities and those responsible for nuclear waste management have sufficient and comprehensive nuclear engineering expertise and other facilities at their disposal. (YEL 53a).

The national education system for the university level studies (MSc, PhD) in nuclear sciences (and similar) is based on the training programs of the Lappeenranta University of Technology, Aalto University and University of Helsinki. These universities have a strong tradition of providing education programs with the nuclear (and other relevant topic area in engineering and sciences) specific content. In general, the funding of these programs rely on two main sources: about a half of the funding is from

the basic national funding driven by the Ministry of Education and Culture. The rest of the funding is acquired from various competitive sources of funds such (as European Commission, Academy of Finland etc.) by each of the universities.

The main organisations in the nuclear energy sector in Finland develop and organize the basic professional training course on nuclear safety (YJK course), which is a annually held approximately 6-week training programme for students and staff members of the participating organisations (STUK, the licensees, VTT, Aalto University and Lappeenranta University of Technology, Ministry of Economic Affairs and Employment, main TSOs in the area of nuclear waste management). The first course commenced in September 2003. In 2017 the original training course was updated by including the modules of (previously separate) nuclear waste management course as part of the curriculum. So far, about 1200 newcomers and junior experts have participated in these courses. The content and the structure of the course has been enhanced according to the feedback received from the participants – and also by reflecting the development and changes of the nuclear sector (nationally and globally).

In October 2010, the Ministry of Employment and the Economy set up a committee to examine the long-term competence needs of the nuclear energy sector. The study included the main organizations of the Finnish nuclear sector (including education institutions). The study compiled a national forecast for competence needs of nuclear industry - and a view on national capabilities (E&T and research infrastructure) for the development of the needed competence. One of the key conclusions was that comprehensive high-standard national competence is needed by nuclear sector companies and research institutes, as well as by authorities. An updated competence survey was published in 2019. The studies indicated that Finland has the adequate national infrastructure (e.g. education institutions with needed training structures and degree programs needed by the nuclear sector) to develop the competences needed by its nuclear energy sector in present day as well as in the future. However, certain competence areas remain as an item of special interest. The MEAE is committed to keep the competence survey up-to-date and the review is repeated at a regular interval.

On the basis of the first competence report the MEAE set up another working group in January 2013 to prepare a research strategy for the nuclear energy through 2030. The formulated strategy addresses seven themes aiming to that internationally high-quality Finnish expertise and research will ensure safe, sustainable, and competitive use of nuclear energy and promote business opportunities. The strategy has been implanted among other things through the national nuclear and waste management research programs SAFIR and KYT. Up-to-date infrastructure is seen as a key asset fort high level nuclear safety research and significant investments have been made to VTT CNS and LUT thermohydraulic laboratory. The investments on the infrastructure due not limit to national infra. Finland ownership on the Jules Horowitz Research Reactor under construction in France is 2 %.

In addition, organizations involved in radiation or nuclear safety have made arrangements with international organizations (OECD etc.) and bilateral arrangements with other States.

Radiation safety

Qualification requirements and radiation protection competence are stipulated in the Chapter 6 of the Radiation Act. Moreover, use of radiation safety experts is stipulated in the Section 32, training and induction of workers in the Section 33, supplementary training maintaining professional skills in Section 34 and responsibility of a private entrepreneur and private undertaking's representative for their own radiation protection and education and training in the Section 35.

For education and training of radiation protection experts, the majority of the curricula of Finnish universities contain the necessary courses of study. Cooperation between universities and colleges has been established by support of the Ministry of Social Affairs and Health to establish formal curricula leading to the qualification of a radiation safety expert in the field of industry, research and education. The National Advisory Board of Radiation protection experts (STAKONE) (on the field of industry, research and education) was set up on 10th June 2020 in a Teams meeting with representatives from universities, MESH and STUK. STAKONE acts as the co-ordinator of education and ensures that the education provided by the various universities is appropriate in Finland. The Aalto university was selected to lead the work of the STAKONE. However, it seems that there is no progress in the work based on information on 15th October 2021. This might jeopardize the effective qualification of radiation protection experts in universities.

On the field of medical and veterinary use of radiation the training of medical physicists has already in past included the training of a previous radiation safety officer stipulated in the Radiation Act of 1991, which was a mixture of an expert and an officer. Currently, universities provide radiation protection education and training for radiation safety experts as part of the training of a medical physicist. Pursuant to the Government Decree on University Degrees and Specialization Training (794/2004). The National Advisory Board of Medical Physicists set up by a university acts as the co-ordinator of education and ensures that the education provided by the various universities is appropriate in Finland. The University of Helsinki has appointed the National Advisory Board for the period 2020–2022 and in rotating system the University of Eastern Finland will appoint the next board. The training of a medical physicist includes, as a theoretical part, a licentiate or doctor degree in science or engineering, four years of practical training, and radiation safety and medical physicist examinations. Passing the radiation safety examination is a prerequisite for passing medical physicist examination.

Further provisions are given in the Decree (1044/2018) on the knowledge requirements and sufficient work experience required from radiation safety experts and radiation safety officers. Moreover, further provisions in medical use of radiation on the applicable qualifications and competence criteria for

radiation protection are stipulated in the same Decree and discussed in the module considering Medical Exposure.

The long-term competence needs of the radiation practices have not been examined as it was performed in 2010 by the committee set up by MEAE for nuclear energy sector. Radiation practices covers wide range facilities and activities, however, it might be beneficial in many respects to perform a similar examination on at least industrial and medical sectors.

Radiation safety licensees are not obligated by the Radiation Act to finance research related to radiation safety as nuclear facility licensees are based on YEL. One aim of the research is to ensure that the authorities and undertakings have sufficient and comprehensive education on radiation safety. The radiation safety research and the report National Programme for Radiation Safety Research 2018-2022 are discussed further in the Q1.

STUK personnel

The qualification requirements for STUK's personnel are mainly determined on the basis of the Act on Public Officials in Central Government (750/1994). Decree on STUK (Section 8) includes certain requirements (Section 8) and it is currently under reformation.

According to the proposed new Decree on STUK (section 7 subsection 2) “STUK takes care of training arrangements in order to maintain and develop the expertise and skills of its personnel.” The obligation is based on Article 7 of the Nuclear Safety Directive (2014/87/EURATOM). The obligation in national legislation would cover the entire personnel of STUK, leaving the form, content and implementation of the training to STUKs decision-making. Training can be further targeted within the organization on the basis of the employee's role, tasks and responsibilities, as well as other similar factors.

Question 8.1 How does the government stipulate a necessary level of competence for persons with responsibilities for safety?

Response:

Nuclear safety

The provisions for personnel are stipulated in Nuclear Energy Act and STUK Regulations (STUK Y/1/2018, STUK Y/4/2018) and Guide YVL A.4. According to the YEL (section 7 i) the holder of the licence giving the right to use nuclear energy shall have an adequate number of qualified personnel suitable for their tasks. Only a person approved by the Radiation and Nuclear Safety Authority for the position in question may act as a nuclear facility operator in the control room of the facility. The licence holder shall appoint the persons responsible for ensuring the emergency arrangements and security arrangements and safeguards of nuclear material. Only people approved by the Radiation and Nuclear Safety Authority specifically for each task may be appointed as the persons responsible and as their deputies. The licence holder shall ensure that the persons referred to above occupy the positions required for the task, have sufficient authority and a real opportunity to bear the responsibility vested in them.

The licence holder shall arrange adequate training for the maintaining and development of the expertise and skills of its personnel handling tasks relating to nuclear safety.

The licence holder shall ensure that contractors and subcontractors whose activities affect the nuclear safety of the nuclear facility have an adequate number of qualified and trained personnel suitable for the tasks. (905/2017)

YEL (section 7 i and k) also requires that licensee shall appoint a responsible manager for:

1) for the construction of a nuclear facility;

2) for the operation of a nuclear facility;

3) for mining and enrichment operations aimed at producing uranium or thorium; and

4) for the possession, manufacture, production, handling, use, storage and transport of nuclear materials and nuclear waste, if a separate licence is required for these operations.

Only persons approved by the Radiation and Nuclear Safety Authority (STUK) specifically for each position can be appointed. Competence levels for these persons are given in YEL section 122 and 125 and in STUK guides YVL A.3 and YVL A.4.

The Nuclear Energy Act Section 7 k was modified in 2017 in order to demand appointing a responsible manager also for the decommissioning phase of a nuclear facility.

Section 7m stipulates that members of security shall have necessary training and familiarity. According to Section 5 (17§) necessary expertise of the applicant is a condition for granting a licence of nuclear facility.

According to Section 25 of STUK Regulation STUK Y/1/2018 and Section 38 of STUK Regulation Y/4/2018, the licensee shall have a sufficient number of competent personnel suitable for the related tasks for ensuring the safety of the nuclear facility. Significant functions with respect to safety within nuclear power plants must be designated, and the competences of the persons working in such positions must also be verified. The operation of the organisation shall be evaluated and continuously developed and the risks associated with the organisation's operation are to be evaluated regularly. The safety impacts of significant organisational changes are to be evaluated in advance.

Concerning facility or activity authorisation licensees (authorised parties) expertise and competence is ensured during licence application review and following inspections carried out by STUK.

Radiation safety, see question 8.

Question 8.2 How does the Government ensure that the regulatory body and its support organizations build and maintain their competences necessary for the discharge of their responsibilities for safety?

Response:

STUK actions are guided by Ministry of Social and Health with long-term targets and yearly agreement on STUK's objectives. In this agreement ministry has agreed that an objective and strategic goal is highly professional human resources. Based on act and degree of STUK the director general has power to decide on STUK's human resources. Practices for this and how to ensure competence are described in Guide STUK 5.2.

Government has established together with parties involved in use of nuclear energy specific training program for nuclear safety (YJK-course).

Ministry of Employment and the Economy has surveyed the long-term competence needs of the nuclear energy sector and compiled a view on national capabilities (E&T and research infrastructure) for the development of the needed competence as described in Question 8 (and in more detailed in Module 3). The MEAE is committed to keep the competence survey up-to-date and the review is repeated at a regular interval.

In the context of national framework for development of nuclear competence, individual organizations (both licensees and regulatory body) have the prime responsibility for ensuring that its employees are qualified and authorized for their jobs. The nuclear organizations are responsibility for development and maintenance of the needed support structures for their competence development (e.g. training programs). Accordingly, STUK is responsible for developing its own regulatory capacity and it has developed its internal guidance, structures, and procedures for supporting the development and retaining of the needed regulatory capacity: e.g. STUK maintain an inventory of key competencies needed for its core operations, it carries out competence driven staff planning and recruitment activities, it carries out competence evaluations and personal development discussions regularly, it provides development actions such as training and it aim to continuously develop its capacity building activities. STUK competence management is described in detail in Module 3.

Question 8.3 How does the government ensure the continuous development and the periodic verification of the technical competences of persons working for authorized parties?

Response:

The basic professional education and basic research are done in Finnish universities and government centers, for example in Technical research centre of Finland (VTT).

Nuclear safety

Government has established together with parties involved in use of nuclear energy specific training program for nuclear safety (YJK-course).

The regulatory requirements for human resources are stated in the Nuclear Energy Act (Sections 7 and 20), STUK Regulations STUK Y/1/2018, STUK Y/4/2018 and Guide YVL A.4. According to Section 25 of STUK Regulation STUK Y/1/2018 and Section 38 of STUK Regulation Y/4/2018, the licensee shall have adequate number of competent staff suitable for the related tasks of ensuring the safety of the nuclear facility. Significant functions with respect to safety of nuclear power plants must be designated, and the competences of the staff must be verified. The operation of the organization shall be evaluated and continuously developed, and the risks associated with the organization’s operation are to be evaluated regularly. Furthermore, the safety impacts of significant organizational changes are to be evaluated in advance.

In the context of national framework for development of radiation safety and nuclear competence, individual organizations (licensees and regulatory body) have the prime responsibility for ensuring that its staff are qualified and authorized for their jobs. The lisencees and nuclear organizations are responsible for development and maintenance of the needed support structures for their competence development (e.g. training programs). STUK - as the regulatory body - carry out oversight activities (e.g. requirements, inspections) focusing on the organizational factors of the licensee organizations.

Radiation safety

The regulatory requirements for human resources are stipulated in the Radiation Act (Section 23). According to that the undertaking shall ensure that it has the expertise necessary in terms of the nature and extent of the practice at its disposal and sufficient financial and human resources for the safe implementation of the practice. Moreover, more detailed regulation on human resources is given in the VnA Section 22 for medical use of radiation and for industrial radiography.

The undertaking shall ensure that workers engaged in radiation practices are provided with sufficient and regular supplementary training on radiation protection (SätL Section 34). Further provisions on regular supplementary radiation protection training and the content thereof are given in the Chapter 3 of the Decree of the Ministry of Social Affairs and Health. In connection to an authorization competence of the licensee's staff is reviewed and on regular inspections received radiation protection training in five years periods is inspected.

Question 9 Where necessary, has the government made provision for technical services relating to safety, such as services for personal dosimetry, environmental monitoring and calibration of equipment?

Answer: Yes

Response:

Measurements of ionizing radiation carried out to determine occupational, public or medical exposure and ensure safety in radiation practices or an existing exposure situation shall have the approval of STUK (SätL Section 64). The measurements carried out for assessing the radiation exposure and ensuring safety referred to in the SätL shall be performed with a method suitable for the purpose and proved reliable (SätL Section 59). The results of the measurements must be metrologically traceable to the International System of Units. The radiation meter or measuring instruments shall be appropriately calibrated. Further provisions on the information to be provided in an application are stipulated in the Section 56 of the government decree 1034/2018 and on verifying the reliability of measurements and on the radiation meters' and measuring equipments' calibration, accuracy, use and suitability for a particular purpose in the STUK regulation S/7/2021 on measurements of ionizing radiation.

STUK approves a dose measurement service (SätL Section 60). Competence of the dose measurement service's personnel and maintenance of professional skills are stipulated in the SätL Section 61, quality assurance of dose measurement services in the Section 62 and regulatory control of dose measurement services in the Section 63. Amending and withdrawing the approvals have been stipulated in the Section 65 of SätL.

STUK maintains the national metrological standards necessary to ensure the reliability of radiation measurements (SätL Section 14). STUK also prepares and implements nationwide environmental radiation monitoring programme representing all members of the public to monitor the amounts of radioactive substances in the environment and the magnitude of the public exposure resulting from them (SätL Section 14).

STUK provides also radioactivity measurements and calibration services for external customers.

Question 9.1 How does the regulatory body authorize technical services that may have significance for safety?

Response:

STUK approves a dose measurement service until further notice or, for a special reason, for a fixed period of time (SätL Section 60). The approval requires: 1) the use of a documented dose measurement system compliant with the requirements laid down in section 59; 2) the sufficient competence of the personnel; 3) an accredited quality system applicable to steering the practice, including the operation of the dose measurement service and the methods employed by it; 4) the necessary technical means for delivering the dose data to the workers' dose register. In lieu of accreditation, STUK may accept a quality system pursuant to the standard concerning the competence of European testing and calibration laboratories, provided that there is an adequate, justified reason for the lack of accreditation related to the operation of the dose measurement service. Further provisions on the approval of dose measurement services are given in the Section 55 of the government decree 1034/2018.

Analysis

STRENGTHS FOR 01. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

S1	Accreditations and certifications are taken into use in measurements and laboratory activities supporting regulatory functions.
S2	Finnish national radiation research network (Cores) covers all relevant R&D parties (universities, university hospitals and VTT).
S3	Strong expertise currently still exists in Finland in radiation protection research

S4	Radiation safety act has gone through the comprehensive reform in 2018 and provides now a solid modern framework for safety.
S5	STUK has a solid legal mandate which covers all aspects of radiation and nuclear safety.
S6	The prime responsibility for safety is clearly assigned in the law.
S7	Coordination between different safety regulators is established in the legislation. YEL and SätL provide provision, which regulators have interface with nuclear and radiation facilities and activities. STUK has active and well-established co-operation with certain government agencies (e.g. Border control, customs, police forces).
S8	National action plan for existing exposure situations is required in the legislation. In addition, Finland has extensive guidance for emergency preparedness and recovery.
S9	Finland has a well-established and a mature radioactive waste management framework. In nuclear waste management NPP licensees operate radioactive waste management from cradle to grave and management of radioactive waste including spent fuel has progressed well. Fundamental provisions for radioactive waste management were established early on when use of nuclear power started.
S10	Nuclear facility licensees are obligated by Nuclear Energy Act to finance research related to nuclear safety and nuclear waste management. One aim of the research is to ensure that the authorities, license holders of nuclear facilities and those responsible for nuclear waste management have sufficient and comprehensive nuclear safety and waste management expertise and other facilities at their disposal. (YEL 53a).
S11	Responsibilities of STUK are given in Act and Decree.

WEAKNESSES FOR 01. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

W1	There is no specific funding that is allocated to radiation protection research. For the point of view of resilience, a stable funding would be needed. Training of new experts and continuation of research is dependent on availability of external funding. The national preparedness and resilience is dependent on this expertise.
W2	If no funding is allocated for the Cores network there is a possibility that universities and hospitals will leave the network, jeopardizing the national expertise.
W3	There is a gray area between the scopes of SätL and YEL concerning, for an example, radioactive waste, which is differentiated in legislation based on its origin. This can lead to a situation where safety requirements are different even when waste properties are same. There is also a difference between transport regulations in areas of use of radiation and use of nuclear energy which means that harmonized regulation between nuclear and radiation acts is needed.
W4	MEAE has conducted a study on the long-term competence needs of the nuclear energy sector. There exists no similar study in the radiation safety field which could be used as a bases for assessing the adequateness of national infrastructure (e.g. education institutions with needed training structures and degree programs and national research program) to develop the competencies needed in radiation safety field in present day as well as in future.

OPPORTUNITIES FOR 01. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

O1	The comprehensive reform of the Nuclear energy act is about to begin.
O2	STUK has an active program for improving the effectiveness of the surveillance and increasing the application of the graded approach.
O3	The experiences of the implementation of the SätL (2018-) could give a good starting point for the further improvement of the legal framework in field of radiation safety.
O4	STUK and a few other safety regulators, that have oversight over same licensees, have established co-operation programme (FSTV). As part of the programme oversight methods are shared and developed and also joint oversights activities are planned.
O5	Co-operation group (YETI) for radioactive waste management was established by MEAE and its work has been very effective. YETI-group has evaluated national situation and made several recommendations. Responsibility for actions is appointed to ministries, regulators and waste management operators, who all are participating in YETI work.
O6	National legislation is flexible and STUK can independently decide the coverage and methods for national environmental monitoring and contents of calibration and measurement services.

THREATS FOR 01. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

T1	Up to now, Finland has had enough experts in radiation protection. In future, the universities should take more prominent role in training the experts. Otherwise, there will be lack of experts.
T2	The future availability of the radiation safety experts and officers can be considered as a threat. Finland is unavoidably a small market. The participation to the training programmes is, in some cases, so limited that the training is not profitable for the organizer.
T3	Limited resources for the development and maintenance of the legal framework.
T4	Funding principle of the surveillance in the field of radiation practices regulation has been changed in 2018. In this respect, STUK is more dependent on the budget given by the ministry.
T5	Funding of the radiation safety research is not adequate. This jeopardizes the maintenance and development of expertise and competence.
T6	In Finland emergency radiation measurements are mostly done by STUK. National strategy for measurements has been prepared, but it is not in operative use yet. National action plan needs to be prepared to implement the strategy.
T7	The recent change in the YEL Section 53 a may lead to suggestions to seek funding for such activities that do not fit in the nuclear safety research programme. It should be kept in mind that the background information of the change has to be considered when evaluating the appropriateness of the activities to the research programme.

CONCLUSIONS FOR 01. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

C1	The legal framework is solid. However, major changes have been done and are on-going. It is important that the government allocates adequate resources for this work to ensure the high quality and timely update of the legal framework.

C2	There are well functioning national research programs in nuclear safety and waste management and the funding is ensured by Nuclear Energy Act. The future availability of expertise in the field of RP, however, is a matter of concern in the field of surveillance as well as in the operators' functions (the lack of funding in scientific research, the availability of the training of RPOs and RPEs) MEAE has conducted a study on the long-term competence needs of the nuclear energy sector. There exists no similar study in the radiation safety field which could be used as a bases for assessing the adequateness of national infrastructure (e.g. education institutions with needed training structures and degree programs and national research program) to develop the competencies needed in radiation safety field in present day as well as in future.
C3	The funding for the basic surveillance is adequate. However, there is increasing responsibilities and needs to respond to the technological development but no clearly allocated funding for this.
C4	Coordination between different safety regulators is established in legislation and the expectation of IAEA safety standards are fulfilled.
C5	Finland has a mature radioactive waste management framework and implementation of radioactive waste management facilities and activities has progressed well. Fundamental provisions for radioactive waste management were established early on when use of nuclear power started. Disposal solution for most part of LILW is existing and operating license application for spent nuclear fuel repository has been submitted. Further improvement is still needed to harmonize requirements and oversight between radioactive and nuclear waste. This will be done as part of YEL renewal. MEAE coordinated YETI-group has evaluated needs for improvement in our national framework and waste management implementation. Group made several recommendations, which provide good opportunities to enhance already well functioning system.
C6	The funding of national radiation protection research depends on external funding and its continuation cannot be ensured. This funding (and research) is important for the continuation and development of national expertise.
C7	In Finland emergency radiation measurements are mostly done by STUK. National measurement strategy has been prepared, but it is not in operative use yet. National action plan needs to be prepared to implement the strategy.
C8	STUK published in 2017 a new strategy for 2018- 2022, which aims for major change in regulatory oversight. Strategically STUK aims to emphasise licensee's responsibility and to have commensurate and risk informed oversight. Strategic change is implemented by enhancing risk informed regulations, digital customer-oriented applications and services, data management enabling risk informed oversight, oversight tools and interactions endorsing licensee's responsibility and through regulatory co-operation. Strategic development has a broad scope, and as part of that,

	it aims to enhance implementation of graded approach and coordination and co-operation between different safety regulators.

Module: 02. The Global Safety Regime

Findings

Question 1 Does the government participate in the relevant international arrangements to enhance safety globally and fulfil its respective obligations?

Answer: Yes

Response:

Finland is highly committed to nuclear and radiation safety. It does participate in the relevant international treaties and conventions and other relevant international arrangements considering nuclear and radiation safety (2.3 (b) of GSR Part 1 (Rev. 1).

According to government Act (175/2003, section 8) treaties and other international obligations are handled by the ministry within whose mandate the treaty or obligation falls on the basis of its content.

- The Ministry for Foreign Affairs is responsible for the international aspects of Finland's non-proliferation policy in collaboration with other authorities.
- The Ministry of Social Affairs and Health has supreme authority and highest directing power in supervising compliance with Radiation Act.
- The Ministry of Economic Affairs and Employment (MEAE) has supreme authority and highest directing power in supervising compliance with this Radiation Act in matters concerning the use of nuclear energy as referred to in the Nuclear Energy Act. (SätL, section 13). MEAE is responsible for the supreme management of the nuclear energy field. (YEL, section 54). In addition the MEAE is the Finnish competent authority within the meaning of the Euratom Treaty.

According to Decree on Radiation and Nuclear Safety Authority, STUK is responsible for contributing to international co-operation in its field of activity, and for taking care

of international control, contact and reporting activities, as enacted or prescribed. STUK is responsible for the regulatory control of the safe use of nuclear energy. As well as the regulatory control of safety, STUK is responsible for the regulatory control of nuclear security and emergency arrangements, and for the necessary control of the use of nuclear energy to prevent the proliferation of nuclear weapons; for carrying out research and development activities necessary for regulatory control; and for participating in international co-operation (YEL, section 66).

Treaties and international organisations to which Finland is a party:

- Treaty on the Non-proliferation of Nuclear Weapons; adopted in London, Moscow and Washington on 1 July 1968 (1970), INFCIRC/140 (FTS 11/70).
- The Treaty establishing the European Atomic Energy Community (Euratom Treaty), 25 March 1957:
- Regulation No 5, amendment of the list in Attachment VI, 22 December 1958
- Regulation No 9, article 197, point 4 of the Euratom Treaty, on determining concentrations of ores, 2 February 1960.
- International Atomic Energy Agency (since 1958). Nuclear Energy Agency of the OECD (since 1976). International Energy Agency (since 1992).

Finland is a contracting party to the following international treaties and conventions for ensuring safety in the utilization of nuclear energy and radiation: (the year when the convention entered into force for Finland is given in brackets):

- Convention on Nuclear Safety; opened for signature in Vienna on 20 September 1994 (1996).
- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, adopted on 29 September 1997 in Vienna (2001).
- Convention on Early Notification of a Nuclear Accident; opened for signature in Vienna on 26 September 1986 (1987).
- Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency; opened for signature in Vienna on 26 September 1986 (1990).
- Convention on the Physical Protection of Nuclear Material; opened for signature in Vienna and New York on 3 March 1980 (1989).
- Amendment to the Convention on the Physical Protection of Nuclear Material; as amended on 8 July 2005 (2016)
- Convention on Third Party Liability in the Field of Nuclear Energy; adopted in Paris on 29 July 1960 (1972). Convention Supplementary to the Paris Convention of 29 July 1960 on Third Party Liability in the Field of Nuclear Energy; adopted in Brussels on 31 January 1963 (1977
- The 1988 Joint Protocol Relating to the Application of the Paris Convention and the Vienna Convention; adopted in Vienna on 21 September 1988 (1995).
- Nordic Mutual Emergency Assistance Agreement in Connection with Radiation Accidents; adopted in Vienna on 17 October 1963 (1965)
- Agreement on common Nordic guidelines on 59STUK-B 265 / MAY 2021APPENDIX 3 INTERNATIONAL AGREEMENTS RELEVANT TO NUCLEAR SAFEGUARDS IN FINLAND communications concerning the siting of nuclear installations in border areas; adopted on 15 November 1976 (1976).
- The Agreement between Finland and Sweden on the guidelines to be followed while exporting nuclear material, technology or equipment, 4 March 1983 (FTS 20/1983). Convention on Environmental Impact Assessments in a Transboundary Context (Espoo, 1991)
- Radiation Protection Convention of the International Labour Organization (no. 115)
- Agreements and conventions dealing with transport of dangerous goods: European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), Convention concerning International Carriage by Rail (COTIF), Convention on International Civil Aviation and International Convention for the Safety of Life at Sea (SOLAS)
- Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter
- Convention on Access to Information Public Participation in Decision-making and Access to Justice in Environmental Matters.

Finland has implemented the Code of Conduct on the Safety and Security of Radioactive Sources and the Code of Conduct on research reactors.

Finland has done several Bilateral Safeguards Agreements. In addition Cooperation Agreements considering the Peaceful Uses of Nuclear Energy made by European Atomic Energy Community are applied in Finland.

Finland has also several bilateral agreements for exchange of information on nuclear facilities and on notification of a nuclear and radiation emergency, e.g. with Sweden, Norway, Russia, Ukraine, Denmark and Germany. Agreements relating to early notification of nuclear events and exchange of information on safety of nuclear facilities with Denmark (1987), Norway (1987), Sweden (1987), Germany (1993), the Russian Federation (1996) and Ukraine (1996).

In addition, STUK has done cooperation arrangements with several foreign regulatory bodies, which cover generally exchange of information on safety regulations, operational experiences, waste management etc. Such an arrangement have been made with NRC (USA), ASN (France), FANR (United Arab Emirates), KINS (Republic of Korea), TAEK (Turkey), ENSI (Switzerland), NRA (Japan), SUJB (Czech Republic), Rostechnadzor (Russian Federation), AERB (India), K.A.CARE (Saudi-Arabia), SSM (Sweden) and HAEA (Hungary).

The IAEA safety standards and WENRA harmonised safety reference levels are addressed when developing Finnish legislation, regulation and requirements. In practice, nowadays, the most important references considered in rulemaking are the IAEA safety standards and WENRA reference levels.

The Finnish government has requested several international peer reviews concentrating of safe use of nuclear energy. These peer reviews have been focused on regulatory activities (IRRS, EPREV, ARTEMIS), waste management (EU Peer Review), nuclear power plants (OSART), research reactor (IAEA) and in physical protection (IPPAS) as well as on environmental surveillance program (EC). Topical peer reviews on nuclear power plants are performed every six year in line with EU Nuclear Safety Directive.

Finland has been active in making Finnish experts available in international peer reviews. STUK experts have participated in several IRRS and EPREV missions, and also experts have been nominated to the EU IRRS mission expert pool.

A summary of international co-operation is presented each year in the annual reports of the oversight of nuclear and radiation safety in Finland.

International co-operation play a significant role in development of the regulatory competence and the regulatory framework for emerging technologies in the use of nuclear energy and in the use of radiation. Budget cuts and rejection of budget requests for new activities and research challenge the management and development of STUK's competencies. In addition to decisions not to continue some radiation research activities, STUK has also a challenge to develop competencies for new areas/technologies (e.g. SMRs). See modules 1 and 3.

Question 2 Does the government promote international cooperation and assistance to enhance safety globally?

Answer: Yes

Response:

STUK is participating actively in European and international co-operation in the field of nuclear and radiation safety and security as well as safety of waste management. STUK participates in the activities of IAEA, OECD/NEA, IRPA, ICRP and European Commission. The Finnish policy is to participate in the discussion on developing international safety standards. STUK is an active member of IAEA safety standards committees, in WENRA (Western European Nuclear Regulators' Association) and MDEP (Multinational Design Evaluation Programme) which are important parties for enhancing harmonized approaches for safety. On the field of radiation safety STUK participates actively in Nordic regulators' groups and HERCA (Heads of Radiation Protection Authorities). STUK is also co-operating closely with a number of IAEA Member States and sees bilateral co-operation and technical assistance important for the safety globally. STUK is an active member in standardization organizations such as ISO, IEC and CEN/CENELEC. The efforts that STUK has taken to assist to enhance safety globally have also taken a lot of resources.

According to Decree on STUK (section 1), STUK is responsible for contributing to international co-operation in its field of activity, and for taking care of international control, contact and reporting activities, as enacted or prescribed. The government should ensure continuity of this international co-operation by allocating sufficient resources.

Question 3 Has the regulatory body made arrangements for analysis of operating and regulatory experience (including internationally) and for dissemination of the lessons learned?

Answer: Yes

Response:

STUK analyses both domestic and foreign operational experience from various sources to identify lessons learned and to improve safety at nuclear facilities and activities. STUK uses the feedback from both operational and regulatory experience for improving review, assessment, and inspection activities and for developing the regulatory guides.

STUK has made arrangements for receiving and collecting information from other states and relevant authorized parties. STUK actively disseminates lessons learn from operational experiences to the international community. The most important arrangements are the International Reporting System for Operating Experience (IRS) by IAEA and OECD/NEA. STUK has also very strong cooperation with EU Clearinghouse on Nuclear Power Plant Operational Experience Feedback.

STUK gathers information directly from its cooperation with other regulators, especially with the regulators and plants of Sweden, France and Russia having similar operating plants (BWRs, VVERs, EPR) as Finland. Other sources of operating experience are meetings of regulator groups: OECD/NEA/WG's, WENRA, VVER-forum, MDEP, EU-projects and early information channels like IAEA/NEWS and WGPCNEWS as well as OECD/NEA Topical Databases. Moreover, on the field of radiation safety STUK participates actively in Nordic regulators' groups and HERCA in which regulatory experience and lessons learned are shared. STUK participation to international co-operation in the field of nuclear facilities is reported in the annual report of the oversight and in the field of radiation safety in the annual report 'Radiation practices'.

For review and assessment of OE information abroad STUK has an internal OEF Group for international events with a coordinator and technical experts (16) covering all expertise areas of Nuclear Reactor Regulation and Nuclear Waste and Materials Regulation departments. The group meets monthly and based on the screening and expert assessment in STUK's own IRS database the group members make together an judgement whether there is a need for regulatory or licensee measures on the basis of lessons learned assigning the IRS report into categories with respect to actions to be taken (categories 1 to 3), or not needed (category 0). In the case that an expert to whom the report is assigned for review cannot immediately say if an event requires actions at Finnish plants the report is classified into category 1 (particular issues need clarification) and clarifications of the applicability are initiated with the plant contact persons. After clarifications the event is reclassified. Classification into category

2 (Lessons learned need to be taken into account in certain activities) means that concrete actions are not required but the report contains information which should be considered in inspections by STUK. If actions are required at the Finnish nuclear power plants in operation or under construction the report is classified into category 3 (Actions required). Examples of such events are unexpected failures of components being installed also into the systems or equipment of Finnish plants, or events revealing deficiencies in procedures of the plants. Category 4 (Good practice in Finland) means that actions to prevent an event have already taken or an occurrence of such an event has taken into account in the original design of the plant, or there are special procedures and regulatory requirements in place (YVL guides) preventing a similar event.

Figure 1 shows the distribution of IRS reports into different categories in STUK's review and assessment from 2016 to 2020. Altogether 466 IRS-reports were assessed/screened during that period and most of them (70%), 325 reports, fell into category 0 requiring no further actions. 21% (100 IRS reports) of reviewed reports were classified into category 2 and applicability of lessons learned were checked in the inspections of STUK's periodic inspection programme or evaluated in some other inspections.

In the case of 4 reported events review resulted specific actions at the Finnish nuclear power plants:

- IRS 8505 "Unit removed from service for maintenance due to a through-wall crack formation in the base metal of control rod drive tube in cell 05-38", Russia
- IRS 8315 "EDG failed to start after undetected loss of two phases on 400 kV incoming offsite supply", Sweden
- IRS 8435 "Outbreak of fire in a reactor coolant pump", France
- IRS 8493 "Generic deviations in the 1450 MWe units involving primary reactor coolant pump suction adapter screws", France.

In the six events it was realized that similar kind of events were already well prevented by technical or administrative arrangements, and thus we have good practices in use.

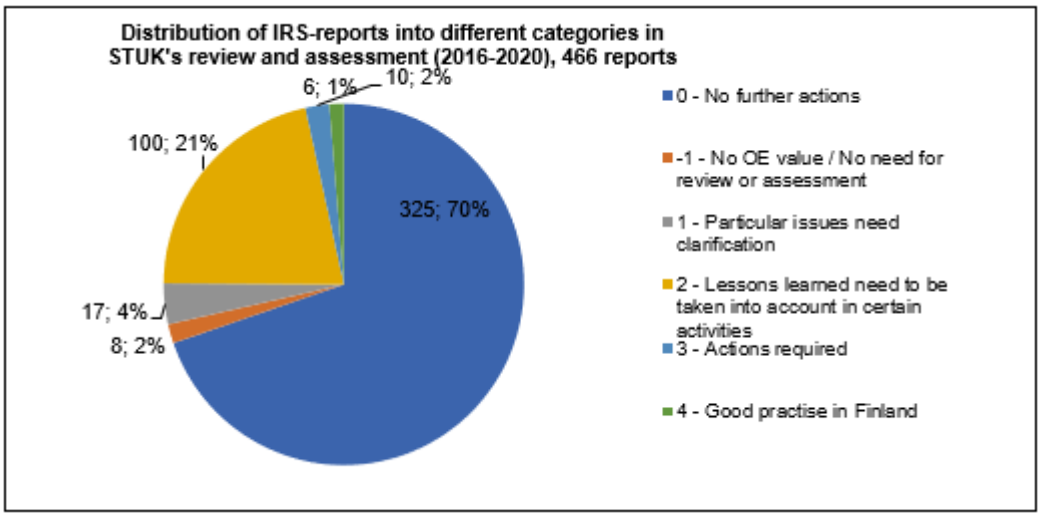


Figure 1. Distribution of IRS-reports in STUK review categories 2016-2020

Reports for the IRS System on safety-significant occurrences at the Finnish nuclear power plants are written by STUK. STUK has delivered 27 new IRS-reports during 2016–2020.

Relevant feedback of OPEX actions taken in Finland are reported through IAEA, OECD/NEA, WANO, WENRA, VVER-Forum, EU Clearinghouse and bilateral co-operations. The Finnish experts are active members of the international working groups and takes part in the development of the up-to date reports and Safety Standards.

One of the leading principles of the Nuclear Energy Act laid down in Section 7 a is the continuous improvements and considering the development of know-how and operating experience. The operating experience is considered in the preparation of the regulations and YVL guides (see Module 9) as well as in the regulatory oversight (see Modules 5-8).

According to Nuclear Energy Act Section 54 a in the event of an accident the consequences of which are significant from the point of view of nuclear safety or radiation protection a self-assessment of the national framework of nuclear safety as well as the national framework of nuclear waste management, shall be made. According to the Section 3 of the STUK Regulation (STUK Y/1/2018), the safety of a nuclear facility shall also be assessed after accidents and, whenever necessary, on the basis of the safety research results.

All of the three nuclear accidents – TMI, Chernobyl and Fukushima - have led enhancement of nuclear safety requirements. After TMI accident in 1979 system to manage severe accident were required in Finland, after Chernobyl Accident 1986 lead to requirements of the safety culture and the TEPCO Fukushima Daiichi accident in 2011 lead to enhancement of requirements concerning extreme external conditions and criteria for the design goals were made more stringent (YEA Section 22b).

According to the Section 21 of the STUK Regulation (STUK Y/1/2018), nuclear power plant operational experience feedback (OEF) shall be collected and safety research results monitored, and both assessed for the purpose of enhancing safety. Safety-significant operational events shall be investigated for the purpose of identifying the root causes as well as defining and implementing the corrective measures. Improvements in technical safety, resulting from safety research, shall be taken into account to the extent justified on the basis of the principles laid down in Section 7 a of the Nuclear Energy Act. STUK Regulation (STUK Y/4/2018) Section 25 lays down similar requirements for waste management facilities.

STUK requires that incidents at nuclear facilities and activities are analysed. Based on the analysis, corrective actions are planned and implemented by the operators. Regulatory requirements are given in STUK's Regulatory Guide YVL A.10. The guide provides detailed requirements and administrative procedures for the systematic evaluation of operating experiences, and for the planning and implementation of corrective actions. Operational events at other nuclear power plants and foreign operational occurrences have to be systematically screened and assessed as well, from their applicability and their significance for the nuclear facilities in Finland.

The licensees have developed the required procedures for analysing operating experiences and root causes for events. The licensees are using WANO and IRS reports as basic material to be screened for external OEF and they have OEF groups for screening, analysing of OE entry into processing and following the corrective actions. The licensees have also their internal audit programme and OEF is one topic in these programmes.

At the Loviisa NPP, VVER reactor operating experience is collected, screened and evaluated by a dedicated operating experience feedback group composed of engineers from the plant operation organisation and from Technical Support. The main information to be handled comes from WANO (Moscow Centre) which links all the VVER reactor operators. Additional information and reports are received from the IAEA, OECD/NEA, NRC (U.S. Nuclear Regulatory Commission) and FROG (Framatome owners group). The activities of the operating experience feedback group are not limited only to VVER reactors. The plant managers of VVER-440 reactors have periodic meetings. The plant operation problems, modernisation, back-fitting, plant life management and safety questions are handled, and experiences are exchanged in these meetings and in further individual contacts.

TVO has also an operating experience feedback group. This onsite group gives recommendations to the line organisation that makes decisions on eventual corrective actions. The industry operating experience from similar reactor types is followed by several means. The main sources of information are NordERF (cooperation between Nordic NPPs) with connection to KSU (Swedish nuclear training centre) and WANO. Information is also coming directly from several sources (IAEA and OECD/NEA, IRS), Loviisa power plant (e.g. operating experience meetings and reports), vendors (Westinghouse Atom, Alstom Power Sweden AB), component manufacturers, BWROG (BWR Owners Group) and BWR Forum (FANP).

IRS reports are also received directly by the licensees via WBIRS and evaluated by them. Almost all plant modifications, as improvements in systems, structures, and components, which have emerged from foreign experience originate from plants that are of the same type as the Finnish plants.

STUK verifies by means of inspections and by reviewing licensee's event reports that the activities of the licensees as regards incident evaluation are effective. In STUK's periodic inspection programme there is inspection focusing to OEF, namely "Operational experience feedback" When necessary, a special investigation team is appointed by STUK to evaluate a certain incident or group of incidents. The evaluation of foreign operational occurrences and incidents is based on the reports of the IRS Reporting System (IAEA/NEA) and on the reports of other national regulatory bodies.

Following targets for development have been recognised during 2018–2020: interface between OEF organization and line organization (roles and responsibilities) and results of the OEF function (learning from experiences).

- The licensee is required to ensure that operating experience feedback has adequate resources and the full support of the top management (YVL A.10 / 301)
- … … means that top management should show more commitment for the OEF

The failure register shall also be utilized in the updating of the probabilistic risk assessment (PRA).

The exchange on information on domestic experiences between the Finnish licensees has also been arranged.

The international practices, OPEX and results of the research and development are considered when the Act and underlying regulations as well as YVL Guides are developed and updated. The current status/or up-to-date references such as IAEA Safety Standards is described in the justification memorandum of the relevant document (see Module 9).

The renewed web pages of STUK provide more prompt and accurate information for all stakeholders about events and incidents, current regulatory decisions and issues. In addition, STUK uses newsletters to notify public and media as well as users of radiation about changes in regulatory work and guidance, and other current issues.

STUK has started publishing email-based newsletters to the public and media and in particular to the users of radiation (industry and health care). These newsletters are published 2 – 4 times a year.

STUK has also been more activate in social media. For instance, STUK's Director General has a Twitter account, where the DG publishes current topics on radiation and nuclear safety. Also other directors and communications people have their own Twitter accounts, in addition to STUK's twitter account.

STUK has been very active in sharing information internationally. Based on Fukushima accident many international programmes have been launched. STUK has continued to participate actively in these programmes, such as IAEA action plan and EU stress tests. New arrangements have been agreed with several foreign regulatory bodies.

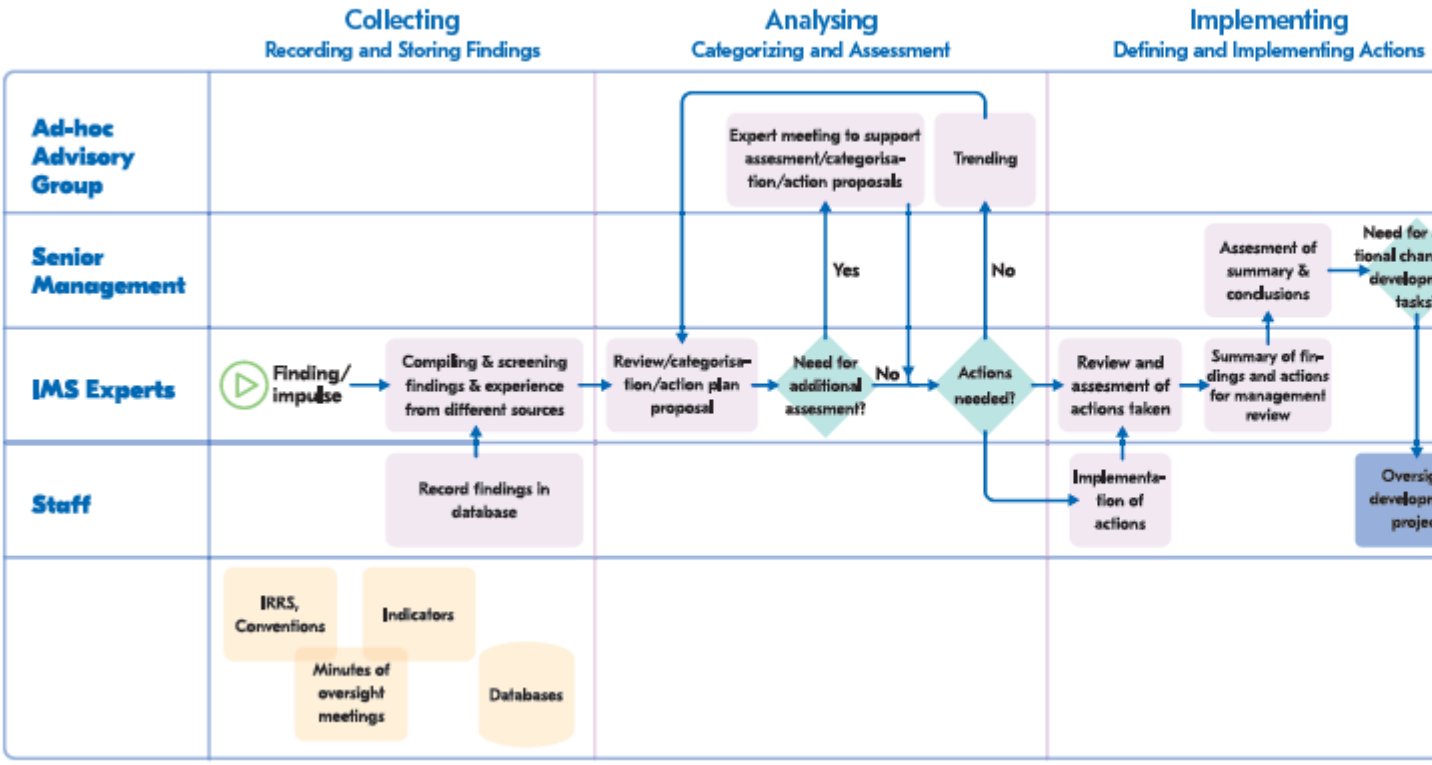
Regulatory experience

STUK has recently (2018/2019) developed a process for managing regulatory experience from various sources (fig 2). This process has been as a pilot use in Nuclear Reactor Regulation and Nuclear Waste Management Departments. The aim is to improve regulatory processes, functions and regulation based on the experience, and to share lessons learned with interested parties.

The process is designed for gathering and analyzing findings of STUK´s regulatory experience framework. Managing the findings comprises screening, systematic categorizing and analyzing and defining the actions to be taken.

The process was introduced in the beginning of 2019 and the regulatory staff has been encouraged to record their findings to a database developed for this purpose. The results seem promising and have revealed needs for further improvement of both regulatory and support processes as well as the Regulatory experiences process itself. The future objective is to expand the pilot process to cover all of the STUK regulatory departments and to share the lessons learned with other stakeholders an integrate this procedure to STUK's integrated management system.

Figure 2: Process for Managing Regulatory Experience at STUK



Radiation practices; analysis of operating and regulatory experience (including internationally) and for dissemination of the lessons learned

Section 183 of SätL states that "STUK uses the inspection findings and other observations pertaining to radiation safety to develop regulatory control and reports on them to undertakings, authorities and any other parties concerned in the extent as is necessary to promote safety".

Regulatory experience is collected and analysed through the VASARA. All regulatory decisions, inspection findings, actions of enforcement and radiation safety deviations are recorded to VASARA in a systematic manner. VASARA enables analysing statistics, for example, of different types of inspection findings and safety deviations in different types of activities and facilities. Analysis of inspection findings are used for targeting regulatory control, for example, in the annual planning for inspections and other regulatory activities. Statistics and individual examples of radiation safety deviations are published and disseminated as lessons learned to the licensees in the Annual Report on Radiation Practices.

An example of considering operating and regulatory experience is a safety deviation in 2016 caused by a leaking sealed Cs-137 source in the premises of a company conditioning disused sealed sources for disposal. The company's premises were in the same building as STUK; it is a former STUK service which had been privatized several years earlier. The leakage resulted in contamination within the building, including some STUK premises. The radiation doses caused were very small but significant cleaning and waste management costs resulted. Because of the exceptionality of the case, STUK proposed OTKES (Safety Investigation Authority in Finland) to investigate it. The OTKES investigation report made several recommendations to improve regulatory requirements and STUK's functions. Consequently, the requirements for leakage testing and contamination measurements were revised and a study (a graduate engineer thesis) on the tightness of sealed sources and factors affecting it was launched. The results of the study lead to the incorporation to the SätL of a prohibition to use over 40 year old sealed sources. The SätL also extended the requirement for a financial security for waste management and cleaning from high-activity sealed sources to practices which include numerous smaller sealed sources. Also many amendments were made to STUK's management system documents on regulatory control, emergency preparedness and communication arrangements.

Analysis

STRENGTHS FOR 02. THE GLOBAL SAFETY REGIME

S1	Finland and STUK are active players in international co-operation and very often have even a bigger role than the size of the country would indicate.
S2	For review and assessment of nuclear safety OE information abroad STUK has an internal OEF Group.
S3	STUK has recently (2018/2019) developed further the process for managing regulatory experience from various sources. This more enhanced process has been as a pilot use in

	Nuclear Reactor Regulation and Nuclear Waste Management Departments. There is still need for further development (see weaknesses).

WEAKNESSES FOR 02. THE GLOBAL SAFETY REGIME

W1	The efforts that STUK has taken to assist to enhance safety globally have also taken a lot of resources. STUK has not commonly agreed strategy or identified focus areas for international cooperation, although departments are continuously discussing and following their own focus areas.
W2	STUK has an internal OEF Group for inter¬national events with a coordinator and technical experts (16 persons). Although the group is working well, this activity is taking quite a lot of resources, and there is some need to further develop the activity focusing on the most safety significant issues and feeding the findings into the STUK's oversight processes.
W3	More systematic process for managing regulatory experience does not yet cover all STUK's regulatory departments and is not yet integrated in STUK's management system.

OPPORTUNITIES FOR 02. THE GLOBAL SAFETY REGIME

O1	Geographical position of Finland and common EU border with Russia increases importance of boarder control. This gives opportunities for international funding and co-operation and the adaption of new technologies.

CONCLUSIONS FOR 02. THE GLOBAL SAFETY REGIME

C1	Finland and STUK are active players in international co-operation and very often have even a bigger role than the size of the country would indicate. However, the efforts that STUK has taken to enhance safety globally have also taken a lot of resources. There is an opportunity to further enhance the effectiveness and efficiency of STUK's international cooperation and to focus the use of resources.
C2	STUK has an internal OEF Group for international events with a coordinator and technical experts (16 persons). Although the group is working well, this activity is taking quite a lot of resources, and there is some need to further develop the activity focusing on the most safety significant issues and feeding the findings into the STUK's oversight processes. STUK has already started some further development work on this. No additional new actions are needed.
C3	STUK's current practices include many elements of the management of regulatory experiences. STUK has recently (2018/2019) developed further a more systematic process for managing regulatory experience from various sources. This more systematic process for managing regulatory experience does not yet cover all STUK's regulatory departments and is not yet integrated in STUK's management system.

Module: 03. Responsibilities and Functions of the Regulatory Body

Findings

Question 1 Does the regulatory body's organizational structure enable it to discharge its responsibilities and perform its functions effectively in a manner commensurate with the radiation risks associated with facilities and activities?

Answer: Yes

Response:

Organizational structure of the regulatory body

According to the Section 5 of the Decree (618/1997) on Radiation and Nuclear Safety Authority ([Päivitettävä uuteen asetukseen, kun se on valmis) organization and decision-making authority within STUK can be decided by STUK's Director General. This means in practice that STUK's Director General has the authority to decide about STUK's organizational structure and management of STUK's resources without any consent from outside STUK (with the exception of selection of STUK's Director General). It also ensures that STUK's organizational structure and use of resources supports both effective and efficient regulatory activities.

STUK´s duties are defined in the Decree on STUK, and according to the Decree STUK has the following duties:

1. duties according YeL (990/1987)
2. duties according SätL (859/2018)
3. duties according Act of vaarallisten aineiden kuljetus (1994/719)
4. duties according pelastuslaki (379/2011)
5. acting as an expert during radiation hazards???
6. monitoring the radiation situation in Finland, and maintaining of preparedness for abnormal radiation situations
7. maintaining of national metrological standards in the field
8. research and development work for enhancing radiation and nuclear safety
9. communication and education /training in the field
10. producing expert and metrological services in the field

11. participating to national and international co-operation in the field

12. , and taking care of international control, contact or reporting activities as enacted or defined

13. making proposals for legislation and improvement in the field and …….

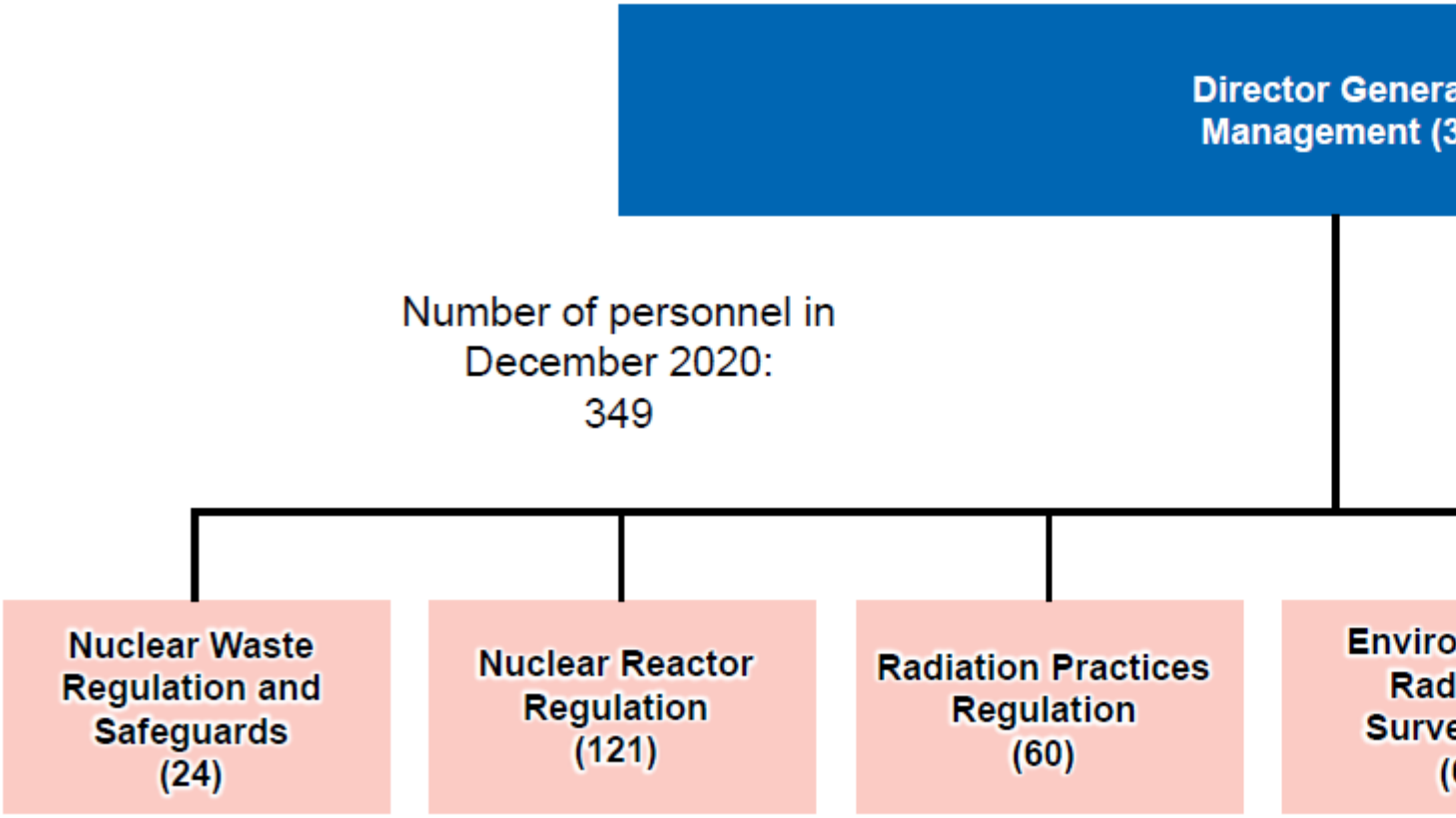


Figure 1. Figure 1. STUK's organization December 2020 (päivitettävä/KaK)

STUK's current organization (see figure 1) reflects the most significant duties of STUK, namely oversight of the use of radiation and nuclear energy and environmental radiation surveillance. Organization and the duties as well as use of resources are described in more detail in STUK's Management System (Guides STUK 2.1, STUK 2.2 and STUK 2.6). STUK's organizational structure reflects the structure of legislation (YeL and SätL) and duties described in it. Both the organizational

structure and use of resources are periodically evaluated which enables the identification of needs for changes. The evaluation is based on strategic and annual plans and management reviews, including:

- STUK's Results Agreement with MSAH 2020-2024, annual goals 2022 # …, Dec 2021
- STUK's annual HR-plan 2022 #..., Dec 2021
- STUK's budget and procurement plan 2022 #..., Dec 2021
- STUK's management review 2021 #..., Jan 2022[KK(1]

[KK(1]SAHA-linkit lisättävä kun dokumentit olemassa

STUK is a regulatory body but it also is an expert organization providing expert services in its field of expertise. These activities are coordinated by a dedicated department but experts from all departments participate in the work, depending on the expertise needed and the availability of resources. In addition, STUK is a research organization on radiation safety; these activities are performed in the Radiation Practices Regulation and Environmental Radiation Surveillance Departments. However, the role of research has changed since 2015 due the major changes on the research funding. Research funding is discussed in more detail in Question 3.

The legislation incorporates a graded approach to regulation, which is directly reflected in the organizational structure of STUK as it is based on the duties of STUK defined in the legislation. In addition, the graded approach to regulation is implemented through the STUK's management system which describes strategic as well as annual planning, and implementation of regulatory activities according to the processes. Another prerequisite for the practical implementation of a graded approach is naturally staff competence. Number of staff in different organizational units (in figure 1) indicates that resources are allocated with a graded approach on safety and considering the extent of the supervision area e.g. number of license holders. According STUK's management by results, all units are annually assessing their resource and competence needs coming from the strategy and future needs for capacity and updating their HR-plans accordingly. Use of resources in different organizational units is recorded and tracked to ensure that plans for regulatory oversight is met also resource wise. The use of resources on the main sectors can be seen in figure 2 The figure illustrates that most of the resources are used to ensure that the use of nuclear energy is safe.

Figure 2. Figure 2. Kuva tilinpäätöksestä resurssien käytöstä (lisätään 2021 tilinpäätöksestä)

Question 2 Does the regulatory body perform its functions in a manner that does not compromise its effective independence?

Answer: Yes

Response:

Objectivity and the official's impartiality form the foundation of the operation of public authorities. Officials must take particular care that their activities are impartial, and they must also be seen to be impartial from the perspective of interest groups and citizens. Under section 15 of the State Civil Servants' Act, a civil servant is not permitted to demand, accept or receive a benefit, if it could undermine trust or confidence in the civil servant or authority. In the Criminal Code, impartiality of the work of public authorities is particularly safeguarded by the penal provisions in sections 16 and 40 concerning giving and receiving bribes and bribery offences, as well as the other provisions of the Criminal Code, section 40, concerning malfeasance.

STUK is a governmental body and the Administrative Procedure Act (434/2003) is applied in all its activities. The Act lays down provisions on the foundations of good administration and on the procedure to be applied in administrative matters.

Section 18 of the State Civil Servants' Act (750/94) issues provisions on the restrictions concerning outside employment engaged in by public officials. The consideration of the issue of an outside employment permit must consider the fact that the secondary job may not compromise the impartiality of the public official in his or her duty. The outside employment may also not threaten trust in the official's fairness in performing his or her task or hinder the management of the duty in any other way or cause apparent damage to the employer as competitive activity.

In addition to what is described in the legislation, STUK's Management System addresses the expectations and gives guidance in more detail to ensure independence at all levels of STUK's activities. The independence of STUK and STUK's staff is addressed in the training of all employers. One of the essential elements of the regulatory independence is the competence of STUK and its staff. The expectation is that both management and staff at STUK have the knowledge and other professional competence needed for in-depth discussion on safety issues with the regulated parties.

As STUK provides some services (such as radon and other measurements), STUK's organization is structured so that its effective independence is not compromised. This is done by clear separation of regulatory activities and services to different organizational units. In addition, STUK`S external services are regularly evaluated by intendent external bodies (Finnish accreditation body, FINAS and CIPM MRA) Within the STUK's management system, Guides STUK 3.1 and 2.17 are key documents ensuring that STUK performs its functions in a manner that does not compromise its effective independence. Guide STUK 3.1 prescribes the principles and procedures of regulatory control. The general principles are (see Section 4.2 of STUK 3.1 for more detail prescription on each of these):

- legality and legal certainty
- equality
- impartiality and the prohibition of abuse of power and discretion
- proportionality
- legitimate expectations
- publicity and transparency
- verifiability
- efficiency
- serviceability

It is the responsibility of all STUK staff to follow these principles in all regulatory functions.

The Ministry of Finance's (MoF) guidance on Hospitality, Benefits and Gifts (VN/12079/2021, 1.5.2021), sets out principles for assessing the boundary between what is prohibited and what is permitted in situations of incoming interaction. On basis of the MoF guidance, Guide STUK 2.17 provides STUK staff with guidance and criteria for consideration when dealing with external stakeholders, in particular representatives of organizations subject to regulatory control. It also addresses the issue of the provision of benefits, in particular hospitality.

Question 2.1 How do the regulatory body rules for recruitment and training of staff maintain the effective independence of the regulatory body?

Response:

Under the Constitution of Finland, the general qualifications for public office shall be skill, ability and proven civic merit. The integrity of the official shall also be considered.

Section 8 c § of the State Civil Servants' Act (750/94, as updated 19.12.2017) state that "In considering an appointment, the authority shall have regard to the integrity of the person to be appointed and shall ensure that he or she has no interests which might conflict with the proper performance of his or her duties and that he or she is able to perform his or her duties with independence and integrity in all other respects".

A civil servant's relationship with his or her former employer and the resulting possible grounds for disqualification must be considered when a new person steps into a civil servant position. According to the general clause in the Administrative Procedure Act concerning grounds for disqualification an official shall be disqualified, if his or her impartiality is compromised for a specific reason. Based on the above, an official must not handle matters concerning his or her former employer or a partner or competitor of his or her former employer which can compromise the impartiality of the official. When organizing the tasks of an official, his or her former employer will be considered for at least a period of six months from the beginning of his or her employment. There is also an internal rule in STUK that a new staff member who has worked for a licensee shall not participate in regulatory activities regarding his former employer's installations for a period of at least six months or even longer when necessary. The integrity and disqualification of civil servant is under evaluation during the hole career. These aspects are also discussed with applicants during interviews when STUK is recruiting new staff members.

Every new STUK employee will have a personal training programme tailored for the task he/she is responsible for. The principles mentioned above are included in the introduction plan of the newcomers to ensure that they understand their roles. And as a part in introductionary training all new staff members shall take e-lectures on ethics for governmental officers (eOppiva johdanto virkamiesetiikkaan) The requirement of independence is also discussed with newcomers and they are advised to read internal guidance related to this.

Question 2.2 How does the regulatory body ensure, in its liaison with interested parties, it has a clear separation from organizations or bodies that have been assigned responsibilities for facilities or activities or for their promotion?

Response:

The independence of STUK is ensured by different ways (legislation, mandate, financial, and institutional). In addition, STUK's management system describes the expectations and guidance in more detail to ensure independence at all levels of STUK's activities (for example, see Question 2 for more detailed discussion on Guides STUK 2.17 and 3.1)

One important prerequisite for ensuring independence from organizations or bodies charged with responsibilities for the promotion or application of nuclear or radiation related technologies is competence of STUK's staff. The expectation is that both management and staff at STUK have knowledge and other professional competence needed for in-depth discussion on safety issues with the regulated stakeholders. Independence is also ensured in cases when someone formerly worked for licensee is recruited to STUK's staff as described in Question 2…… In cases STUK uses subcontractors for any work the requirement for independency is included in contracts.

Radiation protection research is often carried out together with universities and university hospitals that are also license holders. Research partners include also other authorities and research centres. STUK does not receive funding from license holders nor gives funding to licence holders. The research co-operation is largely based on agreement under the Cores network and each party is responsible for its own funding and deliverables. The Cores network does not have its own financial resources, and all parties apply research funding independently from external sources.

Question 2.3 How does the regulatory body exercise its authority to intervene in connection with any facilities or activities that present significant radiation risks?

Response:

STUK's rights to intervene in the activities of the regulated areas are described in Chapter 10 of YEL and, Chapter 20 of SätL. STUK's enforcement policy and procedures are prescribed in STUK's management system and are discussed in more detail in Module 9.

STUK applies a graded approach in all regulatory activities. Accordingly, the costs to the licensee compared to the risks reduced can be a factor to be considered, especially when the risks are minor. However, no provision in the legislation nor in the STUK Management System documents refer to costs to the licensee as a factor hindering STUK from exercising its authority to intervene in case of significant radiation risks. The following examples demonstrate some STUK's interventions causing significant costs to the licensee:

In the past in some rare cases STUK has limited the operation of the NPPs or prevented the start-up of the reactor from annual outage until the unresolved safety issues have been satisfactorily resolved.

During the construction of a new OL3 nuclear power plant regulatory decisions were taken in a timely manner as necessary. Significant regulatory issues were the digital I&C, replacement of cables in the containment, …. In case of radiation practices, STUK has, for example, discontinued the operations of an industrial radiography company due to safety lacks (by on-site decision of an inspector followed by a confirming STUK decision).

Question 3 Does the regulatory body employ sufficient number of qualified and competent staff, commensurate with the nature and number of facilities and activities to be regulated, to carry out its functions and discharge its responsibilities?

Answer: Yes

Response:

As a self-standing and independent regulator, STUK is committed to developing and sustaining adequate competency to carry out its functions and discharge its responsibilities. STUK has established a strategy for a five-year period. The implementation of strategy is ensured by 'Change programme' and detailed goals are included in STUK's annual plan. The implementation of the strategy is followed up by the management team at least twice a year and strategy is also assessed on annual basis and, if needed, changes can be done.

STUK's competence and human resource needs are evaluated during each of the steps mentioned above (strategy and annual plans). To fulfill its responsibilities, STUK needs adequate and competent personnel. On the other hand, the balancing of the state budget will make it necessary to keep personnel expenses under control. Consequently,

· the management carefully assesses the importance of different tasks and allocates resources to the essential tasks

· the personnel are supported towards continuous development

· STUK's budget is strengthened through fee-charging operations and services - that simultaneously support the development and sustainability of STUK's competency. Lately STUK's budget has been cut by

MoF and this has affected STUK's radiation safety research activities but not directly regulatory oversight.

STUK's management system provides guidance on the human resource management, resource allocation and competence development as briefly explained below.

According to Guide STUK 5.1, Human Resource Policy:

Competent, co-operative and motivated people are a fundamental success factors in STUK operations.

The cornerstones of STUK's human resource management are:

- Competent personnel, learning and development
- Leadership and effective management
- Equality and equity in workplace
- Employee wellbeing and early support
- Open interaction, feedback and motivating compensation

According to Guide STUK 5.2 Competence Management in STUK

As an expert organization and a safety authority STUK is dependable of its expertise and human capacity in order to perform its mission and related tasks.

STUK has an overall process for competence management. The process links competence management and development activities with STUK's overall operational and strategic planning processes as it e.g. gathers input from the overall strategy and operational plans. The competence management process steers the competence development activities in STUK. The process forms a continuous loop that has four main phases: Identification and Evaluation of competence needs, Development planning, Development actions and Evaluation. Each stage has its own objectives and methods - and they are performed on various levels in the STUK's organization. STUK still have some challenges to include all identified training in annual training programme of individual development plans.

Tähän kohtaan kuva osaamistarpeista (kuva suomeksi - käännettävä englanniksi)

In broader scope, STUK's capacity needs are identified during the operational planning. The planned activities and their outcomes are analyzed and needed human capacity is evaluated in the units and departments. The staff plans are compiled, reviewed and updated accordingly. Staff planning is carried out on annual level but also for longer time periods (e.g. 5 year staff forecasts).

Potential use of external support (e.g. TSOs, consultants etc.) is considered as part of the staff planning. In general, STUK utilizes external support temporarily to complement its own human capacity (e.g. temporary peaks in workload) or to supplement STUK's own core competency (e.g. with used of specialized independent/external analyzes). STUK's recruitments are planned and allocated to enhance the competencies required by STUK's core or support processes and activities - in long-term perspective.

STUK's capacity consist of various competencies that are generally managed as 'competence profiles'. The profiles are compiled by identifying competence needs of the operational activities and the targeted outputs. The competence areas are specified on different levels: e.g. units, departments and on general STUK-level. In addition, role-specific competence profiles are compiled for cross-organizational roles such as managers, project professionals and assistants. The competence evaluations are conducted periodically, and development needs are turned into personal development plans. Ultimately, development needs of each individual combine the perspectives of organizational needs for competency (top-down input) and personal interests and aspirations for professional growth (bottom-up).

STUK's competencies are developed by employing various methods. Many of the most effective methods are considered as forms of on-the-job learning (e.g. task planning, job rotation, national and international cooperation and networking, role and job design/crafting, cooperation, participation). As the defined roles and responsibilities of STUK's employees vary greatly the practical, individually planned and close-to-work -methods are often the most valuable for individual's competence development and professional growth. As the nuclear and radiation safety regulatory body in Finland, STUK is responsible for developing its regulatory competency. Consequently, STUK implements and develops its own training system for its staff.

The training system consists of training content that are designed based on e.g. the competence needs, strategic goals and contemporary topics and competence areas. Changes in competence needs (aging staff, changes in STUK's operation or operating environment etc.) are identified and considered when training plans are developed. Some of the training events or programs are conducted in-house and some or the trainings are provided by external parties or in cooperation with other organizations. STUK's training activities are conducted based on annual training plans that pay attention to topical needs and adequate repetition of the training events.

The introduction of new employees is conducted according to a specific process (Guide STUK 5.8). The aim of the introduction process is supporting the proficient start for the newcomers in STUK - and to ensure that the common STUK knowledge, shared practices and procedures are presented and adopted by the newcomers. Every new employee has an introduction plan that are partly specified to their individual needs (based on their background and intended role and competence needs in STUK). The unit heads are responsible for supporting new recruits and familiarized them with the new tasks and new work environment. Coworkers of the newcomer may also be involved into introduction (and qualification) process. HR services coordinate e.g. training for the newcomers and provides basic information of how STUK acts.

The unit heads are responsible for ensuring that the necessary preconditions are arranged for their subordinates to develop their professional competence (e.g. to attend training that is necessary for the operations of the unit). However, development of the professional competence as well as the strive for continuous personal development is ultimately the responsibility of each individual.

STUK encourages its personnel to develop its professional skills and to expand its competence to new tasks as well. STUK grants leave of absence for the purpose of working for another employer, if working elsewhere develops competence in STUK related tasks and the execution of the unit's tasks doesn't become considerably more difficult as a consequence. STUK supports its staff in their further studies on his/her own terms, when the new knowledge also benefits the work. E.g. possible working time and task arrangements can be settled with the closest supervisor. In some occasions STUK may also participate in the studying expenses.

In order to support the development of broad understanding and knowledge among its staff, STUK support its employees' efforts to grow professionally through e.g. inter-organizational job rotation and inspector exchange arrangements. These arrangements allow STUK's employees to work a fixed time-period in other relevant organization e.g. other country's regulatory body and learn from their operation, procedures and methods. Furthermore, STUK grants leave (without pay) for its employees in case they wish to gain further experience by working in e.g. an international organization on a fixed-term basis. During this this time, the employee will maintain his/her employment relations with STUK.

As stated earlier, the matching of the development objectives of the unit and the personal development needs – is done e.g. in the annually held personal discussions on results and development. After the discussions and after the training needs of each person have been agreed upon and documented, they are gathered together and included in the training plans.

Steered by the overall process of competence management in STUK the HR services is responsible for coordinating and supporting the competence management in STUK. The responsibility includes various coordination, development and evaluation tasks and procedures related to competence assessment, development and attainment of needed competence at the level of the entire STUK. Accordingly, HR services conduct and coordinate competence mapping and evaluation activities (competence discussions), competence development activities (training, mentoring etc.) and recruitment activities (recruitment plans, recruitments, employer image development etc.). The competence management is carried out in continuous and close cooperation between the HR Services, STUK's departments and the management.

Inspector Qualification

STUK has developed its own qualifications procedure for inspectors of Nuclear Reactor Regulation and Nuclear Waste Regulation and Safeguards. The common qualification procedure support the consistency of oversight processes. The inspector qualification process is presented in Guide YTV 6.b.

The qualification requirements for inspectors and other staff of Radiation Practices Regulation are presented in Annex 2 of Guide SKV 12.4. For example, the inspector shall have a formal qualification of a radiation safety officer. The induction programme for new inspectors of radiation practices is presented in Annex 1 of Guide SKV 12.2. For each part of the induction programme, the Section Head appoints a person responsible for induction. On completion of the induction, the Section Head will sign off the induction programme to certify that the person is competent to act independently as an inspector.

Question 3.1 What is the strategy to compensate for the departure of qualified staff?

Response:

In order to maintain a clear vision and status of the departing staff STUK updates its human resource plan annually as a part of the annual planning. Furthermore, STUK maintains a mid-term staff forecast for 5-year period in order to evaluate the effects of retirements, fixed-term contracts, long-term leaves/absences - and to estimate recruitment needs in near future.

In addition to staff forecasts and plans, competence evaluations are performed regularly. The competence analyses support the identification of competence gaps and future competence gaps. The competence evaluations are carried out by using STUK specific competence profiles and an assessment tool by which the current level of knowledge, skills and abilities necessary for each individual are defined. The competence evaluations also include the target level of knowledge, skills and abilities and provide input for individual development plans on how the individual's competence should be developed in the future.

Retirement of experienced employees is usually predictable and therefore the departing competence can be defined to a certain extent. In many cases the retaining of competence is started well ahead of the retirement. E.g. the senior expert may work together with his/her successor or he/she will act as a mentor for the next generation experts. Furthermore, senior experts may be used in training and internal consultative roles.

In general, there are two initiators for recruitment process: The need for a new person/competence arise as a result of strategic work or annual planning, or as an employee retires or resigns from STUK's service creating a loss of capacity. Due to the current budget constraints in the government organizations, STUK has to first consider if open position can be filled using STUK's existing resources without recruiting outside STUK (e.g. use of job rotation and allocation of existing resources).

Regarding regulation of nuclear facilities, the majority of regulatory authority functions are financed via fees collected from licensees and, therefore, budget constraints coming from government level do not have a major impact on recruitment of e.g. inspector positions. However, in case of regulation of radiation practices, which are financed via state budget, recruitment of inspectors and other regulatory staff may be affected by budget constraints. Competence needs are defined before opening the vacancy and published in an advertisement.

According to STUK's management system (Guide STUK 5.7):

When a person resigns or retires from STUK's service, or moves to another position within STUK, it shall always be firstly considered, if his/her old task could be taken care of in a safe manner by rearranging tasks without adding any new personnel.

If an open vacancy is decided to be filled, an advertisement of the open vacancy is published with competence needs as one of the selection criteria. The objective for a recruitment process is to find and

to appoint the best candidates for the open positions. When a final selection is made between two or more equally well-suited candidates, the person with stronger competency and evaluated adaptability (personality and personal traits etc.) to STUK's organization and to the role at hand is selected.

Question 4 Does the regulatory body have adequate arrangements for obtaining technical or other expert professional advice or services as necessary, in support of its regulatory functions?

Answer: Yes

Response:

STUK's Advisory Committees

STUK has four advisory committees that have been defined in the legislation. STUK's Advisory Committee is laid down in the Decree on STUK Section 2. The Advisory Committee on Nuclear Safety and The Advisory Committee on Nuclear Security are defined in the Nuclear Energy Act Section 56 and the Advisory Committee on Radiation Safety in Section 18 in the Radiation Act. The composition, quorum, term and tasks of the safety and security committees are defined in associated government decrees.

STUK's Advisory Committee was established in March 2008. Advisory Committee helps STUK to develop its functions as a regulatory, research and expert organization in such a way that the activities are in balance with the society's expectations and the needs of the citizens. Advisory Committee can also make assessments of the STUK's actions and give recommendations to STUK. The Advisory Committee is nominated by STUK.

An Advisory Committee on Nuclear Safety (YTN) was established in 1988 by a Decree. ThisCommittee gives advice to STUK on important safety issues and regulations. The Committee also gives its statements on license applications. The Advisory Committee has now two international subcommittees, one for reactor safety (RSC) and one for nuclear waste safety and decommissioning (NWSC).

An Advisory Committee on Radiation Safety has been established (SätL Section 18). The duties of the committee are to make statements on planned, existing and emergency exposure situations as well as other matters relevant to radiation safety, to make statements on draft radiation safety legislation and regulations, to follow the development and research in the field, to promote national and to follow international co-operation and to make initiatives to competent authorities on necessary measures for radiation safety (VnA Section 59).

The members of the Advisory Committee on Nuclear Safety and the Advisory Committee on Radiation Safety are nominated by the Government.

To assist STUK's work in nuclear security, an Advisory Committee on Nuclear Security was established in 2009. The members of the committee come from the various Finnish authorities, and the nuclear licensees also have their representatives as experts. The duties of the committee are stipulated in the Government Degree 1016/2016 and include the assessment of the threats in the nuclear field as well as consultation to STUK in important security issues. The committee also aims to follow and promote both the international and domestic co-operation in the field of nuclear related security issues. The members of the Advisory Committee on Nuclear Security are nominated by the Government.

For authorization processes of nuclear facilities (Decision in Principle, Construction and Operating license steps for nuclear facilities), STUK is obliged to ask a statement from YTN. In addition, STUK asks statements from YTN on new safety regulations, on major plan modifications or other areas STUK deems necessary. For authorization purposes, STUK must attach YTN’s statement on STUK’s statement submitted to the Ministry of Employment and the Economy. The members of YTN have to conform to the Administrative Procedure Act (434/2003) which specifies the principles of independency and grounds for disqualification. According to the Act the nominated members are obliged to leave the meeting if there is any suspicion of impartiality of the member concerning the mater under discussion. The Advisory Committee meeting minutes and statements are public and available at STUK website with exception of the Advisory Committee on Nuclear Security.

As a part of the nomination process the Advisory Committee members give a written statement of their possible national or international commitments that may compromise their impartiality. The form to be field covers membership in national or international bodies and financial commitments. The following information is requested from the committee members:

- Pursuit of business and profession - company name and industry
- Positions of trust and governance in companies and communities
- Positions of trust of municipalities and other public entities
- Side activities
- Other tasks
- Other interests that may be relevant to the assessment conditions for carrying out the tasks arising from membership (see no financial links)
- and financial interests:
- Shareholdings and other holdings in companies
- Other sources of income (significant for membership)
- The size and basis of liabilities and other financial liabilities; also, commitments made on behalf of third parties (significant for membership)

- Other financial ties that may be relevant in assessing my ability to perform the duties of membership.

In addition to advisory commissions, STUK uses expert organizations to support STUK in its regulatory functions. STUK's main support organization in Finland is VTT Technical Research

Centre of Finland. STUK and VTT have a framework contract and rules on the co-operation to ensure independent advice and to avoid conflict of interest. In addition to VTT, STUK uses other organizations in Finland and abroad. The advice and assistance from external organizations does not have a formal status and it does not relieve STUK of its assigned responsibilities. The independence as well as possibilities to conflicting interests are addressed in the course of contracting.

Currently there are framework agreements on the following areas:

lista

Kuvat ydinturvallisuusvalvonnan tilauksista eri vuosina laitoskohtaisesti (vuosikertomus tai ydinturvallisuuden vuosirapo) ja grafiikkaa jakaantumista eri teknistieteellisille aluille.

Use of external experts

STUK may in its regulatory control duties rely on the assistance of an outside expert for the performance of inspections, investigations, studies and measurements to clarify a matter relevant to the regulatory control. The outside expert shall have the qualifications required by the tasks they perform. When performing duties referred to in this Act, the outside expert is subject to provisions concerning penal liability as a public official. (SätL, Section 181).

Question 4.1 How does the regulatory body maintain an adequate core competence to make informed decisions on the use of advice and assistance provided by external parties and to retain responsibility for the regulatory actions?

Response:

As a self-standing and independent regulator, STUK is committed to developing and sustaining adequate competency to carry out its functions and discharge its responsibilities. Traditionally, STUK establishes a strategy for a five-year period. The strategy is implemented by department specific

operating plans for the same period. The established operating plans are revised and updated annually as part of an annual operational planning. These plans reflect as accurately as possible the regulatory duties and the work of STUK. STUK's competence and human resource needs are evaluated during each of the steps mentioned above (strategy, operating plans and annual plans). To fulfill its responsibilities, STUK needs adequate and competent personnel. On the other hand, the balancing of the state budget will make it necessary to keep personnel expenses under control. Consequently,

- the management carefully assesses the importance of different tasks and allocates resources to the essential tasks
- the personnel are supported towards continuous development
- STUK's budget is strengthened through fee-charging operations and services - that simultaneously support the development and sustainability of STUK's competency.

STUK's process of Competence management supports the development and retainment of adequate regulatory capacity. The process links competence management and development activities with STUK's overall operational and strategic planning processes as it e.g. gathers input from the overall strategy and operational plans. The competence management process steers the competence development activities in STUK. The process forms a continuous loop that has four main stages: Identification and Evaluation of competence needs, Development planning, Development actions and Evaluation. Each stage has its own objectives and methods - and they are performed on various levels in the STUK's organization.

The competence management process is linked with STUK's operational planning and one of the outcomes the planning process are the updated staff plans and a 5-year forecast. These plans and forecasts address STUK's own staff and planned growth or downsizing. While compiling the plans and allocating human capacity the requirement for STUK's self-sufficiency and independence as a regulatory body is taken into consideration. Accordingly, the use of external support (e.g. TSOs, consultants etc.) is considered as part of the staff planning. In general, STUK utilizes external support temporarily to complement its own human capacity (e.g. temporary peaks in workload) or to supplement STUK's own core competency (e.g. with used of specialized independent/external analyzes). STUK's recruitments are planned and allocated to enhance the competencies required by STUK's core or support processes and activities - in long-term perspective. To secure its reliable operation, STUK makes general agreements with external parties in the specifically competence areas where the need for added capacity is estimated. When STUK utilizes external support it still remains as 'intelligent customer', as it has the adequate competence in-house to steer and evaluate the work of the external party.

In addition to competence aware staff planning, competence development and the use of external support as supplementary capacity, STUK is an active participant in international nuclear safety and radiation safety communities. E.g. STUK participates actively in preparation and development work of international recommendations and requirements. Active participation in the international communities

provides STUK a valuable information about the changes and new developments in the areas of nuclear and radiation safety.

In the area of nuclear safety, STUK participates in national research programs and supports cooperation e.g. in training. The national research programs and national training programs have an important role in development and preservation of up-to-date and first-hand nuclear competence in STUK and in Finland.

YEL Section 53a § to 53e§ "Ensuring expertise" establish legal framework for national nuclear safety and national nuclear waste management programmes. The main purpose of the programmes is to develop national capability in assessing nuclear safety so that TSO support is available for STUK whenever needed. All the relevant stakeholders such as STUK, licensees and research organizations participate in the steering of the research. STUK is chairing the management board of the research programmes and it has leading role in the defining the content of the research programmes, the funding of the projects and steering the research.

The research projects are selected so that they support and develop the competences in nuclear safety and to create preparedness for the regulator to be able to respond on emerging and urgent safety issues. These national safety research programs are called SAFIR and KYT. See more in Module 1, primary Question 1.

Question 5 Has the regulatory body established formal and informal mechanisms of communication with authorized parties on all safety related issues?

Answer: Yes

Response:

The following ways to foster mutual understanding and respect are applied:

- Formal and informal mechanisms for communication
- Authorized parties are given possibility to be heard when regulatory decisions are made prior their issuance
- Authorized parties are given possibility to participate in regulations update process
- Stakeholder feedback is collected via questionnaires and interviews
- E-newsletters and webinars

The formal and most frequently and regularly used mechanism for communication is through correspondence between regulatory body and authorized parties as well as inspections on the authorised activities and organisations. It is also possible for STUK to invite authorised parties to a formal meeting. These mechanisms (regulatory processes) are described in detail in STUK's management system. The informal mechanisms for communications consist of informal meetings as well as discussions between individuals at different levels of the organisations: The regulatory body holds regular meetings and workshops with authorised parties concerning safety issues and operating experience feedback.

STUK is a governmental body and Finnish the Administrative pProcedure Act (434/2003) is applied in all its activities. The Act lays down provisions on the foundations of good administration and on the procedure to be applied in administrative matters. These include, for example, provisions on hearing the views of parties in regulatory decisions (for example, a decision on a safety license or an inspection report): Section 34 of the Act states that "Before a matter is decided, each party shall be provided with an opportunity to express an opinion on the matter and to submit an explanation of claims and of evidence which may influence the decision". These requirements have been taken into account in defining STUK's regulatory processes (which are prescribed in relevant STUK's Management System documents). According to Section 199 § of SätL STUK shall hear stakeholders before issuing requlations. STUK regulations are published in the Finlex and STUKlex. STUK maintains also a webpage on STUK regulations with their motivations: https://www.stuk.fi/saannosto/stukin-maaraykset

STUK collects feedback from the licensees by means of questionnaires, in case of use of radiation, a systematic questionnaire has been sent to the licensee soon after each inspection as to seek information on licensee's perception on the conduct of the inspection. This feedback was analysed and reported for management review and to improve inspection activities. As the feedback seemed to stabilize (almost same answers were repeatedly receive) this activity has now been replaced by sending out a questionnaire less frequently, but covering broadly all STUK's regulatory activities, STUK publishes e-newsletters. For radiation users there are two different e-letters: one for medical and veterinary use of radiation and one for industrial, research and educational use of radiation. STUK has arranged for more than 30 years annual or biannual stakeholder meetings for radiation users on different fields. Since 2020 STUK has arranged several webinars for radiation users on topical issues.

STUK uses the inspection findings and other observations pertaining to radiation safety to develop regulatory control and reports on them to undertakings, authorities and any other parties concerned in the extent as is necessary to promote safety (SätL, Section 183)**.** Radiation safety deviations and results of investigations thereof shall be reported to STUK (SätL Ssection 130 and 131). Summaries of inspection findings and radiation deviations are published in an Annual Report on Radiation Practices which provides means to communicate them to all licensees.

STUK also gathers information on practices through questionnaires on specific topics such as those related to exposures of patients and prepares reports on them.

Question 5.1 How does the regulatory body justify and explain its decisions to authorised parties?

Response:

According to the management system, STUK's decisions and requirements has to have a sound legal basis and the requirements set has to be commensurate with safety.

The basis for the decision, evaluation criteria, and scope of the review as well as basis for possible requirements set to the authorised parties has to be presented in the justification memorandum, which has to be attached to the decision and is submitted to the authorised parties.

As prescribed under Question 5, stakeholders are being heard in decision making and in preparation of STUK regulations.

STUK has established a web-based regulatory and guidance service "SAMMIO" for radiation legislation. With the service anyone can search for requirements from different levels of legislation and STUK regulations. The search result includes the individual requirement, its justification and further guidance including STUK's expectations on its practical application. As being an electronical system, the guidance can be updated easily, and further guidance can be added where the need for such is identified. The guidance serves both the users (mostly licensees) and the regulatory staff as a mechanism to manage and preserve STUK's expectations on the practical application of individual requirements.

Question 6 Does the regulatory body ensure that regulatory control is stable and consistent?

Answer: Yes

Response:

Regulatory control activities of STUK are based on legislation, including the Act of Administrative Procedures, YeL and SätL. STUK's activities and decisions must be justified making a reference to the relevant provisions in legislation. The obligations of STUK presented in the legislation are implemented through the management system. STUK's managements system policies and procedures shall be observed in all regulatory processes.

STUK's processes are prescribed in the management system. Regulatory control of the use of radiation, nuclear facilities and nuclear non-proliferation and nuclear waste management is prescribed in Guide STUK 3.1 Regulatory Control.

Procedures for regulatory control are prescribed in relevant YTV Guides, SKV Guides and VALO guides. These include the process descriptions for the control of nuclear facilities, the control of nuclear waste and nuclear material and the control of radiation practices. These include separate Guides for all regulatory activities, such as establishment of regulatory requirements, licensing, review and assessment, inspection and enforcement. STUK's regulatory decisions are made by two persons with the exception of the decisions related to inspections at the facilities and the review and assessment by several persons, depending on the scope, complexity and safety significance of the matter. However, some minor license matters concerning radiation practices can be reviewed and decided by an individual inspector (see below more information on cross-checking of these decision for consistency). In the management system for each type of decision the responsibilities are defined. Those responsibilities are also defined in the electric workflow in the document management system SAHA. The process and number of reviewers will in part ensure that regulatory decisions are consistent.

The preparation process of regulations includes internal and external commenting of STUK and the stakeholders and hearings of relevant advisory committees which in part ensure that requirements remain stable and changes are introduced only thorough consideration. These processes, as well as, those related to publishing and informing licensee and other stakeholders on the new or updated regulation are precibed in more detail in Module 9.

When a new or revised YVL Guide is issued, licensees are asked to send a letter in which they explain how the requirements of the new YVL Guide will be applied at their facilities. STUK will then by a separate decision define how the new YVL Guide will be applied at the existing installations. The areas for exemptions are defined in the YEA. Their application on the YVL Guide requirements on the operating NPPs are stored into a Polarion database that is available for the personnel. The decisions on the exemptions are discussed in the safety group of the nuclear regulation departments before making the decision. This ensures consistent approach to application of the new YLV Guides to nuclear facilities.

The process of drafting new YVL Guides and informing their content to licensees and other stakeholders is described in Module 9.

In general, requirements in legislation, STUK regulations and YVL Guides are, as a whole, such comprehensive that there is usually no need to set case specific conditions to a license. This in part ensures that license decisions are consistent.

Regarding radiation practices, inspection report prepared by individual inspectors are regularly cross-checked between inspectors and between supervisors and management (Guide SKV 3.2, Chapter 3) as to ensure consistency and to improve their quality. The inspectors are responsible for ensuring that the target is met for their own decisions and inspection reports. The target is for another inspector to check 25% of the reports, the manager 10% and the head of department or deputy head 1% of the reports.

An important tool for ensuring that regulatory control is stable and consistent is the regulatory and guidance service "SAMMIO" for radiation legislation (see more detail in Question 5). The service is used for managing and preserving STUK's expectations on the practical application of individual requirements.

Question 6.1 How does the regulatory body prevent subjectivity in decision-making by individual staff members of the regulatory body?

Response:

Following arrangements are in place to prevent subjectivity in decision making

- Guidance and criteria presented in the management system which shall be applied by members of the staff
- The process of decision making and the fact that most regulatory decisions are made with two signatures
- Hearing process applied prior decision making enabling authorised parties to raise concern on subjectivity if needed
- Section head role to follow decisions made in the area unit is responsible
- Training of the inspectors to ensure consistency in decision making

In addition, in the regulation of nuclear facilities

- Fairly detailed regulatory guides that present the legal basis for decision making
- Separate decisions on the application of new YVL Guide to existing nuclear facilities, database on the application of the YVL Guides available to all inspectors (see also Question 7 records)

In addition, in the regulation of radiation practices

- Cross-checking of inspection reports (see prescription in above under the main question 6)
- Guidance of the SAMMIO shall be followed by the members of the staff

Question 6.2 How does the regulatory body emphasize the continuous enhancement of safety while recognizing the risks associated with making modifications to well established practices?

Response:

The formal process for updating STUK's safety requirements (regulations) is described in STUK 3.6 Regulations. STUK's process follows the guidance for updating legislation given by the Ministry on Justice.

Nuclear facilities

The implementation of YVL Guides (regulatory guides) is given in Guide YTV 5.b

The process to issue has 4 steps (four drafts). Two first steps are internal to STUK (with an exemption that there could be a support group consisting of external experts working on draft two). Authorized parties have a possibility to give their feedback formally to STUK prior to issuance of the new or updated guide.

In the final step prior issuance of the new or updated guide advisory commission gives its statement on the guide. After that Director General of STUK approves the new guide to be issued.

The new or updated YVL guide is sent to authorized parties for implementation assessment. In the assessment parties assess how new requirements are fulfilled or will be fulfilled. The assessment is submitted to STUK for approval and STUK (Director General) makes final decision on the implementation of the new requirements after assessing authorized parties responses.

When the draft regulatory guide has progressed to second step (draft 2) it is send for comments and also published for comments at STUK's website. Draft is sent to comments to interested (authorized) parties as well as to independent consultants or experts and also to other appropriate ministries and other authorities or expert organizations, if necessary. A negotiation or meetings are arranged in connection with this procedure, if needed. When the draft regulatory guide has progressed to fourth step (draft 4) it is send for statement to Advisory Commission for Nuclear Safety and Advisory Commission for Radiation Safety.

For the YVL Guides hearings and implementation of Guides is arranged in the following way (Guide YTV 5.b:

The purpose of a hearing procedure is to give a licensee, or another organization concerned, an opportunity to present its opinion on how existing activities comply with the new requirements of the guide related to the safety level and its verification. At the same time, a statement is requested from the licensee on which change and improvement measures the licensee considers as justified.

Hearing is implemented according to the following principles:

- when a guide is confirmed, it is noted to become in force about six months after the issuance date
- a request for hearing is submitted to organizations concerned immediately, when a guide has been confirmed and published a needed time period is reserved for hearing, normally about two months
- meetings may be arranged in connection with hearings, if necessary; those questions are discussed in meetings, which are important when the application of a guide's new requirements to existing activities is considered.

After hearing, the Director of the appropriate responsibility area shall take care of the following: STUK's implementation decision or decisions are prepared on the application of the guide's new requirements to existing activities. When a decision is prepared, the principles for improving safety, presented in YEL 7a§, are considered. According to these principles, requirements are given in the decision on measures, which a licensee or other appropriate organization shall implement based on the new guide.

Director General makes an implementation decision on the presentation of the Director of the responsibility area in question

Radiation practices

STUK issues regulations on specific issues under the various authorizations given in the different sections of the SätL. When preparing new regulations or updating existing ones, an impact assessment is included in the explanatory memorandum. No legally binding regulatory guides can be issued under SätL. However, by its mandate, STUK issues guidance on the implementation of the legislation and regulation through the SAMMIO. The process for the inclusion of guidance into the SAMMIO is under development; the current process applied is prescribed in a separate document (#1988559) but, as prescribed under question 5, the process prescription is going to be incorporated to SKV guides.

The development and implementation of regulatory processes, regulations and guidance in the SAMMIO are governed by Section 11 of the SätL which states: "When supervising compliance with obligations pursuant to this Act, the regulatory authority considers: 1) the nature and extent of the exposure situation; 2) the risks associated with radiation exposure and radiation sources; 3) the impact that the regulatory control may have in the reduction of risks and the improvement of radiation safety."

Question 7 Has the regulatory body made provision for establishing, maintaining and retrieving adequate records relating to the safety of facilities and activities?

Answer: Yes

Response:

Use of nuclear energy

The fundamental basis for establishing and maintaining adequate and retrievable records relating to the safety of facilities and activities is given in the YEL (Section 63 on the Supervisory right of STUK) which defines that STUK has rights to receive necessary information and be provided with the plans and contracts and their grounds concerning the fabrication, quality control or processing of nuclear materials, nuclear waste, the nuclear facility and its structures and equipment.

YEA defines the documentation needed to be submitted to STUK in the different phases of licensing of nuclear facilities as well as for nuclear materials, nuclear waste and for materials, devices and equipment. These are further detailed in several regulatory guides. These documents form the basis for the safety related records needed for safe operation of a facility.

When safety significant modifications are made to the nuclear facility (systems, structures, components) licensee is obliged to submit the modification plans to STUK's review and approval. STUK approval is a prerequisite for the implementation of the modification. Licensee has to take care also that the documents submitted for the licensing of the facility (e.g PSAR, FSAR) are also updated correspondingly. This obligation is defined in section 112 of the YeA and forms a basis for maintaining the safety related records throughout the lifetime of the facility (both for the regulator as well as for the licensee).

Regulatory guides set specific requirements on licensees on areas and topics that they are required to report to STUK during design, construction, commissioning and operation of a facility. For example, during operation reporting consists of regular reports are well as on event reports. Criteria for this type of reporting are described in general in regulatory guide YVL A.9 "Regular reporting on the operation of a nuclear facility" and in YVL A.10" Operating experience feedback of a nuclear facility"

Regulatory guides (YVLs) set specific requirements on licensees on areas and topics that they are required to report to STUK during design, construction, commissioning and operation of a facility. For example:

- During construction licensee is required to report to STUK on the results of different inspections, tests, analysis made on the structures and components of the facility to justify compliance with requirements as well as any non-compliance and their correction.
- During commissioning licensee is obliged to report to STUK on the results of the commissioning tests.
- During operation licensee is obliged to report on the results of the periodic tests and other maintenance activities on safety significant systems, structures and components.
- Licensee is obliged to report on the radiological consequence of the operation of the plant to the environment.

Reports submitted to STUK in different phases of the lifetime of the facility are required to justify for the regulator that facility is always kept and operated in compliance with the requirements.

At plant design stage, STUK reviews and archives the proposed design also according to the below mentioned paragraph of YVL 1.0 "Safety criteria for design of nuclear power plants, paragraph 2.5 Decommissioning":

Provision for a nuclear power plant's decommissioning shall be made already during the plant's design phase. One criterion when deciding the plant's materials and structural solutions shall be that the volumes of decommissioned waste are to be limited. It shall be possible to decommission the plant and remove radioactive structures and components in such a way that the radiation exposure of workers and the environment remains low.

YVL on “Radiation safety aspects in the design of a nuclear power plant. 2.6 Decommissioning of the plant”:

The radiation sources and amounts of activity during the decommissioning of a nuclear power plant shall be assessed in the design phase of the plant. Radiation sources include, for instance, activated components and structures of the reactor pressure vessel and those in its vicinity, and the contamination accumulated in the reactor cooling system. From the point of view of major repairs and decommissioning, it is also important that the following issues, for instance, are considered in designing the plant layout: facilitating the removal of large components; facilitating the handling of activated components; enabling the decontamination of systems.

Arrangements are based on requirements for reporting on releases from the plant and archiving these reports. Reporting requirements are presented in YVL Guides 1.5, 7.1 and 7.8.

An event report (special report, disturbance report or incident report) shall be compiled if the requirements on reporting are fulfilled. A special report shall always be compiled on events in groups A-D. Group B (Events related to radiation safety) says “Radioactive releases into the environment have exceeded the limit (Guide YVL 7.1).”

The daily report shall be submitted to STUK for information every day. The report shall include the following, as applicable:

Releases of radioactive materials exceeding the reporting threshold. The reporting threshold is 5 × the reference release rate, average over a week at most (YVL 7.1).

Information on releases, (dispersion conditions and monitoring of the external dose rate in the environment) shall be submitted quarterly to STUK for information within a month from the end of each annual quarter.

The annual report concerning the results of the previous calendar year shall be submitted to STUK. The report shall include, among other things, a summary of the operation of the plant unit from the viewpoint of environmental radiation safety: release information, dispersion information, results of

dose calculations and results of radiation monitoring based on environmental measurements as well as information on nuclear waste exempted from the regulatory control.

With regards to use of nuclear energy, authorisation or its amendment, renewal, suspension or revocation always requires a formal regulatory decision. Basis for authorisation or its amendment, renewal, suspension or revocation has to be recorded in the decision. More justification is recorded to the justification memorandum which is attached to the decision.

The submissions and regulatory documents merged in SAHA-document management system. Electric submission of document is organized between STUK and licensees. A workflow is established for each submission and all related review and assessment inspection, justification, decisions STUK statements are stores in SAHA system. The documents are signed electrically. Quick transition to remote work in 2020 was facilitated by electric management of the regulatory documents. SAHA document management system is be used for the follow up of the decisions and safety issues as well as for the management of the work.

The records of inspection programme related to construction and operation of the nuclear facilities (RKT/RTO/KTO) records are stored in SAHA. The observations on the performance of the organizations are stored in Polarion-HAKE application. The inspection reports related to the oversight of operation (KV) and the mechanical components and structures are made and stored in STARE (earlier TARKKA) system. The integrated safety assessments of the NPPs and nuclear waste facilities are stored in the Polarion- application as well as the decisions on the application of the new YVL guides to operating NPPs and waste management facilities. All of the personnel involved in the oversight of the nuclear facilities have access to document and data management systems. User friendliness and ease of access has been considered in the development of the document and data management systems.

STUK keeps registers on the following topics:

- pressure equipment that shall be registered at the nuclear facilities (Pressure equipment law 51§)
- register of the Authorized Inspection Bodies (YEL 60a§)
- nuclear material register Safka (also all the materials mentioned in YEA Annex A)
- nuclear waste register (YEA 88§)
- register for doses is under SätL

<u>Dose register</u>

Section 92 of SätL states that individual monitoring shall be arranged for radiation workers belonging in category A. The individual monitoring shall be based on individual measurements performed by a dose measurement service. Section 101 of SätL sets the requirement to deliver information on individual monitoring to the dose register on regular basis. Further provisions on delivering information to the dose register are given in Sections 13 and 14 of S/1/2018.

Section 20 of SätL defines the workers' dose register which is maintained by STUK. The purpose of the register is to ensure the health of radiation workers, emergency workers, emergency helpers and radiation safety. Section 20 of SätL and Section 42 of SätA define the information contained in the register; the dose register contains the identifying information of each worker and information on: 1) their tasks; 2) undertakings and the employers of outside workers; 3) the methods employed for determining individual radiation doses; 4) factors impacting radiation exposure; 5) the results of individual monitoring.

Section 21 of SätL prescribes disclosure and storage of information included in the workers' dose register. The information in the dose register is stored for as long as the worker is engaged in radiation work and, subsequently, until the person in question attains or would have attained the age 75 years, although until 30 years have elapsed from the termination of the radiation work. STUK may store the aforementioned information for longer than this for research purposes related to ensuring radiation safety.

The dose register is part of the regulatory control system VASARA.

Radiation practices

Registers maintained by STUK for the purposes of carrying out its tasks are specified in Section 19 of SätL. Registers relevant to safety of facilities and activities include:

- a workers' dose register
- a register on radiation safety experts
- a safety licence register containing information on radiation practices and the related undertakings, radiation safety officers, radiation sources and the facilities and places in which radiation practices are carried out

- a register on the radon concentrations in workplaces.

In addition, STUK's registers may contain data on the supervision targets falling under the scope of SätL necessary for the regulatory control and its development.

The sources of information maintained by STUK include:

- applications for a safety license (Section 51of SätL and Annex 5 of VNa 134/2018)
- applications and notifications regarding changes in the practice and amending the safety license (Section 52 of SätL)
- safety assessments (Section 26 of SätL, Sections 13 – 17 of S/6/2019)
- inspection findings (Sections 176 and 182 of SätL)
- notifications on the inventories and transfers of radiation sources and transport of high-activity sealed sources (Sections 71 and 72 of SätL)
- notifications and declarations made under the Council Regulation 1494/93/Euratom dealing with shipments of radioactive substances between European Union Member States
- notifications and declarations received from other countries based on the IAEA CoC Import and export guidance
- notifications of orphan sources and contamination caused (Section 86 of SätL)
- reporting of information on discharges and on their monitoring (Section 127 of SätL)
- notifications of radiation safety deviations and related investigations and remedial measures (Sections 130 - 131 of the SätL)
- notifications of mining activities and some other activities potentially causing exposure to natural radiation (Section 145 of SätL)
- notifications on the results of investigations on the exposure caused by natural radiation (Section 146 of SätL)
- requesting from the undertaking any information necessary for supervision, non-disclosure provisions notwithstanding, and, in terms of personal data, the absolutely necessary information (Section 176 of SätL);
- obtaining information through investigating a radiation safety deviation or a procedure observed in radiation practices which has or may have material relevance for safety (Section 176 of SätL)

The data obtained from undertakings is entered in electronic regulatory control system (VASARA) and the documents in the document management system SAHA. Also are included related regulatory decisions and actions, including:

- decisions of license amendments
- particulars and findings of inspections
- orders to licensees and corrective actions
- enforcement actions.

Information of sealed sources and radiation generators has been included in paper form since the end of 50's in connections with the license documentation. Electronic register for licenses and sources was established in the 80's. Nowadays information of sealed sources and radiation generators are recorded in VASARA. VASARA includes data of all sealed sources exceeding the exemption level and data of radiation generators capable of operating with a higher voltage than 5 kV.

Consistency of the data of radiation sources in STUK's register is continuously validated by comparing notifications received from suppliers (transfer to or from licensees), notifications of the licensee (receiving or transferring a source), the company collecting and conditioning radioactive waste (Nukliditekniikka), verification checks during inspections, as well as, notifications and declarations received und the Council Regulation 1494/93/Euratom on the IAEA CoC Import and export guidance.

For the use radiation there is no need for separate recording system of the closure of facilities. Where necessary, adequate information is included in STUK's decisions to suspend the licensed activity and in supporting memos identifying the grounds for the decision. Verification of the safety of decommissioned facility is done by reviewing the licensee's investigating report or by STUK's on-site inspection. STUK's decisions, memos and inspection reports as well as licensee's reports are entered in the regulatory control system (VASARA).

Question 7.1 How does the regulatory body ensure that the authorized party maintains all the records necessary for the safe operation of facilities and the safe conduct of activities?

Response:

Information needed to be maintained by the licensee necessary for the safe operation of facilities and the safe conduct of activities has to be identified and maintained by the licensee. To ensure that licensee is maintaining necessary information some of the information is submitted to STUK as described above, in some cases the availability of information is verified in STUK's inspections.

<u>Use of nuclear energy</u>

Requirements for documents, computer codes and other records relating to safe operation of a nuclear power plant and which shall be defined and kept up-to-date (YVL A.3)

Documents, computer codes and other records relating to safe operation and which shall be kept up-to-date shall be specified in the management system. Updating means that the requirements are fulfilled and that documents are mutually consistent and in accordance with the state of affairs.

Licensing documents defined in YEA and YVL A.1 shall be kept up-to-date:

- ·technical specifications
- final safety analysis report
- probabilistic safety assessment
- classification documents computer codes related to maintenance and inspection
- nuclear material accounting and control manual
- security plan
- emergency plan
- administrative rules
- organization manual
- integrated management system
- in-service inspections program
- ageing management program
- operating procedures and guidelines.

The requirements related to management of records are presented in more detail in each specific YVL Guides. As an example, the management of the nuclear power plant design and configuration as well as related documentation and computer codes are presented in YVL B.1. YVL A.5 draws up requirement concerning the construction and commissioning of the nuclear facilities. The requirements for the operation of the nuclear power plants are presented in YVL A.6 and for waste management facilities in YVL D.4 and for disposal of spent fuel in YVL D.5. documents important to safety. The correctness of these documents shall be periodically checked.

Radiation practices

SätL includes several provisions requiring that the authorized party maintains records necessary for the safe operation of facilities and the safe conduct of activities (Sections in brackets refer to the Section of the SätL):

- The safety assessment shall be prepared in writing and kept up to date (Section 26);
- The licensee must have a written management system (Section 29);

- The results of the quality assurance must be documented. The quality assurance programme shall be reviewed on a regular basis and updated when necessary (Section 30).
- Documents pertaining to the safety of radiation practices and information equivalent to them must be stored for as long as it is necessary to ensure the radiation safety of the practices (Section 31);
- The undertaking shall keep a worker-specific record on the radiation protection training and induction and supplementary radiation protection training for which it is responsible (Sections 33 and 34);
- The licensee shall keep a record on the radiation sources related to the safety licence (Section 71);
- The licensee who manufacture, safekeep, trade, export or import radiation sources shall deliver data on the radiation sources received, handed over and in its possession to STUK once every calendar year (Section 71)
- The licensee deliver data on the high-activity sealed sources in its possession to STUK once every calendar year (Section 71).
- When a radiation source is handed over only to an undertaking the recipient shall provide the transferor with a certificate on the reception of the source (Section 72);
- When handing over a radiation source, the manufacturer or importer shall provide the recipient with detailed information on the structure of the source and its properties having an impact on safety together with the source. A sealed source is also subject to a certificate demonstrating compliance with regulations. The undertaking handing over a radiation source to another is obligated to provide the recipient, in connection to the handing over, with any information and certificate and other information relevant to radiation safety in its possession, received from the manufacturer or importer (Section 73);
- The results of radiological surveillance and individual monitoring must be recorded and followed regularly to ensure compliance with the requirements applicable to occupational exposure (Section 92);
- The undertaking shall have individuals engaged in medical radiological procedures to carry out self-assessments to develop the practices. The undertaking shall organize a systematic evaluation of procedures resulting in medical exposure (clinical audit) at regular intervals. Self-assessments and clinical audits are subject to the preparation of a report (Section 118).
- The undertaking must record such information on examinations, procedures and treatment resulting in exposure to radiation based on which the radiation dose caused by the examination, procedure or treatment to the individual being examined or treated can be determined, when necessary. The estimated radiation dose of a foetus, and information about the examination, procedure or treatment relevant in terms of the radiation exposure must be recorded in the health records (Section 119).
- A record must be kept of discharges (Section 127);
- A record shall be kept of radiation safety deviations and their investigations and the results of said investigations (Section 131).

The compliance with these requirements are reviewed and assessed by STUK as part of the authorization processes (new license or license modifications) and inspections.

When necessary, specific information on licensee's records can be ordered to be submitted to STUK entitled by SätL Section 176 which states that STUK is authorized to obtain the from the undertaking information necessary for supervision

In addition to regular inspections, inventory enquiries have been made to special groups of licensees (e.g, large-scale users possessing more than 20 sealed sources). Such enquiries are typically made if inspection findings or other regulatory control indicates that deviations from regulations or authorization conditions appear more frequently in certain activities.

Question 7.2 How does the regulatory body ensure that applicants are responsible for ensuring the recording of information relating to facilities and activities, and analyzing it, for the purposes of demonstrating safety ? How does the regulatory body use such records?

Response:

Use on Nuclear energy

Information needed to be maintained by the licensee necessary for the safe operation of facilities and the safe conduct of activities has to be identified and maintained by the licensee. To ensure that licensee is maintaining necessary information some of the information is submitted to STUK as described above, in some cases the availability of information is verified in STUK's inspections.

The requirement concerning the record are presented in question 7.1. The licensing, authorization and the inspection of the nuclear facilities are utilizing the recorded information and these issues are discussed in module 5 to 9. There are specific inspection programmes for the operating nuclear power plants and facilities under construction in which the licensee's processes and management of records are inspected.

The regulatory processes are described in the management system. All the submissions are stored into SAHA document management system in which for all of the submission a workflow is defined, and related actions are made.

For the operating nuclear power plant an integrated safety assessment is made three times a year to support the regulatory oversight process. In this process all the available information is used (YTV 1.b). The assessment is available for all of the personnel at Polarion database.

Use of radiation

The records kept by the undertaking are prescribed under Question 7.1. In addition, SätL include some specific provisions on the obligation to follow and analyse recorded data, including Section 92 which states “The results of the radiological surveillance and individual monitoring must be recorded and followed regularly to ensure compliance with the requirements applicable to occupational exposure”.

All inspection findings are recorded into VASARA which allows for analysing them, for example, for seeking for trends and certain types of occurrences. The records of inspection findings are utilized to give special attention in future inspection in matters where deficiencies are frequently encountered in specific activities. Licensees are encouraged to make use of lessons learned from radiation deviations. Information of radiation deviations is largely disseminated in annually published report of radiation practices and seminars and other meetings with licensees. When it is necessary on the grounds of radiation deviations or other safety related records, STUK issues orders to improve the safety of the activity or facility.

Question 8 Does the regulatory body promote the establishment of appropriate means of informing and consulting interested parties and the public about possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body?

Answer: Yes

Response:

STUK has several internal guidance related to communication with interested parties and public;

- STUK 4.21 Principles for communication,
- STUK 4.22 STUK’s employee as communicator
- STUK 4.25 Criteria for communication
- STUK 4.26 Principles for crisis communication
- STUK 4.28 External communication via web

STUK uses following communication mechanisms to inform interested parties and the public about its regulatory requirements, actions and decisions

Correspondence – STUK submits decisions to relevant parties (mostly to licensees) by mail [KK(1] for action or for information depending on the case.

The public involvement in the licensing of nuclear facilities is discussed in Module 1.

- Public meeting in the vicinity of NPPs
- STUK organizes annually communication events that cover extensively all aspect of regulatory oversight and its outcome at the nuclear facility in the vicinity of Loviisa and Olkiluoto NPPs. The concerns raised by public are discussed.
- STUK participates to the meetings of the municipal on request and STUK reports are submitted to the municipal bodies

STUK's website

- Regulatory requirements (Legislation, regulations, YVL and VAL Guides) are publicly available via STUK's website.
- STUK's ediary is available at STUK's website for public https://ediaari.stuk.fi/
- STUK also publishes safety significant decisions on STUK's website (issues STUK assumes to interest public and stakeholders e.g. STUK decisions after Fukushima accident) [JM(2]
- Regular reports on the oversight and safety assessment (Quarterly and Annual), see below "reports"
- Case specific safety assessments or STUK's statements are published on the website (e.g safety assessments during licensing phases or a PSR).

Press releases

- STUK issues press releases in case of safety significant regulatory requirements that have been issued to ensure safety of the facility and the public and environment (e.g. STUK has required plant to be shut down for repairs or power decrease to ensure safety).
- STUK also issues press releases in case of safety significant events (INES 1 or higher). In case of other events STUK publishes web releases to inform public on the events
- STUK also issues press releases in case of major safety assessments that have been finished (e.g. in different licensing steps, PSRs).
- Reports
- STUK publishes annual reports on the safety of Finnish facilities and on the radiation practices. The results of the annual safety assessment are presented by STUK's management to the licensees as well as to the public in the municipalities where NPPs are located.
- STUK publishes quarterly reports on the operation and safety significant events at NPPs. Reports also have a description on STUK inspection activities and inspection findings during the period (also available in paper form and distributed automatically to parties indicating interest to receive them).

For emergencies there are specific contact points documented in STUK's emergency procedures for ministries, government agencies, rescue services and police, border control etc.

STUK has direct and assigned contact persons in the Ministry of Social Affairs and Health as well as in the Ministry of the Economy and the Employment which are contacted when needed.

STUK's annual reports are submitted to the relevant ministries and government agencies and also published at STUK's website

To collect opinions and documents from private or public organizations or persons following mechanisms are used

- For opinions on any matter STUK's communication unit's contact information is publicly available for online reporting
- STUK's office is open daily (working days) for public citizens or organisations to give their opinions.
- For draft regulatory guides private or public organizations or persons can give their opinions via the website open for the public
- On specific occasions STUK organizes public hearings to give the public and organisations an opportunity to be heard and give opinions on safety issues

Consultation is asked for e.g. following matters:

- For security related matters (regulations, security plans) STUK has to ask statement from the ministry of interior as well as from the advisory commission for nuclear safety (via correspondence)
- For emergency related matters (regulations, emergency plans) STUK has to ask statement from the ministry of interior as well as from the advisory committee for nuclear safety (via correspondence)
- For country reports drafted by STUK (such as Nuclear Safety Convention) STUK asks statement and consultation from ministries as well as from the advisory committee for nuclear safety and from licensees.
- For draft regulatory guides STUK asks comments and opinions from private or public organizations or persons via the website opened for public.

In case of a radiological emergency STUK contacts domestic stakeholders (ministries, government agencies, rescue services, police and border control etc.) as well as international organisations and public according to pre-established criteria and methods described in the emergency procedures (phone, email, fax, press releases).

In case of other incidents and abnormal occurrences STUK informs relevant stakeholders mostly by press releases and web releases depending on the severity and public interest on the incident or occurrence.

Abnormal incidents are reported in quarterly and annual reports which are delivered to licensees and to relevant ministries and governmental agencies. The reports are available to the public in STUK's website and also in English for the international community.

STUK applies graded approach in informing the public in the following way

- General information on the associated radiation risks is given on STUK's website, STUK's printed publications and brochures (also available on website), Public meetings as described in response to question
- The overall performance of the licensee and their facilities and realised radiation risks are described in more detail in the quarterly as well as annual reports of STUK
- In case of an occurrence classified as INES 0 or below, STUK utilises only web releases to inform the public of an occurrence at a facility
- In case of an occurrence classified as INES 1 or INES 2, STUK publishes press release on the event to inform the public
- In case of a radiological emergency public is informed timely according to the emergency response procedures (e.g. via sirens and national broadcasting company)

Question 8.1 How does the regulatory body ensure that interested parties residing in the vicinity of authorized facilities and activities are consulted in an open and inclusive process?

Response:

Information on the possible radiation risks associated with facilities and activities in Finland is presented on STUK's website, STUK's printed publications and brochures (also available on website), Public meetings held regularly (e.g. annual meetings with the public and the media at the municipalities siting operating reactors) and public meetings have been organized also 2011 and 2012 [KK(1] at the Pyhäjoki municipality chosen to be the site for Fennovoima's new nuclear power plant .

Regulatory processes are described on general level in the annual reports of STUK on the oversight of nuclear power plants and on the use of radiation, as well as on the STUK's website and in more detail in the legislation and regulatory guides (e.g. YVL A.1 and ST 1.1).

STUK's formal obligations to be involved in consultations with or by the interested parties in the vicinity of authorized facilities are described in the legislation. These has to do e.g. with the hearings organised (by the ministry of employment and the economy) in connection with the licensing of nuclear facilities, planning of land use for nuclear power plants (organised by local authorities responsible for land use planning). STUK organizes annually communication events that cover extensively all aspect of regulatory oversight and its outcome at the nuclear facility in the vicinity of Loviisa and Olkiluoto NPPs. The concerns raised by public are discussed.

Regarding radiation practices Section 126 of SätL states that: "The protective shielding and the practice must be planned and implemented in such a way that there is no need to carry out measures to ensure the radiation safety of members of the public in the surrounding areas of the facility and place under the supervision and control of the undertaking." Based on this SätL does not include spesific provisions for consulting interested parties residing the vicinity of authorized facilities and activities.

In case of mining or milling activities (also in case when it involves NORM and is regulated from that respect also by the SätL), interested parties are consulted through the mechanisms of the Act on Environmental Impact Assessment Procedure (252/2017).

STUK's experts answer regularly on questions public asks via STUK's website or by other means. Communication mechanisms within STUK includes the following

- Meetings and minutes of the meetings distributed to relevant people (there is a specific agenda point on significant regulatory decisions)
- Formal decisions are distributed to people participated to the review process as well as to the necessary persons
- Documentation related to and needed for the decision making is available to all members of the organisation in the document management system (with restrictions related to security classified issues).
- Significant issues are discussed in relevant STUK's internal working groups in which all relevant departments and other units are represented. Functions and tasks of internal working groups are specified in Guide STUK 2.9 and examples of working groups related to regulatory activities are:

- WG on radiation protection

- WG on radioactive waste

- WG on security issues

Question 8.2 How does the regulatory body ensure that authorized parties inform the public about possible radiation risks associated with their facilities and activities.

Response:

Regarding use of nuclear energy It is the obligation of the license applicant to inform the public about possible radiation risks associated with its facilities and activities first in connection with the Environmental Impact Assessment and later on in connection with the hearings organised during the licensing steps. YEL 10 a §, issued in 2017 lays down requirements for the licensee to communicate on the operation of the nuclear facilities and applied safety principles. Quite often both STUK and the licensee participate to the same meeting with the municipal bodies and public.

YVL A.3 6.6 Communication states that :

641. The management system shall include procedures and means for communicating matters related to nuclear and radiation safety and quality, within the organisation and to interest groups. [2019-03-15]

642. Communications shall be implemented in a systematic manner. Changed and unexpected situations shall also be taken into account in communications. [2019-03-15]

And for emerging situations there are requirements also in VNa Y/2/2018 which states in section 4 that The licensee shall be prepared to carry out the measures required in emergency situations, the analysis of emergency situations and the consequences thereof, assessment of the anticipated development of emergency situations, the mitigatory actions needed to control or limit the accident, the continuous and effective exchange of information with the authorities, and communications to the media and the members of the public.

STUK applies graded approach in informing the public in the following way

Regarding radiation prctices, SätL does not include spesific provisions for authorized parties to inform the public about possible radiation risks associated with their facilities and activities. The objective is that such information is not needed because the protective shielding and the practice must be planned and implemented in such a way that there is no need to carry out measures to ensure the radiation safety of members of the public in the surrounding areas of the facility (SätL Section 126).

Analysis

STRENGTHS FOR 03. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

S1	STUK has institutional freedom determine the organizational structure. According to the Section 5 of the Decree (618/1997) on Radiation and Nuclear Safety Authority (STUK) organization and decision-making authority within STUK can be decided by STUK's Director General.
S2	STUK organizational structure has been determined to reflect the duties of STUK which are defined in the Decree on STUK. The organization of STUK is described in the management system of STUK (Guide STUK 2.1 Rules of Procedure and Guide STUK 2.2 Performance management system). The tasks and duties of the different organizational units are described in more detail in the separate (part of STUK`s management system). However, cross cutting processes are not necessarily effectively used in every department.
S3	STUK's budget is strengthened through fee-charging operations and services - that supports the development and sustainability of STUK's competency. STUK has been able to use the money received from the expert services for radiation protection research, and the volume of research has been able to increase from previous years. New innovations have been created.
S4	STUK has extensive peer-to-peer network both in regulatory, emergency preparedness as well as research and development sector. STUK has wide operation area (surveillance, regulatory, emergency preparedness, R&D, expert services)
S5	STUK has established annual planning process for the tasks including allocation of resources
S6	STUK has an overall process for competence management and STUK has developed further for example inspector qualification methodology.
S7	Potential use of external support (e.g. Technical Support organisations, consultants etc.) is considered as part of the staff planning and STUK has well established practices for using for example VTT Technical Research Centre of Finland to support STUK in its regulatory functions in nuclear safety oversight.
S8	Open relationship and communication between STUK and the licensees. There are solid legal requirements in Finland to ensure that all decisions are reasoned to the licensee and there are mechanisms to give feedback to the authority before the decision is made. In addition, STUK has established many ways to communicate with the licensees and other stakeholders informally at all levels of organizations (seminars, webinars, person-to-person discussions).
S9	STUK has fostered the understandability of the regulations by establishing a web-based regulatory and guidance service "SAMMIO" for radiation legislation. With the service

	anyone can search for requirements from different levels of legislation and STUK regulations. The search result includes the individual requirement, its justification and further guidance including STUK's expectations on its practical application.
S10	Well established process for developing and updating regulations. Strong experience in preparing regulations and proposals for legislation. Active participation from licensee side and well-functioning communication between STUK and licensees.
S11	Mature process for decision making involving different expert roles that have responsibility to evaluate the stability and consistency of regulatory decision making.
S12	STUK has established comprehensive regulations that set requirements for licensee's safety related records and submittal of information to STUK.
S13	STUK has fully digitalized system for records, which makes the use and retrieval of information more effective.
S14	STUK has established a wide range of methods for public communication. All employees are allowed and encouraged to communicate with the public and news media.
S15	Direct person-to-person contacts at all levels of organizations between the authorities and the ministries.

WEAKNESSES FOR 03. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

W1	STUK has no own budget for radiation protection research. Basic research is done at universities. However, research at sectoral institutions is needed in order to guarantee the resilience of society. Sectoral institutions conduct long-term research while universities launch projects as needed.
W2	Budget cuts and rejection of budget requests for new activities challenge the management and development of STUK's competencies. STUK had to made decisions not to continue some radiation research activities since STUK has no budget money for that. Due to the budget cuts STUK is not able to maintain and develop its competencies in radiation safety research activities. STUK has also a challenge to develop competencies for new areas/technologies (e.g. SMRs). For example, there is a following objective stated in the annual performance agreement between STUK and the Ministry of Social Affairs and Health: "STUK is significantly enhancing its competencies related to SMRs". STUK asked more money for that task for its budget, but the request was rejected by the Government/parliament.
W3	Although STUK has an overall process for competence management, its full implementation still needs to be ensured (for example implementation of training programme, full implementation of the nuclear safety inspector qualification programme).

OPPORTUNITIES FOR 03. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

O1	Expanding and conducting radiation protection research together in research networks with universities and university hospitals. Broader infrastructure is in use as well as wider competence.
O2	STUK has currently good competencies in all areas to perform all the necessary regulatory functions. Staff planning is carried out on annual level but also for longer time periods (e.g. 5

	year staff forecasts). This long-term planning could be even further improved by doing more thorough environmental scanning which would include different scenarios for future tasks (including the needed oversight volumes and competencies for different kind of facilities and activities).
O3	Communication methods are not fully exploited and integrated to support the safety and regulatory control. Especially with the low-risk practices, communications methods could be used instead of direct contact and inspections to improve the cost-effectiveness of the surveillance and graded approach.
O4	STUK is transforming its digital processes and tools. A good example of a new type of digital service is SAMMIO. Further development and enlargement of SAMMIO can provide better guidance to licensees, enhance interaction and also support in consistent regulatory work.
O5	STUK is transforming its digital processes and tools. One aim is that information (data) in record keeping systems would more automatically compile information needed to support regulatory functions. Integration of information from different sources (e.g. STUK and other regulators) would provide more comprehensive understanding of licensee situation.

THREATS FOR 03. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

T1	If STUK does not receive independent research funding from the ministry, this will jeopardize the independence of the radiation protection research.
T2	Increase importance of environmental issues may lead political control in environmental surveillance. This phenomenon can be already seen in mining industry. However, the current structures prevent this having an impact on STUK's operations.
T3	Radiation legislation and related regulations have been recently updated. Similar extensive renewal is planned for Nuclear energy act. Large change of structure and content of regulations pose a threat to stability and consistence of regulatory decision making. As part of this also the process for evaluating effects of new regulations needs to be enhanced.
T4	Budget cuts in general challenge STUK’s competence management as STUK is forced to cut its costs and might be forced to freeze the level of salaries to be paid for the experts. It has been STUK’s strength to pay even level salaries with regulated industries experts.

CONCLUSIONS FOR 03. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

C1	Independence of STUK is well defined (regulatory, research and development, expert services). It is important utilize knowledge from research and development in regulatory work and expert services.
C2	STUK should have separate budged for research and development. This guarantees independent radiation protection research. Otherwise money applied from external sources controls too much STUK´s research topics.
C3	STUK has established annual planning process for the tasks including allocation of resources. Potential use of external support (e.g. TSOs, consultants etc.) is considered as part of the planning process. Staff planning is carried out also for longer time periods (e.g. 5 year staff forecasts). This long-term planning could be even further improved by doing more thorough environmental scanning which would include

	different scenarios for future tasks (including the needed oversight volumes and competencies for different kind of facilities and activities).
C4	STUK's budget is strengthened through fee-charging operations and services - that supports the development and sustainability of STUK's competency. However, possible budget cuts and rejection of budget requests for new activities challenge the management and development of STUK's competencies.
C5	STUK has an overall process for competence management and STUK has developed further for example inspector qualification methodology. Its full implementation still needs to be ensured (for example implementation of training programme, full implementation of the nuclear safety inspector qualification programme).
C6	The processes of informing and involving the authorized parties have a solid legal basis concerning all levels of administration.
C7	STUK has established a wide range of methods to liaise with the authorized parties both formally and informally. Integration of the communications methods to the regulatory control is ongoing.
C8	The stability and consistency of regulatory decision making is ensured through mature and well-established process for decision making. Process involves in most cases a set of experts and decision makers that evaluate stability and consistency. STUK expert's training programme and in general the level of competencies has its role in ensuring stability and consistency. Criteria for decision making is given in binding regulations and in nuclear energy side also in YVL guides. These are publicly available. STUK management system and internal guidance provides also further advice for example to implementation of graded approach. STUK has well established process for developing and updating regulations and strong experience in preparing regulations and proposals for legislation. Active participation from licensee side and well-functioning communication between STUK and licensees. The need for changes and their effectiveness are evaluated in different steps of process. Opportunities for enhancement are seen especially in digital transformation. A good example is digital service for regulations and guidance (Sammio). Further development and enlargement of Sammio can provide better guidance to licensees, enhance interaction and also support in consistent regulatory work.

	Radiation legislation and related regulations have been recently updated. Similar extensive renewal is planned for Nuclear energy act. Large change of structure and content of regulations pose a threat to stability and consistence of regulatory decision making. As part of nuclear energy regulation, the process for evaluating effects of new regulations needs to be enhanced.
C9	STUK has established comprehensive regulations that set requirements for licensee's safety related records and submittal of information to STUK. STUK has fully digitalized system for records, which makes the use and retrieval of information more effective. STUK is transforming its digital processes and tools and opportunities for enhancement are seen in this area. One aim is that information (data) in record keeping systems would more automatically compile information needed to support regulatory functions. Integration of information from different sources (e.g. STUK and other regulators) would provide more comprehensive understanding of licensee situation.
C10	STUK has established a wide range of methods for the effective communication with the public and the other stakeholders. All employees are allowed and encouraged to communicate with the public and news media. Communications are considered one of the major strategic focuses of STUK.

Module: 04. Management System for the Regulatory Body

Findings

Question 1 Do managers demonstrate leadership for safety and commitment to safety?

Answer: Yes

Response:

Senior management demonstrates leadership for safety

STUK's senior management is committed to demonstrate leadership for safety to their best ability (Safety-, Quality- and Information security Policy of STUK (STUK 1.1)). As the Senior management are expected to demonstrate leadership for safety and their commitment to safety - they are also accountable for ensuring that the needed policies, structures and resources are in place and that the safety as a value and priority is demonstrated in daily operation.

The safety culture aspects have been adopted in the Safety-, Quality- and Information Security Policy of STUK and Rules of Administration (Guides STUK 1.1 and STUK 2.1). STUK's Safety-, Quality-

and Information Security Policy states that safety and quality are emphasized in operation. STUK is committed to develop and maintain healthy safety culture in its operations.

The bases of Safety-, Quality- and Information Security Policy for STUK's regulatory activities support good regulatory culture and independence of the regulatory body (Guide STUK 3.1). In addition, the safety significance of the handled issues shall be recognized and the emphasis on ensuring safety shall be given in STUK's regulatory activities. Thus, the development and maintaining of healthy safety culture is being promoted in all use of nuclear energy and radiation practice.

STUK contributes to the licensees and partners understanding of the importance of safety culture, STUK is a service minded organization. Good service entails STUK promptly fulfilling its obligations and engagements as well as paying attention to the needs of its customers and stakeholders. STUK´s strategy 2018-2022 https://www.stuk.fi/web/en/about-us/stuk-s-strategy-2018-2022 .

The Radiation and Nuclear Safety Authority's Strategy for 2018-2022 highlights the STUK's role in ensuring the radiation safety of people and the environment. Within the strategy, generally identified characteristics of a healthy safety culture are encompassed e.g. in the vision, mission and values. STUK's strategy highlights areas for development needs and sets strategic targets that include targets related to STUK's resources, effectiveness targets and societal targets. The strategic targets and expected outcomes of the planned development work affect not only STUK's daily operation, but also its organizational culture - and has an impact to regulatory body's safety culture. The senior management have understood that the strategy demands change that is also a cultural one. STUK's staff have been broadly involved in the strategy work.

STUK's management uses a performance management system that ensures that STUK achieves the goals set for it. Operational planning emphasizes risk management, work efficiency and quality.

Senior management is expected to demonstrate leadership for safety through their daily actions and interaction. STUK's Safety Culture Program was developed in 2019 and launched in 2020. The program supports the development of healthy safety culture in STUK. The Safety Culture Program was established after an independent safety culture assessment in 2018 and the Country Specific Safety Culture Forum Finland (by NEA, WANO and STUK) in 2019 (https://www.oecd-nea.org/jcms/pl_15146). Senior management's role and their abilities to demonstrate leadership for safety are among the interest points observed and evaluated in the Safety Culture Program. The program compiles annual reports on the safety culture in STUK. The annual reports are presented to senior management and the key findings and/or outcomes of the safety culture work are discussed and turned into development actions if needed.

The establishment, implementation, assessment, and continuous improvement of STUK's management system support the planned and systematic performance of regulatory activities. By these actions the management system of STUK enhances the safety culture in the organization.

The Leadership Competencies for STUK's senior management were identified and developed in 2020. The Leadership Competencies encompass capabilities supporting the underlying factors of healthy safety culture. STUK is developing a leadership and managerial training program that will support the development of the identified leadership and managerial competencies.

Managers ensure that their leadership supports healthy safety culture:

The Senior management have defined STUK's vision and values (STUK´s strategy https://www.stuk.fi/web/en/about-us/stuk-s-strategy-2018-2022). STUK's staff members were encouraged to participate e.g. the value definition process. The values were approved by the STUK's senior management and they are to give guidance to all employees for their work and e.g. for the decisions and choices they make. The values apply to all STUK's staff - including the directors and managers.

Behavioral expectations of the STUK's management are published in a separate guide Guide STUK 6.12 (Good working community -guidance) which is available also on STUK's intranet. The Guide 6.12 also gives guidance and rules related to e.g. equal and uniform treatment of STUK's employees.

The Safety-, Quality- and Information security Policy statement (STUK 1.1) sets forth the fundamental principles STUK's management considers important and pledges to follow, expecting everyone at STUK to do the same. As a means of achieving quality objectives, the management emphasizes good co-operation with the personnel. The prerequisites for high quality operation include the professional competence, work motivation and service mindedness of the personnel and their managers. Everyone is expected to assume responsibility for the quality of his/her own work. The responsibility for the quality of work is considered as an important driver for STUK's overall mission: ensuring the radiation safety of people and the environment for the present and future generations.

The basic values which guide all operations - including managerial work - are competence, openness, co-operation and courage. Decisions, positions and other measures are based on professional knowledge and competence. Actions are open and honest towards both stakeholders and citizens as

well as in internal communication. Co-operation within STUK is based on good working relationships, empowerment and mutual respect. Stakeholders are included in the preparation of actions. Identified problems and personal views are rigorously brought up. Responsibility for decisions is acknowledged, and errors are corrected. Each of the basic values also manifest the importance of safety.

The values have been actively implemented within STUK. Managers encourage staff members to develop their competence and to cooperate extensively (Guide STUK 2.2. Annual discussions between manager and subordinate). Openness is a norm in all activities in STUK. STUK and its staff members explicitly and constantly express their position in safety issues.

Between 2020-2022 STUK's safety culture program emphasizes three main topic areas as 'the guiding stars': 1) Vigilance and Questioning attitude, 2) Sense of Responsibility and Assertiveness, and 3) Manageability of Work. The guiding stars set expectations for the behavior and actions taken by STUK's senior management, managers and specialists. Leadership and managerial work are constantly evaluated from the safety culture perspective e.g. by conducting observation of daily life - and by conducting personnel surveys (e.g. VM Baro survey).

STUK's operations and their goals are carefully planned (Guide STUK 2.2). The objectives and goals are set and aligned according to a defined process. Guide STUK 2.2, Attachment 7: Chapter 4.1 provides guidance concerning the discussions on performance and results of an organizational unit. Suggested topics in these discussions are e.g. repetition of STUK's mission and values and how the tasks and duties of the unit and individuals are linked to STUK's mission and safety. Guide STUK 2.2, Attachment 7: Chapter 4.2 provides guidance concerning the discussions on performance and results of an individual employee.

Directors and managers are informed and trained about the safety culture topics and e.g. they are regularly invited to reflect and discuss the safety impact of their actions as managers and leaders. Raising awareness and building understanding of how the daily leadership and managerial work impact safety culture is - and will continue to be - an important development area under the safety culture program and STUK's leadership and managerial training.

Ensuring that their actions serve to encourage the reporting of safety related problems, to develop questioning and learning attitudes, and to correct acts or conditions that are adverse to safety.

One of the basic values which guide all operations at STUK is courage (Guide STUK 1.1). This means that STUK encourages the attitude that any identified problems and personal views are rigorously brought up. Responsibilities for decisions are acknowledged, and errors are corrected in a constructive manner. The same core attributes of healthy safety culture are highlighted by STUK's Safety Culture Program as the program fundamentals. The Safety Culture Program carries out continuous observation

of STUK's daily life. Part of the observation task is to monitor e.g. STUK's work climate, managerial work, reactions and actions caused by the identified and brought-up problems.

During all regular meetings within STUK the individuals are encouraged to bring forth all kinds of concerns they may have encountered in their work and to discuss these with other team members. Furthermore, the employees are responsible for reporting any corrective measures, and receiving feedback and delivering this to the quality personnel and register of feedback and deviation (Guide STUK 1.1, Guide STUK 2.16). The managers are expected to develop and foster good and open work climate that supports employees e.g. to report any concerns.

STUK's Safety Culture Program provides an opportunity to report safety culture related concerns. The platform allows any STUK employee to express their concerns even if they are not clearly defined. The concerns are handled with a high confidentiality. If possible or requested, the employee with the concern will receive updates about the direct actions taken based on the concern.

STUK's management system is based on a continuous improvement principle. This involves questioning and learning attitude. The employees are committed to this behavior by means of annual discussions, regular team meetings, self-assessments etc. Individuals are engaged in drafting and commenting internal guidance for regulatory activities and managers encourage them to bring up ideas for improvement.

Furthermore, all the guides in the Management System are written to help the individuals and teams to carry out their tasks safely and successfully. STUK also strongly supports further training and education and urges its workers to enhance their capabilities through continuous training (STUK 1.1, Guide STUK 5.2).

STUK's management system requires that annual discussions between every employee and his/her head are carried out. It is also the duty of every supervisor to help employees in any problems (Guide STUK 2.2). The scope of the discussions includes e.g. evaluation of the results of the last year, discussions on the plans of the next year, training needs, evaluation of the working environment, and possible issues preventing successful activities.

During inspections and in other communication representatives of STUK behave in a manner that promotes development of good safety culture in the use of radiation and nuclear energy (STUK 1.1).

Encourage and support all individuals in achieving safety goals and performing their tasks safely;

The continuous improvement of the management system of STUK supports the safety culture and the successful performance of the regulatory activities. STUK's strategic and annual planning are the corner stones for effective and safety driven implementation of regulatory activities. Safety culture aspects are considered in the strategic and annual plans. The implementation of annual plans is regularly evaluated and daily life in STUK is continuously observed.

STUK will continue to develop its Safety Culture Program and to carry out the related development plan for 2020-2022. By continuing the Safety Culture Program STUK will continuously observe, reflect and analyze its daily life and operations - and take development actions that pay attention to the safety culture perspective. In addition, further development of the leadership and managerial training program will be continued in 2021 Also, STUK continues to develop its management system and e.g. related processes supporting risk awareness and learning from regulatory experiences.

As an example of an assessment of safety, STUK has earlier participated in a national survey on safety culture in organizations in the field of safety or related to high risks (SAFEX). Furthermore, an external assessment of STUK's Safety Culture was conducted in 2018. According the results STUK's employees take safety into account in their work in a proper way. The results were also discussed with staff in order to seek opportunities to improve performance. STUK's Safety Culture Program was developed in 2019. The results and key findings of the external Safety Culture assessment and the Country Specific Safety Culture Forum in Finland 2019 (by NEA, WANO and STUK) served as the basis for development of the Program. STUK´s Safety Culture Manager leads the work of STUK´s Safety Culture working group. STUK also has Safety Culture Network, which has members from each department.

Evidences

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Question 2 Has the regulatory body established and implemented a management system that is aligned with its safety goals and contributes to their achievement?

Answer: Yes

Response:

Has the regulatory body established and implemented a management system that is aligned with its safety goals and contributes to their achievement?

The functions and responsibilities of STUK and regulatory safety goals are stipulated in the Finnish legislation (e.g. Radiation Act (859/2018), Nuclear Energy Act (990/1987), Act on STUK (1069/1983), and Decree on STUK (618/1997)).

The regulatory safety goals of STUK are written in the Safety-, Quality- and Information security Policy of STUK (STUK 1.1). The directors have committed themselves to follow the quality policy requirements and request every STUK employee to do the same.

The regulatory procedures described in the STUK management system are derived from the legislation and the STUK Safety-, Quality- and Information Security Policy. The management system and its appropriateness and adequacy are assessed and reviewed continuously in many ways and amended and improved, if necessary.

The regulatory body has established and implemented a management system whose processes are open and transparent.

STUK established its first comprehensive Quality Management system in 1997-98 covering all activities in STUK. Since 1970's special management guidance have been issued both at STUK level and at departmental level.

Guide STUK 1.3 describes elements of STUK's current integrated Management System. The Management System means integrated system of core, manageral, support and sub-processes processes, organization structure of STUK, rules of administration, managerial procedures, guides and protocols, values and organizational culture including safety culture as well as procedures for assessment and continuous improvement including audit processes and management reviews.

Management procedures include e.g. strategy process, financial and operative planning procedures with balanced score card, project portfolio management, process management, data management, risk management, competence management and quality management. In the Finnish governmental system multiannual financial and operative plans include general alignments and focus points as well as most important targets for development of societal effectiveness and efficiency.

Conduct of work at STUK is guided by the Management System Manuals. The manuals are a comprehensive set of orders and guides that give instructions for all STUK`s operations, including both administration and professional work.

The structure of STUK`s management system documentation has four levels of hierarchy:

a. Principles, like Safety-, quality- and information security Policy of STUK (STUK 1.1) sets forth the fundamental principles applied in STUK activities.

b. STUK Management System Manual is a comprehensive set of orders and guides covering all STUK`s operations. Main part of the Manual consists of description of STUK`s procedures and guidance for managing those procedures. It also describes the tasks and responsibilities of organization, as well as practices of management and internal communications. There are also guides for specific STUK activities like financing, personnel, emergency preparedness, information technology and communication.

c. Management System Manuals of Departments. These include more detailed guides and procedures.

d. Detailed guides (working instructions), laboratory handbooks, and equipment manuals.

Management System Manuals are the following:

– STUK level Management System Manual

– Management System Manual of Nuclear Safety Regulation (YTV)

– Management System Manual of Radiation Practices (SKV)

– Management System Manuals of Laboratory Department (VALO), e.g. environmental radiation surveillance

– Management System Manual of Administrative Department

To foster and support a safety culture in the regulatory body through the development and reinforcement of leadership as well as good attitudes and behavior in relation to safety on the part of individuals and teams.

The safety culture aspects have been adopted in the Safety-, Quality- and Information Security Policy of STUK and Rules of Administration (STUK 1.1 and Guide STUK 2.1). STUK's Safety-, Quality- and Information Security Policy states that safety and quality are emphasized in operations. STUK and all its employees are committed to develop and maintain healthy safety culture and demonstrate safety as an overriding value through their actions. The management system steers STUK to operate in a controlled manner that has a documented basis for the decisions. Also, the management views and essential information on important decisions are communicated and discussed in the staff briefings and meetings taking place regularly.

STUK Safety Culture Program was developed in 2019 and launched in January 2020. The program supports the development of healthy safety culture in STUK. The Safety Culture Program was established after an independent safety culture assessment in 2018 and the Country Specific Safety Culture Forum Finland (by NEA, WANO and STUK) in 2019. Senior management's role and their abilities to demonstrate leadership for safety are among the interest points observed and evaluated in the Safety Culture Program. The program compiles annual reports on the safety culture in STUK. The annual reports are presented to senior management and the key findings and/or outcomes of the safety culture work are discussed and turned into development actions if needed.

STUK Safety Culture Program emphasizes (2020-22) three main topic areas as "the guiding stars": 1) Vigilance and questioning attitude, 2) Sense of responsibility and assertiveness, and 3) Manageability of work. The guiding stars set expectations for the behavior and actions taken by STUK's senior management, managers and specialists. Leadership and managerial work - as well as the behavior and actions of the specialists - are continuously observed from the safety culture perspective e.g. by conducting observation of daily life, by conducting personnel surveys and by collecting information from various other sources.

Continuous observation (and monitoring) is an essential principle of the Safety Culture Program. In order to gain deeper understanding of the culture for safety in STUK, daily life is observed and information is gathered in various ways: Daily operation of STUK is observed by use of various methods e.g. observation of daily life (e.g. meetings and staff events) in STUK, surveys, training events, reflection activities, personal discussions with management and personnel, Safety Culture reporting channel, Safety Culture Network activities, observation of various databases (incl. remarks and comments made in oversight work) and the outcomes of other surveys etc. conducted in other activities in STUK. The continuous observation pay attention to all STUK staff - from senior management to technical specialists and administrative employees.

The core team of Safety Culture Program compiles information actively and reflects the safety & safety culture significance of different factors and remarks. Further information is gathered by allocating further observation in the area. Also, organizational awareness is raised by arranging topical discussions with the groups, employees, managers and leaders in question. Potential safety culture concerns are reported to senior management, management of the departments or process owners in order to discuss and activate the development activities.

Safety Culture Program includes a dedicated Development Plan that defines the planned development actions for the planning period (currently 2020-22). The plan supports and highlights the importance of further development of specific activities supporting the healthy safety culture in STUK. In addition to specific development actions the key aspects of healthy safety culture are included in the STUKs training program - and in the agenda of other staff meetings and events. The overall knowledge and

understanding of safety culture and organizational factors - and consequently the attitudes and behavior in relation to safety - are embedded and included in the objectives of e.g. various training events. Different training events are developed for different target groups and e.g. safety culture, organizational factors, leadership for safety are addressed in various occasions. Close and continuous cooperation between competence development and safety culture development programs is needed.

Question 2.1 How does senior management discharge its responsibility for establishing, applying, sustaining and continuously improving a management system to ensure safety?

Response:

Senior management has established the Safety-, Quality- and Information Security Policy of STUK (STUK 1.1.), where the safety culture aspects have been adopted.

The establishment, implementation and assessment of the management system support the planned and systematic performance of regulatory activities. Senior management has assigned responsibilities in their respective departments to individuals for being responsible of development, application and maintenance of management system and quality issues. Senior management has assigned responsibilities to maintain official internal guides and instructions. Manuals, guides and working instructions are updated regularly, and approved by management level. By these actions the management system of STUK enhances the safety culture in the organization. There are also procedures in the STUK management system for continuous improvement (Guide STUK 1.3.), e.g. management reviews (Guide STUK 2.11.), follow-up of metrics of processes (Guide STUK 2.2. and 2.11.), handling of non-compliances and other findings (Guide STUK 2.16.), corrective actions procedures (Guide STUK 2.16.), and handling of customer feedback (Guide STUK 2.13.), internal audits (Guide STUK 2.12.), self-assessments (Guide STUK 2.14.).

Question 3 Has senior management established goals, strategies, plans and objectives that are consistent with the regulatory body's safety policy?

Answer: Yes

Response:

The time span for STUK's strategic planning is five years. STUK's strategy covers all operations. The strategy is based on an analysis of environmental factors, operations and resources to the extent necessary. The analysis of environmental factors pays attention to foreseeable changes in the operating environment.

In preparing the strategy, the risks associated with strategic priorities and choices are being weighed and, where necessary, risk management procedures agreed.

The strategy includes the following elements:

- The Vision that sets out a realistic goal of what STUK is like, and what the safety of the use of nuclear energy and of radiation will be like in 5-10 years.
- The Mission that summarizes STUK's basic task.
- Set of values.
- Needs for change in different areas of operations, such as competences, communication and operating methods, due to changes in the operating environment.
- Strategic goals
- Monitoring and evaluation of the implementation of the strategy

STUK´s mission is to ensure radiation and nuclear safety therefore safety is the primary goal in both strategic and annual planning processes which are described in Guide STUK 2.2. (4.1, 4.1.1 and 4.1.2).

The Safety-, Quality- and Information Security policy is outlined according the STUK strategy. The basic safety goal of STUK is to protect people, the society, the environment, and the future generations from the harmful effects of radiation. The policy document Safety-, Quality- and information security Policy outlines further safety goals (STUK 1.1.).

STUK's management uses a performance management system that ensures that STUK achieves the goals set for it. Operational planning emphasizes risk management, work efficiency and quality. Annual action plans based on the strategy are prepared, and more detailed work plans needed for its implementation are prepared for the organizational units and employees. Projects are planned and managed with project management tool and detailed instructions of planning and reviewing a project. The personal performance targets for each employee are agreed upon in a result discussion with the manager. Result agreements include objectives that relate to products or results which are to be achieved.

The performance management system includes the control of operations, the evaluation of the results achieved and the systematic development of operations including safety aspect. Performance targets are accompanied by schedules and available resources. Guide STUK 2.2 gives instructions for the strategic planning, annual planning of activities, the evaluation of achieved results and the systematic development of activities.

They are periodically reviewed against the safety objectives;

STUK's Executive Management team reviews the operational results achieved semi-annually and makes the necessary updates. A comprehensive evaluation of the strategy is carried out in the middle of the strategy period. Responsibilities to set operative targets, and to ensure the follow-up, are described in Rules of Administration of STUK, where tasks to ensure safety are described.

Question 4 Does the management system integrate its elements, including safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements, so that safety is not compromised?

Answer: Yes

Response:

The management system is developed, applied and continuously improved. It is aligned with the safety goals of the regulatory body.

STUK established its first comprehensive Quality Management system in 1997-98 covering all activities in STUK. Since 1970’s special management guidance have been issued both at STUK level and at departmental level.

STUK´s strategy is compiled every 5th year and updated annually. In compiling the strategy, also a SWOT analysis is made to find the strengths and weaknesses and also the opportunities and threats of STUK. When compiling the strategy also the necessary actions for the further development of the management system are evaluated. Guide STUK 2.2 describes the Management by Results System. The focus in the planning of activities is in the quality and effectiveness of the work. The control of activities, the evaluation of achieved results and the systematic development of activities are included in the Management by Results System.

The regulatory safety goals of STUK are written in the Safety-, Quality- and Information security Policy of STUK (STUK 1.1).

STUK´s mission is to ensure radiation and nuclear safety therefore safety is the primary goal in both strategic and annual planning processes which are described in Guide STUK 2.2. (#1022660, chapters 4.1, 4.1.1 ja 4.1.2) including risk management).

See also Q2.

Regulatory requirements are reflected in the management system.

The basis for STUK´s management system is the Finnish legislation, i.e. acts and decrees for radiation and nuclear safety, but also acts and decrees giving requirements and rules to be followed by all governmental authorities and organizations in Finland. Further bases for the management system are international standards ISO 9000, 9001, 9004 and ISO/IEC 17025, ISO 31000, and the IAEA safety standards concerning management systems of the regulatory body.

See also Q2.

Provision is made in the management system to identify any changes (including organizational changes and the cumulative effects of minor changes) that could have significant implications for safety and to ensure that they are appropriately analysed.

Changes in the operating environment are studied in the strategy process and also in operative management, e.g. new applications for use of radiation. Changes e.g. in operations and in the environment are also discussed in management reviews. In addition, STUK has representation in several international working groups; important signals of possible changes as well as needs for change are thus informed and implemented around STUK organization.

Furthermore, STUK’s emergency preparedness process includes identification of changes in the environment. Also project management procedures give instructions about change management in projects. Projects are a significant way of working in STUK. Change management procedures are also

required by Information management law in Finland; STUK refers to project management procedures in its information management model.

STUK's management system includes Guide STUK 2.6. where reviewing organizational changes is instructed. Accordingly, some reviews have been conducted after organizational changes in STUK in recent years. However, process of organizational changes is in some cases long-lasting/could be more efficient and people could be more engaged with this process.

Arrangements are established in the management system for an independent review to be made before decisions significant for safety are made. The requirements on the independent nature of the review and on the necessary competences of the reviewers are specified in the management system.

In major changes or crucial alignments for safety or safety requirements, STUK has procedures to address the changes made to ensure safety both in regulatory bodys´ implementation in oversight processes as well as its effects on the licencees' actions.

In cases of nuclear safety, these issues are addressed, for example, in the Security group (guide YTV 7.c, append. 1.1.), or in the Supervisory steering meeting for regulatory issues (guide YTV 7.b, append. 5). In case of radiation practices regulation, these issues are addressed in the Radiation protection group (Guide STUK 2.9. append. 1).

In addition, there is the Advisory Committee on Radiation, which is based on Radiation Law §18 (and Government Decree 1034/2018 §59-64), as well as the Advisory Board on Nuclear Safety.

Question 4.1 How are the organizational structures, processes, responsibilities, accountabilities, levels of authority and interfaces within the organization and with external organizations specified in the management system?

Response:

Guide STUK 2.6 explains the structure of STUK's organization. The Rules of Administration (STUK 2.1) provides the functional responsibilities of organizational units and directors, and decision making rules. Rules of Administration are confirmed based on Section 5 of the Decree (618/1997) on Radiation and Nuclear Safety Authority.

STUK's Executive Management Team (directors and representation of staff) has regular meetings, where directors bring up important issues from their respective departments. Decisions of the meetings are documented and distributed in the intranet of STUK. Each department has also their own executive management meetings, which are also documented in the intranet.

Processes are described and developed taking into account interfaces between organizational departments (more information in Q8).

The expectations of stakeholders are taken into account when STUK's strategy, strategic change programmes for core processes and annual plans are prepared. Guide STUK 2.2. instructs to find out expectations of STUK's stakeholders. For this purpose STUK actively collects feedback through meetings, surveys and interviews from all interested parties. For regulatory control of nuclear facilities regular meetings are held between STUK and licensees' top management. Special outage meetings are arranged before and after outages at NPPs, in which the licensee's and STUK's needs and experiences are discussed. Feedback is also received in conducting regulatory control of activities and facilities.

During the preparation process of the regulatory guides they are circulated for comments to the interested parties such as licensees and operators. All drafts of STUK regulations with explanatory memoranda are posted on the Lausuntopalvelu.fi website before they are confirmed. Any citizen can comment on STUK's draft regulations via the internet https://www.lausuntopalvelu.fi/FI/Instruction/Instruction?section=Instructions. All comments are considered before finalizing the order.

STUKLex website contains all STUK regulations. IT tool Sammio contains regulations related to radiation legislation and orders given by STUK (www.Sammio.STUK.fi).

In connection with the annual planning, the departments plan customer satisfaction surveys. At STUK's website there is also the opportunity to provide feedback on the front page. Customer feedback is recorded and reviewed regularly (Guide STUK 2.12).

Guide STUK 9.2 includes guidance on rectification and notification processes. Dissatisfaction towards STUK operations can be expressed either in writing or orally. The primary place for reacting towards rectification and notifications is the appropriate organizational unit. If a customer requests e.g. that a change should be made to a statement or an order presented in the inspection protocol, he/she is asked to prepare a justified rectification request in writing. The same procedure is followed when a customer argues that essential facts require that a change should be made in a STUK decision.

Question 4.1 How is the management system applied to achieve goals safely, to enhance safety and to foster a strong safety culture?

Response:

The establishment, implementation, assessment and continuous improvement of the management system support the planned and systematic performance of regulatory activities. In its regulatory duties, STUK is obliged to recognize the significance of safety in matters handled by it and stress the priority of safety. In this way, STUK encourages the enhancement and maintenance of proper safety culture in all nuclear and radiation activities. By these actions the management system of STUK enhances the safety culture in the organization. The management system and its elements are described in Guide STUK 1.3.

The safety culture aspects have been adopted in the Safety-, Quality- and Information Security Policy of STUK and in the Rules of Administration (STUK 1.1 and STUK 2.1).

STUK's Safety-, Quality- and Information Security Policy states that safety and quality are emphasized in operations. STUK develops and maintains a high safety culture in its operations.

Bringing together in a coherent manner all the necessary elements for safely managing the organization and its activities;

STUK's strategic and annual planning are the corner stones for implementation of important regulatory activities. Also safety culture aspects are taken into account in the strategy and annual plans. The implementation of annual plans is regularly evaluated.

The performance of regulatory activities is continuously evaluated by regular audits, self-assessments and management reviews (Guides STUK 2.11., STUK 2.12., and STUK 2.14.). These assessments include also identification of corrective actions and measures.

In addition, results of external and evaluations are regularly used for identification for opportunities to improve regulatory activities, including safety culture.

Describing the arrangements made for management of the organization and its activities;

Organization of STUK is described in the Guide STUK 2.6. Rules of Administration STUK 2.1. describes responsibilities and powers of certain roles in STUK's organization and management system. Also duties of different departments of STUK are described. The management system of STUK (Guide STUK 1.3.) comprises of different management processes and procedures, guides and instructions, which allow the management system to be applied in a coherent way.

Process structure of STUK and descriptions of processes are described in the management system IT tool IMS (Integrated Management System).

Describing the planned and systematic actions necessary to provide confidence that all requirements are met;

STUK ensures by systematically that the staff is aware of the policies and procedures, and that they are followed and implemented:

- Management System guides are available to all STUK's employees in intranet
- Always when STUK's policies are revised all staff members of STUK are widely informed, e.g. in intranet, staff meetings in departments and in staff meetings which STUK´s Executive Management Team arranges regularly.
- STUK's Management System is presented to the newcomers in the initiation training; this is responsibility of the superior. (Guide STUK 5.8.)
- Managers' duty is to see to that the regulatory policies and procedures are properly followed .

Consistency of decisions

In order to ensure the consistency and quality of inspection reports and decisions of radiation activities, these are regularly cross-checked between inspectors and by supervisors and management (Guides SKV 3.2. and SKV 3.4.; guides concerning the processing of a safety license and regulatory activities in radiation activities requiring a safety license). The inspector is responsible for ensuring that the objective is met for his own documents. It can be considered good practice for 25% of the inspection reports to be inspected by another auditor, 10% by the supervisor and 1% by the head of department or deputy director. The inspector always makes a note of the cross-check in the Vasara IT-system.

In nuclear safety regulatory activities preparation of the decision letter and presentation memorandum and document review related to those are key tasks. Many experts view decisions. Different persons present the decision

and make the final decision (YTV 8a chapter 4.4.7). Specific rules related to processing documents and decisions are described in guide YTV 8a (especially chapters 4.3. and 4.3.2.). Furthermore, safety related issues are delt with in the Safety Working Group, and in so called Oversight meetings.

Staff qualifications and training

The aim in STUK is to have a high level of competence and professionalism of the staff. In overall competence management, learning at work is of paramount importance, complemented by various training and coaching. Joint training, the themes of which are e.g. general working life skills and STUK expertise, are organized centrally. STUK's competence management process and principles are described in Guide STUK 5.2. STUK´s HRD-team coordinates competence management in STUK.

The departments take care of the development of professional competence in their own field of substance. The director of the department is responsible for ensuring that the department's competence and its development are managed in a planned manner and in accordance with the strategy. The management of the department (director, deputy director and heads of units) is responsible for the adequacy of material resources in their area of responsibility and, consequently, for arranging the conditions for the development of staff skills. The heads of the units are responsible for ensuring that the persons working in the unit are provided with the conditions to develop their own professional skills and that they receive the training necessary for the operation of the unit and the department. Sharing knowledge is part of everyone’s job.

In the Radiation Practices Regulation Department, according to guide SKV 12.2, a personal written orientation program with a schedule is prepared for the inspector or researcher starting in the new position, in addition to STUK's general induction program (Guide STUK 5.8). The orientation program includes matters in accordance with the terms of reference of the inspector / researcher.

The supervisor designates a responsible person for each section of the orientation program who is responsible for the orientation. Upon completion of the orientation, the supervisor shall determine that the person is qualified to act independently as an inspector by signing the completed orientation program. The department's various business units have their own orientation programs.

Procedures for competence building in YTO and YMO departments is described in Guide YTV 6.b. For inspectors in Nuclear regulations there is an introductional plan and personal orientation program for new staff. They are used in terms of changing responsibilities or roles and job description. YTO and YMO has also a procedure for inspector qualification (Guide YTV 6.b chapter 11).

Also VALO department considers that competent and knowledgeable personnel as well as the continuous development and maintenance of personnel's professional skills are the basic preconditions for successful operations, in particular because in this sector scientific and technical development is fast. In addition, continuous internationalization places its own demands on staff training and self-studies.

The responsibilities, rights and qualifications of the VALO personnel and the monitoring of the competence of the personnel are described in the Management System Manual of the VALO department. The guidelines also describe the principles, responsibilities and key procedures followed by the department in competence development and training activities. The competence of the personnel is developed in a planned manner and takes into account the needs of the organization (e.g. the required competences, strategy, vision, values), but also individual wishes where possible. It is the responsibility of everyone to maintain the professional skills required for their job duties.

Employee orientation and qualification requirements are described in the VALO department's Management System Manual. The work in the units of the VALO department requires special expertise. The jobs require at least different levels of vocational training. Task-specific training requirements have been defined. The duties and responsibilities of the responsible and deputy persons in the different test areas are defined in the VALO department's Management System Manual. Responsible and reserve persons have been appointed for different test areas. Depending on the field of testing, at least a bachelor's degree or equivalent information is required from those responsible for the test field and deputy persons in charge. Those responsible for extensive testing areas are required to have a master's degree and experience in the field. VALO department maintains files on the qualifications and rights of all persons for various tasks related to testing and regulatory activities. The criteria for granting rights and qualifications have been instructed and the retention of qualifications is monitored.

Every year, VALO department participates in about dozens of international and national laboratory benchmark measurements or proficiency tests. One reference measurement may contain several samples and may determine the activity concentration of several radionuclides or the concentration of a stable element. Mostly benchmarking or proficiency tests that are attended are international. The results of these tests have generally been very good or good.

Audits and evaluations

Through STUK’s multi-annual program and annual audit plan, which concern all departments, it is ensured that the Management System is implemented correctly (Guide STUK 2.12). STUK’s Quality Manager prepares annual plan for internal audits with the STUK Quality group; departments and units make their own suggestions on the activities and functions that are included to the annual audit plan. Director General of STUK approves the annual audit plan.

The activities of VALO department are evaluated both internally and by an external party. According to the evaluations, the activities have been of a high standard and well planned and meet the requirements set for it (ISO 17025: 2017 standard, Radiation and Nuclear Energy Act, Euratom Treaty). FINAS (the national accreditation body in Finland) conducts periodic assessments related to the accreditation and maintenance of the VALO department annually. A re-assessment of accreditation is carried out every four years. The qualification assessment principles followed by the FINAS accreditation service are in line with international principles and guidelines.

Ensuring that safety is taken into account in decision making and is not compromised by any decisions taken.

Legislation defines matters on which STUK makes the decisions and regulatory guides give detailed guidance regarding issues or matters which need application of STUK's decision.

Rules of Administration STUK 2.1 gives a list of matters and defines by whom the decisions shall be made.

All relevant information is gathered and used when a decision is being prepared. An essential part of the process is extensive communication between the experts participating in the preparation. The principal reviewer is familiar with the relevant regulations, STUK´s general policies and previous decisions in similar cases. If necessary, research or advisory opinions are ordered from external experts to support decision making (guide 9.2. Preparation of documents, chapter 4.3.).

Regulatory decision making emphasizes the substance of the issues, and the consistency with the mission of STUK. Essential bases for the decisions and statements are presented in writing. Requirements that are presented in connection with the decisions are proportional to the safety relevance and increase the actual quality and safety. A decision can be changed if additional arguments presented later on give a good reason for a new decision (guide 9.2.). Regulatory activities are recorded with a goal in mind, that the manner of processing and the basis for the decision can be traced if necessary. More detailed guidance on decision making is given in guides YTV 7.a and YTV 7.b as well as in guide SKV 2.5 (+appendix).

STUK's Safety Culture Program implements continuous observation of the safety culture in STUK. An element of this observation scheme is an annual safety culture survey. The first survey was conducted in 2020 and the overall results indicated that safety is considered in decision making and safety is not compromised by the decisions taken. Also, the conclusions based on the active observation of STUK's

daily operation supports this overall outlook. In addition, the previous independent safety culture assessment (conducted in 2018) indicated the same overall results. However, ’Taking safety into account while preparing and making decisions’ will remain as an interest point of STUK’s Safety Culture Program in the following years.

Question 4.2 What are the arrangements in the management system for the resolution of conflicts arising in decision making processes?

Response:

Rules of administration of STUK (Guide STUK 2.1.) and corresponding documents of the departments prescribes decision making powers in different situations. In matters of principle and wide scope, the decision-maker is usually the Director General or the Head of department.

The basis for regulatory control activities are presented in Guide STUK 3.1. It lists principles that are the universal cornerstones of a good regulatory culture, irrespective of the regulatory branch. These principles must be followed also in STUK. Among these principles are e.g.:

- legality: All regulatory actions are based on the legislation
- independency: All decisions and actions shall be assessed independently.
- equality: All citizens and responsible parties are treated in an -equal manner.
- transparency: All regulatory activities are documented, and documents are archived.

One of the four values (“cornerstones”) of STUK is openness (Guide STUK 1.1). Openness and transparency are included into the basic principles for the regulatory control activities (Guide STUK 3.1). All STUK decisions are based on expert judgement including hearing all relevant parties, as appropriate. Identified problems and personal views are rigorously brought up. Responsibilities for decisions are acknowledged, and errors are corrected. Each of the basic values also manifest the importance of safety.

Another cornerstone of STUK is “courage” which means that any problems and differing opinions are openly expressed. Cases of conflicting opinions are dealt with in discussions in which a consensus is sought. If consensus is not achieved, the person with a conflicting opinion expresses his/her opinion in a written document. This document is signed by him/her and also by the person making the decision in the case concerned. The document is attached and archived/filed together with other documents pertaining to this case (Guide STUK 9.2).

A decision must be based on grounds that pertain strictly to STUK´s duties, not anything else. It is ensured that STUK´s employees are independent on a case with connections to organizations or persons belonging to his/her personal interests. Further, Guide STUK 3.1 states (para 4.4.) that STUK´s employees must restrain himself/herself from any such offer or action that might jeopardize the independence and objectivity of STUK.

If any violations are observed in carrying out of the duties of an employee or in his/her behaviour STUK will take actions prescribed in Guide STUK 5.10 on neglecting official duties.

If a customer feels that a decision from STUK is incorrect he/she may appeal against the decision. This appeal is handled by the court, not STUK (Guide STUK 9.2.).

The decisions and procedures of STUK are open to publicity, if not otherwise decided by legal grounds (Law on publicity of the activities of public authorities 621/1999). Guide STUK 9.4. gives instructions about publicity of documents.

The regulatory control of the safe use of nuclear energy and radiation is independently carried out by STUK based in the Nuclear Energy and Radiation legislation. Other governmental bodies cannot take for their decision a matter that has been assigned by law to STUK. STUK has no responsibilities or duties which would conflict with regulatory control.

Guide SKV 2.5. describes decision powers in different situations in the department of Radiation Practices Regulation. In processing an application for a safety licence, the decision-maker is the head of the department instead of the head of the unit in exceptional matters, for example when applying for a licence for a new type of activity. If necessary, one also has to contact STUK lawyer.

In nuclear regulation matters, Guides YTV 7.a and 7.b describe decision powers in different situations. Guide YTV 8.a describes the general procedure in detail the procedure for dissenting opinion is described in chapter 4.4.2 If there arises different views or dissenting opinion in inspection and decision-making process among inspectors, it is the draftsman responsibility to arrange a meeting for deal with the issue. There must be sufficient and relevant roles in the meeting such as inspectors handling the issue, coordinator, presenter and solver, relevant unit and/or project leaders- as well as directors or deputy directors. The purpose of the meeting is to find an alignment and solution for continuing the decision process in such matter that all specialists commit to it. If consensus is not met, presenter prepares a decision suggestion for the department director to decide upon. If needed the presenter may express his/her dissenting opinion on the decision. They can express it in STUK´s Case Management System (SAHA) and compile a memo on it.

Question 5 Is the management system developed and applied using a graded approach?

Answer: Yes

Response:

The nuclear energy and radiation legislation include the principle for graded approach. According to the Finnish Nuclear Energy Act Section 7 a "The safety requirements and measures for ensuring safety shall be graded and targeted so as to be commensurate with the risks in the use of nuclear energy". This is seen e.g. in licensing requirements for different type of facilities and activities. Accordingly, this approach has been considered in regulatory activities. [Nuclear Energy Act, Section 7a, amendment 499/2013. English translation available: https://www.stuklex.fi/en/ls/19870990.]

Use of graded approach is in the focus when developing further STUK's regulatory oversight processes. During the current strategic period, the objective is to develop more systematic, practical and documented approaches and tools for the risk-informed and graded oversight; review and assessment, inspections, oversight of structures and components, and the use of overall safety assessment for focusing regulatory oversight. Use of graded approach in oversight activities was already mentioned in the previous strategy but it has even more emphasis during the strategy period 2018-2022. One of the altogether nine strategic targets is called "risk-informed and commensurable oversight". The aim is that STUK will conduct oversight in a more risk-informed manner in STUK's entire field of operations. Oversight is based on safety requirements that are determined in proportion to the risks of the plant or the operations. Graded approach has been applied for a long time for example through safety classification of systems, structures and components and different PRA applications.

Conduct of work at STUK is guided by the Management System Manuals. The manuals are a comprehensive set of orders and guides that give instructions for all STUK`s operations, including both administration and professional work. They reflect the graded approach.

Graded approach is a key principle in Guide STUK 3.1 applied to all STUK's regulatory oversight activities. When developing STUK's management system processes, manuals and documents this principle is incorporated also to the more specific management system guides (e.g. YTV Guide 6.c, SKV Guides) regarding STUK's oversight processes and activities. The requirements, orders and sanctions, which STUK as an authority directs to a responsible party under regulatory control, are in a correct and reasonable relationship with the concerning defect or non-compliance. In addition, the safety significance of the handled issues shall be recognised and the emphasis on ensuring safety shall be given in STUK's regulatory activities.

Guide STUK 3.1 states: “Safety requirements and safety oversight are proportionate to the safety risks of radiation activities and the use of nuclear energy, taking into account normal operation and disturbances and accidents. This is known as graded approach.” In its regulatory duties, STUK is obliged to recognize the significance of safety in matters handled by it and stress the priority of safety. In this way, STUK encourages the enhancement and maintenance of proper safety culture in all nuclear and radiation activities.

- *The complexity of the organization of the regulatory body;*

Graded approach is applied to all STUK’s regulatory oversight activities (one of the key principles in Guide STUK 3.1) and the quality and process documents of STUK are prepared in consideration of the graded approach. In addition to the STUK Guides there are internal guides covering regulation of nuclear power plants and nuclear waste facilities (YTV Guides) and regulatory oversight of the use of radiation (SKV and VALO Guides).

STUK´s risk management guide (Guide STUK 2.15.) gives instructions, how to handle risk assessment taking account graded approach principle. According to the guide, the scope and level of detail of risk management is proportional to the risk significance of the case. Risk assessment is started at a rough level by dividing the subject of the assessment into suitable sub-entities for which a preliminary risk significance is defined. Preliminary risk significance is usually inferred from the nature, extent, purpose and context of the case.

- *The scope and range of regulated facilities and activities;*

As regards nuclear power plants and nuclear waste facilities the graded approach has specifically taken into account in the safety classification of the systems, structures and components (YTV 6.c Application of the Graded Approach to regulatory oversight of nuclear installations). Graded approach is also applied in regulation of nuclear energy activities. All regulatory requirements are based on safety significance and it is taken into account in regulatory processes.

The systems, structures and components important to safety shall be designed, manufactured, installed and operated so that their quality level and the inspections and tests required to verify their quality level are adequate considering any item's safety significance.

To comply with the above principles, the systems, structures and components of the nuclear facility are grouped into Safety Classes 1, 2, 3, 4 and Class EYT (classified non-nuclear). The items with the highest safety significance belong to Safety Class 1. Safety class determines what quality requirements apply to the facility's systems, structures and components and to their quality assurance. The scope of the regulatory control of systems, structures and components is determined by safety class. The regulatory control of systems based on safety classification is described in Guide YVL B.2, among others. The inspection and control practices for structures and components in Safety Classes 1, 2, 3, 4 and Class EYT are described in the relevant YVL guides.

Application of graded approach in STUK's regulatory oversight of the use of radiation is explained in guide SKV 3.4. (Regulatory control of radiation activities requiring a safety license). In the application of graded approach principle, we take into account e.g. nature of the activity, historical data of the operator, potential exposure, possibility of emissions, radiation safety deviations that have occurred, experience from previous supervision or evaluation of a new type of activity (guide SKV 3.4. chapter 7).

In the implementation of regulatory activities under the Radiation Act, e.g. radiation safety assessments are used, which are submitted by operators as part of an application for a safety permit. The confirmation of the safety assessment is being addressed in guide SKV 3.2. appendix 11. The safety assessment presents the following classifications for radiation activities, which are confirmed by STUK:

- Occupational exposure
- Exposure of population
- Medical exposure
- Open sources in the laboratory
- Releases of radioactive substances
- Sealed sources
- Mounding of waste

These can be category 1 (maximum), 2, 3 or E (there is not even potential exposure for that type).

These categories influence the choice of operators included in regulatory activities. The objects of regulatory activities are all activities that require a safety permit, as well as the locations and sources of radiation activities included therein. Other operators may also be subject to regulatory activities.

Planning of regulatory activities in radiation sector, inspections, regulatory methods and control intervals take into account operational risks (principle of graded approach) and the effectiveness of regulatory activities. Operations are monitored with intensity based on risk and the effectiveness of regulatory activities throughout the operation. Regulatory activities during operations is targeted on a risk-based basis through various control projects. The selection of control sites also takes into account the indicative intervals set out in the appendix of the guidelines, so that STUK maintains a sufficient understanding of the situation in the entire field. New or changed activities should be subject to an on-site inspection if the risks of the activity so require or it is otherwise difficult to form an overall view of the activity. In the case of high-risk activities, the safety authorization may even be conditional on the new or modified activity not being commenced before the inspection.

Guide SKV 3.4. (chapter 7.1.) says: regulatory activities are primarily targeted at the operators whose activities

- may cause exposure relevant to radiation safety, also taking into account potential exposure
- may cause significant contamination or loss of radiation source from the point of view of radiation safety
- may cause an adverse event which can reasonably be considered possible
- are such that monitoring can achieve a significant improvement in radiation safety and operational compliance and no other equally effective means are available.

In addition, regulatory activities will be clearly targeted at new entrants and, where appropriate, for other strategically important reasons, such as radiation activities

· which STUK doesn’t have enough knowledge to estimate the risks

· where the essential requirements set out in the legislation under STUK's supervisory responsibility are known to be violated in general

· which has great societal significance

· for which the public interest requires STUK to take action

Environmental radiation surveillance closely monitors those sites that are more sensitive to radioactivity or that play a significant role in the human food chain. Those with slow accumulation of radioactivity are less frequently monitored during the strategy period.

The main goal of radon control is that no worker in Finland is excessively exposed to radioactive radon gas that may cause lung cancer. Control contributes to ensuring that any measures that are potentially needed at workplaces are scaled appropriately and taken sufficiently quickly. It is the employer's duty to have the radon concentration of the workplace measured at least in the following cases: 1) in all work spaces that are located wholly or partly underground in the whole country, 2) in areas where the radon concentrations measured earlier exceeds the value of 300 Bq/m³. (STUK maintains a list of such areas). 3) at workplaces throughout the country if they are located on ridges or very air-permeable gravel or sand formations, 4) in an installation that distributes household water where the water does not derive solely from a body of surface water and has contact with indoor air.

- *The complexity of the licensees' organizations;*

As regards nuclear power plants and nuclear waste facilities one of the risk informed tools that are currently in pilot use and further development is ongoing is grading of oversight activities related to organizations:

- assessment of organizational performance and capability
- qualitative indicators covering following areas: commitment to safety (e.g. leadership, decision making), improvement of safety (e.g. awareness of safety, progression, management of supply chains and projects), resource and organizational structures (e.g. personnel, competence, structures, processes, human & machine interfaces)

- *The hazards and the magnitude of the potential impacts (risks) associated with the safety, health, environmental, security, quality and economic elements of regulated facilities and activities;*

A comprehensive and systematic risk management process is under development with the aim to integrate all risk assessment procedures currently in use for different areas and activities at STUK. Risk assessment of operations is carried out in each department in connection with annual planning process.

Departments identify risks related to departmental objectives and tasks in the context of annual planning. The risk analysis is performed in connection with the setting of targets. At the same time, preventive or management-related means and / or measures are identified. Risks are assessed and reviewed periodically e.g. in the monitoring of annual planning or in management reviews. Graded approach is taken into account in the annual planning process. Plans for regulatory activities and oversight are drawn up annually and cover different operators, activities or areas of operations each year, so that regulatory activities do not always focus on the same operations. The annual planning

therefore takes into account both the risks of STUK´s own operations and the graded approach concerning the objects of regulatory activities.

- *The possible safety consequences if a failure or an unanticipated event occurs.*

Graded approach is taken into account in the assessment of operational events at nuclear facilities. Guide YTV 3.c.11 describes the regulator's event assessment and oversight procedures in more detail and refers to the Guide YTV 6.c regarding the use of graded approach in the assessment of operational events and in defining regulator's oversight activities (using YTV 6.c, attachment 2, YTV 3.c.11, YTV 3.c.13 (INES)).

When an abnormal finding occurs in environmental radiation surveillance, the cause is sought to be determined. The event often requires contact with the relevant domestic and / or foreign partners and immediate information to the public. The events to be investigated typically involve notifications, observations and information that require further clarification as a matter of urgency.

Deviations in environmental radiation monitoring are investigated within the framework of normal operation (basic readiness). Depending on the need, the situation may require enhanced preparedness or full readiness. When a possible cause for an anomalous observation is found, an observation report is written about the observation.

The investigation of anomalous radiation exposure of workers is carried out in co-operation with STO department and the procedures are presented in guide SKV 3.8.

Radiation safety deviations are recorded in the control system Vasara (guide SKV 3.5.). Deviations are also announced, for example, in seminars and in the annual report. If necessary, an INES declaration will be made.

In enforcement, the radiation and nuclear energy legislation give graded means to STUK. First, STUK can give orders, and if they are notaplied, STUK can use threats' of fine and finally fines. More specific guidance on enforcement procedures are given in internal guides (Guide STUK 3.1, guide

YTV 5.a Enforcement and coercive measures, Guide SKV 3.7 Enforcement procedures for radiation monitoring).

Documentation for the systems, structures and components of nuclear facilities to be sent for STUK's review takes into account the safety classification. The documentation is the most comprehensive for Safety Classes I and II. This means also that STUK's review activities are focused according to safety classes. The Guide YTV 6 c emphasizes that safety significance shall be taken into account in the review of the documentation.

Safety significance is also taken into account in STUK's inspections. The basis for regulatory inspections is in the legislation and in YVL-guides which both include graded approach.

- *Resources:*

Graded approach has been taken into account when planning and developing STUK's resources in various regulatory activities in the fields of the use of radiation and nuclear energy. The prioritisation of activities and the most important objectives are set out in the strategy and taken into account in annual target plans.

Question 6 Is the management system documented?

Answer: Yes

Response:

STUK started in 1997 to develop a coherent management system with various quality tools (e. g. self assessments and internal audits) connected to this system. The basic idea for preparation of STUK's Quality Manuals was to reflect the characteristics and activities of STUK. In this development phase all relevant processes and activities of STUK were evaluated. The principle of continuous development was adopted in the very beginning of this work.

The complexity of processes and their interactions has been taken into STUK's Management System Manual. As an example, all the common guidance for the regulatory control activities is given in Guide STUK 3.1. In addition, common principles on e.g. financial, personnel administration, information

technology, emergency preparedness and communication is given STUK-level guides. More detailed guidance is further given at departmental level guides.

Documentation of the management system includes strategy, policy statements, goals of STUK, planning and reporting documents, guides and instructions as well as documentation of all management procedures e.g. risk management or competence management. The Management System Manuals are a comprehensive set of orders and guides. Processes are being described/updated in the Integrated Management System IMS tool, and also in detailed guides and instructions of departments.

Generally, the STUK management system is described in Guide STUK 1.3. The structure of STUK`s management system documentation has four levels of hierarchy:

a. Safety-, Quality- and Information Security Policy of STUK (STUK 1.1) sets forth the fundamental principles applied in STUK activities.

b. STUK Management System Manual is a comprehensive set of orders and guides covering all STUK`s operations. Main part of the Quality Manual consists of description of STUK`s work processes and guidance for managing those processes. It also describes the tasks and responsibilities of organization, as well as practices of management and internal communications. In addition to STUK Quality Manual there are manuals for specific STUK activities (financing, personnel, emergency preparedness, information technology and communication)

c. Management System Manuals of Departments. These include more detailed guides and procedures.

d. Detailed guides (working instructions), laboratory handbooks, and equipment manuals.

Management System Manuals are the following:

- STUK level Management System manual
- Management System Manual of nuclear safety and nuclear waste regulation (YTV)
- Management System Manual of radiation practices (SKV)
- Management System Manuals of Laboratory Department (VALO), e.g. environmental radiation surveillance
- Management System Manual of Administrative Department (HAE handbook)

Policy statements of the regulatory body on values and behavioral expectations;

The Senior management have defined STUK’s vision and values. STUK’s staff members were encouraged to participate the value definition process. The values were approved by the STUK’s senior management and they are to give guidance to all employees for their work and e.g. for the decisions and choices they make. The values apply to all STUK’s staff - including the directors and managers.

The basic values which guide all operations - including managerial work - are competence, openness, co-operation and courage.

Behavioral expectations of the STUK’s management are published in a separate guide Guide STUK 6.12 (Hyvä työyhteisö –opas7/ Good working community) which is available also on STUK’s intranet. The Guide 6.12 also gives guidance and rules related to e.g. equal and uniform treatment of STUK’s employees.

Safety-, Quality- and Information Security Policy STUK 1.1 includes the main policy statements and goals of STUK. It provides common understanding of high quality criteria in STUK activities. The Quality Policy of STUK sets out the mission, vision, and values and prescribes management objectives.

Risk Management Policy STUK 1.5. states that risk management is used in STUK to identify, assess and manage uncertainties related to the achievement of the organization's operational objectives. Risk management is included in STUK's organizational culture and belongs to all personnel. Every STUK employee must have an understanding of the risks related to their own work and knowledge of STUK's most important risks.

STUK’s policies and strategy are derived directly from the legislation. The directors have committed themselves to the policies expecting every STUK’s worker to do the same.

In the Guide STUK 3.1 the main principles for regulatory activities are presented: legality, openness, independence, equality, relativity, verifiability, efficiency and effectiveness and service-mindedness.

The fundamental safety objective;

Radiation and Nuclear Safety Authority (STUK) is a regulatory authority, research institution and expert organisation, whose mission is to prevent and restrict any harmful effects of radiation.

Goals are described in the document STUK 1.1 Safety-, Quality- and Information Security policy. The fundamental goal of STUK is to protect people, society, the environment and future generations from the harmful effects of radiation. The goals are to prevent radiation and nuclear accidents, improve safety and keep the radiation exposure of citizens as low as possible through practical measures.

The basis for high-quality operations is the Management System, which is sustained by Quality manuals guiding these operations. High quality is achieved through the professional competence of the personnel, high working motivation and service orientation.

STUK's management commits itself, in the course of its own work, to complying with the Management System it has endorsed and to improving the quality of operations. From the personnel the management expects work results of high quality and the bringing forward of any quality problems that have been acknowledged during everyday work.

A description of the organization and its structure;

The structure of the regulatory body (Guide STUK 2.6.) and the functional responsibilities are described in management system documentation. The Rules of Administration (STUK 2.1) provides the structure of STUK and the functional responsibilities of organizational units and decision making rules.

A description of the responsibilities and accountabilities;

The Rules of Administration (STUK 2.1) provides the structure of STUK and the functional responsibilities of organizational units and decision making rules. Rules of Administration are confirmed based on Section 5 of the Decree (618/1997) on Radiation and Nuclear Safety Authority.

At departmental level the Quality Manuals describe the responsibility of the Directors, Section Heads and Head of laboratories, and basic procedures of the activities and instructions of the work of the department. The task and responsibilities of each staff member are also included in written documents, and also in HR system Sympa. In addition, there are more detailed guides (working instructions) available.

A description of how the management system complies with regulatory requirements that apply to the organization;

The functions and responsibilities of STUK as a regulatory body are stipulated in the Finnish legislation: Radiation Law (859/2018), Nuclear Energy Law (990/1987), and the Acts and decrees based on these laws, Law on the Radiation and Nuclear Safety Authority (1069/1983), Act on STUK (618/1997).

In 1997, STUK started to develop a coherent management system with various quality tools (e. g. self assessments and internal audits) connected to this system. In this development phase all relevant processes and activities of STUK were evaluated. When the management system was established and when it is developed the national statutory and regulatory requirements are taken into account. The functions and responsibilities of STUK are also described in the Management System Manuals as well as the rights and responsibilities of the organizational units and personnel (departmental manuals).

Relevant IAEA requirements are identified and integrated in STUK Management System Manuals.

STUK knows the IAEA safety standards concerning the management systems. When developing STUK's Management System and the Quality Manuals the relevant safety standards are taken into account.

The following codes and standards are identified and integrated in the STUK Management System:

- ISO 9001, 9004
- ISO/IEC 17025

- CAF Common Assessment Framework (self-evaluation model used in European public administration)

A description of the interactions with external organizations and with interested parties.

Stakeholders for STUK are ministries and other governmental agencies, foreign authorities, research organizations, universities, international organizations, citizens, media as well as license holders and other responsible parties for the use of nuclear energy and radiation.

STUK has some formal agreements with other governmental organizations.

STUK makes multi-annual result agreement with the Ministry of Social Affairs and Health and updates the agreement for each year. In this plan also needs of other relevant ministries are taken into account.

These agreements are taken into account in STUK's Management System Manual, e.g. concerning purchasing and emergency response.

The needs and requirements of stakeholders are also identified by customer/stakeholder satisfaction enquiries and studies (Guide STUK 2.13). The identified needs and requirements are integrated into the management system, if necessary. However, it must be noted that STUK is a governmental authority. Thus, the activities and the management system of STUK are strongly bound to legislation. STUK does not have any formal agreements with the license holders. However, STUK has continuous contacts with the licensees and other responsible parties (e.g. site inspections, meetings, training events). These contacts give understanding for the needs of stakeholders. Stakeholders can also use governmental commenting IT-tool, Service for Opinions, where anyone can give their opinion about e.g. laws being updated.

Question 6.1 How is the documentation (Documents and Records) of the management system controlled?

Response:

STUK uses document and case management system (Saha). The National Archives Authority approves application storage times for different type of documents, this is archiving plan of STUK. Archiving plan is based on the order under the National Archives Act (8§). If a document needs permanent

archiving, it is transferred to the national archive. Otherwise it is disposed after determined archiving life.

Rights to use Saha-system come directly from the governmental Active Directory IT-system, where each STUK staff member has his or her respective rights to handle documents. Those rights are dependent on the responsibilities and tasks of the employee. Also safety classifications and rules of secrecy of documents related to data management law determine rights to use a certain document (Guide STUK 9.5).

In the Saha system, when the document is in draft mode, you can select new version, new sub-version, new document or replace original, when saving the document. If the status of the document is "finished", only a new document can be created when saving the document. Only a finished document can be electronically signed, and "published". In addition, the system keeps logs of all events. The document receives an id number when it is first saved. (Guide STUK 9.3).

Question 6.2 How does the regulatory body ensure that the documentation is usable, readable, clearly identified and readily available at the point of use?

Response:

In the document and case management system Saha, documents are recorded under case processes, which are linked to a classification list based on the authority's tasks (Guide STUK 9.2). Each case process receives its own ID, in addition to which the documents included in the case process receive their own document number. Metadata is attached to files and documents, metadata is partly generated by the system and partly associated by the user. The metadata format is based on a binding regulation of the National Archives Authority in accordance with section 8 of the Archives Act. The regulation is based on international standards and other guidelines in the field. The minimum requirement for metadata is also prescribed in the Data Management Act. The materials are searchable with metadata and their combinations, as well as content search within the limits of access rights.

When document is handled in Saha-system, the system produces automatically versions of documents, and shows the author.

Question 6.3 How does the regulatory body ensure that retention of records and documents is consistent with the statutory requirements and with the obligations for knowledge management of the regulatory body?

Response:

The document and case management system (Saha) of STUK is approved by the National Archives Authority and meets the requirements for electronic document and case management. The National Archives Authority has validated the system in year 2014, and granted the permission for permanent electronical archiving of documents. Also, the Authority has validated the technical method to move documents from STUK's document and case management system to the national archive system. This means that all prerequisites for electronical archiving of documents, including meta-information, have been fulfilled.

The national archival authority has also specified the storage formats to be used; for electronical documents STUK uses PDF/A. All electronically incoming material in STUK is automatically saved in this format, which means that documents are blocked from being modified. All new created documents are given PDF/A format when they are electronically signed; this means that you cannot sign the document unless it is in the right format and has "finished" status.

All documentation which is send outside STUK, is electronically signed (Guide STUK 9.7.), which means you cannot modify it afterwards. The signature IT-system meets the requirements of the law of electronic signature and is accepted by the National Security Authority.

All files and documents are locked during archiving and can no longer be changed, this ensures the originality and integrity of the material. In addition, the Information Management Act requires the authority, on the basis of a risk assessment and applying the principle of multi-level protection, to define an appropriate and sufficient combination of security measures, consisting of administrative, operational and physical means.

With regard to technical information security, in accordance with the law, the authority must ensure the implementation of the following functionalities:

· Ensuring the security of data materials

- Immutability ensured

- Protected against technical and physical damage

- Originality, timeliness and accuracy guaranteed

- Availability and usability ensured

- Restricting availability if necessary

- Can be archived as needed

- Management of access rights to information systems
- Collection of log information
- Document security classifications

In addition, the authorities are instructed on the above legal requirement by an instruction from the Ministry of Finance

https://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/162649/VM_2021_5.pdf?sequence=1&isAllowed=y . In addition, STUK has its own instructions on technical information security as necessary.

Question 7 Does senior management determine the competences and resources necessary to carry out the activities of the regulatory body safely and provide them?

Answer: Yes

Response:

Does senior management determine the competences and resources necessary to carry out the activities of the regulatory body safely and provide them?

The Management System of STUK provides requirements for competence management. According to STUK's Safety-, Quality- and Information Security Policy the personnel's competence is systematically developed taking into account the needs of the organization and the wishes of the individuals. Everyone's obliged to maintain professional skills as presupposed by their duties. Those aiming at an expert's career are valued as highly as those interested in managerial duties (Guide STUK 1.1 and STUK 5.1)

STUK's competence management process and principles are described in Guide STUK 5.2. The aim of the process is to secure the competence that is essential for STUK's operations and operational readiness now and in the future. Employees are responsible for assessing and highlighting their own competence needs and for planning and implementing the maintenance and development of their competence.

The maintenance and development of employees' skills is supported by many procedures. Supervisors are responsible for ensuring that the employees of their units have the prerequisites to develop the skills necessary for operations. STUK's management is responsible for resourcing STUK's operations and the adequacy of resources in relation to the intended and required performance. The Human Resources Unit coordinates STUK's competence management process and takes care of the implementation of

measures in accordance with it. In addition, the HEP unit takes care of STUK's centralized competence development planning, training coordination and evaluation.

The management of STUK is responsible for adequate resources in various main regulatory activities (regulatory control of safety and security of NPPs, nuclear waste management and use of radiation). This is reflected in the organization of STUK (Guide STUK 2.6).

When new staff is recruited the targeted competence requirements are defined for each duty in question. Prerequisite for STUK staff in all regulatory functions is a university degree. The tasks of each employee are defined based on his/her education, existing competence and professional experience.

STUK’s recruiting processes are described in Guide STUK 5.7. When a person resigns or retires from STUK’s service, or moves to another position within STUK, it shall always be firstly considered, if his/her old task could be taken care of by rearranging tasks without adding any new personnel.

STUK arranges adequate in-house and external training for staff members. Staff is encouraged to attend training on various topics regularly. Also important is on-the-job-training in teams and with senior staff members is supported. A standard introduction training courses are arranged several times a year for the newcomers. Managers are responsible for developing introduction plans with basic training plans for each newcomer. In order to support knowledge retention and to capture knowledge of retiring and staff leaving STUK the managers interview them. One item in these interviews is how knowledge has transmitted. STUK has also recruited new staff 6-12 months before retirement of experienced staff and in these cases the senior expert has taken part in supporting the newcomers’ on-the-job-training.

A Management by Results System is in use in STUK. The focus in the planning of activities is not only in goals but also in the quality and effectiveness of the work. The follow-up of activities, the evaluation of achieved results are also covered by the Management by Results System. Within the system objectives and timelines as well as resource allocation for all activities are determined. (Guide STUK 2.2).

The most important goals of STUK and weighting between its different regulatory activities are tackled with in STUK´s strategy, which is compiled every 5 years. These weightings and goals are considered in annual plans.

In annual planning resources are allocated to different areas of regulatory activities. Based on the detailed work time recording system the real time used is followed and assessed. One part of annual planning is human resource plan, all departments prepare HR-plan for next coming year and also a long-term one for next five years. These plans are approved by DG.

STUK has identified and defined key leadership competencies, and in 2021 work will continue on defining managerial competencies. The development of leadership, management and supervisory work is systematic and is based on defined competencies and strategy and operational objectives. Leadership, management and supervisory work are supported in various ways at both group and individual levels based on common and individual development needs. Management and supervisor work is developed, for example, through internal coaching and networking. Supervisors also participate in external training or coaching as needed.

Competences for fostering and sustaining a strong safety culture

STUK's Safety Culture Program includes a dedicated Development Plan that defines the development actions for the planning period (currently 2020-22). The plan supports and highlights the importance of further development of specific activities supporting the healthy safety culture in STUK. A continuous for the Safety Culture Program and its core team is to provide and develop STUK's internal safety culture training for different target groups (e.g. introduction training, general safety culture training and managerial training). Enhancement of the overall knowledge and understanding of safety culture - and cultural aspects in general - is embedded and included in the training objectives of various training events.

Besides the traditional classroom training, safety culture topics are included regularly in the agendas of staff meetings, briefings and other events. Consequently, the attitudes and behavior in relation to safety are addressed directly and indirectly in various occasions. In order to foster and sustain healthy safety culture, continuous cooperation between competence development and safety culture development programs is needed in STUK.

The competences and resources necessary to carry out the regulatory activities are provided.

The management of STUK is responsible for adequate resources in various main regulatory activities (regulatory control of safety and security of NPPs, nuclear waste management and use of radiation). This is reflected in the organization of STUK (Guide STUK 2.6).

A Management by Results System is in use in STUK. The focus in the planning of activities is not only in goals but also in the quality and effectiveness of the work. The follow-up of activities, the evaluation of achieved results are also covered by the Management by Results System. Within the system objectives and timelines as well as resource allocation for all activities are determined. (Guide STUK 2.2).

In annual planning resources are allocated to different areas of regulatory activities. Based on the detailed work time recording system the real time used is followed and assessed. One part of annual planning is human resource plan, all departments prepare HR-plan for next coming year and also a long-term one for next five years. These plans are approved by DG.

Question 7.1 What are the arrangements to ensure that the regulatory body has in-house, or maintains access to, the full range of competences and the resources necessary to conduct its activities and to discharge its responsibilities?

Response:

STUK's Quality Policy states that the prerequisites for high quality operation include the professional competence, work motivation and service mindedness of the personnel. Everyone is expected to assume responsibility for the quality of his/her own work. Further the personnel's competence is systematically developed taking into account the needs of the organization, the role of the individual and the wishes of the individuals. All employees obliged to actively maintain their professional skills as presupposed by their duties. Those aiming at an expert's career are valued as highly as those interested in managerial duties.

The top management is responsible for adequacy of resources and, therefore, the conditions for organizing staff development. Accordingly, the management has established the necessary prerequisites for systematic training. This covers initial training, annual common and specific training, training outside STUK as well as arrangements for personal development.

Existing competencies and skills are identified as well as the views and wishes of the necessary competence development are identified during the annual discussions between managers and their

subordinates. Competence development can e.g. focus on strengthening of the general understanding and broad-scaled knowledge or on maintaining and developing the more precise expertise.

Competence requirements for individuals at all levels are specified and training is conducted, or other actions are taken, to achieve and to sustain the required levels of competence. An evaluation is conducted of the effectiveness of the training and of the actions taken.

The competencies required in STUK are compiled into competence profiles: STUK's competence profiles combine STUK's general competencies and the departmental and unit-level substantive competencies into another entity. The exact content of an employee’s competency profile is determined by the unit where he/she works, and the tasks. The current and target levels of the competencies described in the competency profile are assessed to support and guide personal development.

STUK's general competencies consist of general areas of expertise that belong to the basic skills of each STUK employee, such as language skills and general communication skills. Department-specific competencies refer to those areas of expertise that the departments have identified as their common expertise needs. The competencies of the departments are more detailed than STUK's general competencies. The competencies of different departments vary depending on the department's area of responsibility. The competencies of the units cover the areas of competence that each unit has identified as prerequisites for the performance of its tasks and responsibilities. The competencies of the units are more detailed professional competencies than the department level. However, not all areas of expertise required by a unit apply to all its employees with the same weight.

STUK provides training for its personnel in order to achieve and maintain required level of competence. STUK establishes annually a common training programme. This programme covers the areas such as project management, emergency preparedness, legislation, language skills, general working skills and regulatory practises and culture, human relations skills, leadership, financial administration, IT-skills (Guide STUK 5.2). Also other methods than training are very important and widely used, for example mentoring, on-the-job-training, discussions. In addition all departments provide annually specific training for their own staff members.

As a part of annual discussion between manager and employee also training needs shall be covered. The basis for planning the training program include the current and planned tasks of each section and outcome targets set for them as well as the capabilities of the existing personnel and its required level of knowledge and skills.

The head of the section is responsible for making sure that the necessary preconditions are arranged for those working for the section to develop their professional knowledge and skills, and to receive training that is necessary for the operations of the section. Development of the professional knowledge and skills as well as of acknowledgement of personal development needs is, however, ultimately the responsibility of each individual.

STUK encourages its personnel to develop its professional skills and to expand its competence to new tasks as well. One factor that is taken into account in the recruitment process is the advancement of internal job rotation. STUK grants leave of absence for the purpose of working for another employer, if working elsewhere develops competence in STUK related tasks and the execution of the unit's tasks doesn't become considerably more difficult as a consequence.

STUK supports its personnel in its studies on his/her own terms, when the new knowledge also benefits the work. Possible working time and task arrangements can be settled with the closest foreman. STUK can also participate in the studying expenses.

In order to develop experience and competence of the personnel STUK is ready for paying the expenses, and either whole or part time salary, for a fixed-term work with a foreign organisation, if the bases for this are considered adequate.

Arrangements are in place for the regulatory body to access competences and resources which are not available in-house.

Arrangements are in place for the regulatory body to access competences and resources which are not available in-house. In case STUK needs support or more knowledge on a specific topic relevant for safety, it can use TSOs, other external consultants to support the development of in-house knowledge.

As part of personnel planning, the heads of units and departments ensure that the competence needs of their areas of responsibility are met at an adequate level. This planning also takes into account the renewal of competence and, for example, the possibilities of using external resources during temporary workload peaks.

Question 8 Are processes and activities developed and effectively managed to achieve the regulatory body's goals?

Answer: Yes

Response:

STUK established its Quality Management System already in late 90's. All procedures were defined and described in 1998. In the beginning of 20 century processes were identified and process descriptions were published. All general management system processes were present in STUK's Management system. A new iteration of STUK's processes was executed in years 2016-2017. Process work is undergoing year 2021, with target of updating core processes, general management system processes and supporting processes. Also responsibilities of process owners are going to be updated.

STUK's processes are described in STUK Management System Manual, e.g. chapter 3 describes STUK's core processes, the other chapters supporting processes including general management system processes such as procurement, administration, document management. Departments' Management System manuals describe the procedures for core processes and subprocesses, taking account safety issues, and give guidance to STUK employees on how to tackle with the requirements in legislation and how to impose these requirements on those running radiation or nuclear practices. Further, in every guide a reference is made to legislation, as far as possible.

Process chart of STUK as well as process flow charts and definitions of processes can be found in the IT-tool IMS (Integrated Management System), where each process has information about responsibilities, critical features, inputs and outputs as well as connections with specific STUK guides or interfaces with other internal processes. The process descriptions in IMS are approved by managerial or department director level. IMS is built according ISO 9001, and has e.g. version management and approval procedures.

Processes are described and developed taking into account interfaces between organizational departments. In the context of building the data management model, STUK´s processes related to regulatory activities were described in more detail.

The measurement criteria for each process are presented when needed in the process description of relevant guide. The performances of processes are described in annual reports and there are reviewed at Management group meetings as stated in Guide STUK 2.3 (Management Group). The Performance is also monitored yearly at STUK level and department level at management reviews as stated in Guide STUK 2.11 (Management Reviews).

Question 8.1 How is effective interaction between interfacing processes ensured?

Response:

Process chart and sequencing of STUK processes as well as process flow charts and definitions of processes can be found in the IT-tool IMS (Integrated Management System), where each process has information about responsibilities, critical features, inputs and outputs as well as connections with specific STUK guides or interfaces with other internal processes.

The complexity of processes and their interactions has been taken into account in STUK's Management System Manual, which describe the procedures for core processes and subprocesses. As an example, all the common guidance for the regulatory control activities is given in Guide STUK 3.1. In addition, common guidance on financial, personal administration, information technology, emergency preparedness and communication is given STUK-level guides. More detailed guidance is further given at departmental level guides. Connections between guides are described in each guide (Guide STUK 1.4).

In nuclear safety departments' procedures tasks for process management are described. The tasks of the person in charge of the process in nuclear safety departments are:

- is responsible for the operation and development of the main process and related sub-processes
- is responsible for the description and maintenance of the process
- takes care of the functionality and evaluation of process interfaces with other persons in charge of processes
- reports on the functioning of the process at process meetings for management reviews
- defines and develops indicators suitable for the process, which are used to monitor the functionality and effectiveness of the process

A development project of program can have interactions with several processes; procedures are described in Guide STUK 2.5 (Project Management).

Question 8.2 How is each process or activity that could have implications for safety carried out?

Response:

The activities and regulatory procedures of the Radiation and Nuclear Safety Authority's management system are derived from the legislation. Strategy for 2018-2022 highlights the STUK's role and targets in ensuring the radiation safety of people and the environment.

STUK's operations and their goals are carefully planned (Guide STUK 2.2: the Management by Results System). STUK's strategic and annual planning are the corner stones for effective and safety driven implementation of regulatory activities. Safety aspects and risk evaluation are considered in the strategic and annual plans. Risk Management Policy STUK 1.5 states that risk management is used in STUK to identify, assess and manage uncertainties related to the achievement of the organization's operational objectives.

The focus in the planning of activities is in the quality and effectiveness of the work. The control of activities, the evaluation of achieved results and the systematic development of activities are included in the Management by Results System.

During the current strategic period, the objective is to develop more systematic, practical and documented approaches and tools for the risk-informed and graded oversight; review and assessment, inspections, oversight of structures and components, and the use of overall safety assessment for focusing regulatory oversight.

Conduct of work at STUK is guided by the Management System Manuals. The manuals are a comprehensive set of orders and guides that give instructions for all STUK`s operations and processes, including both administration and professional work. All the guides in the Management System are written to help the individuals and teams to carry out their tasks safely and successfully. Departments' Quality manuals describe the core processes and subprocesses and give guidance to STUK employees on how to tackle with the requirements in legislation and how to impose these requirements on those running radiation or nuclear practices. Further, in every guide a reference is made to legislation, as far as possible.

Senior management has assigned responsibilities to maintain official internal guides and instructions. Manuals, guides and working instructions are updated regularly to describe comprehensively and correctly procedures. Guides are inspected by nominated inspectors, and approved by the management level (Guide STUK 1.4). New or updated STUK-level instructions are reviewed by the departments, and based on the comments, the instructions are modified (Guide STUK 1.4).

New guides are presented at departmental meetings, and briefings or trainings are held on implementation of significant guides. All new guides are published on the intranet, where the main content or changes of the new or updated guide is described.

STUK also strongly supports further training and education and urges its workers to enhance their capabilities through continuous training (STUK 1.1, Guide STUK 5.2).

Deviations or non-compliances from the approved process or instructions are registered in the deviation IT-systems Granite and Kryptonite and handled according instructions (Guide STUK 2.16).

Question 9 Has the regulatory body put in place arrangements with vendors, contractors and suppliers for specifying, monitoring and managing the supply to it of items, products and services that may influence safety?

Answer: Yes

Response:

STUK's procurement policies are based on national legislation (Act on Public Procurement and Concession Contracts, 1397/2016), which implements:

- Directive 2014/24/EU of the European Parliament and of the Council on public procurement and repealing Directive 2004/18/EC;
- Council Directive 89/665/EEC on the coordination of the laws, regulations and administrative provisions relating to the application of review procedures to the award of public supply and public works contracts;
- Directive 2007/66/EC of the European Parliament and of the Council amending Council Directives 89/665/EEC and 92/13/EEC with regard to improving the effectiveness of review procedures concerning the award of public contracts; and
- Directive 2014/23/EU of the European Parliament and of the Council on the award of concession contracts.

Relevant legislation is also included Public Defence and Security Procurements Act (1531/2011).

Within its management system, STUK has internal guidance Guide STUK 8.11 The management and organization of the procurements, STUK 8.12 Guidance on procurements under national threshold and Gudie YTV 8.d Procurements related to technical support for supervision of nuclear safety. These guidance documents contain the main principles for the procurements.

Act for Public Contracts gives detailed specifications of the product in the invitation for and assessing of tenders. Detailed requirements are also given in JYSE (Term of agreement for public contracts) which are mandatory in all public procurement.

STUK expects from its contractors the same high quality of work as it expects from itself.

Question 10 Do individuals in the regulatory body, from senior managers downwards, foster a strong safety culture?

Answer: Yes

Response:

Safety, security, risk awareness, quality matters, competencies (knowledge, skills, attitudes), culture for safety and leadership for safety are all regular discussion topic in STUKs normal operation. All employees are expected to foster and manifest the characteristics of healthy safety culture through their actions.

The safety culture aspects have been adopted in the Safety-, Quality- and Information Security Policy of STUK and Rules of Administration (STUK 1.1 and STUK 2.1). STUK Safety-, Quality- and Information Security Policy states that safety and quality are emphasized in operation. STUK and all of its employees are committed to develop and maintain healthy safety culture and demonstrate safety as an overriding value through their actions. The management system steers and supports STUK to operate in a controlled manner that has a documented basis for the decisions. Also, the management views and essential information on important decisions are communicated and discussed in the staff briefings and meetings taking place regularly.

STUK Safety Culture Program was developed in 2019 and launched in 2020. The program supports the development of healthy safety culture in STUK. The Safety Culture Program was established after an independent safety culture assessment in 2018 and the Country Specific Safety Culture Forum Finland (by NEA, WANO and STUK) in 2019. Senior management's role and their abilities to demonstrate leadership for safety are among the interest points observed and evaluated in the Safety Culture Program. The program compiles annual reports on the safety culture in STUK. The annual reports are presented to senior management and the key findings and/or outcomes of the safety culture work are discussed and turned into development actions if needed.

The Safety Culture Program provides the framework for the development of safety culture in STUK. The program e.g. presents key safety culture concepts and characteristics of healthy safety

culture. Furthermore, STUK Safety Culture Program emphasizes (2020-22) three main topic areas as its ‘guiding stars’: 1) Vigilance and Questioning attitude, 2) Sense of Responsibility and Assertiveness, and 3) Manageability of Work. The guiding stars set expectations for the behavior and actions taken by STUK’s senior management, managers and specialists. Leadership and managerial work - as well as the behavior and actions of the specialists - are continuously observed from the safety culture perspective e.g. by conducting observation of daily life, by conducting personnel surveys and by collecting information from various other sources.

Continuous observation (and monitoring) is an essential principle of the Safety Culture Program. In order to gain deeper understanding of the culture for safety in STUK, daily life is observed and information is gathered in various ways: Daily operation of STUK is observed by use of various methods e.g. observation of daily life (e.g. meetings and staff events) in STUK, surveys, training events, reflection activities, personal discussions with management and personnel, Safety Culture reporting channel, Safety Culture Network activities, observation of various databases (incl. remarks and comments made in oversight work) and the outcomes of other surveys etc. conducted in other activities in STUK. The continuous observation pay attention to all STUK staff - from senior management to technical specialists and administrative employees.

The core team of Safety Culture Program compiles information actively and reflects the safety & safety culture significance of different factors and remarks. Further information is gathered by allocating further observation in the area. Also, organizational awareness is raised by arranging topical discussions with the groups, employees, managers and leaders in question. Potential safety culture concerns are reported to senior management, management of the departments or process owners in order to discuss and activate the development activities.

Safety Culture Program includes a dedicated Development Plan that defines the planned development actions for the planning period (currently 2020-22). The plan supports and highlights the importance of further development of specific activities supporting the healthy safety culture in STUK. In addition to specific development actions the key aspects of healthy safety culture are included in the STUKs training program - and in the agenda of other staff meetings and events. The overall knowledge and understanding of safety culture and organizational factors - and consequently the attitudes and behavior in relation to safety - are embedded and included in the objectives of e.g. various training events. Different training events are developed for different target groups and e.g. safety culture, organizational factors, leadership for safety are addressed in various occasions. Close and continuous cooperation between competence development and safety culture development programs is needed.

The overall findings of the Annual Safety Culture Report in 2020 indicate that the overall level of safety culture in STUK is good. However, the areas for further development were identified - and they were in line with the independent assessment report from 2018: questioning attitude, assertiveness and manageability of work should be improved and supported in the following years. Consequently, the

activities of the Safety Culture Program and the Safety Culture Development Plan (for 2020-22) shall be executed.

Question 10.1 How does the management system foster and sustain a strong safety culture?

Response:

The establishment, implementation, assessment and continuous improvement of the management system support the planned and systematic performance of regulatory activities. By these actions the management system of STUK enhances the safety culture in the organization.

The safety culture aspects have been adopted in the Safety-, Quality- and Information Security Policy of STUK and Rules of Administration (STUK 1.1 and STUK 2.1). STUK's Safety-, Quality- and Information Security Policy states that safety and quality are emphasized in operation. STUK and all of its employees are committed to develop and maintain healthy safety culture and demonstrate safety as an overriding value through their actions.

Guide STUK 2.1 states: Safety culture followed in the activities of STUK requires always that:

- safety significance of the matter or situation to be dealt with at the time is recognized
- responsibility related to decisions and resolutions is recognized
- bases of decisions and resolutions are found out and presented
- personnel at all levels of the organization is committed to high quality.

The bases of quality policy for STUK's regulatory activities are parts of good regulatory culture and independence of the regulatory body (Guide STUK 3.1). In addition, the safety significance of the handled issues shall be recognized and the emphasis on ensuring safety shall be given in STUK's regulatory activities. Thus, the development and maintaining of proper safety culture is being promoted in all use of nuclear energy and radiation practice.

STUK ensures and enhances the safety culture by conducting a specific safety culture program that e.g. observes the STUK's organization continuously, steers the safety culture development activities and develops safety culture training. Furthermore, STUK's management system has a fundamental role in fostering and sustaining a healthy safety culture. The management system steers and supports STUK to operate in a controlled manner that has a documented basis for the decisions. Also, the management

views and essential information on important decisions are communicated and discussed in the staff briefings and meetings taking place regularly.

STUK's management system support the continuous improvement of regulatory activities (incl. their support activities) in a structured and systematic manner. The activities are planned on the strategic level and on the level of annual action plans. Regulatory work is conducted according to guided, a comprehensive set of standing orders, guides, check lists, work processes and guidance for managing processes and procedures that give instructions for all operations, including both administration and professional work. Regulatory operations and performance are assessed both internally and externally. STUK strives for continuous improvement of work processes and regulatory effectiveness. Implementation of improvements are based on the results of audits, external assessments, self-assessments and evaluations, but development can be started also based on other initiatives. Information received from operating and regulatory experience is also considered.

STUK contributes to the licensees and partners understanding of the importance of safety culture. E.g. during inspections and in other communication representatives of STUK behave in a manner that promotes development of good safety culture in the use of radiation and nuclear energy (Guide STUK 1.1). Good service entails STUK promptly fulfilling its obligations and engagements as well as paying attention to the needs of its customers and stakeholders.

Responsibilities and authorities of STUK management and staff are documented and described in Quality Manuals (e.g. STUK Quality Manual, Nuclear Safety: Guides YTV 7.a – YTV 7.b and Radiation Safety (Guides SKV 2.1 – 2.6). All the guides in the Quality Manuals are written to help the individuals and teams to carry out their tasks safely and successfully. STUK also strongly supports further training and education and urges its workers to enhance their capabilities through continuous learning (Guide STUK 5.2).

Further, in all regular meetings within STUK the individuals are welcomed to bring forth any kinds of concerns they may have encountered in their work and to discuss these with other team members and manager(s) present. In addition, STUK's Safety Culture Program provides an opportunity to report safety culture related concerns. The platform allows STUK employees to express their concerns even if they are not clearly defined. The concerns are handled with a high confidentiality. If possible or requested, the employee with the concern will receive updates about the direct actions taken based on the concern.

STUK's management system requires that annual discussions between every employee and his/her head are carried out. It is also the duty of every supervisor to help and support any employee any day in any problem (Guide STUK 2.2). The scope of the discussions include e.g. evaluation of the performance and the results of the previous year, discussions on the plans and the targets of the next year, training and competence development needs, evaluation of the working environment, and possible issues preventing successful and safe activities.

Question 11 Is the effectiveness of the management system measured, assessed and improved to enhance safety performance?

Answer: Yes

Response:

The management system and its appropriateness and adequacy are assessed and reviewed continuously and amended and improved.

STUK makes an annual result agreement including target setting with the Ministry of Social Affairs and Health. STUK prepares an annual report on its activities for the Ministry and for the State Auditor's Office. It is prepared according to the Decree on the State budget. In this report especially the accomplishment of objectives included in STUK's result agreement is evaluated. The annual report is also a document for closing of the accounts. In addition to the Decree on the State budget, the instructions given by State Treasury are taken into account in preparing the report.

The output of the operative plans, implemented by processes, is regularly reviewed on all organization levels.

At each level the implementation status is evaluated at least semi-annually. Depending on nature of functions of the units evaluation can be done more frequently. All departments report the implementation status in August and January. In the end of each year all departments prepare a report on accomplishment of its objectives.

The management is committed to the implementation of the Management System and

expects the same from all of the personnel (Guide STUK 1.3). Directors and section heads are obliged to supervise the fulfillment of the management system in his/her own sector. Directors appoint people responsible for monitoring, reporting and developing the performance of the management system. These people are also members of the STUK quality group. Every STUK employee is responsible for

the quality of his/her work (Guide STUK 1.3). The accomplishment of personal result objectives to implement processes is evaluated in connection with result discussions. If the result objectives are not achieved at all or partially achieved, reasons influencing are analysed and corrective measures are considered.

STUK monitors and measures the effectiveness of its Management System regularly by various means. Opportunities for improvement for STUK's Management System and activities are systematically identified by means of

– self-assessments (Guide STUK 2.14), e.g. CAF (Common Assessment Framework)

– internal surveys

– stakeholder feedback (Guide STUK 2.13)

– customer satisfaction surveys

– annual result discussions

– internal audits (Guide STUK 2.12)

– external audits

– management reviews (Guide STUK 2.11)

Personnel has the right and the responsibility to report to the management on the work-related problems or other factors that have a negative impact on the working conditions or work motivation (Guide STUK 2.16).

Once the opportunities for development have been identified, registered and analyzed, corrective measures are taken and followed up to improve the quality of the operations (Guide STUK 2.16). The measures taken are described also in the following guides:

STUK 2.12 Internal auditing

STUK 2.15 Risk management

STUK 2.13. Customer and stakeholder feedback

STUK collects information from customers and stakeholders in many means to investigate the satisfaction of customers and interested parties with STUK's operations and to investigate the demands, needs and expectations. Views of stakeholders are gathered to improve operations. Lessons from experience are utilized in Managing regulatory experience -procedures (see module 2).

All processes are regularly evaluated for their effectiveness and for their ability to ensure safety.

The measurement criteria for a process are presented in the process description of relevant guide. The performances of processes are described in annual reports and there are reviewed at Management group meetings as stated in Guide STUK 2.3 (Management Group). The Performance is also monitored regularly at STUK level and department level at management reviews as stated in Guide STUK 2.11 (Management Reviews). Process indicators have been developed and used for the regulatory safety oversight, related to process efficiency.

Question 11.1 What independent assessments and self-assessments of the management system are regularly conducted to evaluate its effectiveness and to identify opportunities for its improvement?

Response:

Requirements and items to further develop the management system are systematically identified in self assessments, internal and external audits and management reviews. Further identification is made in active connections with stakeholders and in international cooperation.

The implementation of Management System is independently assessed by annual audit plan (Guide STUK 2.12), internal inspections and external audits. Also self-assessments are carried out in STUK (Guide STUK 2.14). The main focus of these assessments is to identify measures for the improvement of the management system.

STUK has a multiannual programme for internal audits, which includes all regulatory processes and support processes. Based on this plan an annual audit plan is developed. The main purpose of the audits is to find out whether or not the STUK processes and tasks are performed according to the requirements of the management system. STUK’s Quality Manager prepares annual plan for internal audits with the STUK Quality group; departments and units make their own suggestions on the activities and functions that should be included to the annual audit plan. Quality manager is also responsible for the execution of the annual audit plan. Individual audits are carried out by a separately

nominated team, consisting normally two or three auditors. There are qualification criteria for auditors (Guide STUK 2.12). A person trained for auditing is appointed as the head of the team. Audit training is arranged regularly for team of internal auditors. Quality Manager appoints the teams for individual audits based on the preparatory discussions. It is taken into account in the nomination of a team that nobody taking part in the auditing work is auditing his/her own responsibility area (Guide STUK 2.12). STUK Management Group gives annual focus points for internal audits e.g. related to implementation of the strategy. This is discussed in connection with next year's planning process. Director General approves the annual audit plan.

The self-assessments are selected by the STUK management group. Latest self-assessment, where all the departments of STUK were involved, was conducted in year 2020. STUK uses a total quality management CAF-model (Common Assessment Framework) for self-assessments. In the assessments all areas of the CAF-model are being evaluated. This includes enablers (leadership, people, strategy and planning, partnerships and resources as well as processes) and result areas (people results, customer results, social responsibility results and key performance results) of the model.

Results of self-assessment target for continuous improvement which is a fundamental principle in all STUK's activities (Guide STUK 1.3). Procedures, responsibilities and objectives for self-assessments in STUK are described in the Guide STUK 2.14. The objectives for self assessments are as follows:

- To analyse the operations of STUK and its various units
- To identify the strengths and weaknesses of the operations of STUK and its various units
- To identify areas for development in STUK and its various units
- To increase awareness of the importance of quality in operations.

STUK could participate more focused to international cooperation (e.g. OECD/NEA) work for promoting leadership for safety and to learn from other regulators experience.

The frequency of external audits is determined based on other factors (need for re-certification, etc.).The scope of the external audits may include e.g. financial areas (e.g. procurement) as well as those audits needed for re-certification (e.g. for ISO, dosimetry).

Finnish Accreditation organization FINAS is carrying out annual assessments in STUK's accreditated laboratories and similarly Center of metrology and accreditation (MIKES) is assessing DOS - laboratory.

STUK's activities are also subject to external control. State auditors and State Auditor's Office are external national auditing bodies. State Auditor's Office carries out annual audits in governmental offices and independent audits as regards legality and expediency.

An external assessment of STUK's Safety Culture was conducted in 2018. According the results STUK's employees take safety into account in their work in a proper way. The results were also discussed with staff in order to seek opportunities to improve performance.

Results of evaluations are registered either in Granite IT-system, which has been in use since year 2014 for tracking the conduct of different evaluations and the corrective actions resulting from assessments and audits. To connect the essential non-compliances with the processes, a new IT-tool IMS (Integrated Management System), was introduced in year 2021 to collect data from internal audits and also other specific evaluations. All STUK staff have access to Granite and IMS tools.

Individuals conducting independent assessments of the management system are not assigned responsibility to assess areas under the responsibility of their own line management.

When nominating audit groups for internal audits, it is taking care that auditors are independent and that none is assessing their own work nor processes on their own responsibility (Guide STUK 2.12).

Question 11.2 How does senior management conduct a review of the management system?

Response:

According to Guide STUK 2.11. management system review is carried out annually or semi-annually. Management system review provides an overview of operations, the risks associated with achieving results, future pressures for change and shortcomings or obstacles in operations, and outlines future development measures. The purpose of the management review is to ensure the suitability, appropriateness and effectiveness of the management system in relation to operations and strategic guidelines.

In reviews ISO9000 series requirements for management system review are used as a basis. The top management assesses the effectiveness and functionality of STUK's management system in a review. Before STUK-level management review, the department management assesses the effectiveness and functionality of the department's management system. The most important results of the departments are presented in the STUK-level management review.

The scope of review depends on the level. At STUK level at least following issues are reviewed:

- results of activities (incl. audits)
- feedback from interested parties
- process performance and product conformity
- status of preventive and corrective actions
- follow-up actions from previous management reviews
- changes that could affect the Management System
- recommendations for improvement

At the departmental and unit level the scope might be broader and the list of issues that shall be included the review is more detailed. Need to make changes to or improvements in policies, goals, strategies, plans, objectives and the processes is always discussed in management review. The reports of management reviews are used as input for annual and strategic planning. The identification of opportunities for improvement is elementary part of management reviews.

In the end of each review an evaluation of management system and the necessary improvements are discussed and recorded in the review report.

The results of management reviews are reported without any unnecessary delay and the results are evaluated by managers and directors responsible for activity assesses. Depending on findings the actions needed are decided either immediately or they might be included in special action plan.

Question 12 Does senior management regularly commission assessments of leadership for safety and of safety culture in the regulatory body?

Answer: Yes

Response:

As STUK strives for continuous improvement of its operations, it regularly conducts various assessments and surveys in order to find areas of improvement and to better understand its current status and maturity as a regulatory body. Some of these assessments, surveys, audits, inspections etc. are internal as some of them are external. Furthermore, many of the assessments are repeated periodically.

Leadership for safety and safety culture are among the topic areas of continuous interest in STUK. The Safety Culture Program observes STUK's organization continuously from the perspective of safety culture and leadership for safety. In addition to the internal observation work, STUK conducts external safety culture assessment periodically. The period between the external safety culture assessments is approximately four years. The internal safety culture observation and the external safety culture assessments address the leadership topics as well as the fundamental characteristics of safety culture. The results of the assessments are discussed with the senior management and all of STUK's staff and the findings are included in the development activities.

STUK conducts a variety of staff surveys and studies annually. The main topic of these surveys and studies vary greatly. However, the findings and key conclusions based on these activities serve as one of the information sources for the continuous observation of Safety Culture in STUK.

Analysis

STRENGTHS FOR 04. MANAGEMENT SYSTEM FOR THE REGULATORY BODY

S1	STUK has a Safety Culture Program included also in STUKs training program - and in the agenda of other staff meetings and events supporting the development of healthy safety culture and setting expectations for behavior and actions taken by STUK's senior management, managers and specialists.
S2	STUK has done persistent work for developing its management system; the first comprehensive Quality Management system developed in 1997-98 covering all activities in STUK.
S3	STUK's procedures for strategic leadership and performance management are being tested and both procedures and results are regularly evaluated.
S4	STUK has involved strongly its staff in preparation of strategy.
S5	Graded approach is a key principle in Guide STUK 3.1 and applied to all STUK's regulatory oversight activities.

S6	STUK’s management system is documented and available for staff via intranet and document management system.
S7	STUK’s personnel’s competence is systematically developed taking into account the needs of the organization and the wishes of the individuals (STUK’s Safety-, Quality- and Information Security Policy).
S8	STUK's competence management process and principles are described (Guide STUK 5.2 Competence management at STUK) and targeted to secure the competence that is essential for STUK's operations and operational readiness now and in the future.
S9	Performance of STUK’s processes and activities are monitored at departmental level regularly.
S10	STUK has internal guidance in place (Guides STUK 8.11 Procurement guidance and orientation, STUK 8.12 Low value procurements and YTV 8.d Procurements related to technical support for supervision of nuclear safety) containing the main principles for the procurements. (More detailed specifications are given in the Act for Public Contracts and in JYSE (General Terms of Public Procurement in Service Contracts, JYSE Services April 2017), mandatory in all public procurement.)
S11	A healthy, good safety culture is actively present in everyday life.
S12	Senior management initiate safety culture assessment and on the basis of it also a safety culture programme was developed.
S13	STUK’s leaders monitors performance of STUK’s processes and activities regularly in management reviews.
S14	STUK conducts a variety of staff surveys and studies annually. The main topic of these surveys and studies varies greatly. However, the findings and key conclusions based on these activities serve as one of the information sources for the continuous observation of Safety Culture in STUK.

WEAKNESSES FOR 04. MANAGEMENT SYSTEM FOR THE REGULATORY BODY

W1	Work for defining regulatory oversight process at STUK has been going on for a long time/multiple rounds, and this work is still going on (without clear finishing of previous phases).
W2	Process for monitoring and closing corrective actions takes sometimes too much time.
W3	Process of updating internal guidance may sometimes be heavy and take too much time (could be easier).
W4	The link between safety culture development and Competence management could be stronger to ensure that SC in addressed in inspector training.
W5	STUK could improve the analysis of results of different assessments and also strengthen methods to spread good practices.

OPPORTUNITIES FOR 04. MANAGEMENT SYSTEM FOR THE REGULATORY BODY

O1	STUK’s IMS-quality tool used by STUK, and the coordinating influence of the LaKe group, enable for better coordination development of MS.

THREATS FOR 04. MANAGEMENT SYSTEM FOR THE REGULATORY BODY

T1	If the updating process of internal guides takes too long guidance becomes out of the date and may even mislead with wrong procedures and decisions.
T2	Without clear and shared definition of STUK's regulatory oversight processes there may become a lack of coherence of conducted procedures (and be e.g. more personal/departmental dependent).

CONCLUSIONS FOR 04. MANAGEMENT SYSTEM FOR THE REGULATORY BODY

C1	STUK's management system is in line with IAEA requirements, however, there is still room for further improvements (e.g. process development).
C2	STUK's management is committed to healthy safety culture and leadership for safety, and these are integrated in STUK's integrated management system.

Module: 05. Authorization

Findings

Question 1 Is there a requirement for authorization of facilities and activities by the regulatory body?

Answer: No

Response:

STUK is a governmental body and Finnish the Administrative Procedure Act (434/2003) is applied in all its activities including authorizations. The Act lays down provisions on the foundations of good administration and on the procedure to be applied in administrative matters. These include, for example, provisions on hearing the views of parties in regulatory decisions, right of appeal and archiving of documents. The above-mentioned issues are described in detail in modules 3 and 4.

Nuclear Facilities:

The licensing process is defined in the Finnish legislation. In accordance with YEL 990/1987 Section 8 the use of nuclear energy without the licence is prohibited. As per the YEL 990/1987 Section 3 the use of nuclear energy means e.g. the construction, operation and decommissioning of a nuclear facility, transportation of nuclear materials and waste and mining and milling operations aimed at producing uranium or thorium. The licensing process (regarding the licenses granted by the Government) is led by the Ministry of Economic Affairs and Employment and the licenses are granted by the Government as per the YEL 990/1987 Section 16 with some exceptions defined in the Section 16 (e.g., transport license). The conditions for granting a licence for a nuclear facility are prescribed in the YEL 990/1987 Chapter 5 (Sections 16-27). For a nuclear power plant, nuclear waste disposal facility, or other significant nuclear facility the process consists of four steps described in the Figure 1 below.

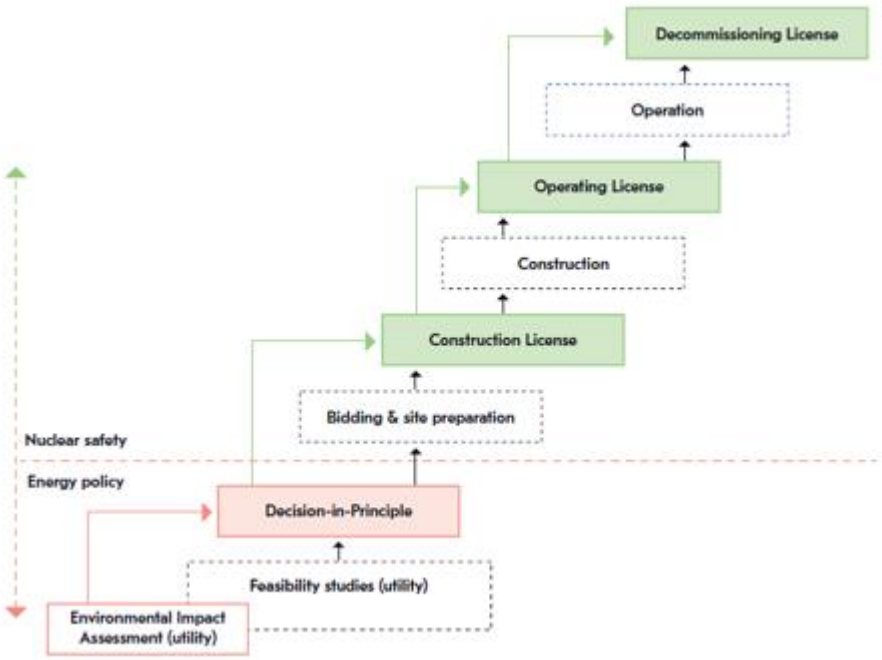

Figure 1: Four steps of licensing of nuclear facilities. Decision-in-Principle is made by the Government and ratified by the Parliament. Construction Licence, Operating Licence and Decommissioning Licence are granted by the Government.

Finland is a party to the Convention on Environmental Impact Assessment (EIA) in a Transboundary Context, done in Espoo in 1991. The EU Directives 2011/92/EU and 2014/52/EU on the EIA procedure have been enforced by the Act on the Environmental Impact Assessment Procedure (252/2017) and by the Decree on Environmental Impact Assessment Procedure (277/2017). The detailed requirements on the EIA are provided in this Act and Decree. The Convention is applied for Finnish nuclear facility projects by providing a full participation to all countries which announce the willingness to participate in the environmental impact assessment procedure in question. The EIA is conducted by the licence applicant or the licensee. The Ministry of Economic Affairs and Employment is the competent authority of the EIA procedure for nuclear installations and arranges the public hearings. The Ministry of the Environment arranges the international hearing according to the Espoo Convention. STUK gives its statement on the parts of EIA relevant to nuclear and radiation safety, nuclear security and safeguards.

Before a construction licence for a nuclear power plant, nuclear waste disposal facility, or other significant nuclear facility can be applied for, a Decision-in-Principle (DiP) by the Government and a subsequent ratification of the DiP by the Parliament are required. DiP-process is prescribed in the YEL

990/1987 Chapter 4 (Sections 11–15) and in the YEA 161/1988 Chapter 4 (Sections 23-30). An EIA procedure has to be conducted prior to the application of the DiP and the EIA report has to be annexed to the DiP application. YEA 161/1988 has been complemented in 2017 with a requirement (Section 24) that the applicant shall submit as a part of DiP application a reasoned conclusion by the competent authority on the EIA assessment report as a conclusion of successful EIA process. The amendment was introduced as a lesson learned from Fennovoima Hanhikivi 1 DiP and EIA processes. A condition for granting the Decision-in-Principle is that the construction of the facility in question is in line with the overall good of society as per YEL 990/1987 Section 11. Further conditions are as follows: the municipality of the intended site of the nuclear facility has to be in favour of constructing the facility and no factors have appeared which indicate that the proposed facility could not be constructed and operated in a safe manner.

The Decision-in-Principle further requires the ratification by the Parliament. The Parliament cannot make any changes to the Decision. It can only approve it or reject it as it is. The stakeholders involved in the Decision-in-Principle process and their tasks are described in the Figure 2. In Decision-in-Principle phase STUK prepares a statement on safety and preliminary safety assessment concerning the applicant, the proposed plant designs and plant sites as per YEL 990/1987 Section 12. However, regarding the safety assessment of the suitability of plant sites, there is no specific or separate authorization phase for the site licensing in the Finnish regulatory framework. STUK also asks statements e.g. from the Advisory Committee on Nuclear Safety. In addition, the Ministry of Economic Affairs and Employment is responsible for organizing a public hearing for this licensing phase as per YEL 990/1987 Section 13.

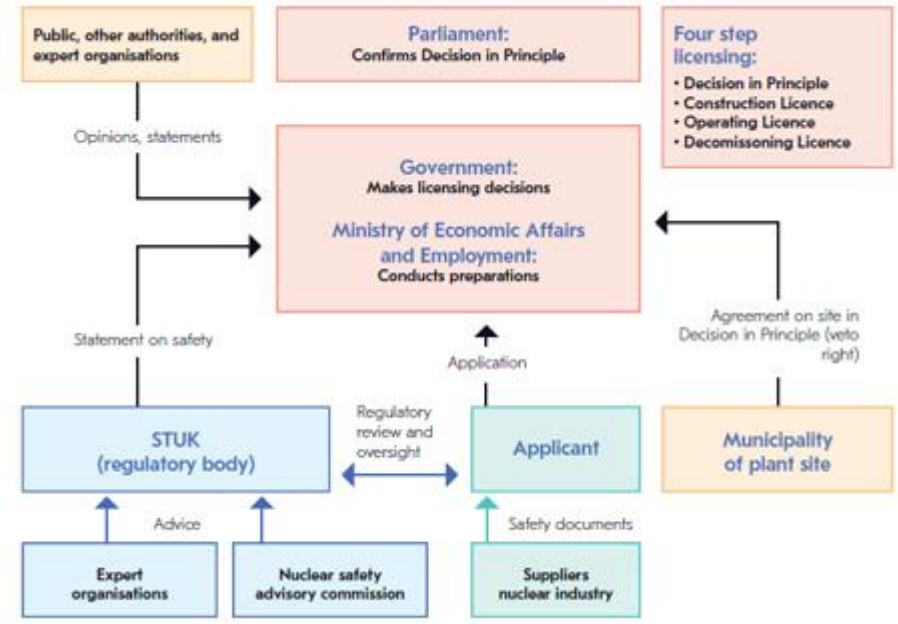

Figure 2: Stakeholders in the licensing process.

The process of the construction, operating and decommissioning licences is prescribed in the YEL 990/1987 Chapter 5 (Sections 16–27) and in the YEA 161/1988 Chapter 5 (Sections 31-40). For the construction, operating and decommissioning licence application, the Ministry of Economic Affairs and Employment asks STUK's statement on safety. Construction, operating and decommissioning licence application documents to be submitted to STUK for approval in these phases are defined in YEA 161/1988 Sections 35, 36 and 36a, respectively. STUK also asks statements e.g. from the Advisory Commission on Nuclear Safety and from the Ministry of the Interior on the plans for emergency and security arrangements as per YEA 161/1988 Section 37. After receiving all statements for the construction, operating or decommissioning license application, the Government will make its authorization. In the construction, operating and decommissioning licence phases the acceptance of the Parliament and the host municipality are no more needed. However, the host municipality gives its statement in these phases, too.

The licences, excluding the construction licence and the licence for decommissioning, are granted for a fixed term as per YEL 990/1987 Section 24. The term of the operating licence depends on the facility. When considering the length of the term, attention shall be given to the estimated duration of the operations, which is estimated by the Ministry of Economic Affairs and Employment, and ensuring the safety that is assessed by STUK. If the operating licence is granted for more than ten years STUK proposes as a condition for the licence that the licensee carries out a periodic safety review in accordance with the YEL 990/1987 Section 7e.

In all above mentioned licencing phases the necessary conditions are included in the licence as per the YEL 990/1987 Sections 14a and 25. The licensing authority shall also take into account the proposals relating to safety presented in the statement of STUK.

The licensing body has the authority to cancel a license wholly or partly if implementation of the general principles for the use of nuclear energy provided in the YEL 990/1987 are essentially endangered as per the Section 26. When cancelling a licence, the same procedure is followed, as appropriate, as when the licence was granted. In addition, in case the licence terms or conditions are amended, the same procedure is complied with, where applicable, as in the case of a new licence (Section 25).

Concerning the license applicant's or licensee's personnel, according to the YEL 990/1987 Section 7k the licensee shall appoint a responsible manager and his or her deputy. Manager's task is to ensure that

the provisions, license conditions and regulations issued by STUK concerning the safe use of nuclear energy, security arrangements, emergency arrangements and the safeguards of nuclear material are complied with. The responsible manager is approved by STUK. The appointment of the responsible manager shall be proposed when applying for a licence. In addition, according to the YEL 990/1987 Section 7i the licensee shall appoint persons responsible for ensuring the emergency arrangements and security arrangements and safeguards of nuclear material. Appointed persons shall be approved by STUK. STUK shall also approve the control room operators of a nuclear facility in accordance with the Section 7i. In addition, STUK approves manufacturers of nuclear pressure equipment for their duties and inspection organisations and testing organisations for duties pertaining to the control of pressure equipment at nuclear facilities in accordance with the YEL 990/1987 Section 60a.

In addition to the above described licensing process, there are also other authorization or regulatory hold points for the nuclear facilities in the Finnish legislation. YEA 161/1988 Sections 108, 110 and 112b prescribe that the various phases in the construction, commissioning or decommissioning of a nuclear facility cannot be commenced until STUK has, on the basis of the licensing documents and other detailed plans and documents, ascertained for each phase that all safety-related factors and safety regulations have been given sufficient consideration. In other words, STUK has the right to specify conditions or requirements necessary for safety. Furthermore, the fresh nuclear fuel cannot be brought to the nuclear power plant until STUK has ascertained the licensee's preparedness to safely receive fresh nuclear fuel as provided in YEA 161/1988 Section 110a. In addition, the operation or decommissioning of a nuclear facility shall not be started on the basis of the licence granted for it until STUK has ascertained that the nuclear facility meets the safety requirements in accordance with the YEL 990/1987 Sections 20 and 20a, respectively.

Licensing pertaining the import and export, transport, mining and enrichment, nuclear facility in a vehicle, information and agreements and nuclear waste management are prescribed in YEA 161/1988 Sections 7, 8, 9, 10, 11 and 12, respectively. STUK can give authorizations for transportations and import of nuclear materials and radioactive waste. The export license can be granted by STUK for radioactive waste and ores, but not for nuclear materials. (Nuclear Energy Act section 16)

According to Section 27 c of the Nuclear Energy Act (161/1988), Nuclear waste other than spent nuclear fuel may, regardless of its radioactive nature, be reused, recycled, recovered and disposed of in accordance with the provisions of the Waste Act (646/2011) if the amount of radioactive substances within it does not exceed the clearance level provided by the virtue of YEA 161/1988 Section 7q. If the amount of radioactive substances within the waste is greater than the clearance level set in YEL, the operations will require the approval of the Radiation and Nuclear Safety Authority.

A notification process to replace authorization of some facilities or activities is not clearly in use regarding the use of nuclear energy. However, some of the documentation is required to be submitted to STUK for information, which is a process close to the notification process.

In principle, licensing SMRs (at least those based on light water technology) is possible with the current licensing model and requirements. However, the present requirements have been written for large light water reactors that are meant for electricity production and are situated in relatively remote areas. The present requirements may be challenging for other technologies or business models that may emerge e.g. with deployment of SMRs.

The Guide YTV 2.a describes STUK's processes and tasks regarding the regulatory oversight for different phases of nuclear facilities' licensing.

Radiation practices:

The licensing process for the use of radiation is defined in the SätL. According to Section 48 of SätL the use of radiation requires a licence (safety licence). A licence is granted by STUK upon written application until further notice or, for a special reason, for a fixed period of time. All information related to licensing or application is stored at VASARA system. The licence may also be granted separately for different stages of the practice including the construction of a facility or operating premises, the commissioning of radiation sources or operating premises, the actual operation of radiation practices, decommissioning and associated decommissioning of sources, and any decontamination of the premises. The licence may include conditions necessary for ensuring safety. Paragraph 2 of section 48 of the SätL provides that 'An authorization may be granted separately for different phases of an activity'. In internal guide SKV 3.2 (chapter 4.5.2) the matter is discussed as follows: The licensee can already at the planning stage of a construction project apply for a safety licence for the first phase of the project. The application then concerns the validation of the safety assessment. At that stage, protection calculations and exposure estimates have already been made, but nothing has yet been built. However, since a safety licence cannot be granted at this stage because there is no activity (and therefore no use of radiation) and no new site, imaging room or facility can be added to the existing safety licence, the protection calculations, exposure estimates and classification can be presented in the safety assessment or in an updated safety assessment. STUK confirms the safety assessment or updated safety assessment and, if necessary, makes comments. The decision at the next stage (e.g. new location and equipment) may also be subject to conditions necessary to ensure safety, which in such a case could mean, for example, verifying the adequacy of protection by measurement, or even presenting a structure for inspection before hiding it in panels. The safety licence may also be granted in part, e.g. possession and technical testing. In these cases, a new decision on the extension of the activity will be taken on application. The decommissioning of the use of radiation in a situation where the operator has been using radioactive substances can be dealt with in stages, if necessary. First, the notification of the disused sources is processed, and the safety licence is withdrawn after the premises have been found to be clean by measurements.

Transparent guidance for implementation of requirements is available in SAMMIO (STUK's online regulation and guidance service). The STUK website (www.stuk.fi/lomakkeet) contains specific authorization forms for applying for a safety licence (separate forms for radiation activities, operating sites and radiation equipment).

Approval by a notification or registration process is not in use in Finland. According to section 72 of SätL a radiation source the holding of which is subject to a safety licence may be handed over only to an undertaking with the necessary safety licence. The transferor shall ensure that the recipient has the required safety licence. According to section 11 of SätL the objective of STUK's regulatory measures is to keep radiation sources subject to a safety licence under regulatory control throughout the source's entire life cycle which means that for radioactive sources and radiation generators, the regulatory control continues over their entire lifetime.

If the occupational or public exposure to natural radiation exceeds the reference level despite the measures limiting radiation exposure, the undertaking needs to apply for a license (SätL section 148) after which the activities are regulated similarly to the use of radiation sources (SätL section 149, 150).

According to Section 4 of SätL use of radiation means:

a) the use and manufacture of, trade in, installation, maintenance and remediation of radiation sources;

b) the possession, safekeeping, import, export, transfer and storage of radiation sources and radioactive waste;

c) the transport of radioactive substances and radioactive waste;

d) rendering radioactive waste harmless;

A safety licence is granted provided that:

1) the radiation practice complies with the principles of justification, optimization and limitation;

2) a safety assessment has been drawn up for the radiation practice;

3) the practice can be carried out safely;

4) the undertaking has the right to engage in a trade in Finland.

Annex 5 to VnA 1034/2018 prescribes in detail the information which shall be provided in the application. For example, data for each radioactive source, that is intended to be used, must be submitted to STUK in the application.

In case where radioactive sources are involved, a condition for obtaining a licence is that the applicant presents a plan on the intended way to handle the sources once they become disused. Only a sealed source whose manufacturer has made a commitment to receive the sealed source after its use has come to an end or a sealed source containing a radioactive substance whose half-life is such that the appliance can be safely aged may be imported or transferred to Finland (Section 76 of SätL).

In practices subject to a safety licence, the licensee shall nominate a radiation safety officer (RSO) and if necessary, deputy. The qualifications of a radiation safety officer are described in chapter 41 of SätL. A radiation safety officer shall furthermore possess the radiation protection training required by the practice type-specific field of expertise and sufficient work experience in a field suitable for the task. The contents of such training are prescribed in the Annex 2 and 3 of STMA (1044/2018). Curricula of private organizations providing the training are approved by STUK. Furthermore, there are several universities providing the training that STUK does not approve. (Issues related to qualification and training are described in detail in module 1.) The licensee must ensure that all other personnel working with radioactive sources and radiation generators receive adequate training and guidance for their duties. The undertaking shall keep a worker-specific record on the radiation protection training and familiarization for which it is responsible.

The undertaking shall ensure that it has the expertise necessary in terms of the nature and extent of the practice at its disposal and sufficient human resources for the safe implementation of the practice as required in SätL section 23.

The implementation of requirements concerning employees and their qualifications, arrangements for the use of experts, the allocation of responsibilities and the description of information flow among other things are set out in the report on the management system of radiation practices according to SätL section 29. The report on the management system is part of information required in the authorization process according to VnA 1034/2018 section 23 and annex 5.

Use of a radiation safety expert is defined in section 32 of SätL and 17 of VnA. The undertaking/licensee must ensure that the radiation safety expert is either closely involved in the radiation practice (if the class of the occupational or public exposure is 1 or 2) or available for the radiation practice (when the class of the occupational or public exposure is 3). A radiation safety expert shall be used in accordance with section 17 in the situations described in section 16 of VnA.

For practices involving use of radiation in healthcare additional requirements are given. The undertaking must employ a medical physics expert for the purpose of the activity, as appropriate, according to VnA section 20. Qualification requirement for medical physics expert is given in SätL section 38. The qualification requirements and the roles, duties and responsibilities of the referring doctor or dentist and the doctor or dentist responsible for medical exposure are defined in SätL sections 113 and 114. The qualifications, roles and responsibilities of the employee carrying out the examination, procedure or treatment are described in SätL sections 115 and 116. Requirements for the competence of health care workers in radiation protection are given in SätL section 47.

Whenever major changes are planned within a practice, the licensee must apply for an amendment to the licence (section 52 of SätL and in detail sections 25 and 26 of VnA). Typical changes requiring prior amending of the safety licence are:

1) a change in the holder of the safety licence;

2) a change due to which the security referred to in section 54 of SätL would have to be changed or the high-activity sealed source specified in the security changes;

3) the use of the radiation source for a purpose other than for which the license was issued;

4) a change in the installation where the practices are carried out.

The following changes to a practice subject to a safety licence must be reported to STUK within two weeks of the change:

1) a change in the contact details of the holder of the safety licence;

2) a change due to which the class of the radiation exposure or radiation source changes from class 2 or 1 to class 3, or from class 1 to class 2;

3) the start-up of

a. a high-activity sealed source other than high-activity sealed source specified in the security

b. a radiation source to be used for a therapeutical purpose or

c. a radiation source which differs in terms of its radiation or radiation safety properties, from what is already in use in the practice pursuant to the safety licence or if its in-service radiation safety requires changes to structural protections or arrangements related to the place of use;

4) a significant change to the quality assurance programme of radiotherapy;

5) a radiation source's removal from use;

6) the winding up of radiation practices in part or in full.

According to section 29 of SätL the undertaking must have a written management system in practices subject to a safety licence. The management system must include the name, birthdate and contact details of the radiation safety officer and, taking into account the nature and extent of the radiation practice and the conditions at the facility or place where the practice is carried out, sufficient information on:

1) the qualifications, training and induction of workers engaged in radiation practices and radiation safety expert.

2) tasks which are significant in terms of radiation safety and security arrangements, the division of responsibilities and flow of information;

3) measures to maintain and develop a good safety culture

4) arrangements for the use of a radiation safety expert and a medical physics expert;

5) other administrative and organizational arrangements aiming to ensure radiation safety and to implement the security arrangements.

The applicant is also required to submit an adequate demonstration of safety when applying for a safety licence. According to section 26 of SätL the undertaking shall carry out a safety

assessment concerning the radiation practice if the practice is subject to a safety licence. The safety assessment is discussed in more detail in primary question 2.

According to section 86 in SätL practices which repeatedly handle, or store orphan sources are subject to a safety licence. Furthermore, the undertaking shall immediately notify STUK if it suspects or knows

of the finding or melting of an orphan source or any significant contamination caused by such an orphan source.

According to section 53 of SätL the licencing body (STUK) withdraws a safety licence when the radiation practice specified in the licence has been discontinued and the licensee has demonstrated in an acceptable manner that it has relinquished or rendered harmless the radiation sources specified in the licence and the radioactive waste generated in the practice and the waste referred to in section 78, subsection 3. STUK can also withdraw the safety licence if the prerequisites for granting it are not met or if the licensee repeatedly or essentially breaches the conditions for the licence or the provisions and regulations provided in SätL or pursuant to it and fails to remedy the deficiencies or its conduct despite a request to do so.

Prepared forms for the applications exist and STUK’s internet site contains guidance for applying for the safety licence.

A total of 2 944 safety licences for the use of ionising radiation were current at the end of 2020. More detailed information on the distribution of safety licences between different activities (e.g. industry, healthcare, research) can be found in STUK's annual report "Radiation practices: annual report 2020" (figure 1 and appendix 1, https://www.julkari.fi/handle/10024/142986)

Requirements for and implementation of exemption and clearance

Sections 50 and 51 of SätL and sections 27 and 28 of VnA determines which practices or sources within practices are to be exempted from some or all aspects of regulatory control. When value of the activity or the activity concentration used or possessed at any time, is less than or equal to the exemption value given in STUK SY/1/2018, a safety licence is not required under section 49, subsection 1, paragraph 2 of SätL. In case of sealed sources, only the exemption value for activity is applied. Exempted practices are those listed in section 49 of SätL. Further provisions on practices exempt from a safety licence as referred to in subsection 1, paragraph 9 of section 59 of SätL are given by government decree (section 27 and 28 of VnA).

According to section 50 of SätL STUK may exempt radiation practices when appliances are not used in medical exposure or non-medical imaging exposure. Further provisions on the prerequisites for exemption from a safety licence are given by government decree (section 28 of VnA).

Practices in which the radioactive substance is derived from a permitted discharge of a radioactive substance and from radioactive waste or a radioactive material which has been reused, recycled, utilized or disposed of in a manner specified under section 84 of SätL, are exempted of regulatory control.

Exempted practices are also

- the transfer of a radiation sources,
- the export of a radiation source which does not contain a radioactive substance,
- the transport of radioactive substances, excluding the road or rail transport of high-activity sealed sources
- the holding of health care or veterinary medicine X-ray equipment, provided that the holder has a safety licence for the use of equivalent appliance in the field of health care or veterinary medicine or for the installation, maintenance or remediation of such an appliance
- remediation or maintenance work of a radiation appliance which does not concern the appliance's parts producing radiation or shielding from radiation or any equivalent parts in a way that impacts safety

Other practices which meet the criteria for an exemption from a safety licence, if exemption is the most appropriate alternative and the radiation exposure and potential exposure caused by the practice is insignificant enough not cause a health detriment. The practice shall be justified and inherently safe.

Practices which don´t need authorization according to section 27 of VnA 1034/2018 are:

1. The use, manufacture, trade, installation, possession, safekeeping, import, shipment or storage of an appliance which produces ionizing radiation electrically, provided that the appliance operates with a maximum voltage of 30 kilovolts. Appliance does not cause, within a ten centimeter distance of the appliance's accessible surfaces, a greater dose rate than one microsieverts per hour.
2. The use of fire alarms and smoke detectors containing radioactive americium-241 isotope in the purpose they have been designed for or their resale and use or the possession, retention, storage, installation, maintenance or repair related to their use and resale. New fire alarms may nevertheless contain a maximum of 40 kilobecqurels of the americium-241 isotope.
3. For the use of a sealed source with radiation safety properties meant for educational use and contains a maximum of 40 kilobecquerels of the americium-241, strontium-90 or caesium-137 isotope as a teaching aid in schools, vocational schools and comparable institutions, provided that the educational institution has appointed a person in charge of radiation safety.
4. The use of lamps and igniters containing a maximum equal to the exemption value of a radioactive substance in the purpose they have been designed for or their resale and use or the possession, retention, storage, installation, maintenance or repair related to their use and resale.

STUK has issued regulations on clearance level for radioactive material in the STUK SY/1/2018.

Authorization for import or export of radioactive sources

Finland has committed to follow the non-binding IAEA Guidance on the Import and Export of Radioactive Sources (to the extent that it is not contradictory with the legally binding EU legislation). STUK has been designated as the national contact point relating to import and export of radioactive sources.

Prior approval of STUK must be sought for each consignment whenever a high-activity source is exported to or imported from a country outside of the European Union. STUK submits the necessary enquiries and notifications, as prescribed in the above-mentioned Import/Export guidance, to competent authorities abroad. The approval decision will impose requirements, as necessary, concerning the special notifications or other measures that must be performed by the applicant. Prior to the export approval, STUK ensures from the regulatory authority of the destination country that there is no impediment to the transfer of a high-activity sealed source in the said country and that the recipient of the transfer is authorized to receive the source (section 24 of VnA 1034/2018).

Because of the legally binding Council Regulation (Euratom) 1493/93, transfers of radioactive sources within the European Union are regulated in a different way. The Regulation doesn't recognize IAEA source categorization; all sources above the exemption level are treated the same way. A holder of sealed sources who intends to carry out a shipment of such sources or to arrange for such a shipment to be carried out, must obtain a prior written declaration by the consignee of the radioactive substances to the effect that the consignee has an authorization complied, in the EU member state of destination. STUK is the competent authority in the meaning of the regulation.

Concerning import from outside the European Union, the Finnish Customs is responsible for controlling that importers of radioactive substances are authorized by STUK. The Finnish regulations for the safe transport of radioactive sources are based on the IAEA Regulations for the Safe Transport of Radioactive Material.

Management of disused radioactive sources

When new sources are authorized for use, the applicant must be prepared to manage used radiation sources and radioactive waste generated by the practice as well as to clean the facilities used in the practice from radioactive substances (section 83 of SätL). Essentially there are two main options: the undertaking shall remove any radioactive sources subject to a safety licence which have become obsolete by returning them to the manufacturer or supplier or by transferring them to another undertaking with the appropriate safety licence. A source may nevertheless be stored without returning or transferring it, provided that the source's half-life and activity are such that it can be aged safely.

The undertaking can either have an agreement with the provider on returning the source or that the source will be transferred to the national long-term storage for disused sealed sources located at the Olkiluoto Nuclear Power Plant site. In both cases, the licensee is responsible for all the costs related to the management of disused sources. Sources manufactured in Finland can be returned to Finland once they have become disused sources.

The annual fee for holding a license depends on the number of sources in licensee's possession and, therefore, there is some financial incentive to transfer disused sources back to the provider (and thereof to the manufacturer) or to the central storage managed by the State.

According to section 84 of SätL waste and other material deriving from radiation practices may be reused, recycled, utilized and disposed of in accordance with the Waste Act, provided that the amount of radioactive substance it contains does not exceed the clearance level referred to in section 85 of SätL.

Sealed sources can be reused by another registrants and licensees with sufficient safety licence. According to section 72 of SätL and in more detail section 33 of STUK S/5/2019 the transferor of a sealed source subjected to safety licence shall ensure that the recipient has the required safety licence. The transferor shall ensure that:

1) the useful life of the sealed source recommended by the manufacturer has not ended;

2) the sealed source and its shielding as well as the information and documentation supplied with the source meet the applicable requirements;

3) the leak tests referred to in section 30 of STUK S/5/2019 have been conducted for the sealed source;

4) the sealed source has a transport packaging which meets the applicable legal requirements.

STUK checks the preconditions/requirements for the re-use of a radiation source during the licensing process as described in the internal guide SKV 3.2.

According to the Section 83 of SätL the licensee is required to take all the measures needed to render harmless radioactive wastes arising from its operations. The undertaking must clean any areas, facilities and their structures contaminated by radioactive substances in such a way that the remaining amount of radioactive substances does not exceed the clearance level referred to in section 85 of SätL. The cleaning requires a safety licence if the amount of radioactive substances prior to the cleaning is greater than the clearance level.

In section 11 of STUK S/5/2019 are set special requirements in relation to contamination. According to this regulation when unsealed sources are used and in other activities involving the risk of contamination, solutions shall be implemented in the spaces where radiation sources are used and stored which allow the organization of activities in such a way that during normal operation and in case of a radiation safety incident:

1) contamination can be removed from surfaces as easily as possible;

2) spreading of radioactive substances to indoor air in the place of use and to the other premises of the building can be restricted effectively;

3) releases of radioactive substances to the environment can be restricted effectively;

4) transfer of contamination outside the place of use with the employees can be restricted effectively;

5) waste generated in the operations can be processed safely.

More regulations on the in-service radiation safety of radiation sources and taking contaminated premises out of use are laid down on section 34 of STUK S/5/2019 and its appendices.

If the origin of the waste is unknown, like in case of orphan sources, the State has a secondary obligation to render the radioactive waste harmless (section 80 of SätL). In such case, the licensee – if identified later – shall compensate the State for the costs incurred in such action.

STUK has issued guidance on the life cycle management of radioactive sources which can be found on STUK's webpage (https://www.stuk.fi/stuk-valvoo/sateilyn-kayttajalle/).

Question 1.1 What are the plans or proposals to establish the legal requirements and processes for regulatory authorization of facilities and activities (with respect to safety)?

Response:

Nuclear facilities:

The licensee is under an obligation to ensure the safe use of nuclear energy as per YEL 990/1987 Section 9. YEA 161/1988 Sections 32, 34 and 34a prescribe the information and descriptions to be attached to the construction, operating or decommissioning license application, respectively. In addition, YEA 161/1988 Sections 35, 36 and 36a define the deliverables to be submitted to STUK by the license applicant or the licensee when applying for a construction license, an operating license or a decommissioning license, respectively, for a nuclear facility. STUK prepares a safety assessment based on the review of the mentioned deliverables and on the other regulatory oversight such as inspections and oversight on the site. Based on this safety assessment STUK issues a statement on the license application to which are attached statements from the Advisory Commission on Nuclear Safety and from the Ministry of the Interior. STUK also makes separate assessment on the documents required under either the Section 35, 36 or 36a of the YEA 161/1988. After all this, STUK issues the statement (to which are attached the safety assessment and assessment of the above-mentioned licensing documents) to the Ministry of Economic Affairs and Employment.

In addition, STUK Y/1/2018 Section 3 and STUK Y/4/2018 Section 3 require that the safety of a nuclear facility shall be assessed e.g. when applying for different licenses or in the connection with the plant modifications. Furthermore, it shall be demonstrated that the nuclear facility has been designed and implemented in a manner that meets the safety requirements, and the assessment shall cover the operational states and accidents of the plant. Further requirements are given in the above-mentioned Sections.

More detailed requirements for the scope and contents of the deliverables are given in the Guide YVL A.1 Annex A that also gives references to other relevant YVL Guides such as e.g. to the Guide YVL B.1 Chapter 6.1. The given example Guide YVL B.1 Chapter 6.1 gives detailed requirements concerning the safety design related contents of the safety analysis reports. In addition, the Guide YVL A.5 Chapter 3.3 requires the licensee to draw up a licensing plan describing how the fulfillment of nuclear and radiation safety requirements is ensured and demonstrated in the different phases of the construction or plant modification project. Full list of requirements concerning the licensing plan is given in the Guide YVL A.5 Chapter 3.3. For decommissioning phase, the requirements for safety analysis report and for periodic safety reviews are presented in YVL D.4 (Chapter 6). The requirements for the post closure safety analysis (safety case) of final disposal facilities is presented in regulation STUK Y/4/2018 Chapter 8 and more detailed in YVL Guide D.5 (Chapter 3.2 and Appendix A).

The safety requirements and measures for ensuring safety shall be graded and targeted so as to be commensurate with the risks in the use of nuclear energy in accordance with the YEL 990/1987 Section 7a. This also concerns the safety demonstrations of a nuclear facility. The graded approach is further dealt with in the connection of the Core Question 1.2 of the Module 6.

The Guide YTV 2.a describes STUK's processes and procedures to the review of the submitted documents and to the writing of the statement and the safety assessment. It also describes the goals of STUK's review in different authorization phases. More detailed guidance on the STUK's review work is given in the Guides of the Series 3 of YTV Guides (e.g. Guide YTV 3.a.2 regarding the oversight of the electrical and I&C systems and components) to which references are made in the Guide YTV 2.a.

Radiation practices:

The applicant is required to submit an adequate demonstration of safety when applying for a safety licence. According to section 26 of SätL the undertaking shall carry out a safety assessment concerning the radiation practice if the practice is subject to a safety licence. The safety assessment

1) identifies ways in which the practice can cause radiation exposure, considering any possible radiation safety deviations;

2) assesses the magnitude of the occupational, public and medical exposure arising from the practices as well as the probability and magnitude of the potential exposure;

3) presents measures to ensure radiation safety and the optimization of radiation protection;

4) presents measures to prevent and prepare for identified radiation safety deviations;

5) presents the categorization of the radiation practice (section 27 of SätL and section 16 of VnA 1034/2018).

The safety assessment shall be prepared in writing and kept up to date. STUK confirms the safety assessment either as part of granting the safety licence or separately.

More detailed regulations on the content and preparation of the safety assessment are issued in chapter 3 and 4 of STUK S/6/2019.

The safety assessment concerning a radiation practice must be carried out prior to the commencement of the practice and it must be revised in terms of occupational, public, and medical exposure:

1) every two years, if the category of radiation exposure is 1;

2) every three years, if the category of radiation exposure is 2;

3) every five years, if the category of radiation exposure is 3.

The safety assessment must also be revised, if this is not clearly unnecessary in terms of radiation safety, in connection to a change of the practice, after a radiation safety deviation, and to account for experiences gained from other comparable practices, the results of a safety investigation, and the development of technology.

The safety assessment concerning radiation practices must present the following per worker and population group:

1) radionuclides, radiation types, radiation energies, and exposure pathways;

2) the key structural solutions and operational arrangements by which radiation exposure is limited; furthermore, in terms of these solutions and arrangements:

a) the estimated radiation dose and its key assessment criteria;

b) the number of persons exposed;

c) the applicable dose constraint and its selection criteria.

Furthermore, the safety assessment concerning radiation practices must present the following of the most significant identified radiation safety deviations per groups of workers, members of the public and patients:

1) a description of the deviation;

2) the key structural solutions and operational arrangements by which:

a) the probability of the deviation's realization is reduced;

b) the deviation's consequences are mitigated;

c) the practice is returned to a safe status.

3) taking into account the solutions and arrangements referred to in paragraph 2:

a) the number of potentially exposed persons;

b) the magnitude of the potential exposure;

c) the probability of potential exposure;

d) the applicable limit for potential exposure.

STUK's internet site contains prepared forms and guidance on carrying out the safety assessment (www.stuk.fi/lomakkeet, available in Finnish and Swedish). As a mean to implement a graded approach, there is an easy-to-fill template to carry out a safety assessment for dental health care and veterinary practices. Otherwise, the graded approach is not widely used in the licensing process. The licensee must submit a safety assessment with the application in the situations described in the internal guide SKV 3.2. A project has been launched to identify possible means to enhance the application of a graded approach in the licensing process including in demonstrating safety through a safety assessment.

Question 2 Is the applicant required to submit an adequate demonstration of safety in support of the application for authorization of a facility or an activity?

Answer: Yes

Response:

Nuclear facilities:

The licensee is under an obligation to ensure the safe use of nuclear energy as per YEL 990/1987 Section 9. YEA 161/1988 Sections 32, 34 and 34a prescribe the information and descriptions to be attached to the construction, operating or decommissioning license application, respectively. In addition, YEA 161/1988 Sections 35, 36 and 36a define the deliverables to be submitted to STUK by the license applicant or the licensee when applying for a construction license, an operating license or a decommissioning license, respectively, for a nuclear facility. STUK prepares a safety assessment based on the review of the mentioned deliverables and on the other regulatory oversight such as inspections and oversight on the site. Based on this safety assessment STUK issues a statement on the license application to which are attached statements from the Advisory Commission on Nuclear Safety and from the Ministry of the Interior. STUK also makes separate assessment on the documents required

under either the Section 35, 36 or 36a of the YEA 161/1988. After all this, STUK issues the statement (to which are attached the safety assessment and assessment of the above-mentioned licensing documents) to the Ministry of Economic Affairs and Employment.

In addition, STUK Y/1/2018 Section 3 and STUK Y/4/2018 Section 3 require that the safety of a nuclear facility shall be assessed e.g. when applying for different licenses or in the connection with the plant modifications. Furthermore, it shall be demonstrated that the nuclear facility has been designed and implemented in a manner that meets the safety requirements, and the assessment shall cover the operational states and accidents of the plant. Further requirements are given in the above-mentioned Sections.

More detailed requirements for the scope and contents of the deliverables are given in the Guide YVL A.1 Annex A that also gives references to other relevant YVL Guides such as e.g. to the Guide YVL B.1 Chapter 6.1. The given example Guide YVL B.1 Chapter 6.1 gives detailed requirements concerning the safety design related contents of the safety analysis reports. In addition, the Guide YVL A.5 Chapter 3.3 requires the licensee to draw up a licensing plan describing how the fulfilment of nuclear and radiation safety requirements is ensured and demonstrated in the different phases of the construction or plant modification project. Full list of requirements concerning the licensing plan is given in the Guide YVL A.5 Chapter 3.3. For decommissioning phase, the requirements for safety analysis report and for periodic safety reviews are presented in YVL D.4 (Chapter 6). The requirements for the post closure safety analysis (safety case) of final disposal facilities is presented in regulation STUK Y/4/2018 Chapter 8 and more detailed in YVL Guide D.5 (Chapter 3.2 and Appendix A).

The safety requirements and measures for ensuring safety shall be graded and targeted so as to be commensurate with the risks in the use of nuclear energy in accordance with the YEL 990/1987 Section 7a. This also concerns the safety demonstrations of a nuclear facility. The graded approach is further dealt with in the connection of the Core Question 1.2 of the Module 6.

The Guide YTV 2.a describes STUK’s processes and procedures to the review of the submitted documents and to the writing of the statement and the safety assessment. It also describes the goals of STUK’s review in different authorization phases. More detailed guidance on the STUK’s review work is given in the Guides of the Series 3 of YTV Guides (e.g. Guide YTV 3.a.2 regarding the oversight of the electrical and I&C systems and components) to which references are made in the Guide YTV 2.a.

Radiation practices:

The applicant is required to submit an adequate demonstration of safety when applying for a safety licence. According to section 26 of SätL the undertaking shall carry out a safety assessment concerning the radiation practice if the practice is subject to a safety licence. The safety assessment

1) identifies ways in which the practice can cause radiation exposure, considering any possible radiation safety deviations;

2) assesses the magnitude of the occupational, public and medical exposure arising from the practices as well as the probability and magnitude of the potential exposure;

3) presents measures to ensure radiation safety and the optimization of radiation protection;

4) presents measures to prevent and prepare for identified radiation safety deviations;

5) presents the categorization of the radiation practice (section 27 of SätL and section 16 of VnA 1034/2018).

The safety assessment shall be prepared in writing and kept up to date. STUK confirms the safety assessment either as part of granting the safety licence or separately.

More detailed regulations on the content and preparation of the safety assessment are issued in chapter 3 and 4 of STUK S/6/2019.

The safety assessment concerning a radiation practice must be carried out prior to the commencement of the practice and it must be revised in terms of occupational, public, and medical exposure:

1) every two years, if the category of radiation exposure is 1;

2) every three years, if the category of radiation exposure is 2;

3) every five years, if the category of radiation exposure is 3.

The safety assessment must also be revised, if this is not clearly unnecessary in terms of radiation safety, in connection to a change of the practice, after a radiation safety deviation, and to account for experiences gained from other comparable practices, the results of a safety investigation, and the development of technology.

The safety assessment concerning radiation practices must present the following per worker and population group:

1) radionuclides, radiation types, radiation energies, and exposure pathways;

2) the key structural solutions and operational arrangements by which radiation exposure is limited; furthermore, in terms of these solutions and arrangements:

a) the estimated radiation dose and its key assessment criteria;

b) the number of persons exposed;

c) the applicable dose constraint and its selection criteria.

Furthermore, the safety assessment concerning radiation practices must present the following of the most significant identified radiation safety deviations per groups of workers, members of the public and patients:

1) a description of the deviation;

2) the key structural solutions and operational arrangements by which:

a) the probability of the deviation's realization is reduced;

b) the deviation's consequences are mitigated;

c) the practice is returned to a safe status.

3) taking into account the solutions and arrangements referred to in paragraph 2:

a) the number of potentially exposed persons;

b) the magnitude of the potential exposure;

c) the probability of potential exposure;

d) the applicable limit for potential exposure.

STUK's internet site contains prepared forms and guidance on carrying out the safety assessment (www.stuk.fi/lomakkeet, available in Finnish and Swedish). As a mean to implement a graded approach, there is an easy-to-fill template to carry out a safety assessment for dental health care and veterinary practices. Otherwise, the graded approach is not widely used in the licensing process. The

licensee must submit a safety assessment with the application in the situations described in the internal guide SKV 3.2. A project has been launched to identify possible means to enhance the application of a graded approach in the licensing process including in demonstrating safety through a safety assessment.

Analysis

STRENGTHS FOR 05. AUTHORIZATION

S1	For occupational and public exposure to natural radiation there are clear criteria and mechanisms defining the situations where a safety license is required. The license is required if the relevant reference level is exceeded despite corrective actions taken. In case of occupational exposure to radon, the need for a safety license is based on measurements of radon concentration in the workplace.
S2	STUK has recent experience in licensing of nuclear facilities – competent resources, experience in oversight project organization and proven review and inspection processes. STUK utilizes its project management procedures and guidance as well as IT-tools developed to support the authorization process (case management with workflow management and requirement management).
S3	All areas of safety (radiation, nuclear, security and safeguards) are in one house that allows integrated and optimized oversight of practices for compliance with all the respective requirements.
S4	STUK issues periodical public progress reports in its web pages on authorization processes i.e. new build NPP independent review and assessment progress (three public reports per annum), which enables the Ministry to plan its authorization activities. These public progress reports are well referenced in Finnish news media and stakeholders have found the STUK periodical reporting appropriate.
S5	In authorization of medical and veterinary use of radiation graded approach has been implemented so that a simplified safety assessment is required and the requirements to use radiation safety experts are minimized in practices where risks are minimal, such as dental practices.
S6	The authorization process for radiation practices (for example amendment of a license) is simplified in the way that only relevant evidence is required to be submitted attached to the application but is verified on inspections (for example documents on continuous radiation protection training), unless there are doubts on lack of evidence.

WEAKNESSES FOR 05. AUTHORIZATION

W1	The undertaking starting a practice involving NORM is required to submit similar information and documents, as needed for a safety license, to other authorities supervising other aspects of the practice. This may seem administratively complicated from the undertaking's point of view.
W2	Finnish admirative legal framework enables the licence applicant for nuclear facility to submit the complete licence application in several batch wise submittals without

	requirement on logical application entity. This could lead to complex review and assessment as well authorization processes.
W3	Requirement of paragraph 3.123 of the GSR Part 3 on establishing operational limits is not fully implemented except for establishing authorized limits for discharges.
W4	The licensing process for radiation practices does not consider all the possibilities foreseen in the SätL for the application of a graded approach. A project has been initiated to examine possibilities to improve and it may show also needs for adjustments to the SätL.
W5	Decommissioning license was added into the nuclear energy act in 2017. Now e.g. the documentation requirements for the decommissioning license application follows quite much the requirements for the operating license application. In practice this means that you could do almost the same things under both licenses except electricity production, which requires operating license. In the future the transfer from the operating license to decommissioning license and further grading and clarification of requirements should be evaluated.
W6	The present Nuclear Energy Act do not include requirements for uranium extraction facilities' operating organization. In future renewal of Nuclear Energy Regulations this feature should be considered.
W7	Nuclear waste management and radioactive waste from other sources have separate legislation and regulations. Also, regulatory oversight is divided in different STUK departments. This has led to some differentiation of requirements and practices.
W8	Requirements concerning transport on dangerous goods, and specifically related to radioactive material, are provided in three or more acts. It is difficult for transport companies providing service to Class 7 transportation to have clear view of all requirements. There is also risk that requirements differ between different areas.
W9	Budget cuts jeopardize preparation for the authorization of new technologies, like SMRs and makes the Competence management in general more difficult as STUK is forced to cut its costs.

OPPORTUNITIES FOR 05. AUTHORIZATION

O1	Further cooperation between relevant authorities would enable the simplification of the licensing process for practices involving NORM.
O2	STUK's strategy underlines licensee's responsibility and allows staff to focus on the most important matters for safety (using of graded approach principle).
O3	Overall renewal of nuclear energy legislation (act, degree, STUK regulations and YVL guides) gives opportunity to re-evaluate the licensing process, STUK's role in different authorizations (inc. authorizations of persons and organizations) and ensure that different kind of facilities (technologically neutral requirements) and life cycle stages are considered.
O4	Further co-operation and bench marking with other national regulatory bodies within the safety critical industries could be utilized while developing further the authorization practices.
O5	New working methods during Covid pandemia lock down have been established and there are opportunities to even develop the way of working and collaboration with aid of new IT-tools and platforms.

O6	Digitalization provides an opportunity to improve work efficiency and enhance the use of existing information.

THREATS FOR 05. AUTHORIZATION

T1	There is shortage of radiation protection experts who are specialized in NORM industry and this may jeopardize e.g. the safety assessments.
T2	Budget cuts jeopardize preparation for the authorization of new technologies, like SMRs.

CONCLUSIONS FOR 05. AUTHORIZATION

C1	In general, STUK fulfills expectations given by the IAEA and has recent experience in licensing of different kind of facilities and activities and well-working and proven processes for it.
C2	The overall renewal of all levels of nuclear energy legislation has been started. It gives opportunity to - ensure that the authorization model enables new technologies and needs in this regard (e.g. operator vs. licensee vs. ownership, smaller unit sizes and higher number of standardized units, new innovative technological solutions) - STUK's oversight is proportionate to the safety significance and emphasizes licensee's responsibility, for instance authorization vs. notification - view STUK's role in the authorization of responsible persons, control room operators and different organizations - ensure that site related aspects are processed in a timely manner (there are no separate site license or permit prior the construction license phase of a nuclear facility).
C3	There have been budget cuts that jeopardize STUK's preparation for the authorization of new technologies, like SMRs (more in module 3).
C4	Requirement of paragraph 3.123 of the GSR Part 3 on establishing operational limits is not fully implemented. Implementation is lacking regarding occupational exposure, as well as, public exposure except for establishing authorized limits for discharges.
C5	There is a need to examine and implement appropriate measures to enhance the application of the graded approach in the licensing of radiation practices. STUK has started a project to this effect.
C6	There is room for more close cooperation between different authorities licensing practices involving NORM for different aspects, as to simplify the licensing processes from the undertaking's perspective.

Module: 06. Review and Assessment

Findings

Question 1 Does the regulatory body perform review and assessment of relevant information for determining whether the applicant for authorization or the authorized party complies with applicable regulatory requirements?

Answer: Yes

Response:

Nuclear Facilities:

STUK performs its review and assessment always prior to any decision or authorization. Safety related requirements which fulfilment is evaluated via review and assessment process are presented in the legislation and regulations. Review and assessment processes are described in STUK's internal guides.

Mandatory requirements for safety of nuclear facilities are given in Nuclear Energy Act (YEL), Nuclear Energy Decree (YEA) and STUK regulations. More detailed requirements are given in YVL guides. The above-mentioned requirements are also the guiding principles in the review and assessment process of STUK.

YEL establishes general requirements for safe use of nuclear energy and nuclear facilities. General requirements concerning safety are stated in chapter 2a of YEL including, for example, "Safety as high as reasonably achievable"-principle (SAHARA), graded approach, and defense-in-depth-principle.

According to Section 7e of YEL ("Verification and assessment of safety") compliance with the requirements concerning the safety of a nuclear facility shall be reliably proven and the overall safety of a nuclear facility shall be assessed at least at 10-year intervals.

YEA includes administrative details for licensing and regulatory oversight including release from regulatory control. STUK regulations set mandatory requirements for nuclear safety, emergency arrangements, nuclear security, safety of nuclear waste (radioactive waste, which is resulting from the use of nuclear energy) disposal and mining and milling. According to section 7r of YEL STUK issues detailed requirements (YVL guides) which specify the implementation of safe use of nuclear energy.

YTV guides are part of STUK's management system, and they describe the processes and duties related to the supervision of the use of nuclear energy. Review and assessment are STUK's core regulatory functions, and they are included in YTV guides. However, YTV-guides do not impose any additional requirements for nuclear safety. In other words, requirements for nuclear safety are included in YEL, YEA, STUK regulations and YVL guides. Thus, the criteria for regulatory review are consistent with national legislation.

STUK's management system has several guides concerning review and assessment. Guides deal with e.g. overall safety assessment of a nuclear facility (YTV 1.b), system design, automation, structural design, probabilistic and deterministic analyses, organization performance, waste management, safeguards and so on.

The review and assessment of system design is dealt with in YTV 3.a.1, the control of automation systems and equipment in YTV 3.a.2, and the inspection of structural design and site supervision in YTV 3.a.3.

Deterministic safety analyses and probabilistic risk analyses for nuclear power plants shall be continuously updated and acceptance and conclusions of the analyses shall be assessed by STUK. Changes to the analyses are reviewed and assessed annually and deterministic and probabilistic approaches complement each other. Review and assessment of deterministic and probabilistic analyses are presented in YTV 3.b.1 and YTV 3.b.2.

The technical condition of nuclear facilities is supervised by assessing the operation of the facility in accordance with the requirements of the safety-related operating conditions, fire safety, radiation safety, security, emergency response, water chemistry, fuel and control rods, waste management, domestic and foreign events in accordance with the procedures in YTV 3.c Guides. Ageing management is covered by YTV 7.c.3.

The objective of organizational performance review is to ensure that the organizations of the license holder and its key suppliers operate at all levels to ensure the safety of the facility. The performance of organization is assessed by reviewing safety management, the effectiveness of management systems, the competence and training of nuclear personnel and operational experience within the framework of the operational inspection programme. For the above issues, the procedures for supervision and inspection are described in YTV 3.d.

The long-term safety of the disposal of nuclear waste is assessed by reviewing the safety case for the disposal and, as part of this, the safety analyses of the disposal. The review focuses on the operational capability of the disposal system, the scenario analysis, the safety analysis, and the reliability of the safety justification. Nuclear waste management controls are discussed in more detail in YTV 3.e Guides.

Safeguards ensure that licensees and other operators provide accurate and complete information on their nuclear materials and activities under safeguards and that they have no undeclared activities. As part of safeguards, the operator's reporting, record keeping, and related procedures are assessed. Safeguards are discussed in more detail in the YTV 3.f Guides.

Review and assessment process is based on several general principles. Major legal principle in the Finnish framework is the licensee's ultimate responsibility on nuclear and radiation safety. In other words, it is essential that the license applicant presents their safety assessment and statement on acceptability of design, plans and activities to STUK during the review and assessment process.

Another major principle is the use of graded approach. Possible factors in grading of review and assessment include, for example safety significance, whether the component, system etc. is first of a kind or known and performance of the licensee (level of quality displayed by the licensee). Safety significance refers to how a failure of an equipment or a system impacts on safety function or other possible consequences. However, graded approach is not limited to these factors in the review and assessment process. Graded approach is discussed in detail in SQID 1.2 of this module.

Figure 1: Review and assessment process of STUK

STUK's review and assessment process is presented in figure 1 and discussed in detail in guide YTV 8.a. Main principle in the review process is that STUK always evaluates whether the application fulfills each relevant requirement given in the relevant regulations before any decision is made.

Before the actual review a preliminary inspection is performed to clarify whether licensee's application and its material enable a decision to be taken. If the maturity of the application is not sufficient application is rejected or additional information is requested to be submitted. In the actual review all necessary disciplines shall be involved and meetings with the licensee are held to clarify issues if needed. Relevant YTV-guides steer the review and assessment work of each discipline. It is possible to include technical support organizations at this point to give expert opinions or perform independent analyses. However, STUK shall always have enough competence to interpret and act on TSO results.

Final step in the review process is STUK's decision which, in practice, stands for approval, approval with requirements, rejection or clarification request. STUK's decisions shall always have sound legal basis, STUK shall be able to justify the decisions and the decision-making process shall be consistent. Before the decision is sent a hearing of the licensee is conducted. In the hearing the licensee is given a chance to comment the content and the deadlines of possible requirements. Purpose of the hearing is no to answer the requirements but to correct possible mistakes or misunderstandings.

Review and assessment process is based on different roles and assigned persons. Register office, coordinator, responsible person, experts, and decision-maker have various tasks and responsibilities when the licensee's application is received by STUK, during the review and after completing the review. Roles and responsibilities are presented in figure 2.

Figure 2: STUK's review and assessment process roles and responsibilities

STUK's review and assessment process is based on comprehensive support processes which include, for example document management, decision making process and requirement management. All the review and assessment documents are stored in STUK's document managements system called SAHA. In addition, SAHA enables monitoring of application processing times. Basic principle is that applications should processed without unnecessary delay considering the urgency and safety significance of the application. STUK receives several hundred documents for review and assessment each year. For example, in 2018 STUK received around 2500 applications concerning LO1&2, OL1&2 and OL3 NPPs.

Several different documents are related to review and assessment process including licensee's application documents, STUK's decision and related justification memorandum, review memorandums by the experts, possible communication with the licensee (emails, minutes of meetings etc.) and other information related to processing of the application (persons involved, dates etc.). When the review and assessment process is finalized decision letter along with justification memorandum and legal bases is delivered to licensee. Memorandums by the experts are STUK's internal documents and not included in the decision. However, findings and conclusions presented in the expert memorandums provide input for the decision and justification memorandum.

Radiation practices:

STUK's review and assessment is in principle based on a review of the information received from the undertaking in the safety licence application (or in the application for amendment of the safety licence). All information related to licensing or application is stored at VASARA system. Review and assessment focuses on the safety assessment and its review (see Primary Question 2 in Module 5). When necessary, information is obtained by other means, for example by inspection (if it is decided to do so before issuing a safety licence). When issuing a new safety licence STUK uses a checklist for a new safety licence (appendix 12 in the internal guide SKV 3.2). The same checklist can also be used in cases where the application for amend a safety licence is complex. Transparent guidance for implementation of requirements is available in SAMMIO.

In cases of medical use of radiation clinical audits are assessed and reviewed during the course of the activity, typically during inspections. Clinical audits shall be organized periodically during the operation and the periodicity of a clinical audit depends on the classification of medical exposure given in the safety assessment which is confirmed during authorization or separately.

According to the section 51 of SätL the application for authorization shall demonstrate:

1) information of the applicant;

2) the purpose of the practice and information on the facility or place where the practice is carried out;

3) the management system for the radiation practice;

4) the certificates verifying the qualifications of the radiation safety expert and radiation safety officer;

5) the safety assessment concerning the radiation practice;

6) a plan on the security arrangements;

7) information on the radiation sources, the related appliances and shieldings and on the maintenance arrangements concerning the sources and appliances;

8) the arrangements for managing the waste and discharges containing radioactive substances generated by the practice during its operations and when discontinuing the practice;

9) the quality assurance procedures complied with in the practice;

10) information other than what is specified in paragraphs 1 through 9 relevant to the safety of the practice.

Further provisions on the information to be provided in an application for a safety licence are given in VnA (1034/2018) (Annex 5):

1. A safety licence application shall include the following based on the quality and extent of the practice:

1.1 a report on the practice and its purpose, if the case involves a new type of practice;

1.2 a report on the justification for the practice should this be necessary according to section 24 of SätL;

1.3 the street address of the location where the practice is engaged in or other equivalent information identifying the location where the practice is engaged in;

1.4 technical specifications which show that the facility where the radiation sources are used and stored meet the in-service safety requirements set by STUK.

1.5 pictures and drawings of the areas and premises of the location where the practice is engaged in (including scale), which indicate the purpose of the areas and premises, the locations of the radiation sources, controlled and supervised areas, structural protections, including information on materials, passageways and the location of warning systems, fixed radiation control meters and access control points.

2. Technical information on the radiation sources and the related appliances and equipment which show that they meet STUK's regulations on in-service radiation safety shall be presented. The following information on radiation sources must also be included:

2.1 on a radiation source containing a radioactive substance: radionuclide, activity and the activity's determination date;

2.2 of an unsealed source, the greatest activity to be processed and stored at any one time nuclide-specifically as well as information on the type of processing in question;

2.3 of an appliance producing radiation electrically: the radiation type and the values of the key parameters influencing the radiation output;

2.4 of sealed sources: the code identifying the sealed source provided by the manufacturer and the manufacturer's document concerning the identification;

2.5 of a sealed source: a certificate of compliance and a special form certificate, if the sealed source is transported according to the requirements applicable to special form sources, as well as the manufacturer's commitment to receive the sealed source after its use has come to an end in accordance with section 76 of SätL;

2.6 of a high-activity sealed source: a picture of the sealed source's structure and transport package as well as of the appliance and container in which the sealed source is used or stored;

2.7 an itemization of the export, import or shipment of high-activity sealed sources separately for each sealed source batch to be exported, imported or shipped.

3. Information on a radiation source's individual control code provided by STUK may be presented in lieu of the information referred to in section 2 above.

4. The application must include the following on safety arrangement and security arrangements according to the quality and extent of the practice:

4.1 a safety assessment;

4.2 information on the management system referred to in section 29, subsection 2 of SätL;

4.3 a report on the practice's different work phases key to radiation safety and the procedures complied with in them;

4.4 a plan for radiation safety incidents;

4.5 the categorization and number of radiation workers and information on how the monitoring of exposure conditions and the individual monitoring and health monitoring of radiation workers belonging in class A has been organized;

4.6 the dose constraints complied with in the practice;

4.7 a plan concerning security arrangements;

4.8 information on the quality system concerning the practice and on the procedures used in quality management;

4.9 the volumes and types of radioactive waste generated in the practice and of waste referred to in section 59, subsection 3 as well as the arrangements concerning the waste, itemized according to the quality of the waste;

4.10 plan on discharges.

5. The application must include the civil status document of the holder of the safety licence or, if the applicant is a private corporation or foundation, an extract from the relevant register.

If the application pertains to the import, export or shipment of radioactive waste, the application must be submitted in compliance with the requirements provided in Article 6, 7, 10 and 13–15 of the Commission Decision establishing the standard document for the supervision and control of shipments of radioactive waste and spent fuel referred to in Council Directive 2006/117/Euratom (2008/312/Euratom).

Requirements for a safety assessment (paragraph 4.1 in Annex 5) are set out in section 26 of SätL and chapter 3 and 4 in STUK S/6/2019. According to section 27 of SätL in practices subject to a safety licence, the undertaking shall categorize the radiation practices based on the radiation exposure caused by the practices and the radiation sources used in the practices. The categorizations shall be presented in the safety assessment. STUK confirms the categorizations concerning the radiation practice as part of granting the safety licence or separately. If the categorization is made separately after granting the licence (i.e. because amendments made the the licence/radiation practice) the graded approach can be used in radiation practices related to dental health care and veterinary when it comes to carrying out a safety assessment due to an easy-to-fill tick-box template for licensees. Otherwise, the graded approach is not widely used in the review and assessment process (see answer to question 1.4).

When processing the application STUK compares the content of the application with the requirements set out in SätL and in VnA. Furthermore, review and assessment of information relevant to safety concerning radiation practices are conducted during licensing and inspection processes described in internal guides SKV 3.2 and 3.4. Furthermore, the licensee is obliged to revise the safety assessment at set intervals (STUK S/6/2019). The safety assessment must also be revised, if this is not clearly unnecessary in terms of radiation safety, in connection to a change of the practice, after a radiation safety deviation, and to account for experiences gained from other comparable practices, the results of a safety investigation, and the development of technology.

Only if the exposure to natural radiation is higher than the reference level and cannot be remediated, the activity needs a safety licence from STUK as stated in SätL section 148. STUK's inspection processes related to exposure to natural radiation is described in internal guide VALO 7. Compliance with requirements is mainly done by document inspections. These documents include e.g. results of the measurements such as indoor radon concentrations or activity concentrations of natural radionuclide in materials, and information on working time, ventilation and decribtion of the process. Targeted surveys and requests for clarifications are used in order to increase awareness of the requirements. In-house RAMI-database and stukasiointi.stuk.fi -service for employers are used to manage radon in usual workplaces. For underground workplaces and NORM related activities e-forms are provided by STUK.

According to the SätL section 155 an employer shall investigate the radon concentration in a workspace or other place of work if the facilities are located:

1. in areas defined by STUK (Areas requiring radon measurements in workplaces - stuk-en - STUK);
2. on an esker or other gravel or sandy soil with good air permeability (maps in Finnish: https://www.stuk.fi/documents/12547/214083/Läpäisevät+maaperät+zoomkartta/0dc302ac-819a-8ef4-4095-213fec58a194?t=1550477368607);
3. wholly or partly underground;

4. an installation which distributes water or in a food establishment the water of which does not derive solely from a body of surface water and has contact with indoor air.

However, the investigation need not be carried out if none of the workers work in the workspace for more than 20 hours in a year or if the workspace is located on the second or upper floor of the building seen from the ground level, or if the floor and walls of the building are not in contact with the ground and the good ventilation of the space in between is apparent. (SätL section 155)

The radon concentration in workplace shall be measured on a regular basis if the workspace or other workplace is in an underground quarry or an underground mining site as referred to in the Mining Act (621/2011) (SätL section 155).

For NORM-involving industries, information about discharges need be presented in the required exposure assessment (SätL section 146, STUK S/3/2019 section 3). If the information is missing, it is required by the regulator.

According to SätL section 127, the licensee must have records of releases and provide regular information about the monitoring of authorized discharges. According to STUK S/3/2019 section 9 the report about monitoring of discharges must be done quarterly and it must contain the nuclide specific information about quantities and alto temporal variations. Based on STUK S/3/2019 section 11, the monitoring of public exposure must take into account external and internal exposure and the exposure from radionuclides that are accumulated in the environment in long-term operations. The monitoring of public exposure must be planned and performed regularly so that short-term and long-term changes to public exposure are identified. The monitoring of public exposure must be done in a way that allows comparison to the results of radiological environmental baseline survey results.

Question 1.1 Over a life time of a facility and duration of an activity, how does the Regulatory Body continue to review and assess as necessary, relevant information associated with the authorization?

Response:

Nuclear Facilities

STUK's review and assessment process is based on the same principles and requirements presented in primary question 1 during the whole life cycle of a nuclear facility. Hence, the criteria for regulatory review and assessment are consistent with the national legislation and possible conditions attached to authorizations during the whole life cycle of a nuclear facility.

IAEA regulatory process stages are initial review, subsequent reviews, reviews of changes to safety related aspects of the facility or activity, reviews of operating experience, or reviews of long-term operation, life extension, decommissioning, or release from regulatory control. In practice in Finland the corresponding stages for a nuclear facility are decision-in-principle, construction license, operating license, possible plant modifications, periodic safety reviews and decommissioning. In addition to these hold points review and assessment is performed during construction, operating phase and decommissioning phase whenever documentation related to these phases is delivered to STUK.

In Finland reviews of changes to safety related aspects of the facility or activity cover not only plant modifications but also other changes requiring approval by STUK, for example updates in licensing documentation or technical specifications. Concerning modifications, YEA Section 112 prescribes that the licensee shall obtain approval from STUK for modifications that influence safety and involve changes in the plans or documents approved by STUK before they are carried out.

Decision-in-principle

Requirements related to decision-in-principle are considered in chapter 4 of YEL and chapter 4 of YEA. In addition, YVL A.1 section 3.1 and Annex A include requirements for decision-in-principle. When applying for a decision-in-principle, descriptions of the facility options in question shall be submitted to STUK, in addition to the documents required in Section 24 of the YEA.

The following information, i.e., shall be given about each facility option for review and assessment:

- The design principles and description of operation of the nuclear facility and its safety systems, and where a nuclear power plant in concerned, also those of its reactor, primary circuit, and containment
- Preliminary principles for the siting and layout of the facility, buildings and structures of the facility, and preliminary plans for provisions for internal and external threats
- Preliminary principles for the provisions for aircraft crash

- Summary of the safety analyses pertaining to the facility option concerned, including an environmental impact analysis of the worst-case accident scenario and principles according to which offsite radiation doses and releases are limited and monitored
- General plans pertaining to the organization implementing the plant, the suppliers of the plant and its major components, and quality management of the implementation
- Preliminary personnel plan
- References to the nuclear facilities that have served as models, and a summary of the most significant modifications made compared to them
- The license applicant's own assessment of the feasibility of the implementation of the nuclear facility project concerned in compliance with the Finnish safety regulations

STUK may request detailed information on each facility option at need. Based on the provided information STUK will draw a preliminary safety assessment of the application for a decision-in-principle.

Construction license

When applying for a construction license, the documents listed in Section 35 of the YEA, and other reports considered necessary by STUK under Subsection 2 of Section 35 of YEA shall be submitted to STUK for review and assessment. STUK issues a statement about the construction license application only after having approved essential parts of each of these documents by a separate decision.

According to YEA, when applying for a construction license, the applicant shall submit the following to STUK for review and assessment:

- The preliminary safety analysis report, which shall include the general design and safety principles of the nuclear facility, a detailed description of the site and the nuclear facility, a description of the operation of the facility, a description of the behavior of the facility during accidents, a detailed description of the effects that the operation of the facility has on the environment, and any other information considered necessary by the authorities;
- A probabilistic risk assessment of the design stage
- A proposal for a classification document, which shows the classification of structures, systems, and components important to the safety of the nuclear facility based on their significance with respect to safety
- A description of quality management during the construction of the nuclear facility, showing the systematic measures applied by the organizations that take part in the design and construction of the nuclear facility in their operations affecting quality
- Preliminary plans for the arrangements for security and emergencies

- A plan for arranging the safeguards control that is necessary to prevent the proliferation of nuclear weapons
- Programme for determining the baseline environmental conditions of the nuclear facility
- Decomissioning plan

An applicant for a license shall also provide STUK any other reports considered necessary.

Operating license

When applying for an operating license, the documents listed in Section 36 of YEA, and other reports considered necessary by STUK under Subsection 3 of Section 36 of YEA shall be submitted to STUK for approval. When applying for an operating license, the applicant shall provide the following to STUK for review and assessment:

- The final safety analysis report
- A probabilistic risk assessment
- A classification document, which shows the classification of structures, systems, and components important to the safety of the nuclear facility, on the basis of their significance with respect to safety
- A quality management programme for the operation of the nuclear facility
- The Technical Specifications, which shall at least define limits for the process quantities that affect the safety of the facility in various operating states, provide regulations on operating restrictions that result from component failures, and set forth requirements for the testing of components important to safety;
- A summary programme for periodic inspections
- Plans for the arrangements for security and emergencies
- A description on how to arrange the safeguards that are necessary to prevent the proliferation of nuclear weapons
- Administrative rules for the nuclear facility
- A programme for radiation monitoring in the environment of the nuclear facility
- A description of how safety requirements are met; and
- A programme for the management of ageing
- Decomissioning plan

When the application for an operating license is made for a nuclear facility that has already been in operation, the documents mentioned in subsection 1 need be submitted to STUK only to the extent that they have not been submitted before.

In addition, the applicant shall provide STUK with any other information considered necessary.

Plant modifications, including power uprates

According to Section 112 of the YEA, if the licensee intends to carry out modifications to the nuclear facility systems, structures, nuclear fuel or the way the facility is operated that influence safety and involve changes in the plans or documents approved by STUK, the licensee shall obtain approval from STUK for such modifications before they are carried out.

In addition, the licensee shall ensure that the documents submitted to STUK as provided in Sections 35 and 36 of YEA are revised accordingly.

Periodic safety reviews and lifetime extensions

In accordance with section 24 of YEL, the license, excluding the construction license, shall be granted for a fixed term. The renewal of the operating license always involves a periodic safety review of the facility. Periodic safety reviews are performed for nuclear power plants on 10-year interval and on 15-year interval for decommissioning facilities unless otherwise stated in the conditions of the operating license.

The renewal of the operating license and the periodic safety review are mainly based on the documents referred to in Section 36 of YEA. They shall be continuously updated, and the updated versions shall be regularly submitted to STUK. When applying for renewal of the operating license, the documents may be submitted to STUK only insofar as they have been amended since the previous updates. Furthermore, the application shall include a summary of the most significant changes to the documents after the granting of the valid operating license and a description of the documents' updating status.

The licensee shall also submit a periodic safety review of its own concerning the safety status of the nuclear facility, potential areas of development and maintenance of the safety.

Decommissioning

YEL section 7g states, that the design of a nuclear facility shall provide for the facility's decommissioning and that the related plan is to be kept up to date. According to section 20a of STUK Y/1/2018 the holder of the nuclear facility's decommissioning license shall ensure during decommissioning that the dismantling of the nuclear facility is implemented in conformity with the safety requirements and using approved plans and procedures.

According to YVL A.1 Annex A17 already in the construction license application stage, the license applicant shall submit to STUK for approval a plan based on the decommissioning strategy established for the nuclear facility concerned that provides an outline of the implementation stages involved in decommissioning complete with timetables, the dismantling and waste management solutions adopted, and the end state of the facility site. The update of decommissioning plan is required in operating license application (YEA section 36) and regularly after every six years during operation of a nuclear facility (YEL section 7 g). The final decommissioning plan is required for the decommissioning license application (YEA section 36a).

Release from regulatory control

Release from regulatory control is covered by YEL section 27 c, YEA section 75 and STUK regulation SY/1/2018. Additional requirements are presented in YVL D.4 and D.5. According to YVL D.4 requirement 718 when the decommissioning of a nuclear facility has been brought to completion and all waste has been removed from the site, the license holder under a waste management obligation shall submit to STUK for approval an application for the clearance of the site and any buildings.

Radiation practices:

Review and assessment of information relevant to safety concerning radiation practices are conducted during licensing and inspection processes described in internal Guides SKV 3.2 and 3.4.

The safety assessment that the undertaking shall carry out in practices subject to a safety licence (section 26 of SätL) must be prepared in writing and kept up to date. STUK confirms the safety assessment either as part of granting the safety licence or separately (for example when amendments are made to the already granted safety licence) (internal guide SKV 3.2). According to STUK S/6/2019 the safety assessment must be revised at set intervals and, if this is not clearly unnecessary in terms of radiation safety, in connection to a change of the practice, after a radiation safety deviation, and to account for experiences gained from other comparable practices, the results of a safety investigation, and the development of technology. Guidance for carrying out a safety assessment is available at STUK's webpage (www.stuk.fi/lomakkeet). Furthermore, transparent guidance for implementation of requirements is available in

SAMMIO.

STUK assesses radiation practice in cases such as:

1. If the practice changes from what is described in the safety assessment, the safety assessment must be updated. STUK will then assess the licence amendment and the updated safety assessment.
2. The operator identifies a significant need for updating the safety assessment during the regular review of the safety assessment. STUK will the assess the safety assessment and confirms the new safety assessment,
3. During the inspection, STUK can identify the need for a reassessment of the licensee's activities/practices and therefore the safety assessment carried out must be updated.

STUK supervises the safety of the use of ionizing radiation and other radiation activities, for example by inspections at the places where radiation is used and by other control methods, such as control surveys. The supervision ensures that the radiation legislation and the regulations, instructions, licence conditions and requirements issued under it are complied with, and that the activities are otherwise carried out in a safe and acceptable manner. The planning of supervision, inspections, supervision methods and intervals take into account the risks associated with the activity (graded approach) and the effectiveness of supervision. Activities are reviewed at an intensity based on risk and control effectiveness throughout the life of the activity. Supervision during operations is targeted on a risk basis through a series of supervision projects (internal guide SKV 3.4).

All the possible ways to supervise the safety of the use of ionizing radiation and other radiation activities are listed in the internal guide SKV 3.4.

Furthermore, STUK supervises compliance with the deadlines set in the decisions and inspection reports in accordance with the internal guides SKV 3.2 and 3.4.

Question 1.2 How does the Regulatory Body ensure that review and assessment of a facility or activity is commensurate with the radiation risk associated with the facility or activity?

Response:

Nuclear Facilities:

Section 7a of the Nuclear Energy Act states that the safety requirements and measures for ensuring safety shall be graded and targeted so as to be commensurate with the risks in the use of nuclear energy. This principle is followed in STUK's internal guides and processes in practice.

Internal guide STUK 3.1 describes the regulatory control process of STUK, i.e., regulatory control related to radiation and nuclear safety. This guide provides the overall principles and practices to be followed in the regulatory control activities. Among others, the following principles are stated in the guide:

- Safety requirements and safety oversight are proportionate to the safety risks of radiation activities and the use of nuclear energy, taking into account normal operation and disturbances and accidents. This is known as graded approach.
- STUK shall operate transparently, effectively and in a cost-aware manner both in internal activities and in relation to its customers. Oversight is targeted in matters that have importance to safety.
- In its regulatory duties, STUK is obliged to recognize the significance of safety in matters handled by it and stress the priority of safety. "STUK operates in a clear, efficient and cost-conscious manner, both within its own operations and in relation to its customers. Supervision is targeted in a timely manner at issues of real safety significance."

STUK's strategy for 2018–22 include similar strategic targets, e.g.,

- cost-ware operations
- risk-informed and commensurable oversight
- flexible and efficient working methods

With regard to STUK's organizational structure and management system to facilitate graded approach, see also responses to the primary question 1 of module 3 and the primary question 5 of module 4.

As regards nuclear power plants and nuclear waste facilities application of the graded approach principle in STUK's regulation is described in Guide YTV 6.c. The Guide includes the definition of graded approach as well as procedures to be followed in different regulatory activities regarding nuclear facilities; licensing, review and assessment, inspections and in case an unanticipated operating event or incident occurs.

According to chapter 4.1 of YTV 6.c, the graded approach principle means that all factors that can contribute to nuclear or radiation safety are taken into account when deciding appropriate control measures. This principle shall be applied to both plant structures, systems and components (SSCs) as well as to processes and procedures. Risk is defined as the product of the consequences of an item's inoperability and the probability of such event. When applying the graded approach principle both consequences and probabilities should be assessed.

An item's inoperability refers to an event or state where the item does not fulfil its requirements (e.g. termination of the function, inadequate or erroneous function, wrong end product). Severity of consequences determines the safety class of SSCs.

The probability of inoperability of an item is dependent on its operational circumstances. Additional factors that may increase the probability are complexity, uniqueness and first of a kind (FOAK) of an item. Safety class of SSCs affects also the probability of inoperability, since higher safety SSCs have more stringent technical and quality requirements. By this way, an acceptable level of risk will be achieved for each item.

Safety classification cannot, however, take into account in advance all factors contributing to the overall risk. For instance, FOAK and complexity are such factors. Graded approach principle means that the other factors should be assessed too, when deciding the control measures, such as the review class of the subject. Review class (RC), in turn, determines depth of the review:

- RC1: detailed, full-scope review or inspection
- RC2: review or inspection is focused on safety-significant items
- RC3: spot-check review or inspection.

Application of the graded approach principle is further specified in several other discipline-oriented guides, such as

- Oversight activities related to electrical and I&C systems (guide YTV 3.a.2).
- Review of failure analyses (guide YTV 3.b.3).
- Oversight activities related to chemistry management (guide YTV 3.c.7)
- Oversight activities related to organizations (guide YTV 3.d)

Scope and focus areas of the review or other oversight activities are further specified for each review class in these guides.

Review and assessment of operating experience at domestic nuclear facilities (guide YTV 3.c.11) and the inspection of mechanical structures and equipment (guide YTV 4.b.2) are examples of STUK's oversight areas where quantitative risk metrics obtained from plant-specific PRAs are explicitly used as one of the inputs to determine the inspection (review) class.

Radiation practices:

Section 11 of SätL provides that when supervising compliance with obligations pursuant to the SätL, the regulatory body considers:

1) the nature and extent of the exposure situation;

2) the risks associated with radiation exposure and radiation sources;

3) the impact that the regulatory control may have in the reduction of risks and the improvement of radiation safety.

Application of graded approach in STUK's regulatory oversight of the use of radiation is explained in guide SKV 3.4 (Regulatory control of radiation activities requiring a safety license). In the application of graded approach principle, STUK takes into account e.g. nature of the activity, historical data of the operator, potential exposure, possibility of emissions, radiation safety deviations that have occurred, experience from previous supervision or evaluation of a new type of activity (guide SKV 3.4. chapter 7).

In the implementation of regulatory activities under the SätL, e.g. safety assessments are used, which are submitted by licensees as part of an application for a safety licence. The confirmation of the safety assessment is being addressed in guide SKV 3.2. appendix 11. According to section 14 of STUK regulation S/6/2019 the safety assessment must be revised at set intervals depending on the category of

radiation exposure. Otherwise, the graded approach is not widely used in review and assessment process (see answer to question 1.4).

Question 1.3 How does the Regulatory Body ensure that any reasonably practicable safety improvements identified in the reviews are implemented in a timely manner?

Response:

Nuclear Facilities

Follow-up of the implementation of identified reasonably practicable safety improvements is a central part of the overall safety assessment of nuclear facilities (see STUK's internal guide YTV 1.b). It is thus a regular process consisting of various activities where the progress of the licensee's plans to implement safety improvements are followed and if needed additional actions, including enforcement may be considered.

Typically, needs to consider safety improvements are identified in context to safety assessments (e.g. periodical safety reviews), evaluation of occurred events and operating experience at other facilities, periodic inspection programme, extraordinary or unannounced inspections or oversight exercised by resident inspectors. Depending on the type of source for the issue, the issue is recorded in STUK's information systems (Document handling (SAHA), event observations (HAKE), requirements handling (Polarion), inspection protocols, etc.), which initiates the process. After that the progress of the issue will be followed according to the procedures specified in YTV guides.

Most safety improvements will be handled sooner or later through STUK's document handling system SAHA process described in YTV 8.a. STUK's decisions and justification of the decisions are recorded at this system, including deadlines and responsible persons for the follow-up. SAHA also facilities linking of issues, which is an important property to manage interrelated issues and to follow the full history of the handling process, including communication with the licensee.

By the periodic inspection programme, all technical areas of the operation of NPPs are regularly controlled. One of the main topics in those inspections is to discuss the status of considered safety improvements. Such discussion should lead to a resolution of the issue (e.g. technical solution, time plan). Sometimes STUK may require remedial actions or impose a requirement for the licensee to submit a plan how to resolve the issue. These decisions always include a deadline for the licensee's response.

The requirements handling system Polarion is used for several purposes: fulfilment of regulation and regulatory guides, overall safety assessment, periodic inspection programme results, results of periodic safety reviews monitoring of open issues, dedicated oversight actions, operational events. Important features of Polarion are that it keeps the history and enables linking of items. As an example, an important context to assess the need for improvements has been the renewal of regulation and regulatory guides in 2010's. This process has meant that the licensee's of existing NPPs needed to assess how they fulfill the new requirements, whether safety improvements will be implement to fulfill the requirements or whether an exemption will be applied. The status of open issues is followed in Polarion.

A possible area to improve STUK's processes would be to better unify and describe the way of using Polarion. Currently, practices can vary a lot between different section and information is stored in several databases (though linking between databases is used).

An important forum to handle open issues, including implementation of safety improvements are the internal regular meetings where the statuses of the issues are followed, e.g., supported by the tools Polarion and SAHA. Regular meetings include facility specific oversight meetings, section meetings, dedicated oversight project meeting for major plant modifications, common operating reactor oversight meetings and common new reactor oversight meetings. Meeting discussion and decisions are documented in protocols

Another important forum are the bilateral meetings with the licensee, which can take place both at the management level or at technical levels related to specific issues, with the aim to resolve the issues. Such meetings are usually not used to make decisions but rather to exchange information and clarify issues.

Radiation practices:

According to section 177 of SätL STUK or an individual inspector thereof may obligate an undertaking to remedy their practice to such a state that it meets the requirements laid down in the SätL or Governmental Decrees (VnA 1034/2018 and STMA 1044/2018). The undertaking may furthermore be obligated to implement such measures to improve radiation safety as can be considered justified in terms of their quality and costs as well as their improving impact. STUK sets a time limit for the

implementation of the measures. The decision may obligate the undertaking to notify the remediation of the deficiencies and the measures undertaken due to the decision.

STUK supervises compliance with the deadlines set in the decisions and inspection protocols in accordance with the internal guides SKV 3.2 and 3.4. If necessary, the coercive measures set out in the internal guide 3.7 will be used. In this way STUK ensures that any reasonably practicable safety improvements identified in the decisions and inspection protocols are implemented in a timely manner.

Planning of regulatory activities in radiation practices sector, inspections, regulatory methods and control intervals take into account operational risks (principle of graded approach) and the effectiveness of regulatory activities. Operations are monitored with intensity based on risk and the effectiveness of regulatory activities throughout the operation. Regulatory activities during operations is targeted on a risk-based basis through various supervision projects. The selection for on-site inspections also takes into account the indicative intervals set out in the appendix of the guidelines, so that STUK maintains a sufficient understanding of the situation in the entire field. New or changed activities can be subject to an on-site inspection if the risks of the activity so require or it is otherwise difficult to form an overall view of the activity. In the case of high-risk activities, the safety authorization may even be conditional on the new or modified activity not being commenced before the inspection. See also response the primary question 5 of module 4.

Analysis

STRENGTHS FOR 06. REVIEW AND ASSESSMENT

S1	Finland has implemented the first principle of the Vienna declaration in legislation (Nuclear Energy Decree § 22b), and STUK has included in the regulatory guides more detailed and concrete interpretations for the principle (e.g. Guides YVL A.7 Probabilistic risk assessment and risk management of a nuclear power plant, YVL C.3 Limitation and monitoring of radioactive releases from a nuclear facility).
S2	Competent and experienced staff.
S3	Multidisciplinary in-house resources covering all main regulatory activities
S4	Competent and experienced technical support organization (VTT) to support regulatory oversight, review and assessment of nuclear facilities.
S5	Nuclear facilities: Overall safety assessment for focusing regulatory oversight supported. Oversight information from various topics collected in a database tool. Assessment and decision on re-focusing regulatory activities done in every four months.
S6	STUK has profound expertise regarding radon and NORM industries, For indoor radon STUK's expertise covers all the aspects: measurements and metrology, assessment of exposure and corrective actions.
S7	Review and assessment benefits from the SAMMIO guidance so that there is a better consistency and transparency in the results of the process.

S8	Initial investigation of indoor radon at workplaces is carried out with measurements over a period of at least two months. The results are corrected to take into account the seasonal variation. Additional investigation is carried out using continuous measurement over a period of at least one week and it takes into account the daily variation due to ventilation. This measurement approach reduces effectively errors in investigating radon at workplaces. There still may be unknown uncertainties (year-to-year variation, spatial variation) due to limited representativeness or insufficient amount of data obtained from workplaces but further improvements in the measurement approach are unlikely to be feasible.

WEAKNESSES FOR 06. REVIEW AND ASSESSMENT

W1	Nuclear legislation and requirements do not fully take into account new reactor types (e.g. SMRs).
W2	Regulatory procedures and guidance do not fully support graded approach in all regulatory activities, yet.
W3	Foreign material exclusion is not explicitly required, even if a general requirement for maintaining cleanliness and order in the nuclear power plant facilities exists.
W4	The representativeness of measurements (including sampling) upon which the STUK's decisions are based in NORM industry cannot be guaranteed.
W5	Guide SKV 3.2 Processing the safety licence on safety license processing is lacking guidance on reviewing and assessing some other core documentation (including those prescribed in VnA 1034/2018 annex 5 point 4) submitted by an applicant.
W6	Review and assessment of justification of medical exposure has challenges in assessing if appropriate referral guidelines are available, because there is no national guideline that would cover most of the diagnostic procedures in radiology and nuclear medicine. There are several topical and local guidelines of which some are outdated according to opinion of medical practitioners
W7	The current availability of RPEs or other experts with specific competence in NORM exposure assessment is very limited. In addition, there is no requirement that that assessments for determining whether authorization is needed for a practice involving NORM should be performed by a RPE or other expert with specific competence. Accordingly, STUK may need to give a lot of advice to the undertakings which may obscure the responsibilities between the authority and the undertaking.

OPPORTUNITIES FOR 06. REVIEW AND ASSESSMENT

O1	Increased risk informed grading enables better focusing of limited resources to risk significant areas.
O2	Development of nuclear legislation and regulatory requirements enables more streamlined licensing of various reactor types, transition between different phases of facility lifecycle and enhances better risk informed utilization of limited resources.
O3	Increased use of digitalization and tools could enhance regulatory work.
O4	STUK could increase co-operation and enhance wider utilisation of multidisciplinary resources.

O5	There is a working cooperation between different authorities in regulating the exposure to radon. Further exchange of information is considered beneficial, including training and development of risk communication.
O6	STUK has been an active participant in international R&D projects where new information on radon and NORM risks is gathered and new measurement methods are developed (MetroRADON and RadoNORM). These results should be efficiently taken into regulatory use. Further actions should be planned to ensure the continuation of R&D activities.
O7	A national referral guideline on medical exposure could be integrated to existing IT systems in medical centers. Such a guideline could support decision making on justification of diagnostic imaging. (Report STUK-B 273).
O8	By developing further SAMMIO guidance the consistency and transparency of the review and assessment of radiation practices will continuously improve.

THREATS FOR 06. REVIEW AND ASSESSMENT

T1	The present requirements have been written for large light water reactors that are meant for electricity production and are situated in relatively remote areas. The present requirements may be challenging for other technologies or business models that may emerge e.g. with deployment of SMRs.
T2	Loss of competence in certain special areas in the future (motivation, funding, availability of experts)
T3	Re-focusing of regulatory oversight and activities may lead to gaps in nuclear safety. A follow-up process needs to be developed.
T4	New goal-oriented legislation and requirements may lead to subjectivity in review and assessment.
T5	In NORM industry the training of RPEs is not yet at the required level. During this transition period STUK gives consultancy to practitioners and in the long run this may obscure the responsibilities between authority and the undertaking.
T6	Justification of medical exposure might not be adequately in place if a national referral guideline is missing.
T7	Currently STUK has profound expertise regarding radon and NORM industries. However, research and development activities are essential for maintaining and developing this expertise also in the future. This requires appropriate funding.
T8	STUK's expertise concerning non-water-cooled technologies is not as extensive as its expertise of light water technology.

CONCLUSIONS FOR 06. REVIEW AND ASSESSMENT

C1	Upcoming renewal of the regulations and regulatory guides enables more risk-informed and flexible way for oversight and highlights the responsibility of the licensees. At the same time, care must be taken not to neglect safety significant areas and to avoid subjectivity in review and assessment.
C2	SMRs are an emerging technology, not yet fully covered by the present legislation and regulations or by STUK's expertise. STUK is preparing for potential license

	applications by building its competence and taking SMRs into account in the renewal of the regulations and regulatory guides.
C3	The development of methods, tools and procedures related to graded approach has progressed well. However, further development is still needed to cover all main regulatory activities.
C4	STUK's overall safety assessment concept has proven to be a good platform for cross-disciplinary discussions and for supporting decisions making. It also provides means for the identification, categorization and tracking of regulatory issues.
C5	There is a lack of radiation protection experts with specific knowledge of NORM exposure assessments available to practices involving NORM. Additionally, there are no competence requirements for persons conducting assessments for determining whether a practice involving NORM requires a safety license.
C6	STUK has profound expertise regarding radon and NORM industries. However, research and development activities are essential for maintaining and developing the expertise also in the future.
C7	A national referral guideline for diagnostic imaging is missing.
C8	The review and assessment process for radiation practices does not fully apply a graded approach. A project has been launched to identify means to enhance the application of a graded approach.

Module: 07. Inspection

Findings

Question 1 Does the regulatory body carry out inspections of facilities and activities to verify that the authorized party is in compliance with regulatory requirements and the conditions specified in the authorization?

Answer: Yes

Response:

Nuclear Power Plants and other Nuclear Facilities (YEL)

STUK has a mandate to carry out independent inspections of facilities and activities. According to the Nuclear Energy Act (990/1987), STUK is responsible for the regulatory oversight of the safety of the use of nuclear energy. Based on Section 63 of the Nuclear Energy Act STUK has right to inspect and control operations in nuclear facilities and for this purpose have access to any place where such an operation is being carried out, as well as to carry out measurements required for supervision, to take and to receive samples and to install equipment necessary for such supervision.

STUK has implemented Periodic Inspection Program for the inspection of nuclear power plants and nuclear facilities. Periodic Inspection Program has been developed to inspect different areas and activities of the licensee and that covers all relevant areas of nuclear safety and security. The

inspections included in the Periodic Inspection Programme concern the licensee's operations that are important to safety. The program and the procedures to be followed in its implementation are described in STUK's internal guide YTV 4.a.1.

Radiation practices (SätL)

According to SätL(859/2018) 176 §, STUK has, for the purpose of supervision of compliance with the Act, right to inspect the facilities and activities that are subject to the Act. This includes the right to access the facility in which the practice is engaged. According to 11 § of the Act, when supervising compliance with obligations the regulatory authority accounts for risks and considers:

1) the nature and extent of the exposure situation;

2) the risks associated with radiation exposure and radiation sources;

3) the impact that the regulatory control may have in the reduction of risks and the improvement of radiation safety.

The 182 § of SätL(859/2018) states that STUK draws up an inspection programme concerning the inspections of practices subject to a safety licence. The objectives and the contents of the inspection programme are stated in 57 § and 58 § of VnA (1034/2018). In STUK, the inspection programme is a combination of several documents. The general principles for inspections are given in Guide SKV 3.4. The guide depicts different kind of inspections and other measures for supervision. Also in the guide, the suggested intervals for inspections of different kinds of practices are presented. The suggested intervals are based on, for example, the associated risk of the different practices. In the guide, also the concept of thematic inspections and supervision measures are introduced. The thematic inspections focus on a more specific topics and are planned and conducted so that they have high effectiveness in radiation safety. In addition to the Guide SKV 3.4, departments and units performing the inspections have more specific SKV guides and other documents concerning programmes for inspections. These guides include guidelines on how to conduct the inspections, starting from the selection of the sites to be inspected and planning of the inspection trip to measurement guidelines and inspection reports.

After an inspection, an inspection report is made and sent to the licensee. The framework for the report is given as an attachment of the Guide SKV 3.4. The report contains all the relevant findings and measurement results related to radiation safety and the report is saved in our register. Any deficiencies are, in addition to the report, separately saved in the register with the possible deadlines for corrective actions. If deficiencies are found the measures for actions and enforcement methods are depicted in Guides SKV 3.4 and 3.7. The methods vary from stating the deficiency to suspending the use of radiation. The selected method depends on the severity of deficiency in relation to radiation safety.

According to the 183 § of SätL(859/2018), STUK uses the findings from the inspections to develop its supervision processes and reports them to the licensees, other authorities etc. when necessary. For example, the findings are used to determine future themes for inspections.

Question 1.1 How does the regulatory body ensure that regulatory inspections do not diminish the authorized party's prime responsibility for safety and do not substitute for the control, supervision and verification activities conducted under their responsibility?

Response:

Nuclear Power Plants and other Nuclear Facilities (YEL)

The responsibility for the safety rests with the licensee or the authorized party as prescribed in in section 22 of the Radiation Act (859/2018) and in Section 9 of the Nuclear Energy Act. Accordingly, it is the licensee's obligation to assure safe use of radiation and nuclear energy. Furthermore, it shall be the licensee's obligation to assure such physical protection and emergency planning and other arrangements, necessary to ensure limitation of radiation and nuclear damage, which do not rest with the authorities. It is the responsibility of the regulatory body to verify that the licensees fulfill the regulations.

As part of its verification activities, STUK emphasizes the licensee's commitment to the strong safety culture. The obvious elements of licensee's actions to meet these responsibilities are strict adherence to regulations, prompt, timely and open actions towards the regulator in abnormal situations, and active role in improving the safety. According to Section 7a of the Nuclear Energy Act the safety of nuclear energy use shall be maintained at as high a level as practically possible. For the further development of safety, measures shall be implemented that can be considered justified considering operating experience and safety research and advances in science and technology.

Regarding qualification process of safety classified components and structures, YVL Guides have policy which requires that the licensee has done own control, supervision and approval before STUK or Authorized Inspection Organizations starts own inspection process. Guide YVL E.3 gives stipulations:

- YVL E.3 702:The licensee shall approve the construction plan of nuclear equipment in compliance with Guide YVL A.1 and draw up a summary of justifications described in chapter 7.2 of present Guide, before submitting the construction plan to STUK or an authorised inspection body.

- YVL E.3 912: The licensee, the manufacturer and, in plant projects, the plant supplier shall establish the conformity to requirements of the equipment before the construction inspection by STUK or an authorised inspection body.

If licensee's justification for construction plan is insufficient or lacking STUK will require clarification (see Guide YTV 8.a) before continuing inspection process. Precondition for construction inspection of STUK is that manufacturer and licensee have done their own inspections and approval (see Guide YTV 4.b.2).

Radiation practices (SätL)

The section 22 of the SätL(859/2018) states that the undertaking is responsible for the radiation safety of the practice and the responsibility cannot be transferred to another. The section also adds that the obligations imposed on undertakings are not diminished by the appointment of a radiation safety officer or some other person in charge or by the use of experts in the operations. The section 23 of the SätL (859/2018) also states that the undertaking must organize its activities so that it fulfills the requirements given in the legislation. The undertaking must also ensure that it has all the needed expertise and resources to conduct its radiation practices safely.

Question 1.2 What types of inspection does the Regulatory Body perform, and what criteria determines which inspections are performed and when?

Response:

STUK has established inspection programs that cover both the nuclear facilities and other users of radiation sources.

Nuclear Power Plants and other Nuclear Facilities (YEL)

STUK has established periodic inspection program for the inspection of nuclear power plants and nuclear facilities. The periodic inspection program covers all relevant areas of nuclear safety and security. Each year (or half year in case of RTO/RKT-programs) STUK defines the program for the inspections that are planned to be conducted. The plan of inspections is submitted to the licensee's and license applicants. Periodic Inspection Program may be supplemented later with ad-hoc inspections during the year if deemed necessary.

Typically, inspections are announced to licensees in advance, but inspections can also be unannounced. Unannounced inspection is considered if the prior announcement is considered to affect the outcome of the inspection. The purpose of an unannounced inspection is to verify the licensee's activities and to obtain a sample of the licensee's activities and situation at a given moment and without the licensee's preparation.

Reactive inspections can be carried out when necessary. Reactive inspections are considered when there has been a safety significant plant event or significant deviation from safety related issues. The conduct of a reactive inspection must always be based on a judgement about the effectiveness of the inspection. The timing of a reactive inspection should also be carefully considered so that it does not overly influence the management or follow-up of the situation for which the licensee is responsible. The criteria to conduct reactive inspection is described in STUK's internal guide YTV 4.a.1 chapter 4.1.3.

The program and the procedures to be followed in its implementation are described in STUK's internal guide YTV 4.a.1. The Periodic Inspection program consist of the following programs:

- Construction License Inspection Program (RKT)
- Construction Inspection Program (RTO)
- Operation Inspection Program (KTO)
- Authorized Inspection Organizations Inspection Program (TTO)

Construction License Inspection Program (RKT) is an inspection program for nuclear facilities license applicants. RKT is focused to assess construction license applicant's management system and project-specific procedures, as well as their implementation and effectiveness in planning, supervising and directing the construction project. The inspections verify that the management system's procedures and instructions related to safety and quality management meet the set YVL guidelines and that the license applicant complies with these procedures and instructions in its operations. During 2021 RKT inspections have been carried out to inspect Hanhikivi NPP project. RKT-inspection is described in STUK's internal guide YTV 4.a.1.

Construction Inspection Program (RTO) is an inspection program for nuclear facilities under construction. RTO is focused verify that the functions required for the construction of the plant ensure high-quality and approved implementation in accordance with official regulations and without endangering the plants on site during the various phases of the construction project. During 2021 RTO inspections were carried out on Posiva spent fuel facility.

Operation Inspection Program (KTO) is the periodic inspection program for operating nuclear facilities. KTO is focused on the licensee's main working processes and covers management and organizational aspects, broad overlapping processes (such as assessment and improvement of safety, safety functions, PRA, ageing management, operational safety, radiation protection and emergency preparedness) as well as detailed technical issues. During 2021 KTO inspections were carried out in Olkiluoto NPP units 1, 2 and 3 and Loviisa NPPs. Related to KTO see also "Facilities and Activities - Regulation of Nuclear Power Plants" primary question 5.

In KTO, RTO and RKT inspections the size of the STUK's inspection team is typically 3-5 persons. Resident inspectors are recommended to take part to inspections however it is not necessary. Inspections are typically performed in 2 or 3 days depending on the inspection type and scope. The inspections are typically held at the plant site. However, because of the recent pandemic situation most of the inspections since March 2020 have been executed fully or partially (as so called "hybrid"-method) remotely using suitable teleconference software. The experiences with remote and hybrid inspections have been largely positive, however they don't cope with all inspection areas.

The aim of KTO, RTO and RKT inspection is to assess the licensee / license applicant's procedures and the adequacy and appropriateness of the activities in the inspection area against the safety requirements. The means of assessment include interviews, questionnaires and observation of practical activities, evaluation of pre-assigned tasks and other material related to the inspection area, and familiarisation with the licensee's processes and operations. STUK's assessment of the fulfillment of safety requirements should be based on the evaluation and verification of practical activities. Inspection results including possible requirements for remedial actions are consisted into inspection protocol, which is submitted to the licensee within a formal STUK decision. In addition, the inspection findings are entered into the STUK's oversight process, which assesses the overall safety of nuclear power plants. The assessment of the overall safety of nuclear power plants is dealt with in guide YTV 1.b.

In addition to "heavier" inspection types (KTO, RTO, RKT) there is also "lighter" inspection type called KV-inspection (Operation Surveillance inspection). The aim of the KV-inspection is to inspect the licensee's activities as part of STUK's oversight work and document the inspection findings. The inspection scope is typically limited as such that the inspection could be carried out in one working day. The inspection findings are reported to the licensee in official manner by using STUK's electrical protocol software "STARE". For observed non-conformances it is possible to give out requirements for corrective actions. KV-inspections are typically used to supplement inspection activities under the Operation Inspection Program (KTO). KV-inspection is described in STUK's internal guide YTV 4.b.1.

STUK issues YVL Guides that require performance of detailed regulatory inspections for certain areas (construction, manufacturing, installation and commissioning inspections, outage inspections, operator

competence). These technical inspections supplement other regulatory inspections by giving STUK detailed knowledge of safety related systems, structures and components. The inspection process on mechanical components and structures of nuclear facilities is described Component specific YVL-guides (E-series), which give stipulations for construction inspection of components (e.g. YVL E.3 1517). In construction inspection it is ensured that component has been manufactured, installed, modified or repaired in accordance with the approved construction plan and approved procedures, and that the inspections and tests have been carried out on them in accordance with the construction plan. Internal guide to conduct construction inspection is given in Guide YTV 4.b.2 (Inspections of mechanical equipment and structures). Inspection of mechanical equipment is commensurate with the risk caused by loss of serviceability (integrity and performance) of the device. Internal guide YTV 4.b.2 Annex 4 gives grading scope and manner according to which the construction inspection is performed by STUK. During construction inspection STUK inspector may enlarge the scope of inspection when shortcomings in manufacturing are discovered.

At the present STUK carries out inspections of mechanical components and structures mainly in safety classes 1-2. Lower safety classes are given by the decision of STUK to the responsibility of approved Inspection Organizations. Based on Section 60a of the Nuclear Energy Act and Guide YVL E.1 STUK approves Authorized Inspection Organizations (AIO) to their duties to inspect the compliance of the design and manufacture of mechanical components and structures of nuclear facilities as well as to carry out inspections during operation. AIOs are accredited (EN ISO/IEC 17020 Type A) by FINAS and STUK participates in the accreditation process conducted by FINAS as a technical assessor. STUK has a specific Inspection Programme (TTO) for inspection of the authorized Inspection Organizations. The purpose of the TTO-inspection program is to ensure that the activities of the AIO is high quality and meet the regulatory requirements during the period of validity of the AIO licenses. TTO-inspection is described in STUK’s internal guide YTV 4.a.3.

At the present commissioning inspections of safety-classified electrical or I&C systems, equipment or cables are performed by licensee as stated in YVL Guide E.7, Electrical and I&C equipment of a nuclear facility, Chapter 7.4. However, as stated in YVL E.7 requirements 1007, STUK may perform at its discretion its own commissioning inspection of electrical and I&C systems and equipment. As stated in requirement 1008, STUK specifies the systems whose commissioning inspections it will conduct during the pre-inspection of electrical and I&C systems. Commissioning inspections are reported to the licensee by electronic STARE-protocol.

Radiation practices (SätL)

The types of inspection are stated in Guide SKV 3.4. According to the guide inspections concern all practices that require a safety license. The guide does not, however, apply to practices where the exposure is due to natural sources, except for airlines.

According to the guide the inspections can be announced beforehand, or they can be unannounced. For an unannounced inspection, there must be a reason related to the goals of the inspection. For example, if there is a suspicion that the practice does not correspond to the safety license and the shortcomings would not be revealed if the inspection would be announced.

Most of the inspections are programmed or planned. The inspections can be targeted at different phases in the activity of the licensee. Some inspections are related to completely new practices or license holders, or to newly installed devices or sources with possibility of high exposures or risks. Some of these inspections are carried out before the practice can begin. Most of the inspections are so called in-service inspections that are conducted periodically during the normal operational phase of the licensee. When the undertaking has possessed radioactive sources, a decommission inspection may be conducted if seen necessary. STUK also conducts reactive inspections. The need for a reactive inspection can arise if it comes to STUK's knowledge that there are deficiencies in safety that require an inspection on site. These can stem, for example, from a major radiation safety deviation or a notification related to radiation safety.

When planning the inspection (who to inspect, what areas to concentrate on, type of inspection) a graded approach is applied. In an attachment of the guide suggested inspection intervals are presented. Practices with higher risks are inspected more often. Some of the inspections are conducted within supervision projects. In the projects, the whole practice of the licensee is not necessarily inspected, but the inspection is focused on more specific part of the practice. The topics of the projects are chosen based on the risk and possibilities for improvement and effectiveness. Typically, in addition to an inspection report, a project report of the whole project will be published. That way also the licensees that were not inspected during the project can improve their practice based on the findings and conclusions of the project.

One additional method for supervision are surveys. The surveys can be part of supervision projects and linked with the inspections. For example, a survey can be sent to all licensees with specific activities and the licensees to be inspected can be selected based on the answers on the survey. As the surveys are part of supervision by the authority, replying to the survey is mandatory.

The supervision of the use of dental intraoral devices differs from other activities. They are based virtually only on surveys and postal packages, which contain a pair of TLD crystals and an x-ray film to be radiated. The instruction is to use same imaging parameters as in normal bite-wing examinations. The package is to be shipped back to STUK to be analyzed. The radiation dose is determined from the crystals and the film is used to detect other deficiencies with the device. If deficiencies are detected or unusually high doses are measured, corrective actions are required. If seen necessary, an inspection of the activity may be carried out.

Analysis

STRENGTHS FOR 07. INSPECTION

S1	STUK has competent resources to do all necessary inspections at nuclear facilities. Due to STUK approved inspection organizations, STUK has also ability to get necessary additional resources for situations where there are too many inspections for STUK at nuclear facilities.
S2	Regarding to Nuclear Facilities (YEL): STUK approved inspection organizations (mech.) are all accredited according to EN ISO/IEC 17020 and competent
S3	Good safety culture in all organizations involved in ensuring safety of nuclear facilities.
S4	STUK YVL-guides contain all necessary inspection requirements in one place.
S5	Regarding to Nuclear Facilities (YEL): Periodic inspection programs systematically and regularly cover all areas relevant to safety.
S6	Separate inspection programs for all stages of the nuclear facility's life cycle (RKT, RTO, KTO).
S7	Graded approach used in targeting inspections of radiation practices; for example different methodologies are used and on-site inspections to low risk areas are carried out only in rare cases (for example for dental radiography).
S8	There is working co-operation between different authorities concerning radon in workplaces, NORM industry and radioactivity in construction material.

WEAKNESSES FOR 07. INSPECTION

W1	Regarding to Nuclear Facilities (YEL): There is no qualification or training program for persons responsible for the inspection of the periodic inspection program for nuclear facilities (lead inspector).
W2	Inspections for occupational exposure to radon are solely based on measurements and reports made by employers/property maintenance. There is not always certainty that measurements represent appropriately the working areas relevant to radon exposure which may lead to false conclusions on the need for further action.
W3	The current inspection programme for radiation practices is a combination of several documents at department and unit levels. However, there is no clear prescription which of the documents form the inspection programme referred to in Section 182 of SätL and take in account the requirements of Sections 57 – 58 of VnA.

OPPORTUNITIES FOR 07. INSPECTION

O1	Regarding to Nuclear Facilities (YEL): Enough competent inspection organizations to make construction inspections would enable STUK to concentrate more to regulatory control if necessary
O2	Technical innovations enable to develop new methods for inspections e.g. remote inspections
O3	There is strong ambition to harmonize inspection requirements internationally (SMR)
O4	Regarding to Nuclear Facilities (YEL): Remote inspections are also an option in the future. Internal guidance is missing.

O5	Practices for NORM industry are still evolving and there are more possibilities for new inspection methods (such as remote inspections).

THREATS FOR 07. INSPECTION

T1	Regarding to Nuclear Facilities (YEL): Harmonization of inspection requirement internationally may lead to reduction of inspections. This may reduce efforts in ensuring the essential local safety aspects by actual physical inspections instead of quality certificates.
T2	Regarding to Nuclear Facilities (YEL): As experienced inspectors quit or retire, the quality of inspections may decline. There should be qualification program for new persons responsible for the inspection of the periodic inspection program (lead inspector).
T3	Remote inspections have been carried out during the pandemic. Inspections have mainly provided good experience. However, some aspects are lost when not being on site. Thus, remote inspections cannot completely replace on-site inspections and an adequate presence at the facility shall be provided. This can be applied to manufacture audits and inspections as well.
T4	Regarding to Nuclear Facilities (YEL): There is too often tight time schedule from licensee for construction inspections

CONCLUSIONS FOR 07. INSPECTION

C1	Finnish legislation and STUK's inspection process is inline with IAEA requirements. However, some areas for improvement have been identified and are presented in the "ACTION PLAN FOR MODULE 7" section.
C2	STUK has enough resources and resources are competent to do all necessary inspections at nuclear facilities.
C3	Regarding to Nuclear Facilities (YEL): Inspections systematically and regularly cover all areas relevant to safety.
C4	For workplace radon inspections the employers carry out the measurements independently. This enables good coverage of inspections but causes uncertainty on whether the measurements represent appropriately the working areas relevant to radon exposure.
C5	There is no clear prescription which management system documents form the inspection programme referred to in SätL.

Module: 08. Enforcement

Findings

Question 1 Has the regulatory body established and implemented an enforcement policy, within the legal framework, for responding to non-compliance with regulatory requirements or with any conditions specified in the authorization?

Answer: Yes

Response:

Finnish enforcement policy covers GSR Part 1 requirements 30 and 31.

The procedures used in the enforcement of regulatory requirements are based on the mandate of the regulatory authorities given in the legislation. The enforcement tools and measures of STUK are provided in Chapter 10 Sections 64-67 of the Nuclear Energy Act (990/1987) and in various sections of SätL (859/2018), e.g. Chapter 20, Sections 40, 46, 50, 53, 65 and 84. Based on above mentioned legislations STUK has a mandate to implement enforcement actions to respond observed non-compliances. The enforcement policy and practices in general are presented in Guide STUK 3.1. Enforcement actions are implemented based on severity of non-compliance by using graded approach.

STUK's internal Guide YTV 5.a gives more detailed enforcement policy regarding nuclear power plants and nuclear facilities. See also primary question 6 on Self-assessment for Facilities and Activities and Exposure situations - Regulation on Nuclear power plants.

Guide SKV 3.7 gives more detailed enforcement policy regarding the use of radiation.

Question 1.1 How does the regulatory body ensure that the response to non-compliances is commensurate with the significance of the safety of the non-compliance?

Response:

The choice of procedure applied in non-compliances is primarily based, following the principle of graded approach, on the safety significance of the non-compliance where correction has been required. The more significant the non-compliance is, the stronger the authority's intervention in the situation is justified (so-called proportionality principle, see Guide STUK 3.1). The assessment is also influenced by the licensee's operating history, level of previous operations and trend. An enforcement procedure should be initiated when the activities of the licensee involve a significant safety related non-compliance.

<u>Nuclear Power Plants and other Nuclear Facilities (YEL)</u>

The instructions for evaluating the safety significance of the non-compliance are described in section 4.1.2 of Internal management system guide for nuclear safety YTV 5.a. The following factors, among others, may be taken into consideration when selecting a procedure:

- a proven neglect or disregard of the licensee or other responsible party have contributed to the origin of the non-compliance
- actions have not been taken to correct the non-compliance although the licensee has been aware of the it
- the means applied to correct the non-compliance have been inefficient
- licensee has attempted to conceal the non-compliance from the authorities
- regulatory authority discovers the deviation
- the situation has occurred for reasons which are independent from the licensee.

The applied procedures in non-compliances which have minor safety significance are oral notice and request for action by a protocol made by the inspector. Oral notice is used in situations where the deficiencies are minor, and the situation is demonstrably rectified immediately in the presence of the inspector. A written request for action is used when the deficiencies found are not minor, or are minor deficiencies that cannot be remedied immediately, or the oral notice has not been complied with. Otherwise, the situations in which the request for action is used are similar to those for an oral notice, but the matter is brought to the attention of the licensee by a protocol (letter of formal notice).

STUK inspector has right to suspend the performance of an individual function if safety so requires (for example, carrying out work on the site contrary to the instructions). Interruption of the operation is typically made by written request unless there is a minor deficiency that is rectified immediately when oral notice could be used.

The usage of written request for action protocol has been limited to just a few cases in recent years. In most situations oral notice has been effective to handle minor deficiencies.

In case of more severe deficiencies, enforcement actions are implemented by a written decision by STUK. By written decision STUK may require licensee to execute necessary changes in the structure and operation of a nuclear facility (as stated in Section 64 of YEL) and to implement remedial actions (Section 65 YEL). These provisions require STUK to oblige the licensee to take the necessary measures and, if necessary, to provide the licensee with appropriate instructions to clarify the situation.

In addition, if an imminent danger is involved in the case of an irregularity under sections 64 or 65 of YEL, the activity may be suspended or restricted under section 67 of YEL (so-called imminent

administrative penalty). If necessary, the decision prescribes the operating status of the nuclear facility, for example: the operation must be shut down, the operation must not be started up or its power level or similar restrictions changed, before STUK has dealt with a separate application by the license holder.

According to section 66 of the YEL, STUK may intensify its order referred to in section 64 or 65 by a conditionally imposed fine (see 14.12.1990/1113). Other coercive measures legislated in the Nuclear Energy Act are a threat to interrupt or limit the operation or to have the neglected obligation fulfilled at the expense of the neglecting party. However, conditionally imposed fine has never been used as enforcement tool at nuclear facilities in Finland. The use of section 67 based threat to suspend operation has been adequate action, thus it has not been needed to put conditionally imposed fine in place.

The licensee has a right to appeal against the decisions made by STUK. The written appeal shall be sent to Helsinki Administrative Court. The appeal must be applied within 30 days of notification of the decision.

STUK may request official assistance from the police if the operator does not comply with an order issued by STUK (YEL 68 § and 68a §). Assistance may be requested to provide official assistance if the licence holder/operator, for example, does not allow an inspector to enter the place where activities related to the use of nuclear energy are carried out or otherwise obstructs the exercise of the right of supervision provided for in

Section 63 of the Nuclear Energy Act.

In certain cases, the act may also fulfill the characteristics of a radiation offence or an offence punishable under the Criminal Code under the criminal reference provision of the Radiation Act. The criminal investigation of such cases is not the responsibility of STUK and its officials, but of the police authorities, and any prosecution is the responsibility of the public prosecutor. However, it is up to STUK to make an initial assessment of the case and, on that basis, to address a request for investigation to the police authority.

<u>Radiation sources (SätL)</u>

The procedures used in the enforcement of regulatory requirements of the SätL are based on the mandate given by the legislation. The enforcement tools and means provided to STUK are presented in various sections of the SätL.

The duty to commensurate enforcement actions based on graded approach when supervising compliance with obligations is mandated in SätL, Section 11. When supervising compliance, the STUK considers:

1. the nature and extent of the exposure situation;

2. the risks associated with radiation exposure and radiation sources;

3. the impact that the regulatory control may have in the reduction of risks and the improvement of radiation safety.

Furthermore, Administrative Procedure Act (434/2003) Section 6 states that the acts of an authority shall be impartial and proportionate to the objectives sought. These acts shall protect expectations that are legitimate under the legal order.

The most important enforcement actions are (order here is based on ascending Sections of SätL):

- STUK may withdraw a radiation safety expert's approval or prohibit them from acting as a radiation safety expert if the radiation safety expert fails to meet the qualification criteria or if the advice provided to the undertaking by the radiation safety expert has been essentially incorrect and the expert has failed to remedy the deficiencies within a reasonable period of time despite a request to do so (Section 40).
- STUK may withdraw the approval of a radiation protection training (of an RPO) if the prerequisites for the approval cease to exist or if material deficiencies are observed in the provision of the training, and such deficiencies are not remedied within a prescribed period of time despite a request to do so (Section 46).
- In case STUK has exempted a practice from safety license, the decision can be withdrawn if the prerequisites for exemption are not met or if the conditions for exemption have not been complied with and the deficiencies are not remedied within a prescribed period of time despite a request to do so (Section 50).
- STUK may withdraw the safety license (Section 53).
- STUK may withdraw the approval of other radiation measurements (Section 65).
- STUK or an individual inspector may obligate an undertaking to remedy their practice (Section 177).
- The undertaking may be obligated to implement other radiation safety measures (Section 177).

- STUK may decide on the discontinuation or restriction of a practice (Section 178). In urgent cases an inspector can make this decision.
- STUK may also enforce a decision it has made or a prohibition it has given with a notice of conditional fine or at the threat of having a neglected measure taken at the defaulter's expense, or suspending the practice or prohibiting the use of the radiation source (Section 184). The conditional fine can also be imposed to enforce a duty to provide information and obligation to present documents.

STUK may also use the rights given in Act on the Market Surveillance of Certain Products (1137/2016) when enforcing the sales of radiation sources for both occupational and public exposure (sources used in e.g. industry as well as consumer products). STUK may prohibit a legal or natural from manufacturing, importing, exporting, transferring, placing on the market, offering, keeping for sale, selling or otherwise handing over the product that may cause a significant detriment to health.

In addition to administrative enforcement measures it is possible to get assistance from police in a situation where a STUK inspector interrupts an activity or limits it based on acute safety reasons (SätL Section 180).

It is the inspector's duty to follow through any binding enforcement action. These duties are described in internal guidance, STUK 3.1 and SKV 3.7. Enforcement actions are recorded in STUK's document management systems including dates for reporting remedial actions.

The practical methods of enforcement and the basis for choosing them are described in more detail in STUK's internal guidance STUK 3.1 and in more detail SKV 3.7 (for the use of radiation). A summary of the enforcement actions and their basis that are described in internal guidance is presented here:

Implementing measure	Typical situation
Reminder	Failure to comply with the statutory obligation to notify STUK
Request for clarification	Often the first action when you become aware of a deviation or suspicion of such a deviation. Used when more detailed information is needed.
Obligation to correct a non-compliance	
Entry in the control register	The deviation is very small and non-urgent from a safety point of view or requires monitoring and possible development before it is raised with the operator.
Notification to the operator	The safety significance of the deviation is not high, and the operator can be expected to correct the non-compliance without an appealable binding decision
Request to correct the deviation	When an operator can be expected to correct the non-compliance without an appealable binding decision, but a deadline should be set for taking corrective action.
Appealable binding decision	The deviation is significant from a safety point of view, the operator has previously failed to correct the non-compliance or, or there is reason to suspect that the operator may not otherwise correct the deviation.
Suspension or restriction of operations	When the activity is not in accordance with the SätL or it may cause obvious adverse health effects.
Revocation of a safety license	When the conditions for granting a license are not met or the licensee has repeatedly or essentially violated the conditions of the license or the provisions or regulations issued pursuant to the SätL.
Revocation of a decision to exempt a practice from safety license	If the conditions for the exemption are not met or the conditions of the exemption are not followed.
Imposition of a product ban	The product causes significant damage to health.
Imposition of an order or prohibition on a product	The product or product documents or information do not comply with the requirements or are not provided to STUK upon request. Under normal and reasonably foreseeable conditions of use, the product may pose a risk to human health, safety, the environment, property or other public interest.

Revocation of approval of a Radiation Safety Expert	The radiation safety expert does not meet the qualification requirements, or the advice given to an operator has been essentially incorrect.
Withdrawal of training approval (for an RPO)	The conditions for approval cease or significant deficiencies are found in the training.
Revocation of approval of dose measurement service and radiation measurement	If the conditions for approval are not met, there are significant deficiencies in measurements, or the operation does not otherwise meet the requirements laid down in SätL.
Setting a conditionally imposed fine or a threat of commissioning or suspension	Set in conjunction with an appealable binding decision. The imposition is to be considered if there is a significant or urgent non-compliance or if there is reason to suspect that the operator will not otherwise comply with the decision and if the operator has not complied with a previous decision.

Analysis

STRENGTHS FOR 08. ENFORCEMENT

S1	High technical expertise in STUK to evaluate necessary actions.
S2	Usage of the Safety Group for discussions and suggestions on acceptable solutions to be included in formal enforcement decisions regarding NPPs. The Safety Group consists of experienced experts of various technical areas and the deputy directors of Nuclear Reactor Regulation department.
S3	STUK has not needed to use the strongest enforcement actions on NPP licensees, and also very seldom on radiation practices. The most usual enforcement action is a written decision with requirements, for example, on the modification of the plants or regarding operation of the plant. In most cases, STUK's expectations are implemented as such. In some cases, especially in case of NPP licensees, implementation may be supported by discussions and meetings between STUK and licensees to ensure progress of improvements.
S4	Presence of resident inspectors at the NPPs. Based on the findings, the resident inspectors are able to quickly provide feedback to the licensee and an order to correct the deviation (oral notice or a written request for action by a protocol).
S5	STUK has experience and well-working processes for enforcing the necessary actions for limiting the occupational exposure to radon.
S6	SätL provides for a comprehensive set of mechanisms for enforcement and STUK management system documents define clear policies and procedures for their systematic, consistent and risk- based implementation.

WEAKNESSES FOR 08. ENFORCEMENT

W1	There is no process nor methodology to evaluate safety culture in radiation practices. Accordingly, the requirements of SätL on safety culture are not systematically controlled nor enforced.
W2	Although the undertaking for radiation practices is accountable for remedying non-compliances and implementing measures to improve radiation safety, there are no specific requirements for performing a thorough investigation on their reasons and for taking measures needed to prevent re-occurrences. Such requirements exist for radiation safety deviations, but not for non-compliances in general.

OPPORTUNITIES FOR 08. ENFORCEMENT

O1	STUK is implementing strategic change of regulatory oversight. As part of this STUK's goal is to emphasize licensee responsibility even further and to develop oversight that it would take more in count licensee activities and good performance. As part of this work STUK has to

	evaluate the use of enforcement actions, clarify when and how specific enforcement action should be used and enhance the overall use if evaluated effective.

THREATS FOR 08. ENFORCEMENT

T1	STUK has no real experience on using strong enforcement actions on nuclear facility licensees. This may result in over cautiousness in demanding of prompt response and results from the licensees, which consequently may lead to slow progress in specific improvements.

CONCLUSIONS FOR 08. ENFORCEMENT

C1	Finnish legislation and STUK's internal guidance fulfil IAEA requirements but some further improvements are identified.
C2	Regarding radiation practices, there are no specific requirements for performing thorough investigations on the reasons of non-compliance and for taking measures needed to prevent their re-occurrences.

Module: 09. Regulations and Guides

Findings

Question 1 Has the regulatory body established or adopted regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based?

Answer: Yes

Response:

Legal basis for regulations and guides

The principles, requirements and associated criteria for safety upon which regulatory judgements, decisions and actions are based on are laid down in international obligations (treaties and EU legislation) and domestic legislation which includes acts, decrees and STUK regulations. All these legally binding domestic legal instruments are accompanied by rationales that further elaborate their purpose and guide in their application. The rationales are recognized as a source of law, but they are formally not legally binding. The rationales are in forms of government proposals and parliamentary committee material for acts and preparatory/explanatory memorandums of the issuer for decrees and regulations.

STUK has issued such rationales for its own regulations. STUK has also had a strong influence on the rationales in Government's proposals and decree memorandums due to STUK's strong expertise on radiation and nuclear related questions and experience as a regulatory body.

STUK regulations are legally binding instruments that further specify the principles, requirements and associated criteria within the mandate that has been granted by the parliament. According to the Constitution of Finland (731/1999) section 80 the parliament may authorize an authority to lay down legal rules on given matters, if there is a special reason pertinent to the subject matter and if the material significance of the rules does not require that they be laid down by an Act or a Degree. The scope of such an authorization shall be precisely circumscribed. In result of this there is no general authority for STUK to issue regulations.

Guides are legally not binding. STUK and the authorities in general have authority to issue guidance in the field of their statutory tasks without a special legal authorization. The Constitution Committee of the Parliament has on several occasions rejected such authorizing by means of legislation because it is unnecessary and blurs the distinction between binding legal rules and recommendatory guides.

This self-assessment is divided into Radiation Act (SätL) part and Nuclear Energy Act part (YEL). These two areas of legislation are from different eras, SätL from 2018 and YEL from 1987. During the 1990's the role of the parliament has strengthened in relation to other state bodies and that development has also restricted the delegation of legislative powers and issuing of guidance. That can be seen somewhat clearly by taking a closer look on the level of detail of provisions and the authorizations to lay down legal rules in both Acts.

In the field of nuclear energy there are also YVL guides that are issued by STUK. These guides do not perfectly fit to the separation of legal rules and recommendatory guides. YVL guides have elements of both categories. That is further elaborated in YEL section of this self-assessment.

In the field of radiation safety and security there are similar ST Guides available on STUK's website. The ST Guides are based on the Radiation Act (592/1991) that has been repealed in 2018. The ST Guides can be used as guides to some extent. They are currently been replaced by other guide materials.

General legal basis for graded approach

The principle of graded approach has been built into the Finnish legal system. According to the Constitution of Finland (731/1999) section 2 subsection 3 the exercise of public powers shall be based on an Act and in all public activity, the law shall be strictly observed. Administrative Procedure Act (434/2003) section 6 requires that the acts of an authority shall be proportionate to the objectives sought. This applies to all activities of an authority e.g., regulatory oversight, administrative decisions, drafting legislation and issuing guidance.

The graded approach has also been implemented in legislation in SätL and YEL and reaching accordingly to lower-level legislation and guides.

Legal basis for consultation of the interested parties

According to section 14 subsection 4 of the Constitution of Finland (731/1999) the public authorities shall promote the opportunities for the individual to participate in societal activity and to influence the decisions that concern him or her.

If the decision made on a matter could have a significant effect on the living environment, work or other conditions of persons other than the parties, the Administrative Procedure Act (434/2003) requires authorities to provide such persons with an opportunity to obtain information on the bases and objectives of the consideration of the matter and to express their opinion on the matter. Information on the pendency of the matter and on exercising opportunities to exert an influence shall be provided in a manner consistent with the significance and extent of the matter.

The preparation process of regulations also includes internal and external commenting of STUK and the stakeholders and hearings of relevant advisory committees. The public participation is made possible through the websites where the drafts for external commenting are available. A public consultation is made via a specific web page, lausuntopalvelu.fi. Anyone can comment on the regulations and read the comments made by others. This has currently been used within the scope of SätL. In addition, a specific request for comments is made for a chosen group of stakeholders. Requests for comments are used within the scope of YEL.

Prior to issuing the regulations within the scope of YEL, STUK hears the views of the licence holders, the Advisory Commissions referred to in YEL section 56, MEE, MI, ME and the rescue authorities as well as other authorities to the extent necessary.

According to Section 199 of the SätL, prior to issuing regulations under the Act, STUK provides the Ministry of Social Affairs and Health, the Ministry of Economic Affairs and Employment, the Advisory Committee on Radiation Safety and, to the extent necessary, undertakings and other authorities a chance to be heard.

STUK has issued an internal Guide STUK 3.6 which concerns the drafting process of legal rules and YVL Guides. Procedure and consultation will be further elaborated in Question 1.1.

Radiation Act (SätL)

Basic safety requirements for radiation safety and security are set in the SätL. These requirements are then regulated in more detail in either Decrees or STUK regulations. There is also other legislation that has sections concerning radiation safety and security e.g. Health Protection Act (763/1994) and Land Use and Building Act (132/1999).

The reform of the SätL and other legal rules subject to it was based on the EU BSS Directive (Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation), which was based on ICRP recommendations. When Finnish legislation was written, the EU Directive was compared with the IAEA BSS and certain additions and refinements were made. This is stated in the explanatory memorandum to the SätL: "In addition, the recommendations of the International Atomic Energy Agency (IAEA), to the implementation of which Finland is committed, would be taken into account and transposed into national legislation, as appropriate. "In other words, the legislation subject to SätL including STUK's regulations and guides are based on national legislation which takes into account the IAEA guidelines as described above. According to SätL STUK issues more detailed regulations. The authority to issue a specific regulation is given in different sections of the Act concerning particular issues. Currently a single regulation (STUK SY/1/2018) has been issued under both SätL and YEL. Due to the Constitution of Finland, any right for an authority to issue regulations must be detailed and limited in scope. Therefore, there is no general right for STUK to issue regulations. The right to issue regulations is given in SätL as follows:

Section - Issue

10 - General dose constraints applicable to specific radiation practices and radiation sources and on constraints for potential exposure and their use as well as on demonstrating the implementation of the justification and the optimization of radiation protection

12 - Maintenance and promotion of a good safety culture and safety management based on international recommendations.

26 - Content and preparation of the safety assessment.

28 - Deputizing arrangements concerning radiation safety officers.

29 - The information to be presented in the management system.

30 - Quality assurance measures and their performance intervals and instructions as well as the documentation of results.

33 - Provision and content of the radiation protection training and induction when the training or induction is provided in the form of continuing training and supplementary training.

49 - Implementation of European Union legislation in terms of the insignificant amount of radioactivity (exemption level) and an appliance’s safety features.

59 - Verifying the reliability of measurements and on the radiation meters’ and measuring equipments’ calibration, accuracy, use and suitability for a particular purpose.

63 - Performance testing of a dose measurement system.

66 - Radiation safety during use, the markings, (radiation) appliances’ in-service acceptability requirements and other requirements pertaining to the use of the (radiation) appliances.

67 - Security arrangements and their determination in accordance with the radiation sources.

69 - Information pertaining to the identification of a source to be delivered with the sealed source.

71 - Record keeping referred to in subsection 1 (= radiation sources associated with the licence) and on the information to be provided.

72 - Content of the notification (of individual high activity sealed source transport)

73 - Content of the information given (when handing over a radiation source)

74 - Ensuring radiation safety during and at the end of installation, maintenance and remediation work.

75 - Implementation of European Union legislation in terms of the activity values of a high-activity sealed source and the tests to be carried

78 - Limiting occupational and public exposure in the waste management of the waste

83 - Decommissioning of radiation sources and facilities and on their cleaning.

85 - Clearance levels for the implementation of European Union legislation.

89 - Investigation and assessment of radiation exposure.

92 - Organization of the radiological surveillance and individual monitoring at the workplace and on the determination of an individual radiation dose on the basis of the radiological surveillance.

101 - Delivering the information to the dose register.

112 - Practical procedures for optimizing radiation protection in examinations, procedures and treatments and on the optimization of the radiation protection of children as well as pregnant, breastfeeding and asymptomatic individuals. In addition, STUK issues more detailed regulations on the diagnostic reference levels of examinations and procedures and their use.

119 - Recording of the (dose) information.

127 - General limit values of minor discharges and more detailed technical regulations on the plan concerning discharges and their monitoring, discharge monitoring and record keeping and the delivery of the information for the purpose of implementing European Union legislation.

128 - Arrangement of the monitoring referred to in subsection 1 (= public exposure) and the performance of the baseline environmental radioactivity study.

129 - Plan for radiation safety deviations.

130 - Content and preparation of the notifications (of radiation safety deviations)

131 - Investigations concerning radiation safety deviations, on the content of the information to be recorded, and on the content and preparation of the notifications.

136 - Content of the training and the practical implementation of the guidance (for emergency exposure situations).

138 - Performance of the investigation (for an undertaking from whose practice an existing exposure situation arises)

160 - (This section concerns natural sources of radiation)

1) the content of the notification referred to in section 145;

2) the radiation protection of workers and members of the public in practices causing exposure to natural radiation;

3) investigating radiation exposure and the performance of the related measurements and the notifications of the results in the situations referred to in section 145 and section 151–155;

4) measures to limit exposure to radiation in the situations referred to in section 145 and section 151–155;

5) the determination of a radiation dose caused to a worker as referred to in section 149, subsection 3.

The following STUK regulations have currently been issued:

Radiation and Nuclear Safety Authority Regulation on exemption levels and clearance levels	STUK SY/1/20
Radiation and Nuclear Safety Authority Regulation on the investigation, assessment, and monitoring of occupational exposure	STUK S/1/2018
Radiation and Nuclear Safety Authority Regulation on the plan for a radiological emergency and on the actions to be taken during and after a radiological emergency	STUK S/2/2018
Radiation and Nuclear Safety Authority Regulation on the security arrangements for radiation sources requiring a safety license	STUK S/9/202
Radiation and Nuclear Safety Authority Regulation on measurements of ionizing radiation	STUK S/7/202
Radiation and Nuclear Safety Authority Regulation on radioactive waste and discharges of radioactive substances in the use of unsealed sources	STUK S/2/201
Radiation and Nuclear Safety Authority Regulation on practices causing exposure to natural radiation	STUK S/3/201
Radiation and Nuclear Safety Authority Regulation on justification assessment and optimization of radiation protection in medical exposure	STUK S/4/201
Radiation and Nuclear Safety Authority Regulation on exemption levels and clearance levels	STUK SY/1/20
Radiation and Nuclear Safety Authority Regulation on the investigation, assessment, and monitoring of occupational exposure	STUK S/1/2018

Further guidance (rationale) on the intended interpretation, sometimes including examples, concerning each section can be found in conjunction with each section in the preparatory/explanatory memorandum.

STUK has published a web-based service for license holders and other interested parties that contains sections, their rationale and further guidance (sammio.stuk.fi). The service is free and open for anyone. The service allows the use of e.g. search words and to save individual searches. In addition, old ST Guides are available at STUK's website and can be used as guidance in so far as they are not inconsistent with current legal rules.

As a strategic decision, STUK does not issue specific and detailed guidance on how to fulfill individual requirements. The BSS Directive has introduced a new profession, the Radiation Protection Expert (RPE). It is the job of the undertaking, with help of an RPE, to decide how to best meet the requirements. STUK can, however, give examples on decisions made in specific issues at e.g. sammio.stuk.fi or by request.

Graded approach is applied throughout the legislation, in e.g., introducing exposure and source categories in SätL as well as decrees and regulations. However, no notification or registration instead of licensing is used in the use of radiation; some changes in the existing planned exposure situation can be notified, but the planned exposure situation itself requires a license. Some examples on the use of graded approach in legislation and regulations are listed below (the list is not comprehensive).

Act / Decree / Regulation	Issue
SätL 27 §	Obligation for the undertaking to classify radiation activities in respect of radiation exposure level and the types of radiation sources.
SätL 90 §	The classification of radiation workers
SätL 11 §	When supervising compliance with obligations pursuant to SätL, the regulatory authority considers e.g. the risks associated with radiation exposure and radiation sources
SätL 32 §	The Radiation Protection Experts are be used in the appropriate manner, in proportion to the radiation exposure and potential exposure resulting from the practice.
VnA 1034/2018 17 §	The scope of the use of RPEs depend on the classification of doses (E/3/2/1).
VnA 1034/2018 24 §	The requirements of licensing of sealed sources depend in the activity (classification) of the source.
VnA 1034/2018 25, 26 §	Whether a change on a licensed practice requires an application (beforend) or notification (in 2 weeks) can depend on the classification on the practice, or other safety-related issues.
VnA 1034/2018 58 §	The contents of the inspection programme (as per SätL 182 §) must depend on e.g. classifications and and the experience gained from the observations made in previous inspections.
STMA 1044/2018 11, 12 §	Periods of internal and external clinical audits
S/1/2018 2 §	For activities with an occupational exposure category of 3, as well as for healthcare X-ray activities and the use of radiotherapy accelerators, the exposure conditions must be determined by dose rate measurements at the start and change of the activity. Thereafter, monitoring the stability of the exposure conditions is sufficient to monitor the exposure conditions.
S/2/2018 6 §	Some radiation safety deviations can be reported yearly
S/9/2021	Security arrangements depend on risks of the practice.
S/5/2019 7 §	Safety arrangement requirements depend on the potential dose.
S/5/2019 8 §	Additional requirements for industrial radiography, if the occupational exposure category is 1 or 2.
S/5/2019 9 §	Additional requirements if the occupational or public exposure category is 1 or 2 due to potential exposure
S/6/2019 2 §	A deputy STV needs to be appointed when the radiation exposure category is 1.
S/6/2019 Chapter 3	Dose constraints depend e.g. on the exposure category.
S/6/2019 13, 14 §	The scope and review frequency of the safety assessment depend on exposure categories.

Nuclear Energy Act (990/1987)

The Finnish framework of regulations for the use of nuclear energy consists of the following legislation:

- International treaties (this issue is addressed in mod. 2)
- EU legislation
- YEL
- YEA
- STUK regulations
- STUK's YVL guides
- Nuclear Liability Act (484/1972)
- Act on the Control of Exports of Dual-Use Goods (562/1996)
- Act on Environmental Impact Assessment Procedure (252/2017)

Nuclear safety legislation in Finland is based on the YEL. The Act has been amended close to 30 times during the years it has been in force: most changes are minor and originate from implementation of EU directives and changes to other Finnish legislation. In 2008, nuclear energy legislation was updated to correspond to current level of safety requirements and the updated Constitution of Finland (731/1999) which came into force in 2000. Together with the supporting YEA originally from 1988, the scope of this legislation covers e.g. the construction, commissioning, operation and decommissioning of nuclear facilities as well as production, use, handling, storage and transport of nuclear materials or nuclear wastes.

Based on YEL, the Government issued in 2008 Government decrees on the Safety of Nuclear Power Plants, on the Security in the Use of Nuclear Energy, on Emergency Response Arrangements at Nuclear Power Plants and on the Safety of Disposal of Nuclear Waste. The Decrees on the Safety of Nuclear Power Plants and on Emergency Response Arrangements were amended in 2013 mainly due to updating of safety requirements after the TEPCO Fukushima Daiichi accident and new WENRA (Western European Nuclear Regulators' Association) Safety objectives.

In 2011 YEL was amended to implement the Nuclear Safety Directive (2009/71/EURATOM). These amendments included:

- licensee's responsibility to provide adequate training for staff having responsibilities relating to the nuclear safety,
- prohibition to delegate the licensee's responsibility of nuclear safety,

- the Ministry of Economic Affairs and Employment (MEAE) responsibility to arrange periodic self-assessments and invite an international peer review according to the Article 9 of the Directive.

In addition, YEL was amended in 2011 to include provisions on mining and milling operations aimed at producing uranium or thorium. In 2012, YEL was amended with some minor clarifications and to extend the use of inspection organisations and regulator's authority to investigate an abnormal event or procedure in the use of nuclear energy. In 2013, YEL and the Radiation Act (592/1991) were amended to implement the Waste Directive establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste.

In 2012, the Finnish regulatory framework for nuclear and radiation safety was reviewed in the IRRS peer review process. According to the IRRS recommendations, some amendments concerning STUK's independence and legal authorities were made to YEL and the Radiation Act (592/1991) that entered into force in 2015. The amendments gave STUK a mandate to issue legally binding regulations concerning the areas of previous Government Decrees; safety of nuclear power plants, safety of the disposal of nuclear waste, emergency arrangements at nuclear facilities, security arrangements in the use of nuclear energy, and a new area concerning mining and milling operations aimed to produce uranium or thorium. By virtue of Section 7 q of YEL, STUK is authorised to issue more specific regulations on the technical details of the principles and requirements in following matters:

- demonstration of compliance with the safety requirements of a nuclear facility;
- safety classification of a nuclear facility;
- ageing management of a nuclear facility;
- management of human factors relating to the safety of a nuclear facility;
- site safety of a nuclear facility;
- defence-in-depth of a nuclear facility;
- engineered barriers for preventing the dispersion of radioactive substances from a nuclear facility;
- safety functions and provisions to ensure them at a nuclear facility;
- safety of fuel handling and storage at a nuclear facility;
- safety of handling and storage of radioactive waste at a nuclear facility;
- protection against external hazards affecting the safety of a nuclear facility;
- protection against internal hazards affecting the safety of a nuclear facility;
- safety of monitoring and control of a nuclear facility;
- safety of construction of a nuclear facility;
- safety of commissioning of a nuclear facility;
- safety of operation of a nuclear facility;
- taking operating experience and safety research into consideration in order to improve the safety of a nuclear facility;
- operational limits and conditions of a nuclear facility;
- condition monitoring and maintenance to ensure the safety of a nuclear facility;

- structural radiation safety of a nuclear facility, radiation measurements and control and monitoring of releases of radioactive substances as well as assessment of radiation doses caused to members of the public; (905/2017)
- management, organisation and personnel of a nuclear facility to the extent that provisions are needed in order to ensure the safety in the use of nuclear energy;
- planning and implementation of the security arrangements in the use of nuclear energy, personal security, information and cyber security, security control, security personnel, security standing order, preparedness for security threats and actions during a security threat; (964/2020)
- planning of emergency arrangements of a nuclear facility, preparedness to act and response in an emergency situation;
- taking the safety of the decommissioning of a nuclear facility into consideration in the design and the safety of the decommissioning of a nuclear facility;
- design requirements relating to the safety of a nuclear waste facility;
- long-term safety of the disposal of nuclear waste;
- the safety of mining and milling operations carried out for the purpose of producing uranium or thorium; (862/2018)
- the clearance levels for implementing European Union legislation.

STUK has issued five regulations under this authorisation:

- STUK Regulation on the Safety of Nuclear Power Plants (STUK Y/1/2018)
- STUK Regulation on Emergency Arrangements of a Nuclear Power Plant (STUK Y/2/2018)
- STUK Regulation on the Security in the Use of Nuclear Energy (STUK Y/3/2020)
- STUK Regulation on the Safety of Disposal of Nuclear Waste (STUK Y/4/2018)
- STUK Regulation on the Safety of Mining and Milling Operations aimed at Producing Uranium or Thorium (STUK Y/5/2016).

The Nuclear Energy Act was amended in 2017 for implementation of the Council Directive 2014/87/ Euratom amending Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations. The amendment of the Nuclear Energy Act entered into force on 1st January 2018 and supplemented also the former implementation (2013) of the Nuclear Waste Directive (2011/70/Euratom) due to the additional questions by the Commission. The most significant changes caused by the directives concerned transparency of activities, licensee's obligation to provide information and responsibility for subcontractors, involvement of the population in decision-making concerning the nuclear facility licensing and international peer reviews. At the same time, the provisions of the act regarding pressure equipment were updated due to the new Pressure Equipment Act (1144/2016) that entered into force on 1st January 2017. In addition, national legislation was deemed to require disambiguation on matters related to the decommissioning of nuclear facilities and nuclear waste management, which is why further specifications were entered in the act regarding these matters, and the decommissioning licence was added as a new licencing phase for nuclear facilities, and changes were made regarding waste management.

The Nuclear Energy Act was amended in 2020 concerning security arrangements in the use of nuclear energy. The amendment concerns e.g., authorities of security personnel and the temporal dimension of the use of security personnel, especially the point of time when security organisation have to be established in new plant projects. Provisions on health examinations for security and control room personnel and the right to report of the doctor or other medical professional in relation to the health examinations are proposed to be added to the act as completely new items. New items also include rules of jurisdiction concerning defence against drones and unmanned aerial vehicles at nuclear power plant sites.

In the beginning of each STUK Regulation, the scope of the regulation is defined. Regulations are typically written for nuclear power plants and applied to other nuclear facilities as required by the danger they pose. Regulation on the Safety of a Nuclear Power Plant is also applied for handling and storage of spent nuclear fuel. The sections that are applied for low-power research reactors are mentioned separately.

STUK issued the regulations on 1st January 2016. Updates of three (STUK Y/1/2018, STUK Y/2/2018 and STUK Y/4/2018) out of five STUK regulations were published in 2018 and one (STUK Y/3/2020) in 2020. The regulation STUK Y/3/2020 update was prepared by STUK at the same time as the amendment (964/2020) to the YEL concerning safety regulations. STUK has also investigated the need to update the Regulation on the Safety of Mining and Milling Operations Aimed at Producing Uranium or Thorium (STUK Y/5/2016). In this context, it has been stated that updating the regulation would require amendments to YEL, and thus the preparation of the regulation has been suspended for the time being.

According to Section 7 r of YEL, STUK shall specify detailed safety requirements concerning the implementation of safety level in accordance with the Act. These requirements are presented in the Finnish regulatory guides called YVL Guides. The safety requirements presented in 46 YVL Guides are binding on the licensee, while preserving the licensee's right to propose an alternative procedure or solution to that provided for in the YVL Guides. If the licensee can convincingly demonstrate that the proposed procedure or solution will implement the same safety level, STUK may approve this procedure or solution.

The YVL Guides in force are listed below. They have been organized into five topical areas:

A. Safety Management of a nuclear facility

YVL A.1	Regulatory oversight of safety in the use of nuclear energy, 17.3.2020
YVL A.2	Site for a nuclear facility, 15.2.2019
YVL A.3	Leadership and management for safety, 15.3.2019
YVL A.4	Organisation and personnel of a nuclear facility, 15.12.2019
YVL A.5	Construction and commissioning of a nuclear facility, 15.3.2019
YVL A.6	Conduct of operations at a nuclear power plant, 15.6.2019
YVL A.7	Probabilistic risk assessment and risk management of a nuclear power plant, 15.2.2019
YVL A.8	Ageing management of a nuclear facility, 15.2.2019
YVL A.9	Regular reporting on the operation of a nuclear facility, 15.2.2019
YVL A.10	Operating experience feedback of a nuclear facility, 15.2.2019
YVL A.11	Security of a nuclear facility, 12.2.2021
YVL A.12	Information security management of a nuclear facility, 12.2.2021

B. Plant and system design

YVL B.1	Safety design of a nuclear power plant, 15.6.2019
YVL B.2	Classification of systems, structures and components of a nuclear facility, 15.6.2019
YVL B.3	Deterministic safety analyses for a nuclear power plant, 2.9.2019
YVL B.4	Nuclear fuel and reactor, 15.3.2019
YVL B.5	Reactor coolant circuit of a nuclear power plant, 2.9.2019
YVL B.6	Containment of a nuclear power plant, 15.6.2019
YVL B.7	Provisions for internal and external hazards at a nuclear facility, 15.12.2019
YVL B.8	Fire protection at a nuclear facility, 15.12.2019

C. Radiation safety of a nuclear facility and environment

YVL C.1	Structural radiation safety at a nuclear facility, 15.3.2019
YVL C.2	Radiation protection and exposure monitoring of nuclear facility workers, 1.11.2019
YVL C.3	Limitation and monitoring of radioactive releases from a nuclear facility, 15.3.2019
YVL C.4	Assessment of radiation doses to the public in the vicinity of a nuclear facility, 15.3.2019
YVL C.5	Emergency arrangements of a nuclear power plant, 20.1.2020
YVL C.6	Radiation monitoring at a nuclear facility, 15.3.2019
YVL C.7	Radiological monitoring of the environment of a nuclear facility, 19.12.2016

D. Nuclear materials and waste

YVL D.1	Regulatory control of nuclear safeguards, 24.5.2019
YVL D.2	Transport of nuclear materials and nuclear waste, 15.5.2019
YVL D.3	Handling and storage of nuclear fuel, 17.3.2020
YVL D.4	Predisposal management of low and intermediate level nuclear waste and decommissioning of a nuclear facility, 15.12.2019
YVL D.5	Disposal of nuclear waste, 13.2.2018
YVL D.7	Release barriers of spent nuclear fuel disposal facility, 13.2.2018

E. Structures and equipment of a nuclear facility

YVL E.1	Authorised inspection body and the licensee's in-house inspection organisation, 15.3.2019
YVL E.2	Procurement and operation of nuclear fuel and control rods, 2.9.2019
YVL E.3	Pressure vessels and piping of a nuclear facility, 15.12.2019
YVL E.4	Strength analyses of nuclear power plant pressure equipment, 17.3.2020
YVL E.5	In-service inspection of nuclear facility pressure equipment with non-destructive testing methods, 15.2.2019
YVL E.6	Buildings and structures of a nuclear facility, 19.6.2020
YVL E.7	Electrical and I&C equipment of a nuclear facility, 15.3.2019
YVL E.8	Valves of a nuclear facility, 20.1.2020
YVL E.9	Pumps of a nuclear facility, 20.1.2020
YVL E.10	Emergency power supplies of a nuclear facility, 20.1.2020
YVL E.11	Hoisting and transfer equipment of a nuclear facility, 2.9.2019
YVL E.12	Testing organisations for mechanical components and structures of a nuclear facility, 15.3.2019
YVL E.13	Ventilation and air conditioning equipment of a nuclear facility, 23.10.2020

apply new guides to existing nuclear facilities and to facilities under construction is such that the publication of an YVL Guide does not, as such, alter any previous decisions made by STUK. Before an implementation decision is made by STUK the licensees are requested to evaluate the compliance with the new guide. After having heard licensees, STUK makes a separate decisions on how a new or revised YVL Guide applies to operating nuclear facilities, or to those under construction. STUK can approve exemptions from new requirements if it is not technically or economically reasonable to implement respective modifications and if the safety justification is considered adequate. This is a case by case decision. For example Finnish operating NPPs are granted exemptions from the requirements concerning protection against large airplane crashes." In case of non-compliances, the licensee must propose plans for improvement and schedules for achieving compliance.

In compliance with the national strategy and with expectations of IAEA the important references considered in Finnish regulations for nuclear safety are the IAEA safety standards, especially the Requirements documents, and WENRA Safety Reference Levels. Also, the WENRA Safety Objectives for new reactors and the WENRA positions on some key technical issues are considered. Other sources of safety information are worldwide co-operation with other countries using nuclear energy, e.g. OECD/NEA, MDEP (Multinational Design Evaluation Programme) and VVER Forum. The Finnish policy is to participate actively in the international discussions on developing safety standards and adopt or adapt the new safety requirements into national regulations. The regulatory guides are updated

based on advances in science and technology, results of safety research and on analysis of operational experience (YEL section 7 a).

In 2013 the principle of graded approach was explicitly included in YEL (499/2913), where section 7 a states “The safety requirements and measures for ensuring safety shall be graded and targeted so as to be commensurate with the risks in the use of nuclear energy”. The regulatory requirements related to risk informed safety management by the licensees also affect the regulatory oversight and therefore makes also the regulatory actions more risk informed. The regulatory requirements related to the use of graded approach in the management system are introduced in the Guide YVL A.3 “Leadership and management for safety”. In Guide YVL A.7 “Probabilistic risk assessment and risk management of a nuclear power plant” the use of Probabilistic Risk Assessment (PRA) as a tool in every lifecycle phase of a nuclear power plant is explained. The use of risk-based applications supports the graded approach principle by giving importance and priorities for the matters as well as making the related risks transparent.

According to STUK Y/1/2018 section 4 subsection 1 “The safety functions of a nuclear facility shall be defined and the related systems, structures and components classified on the basis of their safety significance. Subsection 2 in turn states “Requirements set for and the actions taken to ascertain the compliance with the requirements of the systems, structures and components implementing safety functions and connecting systems, structures and components shall be commensurate with the safety class of the item in question.” This is taken account in YVL guides, where requirements are more stringent on the systems, structures and equipment, which are most important to safety (safety class 1) and become less stringent along with lower safety classes (safety class 2 and 3).

Related to authority inspections for pressure equipment, mechanical components, and structures YEL section 60 a stipulates so that the equipment most important to safety are inspected by STUK and the other safety related items are inspected by authorized inspection organizations. This division is defined also in YVL guides.

Question 1.1 How does the regulatory body review and revise regulations and guides?

Response:

STUK regularly updates regulations and guides based on advances in science and technology, results of safety research and on analysis of operational experience. In module 2 (question 3) there is described the process of lessons learned from domestic and foreign operational experience. This process gives feedback also to regulations’ and guides’ updating work. Guide STUK 3.6 defines the process and principles for drafting and updating legislation, regulations and guides. According to STUK management system guide STUK 3.6 (page. 5) Act on Collections of Regulations of Ministries and

Other State Authorities 189/2000) and the drafting guides of the Ministry of Justice shall be observed in updating work. Up-to-date drafting guide can be found in the internet address http://lainkirjoittaja.finlex.fi.

Principles in drafting are cooperation, transparency, up-to-dateness and expertise. Transparency, up-to-dateness and expertise have been defined as follows: The safety regulations are clearly organised and sufficiently comprehensive so that the criteria and content, safety requirements and the procedures for their enforcement are transparent and understandable to those subject to enforcement and to the rest of society. The regulations and its amendments are actively communicated. The safety regulations shall be evaluated and revised in the light of technical and scientific progress, the results of safety research, operational experience and the international safety regulations, so that the safety requirements are up to date, proportionate to the safety significance of the subject and contribute to the continuous improvement of safety. The up-to-dateness of an individual regulation or guide shall be assessed, where appropriate, but not later than five years after its adoption. STUK's experts are involved in the preparation of the safety regulation as widely as possible. External independent experts will also be involved in the preparatory work, as appropriate. As part of the preparatory process, external experts will be consulted and organisations subject to or representing regulatory control will be involved, e.g. in hearings, consultation days and working groups, in addition to the consultation procedure. In particular, expertise on the interfaces with legislation is ensured in both external and internal preparation.

STUK's oversight departments are responsible for the up-to-dateness and appropriateness of the safety requirements contained in the regulations and guides, the process for preparing the guides and the preparation and commenting of the IAEA guidelines and standardization work. Directors are responsible for the content and renewal process of YVL Guides published by the STUK. The responsibility of the preparation of VAL Guides lies with Head of Emergency Preparedness. The Legal Section is responsible of legal aspects of the regulations and renewal process of acts and decrees in STUK.

Continuous safety assessment and enhancement approach is presented in the Finnish nuclear legislation. YEL section 7 a states that the safety of nuclear energy use shall be maintained at as high level as practically possible. For the further development of safety, measures shall be implemented that can be considered justified considering operating experience and safety research and advances in science and technology. The implementation of safety improvements has been a continuing process at both Finnish nuclear power plants since the commissioning of the operating reactor units.

After amending the nuclear safety legislation in 2008, the revision of all YVL Guides was commenced to reflect the enhanced safety requirements. Considering the WENRA Safety Reference Levels published in 2007 and 2008, the Finnish policy was to include all of them in the revised YVL Guides. This was done through a systematic approach to tag all the Reference Levels to certain YVL Guides. After the TEPCO Fukushima Daiichi accident it was decided to include lessons learned from the

accident into the revised YVL Guides. The most important changes deal with the design of NPPs and spent fuel storages, consideration of severe external hazards and with the requirements concerning on-site emergency preparedness including multi-unit accidents. STUK participated WENRA's work on the update of the Safety Reference Levels after the Fukushima accident and most of the updated Reference Levels were already taken into account in the revised YVL guides.

The new set of YVL guides was published on December 1, 2013. The publication of 2 guides out of 45 guides took place during 2016. These were left to wait for publication due to the needed changes in the legislation and upper-level regulations. After the renewal of YVL Guides in 2013 nearly all IAEA Safety Requirements documents have been revised. Just because of TEPCO Fukushima Daiichi accident IAEA had updated several requirements documents. The updated WENRA Safety Reference Levels for Existing Reactors taking into account the lessons learnt and the insight from the EU stress tests were published in fall 2014. The updated international requirements were reviewed and assessed by STUK to clarify the need for further modifications of STUK's regulations and regulatory guides. In this connection also the new requirements of Council Directive (2014/87/Euratom) amending NSD Directive (2009/71/Euratom) and BSS directive (2013/59/ Euratom) were reviewed and assessed their impact on the Finnish nuclear safety regulations. The YVL Guide update work began in 2017. In most of the YVL Guides only minor changes were needed and they are mainly clarifications. Until now (August 2021) 46 YVL Guides have been published.

According to STUK management system guide STUK 3.6 the preparation process of a STUK regulation or guide starts with the preparation of the work plan. Also experience and expert opinions from different stakeholders are taken into account.

There are four phases in the preparation process for YVL Guides:

- Draft L1 is the working group's first version of the guide for internal hearing
- Draft L2 is circulated for external comments
- Draft L3 takes into account the external comments and it is presented for the steering groups of relevant departments
- Draft L4 is internally approved. In case of YVL Guides it is submitted to the relevant STUK's Advisory Commission. The draft is finalized after the Advisory Commission statements.

YVL Guides are presented for the approval of Director General by the Director responsible for the regulations.

During the course of the year 2020, STUK participated in the REILA work group steered by Ministry of Economic Affairs and Employment (MEAE) on the development of the regulation of the lifecycle of nuclear facilities. As a result, a final report was published, and in this report, the work group concluded that initiating overall legislation reformation is necessary. This need partly arises from the lack of clarity in the current legislation, but it is also caused by the changes in the operating environment. The work and the conclusions are described more precisely in module 1 (question 2.1).

In accordance with the Ministry's planning of overall nuclear energy legislation reformation, on October 2020, STUK adopted the decision to begin the preparation of the structural and substantive renewal of the safety regulations on the use of nuclear energy. The aim of the renewal of the nuclear safety regulations and guides issued under YEL is to emphasise the licensee's responsibility and to focus the oversight to be based on risk-informed methods, and to make a clear difference between recommendations and binding requirements. More detailed information about renewal is presented in module 1 (question 2.1).

The SätL and the whole radiation legislation has been updated in recent years starting from 2018. The same procedures apply to amending radiation safety related regulations and guides as presented concerning nuclear safety. However, the status of YVL Guides and guides in the SätL scope are a bit different. The former also includes requirements and the latter are recommendatory.

Procedures for updating guidance texts to Sammio guidance service are following: A designated person makes a draft of guidance and sends it for comments to the STUK departments/units affected including the legal unit when needed. Updates for one oversight unit only, without any legislative or regulatory alignments, can be approved by the head of the unit. Guidance in cases involving more than one unit or having a policy relevance must always be approved by the director of the department of Radiation Practices Regulation. After an approval a Sammio administrator updates Sammio and sends information on the updating of guidance to the units or departments involved. The guidance texts are translated to Swedish (and in the future also to English). Documents of the guidance texts are saved in case management system Saha.

Feed-back from users of Sammio is taken into account while up-dating guidance to Sammio e.g. in which cases the users need more accurate guidance in applying regulations.

Question 1.2 How does the regulatory body notify interested parties and the public of its regulations and guides, and make them available?

Response:

In section 20 of the Act on the Openness of Government Activities (621/1999) the authorities are required to produce and disseminate information. The authorities shall promote the openness of their activities and, where necessary for this purpose, produce guides, statistics and other publications, as well as information materials on their services and practices, as well as on the social conditions and developments in their field of competence. The authorities shall publicise their activities and services, as well as the rights and obligations of private individuals and corporations in matters falling within their field of competence. The authorities shall see to it that the documents or the pertinent indexes which are essential to the general public's access to information are available where necessary in libraries or public data networks, or otherwise easily accessible to the members of the public.

The Act on collection of regulations of ministries and other state authorities (189/2000) section 4 requires an authority to publish regulations. An authority may also decide to publish guidance of general importance in the collection of regulations. Regulations shall be published without a delay after their adoption.

STUK Regulations and their rationales (preparatory/explanatory memorandums) are published in Finnish and Swedish. English translations of Regulations issued by virtue of the YEL are also published in English. However, only Finnish and Swedish versions are legally binding. All YVL Guides and their memorandums are published in Finnish and English but not in Swedish, which does not fulfill the requirements of Language Act (423/2003). STUK's Regulations and guides are published in websites Finlex.fi and Stuklex.fi.

Information on new or updated regulations and guides is also presented in STUK's annual reports. To promulgate the nuclear and radiation safety requirements STUK publishes news releases on its website and contacts stakeholders via newsletters on current affairs and organizes stakeholder seminars and meetings. STUK is also active in social media. During the overall renewal of YVL Guides STUK has organized annually seminars with the stakeholders. Within the nuclear safety area STUK experts participate as lecturers to the training courses and seminars organized by the Finnish adult education organizations. At the YJK course, which is the national nuclear safety training course organized by a consortium consisting of universities, the Ministry of Employment and the Economy, STUK, VTT (= a state-owned research institution) and the licensees, the safety regulations are one essential topic.

Analysis

STRENGTHS FOR 09. REGULATIONS AND GUIDES

S1	Finland and STUK are strongly committed to meeting the IAEA requirements in safety standards. STUK is also an active participant in the updating of the IAEA safety standards and

	in Member State commenting phase, and their content is well known in Finland. Principle is to include at least IAEA Requirement Level document issues as part of STUK's regulations and guidelines. The Guide level documents are sometimes too detailed, but some parts can be included, or the Guide documents can be referenced. The recognition, knowledge and understanding of the importance of the IAEA requirements at STUK is profound. In Finland, the Constitution and general administrative legislation safeguard the legal nature of the activities of public authorities, legal security, good administration and the right to information and participation. To some extent, they also implement and provide the basis for implementing and respecting IAEA requirements.
S2	STUK's radiation-related regulations and guides have been revised as part of the overall reform of radiation legislation. The reform has significantly clarified and modernized the regulatory framework. IAEA requirements have been taken into account in the work: the requirements of the BSS-directive largely cover IAEA requirements and national legislation has been supplemented where necessary by IAEA requirements (e.g. safety culture, emphasis on license holder's responsibility, more detailed safety arrangements). The whole of the Radiation Act, including STUK's regulations correspond more comprehensively and precisely to the requirements of the Constitution, the statements of the Constitutional Law Committee of the Parliament and the Guide for Legislators (published by the Ministry of Justice) as well as the Guide STUK 3.6 Regulations and also the IAEA requirements. The clarity and timeliness of the regulation and the separation of norms and guidelines implemented will improve the legal security of the license holder and implement good governance. The constitutionality and timeliness of the regulation means less legal risk, for example that an administrative decision taken under the regulation would be overturned by the court. This has the effect of also providing a stronger legal basis for IAEA-based regulation. The reform has increased the expertise of STUK and its staff in the regulatory process and the content of STUK regulations. This is also directly reflected in improved knowledge of IAEA requirements as part of national legislation.
S3	The radiation legislation reform has been accompanied by the digitalisation of the legislation, regulations, and guides which contributes to the assessment of its timeliness and the access to information and participation rights of operators, STUK experts and the public (SAMMIO). In addition to legislation and regulations, SAMMIO provides guidance with examples of good practices to meet the requirements of the legislation. The SAMMIO database increases consistency of supervision between the regulator and the authority, as the requirements are presented as a logical whole (i.e. "consistency of regulatory content"): SAMMIO allows searching for information on different pieces of legislation and regulations at once: the search function brings together the binding article, its justification and the related supplementary guidance.
S4	The regulations and guidelines issued under the Nuclear Energy Act comprehensively incorporate IAEA requirements. Regulations and guides reflect IAEA safety requirements and best practices. The content of the requirements is up to date, as the overall updates were made in 2013 and 2016/2017. The necessary expertise is therefore available internally at STUK.
S5	The requirements management methodology of the YVL Guides constitutes a strength. The Polarion database contains all the YVL Guide requirements, for which attributes have been defined, e.g. to facilitate searches. These are also distributed to license holder's /applicants.

	The updating of the YVL Guides has been implemented in the database, so that changes, their justification and internal/external comments and their consideration can be found in the database. The implementation of the requirements at operating nuclear facilities or facilities under construction is also recorded in the database. The WENRA Reference Levels 2014 can also be found in the database with links to the YVL Guides. The requirements management has been piloted in the new NPP licensing project (Fennovoima Hanhikivi unit 1), where the review of the application for a construction license uses the sets of requirements retrieved from the database.

WEAKNESSES FOR 09. REGULATIONS AND GUIDES

W1	The overall structure of the YEL and the regulations and guidelines issued under it is outdated. Not all aspects of the current legislation (structure, mandates, etc.) have been drafted in accordance with the requirements of the Finnish Constitution, other legislation (e.g. YVL guidelines have not been published in Swedish) and the Legislator's Guide. The obsolescence over time of the YEL, and the layering due to numerous individual legislative amendments, as well as the extent of the body of rules and regulations, make the overall structure and content unclear and difficult to understand and manage. The obsolescence of the law may entail legal risks (complaints, legal challenges). The lack of adequate basic provisions and of a precise normative power under the law and the possible unconstitutionality of the regulation may lead to a situation where the legal binding nature of the requirements issued by STUK may be called into question. In practice, this may mean that STUK's administrative decision is overturned by an administrative court. This also implies some risk that the IAEA requirements would not be effectively implemented.

OPPORTUNITIES FOR 09. REGULATIONS AND GUIDES

O1	It is possible that the overall reform of YEL and the regulations adopted under it will produce broad positive changes similar to the strengths described under the radiation legislation reform. It is possible that the reform will support license holder's own expertise and responsibility for their activities. The reform has the potential to develop both the supervisory culture of the authorities and the safety culture of the license holder's in a way that promotes nuclear safety. It has the potential to enable the introduction of new innovative technologies and to enable license holders to adopt different safe practices.
O2	The reform of radiation legislation has increased the responsibility of license holders as compared to the old radiation legislation. The reform has developed the working culture of STUK and of license holders in a direction that increases operator responsibility and involvement, which is also in line with STUK's strategy. This trend may continue and will enable a more efficient allocation of STUK resources. The lessons learned from the reform of the Radiation Act can be applied to the reform of the Nuclear Energy Act and its implementing legislation.
O3	The use and further development of requirement management tools (databases) in the reform of STUK requirements and guides will allow for a more systematic consideration of IAEA requirements.

THREATS FOR 09. REGULATIONS AND GUIDES

T1	The need for structural reform of the YEL and STUK requirements and guides has been identified. Reform is both a threat and an opportunity, depending on its planning and implementation. The reform effort will require significant human and financial resources from STUK. The threat is that the resources will not be sufficient, and that the quality of work will suffer, or that the necessary resources will have to be taken from STUK's safety oversight and supporting resources or carried out in a way that undermines STUK's other statutory tasks. The successful implementation of this work requires good planning, perseverance and adequate financial (dedicated) resources and expertise for the overall reform of the legislation, regulations and guides. STUK has already requested additional funding for the reform, but this has not been successful. Vulnerabilities may arise if the reform does not receive sufficient expertise and financial resources to carry out the work to a high standard. For example, there is a risk that obligations based on international conventions or agreements, EU legislation or IAEA requirements are repealed or modified in a way that is contrary to them. A vulnerability of STUK's regulatory reform is that the success of the work is partly dependent on the adequacy of resources and expertise for the YEL reform of the MEAE and the related political decision making. This is the case as the legislation and regulations form a whole. There is also a risk that the reforms are not sufficiently coordinated (in terms of timing and content) or that communication is otherwise deficient. Reform may raise fears or resistance because it may require a change in the operator's culture and is a costly, resource- and time-consuming process. In particular, there are risks if stakeholders are not sufficiently involved and consulted during the reform processes and at an early enough stage. Implementing the reform based on the expectations of the Constitution may lead into quite detailed Nuclear Energy Act requirements. The reform should be made in such way that updating the Act is not needed too often since updating process is not so agile. Also, too detailed or too restricting binding requirements in STUK’s regulations can form a risk for enabling different technologies and approaches. This needs to take into account when drafting the regulations.
T2	Delays in updating the Radiation Act in the coming years could jeopardize the timely implementation of the new requirements. In addition, a delay in updating the annual fees (annexed in the Radiation Act) could also lead to a divergence of the tax-based annual fees collected from operators from the actual costs of their activities. This could mean annual fees for radiation use that are too high or too low. The aim is to ensure that the costs and fees charged are as close as possible to each other in order to be fair and reasonable to the license holders.

CONCLUSIONS FOR 09. REGULATIONS AND GUIDES

C1	Finland meets the IAEA requirements. Regulations and guides reflect IAEA safety requirements and best practices.

	The Radiation and Nuclear Safety Authority has issued safety regulations and guidelines that meet the requirements of Safety Standards Series No. GSR Part 1 (Rev. 1); 32-34. The existence, content, evaluation and renewal/updating of the regulatory framework and public participation and access to information are already implemented – partly through legislation and partly through STUK's internal guidelines (Guide STUK 3.6).
C2	Overall renewal of YEL and the regulations adopted under it will produce broad positive changes similar to the strengths described under the radiation legislation renewal. Also issues identified in Module 5 as opportunities can be covered in the overall renewal. Sufficient financial and human resources must be available for the renewal of nuclear energy legislation (including STUK's regulations and guides) in order to produce high-quality work. The implementation of safety requires the use of STUK's expertise in the work, and its resources must be secured.

Module: 10. Basic Primary responsibilities of the regulatory body (RB) in emergency

Findings

Question 1 Has the government given authority to one or more regulatory bodies (here-in-after: the RB) to regulate on-site emergency preparedness and response (here-in-after: EPR) of operating organizations of regulated facilities or activities that could necessitate emergency response actions?

Answer: Yes

Response:

See the following answers

Question 1.1 What organization(s) have authority to regulate EPR arrangements of operating organizations and what areas they have been given responsibility for?

Response:

According YEL Section 7 p

The planning of emergency arrangements for the use of nuclear energy shall be based on analyses of operational occurrence and accident conditions, and the consequences assessed on the basis of these analyses.

In planning emergency arrangements for a nuclear facility, preparations shall be made for the release of a significant quantity of radioactive substances from the facility.

The nuclear facility shall have persons trained in the planning of emergency arrangements and emergencies (*emergency response organisation*), whose duties shall be specified and who shall have access to the facilities, equipment and communication systems required for their duties.

The emergency arrangements shall be coordinated with the emergency and preparedness plans drawn up by authorities taking into account the provisions of the Rescue Act (379/2011).

According YEL Section 7 q

"The Radiation and Nuclear Safety Authority shall issue further regulations on the technical details of the principles and requirements laid down in this chapter concerning the following matters: … 23) planning of emergency arrangements of a nuclear facility, preparedness to act and response in an emergency situation;"

Requirements for documentation that the licensee shall deliver to STUK in the construction license phase and in the operation license phase are written in the YEA sections 35 and 36. In the construction license phase the preliminary plans for security and emergency response arrangements shall be delivered to STUK and in the operation licence phase plans for security and emergency response arrangements shall be delivered to STUK. The section 36a of the YEA applies for decommissioning license.

Supervisory rights of STUK are presented in the YEL Section 63.

According to MOI Decree 1286/2019 Section 12 (based on the Rescue Act) the Regional State Administrative Agency is in charge of supervising and following the preparation and implementation of the full scope emergency exercises which shall be arranged every three years.

Question 1.2 How coordination is ensured amongst organizations that have relevant authorities and responsibilities in regulating EPR of operating organizations or that may be impacted by the relevant judgements and decisions?

Response:

STUK has in practice sole responsibility for regulation and supervision of emergency arrangements. Radiation Protection Sections (SÄT) of Nuclear Reactor Regulation Department (YTO) is in charge of supervision of licensees' emergency arrangements as a whole.

Every three years there per NPP the regional rescue service organizes full scope emergency exercise with emphasis on the inter-agency cooperation. In practice representatives of Regional State Administrative Agency and STUK take part in planning and evaluating the emergency exercise.

Question 1.3 What resources and organizational structure the RB has to fulfil its responsibilities in regulating the EPR of operating organizations effectively on the basis of a graded approach?

Response:

Radiation Protection Sections (SÄT) of Nuclear Reactor Regulation Department (YTO) is in charge of supervision of licensees' emergency arrangements as a whole. This includes e.g. approval of emergency plans, conducting inspections, following, and evaluating exercises, drawing the regulatory guide (YVL C.5) and STUK's Regulation (Y/2/2018) as well as accepting the responsible persons according to YVL A.4 app C.

In many cases experts of other sections can also participate to the supervision work according to their expertise.

Question 2 Has the RB established or adopted regulations and guides which include principles, requirements and associated criteria for EPR for the operating organization upon which its regulatory judgements, decisions and actions are based?

Answer: Yes

Response:

<u>According to YEL Section 7 p:</u>

The planning of emergency arrangements for the use of nuclear energy shall be based on analyses of operational occurrence and accident conditions, and the consequences assessed on the basis of these analyses.

In planning emergency arrangements for a nuclear facility, preparations shall be made for the release of a significant quantity of radioactive substances from the facility.

The nuclear facility shall have persons trained in the planning of emergency arrangements and emergencies (emergency response organisation), whose duties shall be specified and who shall have access to the facilities, equipment and communication systems required for their duties.

The emergency arrangements shall be coordinated with the emergency and preparedness plans drawn up by authorities taking into account the provisions of the Rescue Act (379/2011).

RB (STUK) has established The Regulation Y/2/2018 *"Radiation and Nuclear Safety Authority Regulation on the Emergency Arrangements of a Nuclear Power Plant*", which gives the bounding regulations. This regulation shall apply to the emergency arrangements of a nuclear power plant The regulation shall also apply to other nuclear facilities as required by the danger they pose.

According to Section 7 r of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority (STUK) shall specify detailed safety requirements for the implementation of the safety level in accordance with the Nuclear Energy Act.

The Regulatory Guide YVL C.5 *"Emergency arrangements of a nuclear power plant"* describes a nuclear power plant's emergency arrangements. According to Section 3(7) of the Nuclear Energy Act (990/1987), *emergency arrangements* mean advance preparation for accidents or events impairing safety at the nuclear facility or in its site area or other places or vehicles where nuclear energy is used. Preparation also applies to exceptional situations that require the intensification of preparedness to act in order to ensure the safety level of the plant. The Guide YVL C.5 contains detailed requirements on how a nuclear power plant licensee shall plan, implement and maintain emergency arrangements. As applicable, the Guide shall also be applied to other nuclear facilities and to the transport of nuclear materials and waste, as required by the degree of the threat caused by a nuclear accident at the facility or during transport.

Question 2.1 What regulations and guides for EPR of operating organizations have been established or adopted and what principles, requirements and associated criteria for on-site EPR they prescribe?

Response:

RB (STUK) has established The Regulation Y/2/2018 *"Radiation and Nuclear Safety Authority Regulation on the Emergency Arrangements of a Nuclear Power Plant*", which gives the binding regulations. This regulation shall apply to the emergency arrangements of a nuclear power plant The regulation shall also apply to other nuclear facilities as required by the danger they pose.

According to Section 7 r of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority (STUK) shall specify detailed safety requirements for the implementation of the safety level in accordance with the Nuclear Energy Act.

The Regulatory Guide YVL C.5 *"Emergency arrangements of a nuclear power plant"* describes a nuclear power plant's emergency arrangements. According to Section 3 (7) of the Nuclear Energy Act (990/1987) [1], emergency arrangements mean advance preparation for accidents or events impairing safety at the nuclear facility or in its site area or other places or vehicles where nuclear energy is used. Preparation also applies to exceptional situations that require the intensification of preparedness to act in order to ensure the safety level of the plant. The Guide YVL C.5 contains detailed requirements on how a nuclear power plant licensee shall plan, implement and maintain emergency arrangements. As applicable, the Guide shall also be applied to other nuclear facilities and to the transport of nuclear materials and waste, as required by the degree of the threat caused by a nuclear accident at the facility or during transport.

To answer the question listed under title "expectations" above please find the references:

Performs a hazard assessment as a basis for a graded approach in establishing the on-site EPR;

Accident scenarios shall be updated as required by plant modifications. In emergency planning, combinations of nuclear and other hazards (including external hazards, Guide YVL B.7 "Provisions for internal and external hazards at a nuclear facility") as well as hazards relating to unlawful action and their potential consequences shall be taken into account. [YVL C.5 307]

Executes promptly and manages safely and effectively the on-site emergency response including the transition from normal operations to operations under emergency conditions;

Emergency arrangements shall be planned to ensure that emergency situations are quickly brought under control, the safety of the individuals in the site area is assured, and timely action is taken to prevent or limit radiation exposure to the public in the emergency planning zone. [STUK Y/2/2018 Section 3]

Classifies promptly the emergency, declares the emergency class, initiates the on-site emergency response and notifies and provides sufficient information to the off-site notification point;

Decides on and takes mitigatory actions on-site;

In an emergency situation, the licensee shall take the measures required under the emergency plan and other necessary measures without delay in order to control the situation and prevent or limit radiation exposure. [STUK Y/2/2018 Section 9]

The licensee shall notify the Radiation and Nuclear Safety Authority and the regional emergency response centre concerned without delay of any declaration of an emergency situation and the classification of the emergency situation [STUK Y/2/2018 Section 10]

Assesses and determines, at preparedness stage, when and under what conditions assistance from off-site emergency services may be needed to be provided on the site;

Receiving external assistance in an emergency situation shall be prepared for when planning emergency arrangements. [STUK Y/2/2018 Section 3]

The external assistance may be material or, for example, experts coming to the site. In terms of receiving assistance, assistance from Finland and abroad shall both be prepared for. In regard to emergency planning, aspects to be considered include logistics and the access rights and workspaces of the persons coming to render assistance. [YVL C.5 312a]

Assesses the hazards and possible development of hazardous conditions initially and throughout the emergency and takes necessary urgent protective actions to protect all persons present at the site in an emergency;

2. Planning shall take account of a simultaneous threat to nuclear safety occurring in all nuclear facilities in the site area and their potential consequences, especially the radiation situation on the site and in the surrounding area and the opportunities to access the area.

3. Planning shall take account of the fact that the emergency situation could continue for a prolonged period.

4. Planning shall be based on analyses of the time-behaviour progress of severe accident scenarios resulting in a potential release. In such a case, variations in the state of the plant, the development of events as a function of time, the radiation situation at the plant, radioactive releases, radioactive release routes and weather conditions shall be taken into account.

5. Planning shall take account of events deteriorating safety, their controllability and the severity of consequences, and threats related to unlawful action and the potential consequences thereof. [STUK Y/2/2018 Section 3]

Ensures suitable, reliable and diverse means of communication for use in taking protective actions on the site and for communication with relevant off-site officials;

6. To manage emergency operations, there shall be an emergency response centre, which shall be able to maintain proper working conditions during an emergency situation, and which shall also be available during prolonged power failures.

7. There shall be a designated centre outside the site area from which to direct the plant's emergency response operations, if the emergency response centre is not available.

8. There shall be reliable communication and alarm systems in place to manage emergency response operations for the purposes of internal and external communications of the nuclear power plant.

9. The licensee shall ensure that there are automatic data transmission systems in place to send information essential in terms of the emergency operations to the emergency response centre of the Radiation and Nuclear Safety Authority. [STUK Y/2/2018 Section 4]

Protects emergency workers responding on the site;

4. To prepare for an emergency situation, the licensee shall have appropriate staff alarm systems, places of assembly in the site area, evacuation arrangements, the necessary personnel protective equipment, radiation measuring instruments and iodine tablets available. In addition to permanent and temporary personnel working at the site area, arrangements shall also consider all emergency workers and helpers arriving in the site area during an emergency situation. [STUK Y/2/2018 Section 4]

Communicates with the public effectively in a nuclear or radiological emergency and consistently with relevant off-site response organizations;

1. The licensee shall be prepared to carry out the measures required in emergency situations, the analysis of emergency situations and the consequences thereof, assessment of the anticipated development of emergency situations, the mitigatory actions needed to control or limit the accident, the continuous and effective exchange of information with the authorities, and communications to the media and the members of the public. [STUK Y/2/2018 Section 4]

2. During an emergency situation, the licensee shall submit to the director of rescue operations as referred to in Section 34 of the Rescue Act and the regional rescue service concerned as well as to the Radiation and Nuclear Safety Authority a current situation assessment on the event and any relevant decisions concerning the nuclear power plant and justifications thereof. [STUK 2/Y/2018 Section 10]

The licensee shall distribute iodine tablets in advance to the public within the precautionary action zone, and, in the event of an emergency situation, the licensee shall participate in warning the public within the precautionary action zone. [STUK Y/2/2018 Section 13]

Guidance for public communication has been elaborated also on broader level in the Ministry of Interior Decree on Providing Information to Public in Case of Radiological Emergency (774/2011)

Manages radioactive waste generated in an emergency safely and effectively;

Recovery measures include at least the following:

· identification of changes in the nuclear power plants structures, systems or components which impact maintaining the plant in a safe state and managing radioactive substances

· actions which may be needed to keep the plant in a safe state and to prevent and reduce releases

· evaluation of radiation doses caused by an accident

· the necessary decontamination measures and efficient waste management planning

· event analysis including its causes and preparation of an event report

[YVL C.5 370]

Sets conditions, criteria and objectives to be met to terminate the emergency on the site and to provide relevant information in this regard to relevant off-site officials;

1. The emergency plan shall define the criteria governing the termination or reduction of measures taken due to an emergency situation. A precondition for the termination of an emergency situation is that the nuclear power plant has been brought into a safe state, releases of radioactive substances do not exceed the thresholds set for normal operation and the necessary recovery measures are initiated.

2. If rescue operations continue after the termination of the emergency situation, the licensee shall be prepared to engage in co-operation corresponding to that which occurs during an emergency situation. [STUK Y/2/2018 Section 12]

Documents, protects and preserves, to the extent practicable, data and information important for an analysis of the emergency and emergency response;

Analyses the emergency and the emergency response with the aim to identify actions to be taken to avoid other emergencies and to improve emergency arrangements;

4. Emergency arrangements shall be regularly evaluated. When developing the emergency arrangements, attention shall focus on the experience gained and conclusions drawn concerning the management of emergency situations, the experience gained from the exercises as well as on research and technical developments. [STUK Y/2/2018 Section 8]

Develops capability to be able to effectively respond in an emergency which includes:

Clear assignment of authorities and responsibilities in EPR for various positions within its organizational structure;

1. The licensee shall have a management system and organisation in place to ensure a timely response in an emergency situation. The tasks of people assigned to act during an emergency situation are to be defined in advance.

[STUK Y/2/2018 Section 6]

317. The emergency manager shall take care of the following tasks with support from the emergency response organisation:

- assessment of the situation and determination of the emergency action level
- alerting the emergency response organisation

· managing plant safety

· looking after the safety of the personnel including the emergency response organisation at the site area

· organising the alarming and notification of the authorities

· securing the transport and care of those injured

· assessment of the plant' s technical status, radiation situation and radioactive releases, as well as assessment of dispersion of radioactive releases and dose impacts within the emergency planning zone

· preparation of radiation measurements and sampling at the plant, on site area and precautionary action zone

· mitigation and management of damage as well as the decision-making on the corrective measures needed

· decision-making on the extent of the activities of the emergency response organisation

· decision on the possible continuation of operation of other plant units within the site area, and agreeing on the necessary co-operation

· organising event log keeping

· informing the emergency response organisation, power plant personnel and authorities

· assessment of the INES rating describing the severity of the event by means of the international INES scale

· organising communication

· direction of evacuation of the site area together with the rescue authority

· issuing recommendations, if needed, for the evacuation of the public of the precautionary action zone and for carrying out other protective measures in the emergency planning zone until STUK announces its responsibility for the issuance of recommendations

· termination of the emergency situation and emergency response organisation's activities.

318.The emergency plan shall describe how the duties listed in requirement 317 are allocated and how they are implemented. For this purpose, the plan shall contain a description of the emergency response organisation, its tasks and distribution of responsibilities. In addition, the arrangements for obtaining technical support for the operational personnel shall be taken care of. Action teams shall be available to mitigate the consequences of the emergency situation (such as damage containment, corrective actions, fire-fighting).

[YVL C.5 317, 318]

Ensuring adequate number of suitably qualified personnel is available to promptly staff necessary positions in an emergency response as well as in long term if needed;

2. The licensee shall ensure that the personnel needed in emergency situations are promptly available. There shall also be enough personnel to bring a long-term emergency situation under control. [STUK Y/2/2018 Section 6]

319.A sufficient number of trained persons shall be assigned in the emergency plan to perform tasks of the emergency response organisation. These individuals shall be nominated for the tasks primarily so that they take care of duties in the emergency response organisation similar to those they are responsible for under normal circumstances. The emergency organisation's emergency workers shall be nominated. [YVL C.5 319]

Ensuring means for coordination with other organizations in the use of necessary tools, procedures or criteria with the aim to ensure consistency in any relevant assessments made in a nuclear or radiological emergency;

Developing emergency plan, procedures and analytical tools for emergency response which are coordinated with those of other organizations and with other relevant plans;

5. Planning shall take account of events deteriorating safety, their controllability and the severity of consequences, and threats related to unlawful action and the potential consequences thereof.

6. Emergency arrangements shall be consistent with the operation, fire protection and nuclear security of a nuclear power plant.

7. Emergency arrangements shall be consistent with special situation plans, emergency plans and rescue plans prepared by the authorities.

7a. Receiving external assistance in an emergency situation shall be prepared for when planning emergency arrangements.

[STUK Y/2/2018 Section 3]

The emergency plan shall describe the measures to be initiated in emergency situations, and it shall include the instructions on how to carry out these measures. The emergency plan shall include at least the following:

· the classification of emergency situations and the description of events and accidents on which it is based

· the emergency response organisation

· the alarms, notifications and communications arrangements

· emergency situation management and performance of situation assessments

· the safety of workers and radiation protection

· the radiation measurements undertaken at the nuclear power plant, site area and precautionary action zone during an emergency situation

· provision of information to the public

· the premises, equipment and accessories

· termination of emergency situations and recovery measures

· actions to ascertain the causes of the emergency situation and to learn from the emergency situation

· measures pertaining to the licensee's rescue operations

· the emergency response organisation's instructions for emergency situations

· a description of how emergency preparedness is maintained.

[Regulatory Guide YVL C.5 302]

Validation of various procedures and analytical tools through testing them under simulated emergency conditions prior to initial use;

Ensuring adequate tools, instruments, supplies, equipment, emergency response facilities and documentation are available to support the on-site emergency response including, where appropriate, alternative supplies for taking on-site mitigatory actions (such as alternative electrical power supply);

4. To prepare for an emergency situation, the licensee shall have appropriate staff alarm systems, places of assembly in the site area, evacuation arrangements, the necessary personnel protective equipment, radiation measuring instruments and iodine tablets available. In addition to permanent and temporary personnel working at the site area, arrangements shall also consider all emergency workers and helpers arriving in the site area during an emergency situation.

6. To manage emergency operations, there shall be an emergency response centre, which shall be able to maintain proper working conditions during an emergency situation, and which shall also be available during prolonged power failures.

7. There shall be a designated centre outside the site area from which to direct the plant's emergency response operations, if the emergency response centre is not available.

[STUK Y/2/2018 Section 4]

Developing and implementing training and exercise programmes;

1. The licensee shall arrange emergency training for all nuclear power plant personnel and other permanent or temporary employees working at the site area.

2. The licensee shall arrange emergency exercises on an annual basis. At least once every three years the emergency exercise shall be arranged as a co-operation exercise with the authorities. The emergency exercises shall be evaluated based on the set preparedness objectives.

3. The licensee shall draw up at least a three-year training plan to ensure that training is given on all aspects of preparedness to act at regular intervals.

4. Emergency arrangements shall be regularly evaluated. When developing the emergency arrangements, attention shall focus on the experience gained and conclusions drawn concerning the management of emergency situations, the experience gained from the exercises as well as on research and technical developments. [STUK Y/2/2018 Section 8]

Establishing a quality management programme, as part of its management system, to ensure the availability and reliability of all supplies, equipment, communication systems and facilities, plans, procedures and other arrangements necessary for an emergency response which includes review and revisions of emergency plans, procedures and other arrangements on a regular basis and maintaining records.

10. Licensee's management system and organisation shall ensure maintenance and development of the emergency arrangements. [STUK Y/2/2018 Section 4]

1. The licensee shall have a management system and organisation in place to ensure a timely response in an emergency situation. The tasks of people assigned to act during an emergency situation are to be defined in advance.

2. The licensee shall ensure that the personnel needed in emergency situations are promptly available. There shall also be enough personnel to bring a long-term emergency situation under control. [STUK Y/2/2018 Section 6]

The licensee shall appoint a person responsible for the nuclear facility's emergency arrangements as well as a deputy for this person. Only a person approved by the Radiation and Nuclear Safety Authority (STUK) under Section 7 i of the Nuclear Energy Act can be appointed to this task. [YVL C.5 405]

Question 2.2 How does the RB ensure that the operating organization is given sufficient authority to promptly take necessary actions on the site to mitigate the consequences of an emergency even if they could result in off-site consequences?

Response:

<u>According to the YEL Section 9:</u>

The licence holder shall be under an obligation to ensure the safe use of nuclear energy. This obligation may not be delegated to another party. The licence holder shall ensure that the products and services of contractors and subcontractors which affect the nuclear safety of the nuclear facility meet the requirements of this Act. (905/2017)

It shall be the licence holder's obligation to carry out such security and emergency arrangements and other arrangements necessary for the limitation of nuclear damage which do not rest with the authorities.

<u>According to STUK Regulation Y/2/2018 Section 9:</u>

1. In an emergency situation, the licensee shall take the measures required under the emergency plan and other necessary measures without delay in order to control the situation and prevent or limit radiation exposure.

<u>According to STUK Regulation Y/2/2018 Section 11:</u>

2. The licensee is in charge of matters related to nuclear safety and radiation safety at the nuclear power plant. In an emergency situation, the emergency manager of the nuclear power plant, as specified in the

emergency plan, shall initiate and direct the work of the emergency response organisation at the power plant.

3. The nuclear power plant's emergency manager issues recommendations for protecting the public to the director of rescue operations, until the Radiation and Nuclear Safety Authority announces responsibility for issuing such recommendations.

Question 2.3 How does the RB ensure that the operating organization reviews and, as necessary, revises the emergency arrangements (a) prior to any changes in the facility or activity that affect the existing hazard assessment and (b) when new information becomes available that provides insights into the adequacy of the existing arrangements?

Response:

According to STUK Regulation Y/2/2018 Section 3

The design basis [of emergency arrangements] must be regularly assessed and always when seen to be necessary.

According to STUK Regulation Y/2/2018 Section 8

4. Emergency arrangements shall be regularly evaluated. When developing the emergency arrangements, attention shall focus on the experience gained and conclusions drawn concerning the management of emergency situations, the experience gained from the exercises as well as on research and technical developments.

5. Facilities and equipment reserved for emergency situations shall be available and maintained in operational condition at all times.

6. The emergency plan and procedures shall be kept up to date.

Question 3 Does the RB verify that emergency arrangements of operating organizations are in place and provide sufficient assurance for an effective on-site emergency response for any regulated facility or activity that could necessitate emergency response actions?

Answer: Yes

Response:

RB (STUK) reviews the preliminary on-site emergency plan in the construction licence phase. Later, in the operating licence phase the RB reviews the on-site emergency plan. Before the fresh nuclear fuel is delivered to the site, the emergency arrangements shall be sufficient. Before the core loading the arrangements shall be as per the on-site emergency plan.

The on-site emergency plan is delivered to STUK for approval. If there are only minor changes, the plan could be delivered to STUK for information.

The on-site emergency arrangements are part of the inspection programmes, and the inspections concerning the emergency preparedness are conducted on a yearly basis for NPPs in operation.

Representatives of STUK takes part in the planning and evaluation work of the emergency exercises.

Question 3.1 How does the RB verify that EPR arrangements of operating organizations are in place and provide sufficient assurance for an effective on-site emergency response before commencement of operation and throughout the lifetime of the facility or during the conduct of the activity?

Response:

RB (STUK) reviews the preliminary on-site emergency plan in the construction licence phase. Later, in the operating licence phase STUK reviews the on-site emergency plan. Before the fresh nuclear fuel is delivered to the site, the emergency arrangements shall be sufficient. Before the core loading the arrangements shall be as per the on-site emergency plan.

According to the STUK regulation Y/2/2018 the emergency plan and procedures shall be kept up to date. During operation the Radiation and Nuclear Safety Authority approves the updates to licensees' emergency plans. Any updates which concern minor revisions are submitted for information. STUK must request an opinion from the Ministry of the Interior on any emergency plan as laid down in Section 37 of the Nuclear Energy Decree. The document is reviewed and approved.

STUK performs regular inspections of nuclear facilities (KTO programme for operating facilities, RTO programme for facilities under construction). In the KTO programmes of the NPPs in operation, the inspection of emergency preparedness is carried out on annual basis. Under RTO programme the inspection of emergency preparedness is done according to the separate inspection schedule prepared by STUK.

Based on the STUKs regulation Y/2/2018 Section 8 the licensee shall arrange emergency exercises on an annual basis. At least once every three years the emergency exercise shall be arranged as a co-operation exercise with the authorities. The emergency exercises shall be evaluated based on the set preparedness objectives. The local rescue department is in charge arranging the full scope exercise and the licensee is in charge arranging the other annual exercises.

Based to the rescue act and MIO's decree 1286/2019 the AVI is in charge supervising the full scope exercises. Representatives of STUK takes part in the planning and evaluation work of both the full scope emergency exercises and the annual emergency exercises.

Question 3.2 How does the RB review and assess the compliance of emergency arrangements of operating organizations against the regulatory requirements and guidance?

Response:

Emergency arrangements are supervised and reviewed according the STUK's internal procedure Guide YTV 3.c.6.

The inspection criteria of the emergency arrangements of nuclear power plants are included in the following regulations: STUK's regulation Y/2/2018 and Guides YVL C.5 'Emergency arrangements of a nuclear power plant', YVL A.4 'Organisation and personnel of a nuclear facility' and YVL C.4 'Assessment of radiation doses to the public in the vicinity of a nuclear facility'.

The records for the inspection and oversight results of emergency arrangements include: the safety assessment for a construction licence, the safety assessment for an operating licence, the safety assessments performed to extend an operating licence, the decision letters and presentation memoranda, the inspection memoranda, the inspection protocols, the assessments of emergency exercises, meeting memoranda and entries into Polarion databases.

Question 3.3 How does the RB perform inspection over emergency arrangements established by operating organizations?

Response:

Please see also the answers to questions 3.1 and 3.1

STUK performs regular inspections of nuclear facilities. In the KTO programmes of the NPPs in operation, the inspection of emergency preparedness is carried out on annual basis

Description how a KTO inspection is planned, conducted, and reported can be found in Guide YTV 4.a.1.

The emergency arrangements of a nuclear power plant may also be inspected by means of operational oversight inspection, which are described in Guide YTV 4.b.1.

In addition to the formal inspections, STUK collects information on emergency arrangements during site visits, meetings, and informal discussions with the licensees. Observations are recorded in the Polarion data base (HAKE).

Question 3.4 How does the RB evaluate some of exercises carried out by operating organizations to test their emergency arrangements in place?

Response:

Evaluation is mainly done by the persons who have taken part to the planning of the exercise, but also other experts can participate depending on the nature of the exercise.

Evaluation of the full scope exercises is typically done according to the Rescue Academie´s procedure and check-lists. STUK has an own check list connected to the procedure YTV 3.c.6.

Question 3.5 How does the RB ensure that the emergency arrangements of operating organizations are integrated with those of relevant off-site response organizations and with other plans (such as security plans and contingency plans established for nuclear security purposes)?

Response:

See the following answers

Question 4 Has the Government assigned the RB with responsibilities in the event of a nuclear or radiological emergency?

Answer: Yes

Response:

See the following answers

Question 4.1 What responsibilities in response to a nuclear or radiological emergency have been assigned to the RB, what type of advice and expert services, if any, is expected to provide in an emergency response?

Response:

STUK's responsibilities in response to a nuclear or radiological emergency are defined in Section 46 of Rescue Act. Further details on the expected advice and expert services during such emergency are given in Ministry of Interior Guide on Radiation Emergencies that is a consolidated document on responsibilities of all authorities during a radiation emergency.

Section 46 of Rescue Act defines STUK's responsibilities as being notifying, warning, and reporting about exceptional radiation situations, analysing the safety significance of the situation, and issuing recommendations on protective actions.

In the Ministry of Interior Guide on Radiation Emergencies, the analysis and reporting of the situation is specified to include following the evolution of the accident, providing prognosis of the evolution, estimating possible releases and their dispersal in cooperation with the Finnish Meteorological Institute. Recommendations on protective actions are to be provided for all authorities responsible for them, with the most important at first being the regional rescue commander, who is responsible for actions that directly protect the public.

In the intermediate phase, STUK's responsibility of analysing the safety significance also includes collecting all measurement results from different authorities and forming and maintaining understanding of the radiation situation in different areas based on these.

Currently legislative framework is fragmented into separate different laws that apply to individual organizations. Multiple laws do not form co-ordinated structure for emergency response. MOI Guide on Radiation Emergencies summarizes responsibilities from different laws, however this does not resolve the problem of inadequate co-ordination

Question 4.2 How does the RB ensure that it has and maintains an adequate capability to fulfil its responsibilities in response to a nuclear or radiological emergency?

Response:

How does the RB ensure that it has and maintains an adequate capability to fulfil its responsibilities in response to a nuclear or radiological emergency?

Emergency Planning

STUK has carried out broad hazard assessment which has identified variety of events that may warrant our response. Startegy for protective actions has been written down in VAL 1 guidance. This protection strategy has been harmonized together with other Nordic countries and published also as a common strategy for all countries. From our national role and hazard assessment we have integrated our role and responsibilities into a consept of operations that has been integrated into the internal set of procedures for emergency response.

Response is graded according to actual impact for safety but also taking into account infromation needs for our counterparts, international community, media and public. STUK has 24/7 on-duty capabilities to initiate and receive alarms and to trigger appropriate response. Each group in response organization has their own procedures for emergencies. STUK response organization has comprehensive understanding of all-hazards approach as our RB´s national function is to provide expertize to all radiological and nuclear aspects regardless their origin. This includes national role and international conventions which define our responsibilities.

Events and Exercises

STUK has a long tradition to operate during emergencies. Since Chernobyl there has been other notable real events that have activated STUK response. To name a few, Fukushima Dai-ichi and event in Sosnovy Bor 1990´s. There have also been domestic events in Loviisa NPP alert status in 2005 and Olkiluoto NPP site area emergency in 2020. These events, among others, has established strong culture to prepare for emergencies.

In addition STUK has taken part or organized numerous emergency exercises through history, both national and international level. They are not limited to NPP exercises but other authorities (police, defence forces, customs, rescue) have organized their exercises where STUK has taken part. Exercises are regulary full response cpx-exercises, involving typically all our capabilities. These exercises involve regulary not only authorities but also exercise-media and relevant private entities as well. Field teams have participated in actual field exercises and also in international exercises in other Nordic countries.

STUK gathers experiences from these exercises and evaluating our response has been used to identify improvements. Our calculation tools have been developed together with National Meteorological Institute and as part of European JRODOS consortium. STUK has also inhouse development for our own systems and software. Development has been carried out with validation programs.

STUK has established and takes part in co-operation and coordination meetings between first responders, NPP response organization and STUK. This co-operation has been long tradition to have smooth interaction between parties in urgent phase of any emergency.

Capabilities

STUK has prepared detailed procedures for emergencies and developed range of computerized tools and platforms to be used during emergencies. STUK also have set of information and communication systems available for internal and external communication.

Our staff has been involved broadly not only during exercises but also during preparedness phase to research, develop and maintain our capabilities to respond. Staff has been assigned to response organization according to their knowledge and skills. Each response group have their own basic and refresher trainings. Persons taking part in exercises and trainings are recorder so that training needs can be tracked.

Question 4.3 How it is ensured that the RB has not been assigned with any responsibility in response to a nuclear or radiological emergency that might compromise or conflict with its discharging of its responsibility for regulating the safety of facilities and activities?

Response:

STUK function during emergencies is clearly defined to give advice to responding competent authorities. Relationship with operating organization during emergencies is co-operative so that up-to-date information and important developments and other relevant information is shared together with other authorities (e.g. rescue or police) This does not change in any way to clear responsibilites that has been assigned for licensee that they have sole responsibility for everything inside NPP site boundary, where as rescues services have a sole decision power to protect the public outside the NPP site boundary. This does not mean that organizations would not interact and co-operate. STUK maintains direct contact with licensee even during the emergencies to better understand actions that are carried out in NPP. This is part of STUK situation assessment and threat evaluation.

Analysis

STRENGTHS FOR 10. BASIC PRIMARY RESPONSIBILITIES OF THE REGULATORY BODY (RB) IN EMERGENCY

S1	Well established requirements and supervision practices concerning licensee's EPR responsibilities and duties.
S2	STUK's clear role regarding emergency preparedness arrangements of the licensees.
S3	Strong commitment of both RB and Licensee towards EPR -arrangements (supportive safety culture).
S4	Learning by doing – regular exercises involving all parties concerned.

WEAKNESSES FOR 10. BASIC PRIMARY RESPONSIBILITIES OF THE REGULATORY BODY (RB) IN EMERGENCY

W1	Co-ordination of the emergencies outside the plants or facilities concerned. Given the character radiological and nuclear emergencies there is no clear co-ordination between the various authorities (responsibilities are divided to several sectors).
W2	Deficiencies in legislation related to post-accident situations, ambiguity of regulatory responsibilities.
W3	No unified communications and situational awareness systems to share information to all relevant stakeholders.

OPPORTUNITIES FOR 10. BASIC PRIMARY RESPONSIBILITIES OF THE REGULATORY BODY (RB) IN EMERGENCY

O1	Sufficient self-criticism – supportative safety culture that enables and is open to improvements.

THREATS FOR 10. BASIC PRIMARY RESPONSIBILITIES OF THE REGULATORY BODY (RB) IN EMERGENCY

T1	Complexity of the operative environment and capacity to respond in emergencies under threats cutting through the whole-of-society.
T2	Co-ordination between different authorities on national, regional, and local level, current legislation does not provide clear responsibilities. This may lead into inappropriate or contradictory protective actions.
T3	Lack of coordination can create confusion among the public, gives room for mis- or disinformation which leads to loss of confidence towards authorities.

CONCLUSIONS FOR 10. BASIC PRIMARY RESPONSIBILITIES OF THE REGULATORY BODY (RB) IN EMERGENCY

C1	STUK has established very strong regulatory requirements and oversight functions in order to verify that operating organizations are well prepared to any emergencies. There is strong Finnish tradition to co-operate across administrative sectors and between public and private sector in preparedness and response functions. This tradition is manifested in day-to-day activities during the preparedness phase, and this is then taken into practise in any real emergencies.
C2	We see major room for improvements regarding response to complex threats cutting through the whole-of-society these may jeopardize effective response in radiological or nuclear emergencies.
C3	In addition, national co-ordination needs updated legislation to achieve better co-ordination between different authorities on national, regional, and local level.

OUTCOMES OF THE SELF-ASSESSMENT FOR FACILITIES AND ACTIVITIES AND EXPOSURE SITUATIONS

Module: Safety Requirements for Medical Exposure

Findings

Question 1 Does the government ensure that relevant parties are authorized to assume their roles and responsibilities and that diagnostic reference levels, dose constraints, and criteria and guidelines for the release of patients are established?

Answer: Yes

Response:

Health care professionals

Requirements for health care professionals are established in Health Care Professionals Act (559/1994). The purpose of the act is given in section 1:

The purpose of this Act is to promote the safety of patients and to improve the quality of health care services by:

1. *ensuring that a health care professional referred to in this Act has the education and training necessary for the practice of the profession, other adequate professional qualifications and other knowledge and skills necessary for the practice of the profession;*
2. *organising the supervision of health care professionals within health and medical care; and*
3. *facilitating professionally appropriate co-operation between and appropriate employment of health care professionals.*

Section 2 stipulates who is considered health care professional:

In this Act, a health care professional is:

1. *a person who, on the basis of this Act, has been given the right to practise a profession (licensed professional) or the authorisation to practise a profession (authorised professional); and*
2. *a person who, on the basis of this Act, is entitled to use the occupational title of a health care professional as laid down by Government decree (professional with a protected occupational title). (1200/2007)*

Health Care Professionals Act (559/1994) sets requirements to right to practice as health care professional. Section 4 of the act sets requirements for profession of physician, dentist, medical specialist or dental specialist and section 5 sets requirements for the profession of head dispenser, psychologist, speech therapist, dietician, pharmacist, nurse, midwife, public health nurse, physiotherapist, laboratory technologist, radiographer, dental/oral hygienist, occupational therapist, optician or dental technician.

Health Care Professionals Decree (464/1994) section 1 lists protected occupational titles of health care professionals:

The protected occupational titles of professionals referred to in section 2 (1) 2 of the Health Care Professionals Act (559/1994) include orthopaedic technician, chiropodist, trained masseur, chiropractor, naprapath, osteopath, practical nurse for social and health care, psychotherapist, hospital physicist (medical physicist), hospital geneticist, hospital chemist, hospital microbiologist, and hospital cell biologist.

Guidance and supervision of health care professionals is established in Health Care Professionals Act section 24. The National Supervisory Authority for Welfare and Health (Valvira) is responsible for the national guidance and supervision of health care professionals. Valvira has a central register of social and health care professionals. Citizens can check the registration status of a social welfare or a healthcare professional in the public information service of the Registers. Information can searched either using the person's first and last name or the registration number. Link to register: JulkiTerhikki (valvira.fi)

Qualifications and recognition of qualifications of medical physicist and radiation safety expert in health care are given in SätL section 37- to 39. SätL section 47 gives requirements on workers radiation protection skills in medical use of radiation.

37 Qualifications of a radiation safety expert

A radiation safety expert shall have a master's degree as referred to in the Universities Act (558/2009) from a suitable field of mathematical-natural science or engineering. Radiation safety experts shall furthermore possess the radiation protection training required by the field of expertise and sufficient work experience in the field of expertise applicable to the task.

In health care and veterinary medicine radiation practices, the radiation safety expert shall also have the right to use the occupational title of a medical physicist by virtue of the Health Care Professionals Act.

Section 38 Qualifications of a medical physics expert

A medical physics expert shall have the right to use the occupational title of a medical physicist pursuant to the Health Care Professionals Act.

Section 39 Approval of radiation safety expert and recognition of qualifications

STUK grants persons who meet the qualification criteria specified in section 37 a right, specific to a field of expertise, to act as a radiation safety expert upon application.

A medical physicist who meets the qualification criteria for a radiation safety expert in the field of health care and veterinary medicine radiation practices may act as a radiation safety expert in said field of expertise without the approval referred to in subsection 1.

If radiation protection training for radiation safety experts in some particular field of expertise is not available in Finland, STUK determines the criteria required by the tasks in terms of the radiation safety expert's education and training and work experience and recognizes the qualifications on a case-by-case basis.

In a case falling under the scope of the Act on the Recognition of Professional Qualifications, STUK decides on the right conferred by radiation safety expert qualifications obtained abroad to act as a radiation safety expert in Finland in the fields of radiation practices in industry and research and the use of nuclear energy pursuant to the Act in question.

What is provided in subsection 4 also applies to the temporary and occasional provision of services. In cases other than those falling under the scope of the Act on the Recognition of Professional Qualifications, STUK may, for a special reason and on conditions determined by STUK, issue a person trained abroad a right to act as a radiation safety expert in Finland in the fields of radiation practices in industry and research and the use of nuclear energy.

Section 47 Radiation protection skills in medical use of radiation

The undertaking is responsible for ensuring that workers engaged in medical use of radiation are in possession of the applicable qualifications, including radiation protection skills.

Further provisions on the applicable qualifications and competence criteria for radiation protection are given by a decree of the Ministry of Social Affairs and Health.

Training and education of medical physicist

A medical physicist is a health professional within the meaning of the Health Care Professionals Act. Hospital physicist training has been provided in Finland for more than 50 years and currently the certificate of completion of specialised training in hospital physics is issued by the University of Helsinki, the University of Eastern Finland and the University of Oulu. Pursuant to the Government Decree on University Degrees and Specialised Training (794/2004), specialised training in hospital physics is included in the degree of licentiate, which is awarded on the basis of a higher university degree in mathematics, natural sciences or engineering.

The National Advisory Board for Hospital Physicists, set up by the University, acts as a cooperation body between universities, hospitals, the Social and Health Licensing and Inspection Agency and the Ministry of Education and Culture in matters of education. It coordinates training and ensures that the training provided by the various universities is appropriate in Finland. The university that appoints the advisory board rotates every three years between the universities providing the training. The University of Turku has appointed an Advisory Board for the period 2017-2019.

The training of a hospital physicist includes a theoretical part of a degree in philosophy or engineering, a four-year (raised to five) practical training period and examinations in radiation safety and hospital physics. To sit the examination for hospital physicists, you must have passed the examination in radiation safety, which currently includes an examination of the Director of Radiation Safety for the general use of radiation in the medical field, and three years of practical training. The Advisory Board for the Coordination of the Specialisation of Hospital Physicists examines whether the conditions for taking the examination have been met. The University will also examine the fulfilment of the practical training of the medical physicist before issuing the certificate and, if necessary, request the opinion of the Advisory Board for the Coordination of Medical Physicists.

Training and education of radiographers

The average duration of training as a radiographer is 3.5 years (bachelor degree, 210 ECTS credits). The studies can be continued either at a university of applied sciences to obtain a Master of Health Sciences or at a university of applied sciences to obtain a Master degree.

The purpose of the radiographers training is to teach the student the necessary skills to become competent in radiography, radiotherapy, the use of radiation for medical purposes and quality control. Student will be able to follow developments in the field and to see their professional expertise in relation to changes in society, the social and welfare sector and radiography and radiotherapy. Professional competence requirements for radiographers (2016).

The studies focus on practical working life needs, international issues and future challenges, and a reflective, critical and research-oriented approach, which requires practical skills in research and development. Students plan and develop their professional expertise by means of individual study plans (ISPs).

The studies are composed of contact teaching and guidance, independent learning and practical training at workplaces. Part of the studies will be completed online and in different projects with working life. Practical training is carried in various radiology and radiotherapy units.

Radiographer's training is offered in six locations: Helsinki, Turku, Tampere, Oulu, Kuopio and Vaasa.

Requirements to assume roles and responsibilities

The basic requirements for medical exposure are stipulated in Radiation Act Sections 113-116.

Radiation Act (859/2018)

Section 113 Oblications of referring physicians and dentists

The physician or dentist giving the referral must ensure the following prior to the performance of the examination, procedure or treatment:

1. any material information on previous examinations, procedures and treatments is acquired;
2. the referral includes the information needed for the optimization of the radiation protection, including the indication of the examination or treatment;
3. the individual exposed to radiation or any other individual concerned is provided with information on the benefits of the examination, procedure or treatment and any possible health detriment caused by the exposure.

The physician or dentist giving the referral must, for their part, assess the justification of the medical exposure caused by the examination, procedure or treatment. The physician or dentist giving the referral must have at their disposal referral guidelines concerning normal examinations, procedures and treatment causing exposure to radiation and information on the radiation doses caused by the examinations, procedures and treatments. If necessary, the referrer must consult experts before giving the referral.

Section 114 Responsibility for medical exposure

The physician or dentist responsible for the medical exposure is responsible for the justification of the medical exposure caused by the examination, procedure or treatment and for the optimization of radiation protection and, for their part, the medical assessment of the results of the examination, procedure or treatment. The responsibility requires qualifications pursuant to the quality of the examination, procedure or treatment.

The undertaking must ascertain the fulfillment of the required qualifications. The undertaking is responsible for that procedures pertaining to assigning and transferring responsibility are clear arranged.

A radiographer may participate in the practical procedures under the authorization of the physician referred to in subsection 1 for the purpose of ascertaining the justification for the medical exposure.

Further provisions on the qualification requirements of a physician or dentist responsible for medical exposure are given by a decree of the Ministry of Social Affairs and Health.

Section 115 Performer of the examination, procedure or treatment

A radiographer may perform the examination exposing a patient to radiation pursuant to the referral and administer the planned treatment independently. Other health care professionals may, under the supervision of the physician responsible for the medical exposure, assist in the use of X-ray equipment they have been educated and trained to operate.

The undertaking and the physician responsible for medical exposure may authorize a health care professional other than a radiographer who has received the appropriate supplementary training and is familiar with nuclear imaging to perform a pre-determined native computed tomography examination pursuant to a standard programme on a nuclear medicine hybrid device, if the examination is a fixed part of nuclear imaging.

A health care professional who has received professional education and training for dental X-ray examinations may perform dental X-ray examinations according to the instructions of a physician or dentist.

Other individuals engaged in the performance of examinations, procedures or treatment causing exposure to radiation must have the education and training and experience required by their tasks.

The undertaking is responsible for the clear organization of the responsibilities and procedures concerning the performance of examinations, procedures and treatment.

Section 116 Responsibilities of the performer of the examination, procedure or treatment

The performer of an examination, procedure or treatment must, for their part, ensure that the examination, procedure or treatment is performed safely before targeting radiation at a human being. In particular, it must be ensured that:

1. the safety and shielding arrangements of the radiation source are in order and the appliances in use function properly;
2. the patient is appropriately protected, and the radiation exposure has been limited to the parts of the body intended to be irradiated;

3. any radioactive substance administered to the patient has been appropriately checked.

Section 32 Use of experts

…

Subsection 2

A medical physics expert shall furthermore be used in the planning, implementation and monitoring of the radiation protection of the person subject to exposure when the case concerns medical exposure or imaging as referred to in chapter 14, which involves the use of medical devices covered by certain EU Directives, such as the Act on Medical Devices (629/2010), the Medical Devices Directive, Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No: No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (hereinafter referred to as the MD Regulation) or Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (hereinafter referred to as the IVD Regulation).

The experts mentioned in subsections 1 and 2 shall be used in the appropriate manner, in proportion to the radiation exposure and potential exposure resulting from the practice.

Further provisions on the use of experts are given by government decree

Government Decree on Ionizing Radiation (1034/2018)

Section 20, *Areas of medical physics expert's use*

A medical physics expert must be used in the management of the dosimetry of medical exposure, including the physical measurements needed for the determination of radiation exposure and to provide advice on radiation appliances.

A medical physics expert must furthermore be used in:

1. the optimization of the radiation protection of a person subject to medical exposure as well as the foetus of a pregnant individual being examined, receiving treatment or subject to a procedure;
2. comparing a patient's radiation exposure to reference levels;
3. the preparation of instructions concerning the performance of conventional radiological examinations, procedures and treatments;
4. the selection of measuring equipment;
5. the technical specifications of radiation appliances;
6. the design of installations;
7. the planning and implementation of a quality assurance programme for radiation appliances;
8. the acceptance tests of appliances and in demonstrating the fulfillment of the appliances' in-service approval requirements and other requirements concerning the appliances and their use;
9. the preparation of a safety assessment with respect to medical exposure;
10. the investigation of any medical exposure deviating from planned exposure and the planning of measures required to prevent comparable events;
11. the planning and organizing of the personnel's radiation protection training.

The basic requirement to establish diagnostic reference levels are given in Radiation Act Section 112 Subsections 3 and 4 and more detailed requirements are given in regulation S/4/2019.

Radiation Act (859/2018)

Section 112 Optimization of radiation protection in medical exposure

The undertaking shall employ the reference levels for the patient's exposure for the purpose of optimizing radiation protection in medical exposure resulting from examinations and procedures.

STUK issues more detailed regulations of a technical nature on the practical procedures for optimizing radiation protection in examinations, procedures and treatments and on the optimization of the radiation protection of children as well as pregnant, breastfeeding and asymptomatic individuals. In addition, STUK issues more detailed regulations on the diagnostic reference levels of examinations and procedures and their use.

Radiation and Nuclear Safety Authority Regulation on justification assessment and optimisation of radiation protection in medical exposure, S/4/2019

Section 10, Reference level for a patient's radiation exposure

The reference levels for a patient's radiation exposure are specified in Annex 1–7. The value of a reference level determined by the undertaking itself may not exceed that which is specified in the Annex.

The undertaking must compare the value describing the average radiation exposure of a patient and the activity administered to a patient to the reference level at least once every three years and whenever examination practices or imaging values are changed in such a way that the radiation dose or activity undergoes a material change. This is not applicable to the use of a dental X-ray device to image an in-mouth image detector.

The average value and activity describing the radiation exposure must be determined as the median of at least ten patients of a normal size, either by measuring or on the basis of a calculated estimate, unless otherwise provided in an Annex.

During the years when the determination is not carried out, it must be ensured that the value or activity describing the radiation exposure has not changed.

If the determined average value or activity describing the patient's radiation exposure exceeds the reference level, the reason for the high radiation exposure or activity must be investigated and, if necessary, measures must be taken to reduce patients' radiation exposure.

ANNEX 1, Reference levels for patients' radiation exposure in the computed tomography examinations of adults

ANNEX 2, Reference levels for patients' radiation exposure in nuclear medicine examinations

ANNEX 3, Reference levels for patients' radiation exposure in paediatric CT scans

ANNEX 4, Reference levels for patients' radiation exposure in cone-beam computed tomography examinations of adults' head region

ANNEX 5, Reference levels for patients' radiation exposure in cardiology

ANNEX 6, Reference levels for patients' radiation exposure in the conventional X-ray ex-aminations of adults

ANNEX 7, Reference levels for patients' radiation exposure in conventional paediatric X-ray examinations

When reference levels and the STUK order where reference levels for patient exposure are given is updated, the draft order is sent on the request for a public consultation. The consultation and the opinion are requested from professional societies, health care districts and major private health care companies using public opinion service (Lausuntopalvelu.fi) Additionally, all citizens can give their comment using the same system (Lausuntopalvelu.fi). Comments and opinion's to draft STUK's order of justification and optimization in medical exposure can be seen behind this link: S/4/2019 - Lausuntopalvelu (in Finnish).

Diagnostic reference levels timeliness is verified from time to time. Nuclear medicines diagnostic reference levels (STUK S/4/2019 Annex 2) timeliness is checked every three-year using the data that is gathered with surveys. Last survey was made concerning year 2018 (A survey on the use of radiopharmaceuticals in diagnostics and therapy in 2018 in Finland). If there has been progress in activity administered to patient then diagnostic reference level can be updated for the study. For diagnostic x-ray examinations and procedures (STUK S/4/2019 Annex 1, 3-7) diagnostic reference level will be updated if there has been significant technical progress that will enable lower patient exposure levels, or if it is seen during inspections that current diagnostic reference levels are not any more relevant, or if long time has been passed since the diagnostic reference levels has been established.

In 2017, a Nordic DLR workshop was organized where CT, plain radiography x-rays, mammography, interventional, dental CBCT and isotope imaging DRL's were discussed and compared.

The prime requirements for establishing dose constrains are given in Radiation Act Section 25. The Government Decree on Ionizing Radiation Sections 10-11 gives more detailed requirements regarding

carer's and comforters exposure to radiation and Section 9 gives requirements for optimization for volunteer participating in a programme of biomedical research.

Dose constrains for carers and comforters

Radiation Act (859/2081)

Section 4 Definitions

For the purposes of this Act, the following terms have the following meanings

a) dose constraint means a constraint on the individual radiation dose of a person other than a patient arising from ionizing radiation during a specific period of time, used to optimize radiation protection in radiation practices;

Section 25 Establishing dose constraints and constraints for potential exposure

The undertaking shall establish the dose constraints and constraints for potential exposure to be used in the radiation practice in advance, unless STUK has established the constraints to be used in the practice in general by virtue of section 10. Constraints on the occupational exposure of an outside worker shall be established in co-operation with the employer of the outside worker.

The constraints for potential exposure of workers and members of the public must be established beforehand for such radiation safety deviations referred to in section 26, subsection 1, paragraph 1, which may result in significant radiation exposure.

The information concerning the constraints referred to above in subsection 1 must be delivered to STUK either as part of the granting of the safety licence or separately. Proposed constraints are compared to international recommendations, e.g. EC Radiation Protection 97, Radiation Protection following Iodine-131 therapy (exposures due to out-patients or discharged in-patients, ICRP

Publication 94 Release of Patients after Therapy with Unsealed Radionuclides and IAEA SRS No. 63 Release of Patients After Radionuclide Therapy. Proposed constraints are accepted if they are in line with Finnish legislation and international recommendations.

Government Decree on Ionizing Radiation (1034/2018)

Section 10 Optimization of comforter's radiation protection

A comforter must be instructed and protected in such a way that their radiation exposure remains as low as practically possible.

Section 11 Discharge of a patient who emits radiation

In the event that medical exposure is attributable to a radiopharmaceutical or a sealed source implanted in the patient, the individual subject to the radiation exposure may not be discharged until the dose caused by the radioactive substance in the body to the comforter or members of the public is expected to remain below the dose constraint.

The physician responsible for the medical exposure is responsible for the patient's discharge and for providing the patient or their representative with written instructions on how to prevent unnecessary exposure to individuals in contact with the patient.

Dose constrains for volunteers participating in biomedical research.

Government Decree on Ionizing Radiation (1034/2018)

Section 9 Optimization of the radiation protection of a research subject taking part in medical research

The radiation exposure of a research subject taking part in medical research as referred to in the Medical Research Act must be planned individually if the health of the research subject is expected to benefit from the research, procedure or therapy. A dose constraint must be applied to an individual who is not expected to gain immediate health benefits from the radiation exposure caused by the research. International recommendations for dose constraints for biomedical research are used as a criteria, e.g. EC Radiation protection 99, Guidance on medical exposures in medical and biomedical research.

As dose constraints are established in STUK orders they will go for public consultation in the same way as diagnostic reference levels. Link to public consultation on The Radiation and Nuclear Safety Authority's Regulation on Radiation Practices Subject to a Safety Licence -draft: STUK S/6/2019 daft - Lausuntopalvelu (In Finnish).

Question 2 Does the regulatory body require that health professionals with responsibilities for medical exposure are specialized in the appropriate area and that they meet the requirements for education, training and competence in the relevant specialty?

Answer: Yes

Response:

Radiation Act (859/2018)

Section 33 Training and induction of workers

The undertaking shall ensure that all workers engaged in radiation practices or whose tasks otherwise require special expertise in radiation protection are in possession of the qualifications, radiation protection education and training and induction to their duties required by the practices and the tasks.

The undertaking shall keep a worker-specific record on the radiation protection training and induction for which it is responsible.

STUK issues more detailed regulations on the provision and content of the radiation protection training and induction referred to in subsection 1 when the training or induction is provided in the form of continuing training and supplementary training

Section 38 Qualifications of a medical physics expert

A medical physics expert shall have the right to use the occupational title of a medical physicist pursuant to the Health Care Professionals Act.

Section 47 Radiation protection skills in medical use of radiation

The undertaking is responsible for ensuring that workers engaged in medical use of radiation are in possession of the applicable qualifications, including radiation protection skills.

Further provisions on the applicable qualifications and competence criteria for radiation protection are given by a decree of the Ministry of Social Affairs and Health.

Decree of the Ministry of Social Affairs and Health on ionizing radiation (1044/2018)

Section 5 Qualifications and competence of workers engaged in medical use of radiation

Workers engaged in the medical use of radiation must possess the knowledge, skills and competence in radiation physics, radiobiology and radiation protection required by their tasks.

The qualifications and radiation protection knowledge requirements of a worker engaged in the medical use of radiation are laid down in Annex 4.

Section 9 Qualifications of a physician or dentist responsible for medical exposure

The qualification requirements of a physician or dentist responsible for medical exposure are:

1. in radiotherapy, a specialist in oncology or other specialist qualified for radiotherapy in their specialty;
2. in nuclear medicine, a specialist in clinical physiology and nuclear medicine or other specialist qualified in nuclear medicine;
3. in X-ray examinations and interventional radiology: a specialist in radiology; other specialist responsible for medical exposure caused by the use of X-ray equipment shall possess the knowledge of radiation protection necessary for the examinations, procedures or treatments performed in their specialty;
4. in dental X-ray examinations: a dentist or other physician with the necessary knowledge of radiation protection.

The qualification requirements specified above in subsection 1, paragraph 3 shall also apply to a physician performing an X-ray examination or procedure.

In examinations, procedures, or treatments other than those specified in subsection 1, the physician responsible for medical exposure must possess the necessary knowledge of radiation protection.

If the necessary knowledge on radiation protection has not been included in the medical studies of a physician referred to in subsection 1, paragraph 3, the knowledge can be acquired by completing the supplementary training referred to in section 8.

All health care professionals referred in health care professional Act (1995/559) are required (and verified) that they have proper education, other professional qualifications and other competencies necessary for the exercise of their professional activities.

Health care professional Act (1994/559), section 1, Purpose of the Act

The purpose of this Act is to promote patient safety and the quality of health care services:

1. *by ensuring that the health care professionals referred to in this Act have the education, other adequate professional qualifications and other competencies necessary for the exercise of their professional activities;*
2. *organising the supervision of health professionals in the provision of health and medical care; and*
3. *facilitating professionally justified cooperation and appropriate use of health professionals.*

Question 3 Is it regulated that registrants and licensees ensure that no person incurs a medical exposure unless there has been an appropriate referral, responsibility has been assumed for ensuring protection and safety, and the person subject to exposure has been informed as appropriate of the expected benefits and risks?

Answer: Yes

Response:

Roles and responsibilities of various healthcare workers regarding the protection and safety for individuals undergoing medical exposures are well defined in SätL 113 § - 116 § and VnA 1034/2018 section 20. The Undertaking is solely responsible for meeting the requirements and demonstrating compliance of requirements.

Radiation Act

Section 22 Responsibility for radiation safety

The undertaking is responsible for the radiation safety of the practice. This responsibility cannot be transferred to another.

(undertaking means the holder of a safety licence as referred to in section 48, the holder of a licence as referred to in section 165, enterprise, corporation, foundation or institution as well as any employer or private entrepreneur conducting a radiation practice;)

The obligations imposed on undertakings are not diminished by the appointment of a radiation safety officer or some other person in charge or by the use of experts in the operations.

Section 113 Obligations of referring physicians and dentists

The physician or dentist giving the referral must ensure the following prior to the performance of the examination, procedure or treatment:

1. any material information on previous examinations, procedures and treatments is acquired;
2. the referral includes the information needed for the optimization of the radiation protection, including the indication of the examination or treatment;
3. the individual exposed to radiation or any other individual concerned is provided with information on the benefits of the examination, procedure or treatment and any possible health detriment caused by the exposure.

The physician or dentist giving the referral must, for their part, assess the justification of the medical exposure caused by the examination, procedure or treatment.

The physician or dentist giving the referral must have at their disposal referral guidelines concerning normal examinations, procedures and treatment causing exposure to radiation and information on the radiation doses caused by the examinations, procedures and treatments. If necessary, the referrer must consult experts before giving the referral.

Section 114 Responsibility for medical exposure

The physician or dentist responsible for the medical exposure is responsible for the justification of the medical exposure caused by the examination, procedure or treatment and for the optimization of radiation protection and, for their part, the medical assessment of the results of the examination, procedure or treatment. The responsibility requires qualifications pursuant to the quality of the examination, procedure or treatment. The undertaking must ascertain the fulfillment of the required qualifications.

The undertaking is responsible for that procedures pertaining to assigning and transferring responsibility are clear arranged.

A radiographer may participate in the practical procedures under the authorization of the physician referred to in subsection 1 for the purpose of ascertaining the justification for the medical exposure.

Further provisions on the qualification requirements of a physician or dentist responsible for medical exposure are given by a decree of the Ministry of Social Affairs and Health.

Section 115 Performer of the examination, procedure or treatment

A radiographer may perform the examination exposing a patient to radiation pursuant to the referral and administer the planned treatment independently. Other health care professionals may, under the supervision of the physician responsible for the medical exposure, assist in the use of X-ray equipment they have been educated and trained to operate.

The undertaking and the physician responsible for medical exposure may authorize a health care professional other than a radiographer who has received the appropriate supplementary training and is familiar with nuclear imaging to perform a pre-determined native computed tomography examination pursuant to a standard programme on a nuclear medicine hybrid device, if the examination is a fixed part of nuclear imaging.

A health care professional who has received professional education and training for dental X-ray examinations may perform dental X-ray examinations according to the instructions of a physician or dentist.

Other individuals engaged in the performance of examinations, procedures or treatment causing exposure to radiation must have the education and training and experience required by their tasks. The undertaking is responsible for the clear organization of the responsibilities and procedures concerning the performance of examinations, procedures and treatment.

Section 116 Responsibilities of the performer of the examination, procedure or treatment

The performer of an examination, procedure or treatment must, for their part, ensure that the examination, procedure or treatment is performed safely before targeting radiation at a human being. In particular, it must be ensured that:

1. the safety and shielding arrangements of the radiation source are in order and the appliances in use function properly;
2. the patient is appropriately protected, and the radiation exposure has been limited to the parts of the body intended to be irradiated;

3. any radioactive substance administered to the patient has been appropriately checked.

Section 111 Justification of the medical exposure of an asymptomatic individual

If the medical exposure required for the early detection of a disease in an asymptomatic individual is not part of a screening programme, the justification of the exposure pursuant to section 109 and 110 is subject to the preparation of special written grounds concerning the individual in question.

The author of the grounds shall be the physician or dentist responsible for the medical exposure, and they must hear the referrer. The preparation of the grounds must comply with the criteria for access to examination drawn up by the Council for Choices in Health Care in Finland, working in conjunction with the Ministry of Social Affairs and Health, a requirement which also applies to health care services referred to in Act on Private Health Care.

The physician or dentist responsible for the medical exposure shall ensure that the asymptomatic individual exposed to radiation has been provided with the information referred to in section 113, subsection 1, paragraph 3.

Approved health screening programs are defined in Government Decree on Screening (339/2011)

Question 3.1 How has it been ensured that no individual incurs a medical exposure as part of a programme of biomedical research unless the exposure has been approved by an ethics committee and a radiological medical practitioner has assumed responsibility and that protection and safety are optimized for persons subject to exposure as part of a programme of biomedical research?

Response:

All new types of use of radiation needs to have justification assessment during authorization for safety license as stipulated in SätL section 24.

Section 24 Justification assessment concerning new types of or existing practices

The undertaking shall demonstrate that a new type of radiation practice subject to a safety licence is justified. The same applies to existing radiation practices if new important information on the efficiency, possible consequences or alternative methods or techniques of the practice is obtained.

STUK confirms the practice as justified either as part of granting the safety licence or separately.

Further provisions on the procedures to be followed in the justification assessment and the necessary explanations are given by government decree.

The principles of justification and optimization of medical exposure are given in SätL section 109 and 112. These principles also apply to biomedical research.

Section 109 Justification assessment concerning medical exposure

When considering the justification for medical exposure, the assessment covers the benefit to be expected of the examination, procedure or treatment which exposes an individual to radiation, including the direct medical benefit to the patient or asymptomatic individual and the benefits to society and, on the other hand, any possible detriment caused to the aforementioned due to the exposure.

STUK issues more detailed technical regulations on the practical measures involved in a justification assessment.

Section 112 Optimization of radiation protection in medical exposure

The undertaking is responsible for the implementation of the requirements concerning the optimization of radiation protection in medical exposure. In addition, the undertaking shall keep the exposure of the carer and comforter and the individual being examined in for medical research as low as possible. The carer and comforter must be at least 18 years of age and they may not be pregnant. The optimization of the radiation protection of a pregnant individual being examined, receiving treatment or subject to a procedure must account for the exposure of the foetus.

The undertaking shall specify the responsibilities in terms of the optimization of radiation protection in medical exposure.

The undertaking shall employ the reference levels for the patient's exposure for the purpose of optimizing radiation protection in medical exposure resulting from examinations and procedures.

STUK issues more detailed regulations of a technical nature on the practical procedures for optimizing radiation protection in examinations, procedures and treatments and on the optimization of the radiation protection of children as well as pregnant, breastfeeding and asymptomatic individuals. In addition, STUK issues more detailed regulations on the diagnostic reference levels of examinations and procedures and their use.

The more detailed requirements regarding medical exposure justification and optimization in biomedical research are given in VnA sections 4 and 9.

Section 4, subsection 2, Individual justification assessment of medical exposure

For the purposes of medical research as referred to in the Medical Research Act (488/1999), the medical exposure caused to the research subject must be assessed and justified in advance.

VnA, Section 9, Optimization of the radiation protection of a research subject taking part in medical research

The radiation exposure of a research subject taking part in medical research as referred to in the Medical Research Act must be planned individually if the health of the research subject is expected to benefit from the research, procedure or therapy. A dose constraint must be applied to an individual who is not expected to gain immediate health benefits from the radiation exposure caused by the research.

Regarding (bio)medical research's justification on VnA section 9 it is required that STUK needs to have for the justification process the assessment from ethics committee. A favourable opinion from the Ethics Committee is necessary to enable the Radiation and Nuclear Safety Authority to ascertain the legitimacy of medical exposure in scientific research.

VnA, Section 7, subsection 3 and 4, Statements and other reports on the justification of practices

The undertaking must ensure that the Radiation and Nuclear Safety Authority has an opinion at its disposal for the purposes of the justification assessment referred to in section 24 of the Radiation Act from:

1. *an ethics committee referred to in the Medical Research Act if radiation is intentionally directed at a human being within the said Act's scope of application;*
2. *the National Institute for Health and Welfare on the assessment of a health care method, provided that the case concerns a new type of method which results in medical exposure which exposes a large number of members of the public or which results in a high degree of medical exposure.*

The ethics committee hears experts on the medical radiological use of radiation in a matter referred to in subsection 3, paragraph 1.

Medical research shall be conducted according to the Medical Research Act (1999/488). On the section 4 it is stipulated that the benefits shall outweigh the risk and harms (detrimental effects of the radiation). On the section 10 d it is further stated that on ethics committees statement shall particularly focus on the appropriateness of the benefit and risk assessment. The risk assessment should also include setup of dose constraints.

Medical Research Act (1999/488), Section 4

Comparison of advantages and harms

In medical research, the interests and well-being of the research subject must always take precedence over the interests of science and society. The risks and harms that the research subject may suffer must be prevented.

Subjects should only be subjected to procedures where the expected health or scientific benefits clearly outweigh the risks and harms that the subject may suffer.

Medical Research Act (1999/488), Section 10 d (23.4.2004/295)

Opinion of the Ethics Committee

The opinion of the Ethics Committee shall be subject to the provisions of Articles 3 and 17. The opinion on a clinical trial shall also take particular account of the following points:

1. *the appropriateness of the trial and its design;*
2. *the appropriateness of the benefit and risk assessment and the justification of the conclusions drawn therefrom;*

…

The government as approved renewed Clinical Drug Trials Act on 8.10.2021. On the renewed act section 18 gives the requirements for the composition of the ethics committee, including requirement to have an expert on medical exposure if radiation is used.

A quorum shall consist of at least six members in addition to the chairperson or vice-chairperson. At least one lay member shall be present when an ethical review of an application is being carried out.

When the Committee deals with the matters referred to in this Act, it shall be composed of the necessary medical, legal and ethical expertise.

An expert in paediatrics shall be represented or heard on the committee when the committee is dealing with a clinical trial involving a minor, and an expert with knowledge of the disease or disability concerned when the committee is dealing with a clinical trial involving a subject referred to in Article 13. An expert on the medical use of radiation shall be represented or heard by the committee if the clinical trial is intended to subject the subject to medical exposure as referred to in Section 4(10) of the Radiation Act (859/2018). The committee may also hear experts at other times. An official of the Finnish Medicines Safety and Development Agency may be heard as an expert.

The expert referred to in paragraph 3 may not participate in the decision-making of the Committee. Instead of hearing the expert orally, the Committee may request a written opinion.

Question 3.2 How has it been ensured that no individual incurs a medical exposure as a carer or comforter unless he or she has received, and has indicated an understanding of, relevant information on radiation protection and information on radiation risks prior to providing care and comfort to an individual undergoing a radiological procedure and that the procedure is optimized?

Response:

Act on the status and rights of patients (785/1992) sets the basic rights of the patient. Section 5 of the act stipulates the patients right to be informed and section 6 explains patients' right to self-determination and section 7 is about the status of minor patients.

Section 6 Patients' right to self-determination

The patient has to be cared in mutual understanding with him/her. If the patient refuses a certain treatment or measure, he/she has to be cared, as far as possible, in other medically acceptable way in mutual understanding with him/her.

If a major patient because of mental disturbance or mental retardation or for other reason cannot decide on the treatment given to him/her, the legal representative or a family member or other close person of the patient has to be heard before making an important decision concerning treatment to assess what kind of treatment would be in accordance 4 with the patient's will. If this matter cannot be assessed, the patient has to be given a treatment that can be considered to be in accordance with his/her personal interests.

In cases referred to in paragraph 2, the patient's legal representatives, a close relative, or other person closely connected with the patient, must give their consent to the treatment. In giving their consent, the patient's legal representatives, close relative, or other person closely connected with the patient must respect the patient's previously expressed wishes or, if no wishes had been expressed, the patient's well-being. If the patient's legal representatives, close relative, or other person closely connected with the patient forbid the care or treatment of the patient, care or treatment must, as far as possible in agreement with the person who refused consent, be given in some other medically acceptable manner. If the patient's legal representatives, close relative, or other person closely connected with the patient

disagree on the care or treatment to be given, the patient shall be cared for or treated in accordance with his or her best interests. (489/1999)

Provisions on treatment given irrespective of the will of the patient are included in the Mental Health Act (1116/1990), the Act on Social Work with Substance Abusers (41/1986), the Communicable Diseases Act (583/1986) and in the Act on Special Care for the Mentally Handicapped (519/1977).

Section 7 The status of minor patients

The opinion of a minor patient on a treatment measure has to be assessed if it is possible with regard to his/her age or level of development. If a minor patient owing to his/her age and level of development can decide on the treatment given to him/her, he/she has to be cared in mutual understanding with him/her.

If a minor patient cannot decide on the treatment given to him/her, he/she has to be cared in mutual understanding with his/her guardian or legal representative

The obligations of the undertaking to provide information to the patient and to the carer and comforter on the radiation are further complemented in SätL section 113. On the justification of the section 113 it is further clarified that the same information that is given for patient must also be given to the carer and comforter.

SätL Section 113 Oblications of referring physicians and dentists

The physician or dentist giving the referral must ensure the following prior to the performance of the examination, procedure or treatment:

…

1. *the individual exposed to radiation or any other individual concerned is provided with information on the benefits of the examination, procedure or treatment and any possible health detriment caused by the exposure.*

Justification of the SätL section 113:

…

The patient must be informed in advance about the planned examination, procedure or treatment that will expose him or her to radiation, the benefits to be gained from it and also the possible harms of the examination, so that he or she can accept or refuse the examination, procedure or treatment if he or she so wishes. This is informed consent and shared decision-making. The patient must be informed about the examination, procedure or treatment and the options for treatment in accordance with Article 5 of the Act on the Status and Rights of Patients. Similar information should be provided to the patient's support person. The patient's right to self-determination is provided for in Article 6 of the said Act.

The VnA section 10 stipulates that the undertaking shall instruct and protect carer and comforter in such way that their exposure remains as low as practically possible. On the VnA section 10 justification it is elaborated that carer and comforter shall be volunteer. After person is informed of the radiation risk involved in carers or comforters role, the person may refuse to be carer or comforter if they feel that the risk exceeds their threshold.

VnA, Section 10 Optimization of carer and comforter's radiation protection

A carer and comforter must be instructed and protected in such a way that their radiation exposure remains as low as practically possible.

VnA, justification of section 10:

For example, a carer or comforter, such as a parent, who must be protected and instructed during the X-ray examination. A carer or comforter can also be a close relative of the patient or another volunteer, for example, if the patient needs help at home after having had an isotope treatment. If a carer or comforter is not available, a person who is repeatedly exposed because of his or her job, for example as a holder, must be a worker under personal dose monitoring.

Further requirements on the optimization of radiation protection of the carer and comforter are given in SätL section 112.

SätL, Section 112 Optimization of radiation protection in medical exposure, Subsection 1

The undertaking is responsible for the implementation of the requirements concerning the optimization of radiation protection in medical exposure. In addition, the undertaking shall keep the exposure of the carer and comforter and the individual being examined in for medical research as low as possible. The carer and comforter must be at least 18 years of age and they may not be pregnant. The optimization of the radiation protection of a pregnant individual being examined, receiving treatment or subject to a procedure must account for the exposure of the foetus.

Regulatory supervision

Fulfillment of the obligations of the undertaking regarding carers and comforters radiation protection are typically verified with on-site inspections by going through licensees procedures and guidance regarding use of carers and comforters.

Question 3.3 How has it been ensured that there is sufficient medical personnel and paramedical personnel available as specified by the health authority?

Response:

There are requirements for a health care provider to ensure necessary human resources for its practice. For public sector these requirements for the conditions for health care are given in Health Care Act 1326/2010 and for private sector in Act on Private Health Care 152/1990. These are supervised by Regional State Administrative Agencies (AVI's) and by National Supervisory Authority for Welfare and Health (Valvira) according legislation relevant to each. SätL also contains requirements for human resources concerning safety in medical exposures.

As part of inspections or other regulatory surveillance STUK verifies that licencees have sufficient human resources at their disposal. For example 2019 there was a surveillance for public healthcare x-ray diagnostic radiology departments concerning adequacy of human resources and the impact of

inadequate human resources for radiation safety (report in Finnish: STUK B 257 Radiologian henkilöstöresurssit 2019 (Human resources in radiology 2019)).

Radiation Act

Section 23 Criteria for organizing practices

The undertaking shall implement the organization of the practice in such a way that the practice meets the requirements provided in this Act and that radiation safety deviations are prevented with adequate effectiveness and that their consequences are as insignificant as possible. The undertaking shall implement such measures to improve radiation safety as can be considered justified in terms of their quality and costs as well as their improving impact.

The undertaking shall ensure that it has the expertise necessary in terms of the nature and extent of the practice at its disposal and sufficient financial and human resources for the safe implementation of the practice.

Further provisions on the requirements concerning the financial and human resources referred to in subsection 2 may be given by government decree.

STUK issues further technical regulations for the prevention of radiation safety incidents and the limitation of their consequences.

Government Decree on Ionizing Radiation

Section 22 Human resources

To ensure safety in medical exposure:

1. an oncologist must be available for every instance of radiotherapy and a specialist of clinical physiology and nuclear medicine must be available for every instance of radionuclide therapy;
2. two health care professionals, of whom one must be a radiographer, qualified to ensure and interrupt therapy must be present whenever administering radiotherapy;
3. a medical physicist must be available for ensuring each dose calculation of radiotherapy and the implementation of the therapy, excluding established radionuclide therapy;
4. a specialist of clinical physiology and nuclear medicine must be available for ensuring the justification assessment prior to every nuclear medicine examination and for the interpretation of images, and a physician trained in interpreting the images of combined examinations must be available for such interpretation;
5. the personnel required for compliance with the good production methods of medicines as referred to in section 14 of the Medicines Act (395/1987) must be available for the production of radiopharmaceuticals;
6. a health care professional, assigned to the task by a physician referred to in section 114, subsection 1 of the Radiation Act, must be available to the subject of the examination or therapy for the administration of radiopharmaceuticals;
7. a radiographer, medical laboratory scientists or a nurse trained for nuclear medicine imaging must be present during a radionuclide examination to ensure the progress of the examination.

Question 3.4 How has it been ensured that any delegation of responsibilities by principal party is documented?

Response:

A document of management system of radiation practices is required to be up to date and it is to be supplied for authorization and it is assessed by STUK before granting a licence. During inspections it is assessed if the practice corresponds to the information given in the document of management system of radiation practices.

Radiation act

Section 29 Management system of radiation practices

In practices subject to a safety licence, the undertaking must have a written management system for the radiation practice.

The management system must include the name, birthdate and contact details of the radiation safety officer and, taking into account the nature and extent of the radiation practice and the conditions at the facility or place where the practice is carried out, sufficient information on:

1. the qualifications, training and induction of persons to verify compliance with the requirements provided in sections 33, 37 and 38;
2. tasks which are significant in terms of radiation safety and security arrangements, the division of responsibilities and flow of information;
3. measures to maintain and develop a good safety culture as referred to in section 12;
4. arrangements for the use of a radiation safety expert and a medical physics expert;
5. other administrative and organizational arrangements aiming to ensure radiation safety and to implement the security arrangements.

STUK issues more detailed regulations on the information to be presented in the management system.

Guidance in STUK Sammio (https://sammio.stuk.fi)

Examples of the different tasks that can be assigned in a management system are

- identification of operational risks, safety assessment and preparedness for radiation safety deviations
- promoting and maintaining a good safety culture
- radiation safety and security arrangements at the site of use, including the classification of work areas and workers involved in radiation work, the implementation of the necessary radiation safety measures and the development of site-specific safety instructions
- maintaining and continuously monitoring radiation safety, including by analysing the results of dose monitoring and monitoring of working conditions
- training and instruction in radiation protection for workers involved in the use of radiation
- liaising with the responsible persons at the site of use and obtaining the necessary expertise
- keeping the safety licence up to date and the organisation for the use of radiation
- reporting and proposing measures to the operator to improve safety
- implementing and monitoring the implementation of the corrective measures issued by STUK and reporting information to STUK
- giving permission to operate a radiation source after the repair work has been carried out, once it has been ascertained that the installation is in working order
- handling of radiation safety deviations at the site of radiation use and reporting of incidents to the STUK.

Radiation act

Section 114 Responsibility for medical exposure

The physician or dentist responsible for the medical exposure is responsible for the justification of the medical exposure caused by the examination, procedure or treatment and for the optimization of radiation protection and, for their part, the medical assessment of the results of the examination, procedure or treatment. The responsibility requires qualifications pursuant to the quality of the examination, procedure or treatment. The undertaking must ascertain the fulfillment of the required qualifications.

The undertaking is responsible for that procedures pertaining to assigning and transferring responsibility are clear arranged.

Question 4 Have relevant parties ensured that medical exposures are justified?

Answer: Yes

Response:

General requirement concerning justification of use of radiation are given in SätL 5 § and 24 § with further specific requirements on justification related to medical exposure given in 109 § -111 § and in more detail STUK S/4/2019 2 § -4 §. These sections cover justification assessment, medical exposure in special circumstances and for foetus and children and for asymptomatic individuals. According to section 111 concerning asymptomatic individuals the criteria for accessing examinations is drawn up by the Council for Choices in Health Care in Finland (Palko, https://palveluvalikoima.fi/en/frontpage).

Assessment of justification of medical exposures retrospectively is a relevant topic for self-assessments and clinical audits, for which there are requirements in SätL section 118 and STMA 1044/2018 sections 11 and 12.

Verification of justification of medical exposures is a part of inspections. For example a justification and referral themed inspection project was conducted in 2019 -2020 (report in Finnish: STUK-B: 271 Röntgentutkimusten oikeutusarvioinnin edellytysten toteutuminen: Terveydenhuollon valvontaraportti (Compliance with the conditions for assessing the justification for X-ray examinations: Inspection report) https://www.julkari.fi/handle/10024/140951).

Radiation Act

Section 5 Principle of justification

Radiation practices and protective actions are justified if the overall benefits achieved exceed the detriment caused (principle of justification).

There are requirements for justification of medical exposures from generic to patient specific. These are specified in answers to questions 4.1 through 4.5.

STUK has published a Guide (in Finnish) in collaboration with experts in the field called Oikeutus säteilylle altistavissa tutkimuksissa – opas hoitaville lääkäreille (Justification in radiological examinations - a guide for treating physicians) (https://www.julkari.fi/handle/10024/126288).

Guide SKV 3.4, Annex 2 Issues to be covered by inspections

…

Medical exposure

Checking that

- the undertaking has procedures in place to ensure that a justification assessment is carried out

Question 4.1 How is it ensured that generic justification of a radiological procedure is carried out?

Response:

There are requirement for generic justification including radiological procedures. General and not patient specific justification issues are considered in authorization process with the assistance of designated stakeholders, if necessary.

STUKs website (in Finnish and Swedish) lists activities that are generally considered to meet the justification principle for the use of radiation as well as some activities that are never consider justified.

This list is intended to be kept up to date. So far, the list is still lacking in field of medical use of radiation (30.8.2021).

https://www.stuk.fi/stuk-valvoo/sateilyn-kayttajalle/hae-turvallisuuslupaa-tai-ilmoita-muutoksesta/oikeutettu-ja-oikeuttamaton-sateilyn-kaytto

There is also a STUK report related to referral guidelines published STUK-B 273/ Helmikuu 2021: Preliminary survey for the development of referral guidelines referred to in the Radiation Act (in Finnish, Esiselvitys säteilylaissa tarkoitettujen lähettämissuositusten kehittämistä varten)

Radiation Act

Section 24 Justification assessment concerning new types of or existing practices

The undertaking shall demonstrate that a new type of radiation practice subject to a safety licence is justified. The same applies to existing radiation practices if new important information on the efficiency, possible consequences or alternative methods or techniques of the practice is obtained.

STUK confirms the practice as justified either as part of granting the safety licence or separately.

Further provisions on the procedures to be followed in the justification assessment and the necessary explanations are given by government decree**.**

Government Decree on Ionizing Radiation

Section 7 Statements and other reports on the justification of practices

As part of the justification assessment of a new type of radiation practice as referred to in section 24 of the Radiation Act, the Radiation and Nuclear Safety Authority requests, unless it is clearly not necessary for the resolution of the matter, a statement from:

1. the Advisory Committee on Radiation Safety;
2. the Data Protection Ombudsman, if the practice involves factors related to data protection;
3. key stakeholders (as necessary) on whom the intended practice may have an impact.

In addition, the Radiation and Nuclear Safety Authority requests, when necessary, a report from an expert institution or some other expert on the technology and safety of the appliance meant for practice referred to in subsection 1.

The undertaking must ensure that the Radiation and Nuclear Safety Authority has an opinion at its disposal for the purposes of the justification assessment referred to in section 24 of the Radiation Act from:

1. an ethics committee referred to in the Medical Research Act if radiation is intentionally directed at a human being within the said Act's scope of application;
2. the National Institute for Health and Welfare on the assessment of a health care method, provided that the case concerns a new type of method which results in medical exposure which exposes a large number of members of the public or which results in a high degree of medical exposure.

The ethics committee hears experts on the medical radiological use of radiation in a matter referred to in subsection 3, paragraph 1.

Question 4.2 How is it ensured that justification of medical exposure for an individual patient is carried out?

Response:

Specific requirements on justification related to medical exposure of an individual are given in 109 § -111 § and in more detail STUK S/4/2019 2 § -4 §. These sections cover justification assessment, medical exposure in special circumstances and for foetus and children and for asymptomatic individuals.

Relating to SätL section 109, there is Finnish participation (HUS) in EuroSafe imaging project EU-JUST-CT with some expected results in 2022.

Radiation Act

Section 109 Justification assessment concerning medical exposure

When considering the justification for medical exposure, the assessment covers the benefit to be expected of the examination, procedure or treatment which exposes an individual to radiation, including the direct medical benefit to the patient or asymptomatic individual and the benefits to society and, on the other hand, any possible detriment caused to the aforementioned due to the exposure.

STUK issues more detailed technical regulations on the practical measures involved in a justification assessment.

Radiation Act

Section 110 Justification of medical exposure in special circumstances

Individual examination, procedure or treatment resulting in medical exposure which is not generally justified may be considered justified with respect to a single individual due to a special need related to them.

The basis must be drawn up on a case-by-case basis and recorded in the health records

STUK S/4/2019

Section 2 Ensuring justification assessment

To ensure the justification assessment, the undertaking must ascertain:

1. the identity of the person subject to medical exposure;
2. the adequacy of the information referred to in section 113, subsection 1, paragraph 1 of the Radiation Act in terms of ensuring the justification assessment of the examination, procedure, or treatment;
3. the accuracy and subject of the examination, procedure, or treatment specified in the referral.

However, what is specified above in subsection 1, paragraph 1 does not apply to carers and comforters.

Section 3 Justification assessment in the absence of referral guidelines

In the absence of referral guidelines, the referring physician or dentist must carry out the justification assessment referred to in section 110 of the Radiation Act.

Section 4 Justification assessment concerning the medical exposure of a foetus or child

Before referring a person of childbearing age to an examination, procedure, or treatment resulting in medical exposure, the referring physician or dentist must investigate whether the person is pregnant. However, the investigation need not be conducted before an X-ray examination or procedure resulting in medical exposure and concerning the teeth, head and neck area, or the extremities, provided that the radiation is not directed near the abdomen or pelvis or when the medical exposure is justified as an urgent procedure necessary for saving the patient's life.

In addition to what is provided in subsection 1, the possibility of pregnancy must be checked with an adequately sensitive and specific method in the case of:

1. radiotherapy;
2. a nuclear medicine examination resulting in a high level of medical exposure for a foetus;
3. an X-ray examination or procedure of the abdomen or pelvis area carried out with computed tomography or some other method causing a high level of medical exposure.

The justification assessment concerning the examination, procedure, or treatment of a pregnant or breastfeeding person causing medical exposure to a foetus or breastfed child must particularly consider

medical methods alternative to the medical exposure or the possibility of postponing the examination, procedure, or treatment to a later date.

The justification assessment concerning an examination, procedure, or treatment causing medical exposure to a child must particularly consider alternative medical methods or the possibility of postponing the examination, procedure, or treatment to a later date.

Question 4.3 How is the justification for radiological procedures to be performed as part of a health screening programme for asymptomatic populations carried out?

Response:

Health screening programmes must be laid down in legislation. Currently active health screening programs are listed in Government Decree on Screening (339/2011) section 2.

Government Decree on Screening

3 § Other screenings

If a municipality organises screening other than that provided for in the national screening programme, it must assess the requirements and impact of the screening on the health care service system before starting the screening. The assessment shall include a review of the disease to be screened, its prevalence and treatment, screening methods, the effectiveness, organisation and overall costs of screening, and ethical issues related to screening.

7 § Guidance and monitoring

Finnish Institute for Health and Welfare monitors and evaluates, in cooperation with other actors in the field, ongoing screening programmes and the methods used in them.

Association of Finnish Municipalities has published a guidance for procurement of cancer service screening in 2013 (Link to publication: Syöpäseulontapalvelujen hankinta | Kuntaliitto.fi). STUK contributed to the publication.

Question 4.4 How is the specific justification for any radiological procedure on an asymptomatic individual that is intended to be performed for the early detection of disease, but not part of an approved health screening programme, ensured?

Response:

The justification of the radiological procedure on an asymptomatic individual is subject to the preparation of special written grounds concerning the individual in question. The preparation of the grounds must comply with special criteria. These criteria for accessing examinations is drawn up by the Council for Choices in Health Care in Finland (Palko, https://palveluvalikoima.fi/en/frontpage). Example, criteria for CT thorax is expected to be published late 2021 or early 2022.

Radiation Act

Section 111 Justification of the medical exposure of an asymptomatic individual

If the medical exposure required for the early detection of a disease in an asymptomatic individual is not part of a screening programme, the justification of the exposure pursuant to section 109 and 110 is subject to the preparation of special written grounds concerning the individual in question.

The author of the grounds shall be the physician or dentist responsible for the medical exposure, and they must hear the referrer. The preparation of the grounds must comply with the criteria for access to examination drawn up by the Council for Choices in Health Care in Finland, working in conjunction with the Ministry of Social Affairs and Health, a requirement which also applies to health care services referred to in Act on Private Health Care.

The physician or dentist responsible for the medical exposure shall ensure that the asymptomatic individual exposed to radiation has been provided with the information referred to in section 113, subsection 1, paragraph 3.

Section 113 Obligations of referring physicians and dentists

The physician or dentist giving the referral must ensure the following prior to the performance of the examination, procedure or treatment:

1. any material information on previous examinations, procedures and treatments is acquired;
2. the referral includes the information needed for the optimization of the radiation protection, including the indication of the examination or treatment;
3. the individual exposed to radiation or any other individual concerned is provided with information on the benefits of the examination, procedure or treatment and any possible health detriment caused by the exposure.

The physician or dentist giving the referral must, for their part, assess the justification of the medical exposure caused by the examination, procedure or treatment.

The physician or dentist giving the referral must have at their disposal referral guidelines concerning normal examinations, procedures and treatment causing exposure to radiation and information on the radiation doses caused by the examinations, procedures and treatments. If necessary, the referrer must consult experts before giving the referral.

Question 4.5 How is it ensured that the medical exposure of volunteers as part of a programme of biomedical research is justified?

Response:

In Finland, The Helsinki Declaration is considered declaration and it hasn't been implemented as a direct regulation. The Finnish Medical Association of which almost all doctors practising in Finland are members, encourages their members to follow the ethical principles laid out in Helsinki Declaration (Lääkäriliitto - Helsingin julistus (laakariliitto.fi)).

Many of the principles of the Helsinki Declaration are put as binding requirements in Medical Research Act (488/1999). For example, section 6 of Medical Research Act requires consent of research subjects

Section 6 (295/2004) Consent of research subjects

Medical research on persons may not be conducted without the research subject's informed consent in writing. …

All (bio)medical research that is to be conducted needs to have favourable opinion from the ethics committee. The section 10 d of the Medical Research Act gives requirement on the opinion of the ethics committee:

Section 10 d (295/2004) Opinion of the ethics committee

The provisions of sections 3 and 17 shall apply to the opinions of the ethics committee. In addition, an opinion on a clinical trial on medicinal products shall take into account in particular the following circumstances:

1. *appropriateness of the trial and its planning;*
2. *appropriateness of the assessment of its benefit and risks and justifiability of any conclusions regarding them;*
3. *the research plan;*
4. *suitability of the researcher and staff;*
5. *the researcher's information package containing clinical and other information on the medicinal product or products used in the trial that is of significance when testing those medicinal products on people;*
6. *quality of the premises and equipment to be used in the trial;*
7. *sufficiency and coverage of the written information given to obtain the informed written consent and the procedure for obtaining the consent, and grounds for trials to be carried out on persons not able to give their consent;*
8. *the grounds on which damages possibly caused by the trial are compensated and insurance policies and other arrangements for covering a compensation payable on account of damages or death;*
9. *amount of the fee or remuneration to be paid to researchers and research subjects or the criteria for determining it and procedures possibly related to the matter, as well as the main content of the agreement to be concluded between the commissioning party and the research site; and*
10. *detailed procedures relating to choosing the research subjects.*

The ethics committee shall give its opinion to the body asking it within 60 days of having received an appropriate request for opinion as well as communicate it to the Finnish Medicines Agency for information. If the trial concerns medicinal products meant for 7 gene therapy or somatic cell therapy or medicinal products containing genetically modified organisms, the opinion must be delivered within 90 days. The committee can however extend this time limit by up to 90 days, if the giving of the opinion requires extensive further investigations. The ethics committee may ask once additional information

from the party asking for opinion. There is no defined period for giving an opinion on xenogenic cell therapy. (780/2009)

The ethics committee shall deliver its opinion on an alteration to the research plan within 35 days of having received the notification of alteration.

The period of time during which further information is requested or delivered shall not count for the purposes of calculating the time limits referred to in paragraphs 2 and 3.

Detailed requirements on ethics committees are given in chapter 4 of the Medical Research Act (488/1999).

The government as approved renewed Clinical Drug Trials Act on 8.10.2021. On the renewed act section 18 gives the requirements for the composition of the ethics committee, including requirement to have an expert on medical exposure if radiation is used.

A quorum shall consist of at least six members in addition to the chairperson or vice-chairperson. At least one lay member shall be present when an ethical review of an application is being carried out.

When the Committee deals with the matters referred to in this Act, it shall be composed of the necessary medical, legal and ethical expertise.

An expert in paediatrics shall be represented or heard on the committee when the committee is dealing with a clinical trial involving a minor, and an expert with knowledge of the disease or disability concerned when the committee is dealing with a clinical trial involving a subject referred to in Article 13. An expert on the medical use of radiation shall be represented or heard by the committee if the clinical trial is intended to subject the subject to medical exposure as referred to in Section 4(10) of the Radiation Act (859/2018). The committee may also hear experts at other times. An official of the Finnish Medicines Safety and Development Agency may be heard as an expert.

The expert referred to in paragraph 3 may not participate in the decision-making of the Committee. Instead of hearing the expert orally, the Committee may request a written opinion.

Requirements on the justification of new types of practices are given in SätL section 24. Additional requirements are given in VnA section 7, including requirement that STUK shall have opinion of the ethics committee for assessing the justification of biomedical research.

SätL section 24, subsection 1 Justification assessment concerning new types of or existing practices

The undertaking shall demonstrate that a new type of radiation practice subject to a safety licence is justified. The same applies to existing radiation practices if new important information on the efficiency, possible consequences or alternative methods or techniques of the practice is obtained.

VnA, Section 7, Statements and other reports on the justification of practices

As part of the justification assessment of a new type of radiation practice as referred to in section 24 of the Radiation Act, the Radiation and Nuclear Safety Authority requests, unless it is clearly not necessary for the resolution of the matter, a statement from:

1. *the Advisory Committee on Radiation Safety;*
2. *the Data Protection Ombudsman, if the practice involves factors related to data protection;*
3. *key stakeholders (as necessary) on whom the intended practice may have an impact.*

In addition, the Radiation and Nuclear Safety Authority requests, when necessary, a report from an expert institution or some other expert on the technology and safety of the appliance meant for practice referred to in subsection 1.

The undertaking must ensure that the Radiation and Nuclear Safety Authority has an opinion at its disposal for the purposes of the justification assessment referred to in section 24 of the Radiation Act from:

1. *an ethics committee referred to in the Medical Research Act if radiation is intentionally directed at a human being within the said Act's scope of application;*
2. *the National Institute for Health and Welfare on the assessment of a health care method, provided that the case concerns a new type of method which results in medical exposure which exposes a large number of members of the public or which results in a high degree of medical exposure.*

The ethics committee hears experts on the medical radiological use of radiation in a matter referred to in subsection 3, paragraph 1.

Requirements to optimize research subjects radiation protection are given in VnA Section 9.

VnA, Section 9 Optimization of the radiation protection of a research subject taking part in medical research

The radiation exposure of a research subject taking part in medical research as referred to in the Medical Research Act must be planned individually if the health of the research subject is expected to benefit from the research, procedure or therapy. A dose constraint must be applied to an individual who is not expected to gain immediate health benefits from the radiation exposure caused by the research.

Regulatory supervision

Justification of biomedical research is verified during authorization with the review and assessment of the ethics committees opinion. Additionally establishment and use of dose constraints for research subject can be check during authorization (the undertaking presents the dose constraints) and their use can be verified during inspection (the dose from examination, procedure or threatment is below the set dose constraint).

Question 5 Are there requirements that registrants and licensees and radiological medical practitioners ensure that protection and safety is optimized for each medical exposure?

Answer: Yes

Response:

The optimization principle is given in SätL 6 §. For medical exposure the requirement for optimization if further elaborated in SätL section 112. The requirements for the performer of the examination, procedure or treatment to ensure safety (and optimization) are given in SätL section 116. On SätL section 117 requirement is given that appliances shall be according to the purpose.

SätL, section 112, Optimization of radiation protection in medical exposure

The undertaking is responsible for the implementation of the requirements concerning the optimization of radiation protection in medical exposure. In addition, the undertaking shall keep the exposure of the carer and comforter and the individual being examined in for medical research as low as possible. The carer and comforter must be at least 18 years of age and they may not be pregnant. The optimization of the radiation protection of a pregnant individual being examined, receiving treatment or subject to a procedure must account for the exposure of the foetus.

The undertaking shall specify the responsibilities in terms of the optimization of radiation protection in medical exposure. The undertaking shall employ the reference levels for the patient's exposure for the purpose of optimizing radiation protection in medical exposure resulting from examinations and procedures.

STUK issues more detailed regulations of a technical nature on the practical procedures for optimizing radiation protection in examinations, procedures and treatments and on the optimization of the radiation protection of children as well as pregnant, breastfeeding and asymptomatic individuals. In addition, STUK issues more detailed regulations on the diagnostic reference levels of examinations and procedures and their use.

SätL. section 116 Responsibilities of the performer of the examination, procedure or treatment

The performer of an examination, procedure or treatment must, for their part, ensure that the examination, procedure or treatment is performed safely before targeting radiation at a human being. In particular, it must be ensured that:

1. *the safety and shielding arrangements of the radiation source are in order and the appliances in use function properly;*
2. *the patient is appropriately protected, and the radiation exposure has been limited to the parts of the body intended to be irradiated;*
3. *any radioactive substance administered to the patient has been appropriately checked.*

SätL, section 117 Applicability of appliances

The undertaking must carry out examinations, procedures and treatment causing exposure to radiation with appliances applicable to the purpose in question.

More detailed requirements for optimization of medical exposure are given in S/4/2019 sections 5 to 9.

Section 5 Practical measures in the optimization of radiation protection in medical exposure

Written instructions must be provided for the performance of the most common examinations, procedures, and treatments, including the phases of the examination, procedure, or treatment process which optimize radiation protection in medical exposure.

The examination instructions concerning X-ray examinations and procedures must detail the examination-specific typical projections and the patient's protective shielding to be used in each examination. The protective shielding must be used if it can materially reduce the radiation exposure of the person or foetus subject to the examination, procedure, or treatment and provided that the shielding does not compromise the performance of the examination, procedure, or treatment.

The indication of the examination or procedure must be accounted for when optimizing radiation protection in the examination or procedure.

The radiation beam in an X-ray examination or procedure must be limited so that it is as small as possible, but nevertheless in such a way that nothing which is material in terms of the examination or procedure is left outside the imaging area.

The undertaking must ensure that the optimization has been carried out in terms of the most common imaging programs of each appliance used for patient imaging.

Section 6 Optimizing the radiation protection of a foetus or child

The effective dose of a foetus may not exceed 1 mSv, unless this is particularly justified in terms of the overall treatment of the person examined. The radiation protection of a foetus must be optimized particularly in medical exposure as referred to in section 4, subsection 2.

The optimization of a child's radiation protection must account for the child's size and any other special characteristics of the examination. An examination, procedure, or treatment exposing a child to radiation must be planned individually and performed with an appliance that allows for achieving the lowest radiation exposure reasonably possible.

Patients must be urged to stop breastfeeding or to take a break from breastfeeding due to a nuclear medicine examination or nuclear medicine treatment so that the radiation exposure of the breastfed child is as low as possible and at the very least not higher than the dose limit for members of the public.

Section 7 Optimization in nuclear medicine

The activity of a radiopharmaceutical or a tracer must be measured with an activity meter prior to administering the pharmaceutical or tracer to the patient.

If the use of alternative radiopharmaceuticals in the examination is possible, a radiopharmaceutical which results, within reason, in the smallest radiation dose for the patient must be selected.

Section 8 The optimization of radiation protection due to a nuclear medicine examination or nuclear medicine treatment

Following a nuclear medicine examination or nuclear medicine treatment, patients must be urged to avoid pregnancy for a sufficient period of time. This ensures that the radiation exposure of an unborn child does not exceed the dose limit for members of the public.

Section 9 Optimizing radiotherapy

In radiotherapy, the radiation must be directed at the target area with the precision required by the objective of the therapy.

In external radiotherapy, the uncertainty of the dose may not be greater than, on average,

3) 5%, when using photon radiation greater than 1 MV;

4) 10%, when using electron or X-radiation.

Medical exposure in radiotherapy must be planned patient-specifically and the magnitude and focus of the exposure must be ascertained. The dose received by tissues and organs other than those targeted must be as low as reasonably possible.

Regulatory supervision

During the authorization the undertaking shall present safety assessment as stipulated in SätL 26. The safety assessment includes section to where the undertaking presents measures to ensure radiation safety and the optimization of radiation protection, including optimization of medical exposure.

On the on-site inspections the inspector shall verify according to the quality guide SKV 3.4 Appendix 2 following items regarding medical exposure:

- the undertaking has procedures in place to ensure that a justification assessment is carried out

- exposure from the activity is optimised
- the responsibilities of the referring doctor or dentist are defined
- the responsibilities of the doctor or dentist responsible for medical exposure are defined
- the tasks of the person carrying out the examination, procedure or treatment are defined
- the equipment is suitable for the operation
- self-assessment and clinical audit are properly organised.

STUK has also used regulatory surveys to assess protection and safety in medical use of radiation. Findings of these surveys are compiled to reports. Example reports: Fulfilment of the conditions for justification in x-ray examinations. Supervision report in health care. STUK-B 271 and Regulatory compliance with the new radiation act in radiation practice. Supervision report in health care, STUK-B 262.

STUK is obligated by SätL section 14 to compile and to publish nationwide assessments on exposures arising from medical use of radiation and their development. These assessments on medical exposures and developments in the use of radiation are carried out by surveys and compiled to reports. Example report: *STUK-A265, June 2021, Patient exposure levels and collective effective dose to the population from radiological examinations - changes from 2008 to 2018 in Finland* (Patient exposure levels and collective effective dose to the population from radiological examinations – changes from 2008 to 2018 in Finland Patient exposure levels and collective effective dose to the population from radiological examinations – changes from 2008 to 2018 in Finland (julkari.fi)

Question 5.1 How are the design considerations regulated?

Response:

Medical radiological equipment and software are subject to EU Regulations MDR 2017/745 and further to national legislation Act on Equipment and Supplies for Healthcare 719/2021 and Act on certain medical devices covered by EU directives 720/2021, for which the supervisory authority is Fimea (Finnish Medicines Agency Fimea).

Requirements for design considerations are given in SätL 66 § and in further detail S/5/2019 15 § and 16 § and Appendices 2-5.

Radiation Act

Section 66 In-service radiation safety

The undertaking shall ensure that a radiation source, the facility and place where it is used and stored, and the equipment and devices related to it are such that the radiation source can be used safely.

…

STUK issues more detailed regulations of a technical nature on the radiation safety during use referred to in subsection 1, the markings referred to in subsection 2 and 3, appliances' in-service acceptability requirements and other requirements pertaining to the use of the appliances.

STUK S/5/2019

Section 15 General requirements

The radiation source and the equipment related to its use shall be suitable for the intended use.

An appliance generating radiation electrically may not be operated at values higher than what is necessary for the purpose.

A sealed source shall comply with the requirements of SFS-EN ISO 2919.

A sealed source must be labelled as "Radioactive", or, if this is not possible, equipped with the label for ionizing radiation in accordance with SFS-EN ISO 361:2015.

Section 16 In-service acceptability criteria for a medical radiation appliance

In addition to what is specified section 15, a medical radiation appliance shall meet the in-service acceptability criteria specified in this section.

The appliance shall meet the performance characteristics and safety properties specified by the manufacturer during operation.

A report shall be available at the place of operation of the appliance, indicating the in-service acceptability criteria and that these are met.

The in-service acceptability criteria for medical and veterinary radiation appliances are specified in Appendices 2-5.

Question 5.2 How are the operational considerations regulated for diagnostic and therapeutic radiological procedures and what are the particular aspects of medical exposures to be considered in the optimization process?

Response:

The basic requirement that appropriate radiological equipment and software is used is for medical exposures given in SätL section 117 and the requirement to use appropriate radiopharmaceuticals is given in S/4/2019 section 7.

SätL, section 117, Applicability of appliances

The undertaking must carry out examinations, procedures and treatment causing exposure to radiation with appliances applicable to the purpose in question.

S/4/2019, Section 7 Optimization in nuclear medicine

The activity of a radiopharmaceutical or a tracer must be measured with an activity meter prior to administering the pharmaceutical or tracer to the patient.

If the use of alternative radiopharmaceuticals in the examination is possible, a radiopharmaceutical which results, within reason, in the smallest radiation dose for the patient must be selected.

Additionally, the safety of radiopharmaceuticals is covered by the Medicines Act (395/1987).

To ensure that appropriate techniques and parameters are used to deliver medical exposure the undertaking is obligated to have written instructions as required by section 5 of S/4/2019.

S/4/2019, Section 5 Practical measures in the optimization of radiation protection in medical exposure

Written instructions must be provided for the performance of the most common examinations, procedures, and treatments, including the phases of the examination, procedure, or treatment process which optimize radiation protection in medical exposure.

The examination instructions concerning X-ray examinations and procedures must detail the examination-specific typical projections and the patient's protective shielding to be used in each examination. The protective shielding must be used if it can materially reduce the radiation exposure of the person or foetus subject to the examination, procedure, or treatment and provided that the shielding does not compromise the performance of the examination, procedure, or treatment.

The indication of the examination or procedure must be accounted for when optimizing radiation protection in the examination or procedure.

The radiation beam in an X-ray examination or procedure must be limited so that it is as small as possible, but nevertheless in such a way that nothing which is material in terms of the examination or procedure is left outside the imaging area.

The undertaking must ensure that the optimization has been carried out in terms of the most common imaging programs of each appliance used for patient imaging.

The requirement to use reference levels is given in SätL section 112 subsection 3.

SätL, section 112, subsection 3 Optimization of radiation protection in medical exposure

The undertaking shall employ the reference levels for the patient's exposure for the purpose of optimizing radiation protection in medical exposure resulting from examinations and procedures.

Regarding image quality in examinations, the undertaking is obligated to have quality assurance program to ensure adequate image quality for the studies as required by S/5/2019 section 27 subsection 1.

S/5/2019, section 25, subsection 1, Quality assurance assurances in the use of radiation in health care and veterinary medicine

The quality assurance programme of the use of radiation in health care and veterinary medicine shall include actions to ensure:

1. *before commissioning a medical radiotherapy appliance, that adequate information on the risk assessment of the patients and the available clinical operation results of the appliance are available;*
2. *the targeting of the treatment dose to the specified target area in the designed magnitude as accurately as possible;*
3. *an imaging quality adequate for obtaining the study result;*
4. *the accuracy of the assessment radiation exposure caused to the patient and the verification of activity administered to the patient.*

Radiation Act (859/2018)

Section 116 Responsibilities of the performer of the examination, procedure or treatment

The performer of an examination, procedure or treatment must, for their part, ensure that the examination, procedure or treatment is performed safely before targeting radiation at a human being. In particular, it must be ensured that:

1. the safety and shielding arrangements of the radiation source are in order and the appliances in use function properly;
2. the patient is appropriately protected, and the radiation exposure has been limited to the parts of the body intended to be irradiated;
3. any radioactive substance administered to the patient has been appropriately checked

STUK S/4/2019, *Section 9 Optimizing radiotherapy*

In radiotherapy, *the radiation must be directed at the target area with the precision required by the objective of the therapy.*

In external radiotherapy, the uncertainty of the dose may not be greater than, on average,

3) 5%, when using photon radiation greater than 1 MV;

4) 10%, when using electron or X-radiation.

Medical exposure in radiotherapy must be planned patient-specifically and the magnitude and focus of the exposure must be ascertained. The dose received by tissues and organs other than those targeted must be as low as reasonably possible.

Regarding medical exposure the undertaking shall specify responsibilities in terms of optimization of radiation protection as stipulated in SätL section 112 subsection 2.

SätL section 112 subsection 2, Optimization of radiation protection in medical exposure

The undertaking shall specify the responsibilities in terms of the optimization of radiation protection in medical exposure.

Detailed responsibilities, including requirement to check administered radiopharmaceutical, of the performer of the examination, procedure or treatment are given in section 116 of SätL. The requirement to measure activity and use optimal radiopharmaceutical is given in S/4/2019 section 7.

SätL, Section 116 Responsibilities of the performer of the examination, procedure or treatment

The performer of an examination, procedure or treatment must, for their part, ensure that the examination, procedure or treatment is performed safely before targeting radiation at a human being. In particular, it must be ensured that:

1. *the safety and shielding arrangements of the radiation source are in order and the appliances in use function properly;*
2. *the patient is appropriately protected, and the radiation exposure has been limited to the parts of the body intended to be irradiated;*
3. *any radioactive substance administered to the patient has been appropriately checked*

S/4/2019, *Section 7 Optimization in nuclear medicine*

The activity of a radiopharmaceutical or a tracer must be measured with an activity meter prior to administering the pharmaceutical or tracer to the patient.

If the use of alternative radiopharmaceuticals in the examination is possible, a radiopharmaceutical which results, within reason, in the smallest radiation dose for the patient must be selected.

The requirement to optimize radiation protection of foetus or child are given in section 6 of S/4/2019. Requirement for justification assessment concerning the medical exposure of a foetus or child is stipulated in S/4/2019 section 4.

S/4/2019, Section 6 Optimizing the radiation protection of a fetus or child

The effective dose of a foetus may not exceed 1 mSv, unless this is particularly justified in terms of the overall treatment of the person examined. The radiation protection of a foetus must be optimized particularly in medical exposure as referred to in section 4, subsection 2.

The optimization of a child's radiation protection must account for the child's size and any other special characteristics of the examination. An examination, procedure, or treatment exposing a child to radiation must be planned individually and performed with an appliance that allows for achieving the lowest radiation exposure reasonably possible.

Patients must be urged to stop breastfeeding or to take a break from breastfeeding due to a nuclear medicine examination or nuclear medicine treatment so that the radiation exposure of the breastfed child is as low as possible and at the very least not higher than the dose limit for members of the public.

S/4/2019, Section 4, Justification assessment concerning the medical exposure of a foetus or child

Before referring a person of childbearing age to an examination, procedure, or treatment resulting in medical exposure, the referring physician or dentist must investigate whether the person is pregnant. However, the investigation need not be conducted before an X-ray examination or procedure resulting in medical exposure and concerning the teeth, head and neck area, or the extremities, provided that the radiation is not directed near the abdomen or pelvis or when the medical exposure is justified as an urgent procedure necessary for saving the patient's life.

In addition to what is provided in subsection 1, the possibility of pregnancy must be checked with an adequately sensitive and specific method in the case of:

1. *radiotherapy;*
2. *a nuclear medicine examination resulting in a high level of medical exposure for a foetus;*
3. *an X-ray examination or procedure of the abdomen or pelvis area carried out with computed tomography or some other method causing a high level of medical exposure.*

The justification assessment concerning the examination, procedure, or treatment of a pregnant or breastfeeding person causing medical exposure to a foetus or breastfed child must particularly consider medical methods alternative to the medical exposure or the possibility of postponing the examination, procedure, or treatment to a later date.

The justification assessment concerning an examination, procedure, or treatment causing medical exposure to a child must particularly consider alternative medical methods or the possibility of postponing the examination, procedure, or treatment to a later date.

For (bio)medical research the medical exposure caused to the research subject must be assessed and justified in advance as required by VnA section 4. The requirement for optimization is given in section 9 of VnA.

VnA, Section 4, Individual justification assessment of medical exposure

The justification of medical exposure resulting from research, a procedure or therapy must be assessed individually in advance. The assessment must account for the purpose and specific objectives of the research, procedure or therapy as well as the characteristics of the person subject to it. An assessment of the benefits and detriment must take into account the alternative methods available for achieving the purpose of the research, procedure or therapy as well as the effectiveness, benefits and risks of these methods.

For the purposes of medical research as referred to in the Medical Research Act (488/1999), the medical exposure caused to the research subject must be assessed and justified in advance.

VnA, Section 9, Optimization of the radiation protection of a research subject taking part in medical research

The radiation exposure of a research subject taking part in medical research as referred to in the Medical Research Act must be planned individually if the health of the research subject is expected to benefit from the research, procedure or therapy. A dose constraint must be applied to an individual

who is not expected to gain immediate health benefits from the radiation exposure caused by the research.

Individuals, subject medical exposure from approved medical screening programme are subject to same optimization requirements as other patients subject to medical exposure. The basic requirement for assess justification of medical exposure is given in SätL section 109. The approved national screening programs are listed in Government Decree on screening (339/2011).

SätL, Section 109 Justification assessment concerning medical exposure

When considering the justification for medical exposure, the assessment covers the benefit to be expected of the examination, procedure or treatment which exposes an individual to radiation, including the direct medical benefit to the patient or asymptomatic individual and the benefits to society and, on the other hand, any possible detriment caused to the aforementioned due to the exposure.

Regulatory supervision

On-site inspections are typically used to verify that appropriate operational arrangements to optimize medical exposure are in place

On the quality guides SKV 3.4 annex 2 is a generic list of issues that shall be covered by inspections. The inspector shall verify that:

- *the operator has procedures in place to ensure that a justification assessment is carried out*
- *the exposure from the activity is optimised*
- *the responsibilities of the referring doctor or dentist are defined*
- *the responsibilities of the doctor or dentist responsible for medical exposure are defined*
- *the tasks of the person carrying out the examination, procedure or treatment are defined*
- *the equipment is suitable for the operation*

- *self-assessment and clinical audit are properly organised.*

Additional guidance for inspections of medical exposure is given in guide SKV 4.1 that is under revision.

Regulatory authority for pharmaceuticals, including pharmaceuticals in radioactive medicinal products is Finnish Medicines Agency Fimea (Fimea - Front page). STUK and FIMEA typically hold an annual meeting to discuss cooperation.

Question 5.3 What are the regulated duties of the medical physicist concerning calibrations?

Response:

Source calibrations

According to STUK S/5/2019 section 26 the acceptance testing is required for radiation appliances in health care and veterinary medicine. Source calibration, as measurement of certain dosimetric quantities in reference conditions that are modality dependent, is part of acceptance testing and commissioning of health care radiation appliances.

S/5/2019, section 26, Acceptance testing of a radiation appliance in health care and veterinary medicine

The quality assurance programme of the use of radiation in health care and veterinary medicine shall include an acceptance testing in which the operation of the radiation appliance is ensured before commissioning the appliance. Also, the reference performance values to be used in the monitoring of the appliance's operational capacity and performance characteristics shall be determined in the acceptance inspection.

The requirement is further elaborated in section 26 justification:

By carrying out an acceptance test on the device, it can be ensured that it is working as intended immediately upon commissioning. It also establishes benchmarks that can be used to ensure that the device has maintained an adequate level of performance during subsequent operation, compared to the initial situation.

The quality assurance in the use of radiation in health care shall include actions to ensure the accuracy of the assessment radiation exposure caused to the patient as stipulated in S/5/2019 section 26(1).

Section 26 Quality assurance assurances in the use of radiation in health care and veterinary medicine

The quality assurance programme of the use of radiation in health care and veterinary medicine shall include actions to ensure:

1. *before commissioning a medical radiotherapy appliance, that adequate information on the risk assessment of the patients and the available clinical operation results of the appliance are available;*
2. *the targeting of the treatment dose to the specified target area in the designed magnitude as accurately as possible;*
3. *an imaging quality adequate for obtaining the study result;*
4. *the accuracy of the assessment radiation exposure caused to the patient and the verification of activity administered to the patient.*

In-service acceptability criteria for medical devices are given in S/5/2019 Appendices 2 to 5.

Appendices:

1. *In-service acceptability criteria for medical X-ray imaging and fluoroscopic equipment, CT scan appliances and bone mineral density measurement appliances based on the attenuation of X-radiation;*
2. *In-service acceptability criteria for X-ray imaging and fluoroscopic equipment and the related auxiliary devices and equipment used in veterinary medicine;*
3. *In-service acceptability criteria for radiotherapy equipment and the related auxiliary devices and equipment;*
4. *In-service acceptability criteria for equipment used in nuclear medicine;*

The quantities and units to be used in measurements (and in calibrations) are stipulated in STUK S/7/2021 section 3:

Measurements shall be made using

1. *the basic units and other SI units laid down in the Government Decree on Units of Measurement (1015/2014);*
2. *the basic units and units of measurement as laid down in the Government Decree on ionising radiation (1034/2018)*
3. *the quantities and units of measurement specified in Annex 2.*

Further requirements for medical exposure measurements are given in S/7/2021 sections 11 and 12.

Section 11, Reliability of medical exposure measurements

For X-ray examinations and interventions and for medical exposure measurements for external beam radiotherapy and nuclear radiation therapy, the measurement parameters laid down in Table 1.2 of Annex 1 shall be used.

If the display of the equipment used for X-ray examinations and interventions uses a different other than that referred to in paragraph 1, the operator shall be familiar with the relationship of this quantity to the quantity referred to in paragraph 1 and the metrological traceability of the measurement results.

For the determination of medical exposure, the requirements of sections 13 and 15(4) shall apply to calculated indications used in X-ray examinations and procedures.

Section 12(1), Reliability of measurements of the activity of radioactive medicinal products

In nuclear medicine studies and treatment, the measurement of radioactive drugs is based on

the activity.

Regarding methods and protocols to be used in calibrations S/7/2021 stipulates that:

Section 13, General requirements for calibration

The radiation meter and the measuring system shall be calibrated before being put into operation.

The radiation meter and the measuring system shall be calibrated on the basis of an appropriate standard. In the absence of a standard, calibration shall be performed using other standardised methods and international good practice.

Calibration at commissioning, after maintenance and at periodical intervals

Calibration shall be done at the time of acceptance testing as explained in previous chapter (source calibrations). Additionally, S/5/2019 section 24 stipulates that safe operation of a radiation appliance shall be ensured after all changes that could affect the operation of the appliance. Verification of safe operation can also mean that source calibration of radiation appliance is carried out.

Section 24, Ensuring the operation of a radiation appliance

The safe operation of a radiation appliance shall be ensured following a substantial repair, maintenance or software update as well as always when there is reason to suspect that there are disturbances or changes in the operation of the appliance. Faults and deficiencies affecting radiation safety must be repaired before using the appliance

In section 26(3) of S/5/0291 it is stipulated that the intervals of quality assurance actions in X-ray operations, nuclear medicine and veterinary medicine may not be longer than what is specified in Appendix 12.

Section 26, subsection 3, Quality assurance assurances in the use of radiation in health care and veterinary medicine

The intervals of quality assurance actions in X-ray operations, nuclear medicine and veterinary medicine may not be longer than what is specified in Appendix 12.

Radiotherapy specific requirements for calibrations and quality assurance are set in section 28 of S/5/2019.

Section 28, Commissioning and regular dose calibration of radiotherapy equipment

Before commissioning a radiotherapy appliance, the operator shall measure or verify the characteristics of the appliance that are needed for the input information of the radiotherapy treatment planning system used.

In order to ensure the quality of the radiotherapy treatment planning system, the system shall be tested before commissioning a new system or modification.

The radiotherapy appliance shall undergo regular dose calibrations.

Dose calibration shall be verified before the radiotherapy appliance is taken into patient use in such a way that:

5) the verification is conducted by a person other than the one conducting the dose calibration;

6) the dosemeter and the equipment used with it during the measurement are others than those used in the dose calibration.

Furthermore, an independent verification of dose calibration shall be conducted before taking a radiotherapy beam with a different nominal energy or other characteristics into patient use.

Section 29, Other quality assurance actions in radiotherapy

Quality assurance of radiotherapy shall include the verification of each individual treatment plan when taking a new method into use.

Furthermore, in vivo dosimetry shall be included in the treatment of the entire body.

The targeting of treatment shall be ensured in the treatment of each patient.

The operator shall have access to measuring equipment suitable for the quality assurance measurements of radiotherapy equipment. The quality assurance of such measuring equipment shall be arranged.

Traceability of calibrations

Section 59 of SätL stipulates that all results of the measurements must be metrologically traceable to the International System of Units. Additionally, all radiation meters and measuring instruments shall be appropriately calibrated.

SätL, Section 59, The reliability of radiation measurements

The measurements carried out for assessing the radiation exposure and ensuring safety referred to in this Act shall be performed with a method suitable for the purpose and proved reliable. The results of the measurements must be metrologically traceable to the International System of Units. The radiation meter or measuring instruments shall be appropriately calibrated.

STUK issues more detailed regulations on verifying the reliability of measurements and on the radiation meters' and measuring equipments' calibration, accuracy, use and suitability for a particular purpose.

Involvement of medical physicist in calibrations

The basic obligation of the undertaking to use experts is given in SätL section 32:

Section 32 Use of experts

In practices subject to a safety licence, the undertaking shall use a radiation safety expert in the planning, implementation and monitoring of the radiation protection of workers and members of the public, excluding such radiation practices which do not cause occupational exposure, public exposure or potential exposure.

A medical physics expert shall furthermore be used in the planning, implementation and monitoring of the radiation protection of the person subject to exposure when the case concerns medical exposure or imaging as referred to in chapter 14, which involves the use of medical devices covered by certain EU Directives, such as the Act on Medical Devices (629/2010), the Medical Devices Directive, Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No: No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (hereinafter referred to as the MD Regulation) or Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (hereinafter referred to as the IVD Regulation).The experts mentioned in subsections 1 and 2 shall be used in the appropriate manner, in proportion to the radiation exposure and potential exposure resulting from the practice. Further provisions on the use of experts are given by government decree.

VnA section 20 defines the areas where medical physics expert shall be used:

Section 20, *Areas of medical physics expert's use*

A medical physics expert must be used in the management of the dosimetry of medical exposure, including the physical measurements needed for the determination of radiation exposure and to provide advice on radiation appliances.

A medical physics expert must furthermore be used in:

1. *the optimization of the radiation protection of a person subject to medical exposure as well as the foetus of a pregnant individual being examined, receiving treatment or subject to a procedure;*
2. *comparing a patient's radiation exposure to reference levels;*
3. *the preparation of instructions concerning the performance of conventional radiological examinations, procedures and treatments;*
4. *the selection of measuring equipment;*
5. *the technical specifications of radiation appliances;*
6. *the design of installations;*
7. *the planning and implementation of a quality assurance programme for radiation appliances;*
8. *the acceptance tests of appliances and in demonstrating the fulfillment of the appliances' in-service approval requirements and other requirements concerning the appliances and their use;*
9. *the preparation of a safety assessment with respect to medical exposure;*
10. *the investigation of any medical exposure deviating from planned exposure and the planning of measures required to prevent comparable events;*
11. *the planning and organizing of the personnel's radiation protection training.*

The dosimetry of medical exposure is considered to include calibration sources. The use of medical physics expert is further elaborated in section 19 of VnA.

Section 19 Use of a medical physics expert

The undertaking must ensure that a medical physics expert is closely involved in radiotherapy practices, excluding established radionuclide therapy.

A medical physics expert must be used in any radionuclide therapy other than that referred to in subsection 1 as well as in interventional radiology, CT scans and other practices causing great medical exposure.

In practices other than those referred to in subsection 1 and 2, a medical physics expert must be used at the commencement of the practice and the expert must be available during the practice.

By way of derogation from what is provided in subsection 3, dental x-rays which rely on panoramic tomography x-ray equipment, cephalostats or dental x-ray appliances for dental imaging using an intraoral imaging receptor are subject to the use of a medical physics expert, provided that advice is required in some matter referred to in section 20.

Any imaging with a medical device as referred to in Chapter 14 of the Radiation Act is subject to subsection 3 and 4.

For radiotherapy dosimetry guidance STUK has published *Determination of Absorbed Dose to Water in Radiotherapy. Calibration of High Energy Photon and Electron Radiation Beams in External Radiotherapy. STUK-STO-TR 1. Helsinki 2005* technical guide.

Regulatory supervision

The fulfillment of the undertakings obligations regarding source calibrations are typically verified with on-site inspections. Verifications are carried out by going through records of quality assurance and calibrations.

Question 5.4 What are the regulated duties of the registrants and licensees concerning patient dosimetry?

Response:

VnA section 20 defines the areas where medical physics expert shall be used.

Vna Section 20, *Areas of medical physics expert's use*

A medical physics expert must be used in the management of the dosimetry of medical exposure, including the physical measurements needed for the determination of radiation exposure and to provide advice on radiation appliances.

A medical physics expert must furthermore be used in:

1) the optimization of the radiation protection of a person subject to medical exposure as well as the foetus of a pregnant individual being examined, receiving treatment or subject to a procedure;

2) comparing a patient's radiation exposure to reference levels;

3) the preparation of instructions concerning the performance of conventional radiological examinations, procedures and treatments;

4) the selection of measuring equipment;

5) the technical specifications of radiation appliances;

6) the design of installations;

7) the planning and implementation of a quality assurance programme for radiation appliances;

8) the acceptance tests of appliances and in demonstrating the fulfilment of the appliances' in-service approval requirements and other requirements concerning the appliances and their use;

9) the preparation of a safety assessment with respect to medical exposure;

10) the investigation of any medical exposure deviating from planned exposure and the planning of measures required to prevent comparable events;

11) the planning and organizing of the personnel's radiation protection training.

The use of medical physics expert is further elaborated in section 19 of VnA.

Section 19 Use of a medical physics expert

The undertaking must ensure that a medical physics expert is closely involved in radiotherapy practices, excluding established radionuclide therapy.

A medical physics expert must be used in any radionuclide therapy other than that referred to in subsection 1 as well as in interventional radiology, CT scans and other practices causing great medical exposure.

In practices other than those referred to in subsection 1 and 2, a medical physics expert must be used at the commencement of the practice and the expert must be available during the practice.

By way of derogation from what is provided in subsection 3, dental x-rays which rely on panoramic tomography x-ray equipment, cephalostats or dental x-ray appliances for dental imaging using an intraoral imaging receptor are subject to the use of a medical physics expert, provided that advice is required in some matter referred to in section 20.

Any imaging with a medical device as referred to in Chapter 14 of the Radiation Act is subject to subsection 3 and 4.

Requirements to use calibrated dosimeters and use of internationally or nationally accepted protocols is explained in answer to question *5.3 What are the regulated duties of the medical physicist concerning calibrations?*

The basic requirement of assessing medical exposure is given in SätL section 119.

Section 119 Assessment of a radiation dose

The undertaking must record such information on examinations, procedures and treatment resulting in exposure to radiation based on which the radiation dose caused by the examination, procedure or treatment to the individual being examined or treated can be determined, when necessary. The estimated radiation dose of a foetus, and information about the examination, procedure or treatment relevant in terms of the radiation exposure must be recorded in the health records.

Upon the request of STUK, an undertaking must provide information on the number of examinations, procedures and treatments resulting in exposure to radiation and on the radiation doses.

STUK issues more detailed regulations on the recording of the information.

The undertaking is obligated to limit and optimize medical exposure as stipulated in VnA section 8 subsection 2:

Unnecessary medical exposure is to be avoided. In this respect, the following must be taken in consideration:

1) the selection of appliances;

2) the selection of parameters influencing the performance capacity of the appliance;

3) the determination of the patient dose and the measurement of the activity of the radiopharmaceutical to be administered to the patient;

4) quality assurance.

The requirement to assess patient's radiation exposure is given in section 10 of S/4/2018.

Section 10, Reference level for a patient's radiation exposure

The reference levels for a patient's radiation exposure are specified in Annex 1–7. The value of a reference level determined by the undertaking itself may not exceed that which is specified in the Annex.

The undertaking must compare the value describing the average radiation exposure of a patient and the activity administered to a patient to the reference level at least once every three years and whenever examination practices or imaging values are changed in such a way that the radiation dose or activity undergoes a material change. This is not applicable to the use of a dental X-ray device to image an in-mouth image detector.

The average value and activity describing the radiation exposure must be determined as the median of at least ten patients of a normal size, either by measuring or on the basis of a calculated estimate, unless otherwise provided in an Annex.

During the years when the determination is not carried out, it must be ensured that the value or activity describing the radiation exposure has not changed.

If the determined average value or activity describing the patient's radiation exposure exceeds the reference level, the reason for the high radiation exposure or activity must be investigated and, if necessary, measures must be taken to reduce patients' radiation exposure.

In radiotherapy the treatment shall be patient specific and exposure shall be ascertained as stipulated in section 9 of S/4/2019:

In radiotherapy, the radiation must be directed at the target area with the precision required by the objective of the therapy.

In external radiotherapy, the uncertainty of the dose may not be greater than, on average,

3) 5%, when using photon radiation greater than 1 MV;

4) 10%, when using electron or X-radiation.

Medical exposure in radiotherapy must be planned patient-specifically and the magnitude and focus of the exposure must be ascertained. The dose received by tissues and organs other than those targeted must be as low as reasonably possible.

In nuclear medicine and in treatments with unsealed sources the typical absorbed doses shall be measured. Typical absorbed dose from unsealed sources can be calculated when radiopharmaceutical

and administrated activity is known. Requirement regrading optimization in nuclear medicine is given in section 7 of S/4/2019:

The activity of a radiopharmaceutical or a tracer must be measured with an activity meter prior to administering the pharmaceutical or tracer to the patient.

If the use of alternative radiopharmaceuticals in the examination is possible, a radiopharmaceutical which results, within reason, in the smallest radiation dose for the patient must be selected.

Regulatory supervision

The fulfillment of the undertakings obligations regarding patient dosimetry are verified with on-site inspections and with surveys. On on-site inspections verifications are carried out by going through records of patient dosimetry, e.g. that the licensee has assessed typical patient doses in most common examinations and compared these values to diagnostic reference level.

Additionally, STUK is obligated by SätL section 14 subsection 5 to compile and publish nationwide assessments on exposures arising from medical use of radiation and their development. The data on medical exposures for these assessment is collected with surveys and on on-site inspections. Results of these surveys are published as reports: 1) Average effective dose for Finnish citizens in 2018 (Suomalaisten keskimääräinen efektiivinen annos vuonna 2018 (julkari.fi)), 2) Nuclear medicine examinations and treatments in Finland 2018: Health care surveillance report (Isotooppitukimukset- ja hoidot Suomessa 2018 (julkari.fi))

These assessments on medical exposures and developments in the use of radiation are carried out by surveys and compiled to reports. Example report: *STUK-A265, June 2021, Patient exposure levels and collective effective dose to the population from radiological examinations - changes from 2008 to 2018 in Finland* (Patient exposure levels and collective effective dose to the population from radiological examinations – changes from 2008 to 2018 in Finland Patient exposure levels and collective effective dose to the population from radiological examinations – changes from 2008 to 2018 in Finland (julkari.fi).

For radiotherapy dosimetry guidance STUK has published *Determination of Absorbed Dose to Water in Radiotherapy. Calibration of High Energy Photon and Electron Radiation Beams in External Radiotherapy. STUK-STO-TR 1. Helsinki 2005* technical guide.

Question 5.5 What are the regulated duties of the registrants and licensees concerning diagnostic reference levels?

Response:

The basic requirement for optimization of radiation in medical exposure, including the use of (diagnostic) reference levels, is stipulated in SätL section 112.

Section 112, Optimization of radiation protection in medical exposure

The undertaking is responsible for the implementation of the requirements concerning the optimization of radiation protection in medical exposure. In addition, the undertaking shall keep the exposure of the carer and comforter and the individual being examined in for medical research as low as possible. The carer and comforter must be at least 18 years of age and they may not be pregnant. The optimization of the radiation protection of a pregnant individual being examined, receiving treatment or subject to a procedure must account for the exposure of the foetus.

The undertaking shall specify the responsibilities in terms of the optimization of radiation protection in medical exposure. The undertaking shall employ the reference levels for the patient's exposure for the purpose of optimizing radiation protection in medical exposure resulting from examinations and procedures.

STUK issues more detailed regulations of a technical nature on the practical procedures for optimizing radiation protection in examinations, procedures and treatments and on the optimization of the radiation protection of children as well as pregnant, breastfeeding and asymptomatic individuals. In addition, STUK issues more detailed regulations on the diagnostic reference levels of examinations and procedures and their use.

More detailed regulations for reference levels are given in section 10 of S/4/2019.

Section 10, Reference level for a patient's radiation exposure

The reference levels for a patient's radiation exposure are specified in Annex 1–7. The value of a reference level determined by the undertaking itself may not exceed that which is specified in the Annex.

The undertaking must compare the value describing the average radiation exposure of a patient and the activity administered to a patient to the reference level at least once every three years and whenever examination practices or imaging values are changed in such a way that the radiation dose or activity undergoes a material change. This is not applicable to the use of a dental X-ray device to image an in-mouth image detector.

The average value and activity describing the radiation exposure must be determined as the median of at least ten patients of a normal size, either by measuring or on the basis of a calculated estimate, unless otherwise provided in an Annex.

During the years when the determination is not carried out, it must be ensured that the value or activity describing the radiation exposure has not changed.

If the determined average value or activity describing the patient's radiation exposure exceeds the reference level, the reason for the high radiation exposure or activity must be investigated and, if necessary, measures must be taken to reduce patients' radiation exposure.

S/4/2019 Annexes 1 to 7:

- ANNEX 1, Reference levels for patients' radiation exposure in the computed tomography examinations of adults
- ANNEX 2, Reference levels for patients' radiation exposure in nuclear medicine examinations
- ANNEX 3, Reference levels for patients' radiation exposure in paediatric CT scans
- ANNEX 4, Reference levels for patients' radiation exposure in cone-beam computed tomography examinations of adults' head region
- ANNEX 5, Reference levels for patients' radiation exposure in cardiology
- ANNEX 6, Reference levels for patients' radiation exposure in the conventional X-ray examinations of adults

- ANNEX 7, Reference levels for patients' radiation exposure in conventional paediatric X-ray examinations

On the Sammio-system (www.sammio.stuk.fi) guidance is given for the undertaking on how to implement requirements. On the guidance text that is connected with the S/4/2019 section 10 subsection 1 it is explained that (Guidance text in Finnish: https://sammio.stuk.fi/#/muistilista/ubgoy02txfck):

Exceeding the reference levels does not necessarily mean that the examination was conducted poorly. The use of radiation exposures higher than the reference level may be justified, for example, because of higher-than-normal image quality. On the other hand, the fact that the reference levels are not exceeded does not mean that the examination is optimized in terms of radiation protection. Even then, it must be ensured that the image quality is sufficient to make a reliable diagnosis and that the radiation exposure is not unnecessarily high.

Question 5.6 What are the regulated duties of the registrants and licensees concerning quality assurance for medical exposures?

Response:

There are comprehensive requirements concerning quality assurance for medical exposures for it is to be organized according to SätL 30 § and S/5/2019.

Radiation Act

Section 30 Quality assurance

The undertaking shall establish quality objectives for practices subject to a safety licence and define and implement systematic measures with which to ensure the realization of the quality objectives (quality assurance) and the fulfillment of the requirements laid down in the law.

The undertaking shall draw up a quality assurance programme for the implementation of quality assurance. The programme must detail the quality assurance measures, their performance, performance

intervals, action limits, measures for when the action limits are exceeded, and responsibilities for taking measures pursuant to the programme. In addition, the progamme must include instructions on performing the technical testing and checking of radiation sources and radiation appliances and other equipment as well as software and auxiliary devices with an impact on safety.

The results of the quality assurance must be documented. The quality assurance programme shall be reviewed on a regular basis and updated when necessary.

STUK issues more detailed regulations on quality assurance measures and their performance intervals and instructions as well as the documentation of results.

Government Decree on Ionizing Radiation

Section 18 Areas of radiation safety expert's use

A radiation safety expert must be used as provided in section 17 at least in:

…

7) the preparation of quality assurance programmes concerning radiation practices;…

10) the adoption of radiation meters and radiation measuring instruments and in ensuring the constancy of the measurements;

…

Section 20 Areas of medical physics expert's use

A medical physics expert must be used in the management of the dosimetry of medical exposure, including the physical measurements needed for the determination of radiation exposure and to provide advice on radiation appliances.

A medical physics expert must furthermore be used in:

…

4) the selection of measuring equipment;

7) the planning and implementation of a quality assurance programme for radiation appliances;

8) the acceptance tests of appliances and in demonstrating the fulfilment of the appliances' in-service approval requirements and other requirements concerning the appliances and their use;

…

STUK S/5/2019

Section 24 Ensuring the operation of a radiation appliance

The safe operation of a radiation appliance shall be ensured following a substantial repair, maintenance or software update as well as always when there is reason to suspect that there are disturbances or changes in the operation of the appliance. Faults and deficiencies affecting radiation safety must be repaired before using the appliance.

Section 26 Acceptance inspection of a radiation appliance in health care and veterinary medicine

The quality assurance programme of the use of radiation in health care and veterinary medicine shall include an acceptance inspection in which the operation of the radiation appliance is ensured before commissioning the appliance. Also the reference performance values to be used in the monitoring of the appliance's operational capacity and performance characteristics shall be determined in the acceptance inspection.

Section 27 Quality assurance assurances in the use of radiation in health care and veterinary medicine

The quality assurance programme of the use of radiation in health care and veterinary medicine shall include actions to ensure:

1) before commissioning a medical radiotherapy appliance, that adequate information on the risk assessment of the patients and the available clinical operation results of the appliance are available;

2) the targeting of the treatment dose to the specified target area in the designed magnitude as accurately as possible;

3) an imaging quality adequate for obtaining the study result;

4) the accuracy of the assessment radiation exposure caused to the patient and the verification of activity administered to the patient.

The radiotherapy quality assurance programme shall include the risk assessment of exposure due to a radiation safety incident or unplanned exposure based on the safety assessment referred to in section 26 of the Radiation Act.

The intervals of quality assurance actions in X-ray operations, nuclear medicine and veterinary medicine may not be longer than what is specified in Appendix 12.

Section 28 Commissioning and regular dose calibration of radiotherapy equipment

Before commissioning a radiotherapy appliance, the operator shall measure or verify the characteristics of the appliance that are needed for the input information of the radiotherapy treatment planning system used.

For quality assurance of radiotherapy activities, before introducing new techniques for dose calculation and radiation use, the calculated and measured dose distributions must be compared using tests corresponding to several different treatment cases and, where appropriate, tests based on dose measurements from actual treatment plans. The radiotherapy appliance shall undergo regular dose calibrations.

Dose calibration shall be verified before the radiotherapy appliance is taken into patient use in such a way that:

1) the verification is conducted by a person other than the one conducting the dose calibration;

2) the dosemeter and the equipment used with it during the measurement are others than those used in the dose calibration.

Furthermore, an independent verification of dose calibration shall be conducted before taking a radiotherapy beam with a different nominal energy or other characteristics into patient use.

Section 29 Other quality assurance actions in radiotherapy

Quality assurance of radiotherapy shall include the verification of each individual treatment plan when taking a new method into use.

In addition, every whole-body treatment must include in vivo dose measurement if the treatment is not based on a slice-based dose schedule.

Treatment targeting must be ensured in the treatment of each patient.

Radiation Act

Section 59 The reliability of radiation measurements

The measurements carried out for assessing the radiation exposure and ensuring safety referred to in this Act shall be performed with a method suitable for the purpose and proved reliable. The results of the measurements must be metrologically traceable to the International System of Units. The radiation meter or measuring instruments shall be appropriately calibrated.

STUK issues more detailed regulations on verifying the reliability of measurements and on the radiation meters' and measuring equipments' calibration, accuracy, use and suitability for a particular purpose.

STUK S/7/2021

Section 13 General requirements for calibration

The radiation meter and the measuring system shall be calibrated prior to their commissioning.

The radiation meter and the measuring system shall be calibrated based on an applicable standard. If there is no such standard, the calibration shall be carried out using other standardized methods and international good practices.

Section 15 Calibration interval

The calibration interval of a reference instrument, field instrument and measuring system may not exceed five years, unless otherwise provided below or otherwise decided by the Radiation and Nuclear Safety Authority when the method of measurement or practice was approved or otherwise.

…

In external radiotherapy, the calibration interval of measuring instruments used for the dose calibration of radiotherapy equipment, and in brachytherapy, calibration interval of radiation sources and measuring instruments used for the calibration of radiation sources may not exceed three years.

The calibration interval of a field instrument used for measuring medical exposure may not exceed two years.

Section 16 Testing of the operation of measuring instruments

A radiation meter shall be in an operating condition. The operating condition shall be verified by means of testing.

The operation of a radiation meter shall be tested at regular intervals using a suitable radiation source or reference instrument. Additionally, the operation shall be tested whenever there is a reason to suspect changes to the operating condition of the meter.

The operation of a radiation meter shall be tested under known and reproducible radiation conditions. The measurement results obtained shall be compared against the radiation values known based on similar measurements previously conducted, and the measuring instrument shall be re-calibrated if necessary.

…

Radiation Act

Section 118 Self-assessment and clinical audit

The undertaking shall have individuals engaged in medical radiological procedures to carry out self-assessments to develop the practices.

The undertaking shall organize a systematic evaluation of procedures resulting in medical exposure (clinical audit) which, at regular intervals,

1) reviews the examination and treatment practices employed, exposures as well as the examination and treatment results;

2) compares the aforementioned to good practices;

3) presents measures deemed necessary to the develop the practices and prevent unjustified exposure.

Self-assessments and clinical audits are subject to the preparation of a report.

Further provisions on the performance and reporting of self-assessments and clinical audits are given by a decree of the Ministry of Social Affairs and Health.

Ministry of Social Affairs and Health Decree on Ionizing Radiation

Section 11 Performance of internal clinical audits

An internal clinical audit supplementing the self-assessments of operations must be carried out at least every four years in operations where the class of medical exposure is 1 or 2.

The audit must rely on up-to-date knowledge and experiences of good medical practices.

Requirement for maintaining records of procedures and results are given in Decree of the Ministry of Social Affairs and Health on medical records (298/2009).

Question 5.7 What are the regulated duties of the registrants and licensees concerning dose constraints in the optimization of protection and safety in any radiological procedure in which an individual acts as a carer or comforter or is subject to exposure as part of a programme of biomedical research?

Response:

The definition of dose constraint is stipulated in SätL section 4 subsection 3. By the definition dose constraints shall also be used for carers and comforters. In section 9 of SätL it is stipulated that dose constraints and constraints of potential exposure shall be used in such way that exposure is anticipated to remain below the constraint due to optimization of radiation protection

SätL section 4, Definitions

3) dose constraint means a constraint on the individual radiation dose of a person other than a patient arising from ionizing radiation during a specific period of time, used to optimize radiation protection in radiation practices;

SätL section 9, Dose constraints and constraints for potential exposure

Dose constraints and constraints for potential exposure are set, taking into account the characteristic features of the practice, in such a way that the exposure is anticipated to remain below the constraint due to the optimization of radiation protection.

On the section 9 justification it is clarified that dose constrains shall be set for carers and comforters and for the volunteers in biomedical research:

Dose constraints and potential exposure constraints are set taking into account the characteristics of the activity in such a way that the exposure is expected to be lower than the constraint as a result of the optimisation of radiation protection. Dose constraints shall be set for the dose to workers or the members of the public and, in the case of medical exposure, to carers and comforters and to the subject of scientific research. Potential exposure constraints may be set for occupational exposure, public exposure or medical exposure. These restrictions may relate to a specific type of activity or source and may also be imposed on a safety authorisation basis.

The definition of medical exposure is given in SätL section 4 subsection 10.

SätL section 4, Definitions

10) medical exposure means:

a) the exposure of patients or asymptomatic individuals as part of their own examination, procedure or treatment intended to benefit their health as well as the exposure of their carers and comforters;

b) the exposure of a research subject taking part in medical research;

On the justification of the medical exposure definition, it is further elaborated on carers and comforters and on volunteers on medical research that:

a) People close to the patient (e.g. parents of a child) and other carers (comforters and carers in the Radiation Safety Directive) may be exposed in the course of their duties when a patient or an asymptomatic person is exposed to radiation. The carers and comforters are not there to assist in the exposure examination by virtue of their profession, but for the personal needs of the patient or the asymptomatic person. The amount of exposure is related to the patient's exposure, for which there are no dose limits, and therefore the dose limits for the public cannot be applied to the exposure of carers and comforters.

b) The Medical Research Act requires written consent from the subject, which fulfils the requirement of the Radiation Safety Directive that participation in scientific research be voluntary.

Requirement for the undertaking to establish constraints is given in SätL section 25.

Section 25 Establishing dose constraints and constraints for potential exposure

The undertaking shall establish the dose constraints and constraints for potential exposure to be used in the radiation practice in advance, unless STUK has established the constraints to be used in the practice in general by virtue of section 10. Constraints on the occupational exposure of an outside worker shall be established in co-operation with the employer of the outside worker.

The constraints for potential exposure of workers and members of the public must be established beforehand for such radiation safety deviations referred to in section 26, subsection 1, paragraph 1, which may result in significant radiation exposure.

The information concerning the constraints referred to above in subsection 1 must be delivered to STUK either as part of the granting of the safety licence or separately.

On the section 112 of SätL it is required that the undertaking shall keep the exposure of the carer and comforter and the individual being examined in for (bio)medical research as low as possible. The carer and comforter must be at least 18 years of age and they may not be pregnant.

Section 112, subsections 1 to 2, Optimization of radiation protection in medical exposure

The undertaking is responsible for the implementation of the requirements concerning the optimization of radiation protection in medical exposure. In addition, the undertaking shall keep the exposure of the carer and comforter and the individual being examined in for medical research as low as possible. The carer and comforter must be at least 18 years of age and they may not be pregnant. The optimization of the radiation protection of a pregnant individual being examined, receiving treatment or subject to a procedure must account for the exposure of the foetus.

The undertaking shall specify the responsibilities in terms of the optimization of radiation protection in medical exposure.

The requirement to use dose constrains for volunteers in biomedical research who are not expected to gain immediate health benefits from research, procedure or therapy is set in VnA section 9.

VnA, Section 9, Optimization of the radiation protection of a research subject taking part in medical research

The radiation exposure of a research subject taking part in medical research as referred to in the Medical Research Act must be planned individually if the health of the research subject is expected to benefit from the research, procedure or therapy. A dose constraint must be applied to an individual who is not expected to gain immediate health benefits from the radiation exposure caused by the research.

Regarding (bio)medical research's justification on VnA section 9 it is required that STUK needs to have for the justification process the assessment from ethics committee. A favourable opinion from the Ethics Committee is necessary to enable the Radiation and Nuclear Safety Authority to ascertain the legitimacy of medical exposure in scientific research.

VnA, Section 7, subsection 3 and 4, Statements and other reports on the justification of practices

The undertaking must ensure that the Radiation and Nuclear Safety Authority has an opinion at its disposal for the purposes of the justification assessment referred to in section 24 of the Radiation Act from:

1. *an ethics committee referred to in the Medical Research Act if radiation is intentionally directed at a human being within the said Act's scope of application;*
2. *the National Institute for Health and Welfare on the assessment of a health care method, provided that the case concerns a new type of method which results in medical exposure which exposes a large number of members of the public or which results in a high degree of medical exposure.*

The ethics committee hears experts on the medical radiological use of radiation in a matter referred to in subsection 3, paragraph 1.

Medical research shall be conducted according to the Medical Research Act (1999/488) and Clinical Drug Trials Act. On the section 4 it is stipulated that the benefits shall outweigh the risk and harms (detrimental effects of the radiation). On the section 10 d it is further stated that on ethics commitees statement shall particularly focus on the appropriateness of the benefit and risk assessment. The risk assessment should also include setup of dose constraints.

Medical Research Act (1999/488), Section 4

Comparison of advantages and harms

In medical research, the interests and well-being of the research subject must always take precedence over the interests of science and society. The risks and harms that the research subject may suffer must be prevented.

Subjects should only be subjected to procedures where the expected health or scientific benefits clearly outweigh the risks and harms that the subject may suffer.

Medical Research Act (1999/488), Section 10 d (23.4.2004/295)

Opinion of the Ethics Committee

The opinion of the Ethics Committee shall be subject to the provisions of Articles 3 and 17. The opinion on a clinical trial shall also take particular account of the following points:

1) the appropriateness of the trial and its design;

2) the appropriateness of the benefit and risk assessment and the justification of the conclusions drawn therefrom;

…

The government as approved renewed Clinical Drug Trials Act on 8.10.2021. The act gives requirements on the patients self-determination (section 7) and on minor patients (section 8). On the renewed act section 18 gives the requirements for the composition of the ethics committee, including requirement to have an expert on medical exposure if radiation is used.

Section 18

A quorum shall consist of at least six members in addition to the chairperson or vice-chairperson. At least one lay member shall be present when an ethical review of an application is being carried out.

When the Committee deals with the matters referred to in this Act, it shall be composed of the necessary medical, legal and ethical expertise.

An expert in paediatrics shall be represented or heard on the committee when the committee is dealing with a clinical trial involving a minor, and an expert with knowledge of the disease or disability concerned when the committee is dealing with a clinical trial involving a subject referred to in Article 13. An expert on the medical use of radiation shall be represented or heard by the committee if the clinical trial is intended to subject the subject to medical exposure as referred to in Section 4(10) of the

Radiation Act (859/2018). The committee may also hear experts at other times. An official of the Finnish Medicines Safety and Development Agency may be heard as an expert.

The expert referred to in paragraph 3 may not participate in the decision-making of the Committee. Instead of hearing the expert orally, the Committee may request a written opinion.

Regulatory supervision

For medical research that is subject to authorization the undertaking is required to present the ethics committee statement that is favorable to the presented practice. The undertaking is obligated to establish or adopt STUK's dose constraints and constraints of potential exposure for their practice. The use of constraints is verified during the authorization. On the on-site inspections, it shall be verified that undertaking uses methods and procedures to optimize the dose so that it is below the set constraints.

Question 6 Are there requirements that registrants and licensees ensure that there are arrangements in place for appropriate radiation protection in cases where a female patient is or might be pregnant or is breast-feeding?

Answer: Yes

Response:

Requirements of radiation protection of pregnant and breast-feeding patients are given in S/4/2019 4 §, 6 § and 8 §. Additional requirement for mandatory warning signs on the premises of the practice for the pregnant are to be included in S/4/2019 for the next revision.

S/4/2019

Section 4 Justification assessment concerning the medical exposure of a foetus or child

Before referring a person of childbearing age to an examination, procedure, or treatment resulting in medical exposure, the referring physician or dentist must investigate whether the person is pregnant. However, the investigation need not be conducted before an X-ray examination or procedure resulting

in medical exposure and concerning the teeth, head and neck area, or the extremities, provided that the radiation is not directed near the abdomen or pelvis or when the medical exposure is justified as an urgent procedure necessary for saving the patient's life.

In addition to what is provided in subsection 1, the possibility of pregnancy must be checked with an adequately sensitive and specific method in the case of:

1. radiotherapy;
2. a nuclear medicine examination resulting in a high level of medical exposure for a foetus;
3. an X-ray examination or procedure of the abdomen or pelvis area carried out with computed tomography or some other method causing a high level of medical exposure.

The justification assessment concerning the examination, procedure, or treatment of a pregnant or breastfeeding person causing medical exposure to a foetus or breastfed child must particularly consider medical methods alternative to the medical exposure or the possibility of postponing the examination, procedure, or treatment to a later date.

Section 6 Optimizing the radiation protection of a foetus or child

The effective dose of a foetus may not exceed 1 mSv, unless this is particularly justified in terms of the overall treatment of the person examined. The radiation protection of a foetus must be optimized particularly in medical exposure as referred to in section 4, subsection 2.

The optimization of a child's radiation protection must account for the child's size and any other special characteristics of the examination. An examination, procedure, or treatment exposing a child to radiation must be planned individually and performed with an appliance that allows for achieving the lowest radiation exposure reasonably possible.

Patients must be urged to stop breastfeeding or to take a break from breastfeeding due to a nuclear medicine examination or nuclear medicine treatment so that the radiation exposure of the breastfed child is as low as possible and at the very least not higher than the dose limit for members of the public.

Section 8 The optimization of radiation protection due to a nuclear medicine examination or nuclear medicine treatment

Following a nuclear medicine examination or nuclear medicine treatment, patients must be urged to avoid pregnancy for a sufficient period of time. This ensures that the radiation exposure of an unborn child does not exceed the dose limit for members of the public.

Radiation Act

Section 119 Assessment of a radiation dose

The undertaking must record such information on examinations, procedures and treatment resulting in exposure to radiation based on which the radiation dose caused by the examination, procedure or treatment to the individual being examined or treated can be determined, when necessary. The estimated radiation dose of a foetus, and information about the examination, procedure or treatment relevant in terms of the radiation exposure must be recorded in the health records.

Upon the request of STUK, an undertaking must provide information on the number of examinations, procedures and treatments resulting in exposure to radiation and on the radiation doses.

STUK issues more detailed regulations on the recording of the information.

Question 7 Is it regulated that registrants and licensees ensure that there are arrangements in place to ensure appropriate radiation protection for members of the public and for family members before a patient is released following radionuclide therapy?

Answer: Yes

Response:

The principle of optimization of radiation protection is given in SätL section 6.

SätL 6, Principle of optimization

To optimize radiation protection, occupational exposure and public exposure to ionizing radiation shall be kept as low as is reasonably achievable, and medical exposure shall be limited to what is necessary to achieve the intended examination or treatment result and performance of the procedure (principle of optimization).

Requirements regarding discharge of a patient who emits radiation are stipulated in VnA section 11.

VnA, Section 11, Discharge of a patient who emits radiation

In the event that medical exposure is attributable to a radiopharmaceutical or a sealed source implanted in the patient, the individual subject to the radiation exposure may not be discharged until the dose caused by the radioactive substance in the body to the comforter or members of the public is expected to remain below the dose constraint.

The physician responsible for the medical exposure is responsible for the patient's discharge and for providing the patient or their representative with written instructions on how to prevent unnecessary exposure to individuals in contact with the patient.

The undertaking is obligated to establish and use dose constraints to optimize radiation protection for the carers and comforters and for the members of the public. The default dose constraint for the members of the public is 0,1 mSv/year as stipulated in S/6/2019 section 8.

S/6/2019, Section 8, Dose constraints for public exposure

The dose constraint for public exposure is 0.1 mSv. However, the dose constraint may be greater than this if it is shown to be justified in the safety assessments, excluding the situations referred to in section 9.

For the carers and comforters there are no default dose constraints. It is up to the undertaking to establish and present dose constraints for the carers and comforters during the authorization. Proposed constraints are compared to international recommendations, e.g. EC Radiation Protection 97, Radiation Protection following Iodine-131 therapy (exposures due to out-patients or discharged in-patients, ICRP Publication 94 Release of Patients after Therapy with Unsealed Radionuclides and IAEA SRS No. 63 Release of Patients After Radionuclide Therapy. Proposed constraints are accepted if they are in line with Finnish legislation and international recommendations.

Regulatory supervision

Setup of dose constraints is verified during authorization. During the authorization the undertaking can also be asked to provide criteria and guidelines that they are using for the release of patients who have undergone therapeutic radiological procedures using unsealed sources or patients who still retain implanted sealed sources. The use of criteria and guidelines can also be verified during onsite inspections.

Question 8 Are registrants and licensees required to ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures and that registrants and licensees promptly investigate unintended or accidental medical exposures and, if appropriate, implement corrective actions?

Answer: Yes

Response:

Preparation and preventive measures for radiation safety deviations

The obligation for the undertaking that radiation safety deviations are prevented with adequate effectiveness and their consequences are minimized is given in SätL section 23.

Section 23, Criteria for organizing practices

The undertaking shall implement the organization of the practice in such a way that the practice meets the requirements provided in this Act and that radiation safety deviations are prevented with adequate effectiveness and that their consequences are as insignificant as possible. The undertaking shall

implement such measures to improve radiation safety as can be considered justified in terms of their quality and costs as well as their improving impact.

The undertaking shall ensure that it has the expertise necessary in terms of the nature and extent of the practice at its disposal and sufficient financial and human resources for the safe implementation of the practice.

Further provisions on the requirements concerning the financial and human resources referred to in subsection 2 may be given by government decree.

STUK issues further technical regulations for the prevention of radiation safety incidents and the limitation of their consequences.

Additionally, the undertaking shall present in written form in safety assessment, as stipulated in SätL 25, the measures to prevent and how they are prepared for identified radiation safety deviation.

Section 26, Safety assessment concerning radiation practices

In practices subject to a safety licence, the undertaking shall carry out a safety assessment concerning the radiation practice, which:

1) identifies ways in which the practice can cause radiation exposure, considering any possible radiation safety deviations;

2) assesses the magnitude of the occupational, public and medical exposure arising from the practices as well as the probability and magnitude of the potential exposure;

3) presents measures to ensure radiation safety and the optimization of radiation protection;

4) presents measures to prevent and prepare for identified radiation safety deviations;

5) presents the categorization of the radiation practice.

Requirement for the undertaking to have an up-to-date plan for radiation safety deviations is given in section 129 of SätL.

Section 129, Preparedness for radiation safety deviations

In practices subject to a safety licence, the undertaking must prepare for radiation safety deviations. The undertaking shall have an up-to-date plan of action for the deviations.

More detailed regulations on the plan for radiation safety deviations are given in S/2/2018 sections 2-3.

Section 2, Plan for radiation safety deviations

The plans for radiation safety deviations shall include separate operating instructions for each place of use in the event of a radiation safety deviation.

The plan shall include training and exercises on the immediate actions to be taken to limit radiation exposure.

Additionally, the plan shall specify measures for determining the causes of a radiation safety deviation and for learning from it.

Section 3, Operating instructions for each place of use

In a practice of class 1 radiation exposure, each place of use shall have written operating instructions in place that are available to the workers. The operating instructions shall at least specify:

1) the immediate actions to be taken to limit radiation exposure, including:

a) identifying and limiting the radiation hazard area;

b) preventing outsiders from accessing the radiation hazard area;

c) the use of respirators if it is suspected that radioactive substances have entered into the breathing air;

d) prevention of the dispersion of contamination;

e) notifying the radiation safety officer of the radiation safety deviation;

f) prevention of the accumulation of radioactive iodine into the thyroid gland;

g) accelerating the decorporation of radionuclides;

h) removal of sealed source radiotherapy apparatus from the patient;

i) removal of the patient from the radiation beam;

2) the procedure for recording the course of events, including:

a) the measures carried out and the times thereof;

b) the names and contact information of the individuals who were exposed or otherwise involved in the radiation safety deviation and, concerning employees, the information referred to in section 42 of the Government Decree;

c) detailed information concerning the exposure;

3) the procedure for reporting a radiation safety deviation:

a) to competent authorities;

b) to those involved in the radiation safety deviation;

4) the actions for determining the magnitude of the radiation exposure;

5) the urgent actions for assessing the state of health of those who were exposed;

6) instructions for informing the patient and his or her attending physician;

7) the procedure for obtaining advice from a radiation safety expert and medical physics expert if applicable.

In a practice of radiation exposure classes 2 or 3, each place of use shall have written operating instructions in place that are available to the workers, and at least the information referred to in paragraphs 1, 2, 3, 4 and 7 of subsection 1 shall be included in the operating instructions.

The basic requirement to investigate radiation safety deviations is given in SätL section 131.

Section 131, Measures after a radiation safety deviation

The undertaking shall ensure that a radiation safety deviation and the reasons for it and the exposures arising from it are investigated. A record shall be kept of radiation safety deviations and their investigations and the results of said investigations. The undertaking shall implement the remedial measures required due to a radiation safety deviation, which prevent similar deviations.

The undertaking shall notify STUK of the results of the investigation concerning the radiation safety deviation and of the remedial measures.

The undertaking shall notify STUK of the summarized information on any radiation safety deviations related to radiation practices other than those referred to in section 130, subsection 2.

STUK issues more detailed regulations on the investigations concerning radiation safety deviations, on the content of the information to be recorded, and on the content and preparation of the notifications.

On the section 130 of SätL it is stipulated that the undertaking shall immediately notify STUK of all significant unplanned medical exposure.

Section 130 Immediate measures in a radiation safety deviation

In the event of a radiation safety deviation, the undertaking in a practice subject to a safety licence shall assess the situation and take the measures necessary to ensure radiation safety. The undertaking responsible for the radiation safety deviation and the authority which becomes aware of the radiation safety deviation shall immediately notify STUK of:

1) the radiation safety deviation due to which the radiation safety of the workers or members of the public at the facility and place where the radiation is used or its surroundings may be compromised;

2) any significant unplanned medical exposure;

3) the loss, unauthorized use or holding of a radiation source subject to a safety licence;

4) any significant spreading of a radioactive substance indoors or in the environment;

5) any other abnormal observations and information which may be of material significance in terms of radiation safety.

…

The notification of a defect or deficiency found or suspected in a medical device is also regulated by the Medical Devices Act, the MD Regulation, the IVD Regulation and the Medical Devices Act (719/2021).

List of what is considered as significant unplanned medical exposure is given in section 4 of S/2/2018.

Section 4 Significant unintended medical exposure

The unintended medical exposure is significant if:

1) the dose caused to the patient by electron or photon radiation generated with radiotherapy equipment deviates or could have deviated from the planned total dose by at least 25%;

2) the dose caused to two or more successive patients by electron or photon radiation generated with radiotherapy equipment deviates or could have deviated from the planned total dose by 5–25%;

3) the activity received by the patient in radionuclide therapy deviates or could have deviated from the planned activity by at least 25%;

4) the activity received by two or more successive patients in radionuclide therapy deviates or could have deviated from the planned activity by 10–25%;

5) a wrong patient is exposed when the medical exposure is of class 1;

6) the additional effective dose caused to the patient or to a wrong patient by the examination or procedure is at least 10 mSv;

7) the examination, procedure or treatment causes deterministic detriment to the patient as a result of additional radiation exposure;

8) the absorbed dose caused to the foetus as a result of additional exposure is at least 10 mGy;

9) systematic additional exposure is caused to at least 10 patients and the exposure of a single patient is at least 50% higher than in a planned exposure in a practice of class 1 or 2 medical exposure;

10) at issue of other medical exposure of which it is important to inform other operators to avoid the occurrence of a similar radiation safety deviation.

Requirements on what is required to be reported and investigation on causes leading to radiation safety deviations and resulting effects, including actions to prevent occurrence of similar radiation safety deviations is stipulated in sections 5 and 7 of S/2/2018.

Section 5, Reporting a radiation safety deviation

The notification referred to section 130(2) of the Radiation Act shall be made by telephone or using other such means of communication with which the notifying party can ensure that the message has been duly received.

Outside of regular office hours, the Radiation and Nuclear Safety Authority shall be contacted by calling the emergency response centre.

The notification shall include:

1) the name of the undertaking and the number of the safety licence;

2) the name of the radiation safety officer;

3) the name and contact details of the individual who submits the notification;

4) the time and place of the incident;

5) the radiation source;

6) description of the radiation safety deviation;

7) information about those who were potentially exposed and the radiation exposure they have sustained; if no radiation dose measurement results are available, the dose shall be estimated based on the available exposure data;

8) an assessment of radioactive substances potentially released to the environment;

9) the immediate measures taken;

10) the first estimates of the cause of the radiation safety deviation.

A notification made orally shall be confirmed in writing without delay.

Section 7, Report on a radiation safety deviation

A written report shall be prepared on the radiation safety deviation that includes the information referred to in section 5(3) above complete with the details of the incident or observation and more detailed information on the causes leading to the radiation safety deviation and the resulting effects. Additionally, the report shall specify measures for preventing the occurrence of similar radiation safety deviations.

The undertaking shall submit the report referred to in subsection 1 above to the Radiation and Nuclear Safety Authority without delay.

Obligations of the undertaking regarding the information sharing are stipulated in SätL 130.

Section 130, subsection 3

The undertaking shall immediately notify any significant exposure arising from a radiation safety deviation and the reasons for it to:

1) the exposed worker;

2) the referrer and the physician responsible for medical exposure as well as the exposed individual or their legal representative, in terms of medical exposure;

3) any other individuals exposed, insofar as possible.

Section 130, subsection 4

The undertaking shall immediately notify any significant exposure arising from a radiation safety deviation and the reasons for it to:

1) the exposed worker;

2) the referrer and the physician responsible for medical exposure as well as the exposed individual or their legal representative, in terms of medical exposure;

3) any other individuals exposed, insofar as possible.

Section 130, subsection 5

The notification of a defect or deficiency found or suspected in a medical device is also regulated by the Medical Devices Act, the MD Regulation, the IVD Regulation and the Medical Devices Act (719/2021).

Additionally, STUK shares information regarding lessons learned from radiation safety deviations according to the graded approach. Information is shared by email (urgent matters), regulatory supervision reports, webinars, inspections and in vocational training days.

Question 8.1 How is it ensured that registrants and licensees investigate unintended and accidental medical exposures?

Response:

How GSR Part 3 paragraph 3.180 and 3.181 requirements are fulfilled is explained within answer to question 8.

Question 9 Is it regulated that registrants and licensees ensure that radiological reviews are performed periodically at medical radiation facilities and that records are maintained?

Answer: Yes

Response:

Requirements on periodic radiological review of facilities in the medical exposure area are given in SätL 118 § and STMA 1044/2018 11 § and 12 §. Radiological reviews known as self-assessments and clinical audits are subject to the preparation of a report.

Reports of the self-assessments and clinical audits shall be available for review during inspections and their regular execution is verified during inspections. Expert Group for Clinical Audits (KLIARY, https://www.kliininenauditointi.fi/) is a national group independent from auditing organizations which coordinates and develops audits, publishes guidelines and evaluates audit programmes.

Radiation Act

Section 118 Self-assessment and clinical audit

The undertaking shall have individuals engaged in medical radiological procedures to carry out self-assessments to develop the practices.

The undertaking shall organize a systematic evaluation of procedures resulting in medical exposure (clinical audit) which, at regular intervals,

1) reviews the examination and treatment practices employed, exposures as well as the examination and treatment results;

2) compares the aforementioned to good practices;

3) presents measures deemed necessary to the develop the practices and prevent unjustified exposure.

Self-assessments and clinical audits are subject to the preparation of a report.

Further provisions on the performance and reporting of self-assessments and clinical audits are given by a decree of the Ministry of Social Affairs and Health.

Decree of the Ministry of Social Affairs and Health on ionizing radiation

Section 11 Performance of internal clinical audits

An internal clinical audit supplementing the self-assessments of operations must be carried out at least every four years in operations where the class of medical exposure is 1 or 2.

The audit must rely on up-to-date knowledge and experiences of good medical practices.

Section 12 Performance of external clinical audits

An external clinical audit, which supplements internal clinical audits and the self-assessments of operations, must be organized at least:

1. every six years in operations where the class of medical exposure is 1;
2. every eight years in operations where the class of medical exposure is 2.

External clinical audits shall be carried out by a group of qualified and experienced experts independent of the responsible party.

Question 9.1 What records are registrants and licensees required to keep and for which periods the regulatory body has specified to maintain the records?

Response:

There are regulatory requirements on keeping records concerning personnel, quality assurance and medical exposures, but specific periods for keeping those records are not given. Some requirements lack the specific mention of keeping of records such as requirements for calibrations for which records are intrinsic.

The regulatory body verifies during inspections that records are being kept as required, or as in the case for medical exposures STUK may request the data separately, as described in Radiation Act section 119. The more detailed regulation on recordkeeping given by STUK mentioned in Radiation Act section 119 are yet to be issued.

Radiation Act

Section 29 Management system of radiation practices

In practices subject to a safety licence, the undertaking must have a written management system for the radiation practice.

The management system must include the name, birthdate and contact details of the radiation safety officer and, taking into account the nature and extent of the radiation practice and the conditions at the facility or place where the practice is carried out, sufficient information on:

1. the qualifications, training and induction of persons to verify compliance with the requirements provided in sections 33, 37 and 38;
2. tasks which are significant in terms of radiation safety and security arrangements, the division of responsibilities and flow of information;
3. measures to maintain and develop a good safety culture as referred to in section 12;
4. arrangements for the use of a radiation safety expert and a medical physics expert;
5. other administrative and organizational arrangements aiming to ensure radiation safety and to implement the security arrangements.

STUK issues more detailed regulations on the information to be presented in the management system.

Section 34 Supplementary training maintaining professional skills

The undertaking shall ensure that workers engaged in radiation practices are provided with sufficient and regular supplementary training on radiation protection.

The undertaking shall keep a worker-specific record on the supplementary radiation protection training for which it is responsible.

Further provisions on regular supplementary radiation protection training and the content thereof are given by a decree of the Ministry of Social Affairs and Health.

STUK S/7/2021

Section 14 Calibration of the radiation meter and the measuring system

The dosimetry system used for individual monitoring and the reference instruments for radiation practices and rescue operations shall be calibrated by an accredited laboratory or national metrological laboratory.

…

The presentation of the calibration results shall satisfy the requirements set out in ISO/IEC 17025 on calibration and testing laboratories and the special requirements set out for a calibration laboratory. In addition to the general information on the calibration, the results of the calibration of the used field instrument shall include at least the information on the calibration procedure, the calibration quantity, the numerical result and its unit and uncertainty.

…

Section 15 Calibration interval

The calibration interval of a reference instrument, field instrument and measuring system may not exceed five years, unless otherwise provided below or otherwise decided by the Radiation and Nuclear Safety Authority when the method of measurement or practice was approved or otherwise.

…

In external radiotherapy, the calibration interval of measuring instruments used for the dose calibration of radiotherapy equipment, and in brachytherapy, calibration interval of radiation sources and measuring instruments used for the calibration of radiation sources may not exceed three years.

…

Section 16 Testing of the operation of measuring instruments

A radiation meter shall be in an operating condition. The operating condition shall be verified by means of testing.

The operation of a radiation meter shall be tested at regular intervals using a suitable radiation source or reference instrument. Additionally, the operation shall be tested whenever there is a reason to suspect changes to the operating condition of the meter.

The operation of a radiation meter shall be tested under known and reproducible radiation conditions. The measurement results obtained shall be compared against the radiation values known based on similar measurements previously conducted, and the measuring instrument shall be re-calibrated if necessary.

The alarm functionalities in the radiation meter shall be tested.

Radiation Act

Section 30 Quality assurance

The undertaking shall establish quality objectives for practices subject to a safety licence and define and implement systematic measures with which to ensure the realization of the quality objectives (quality assurance) and the fulfillment of the requirements laid down in the law.

The undertaking shall draw up a quality assurance programme for the implementation of quality assurance. The programme must detail the quality assurance measures, their performance, performance intervals, action limits, measures for when the action limits are exceeded, and responsibilities for taking measures pursuant to the programme. In addition, the progamme must include instructions on performing the technical testing and checking of radiation sources and radiation appliances and other equipment as well as software and auxiliary devices with an impact on safety.

The results of the quality assurance must be documented. The quality assurance programme shall be reviewed on a regular basis and updated when necessary.

STUK issues more detailed regulations on quality assurance measures and their performance intervals and instructions as well as the documentation of results.

STUK S/5/2019

Section 16 In-service acceptability criteria for a medical radiation appliance

In addition to what is specified section 15, a medical radiation appliance shall meet the in-service acceptability criteria specified in this section.

The appliance shall meet the performance characteristics and safety properties specified by the manufacturer during operation.

A report shall be available at the place of operation of the appliance, indicating the in-service acceptability criteria and that these are met.

The in-service acceptability criteria for medical and veterinary radiation appliances are specified in Appendices 2-5.

Radiation Act

Section 112 Optimization of radiation protection in medical exposure

…

The undertaking shall employ the reference levels for the patient's exposure for the purpose of optimizing radiation protection in medical exposure resulting from examinations and procedures.

STUK issues more detailed regulations of a technical nature on the practical procedures for optimizing radiation protection in examinations, procedures and treatments and on the optimization of the radiation protection of children as well as pregnant, breastfeeding and asymptomatic individuals. In addition, STUK issues more detailed regulations on the diagnostic reference levels of examinations and procedures and their use.

Government Decree on Ionizing Radiation

Section 8 Limitation of exposure in the optimization of radiation protection

The optimization of radiation protection referred to in section 6, subsection 1 of the Radiation Act must, in terms of occupational exposure and public exposure, be implemented in such a way that the magnitude of the dose generated, the probability of the exposure and the number of the exposed individuals is kept as low as possible by practical measures in light of current knowledge and technology as well as economic and societal factors.

Unnecessary medical exposure is to be avoided. In this respect, the following must be taken in consideration:

1. *the selection of appliances;*
2. *the selection of parameters influencing the performance capacity of the appliance;*
3. *the determination of the patient dose and the measurement of the activity of the radiopharmaceutical to be administered to the patient;*
4. *quality assurance.*

On the section 8 justification it is written regarding item 3 that:

3) The patient dose is determined using appropriate methods, currently mainly according to IAEA recommendations. The effective dose is used to compare the radiation doses to the patient from different imaging studies and image-guided procedures. In addition, where appropriate, organ equivalent doses may be used. For radiotherapy, the absorbed dose to the tissue is determined.

STUK S/4/2019

Section 10 Reference level for a patient's radiation exposure

The reference levels for a patient's radiation exposure are specified in Annex 1–7. The value of a reference level determined by the undertaking itself may not exceed that which is specified in the Annex.

The undertaking must compare the value describing the average radiation exposure of a patient and the activity administered to a patient to the reference level at least once every three years and whenever examination practices or imaging values are changed in such a way that the radiation dose or activity undergoes a material change. This is not applicable to the use of a dental X-ray device to image an in-mouth image detector.

The average value and activity describing the radiation exposure must be determined as the median of at least ten patients of a normal size, either by measuring or on the basis of a calculated estimate, unless otherwise provided in an Annex.

During the years when the determination is not carried out, it must be ensured that the value or activity describing the radiation exposure has not changed.

If the determined average value or activity describing the patient's radiation exposure exceeds the reference level, the reason for the high radiation exposure or activity must be investigated and, if necessary, measures must be taken to reduce patients' radiation exposure.

Radiation Act

Section 119 Assessment of a radiation dose

The undertaking must record such information on examinations, procedures and treatment resulting in exposure to radiation based on which the radiation dose caused by the examination, procedure or treatment to the individual being examined or treated can be determined, when necessary. The estimated radiation dose of a foetus, and information about the examination, procedure or treatment relevant in terms of the radiation exposure must be recorded in the health records.

Upon the request of STUK, an undertaking must provide information on the number of examinations, procedures and treatments resulting in exposure to radiation and on the radiation doses.

STUK issues more detailed regulations on the recording of the information.

Radiation Act

Section 131 Measures after a radiation safety deviation

The undertaking shall ensure that a radiation safety deviation and the reasons for it and the exposures arising from it are investigated. A record shall be kept of radiation safety deviations and their investigations and the results of said investigations.

….

STUK issues more detailed regulations on the investigations concerning radiation safety deviations, on the content of the information to be recorded, and on the content and preparation of the notifications.

Analysis

STRENGTHS FOR SAFETY REQUIREMENTS FOR MEDICAL EXPOSURE

S1	A lot of attention has been paid on justification and optimization in medical exposure by issuing new requirements, developing guidance and communicating with lisencees.
S2	New regulations emphasize that ethics committees need to utilize expertise on radiation protection in medical exposure.
S3	STUK guidance has been established based on national and international research projects and that has also enabled to increase competence of STUK staff members.
S4	Unintended exposures have been well reported to STUK based on definitions in regulations how to report remarkable and less remarkable cases.
S5	Education and training of medical practitioners, medical physicists and radiographers is well established to enable them to assume their roles and responsibilities and needed qualifications and learning outcomes are regulated to guarantee the adequate level of training for safety of medical exposure.
S6	SAMMIO supports both STUK staff and licencees in interpreting and implementing requirements on medical exposure in a transparent and harmonized way.

WEAKNESSES FOR SAFETY REQUIREMENTS FOR MEDICAL EXPOSURE

W1	National referral criteria are still missing. MSAH has initiated a preliminary assessment in 2020 to find out the current status in Finland and possible ways forward (results in the report STUK-B 273). The results of surveys sent to physicians and dentists as part of this preliminary assessment indicate that Finland needs a referral guideline that should be integrated in health care IT systems and electronic referral systems and should also provide support for decision-making.
W2	Based on the requirement in SätL Section 111 the Council for Choices in Health Care in Finland, working in conjunction with the MSAH, has started to prepare criteria for imaging asymptomatic individuals, however there is no guarantee of funding to fulfill this requirement in future.

OPPORTUNITIES FOR SAFETY REQUIREMENTS FOR MEDICAL EXPOSURE

O1	Finland will participate as a test country for EU Just-CT project in which justification of about 1000 CT examinations from Finland will be evaluated in 2022. This will give valuable information for licensees to improve their processes and for STUK to improve supervision, as appropriate.
O2	Safety research on medical exposure has supported the regulatory functions and competence building of STUK. Strengthening and ensuring of research resources of STUK would enable continuous improvement related to safety of medical exposures and competence building of STUK staff members

THREATS FOR SAFETY REQUIREMENTS FOR MEDICAL EXPOSURE

T1	In lack of national referral guidelines the medical exposure might not be appropriately justified on national level. There are several guidelines in use, but none of them are integrated in the IT-systems that are used in daily practices.
T2	Medical exposures of asymptomatic individuals based on risks indicated in reports of genomy tests may be problematic if there are not enough resources to make an evidence-based justification. Imaging takes resources and unnecessary medical exposure should be avoided based on the safety principles.
T3	New technologies are emerging and requirements for justification and optimization might not be flexible enough in all possible situations. For example, use of AI and robotics may challenge the basic requirements for responsibilities.

CONCLUSIONS FOR SAFETY REQUIREMENTS FOR MEDICAL EXPOSURE

C1	A lot of attention has been paid on justification and optimization in medical exposure by issuing new requirements, developing guidance and communicating with licensees.
C2	National referral criteria are still missing. MSAH has initiated a preliminary assessment in 2020 to find out the current status in Finland and possible ways forward (results in the report STUK-B 273). The results of surveys sent to physicians and dentists as part of this preliminary assessment indicate that Finland needs a referral guideline that should be integrated in health care IT systems and electronic referral

	systems and should also provide support for decision-making. In lack of national referral guidelines the medical exposure might not be appropriately justified on national level. There are several guidelines in use, but none of them are integrated in the IT-systems that are used in daily practices.
C3	Based on the requirement in SätL Section 111 the Council for Choices in Health Care in Finland, working in conjunction with the MSAH, has started to prepare criteria for imaging asymptomatic individuals, however there is no guarantee of funding to fulfill this requirement in future.
C4	Safety research on medical exposure has supported the regulatory functions and competence building of STUK. Strengthening and ensuring of research resources of STUK would enable continuous improvement related to safety of medical exposures and competence building of STUK staff members.

Module: Regulation of decommissioning of facilities

Findings

Question 1 Do the regulations require that exposures during decommissioning be considered as a planned exposure situation?

Answer: Yes

Response:

The graded approach is applied in regulatory activities concerning spent fuel interim storages and encapsulation plant as it is applied in regulation in nuclear power plants. The regulatory activities are proportional to the importance on the nuclear safety. The basis of the application of the graded approach in regulatory activities is described in the answer for Primary Question 1 in the document *Self-Assessment for Facilities and Activities and Exposure Situations (009 Regulation of Nuclear Power Plants).*

Nuclear Energy Act (990/1987) 7a § states that the safety requirements and measures for ensuring safety shall be graded and targeted to be commensurate with the risks in the use of nuclear energy.

Internal guide STUK 3.6 describes STUK's processes to prepare and manage STUK's regulations and regulatory guides as well as procedures when participating in the preparation of national or international legislation.

General safety requirements concerning the spent fuel interim storage design are described in Regulation STUK Y/1/2018. The requirements concerning encapsulation plant and disposal facility are described in STUK Regulation Y/4/2018. The Chapter 3 in STUK Regulation Y/1/2018 and chapter 4 in STUK Regulation Y/4/2018 describe design related requirements, such as the defense-in-depth

principle. Safety classification requirement is described in Section 4 of Regulation Y/1/2018 and section 5 of Regulation Y/4/2018. Requirements set for and the actions taken to ascertain the compliance with the requirements of the systems, structures and components implementing safety functions and connecting systems, structures and components shall be commensurate with the safety class of the item in question.

Resource allocation applies for regulation of fuel cycle facilities as described in *Self-Assessment for Facilities and Activities and Exposure Situations (009 Regulation of Nuclear Power Plants)*. The same applies for design rules, quality of design, Reliability of items important to safety, Plant layout. The referred Regulatory Guide YVL B.2 *Safety Classification* applies for spent fuel interim storages and encapsulation plant as well. Also, the quality management requirements applied to the systems, structures and components of various safety classes are given in Guides YVL A.3 *"Leadership and management for safety*" applies for spent fuel interim storages and encapsulation plant.

More specific design requirements are given in various regulatory guides. It should be noted that each regulatory guide or its explanatory memorandum makes reference to relevant national and international standards.

Guide YVL B.1 describes overall design requirements. Chapter 4 describes the design requirements for ensuring the reliability of safety functions. Main principles affecting the reliability requirements of SSCs can be connected to the defense-in-depth concept and the design bases (operational occurrences and accidents to be considered).

The Guide YVL D.3 (Handling and Storage of Nuclear Fuel) describes additional design requirements for spent fuel interim storages and encapsulation plant. The graded approach is considered in the design requirements concerning spent fuel storages and encapsulation plants as the issues affecting safety (as amount of reactivity, radioactivity, and decay heat) are lesser in these facilities compared to the NPPs

Regarding review and assessment related activities, see response to the question 1.2 of Module 6. Internal guide YTV 6.c describes the application of the graded approach.

Regarding records of operation, the response in Primary Question 1 in *Self-Assessment for Facilities and Activities and Exposure Situations (009 Regulation of Nuclear Power Plants)* also applies for spent fuel interim storages and encapsulation plant as well as responses concerning integrated safety assessment, inspection program and regulatory inspections, response of the regulatory body to non-compliances and Public information activities.

Uranium Extraction Facility

Risk potential of a uranium extraction facility on nuclear safety is low in this facility type due to small amount of radioactive material. Accordingly, the regulation for this facility type is much lighter and simpler compared to other nuclear facility types. The Nuclear Energy Act (990/1987) 3 § 5 a) defines that the term ‘nuclear facility’ does not mean mines or milling plants intended for the fabrication of uranium or thorium. This means that most of the YVL guides are not applied, except the YVL guides concerning safeguards (YVL D.1) and transport (YVL D.2).

Addition to Nuclear Energy Act, Nuclear Energy Decree is applicable to uranium extraction facility. The detailed requirements concerning uranium extraction facilities are set in STUK regulation Y/5/2016 on the Safety of Mining and Milling Operations Aimed at Producing Uranium or Thorium. The requirements in the regulation Y/5/2016 are set considering the low risk of uranium extraction facilities on nuclear and radiation safety.

Due to the defence in depth concept, the first two levels are applied concerning a uranium extraction facility as the potential risk of hazards of the facility is low. This is further discussed in Response of Primary Question 7

The safety functions in uranium extraction facility aim to restrict the radioactive exposure of personnel and environment. The potential hazards are minor so dedicated safety systems as in other types of fuel cycle facilities are not applied in uranium extraction facilities.

Licensing of uranium extraction facility is performed according to Nuclear Energy Act Section 21. The Section 21 states that a license for the operation may be granted if the use of nuclear energy meets the safety requirements laid down in the Act and appropriate account has been taken of the safety of workers and the population, and environmental protection. This is the only licensing phase required for uranium extraction facility in the nuclear energy regulations.

Regulatory inspections are addressed in Primary Question 5.

The design requirements are addressed in Primary Question 7.

Siting of the facility is addressed in Primary Question 12.

Emergency preparedness is addressed in Primary Question 30.

Question 2 Does the regulatory body ensure that a safety assessment has been prepared for all facilities for which decommissioning is planned and for all facilities undergoing decommissioning?

Answer: Yes

Response:

test

Question 3 Is the regulatory body assigned the responsibility to regulate all aspects of decommissioning throughout all stages of the facility's lifetime, from initial planning for decommissioning during siting and design of the facility, to the completion of decommissioning actions and the termination of authorization for decommissioning?

Answer: Yes

Response:

test

Question 4 Are there regulations that assign responsibility to the licensee for all aspects of safety, radiation protection and protection of the environment during decommissioning, including planning and conducting decommissioning actions in compliance with the authorization for decommissioning and with requirements derived from the national legal and regulatory framework?

Answer: Yes

Response:

test

Question 5 Is the licensee required to select a decommissioning strategy, consistent with the national policy on the management of radioactive waste, and the regulatory body takes responsibility to review the decommissioning strategy to assure it is consistent with the national policy on the management of radioactive waste?

Answer: Yes

Response:

test

Question 5.1 How is it ensured that the decommissioning strategy is something other than immediate dismantling?

Response:

gh

Question 5.2 If the decommissioning strategy is deferred dismantling, has the regulatory body approved a programme for maintenance, monitoring, and surveillance that ensures safety throughout the period of deferral?

Response:

gjh

Question 5.3 If shutdown of a facility is sudden, does the regulatory body review the decommissioning strategy on the basis of the situation that initiated the sudden shutdown, to determine whether revision of the strategy is required? If shutdown is caused by an accident, how does the regulatory body ensure that the facility is brought to a safe configuration before an approved final decommissioning plan is implemented?

Response:

hj

Question 5.4 If shutdown is caused by an accident, how does the regulatory body ensure that the facility is brought to a safe configuration before an approved final decommissioning plan is implemented?

Response:

hj

Question 6 Does the regulatory body assure that the licensee has prepared and maintains a decommissioning plan in accordance with the requirements of the regulatory body that shows that decommissioning can be accomplished safely to meet the desired end state?

Answer: Yes

Response:

hj

Question 6.1 How does the regulatory body ensure that the decommissioning plan is updated periodically?

Response:

hj

Question 6.2 What actions does the regulatory body take concerning authorization for operation of the facility during the period of transition between permanent shutdown of operations at the facility and approval of the final decommissioning plan?

Response:

hj

Question 7 Does the regulatory body assure that a final decommissioning plan is timely prepared by the licensee in accordance with the requirements of the regulatory body and is submitted to the regulatory body for approval?

Answer: Yes

Response:

hj

Question 8 Is the regulatory body authorized and capable to take specific actions to ensure that the licensee implements the final decommissioning plan?

Answer: Yes

Response:

hj

Question 9 Does the regulatory body assure that if operational radioactive waste or nuclear fuel is present in the facility after its permanent shutdown, such material is removed prior to the conduct of decommissioning actions and transported to an authorized facility in compliance with the applicable transport regulations?

Answer: Yes

Response:

hj

Question 9.1 If such removal is not possible during the period of transition between permanent shutdown and the granting of the authorization for decommissioning, does the regulatory body assure the approved final decommissioning plan addresses the removal of these materials as part of decommissioning (during initial phases of immediate dismantling or during the preparatory phase for safe storage).

Response:

hjk

Question 10 Does the regulatory body review the final decommissioning report and verify compliance with the end state criteria to ensure that all regulatory requirements and end state criteria, as specified in the final decommissioning plan and in the authorization for decommissioning, have been met, and decides on termination of the authorization for decommissioning?

Answer: Yes

Response:

hj

Question 10.1 If the approved decommissioning end state is release from regulatory control with restrictions on the future use of the remaining structures, has the regulatory body approved the appropriate controls and programmes for monitoring and surveillance for the optimization of protection and safety, and protection of the environment?

Response:

hj

Question 10.2 Does the regulatory body require that new or revised authorizations are sought if waste remains on the site after decommissioning or if only part of the site is released from regulatory control?

Response:

hj

Analysis

STRENGTHS FOR REGULATION OF DECOMMISSIONING OF FACILITIES

S1	The Finnish legislation contains comprehensively provisions to address decommissioning in the current lifecycle phase of nuclear facilities. The planning for the decommissioning is covered from the design of the nuclear facility to the decommissioning phase. Decommissioning of a nuclear facility must be considered already in the design phase. During operation the decommissioning plan must be updated regularly after every six years.
S2	Funding and financing of decommissioning is covered as part of radioactive waste funding and decommissioning costs are evaluated regularly. The licensee has to evaluate the costs of nuclear waste management and decommissioning after every three years during the operation of the nuclear facility. The licensee has to pay to the nuclear waste management fund the liability amount defined by MEAE to cover the cost of the decommissioning in cases where the licensee could be unable to pay the costs itself. The financing for the decommissioning of a nuclear facilities is ensured.
S3	Management of radioactive waste generated as result of decommissioning has to be addressed as part of decommissioning planning. Nuclear facility licensee, having waste management obligation, is responsible for overall process from gravel to grade. This addresses in many situations the challenge with interdependencies.
S4	SätL includes dedicated provisions for the decommissioning of radiation sources facilities.

WEAKNESSES FOR REGULATION OF DECOMMISSIONING OF FACILITIES

W1	Decommissioning license was added into the nuclear energy act in 2017. Now e.g. the documentation requirements for the decommissioning license application follows quite much the requirements for the operating license application. In practice this means that you could do almost the same things under both licenses except electricity production, which requires operating license. In the future the transfer from the operating license to decommissioning license and further grading and clarification of requirements should be evaluated.

OPPORTUNITIES FOR REGULATION OF DECOMMISSIONING OF FACILITIES

O1	Many other countries are already in NPP decommissioning phase and their regulators have developed a more mature framework for decommissioning. This is an opportunity for Finland as we have possibility to benchmark and learn from other countries.

CONCLUSIONS FOR REGULATION OF DECOMMISSIONING OF FACILITIES

C1	Finnish regulatory framework and regulations fulfill expectations set in IAEA safety standards and are comprehensive for current nuclear facility lifecycle phase. Licensing and requirements for transfer from operation to decommissioning should be clarified. As part of YEL renewal binding requirements for decommission needs to be evaluated.

Module: Regulation of Fuel Cycle Facilities

Findings

Question 1 Are provisions in place for the application of the graded approach to all regulatory activities pertaining to fuel cycle facilities?

Answer: Yes

Response:

The graded approach is applied in regulatory activities concerning spent fuel interim storages and encapsulation plant as it is applied in regulation in nuclear power plants. The regulatory activities are proportional to the importance on the nuclear safety. The basis of the application of the graded approach in regulatory activities is described in the answer for Primary Question 1 in the document *Self-Assessment for Facilities and Activities and Exposure Situations (009 Regulation of Nuclear Power Plants)*.

Nuclear Energy Act (990/1987) 7a § states that the safety requirements and measures for ensuring safety shall be graded and targeted to be commensurate with the risks in the use of nuclear energy.

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Resource allocation applies for regulation of fuel cycle facilities as described in *Self-Assessment for Facilities and Activities and Exposure Situations (009 Regulation of Nuclear Power Plants)*. The same applies for design rules, quality of design, Reliability of items important to safety, Plant layout. The referred Regulatory Guide YVL B.2 *Safety Classification* applies for spent fuel interim storages and encapsulation plant as well. Also, the quality management requirements applied to the systems,

structures and components of various safety classes are given in Guides YVL A.3 *"Leadership and management for safety*" applies for spent fuel interim storages and encapsulation plant.

More specific design requirements are given in various regulatory guides. It should be noted that each regulatory guide or its explanatory memorandum makes reference to relevant national and international standards.

Guide YVL B.1 describes overall design requirements. Chapter 4 describes the design requirements for ensuring the reliability of safety functions. Main principles affecting the reliability requirements of SSCs can be connected to the defense-in-depth concept and the design bases (operational occurrences and accidents to be considered).

The Guide YVL D.3 (Handling and Storage of Nuclear Fuel) describes additional design requirements for spent fuel interim storages and encapsulation plant. The graded approach is considered in the design requirements concerning spent fuel storages and encapsulation plants as the issues affecting safety (as amount of reactivity, radioactivity, and decay heat) are lesser in these facilities compared to the NPPs

Regarding review and assessment related activities, see response to the question 1.2 of Module 6. Internal guide YTV 6.c describes the application of the graded approach.

Regarding records of operation, the response in Primary Question 1 in *Self-Assessment for Facilities and Activities and Exposure Situations (009 Regulation of Nuclear Power Plants)* also applies for spent fuel interim storages and encapsulation plant as well as responses concerning integrated safety assessment, inspection program and regulatory inspections, response of the regulatory body to non-compliances and Public information activities.

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Addition to Nuclear Energy Act, Nuclear Energy Decree is applicable to uranium extraction facility. The detailed requirements concerning uranium extraction facilities are set in STUK regulation Y/5/2016 on the Safety of Mining and Milling Operations Aimed at Producing Uranium or Thorium. The requirements in the regulation Y/5/2016 are set considering the low risk of uranium extraction facilities on nuclear and radiation safety.

Due to the defence in depth concept, the first two levels are applied concerning a uranium extraction facility as the potential risk of hazards of the facility is low. This is further discussed in Response of Primary Question 7

The safety functions in uranium extraction facility aim to restrict the radioactive exposure of personnel and environment. The potential hazards are minor so dedicated safety systems as in other types of fuel cycle facilities are not applied in uranium extraction facilities.

Licensing of uranium extraction facility is performed according to Nuclear Energy Act Section 21. The Section 21 states that a license for the operation may be granted if the use of nuclear energy meets the safety requirements laid down in the Act and appropriate account has been taken of the safety of workers and the population, and environmental protection. This is the only licensing phase required for uranium extraction facility in the nuclear energy regulations.

Regulatory inspections are addressed in Primary Question 5.

The design requirements are addressed in Primary Question 7.

Siting of the facility is addressed in Primary Question 12.

Emergency preparedness is addressed in Primary Question 30.

Question 2 Are provisions in place for authorization (licensing) of fuel cycle facilities during the different phases of their life cycle?

Answer: Yes

Response:

Same procedures and requirements apply for licensing of all types of spent fuel interim storages and encapsulation plant as for nuclear power plants. The answer of the PQ2 in Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants) applies also for above mentioned fuel cycle facilities (#1983611).

Licensing of uranium extraction facility is performed according to Nuclear Energy Act Section 21. The Section 21 states that a license for the operation may be granted if the use of nuclear energy meets the safety requirements laid down in the Act and appropriate account has been taken of the safety of workers and the population, and environmental protection. This is the only licensing phase required for uranium extraction facility in the nuclear energy regulations. Further the Nuclear Energy Act Section 21 states in paragraph 2 that the use of mining and milling operations aimed at producing uranium or thorium shall not be initiated on the basis of a granted licence until STUK has ascertained that

- the use of nuclear energy is in accordance with the safety requirements set,
- the security and emergency arrangements are sufficient,
- the control necessary to prevent the proliferation of nuclear weapons has been arranged appropriately, and that
- indemnification regarding liability in the event of nuclear damage in connection with the operations

has been arranged in compliance with the relevant provisions.

According to Nuclear Energy Act Section 21 paragraph 3 the location of the mine site or the milling plant shall be appropriate with respect to the safety of the intended operations.

STUK regulation Y/5/2016 Chapter 3 sets the requirements for the technical design for mining operations and ore processing activities.

Nuclear Energy Decree Section 112a requires that if a license holder intends to carry out modifications in the mining or enrichment operations that affect safety and involve changes to the documents approved by STUK the licence holder shall obtain approval from STUK for such modifications before they are carried out. STUK shall correspondingly approve measures affecting radiation safety connected with the decommissioning of a mine or enrichment facility. The licence holder shall ensure that the documents mentioned in section 62a are revised accordingly.

STUK regulation Y/5/2016 Section 18 § states that when decommissioning milling activities aimed at producing uranium or thorium, the area used for production shall be cared for in a manner where the rehabilitation of the functions within the scope of the Nuclear Energy Act, including the treatment and disposal of nuclear waste, meets the safety requirements issued on the basis of the Nuclear Energy Act and Radiation Act.

Nuclear Energy Act Section 32 states the conditions when the waste management obligation has expired. Nuclear Energy Decree Section 84 specifies procedures for applying the expiry of the waste management obligation.

Question 3 Does the regulatory body have requirements for the content of the licensing documentation to be submitted by the operating organization in support of a licence application for a fuel cycle facility?

Answer: Yes

Response:

Same requirements are applicable for spent fuel interim storages and encapsulation plant as for nuclear power plants concerning the licensing documentation to be submitted by the operating organization in support of a license application. The response for PQ3 of *Self-Assessment for Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants)* also applies for spent fuel interim storages and encapsulation plant.

Concerning encapsulation plant STUK regulation Y/4/2018 is applied for the content of the licensing documentation to be submitted by the operating organization. STUK Regulation Y/4/2018 includes same requirements as STUK Regulation Y/1/2018 excluding the reactor related requirements and added with the requirements concerning long term safety.

Concerning a uranium extraction facility Nuclear Energy Decree Chapter 9 sets the requirements for the contents of the license application. Section 62, paragraph 1 subparagraph 5 sets requirements for the license application to include an outline of the radiation protection arrangements and the technical features and other arrangements which are used to ensure the safety of the mine and the enrichment plant. STUK Regulation Y/5/2016 Section 6 further specifies the requirements on technical safety design features.

STUK Regulation Y/5/2016 Section 6 subparagraph 8 sets the requirements on the safety design considering internal or external hazards, operational occurrences, and accidents.

Question 4 Are provisions in place for the regulatory body to review and assess information to be submitted by operating organizations of fuel cycle facilities?

Answer: Yes

Response:

The same principles apply for regulatory body to review and assess information to be submitted by operating organization as for spent fuel interim storages and encapsulation plant as for NPPs. The response for the PQ 4 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants)* also applies for spent fuel interim storages and encapsulation plant.

The requirements for the review and assessment of the long term safety are stated in STUK Regulation Y/4/2018 and Guide YVL D.5. These requirements are valid for the encapsulation plant (and disposal facility).

The requirements concerning the regulatory review and asses of the information submitted by the uranium extraction facility are set in Nuclear Energy Act Section 21. It states in paragraph 2 that the use of mining and milling operations aimed at producing uranium or thorium shall not be initiated on the basis of a granted licence until STUK has ascertained that

- the use of nuclear energy is in accordance with the safety requirements set,
- the security and emergency arrangements are sufficient,
- the control necessary to prevent the proliferation of nuclear weapons has been arranged appropriately, and that
- indemnification regarding liability in the event of nuclear damage in connection with the operations

has been arranged in compliance with the relevant provisions.

Due to graded approach principle, Nuclear Energy regulations do not include specific requirements for the regulatory body to review of the operating organization in managing operational safety or ensuring continuing safety of the facility design of a uranium extraction facility.

Question 5 Are provisions in place for a regulatory inspection programme for fuel cycle facilities?

Answer: Yes

Response:

The response for the PQ5 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants)* also applies for fuel cycle facilities.

The spent fuel interim storages are operated by the same organizations as the respective nuclear power plants. For this reason, the regulatory inspection programmes for NPPs also cover the spent fuel interim storages.

As the encapsulation plant is currently under construction, the Construction Inspection Programme (RTO) is applied for this facility. After the operation license is granted for the encapsulation facility the Operation Inspection Program (KTO) is applied.

Due to graded approach, Nuclear Energy Regulations do not include specific requirements targeted to regulatory inspection program for uranium extraction facility.

Question 6 Are provisions in place for the enforcement of regulatory requirements at fuel cycle facilities?

Answer: Yes

Response:

The response for the PQ6 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants)* also applies for spent fuel interim storages and encapsulation plant.

Nuclear Energy Act Sections 65 and 66 specifies the requirements for regulatory enforcement concerning the uranium extraction facility.

Question 7 Does the regulatory framework include requirements relating to the fundamental safety functions, and application of defence in depth at fuel cycle facilities?

Answer: Yes

Response:

The response for the PQ7 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants)* also applies for spent fuel interim storages and encapsulation plant. The response discusses the concept of Defence in Depth (DiD) as it is introduced

in Nuclear Energy Act Section 7b. Both functional and structural DiD concepts are included. These principles apply both spent fuel interim storages and encapsulation plant.

The concept of DiD is further elaborated in STUK Regulations. The Regulation on the Safety of a NPP Y/1/2018 Section 9 applies for spent fuel interim storages. The subsections 2-4 which discuss confinement of a release of radioactive substances in severe reactor accidents are not applicable to the spent fuel interim storages.

The concept of DiD for encapsulation plants is further elaborated in STUK Regulation on Safety of Disposal of Nuclear Waste Y/4/2018. The requirements concerning the DiD are stated in Section 13.

Section 10 of STUK Regulation Y/1/2018 and Section 14 of STUK Regulation Y/4/2018 elaborate requirements concerning the technical barriers for preventing the dispersion of radioactive substances.

The STUK regulation STUK Y/1/2018 section 12 is dedicated for fuel storages and presents the similar high-level requirement of applying defence-in-depth on storages. Requirements for ensuring the safety functions are set in Guide YVL D.3 in Chapter 4.5 in detail.

The requirements for safety functions and provisions for ensuring safety in encapsulation plant are set in STUK regulation Y4/2018 Section 15 and in YVL D.3 Chapter 4.5.

Concerning the uranium extraction facilities, Nuclear Energy Act Sections 7 a and 7 c state the fundamental safety principles safety of nuclear energy use shall be maintained at as high a level as practically possible and releases of radioactive substances caused by the use of nuclear energy shall be restricted in compliance with the optimization principle of radiation protection laid down in section 6 of the Radiation Act.

Within a uranium extraction facility, the first two levels of DiD principle are included in the Nuclear Energy Regulations as risks can be reduced to insignificant levels by means of design and appropriate operating procedures. The first two levels are prevention of abnormal operation and failures and Control of abnormal operation and detection failures. These two levels are included in STUK Regulation Y/5/2016 Section 6 subparagraph 8. It states that when designing the production plant, any risk factors attributable to internal or external hazards that could result in the release of radioactive substances in amounts that are significant in terms of radiation exposure shall be identified and, whenever possible, removed. Operational occurrences and accidents shall be prepared for by means of

technical and administrative arrangements that mitigate their consequences and implement rescue activities, if necessary.

Criticality safety or control of nuclear chain reaction are not relevant within the uranium extraction facility as the amount of fissile material treated is negligible.

Question 8 Does the regulatory framework include requirements for operating organizations of fuel cycle facilities to establish, implement, assess and continually improve a management system that integrates safety, health and environmental elements to ensure safe operation?

Answer: Yes

Response:

Spent fuel interim storages are operated within the nuclear power plants. The same principles concern the storages as described in the response on PQ 8 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants).*

The same response as referred in previous paragraph is applicable for encapsulation plant concerning the references made to Nuclear Energy Act (YEL (9990/1987) and YVL Guide A.3. Regulation concerning safety culture is stated in STUK Regulation Y/4/2018 Section 38.

For a uranium extraction facility STUK Regulation Y/5/2016 Section 12 paragraph 4 sets requirements concerning management, organisation, and personnel of this facility type. The licensee shall have in place a management system that is used to ensure the management of radiation safety and quality. The objective of such a management system is to ensure that safety is prioritised without exception, and that quality management requirements correspond to the safety significance of the activity and function. The management system shall be systematically assessed and further developed.

Question 9 Does the regulatory framework include requirements for operating organizations of fuel cycle facilities to monitor and control all activities performed by vendors, contractors and suppliers?

Answer: Yes

Response:

Spent fuel interim storages are operated by NPP organizations, the response to PQ8 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants)* apply also for spent fuel interim storages.

The same applies also for encapsulation plant except from the reference made to STUK Regulation. The STUK Regulation Y/4/2018 Section 38 sets the requirements for organizations participating in designing, constructing, operating and decommissioning of a nuclear facility.

Nuclear Energy Regulations do not include specific requirements for operating organizations of uranium extraction facilities to monitor and control all activities performed by vendors contractors and suppliers. Industrial quality standards used in conventional industry are applicable in this kind of facility.

Question 10 Does the regulatory framework include requirements for operating organizations of fuel cycle facilities to verify the safety of the facility?

Answer: Yes

Response:

The response for the PQ10 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants)* also applies for fuel cycle facilities and encapsulation plant.

In Nuclear Energy Regulation there are not requirements specifically set for the operating organization of a uranium extraction facility to verify the safety of the facility by performing a systematic safety assessment of the facility at regular intervals.

Question 11 Does the regulatory framework include requirements regarding interfaces of safety with security and safeguards for fuel cycle facilities?

Answer: Yes

Response:

The responses in questions 1.4 and 1.5 of module 10 (Interfaces with nuclear security) also apply this question. The interfaces of safety with security and safeguards have been implemented in legislation, STUK regulations and in regulatory guides.

When licensing a uranium extraction facility Nuclear Energy Decree Section 62a defines the documents that shall be provided to STUK in conjunction with the license application to the Government. The requested documents are a safety analysis report, a plan for security and a plan for arranging the safeguards necessary to prevent the proliferation of nuclear weapons. This implements that safety, security and safeguards are all addressed in an integrated manner.

Considering the security of a uranium extraction facility, Nuclear Energy Act Section 7 § states that a prerequisite for the use of nuclear energy is that there are adequate security and emergency arrangements and other arrangements to limit nuclear damage and to protect the use of nuclear energy against activities that endanger nuclear or radiation safety.

Question 12 Does the regulatory framework include requirements for a site evaluation to the extent that is appropriate for the potential hazards presented by fuel cycle facilities?

Answer: Yes

Response:

The response for the PQ12 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants)* also applies for fuel cycle facilities and encapsulation plant. The referred Section 6 of Nuclear Energy Act applies both facilities and STUK Regulation Section 8 applies for spent fuel interim storages as well as Section 14. The same requirement for encapsulation plant is included in the STUK Regulation Y/4/2018 Section 12 and Section 17.

Detailed requirements are given in regulatory guides YVL A.2 about siting and taking external hazards into consideration and YVL B.7 about provisions for internal and external hazards at a nuclear facility. The Guide YVL A.11 sets the requirements concerning the airplane crash.

Concerning a uranium extraction facility the site evaluation is performed in the licensing phase from the environmental protection point of view as, Nuclear Energy Act Section 21 and subparagraph 1 states: the licence for the operations mining and milling operations aimed at producing uranium or thorium, when required by operations, if the use of nuclear energy meets the safety requirements laid down in this Act, and appropriate account has been taken of the safety of workers and the population, and environmental protection.

Further Nuclear Energy Decree Section 62 paragraph 1 specifies the documentation to be provided within the application. Subparagraph 6 addresses on a description of the effects of the mine or the enrichment plant on the environment and a description of the design criteria that will be observed by the applicant to avoid environmental damage and to restrict the burden on the environment.

STUK Regulation Y/5/2016 Section 5 and 6 require that when planning mining or ore processing the operation shall not cause harmful effects on the environment. Also, external hazards shall be taken into account when planning ore processing activities.

Mining Act (621/2011) Section 19 set requirements for the Mining Area and auxiliary area to mine.

Question 12.1 What are the provisions in the regulatory framework relating to consideration of potential combinations of external natural and human induced events in site evaluations?

Response:

The response for the PQ12.1 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants)* also applies for spent fuel interim storages and encapsulation plant.

Concerning a uranium extraction facility, Nuclear Energy Act Section 21 paragraph 3 states that when considering the granting of a licence for the mining and milling operations aimed at producing uranium or thorium […] the location of the mine site or the milling plant shall be appropriate with respect to the safety of the intended operations.

STUK Regulation Y/5/2016 Section 5 and 6 require that when planning mining or ore processing the operation shall not cause harmful effects on the environment. Also, external hazards shall be taken into account when planning ore processing activities.

Question 12.2 What are the provisions in the regulatory framework relating to consideration of multiple facilities at a single site when assessing the feasibility of emergency plans in the frame of site evaluations?

Response:

The response for the PQ12.2 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants)* also apply for spent fuel interim storages and encapsulation plant.

Concerning a uranium extraction facility, STUK Regulation Y/5/2016 Section 11 sets the requirements for emergency arrangements. Multiple facilities at a single site are not addressed specifically due to the minor radiological risks.

Question 13 Does the regulatory framework include requirements for the specification of criteria and rules, and codes and standards, for the design of fuel cycle facility SSCs important to safety?

Answer: Yes

Response:

The design requirements for systems, structures and components (SSC) important to safety is based in safety classification as explained in the response of PQ 13 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants).*

The requirements for safety classification are stated in STUK Regulation Y/1/2018 Section 4 for spent fuel interim storages and in STUK Regulation Y/4/2018 Section 5 for encapsulation plant.

The Guide YVL B.1 applies for both types of fuel cycle facilities and the design requirements for safety classified SSC are set in Paragraph 4. The Guide YVL B.2 *Classification of systems, structures and components of a nuclear facility* applies both fuel cycle facilities. The requirements 302, 302a, 304, 305 and 406 states that the nuclear facility shall be divided into systems, and each component or structure affecting operation or safety of the facility shall belong to a system and based on the safety significance.

STUK Regulations Y/1/2018 Section 18-20a and Y/4/2018 22-24a state the nuclear facility is constructed, operated, and decommissioned "*in conformity with the safety requirements and using approved plans and procedures*".

The chapter 3 of the guide YVL B.1 is dedicated to requirements concerning design management, i.e. requirement management, configuration control, quality and qualification plans, and so on. YVL B.1 requirement 311 states: "*A nuclear facility and the systems important to safety shall be designed by using design processes and methods appropriate for the required level of quality, and by applying the relevant safety regulations, guidelines and standards. The selection of the standards applied in design shall be justified in terms of suitability and coverage*." The principle is that each system important to safety are defined requirements before the actual design actions of respective life cycle phase (YVL B.1 312).

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he YVL Guide series E (YVL E.1 – E.12) contain component specific requirements. These specific YVL Guides may contain references to specific design codes and standards but mostly the principle stated in YVL B.1 312 is applied that the selection of the standards applied in design shall be justified.

Concerning a uranium extraction facility, the requirements for the safety design are given in STUK Regulation Y/5/2016 Sections 6. These requirements are on general level and are enough in detail due to the potential risk of this type of facility.

The design requirements concerning chemical safety are given in regulation on chemical safety (350/2005, 856/2012)

Question 14 Does the regulatory framework include requirements for the specification of design safety margins for fuel cycle facilities to accommodate the anticipated material properties at the end of their useful life?

Answer: Yes

Response:

Concerning spent fuel interim storages the STUK Regulation Y/1/2018 Section 5 states in paragraph *1. The design, construction, operation, condition monitoring and maintenance of a nuclear facility shall provide for the ageing of systems, structures and components important to safety in order to ensure that they meet the design-basis requirements with necessary safety margins throughout the service life and decommissioning of the facility*. Further paragraph *2. Systematic procedures shall be in place for preventing such ageing of systems, structures and components which may deteriorate their availability, and for the early detection of the need for their repair, modification and replacement.*

STUK Regulation Y/4/2018 Section 6 states the respective requirements which apply the encapsulation plant.

The Guide YVL A.8 *Ageing management of a nuclear facility,* which states more detailed requirements for licensee's ageing management programme. Guide YVL A.8 also sets requirements regarding licensee's ageing management policy (301 and 302)

Nuclear Energy Regulation does not contain specific regulation of ageing management for a uranium extraction facility. This is due to minor risk on safety in this facility type. Although STUK Regulation Y/5/2016 Section 7 includes the requirement for ensuring continuous operability of systems, structures, and components.

Question 15 Does the regulatory framework include requirements relating to consideration of postulated initiating events for the design of fuel cycle facilities?

Answer: Yes

Response:

The response of PQ 17 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants)* applies as such for spent fuel interim storages. The respective requirement for encapsulation plant is in STUK Regulation Y/4/2018 Section 3 sub paragraph 2 as well. Referred Guides YVL B.1 414 and B.3 301, 302 apply both facility types.

Concerning a uranium extraction facility, STUK Regulation Y/5/2016 Section 6 paragraph states that when designing the production plant, any risk factors attributable to internal or external hazards that could result in the release of radioactive substances in amounts that are significant in terms of radiation exposure shall be identified and, whenever possible, removed. Operational occurrences and accidents shall be prepared for by means of technical and administrative arrangements that mitigate their consequences and implement rescue activities, if necessary.

Question 16 Does the regulatory framework include requirements that the fuel cycle facility design must address the prevention of criticality accidents?

Answer: Yes

Response:

STUK Regulation Y/1/2018 Section 12 states the requirements for fuel handling and storage. The paragraph 4 states that *4. The possibility of criticality shall be extremely low.* This applies for spent fuel interim storages. The respective requirement for encapsulation plant is in STUK Regulation Y/4/2018 Section 15 paragraph 4b *The possibility of criticality during the handling and storage of spent nuclear fuel shall be very low.*

Guide YVL B.4 *Nuclear fuel and reactor* sets requirements for the criticality design for nuclear fuel as well as fuel handling and storage systems of nuclear facilities. Section 4 states requirements for the nuclear fuel. It covers the general design criteria as well as detailed criteria for the various operational conditions ranging from normal operational conditions through anticipated operation occurrences and postulated accidents to design extension conditions. Section 5 details the requirements for preventing a criticality accident.

The amount of fissile material is so small in a uranium extraction facility that criticality is not possible.

Question 17 Does the regulatory framework include requirements that the fuel cycle facility design take into account accident conditions?

Answer: Yes

Response:

According to Section 7 d of the Nuclear Energy Act (990/1987), "*the design of a nuclear facility shall provide for the possibility of operational occurrences and accidents. The probability of an accident must be lower, the more severe the consequences of such an accident would prove for people, the environment or property*."

As defined in the Nuclear Energy Decree Section 1 (paragraph 1, subparagraphs 17, 18 and 19), the initial events are required to be classified according to their frequency of occurrence to operational occurrences ($f \geq 1/100$ years), class 1 design basis accidents ($1/1000 \leq f < 1/100$) and class 2 design basis accidents ($f < 1/1000$). Section 22b in Nuclear Energy Decree also sets forth the dose constraints for all the event categories.

Concerning spent fuel interim storages, STUK Regulation Y/1/2018 Section 12 sets requirements for the safety of fuel handling and storage. The aim of these requirements is that the deviation from normal operation is unlikely and if that happens there are means to minimize the consequences. The Defense-in-Depth -principle is applied to spent fuel interim storages as well and this principle is discussed in the response of Primary Question 7.

The requirements in STUK Regulation Y/1/2018 Section 12 are set for spent fuel interim storages. The aim is to apply redundancy, separation and diversity principles to ensure the implementation of the function even in the event of a malfunction. The removal of the residual heat must be secured, also the leak-tightness and mechanical endurance of fuel assemblies. Damage to the cladding of the fuel rods must be prevented. The possibility of criticality and severe accidents shall be extremely low.

The requirements for monitoring and control are set in STUK Regulation Y/1/2018 Section 16:

1. *A nuclear facility shall contain equipment that provides information on the operational state of the facility and any deviations from normal operation.*
2. *A nuclear power plant shall be equipped with automatic systems that actuate safety functions as required, and that control and supervise their functioning during operational occurrences to prevent accidents and during accidents to mitigate consequences.*

The design of the spent fuel interim storages due to large water volume in spent fuel pools and its' cooling capacity is such that there are very few situations in which the automatic systems are required for the safety reasons.

STUK Regulation Y/1/2018 Section 12 sets the requirement for control room in nuclear power plant. This requirement is elaborated to apply the spent fuel interim storages in Guide YVL D.3. In chapter 4.8. requirement 4114 states that *nuclear facilities shall contain equipment that provides information regarding the state of components and systems that are important in terms of the safety of the facility.*

The requirements for monitoring and control for fuel cycle facilities are set in YVL D.3 requirement 4119 and 4120:

4119 *It shall be possible to perform all the measures required for controlling the facility in its operational states and accident conditions from within the control post.*

4120 For operational occurrences and accidents, information essential to the safety of the nuclear facility shall be clearly detectable and readable at an accessible place.

The spent fuel interim storages are part of the nuclear power plant site and under same operating license as NPPs. Thus, same requirements concerning emergency control centre apply spent fuel storages as for NPPs. The requirements for emergency control centres are given in STUK Regulation Y/2/2018 and YVL Guide C.5.

Concerning encapsulation plant, Section 7 d of the Nuclear Energy Act (990/1987) and Nuclear Energy Decree apply as well as referred in the beginning of this response. STUK Regulation Y/4/2018 Section 8 states the general design bases for the safety of a nuclear facility. Section 8 paragraph 2 states that the *design and implementation of the processing and storage of nuclear waste processed and arisen at the nuclear facility shall be made comprehensively taking into account possible dependencies between the different stages of nuclear waste management*.

STUK Regulation Y/4/2018 Section 13 sets the requirements concerning Defense in Depth -principle which considers the accident conditions in the design of nuclear facility. This applies to encapsulation plant. The Section 14 sets the requirements considering technical barriers for preventing the dispersion of radioactive substances. The Section 15 sets the requirements for safety functions and provisions for ensuring them. The Section 19 set the requirements for safety of monitoring and control of the nuclear facility.

Requirements for emergency control center is stated in STUK Regulation Y/2/2018 and Guide YVL C.5. These are applied for encapsulation plant as required by the danger they pose.

Concerning a uranium extraction facility, STUK Regulation Y/5/2016 Section 6 paragraph states that when designing the production plant, any risk factors attributable to internal or external hazards that could result in the release of radioactive substances in amounts that are significant in terms of radiation exposure shall be identified and, whenever possible, removed. Operational occurrences and accidents shall be prepared for by means of technical and administrative arrangements that mitigate their consequences and implement rescue activities, if necessary.

Question 18 Does the regulatory framework include requirements relating to optimal operator performance and human factors for the design and safe operation of fuel cycle facilities?

Answer: Yes

Response:

The requirements for consideration of human factors are set in STUK Regulation Y/1/2018 Section 6 *Management of human factors relating to safety* for spent fuel interim storages and STUK Regulation Y/4/2018 Section 7 for encapsulation plant. These sections require that human factors relating to safety shall be controlled with systematic procedures throughout the entire life cycle of the nuclear facility and that human factors shall be considered in the design of the nuclear facility and in the planning of its operations, maintenance, and decommissioning. It is also required in Section 6 that human factors management shall aim at both enabling high quality human performance and avoidance of human errors.

These requirements are further elaborated in Guide YVL D.3 Chapter 4.3 for spent fuel interim storages and encapsulation plant. Requirement 452 states that an HFE-program shall be used in the design of new nuclear facility projects.

The HFE program required in Guide YVL D.3 requirement 452. The program shall contain an Operating Experience Review which will ensure that relevant operating experiences from the point of view of human factors will be considered in the spent fuel interim storage or encapsulation plant.

Nuclear Energy Regulations do not contain any specific requirements for uranium extraction facility targeting operator performance and human factors for the design and safe operation.

Question 19 Does the regulatory framework include requirements relating to radiation protection and protection from exposure to chemicals in design for fuel cycle facilities?

Answer: Yes

Response:

The response of PQ 30 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants)* applies as such for spent fuel interim storages and an encapsulation plant. The respective requirement for encapsulation plant is in STUK Regulation Y/4/2018 Section 9. In addition, STUK Regulation Y/4/2018 Section 16 subparagraph 3 sets requirements for radiation protection in the handling of spent nuclear fuel or other highly irradiating nuclear waste.

Guide YVL D.3 sets additional requirements for radiation protection in spent fuel interim storages and an encapsulation plant. These requirements are in Chapters 4.4 and 4.9. The requirement 458 specifies that *In defining the scope of radiation protection measures for facilities with nuclear fuel assemblies or casks or canisters containing them, it shall be assumed that the area contains the maximum amount of nuclear fuel. The burnup and cooling time shall be assumed to be conservative.* The requirements 461, 463, 463a 465 set the requirements for decontamination in encapsulation plant and spent nuclear fuel storages.

Concerning a uranium extraction facility Radiation Act Sections 2 and 9 apply to the radiation exposure of the workers and the population in the vicinity of a production unit. The maximum values for radiation workers' radiation exposure are stipulated in Section 13 of the Government Decree on Ionizing Radiation (1034/2018). The maximum values for radiation exposure for members of the public and a comparable worker are set in Section 14 § respectively.

Nuclear Energy Decree Section 22 c set the dose limits for the mining and ore enrichment activity as a result of an anticipated operational occurrence, for the accident conditions, for disposal of nuclear waste generated in the mining and ore enrichment activity and for the situations where the containment structures of the disposal system are impaired as a consequence of unlikely events or human action.

STUK Regulation Y/5/2016 Section 8 sets the requirements for radiation protection arrangements and section 9 for Radiation monitoring. Section 10 set the requirements for environmental radiation safety.

Regulation concerning exposure for chemicals are set in Act on the Safety of Handling of Dangerous Chemicals and Explosives (390/2005) and respective Government Decrees 685/2015 ad 856/2012.

Question 20 Does the regulatory framework include requirements relating to design features to facilitate radioactive waste management and decommissioning of fuel cycle facilities?

Answer: Yes

Response:

The response of PQ 31 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants)* applies as such for spent fuel interim storages and an encapsulation plant. The respective requirements for encapsulation plant concerning the Safety of nuclear waste processing and storage are in STUK Regulation Y/4/2018 Section 16. The respective requirements for encapsulation plant concerning decommissioning are in STUK Regulation Y/4/2018 Section 20.

Concerning a uranium extraction facility, STUK Regulation Y/5/2016 Section 5 and 6 set the requirements for design. Section 5, paragraph 6 states that the amount of waste rock classified as production waste shall be minimised. Waste rock shall be stored in a manner that prevents the release of radioactive substances as effectively as possible. Section 6, paragraph 7 states that Mineral processing waste classified as production waste shall be processed and stored in a manner that effectively limits the release of radioactive substances into the air and their migration into the ground, surface water and groundwater. Further the Chapter 5 of STUK Regulation Y/5/2016 sets the requirements for Nuclear waste management.

The decommissioning of uranium extraction facility is regulated in STUK Regulation Y/5/2016 Section 5 and 6, in both paragraphs 2: the design of the mine (or processing plant) shall consider the closing of the mine and the disposal of production waste.

Question 21 Does the regulatory framework include requirements for operating organizations of fuel cycle facilities to establish and implement a commissioning programme?

Answer: Yes

Response:

Spent fuel interim storages are operated as part of the nuclear power plants. Thus, the same requirements apply to spent fuel interim storages as to nuclear power plants concerning the operating organizations and the implementation of a commissioning programme. The response of PQ 32 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants)* applies as such for spent fuel interim storages. The response applies to encapsulation plant when referred to Nuclear Energy Act (YEA) and YVL Guides. The respective requirements for encapsulation plant concerning commissioning are set in STUK Regulation Y/4/2018 Section 23.

Restart of a fuel cycle facility after a lengthy shutdown period.

Currently in Finland, there are two types of fuel cycle facilities that are defined as nuclear facility according Nuclear Energy Act Section 3, paragraph 1, subparagraph 5: spent fuel interim storages and encapsulation plant. Only spent fuel interim storages are currently in operation. The encapsulation plant is under construction. In the regulatory framework there are no explicit requirement that the requirements for commissioning have to be applied also after a lengthy shutdown period. This question might come into consideration when granting the operation license for the encapsulation plant (and disposal facility; these facilities will be operating within the same license). The operation periods and cycles of the encapsulation plant and the disposal facility are not yet fixed by the licensee.

STUK Regulation Y/5/2016 Section 7 sets the requirements for commissioning of a uranium extraction facility: *Prior to the commissioning of the production unit, the licensee shall ensure that the structures, systems and components important for radiation safety are operating as planned. During commissioning, the licensee shall experimentally demonstrate their performance under normal operating conditions and, whenever possible, also under conditions that are similar to operational occurrences and accident situations.*

STUK Regulation Y/5/2016 Section 7 mentioned above do not specifically require a commissioning programme with the details to be considered during the commissioning.

Question 22 Does the regulatory framework include requirements for operating organizations of fuel cycle facilities to develop operating instructions and procedures before operation commences?

Answer: Yes

Response:

Operational Limits and Conditions

Nuclear Energy Decree Section 36 states that *When applying for an operating licence, the applicant shall provide the Radiation and Nuclear Safety Authority (STUK) with the following:*

[…] 5) the Technical Specifications, which shall at least define limits for the process quantities that affect the safety of the facility in various operating states, provide regulations on operating restrictions that result from component failures, and set forth requirements for the testing of components important to safety

[…] 9) administrative rules for the nuclear facility;

Concerning spent fuel interim storages STUK Regulation Y/1/2018 Section 22 states that Operational Limits and Conditions of a nuclear facility shall include the technical and administrative requirements for ensuring the nuclear facility's operation in compliance with the design bases and the assumptions of safety analyses. Concerning encapsulation plant, the same is stated in STUK Regulation Y/4/2018 Section 26. Furthermore, YVL Guide A.6 chapter 7.5 sets more detailed requirements regarding operating limits and conditions.

Operating instructions and Review and update of operating instructions

Concerning spent fuel interim storages STUK Regulation Y/1/2018 Section 20 states that the control and supervision of a nuclear facility shall utilize written procedures that correspond to the existing structure and the operational state of the nuclear facility. Concerning encapsulation plant, the same is stated in STUK Regulation Y/4/2018 Section 24. Guide YVL A.6 sets the detailed requirements concerning the operating instructions of a nuclear facility. Requirement 302 states that *The safety of operational activities shall be assessed and improved on a continuous basis.*

Operator compliance with operating instructions

The Guide YVL A.3 requirement 508 states that *The management system shall include procedures to ensure that the personnel have the adequate individual competence and qualifications necessary in the tasks specified for them and that the personnel understand the safety implications of their work.* Also, the Guide YVL A.4 requirements 302 states that The licensee shall have sufficient and competent personnel for ensuring the safety of the facility, security and emergency response arrangements, and nuclear safeguards. The Guide YVL A.5 requirement 403 states that *It shall be ensured during commissioning that the instructions and procedures for the operation of the facility, systems, structures and components are adequate and appropriate.* Also, the requirements 407 states that *The licensee's personnel shall participate in the commissioning testing to familiarise themselves with the facility and its systems*.

Identification and investigation of deviations from operating instructions

STUK Regulation Y/1/2018 Section 25 subparagraph 4 states that *Systematic procedures shall be in place for identifying and correcting deviations significant in safety terms*. The same is stated in STUK Regulation Y/4/2018 Section 38 subparagraph 4.

Guide YVL A.6 requirement 743 states requirements for the process for amending or departing from the Operational Limits and Conditions.

Concerning a uranium extraction facility STUK Regulation Y/5/2016 Section 6 paragraph 8 states that operational occurrences and accidents shall be prepared for by means of technical and administrative arrangements that mitigate their consequences and implement rescue activities, if necessary.

There are not requirements that are specifically addressed for operating organizations of a uranium extraction facility to develop operating instructions and procedures. STUK Regulation Y/5/2016 sets requirements for licensee's management system to ensure the management of radiation safety and quality.

Question 22.1 What are the existing provisions to require operational limits and conditions to be prepared before operation of the facility commences?

Response:

Concerning spent fuel interim storages and encapsulation plant, this question is responded in the response of the question 22.

Nuclear Energy Regulation do not require operational limits and conditions to be prepared for the operation of a uranium extraction facility. This is due to graded approach.

Question 23 Does the regulatory framework include requirements for operating organizations of fuel cycle facilities to develop and maintain the competence of personnel?

Answer: Yes

Response:

Spent fuel interim storages are operated as part of the nuclear power plants. Thus, the same requirements apply to spent fuel interim storages as to nuclear power plants concerning the operating organizations to develop and maintain the competence of personnel. The response of PQ 34 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants)* applies as such for spent fuel interim storages. The response applies to encapsulation plant when referred to Nuclear Energy Act (YEA), Nuclear Energy Decree (YEA) and YVL Guides. The respective requirements for encapsulation plant concerning operating organizations' competence are set in STUK Y/4/2018 Section 38.

Concerning a uranium extraction facility, Nuclear Energy Act Section 7 i states that the holder of the licence giving the right to use nuclear energy shall have an adequate number of qualified personnel suitable for their tasks.

For a uranium extraction facility, STUK Regulation Y/5/2016 Section 12 paragraph 1 sets the requirements for competent personnel to ensure the radiation safety of the production unit. Further, according paragraph 2 the radiation protection competence of the persons controlling, and supervising functions related to radiation safety shall be ensured by means of basic and supplementary training programmes, and their adequate understanding of the necessary information shall be verified.

Question 24 Does the regulatory framework include requirements for operating organizations of fuel cycle facilities to conduct maintenance, calibration, testing, surveillance and inspection to ensure that SSCs important to safety are able to function in accordance with the design intent and with safety requirements?

Answer: Yes

Response:

Spent fuel interim storages are operated as part of the nuclear power plants. Thus, the same requirements apply to spent fuel interim storages as to nuclear power plants concerning the maintenance, calibration, testing, surveillance, and inspection. The response of PQ 39 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants)* applies as such for spent fuel interim storages. The response applies to encapsulation plant when referred to Nuclear Energy Act (YEL), Nuclear Energy Decree (YEA) and YVL Guides. The respective requirements for encapsulation plant concerning maintenance, calibration, testing, surveillance, and inspection are set in STUK Y/4/2018 Section 27.

Concerning a uranium extraction facility, this topic is not relevant due to graded approach.

Question 25 Does the regulatory framework include requirements for operating organizations of fuel cycle facilities to establish procedures for the control of modifications which may affect safety?

Answer: Yes

Response:

Concerning modifications, the YEA 161/1988 Section 112 prescribes that the licensee shall obtain approval from STUK for modifications that influence safety and involve changes in the plans or documents approved by STUK before they are carried out. STUK Regulation Y/1/2018 Section 3 and STUK Regulation Y/4/2018 Section 3 states that *1. The safety of a nuclear facility shall be assessed when applying for a construction license and operating license, in connection with plant modifications,*

and at Periodic Safety Reviews during the operation of the plant. It shall be demonstrated in connection with the safety assessment that the nuclear facility has been designed and implemented in a manner that meets the safety requirements. The safety assessment shall cover the operational states and accidents of the plant.

Further requirements are given in the Guide YVL A.1 Chapter 3.13.

STUK Regulation Y/1/2018 Section 25 and STUK Regulation Y/4/2018 Section 38 states that the management system shall cover all organizational activities impacting the nuclear facility's safety. For each function, requirements significant to safety shall be identified, and the planned measures described to ensure conformity with requirements. The operating methods of the organization shall be systematic and instructed.

YVL Guide A.6 Requirement 306 states that *Written instructions shall be prepared for any foreseeable actions affecting safety*.

Nuclear Energy Decree 112a requires that if a license holder intends to carry out modifications in the mining or enrichment operations that affect safety and involve changes to the documents approved by STUK the licence holder shall obtain approval from STUK for such modifications before they are carried out.

Question 26 Does the regulatory framework include requirements for operating organizations of fuel cycle facilities to establish and implement a radiation protection programme?

Answer: Yes

Response:

The response of PQ 36 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants)* applies as such for spent fuel interim storages and a encapsulation plant.

Concerning a uranium extraction facility, Nuclear Energy Decree Sections 22 a, 22c and STUK Regulation Y/5/2016 Section 8 sets the requirements for radiation protection arrangements. A radiation protection program is not specifically addressed. Government Decree on Ionizing Radiation (1034/2018) Section 13 sets the dose limits for members of the public and a comparable worker. Further Section 36 sets the requirements for the arrangements to prevent spreading radioactive contamination.

Question 26.1 What are the existing provisions to ensure that an operating organization run its facility in such a manner as to optimize protection against external and internal exposures of the workforce?

Response:

The previous response 26 addresses this question. Also, the response of PQ 30 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants)* applies as such for spent fuel interim storages and a encapsulation plant.

The Guide YVL C.2 specifies detailed requirements for the radiation protection of nuclear facility workers. These requirements are set in chapter 3. In addition to YVL C.2, Guide YVL D.3 sets requirements specifically for fuel cycle facilities aiming to minimize the radiation exposure of workers. These requirements are requirement 458 for radiation protection design measures; requirements 459, 461 and 465 for decontamination and references to Guide YVL C.1 and to Guide YVL E.6 chapter 6.8 about choosing the pool materials.

For a uranium extraction facility, the answer of Primary Question 26 covers this question too.

Question 27 Does the regulatory framework include requirements for, where relevant, operating organizations of fuel cycle facilities to implement arrangements to ensure that criticality safety is addressed during operation?

Answer: Yes

Response:

The response of PQ 28 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants)* applies as such for spent fuel interim storages and a encapsulation plant. The response addresses to design of fuel handling and storage. The requirements mentioned in this response aim to careful handling of nuclear fuel. This principle aims to control and restriction of spreading of radioactive materials but also to maintain the stored nuclear fuel in subcritical condition.

Operations with spent fuel shall follow same procedures in fuel cycle facility as any operation that has safety significance. Requirements for operating instructions and procedures in fuel cycle facility are addressed within the response of Primary Question 22. Deviations from procedures are addressed in the same response as well. The qualified staff is addressed in response to the Primary Question 23 where the competence of operating organization is discussed. The training of personnel includes to the competence of operating organization.

For a uranium extraction facility, this question is not relevant as the amount of fissile material is so low.

Question 28 Does the regulatory framework include requirements for operating organizations of fuel cycle facilities to establish and implement arrangements for the management of radioactive waste and effluents in operations?

Answer: Yes

Response:

The response of PQ 31 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants)* applies as such spent fuel interim storages. For encapsulation plant the response applies also but the corresponding requirements for safety of nuclear waste processing are set in STUK Regulation is STUK Y/4/2018 Section 16. The requirements concerning decommissioning of an encapsulation facility are set in STUK Y/4/2018 Section 20.

Concerning a uranium extraction facility, STUK Regulation Y/5/2016 Chapter 5 sets the requirements for nuclear waste management: *Nuclear waste generated from mining and milling activities shall be processed and disposed of in a manner that can be considered safe in terms of long-term isolation, while taking into account the amount of the waste, its activity concentration, the other factors affecting radiation exposure and the local conditions.*

STUK Regulation Y/5/2016 Section 15 sets the requirements for disposal of production waste: an adequate protection zone shall be reserved around the disposal area, the waste shall be covered and treated in a manner not to exceed external radiation levels prevailing naturally and prohibit rainwater to flow through the waste resulting passage of radioactive substances from waste to environment. Further, the Section 17 sets the requirement for record keeping and reporting of production waste.

STUK Regulation Y/5/2016 Section 5 paragraph 1 subparagraph 5 sets the requirements for water treatment: *water treatment shall employ methods that effectively limit the leakage of radioactive substances from the mine into the ground, surface water and groundwater.*

Question 29 Does the regulatory framework include requirements for operating organizations of fuel cycle facilities to manage industrial and chemical safety during operation?

Answer: Yes

Response:

Other than radiological hazards are considered by nuclear regulation so far as they considered to be internal threats from the point of view of the facility safety. In addition of the licenses granted based on the nuclear safety legislation the facilities are also licensed based on the environmental legislation (Nuclear Energy Decree, Chapter 5, Section 32, subparagraph 7, Section 34, subparagraph 5, Section 34 a, subparagraph 4, Section 35, subpara 1 and 9, Section 36 subpara 1, 10, Section 36a, subpara 11) and the operator is obliged to the requirements based on the legislation concerning the protection of the employees.

Internal hazards

The internal hazards (STUK Regulation Y/1/2018, Section 15 and STUK Regulation Y/4/2018 Section 18) to be considered are at least the following: *"fire, flood, explosion, electromagnetic radiation, pipe breaks, container ruptures, drop of heavy objects, missiles due to explosions or component failures, and other possible internal hazards. The design shall also consider unlawful and other unauthorised activities compromising nuclear safety*." Hence this covers also the potential harmful effects from system to another, in addition to the other requirements discussed above. The Guide YVL B.7 expands further on the protection against the internal and external hazards whereas Guide YVL B.8 is dedicated to fire protection requirements. Fire safety is also discussed in the response of PQ 35.2 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants)* applies as such for spent fuel interim storages and a encapsulation plant.

The requirements concerning occupational safety are set in Occupational Safety and Health Act (738/2002). The requirements concerning the chemical safety are given in the Act on the Safety of Handling Hazardous Chemicals and Explosives (390/2005)

Concerning a uranium extraction facility, risks from non-radiological hazards to the public, workers and environment are regulated withing Occupational Safety and Health Act (738/2002) and in the Act on the Safety of Handling Hazardous Chemicals and Explosives (390/2005).

Question 30 Does the regulatory framework include requirements for operating organizations of fuel cycle facilities to establish and implement provisions for emergency preparedness and response?

Answer: Yes

Response:

The response of PQ 37 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants)* applies as such for spent fuel interim storages and a encapsulation plant.

Concerning a uranium extraction facility, Nuclear Energy Act Section 9 paragraph 2 states *that It shall be the licence holder's obligation to carry out such security and emergency arrangements and other arrangements necessary for the limitation of nuclear damage which do not rest with the authorities.*

STUK Regulation Section 11 set the requirements for emergency preparedness and response. Paragraph 1, subparagraph 4 states that *emergency arrangements shall be compatible with the external rescue plan prepared by the authorities for the production unit.*

Question 31 Does the regulatory framework include requirements relating to the preparation for decommissioning of fuel cycle facilities?

Answer: Yes

Response:

The response of PQ 40 in *Self-Assessment For Facilities And Activities And Exposure Situations (009 Regulation of Nuclear Power Plants)* applies as such for spent fuel interim storages.

Concerning a uranium extraction facility, STUK Regulation Y/5/2016 Section 5 and 6 paragraphs 2 in both states that the design of the mine and the processing plant shall consider the closing of the mine and the disposal of production waste.

Mining Act Chapter 15 sets requirements for termination mining activity.

Analysis

STRENGTHS FOR REGULATION OF FUEL CYCLE FACILITIES

S1	Regulation and implementation of spent nuclear fuel interim storages is well established and Finland has long experience in operating and regulating spent fuel interim storages.
S2	Interim storages are operated by NPP licensees. This makes it easier to manage interdepencies and optimize the use of resources and competences. This also applies to regulatory oversight since the use same resources can be used.

WEAKNESSES FOR REGULATION OF FUEL CYCLE FACILITIES

W1	The present Nuclear Energy Act does not include requirements for uranium extraction facilities' operating organization.

OPPORTUNITIES FOR REGULATION OF FUEL CYCLE FACILITIES

O1	Uranium extraction facilities are well known facilities around the world, and this creates an opportunity to benchmark their regulatory approach and learn from other countries.

THREATS FOR REGULATION OF FUEL CYCLE FACILITIES

T1	The regulation of uranium extraction facilities is currently not very clear and comprehensive in the Nuclear Energy Act and Nuclear Energy Decree. STUK Regulation dedicated for uranium extraction facilities is established but the detailed guidance is missing and there is a threat that STUK will not succeed in using graded approach for uranium extraction facilities.
T2	Uranium extraction facilities are also regulated within chemical safety and the co-operation between different regulators is not systematic and harmonized.
T3	In case of the encapsulation plant the regulatory framework does not include explicit requirement that the requirements for commissioning must be applied also after a lengthy shutdown period. This question might be necessary to address due the long operating period of the encapsulation plant (and disposal facility; these facilities will be operating within the same license).

CONCLUSIONS FOR REGULATION OF FUEL CYCLE FACILITIES

C1	Finnish regulatory framework and regulations fulfill expectations set in IAEA safety standards and are comprehensive for current fuel cycle facilities. Attention in using graded approach for uranium extraction facilities should be in focus when regulating these facilities and in the renewal of the legislation.

Module: Regulation of Research Reactors

Findings

Question 1 Are provisions in place for the application of the graded approach to all regulatory activities pertaining to research reactors?

Answer: Yes

Response:

Section 7a of Nuclear Energy Act (990/1897) enables the use of graded approach principle for research reactors: "The safety requirements and measures for ensuring safety shall be graded and targeted so as to be commensurate with the risks in the use of nuclear energy".

For the regulation of research reactors there is in principle the same legal and regulatory framework as for the regulation of power reactors. Nuclear Energy Act (990/1987 section 3), Nuclear Energy Decree (161/1988) and Regulations STUK Y/1/2018, STUK Y/2/2018 STUK Y/3/2018 and STUK Y/4/2018. Regulation STUK Y/1/2018 section *1 Scope* defines; what requirements are applied for research reactor.

YVL Guides, which are written for nuclear power reactors, are applied to research reactor as appropriate (there are no research reactor specific YVL Guides). STUK makes separate decisions (implementing decisions), how the YVL-guides are applied to research reactor. During this process, it is decided, what YVL-guides are applied for research reactor and how they are applied. In these decisions the requirements, which are not relevant for the research reactor, will be excluded. Currently these decisions are to be made for research reactor under decommissioning phase for YVL guides in series A, D and C.

You should take into account that the existing research reactor (FiR 1) was commissioned 50 years ago and has entered to a decommissioning phase. The decommissioning License was granted for the FiR 1 research reactor in 17.6.2021. The plan is to start the decommissioning in late 2022. There are no plans to be build new research reactors in Finland.

Question 2 Are provisions in place for the authorization (licensing) of research reactors during the different phases of their life cycle?

Answer: Yes

Response:

The licensing process is defined in Nuclear Energy Act (990/1987) and in more detailed in Nuclear Energy Degree (161/1988). There are licenses for construction, operation and decommissioning. The licensing process is the same as for nuclear power plants (NPP).

Question 3 Does the regulatory body have requirements for the content of the safety analysis report to be submitted by the operating organization in support of a licence application for a research reactor?

Answer: Yes

Response:

The required content of the safety analysis report is described in YVL A.1 Appendix A. The requirements are the same as for NPP’s.

Question 4 Are provisions in place for the regulatory body to review and assess information to be submitted by operating organizations of research reactors?

Answer: Yes

Response:

STUK has an internal guidance for the regulatory oversight of the research reactor written in YTV guide 3.c.16. For the decommissioning phase of the research reactor, a plan for the regulatory oversight during dismantling is written separately (1/F48401/2020 #1957066).

Question 5 Are provisions in place for a regulatory inspection programme for research reactors?

Answer: Yes

Response:

STUK has an internal guidance for the regulatory oversight of the research reactor written in guide YTV 3.c.16. Inspection programme for operation has contained regular inspections in the following areas: security, safeguards, emergency arrangements, operation (includes also organizatorial aspects), radiation safety and radioactive waste management.

For the decommissiong phase a similar inspection programme is developed (1/F48401/2020 #1957066).

Question 6 Are provisions in place for the enforcement of regulatory requirements at research reactors?

Answer: Yes

Response:

The possible enforcement actions are given in Nuclear Energy Act (990/1987) Chapter 10 (See module 8 for further details).

Question 7 Does the regulatory framework include requirements relating to the fundamental safety objective, measures to achieve the fundamental safety objective, fundamental safety functions and application of defence in depth at research reactors?

Answer: Yes

Response:

See the answer to the Primary Question 1 and section 9 of STUK Y/1/2018.

Question 8 Does the regulatory framework include requirements for operating organizations of research reactors to establish, implement, assess and continually improve a management system that integrates safety, health and environmental elements to ensure safe operation?

Answer: Yes

Response:

The requirement regarding Management System is stated in YEL (990/1987) Section 7j *Management system.* A nuclear facility shall have a management system. The management system of the nuclear facility shall take into account in particular the impact of the safety perceptions and attitudes of management and personnel on maintaining and development of safety, as well as systematic practices and their regular assessment and development.

YEL (990/1987) Section 9 prescribes as follows: It shall be the licensee's obligation to assure the safe use of nuclear energy. Regulation STUK Y/1/2018 Section 25, paragraphs 2 set out the requirements for ensuring operating organizations of NPPs have the prime responsibility for safety. *Organisations participating in the design, construction, operation and decommissioning of a nuclear facility shall employ a management system for ensuring safety and the management of quality. The objective of such a management system shall be to ensure that safety is prioritised without exception, and that quality management requirements correspond to the safety significance of the activity and function. The management system shall be systematically assessed and further developed.*

The requirements are set in STUK Y/1/2018 section 25. Detailed requirements are given in Guide YVL A.3 (Leadership and Management for Safety). For more details see Primary Question 8 in 009 Regulation on Nuclear Power plants.

Question 9 Does the regulatory framework include requirements for operating organizations of research reactors to monitor and control all activities performed by vendors, contractors and suppliers?

Answer: Yes

Response:

According to Nuclear Energy Act (990/1987) 7i § The license holder shall ensure that contractors and subcontractors whose activities affect the nuclear safety of the nuclear facility have an adequate number of qualified and trained personnel suitable for the tasks.

Acc. to Nuclear Energy Act the license holder shall be under an obligation to ensure the safe use of nuclear energy. This obligation may not be delegated to another party. The license holder shall ensure that the products and services of contractors and subcontractors which affect the nuclear safety of the nuclear facility meet the requirements of this Act.

The requirements for management of contractors are set in STUK Y/1/2018 section 25 paragraph 5. Detailed requirements are given in Guide YVL A.3 chapter 6.5. For more details see Primary Question 9 in 009 Regulation on Nuclear Power plants.

Question 10 Does the regulatory framework includes requirements for operating organizations of research reactors to verify the safety of the research reactor?

Answer: Yes

Response:

Safety assessments are required in all licensing phases (Nuclear Energy Degree sections 35, 36 and 36 a). Periodic safety reviews shall be done at least after every ten years if not otherwise set in the license conditions (Nuclear Energy Act section 7 e). For more details see Primary Question 10 in 009 Regulation on Nuclear Power plants.

Question 11 Does the regulatory framework include requirements regarding interfaces of safety with security and safeguards for research reactors?

Answer: Yes

Response:

According to the Nuclear Energy Act (1987/990), the nuclear safeguards (safeguards), the safe use of nuclear energy (safety), the protection of the use of nuclear energy against unlawful action (security) as well as the management of nuclear waste shall be a prerequisite for any use of nuclear energy.

Security and emergency arrangements and other comparable arrangements Sufficient security and emergency arrangements as well as other arrangements for limiting nuclear damage and for protecting use of nuclear energy against illegal activities shall be a prerequisite for the use of nuclear energy (Nuclear energy Act section 7). Nuclear energy act defines requirements for security arrangements (section 7l), security control (7m), security standing order (7o), security check and substance abuse testing (7s). More detailed requirements on security arrangements at research reactor s given in STUK Y/3/2020. The requirements are present both for the physical and information safety. The security principles presented in module *10 Interfaces with nuclear security* applies for research reactor.

The detailed requirements for nuclear safeguards are given in Guide YVL D.1. The international treaties on peaceful uses of nuclear energy are binding in Finland. The national nuclear safeguards are based on the Nuclear Energy Act and Decree, and the regulations issued thereunder. Their purpose is to ensure that Finland and Finnish operators fulfil the obligations under the international treaties binding on Finland. Research reactor shall follow the same requirements as NPP's.

Question 12 Does the regulatory framework include requirements for a site evaluation to the extent that is appropriate for the potential hazards presented by research reactors?

Answer: Yes

Response:

The requirements for the research reactor are in principle the same as for power reactors. The requirements for site evaluation are presented in Guide YVL A.2. As research reactor is a lower risk facility that the nuclear power plant, the YVL A.2 can be applied as appropriate for the siting of research reactor. STUK can relax the requirements presented in YVL A.2 based on graded approach with a separate case-specific decision, where the special characteristics of the planned facility can be considered.

Question 13 Does the regulatory framework include general requirements for the design of research reactors and its SSCs?

Answer: Yes

Response:

The design requirements for the research reactor are in principle the same as for power reactors. The guides YVL B.1, B.2, B.3, B.4, B.5, B.6, B.7 and B.8 shall be followed as appropriate. As the guides are written for nuclear power plants, they are not as such suitable for research reactor. STUK can give a separate decision, where it is defined which design requirements are applied for research reactor. During this process the special characteristics of the planned facility can be considered.

Question 14 Does the regulatory framework include specific design requirements for research reactors?

Answer: Yes

Response:

The design requirements for the research reactor are in principle the same as for power reactors. The guides YVL B.1, B.2, B.3, B.4, B.5, B.6, B.7 and B.8 shall be followed as appropriate. As the guides are written for nuclear power plants, they are not as such suitable for research reactor. STUK can give a

separate decision, where it is defined which design requirements are applied for research reactor. During this process the special characteristics of the planned facility can be considered.

Question 15 Does the regulatory framework include requirements relating to optimal operator performance and human factors for the design and safe operation of research reactors?

Answer: Yes

Response:

Human factors relating to safety shall be controlled with systematic procedures throughout the entire life cycle of the nuclear facility. Human factors shall be taken into account in the design of the nuclear facility and in the planning of its operations, maintenance and decommissioning in a manner that supports the high-quality implementation of the work and ensures that human activities do not endanger plant safety. Attention shall be paid to the avoidance, detection and correction of human errors and the limiting of their effects. (STUK Y/1/2018 section 6).

Question 16 Does the regulatory framework include requirements relating to radiation protection in design for research reactors?

Answer: Yes

Response:

The design requirements for the research reactor related to radiation protection are presented in Guide YVL C.1. In addition, there are guidance related to limiting radioactive released from a nuclear facility in YVL C.3.

Question 17 Does the regulatory framework include requirements relating to design features to facilitate radioactive waste management and decommissioning of research reactors?

Answer: Yes

Response:

A nuclear facility shall have premises, equipment and other arrangements to ensure the safe handling and storage of nuclear material required by the facility as well any nuclear waste generated during operation and decommissioning. (Nuclear Energy Act 990/1987 section 7h) A nuclear facility shall have adequate storage space both for unconditioned and conditioned waste. (Guide YVL D.4 450)

Radioactive waste shall be sorted, categorized according to its characteristics, handled and packed in an appropriate manner in terms of its storage and disposal, and stored safely. Limiting values shall be set

for each class, which the waste package used for the waste in question shall meet in terms of the operational safety and long-term safety of the nuclear waste facility. Acceptability criteria shall be defined for the waste and waste packages. Radioactive waste that can be disposed of in a repository shall be conditioned and packed in accordance with the disposal requirements. Radioactive waste that cannot yet be disposed of in a repository shall be safely processed and stored until disposal. (STUK Y/1/2018 section 13)

The planning and implementation of the processing and storage of operational waste shall be carried out with due consideration given to potential dependencies between different waste management stages. The generation of waste that needs to be stored or disposed of shall be limited by means of repair work and maintenance planning, decontamination and volume reduction. The bringing of any unnecessary objects and materials into the controlled area shall be avoided. Where possible, the working methods shall be so selected that the amount of waste generated remains small and the further processing of the waste generated is facilitated. (STUK Y/1/2018 section 13, Guide YVL D.4 443)

Different waste streams, liquid wastes with different chemical composition, activity concentration or radionuclide composition are in general not allowed to mix. The liquid wastes can be immobilized, dried or absorbted in suitable medium. The temporary storage of contaminated oils, chemicals and other similar fluids or sludges shall be resistant to corrosion and fit for the purpose in other regards as well. Non-immobilised waste of this kind may only be stored for long time periods in exceptional cases, such as when ageing them for clearance from regulatory control (Guide YVL D.444-446)

The solid waste shall be packed into containers that facilitate their transfer, prevent the spreading of radioactive contamination and reduce the fire risk associated with the waste. Efforts shall be made to reduce the volume of waste by means of sorting, compaction, cutting or decontamination, for example. Decontamination could be used if it significantly reduces the riks of the spreading of radioactive material or enables clearance from regulatory control. Decontamination should not cause any significant occupational exposure. (Guide YVL D.4 447- 449)

The radioactivity and other properties of waste shall be determined and recorded such as to ensure the availability of the necessary information concerning the waste packages that are to be disposed of, or any waste that is to be stored for a prolonged period of time.

The radiation exposure of workers arising from waste management actions shall be limited, the spreading of radioactive materials inside the facility and into the environment shall be prevented, and preparedness for operational occurrences and accident conditions shall be maintained. (Guide YVL D.4 402)

According Nuclear Energy Act (990/1987) section 7g provision shall be made for the decommissioning of the facility already in design of a nuclear facility. According to Section 17 of Regulation STUK Y/1/2018 and Section 20 of STUK Y/4/2018, the design of a nuclear facility and its operation shall take account of the decommissioning of plant so that it is possible to limit the volume of nuclear waste for disposal accumulating during the dismantling, and radiation exposure to workers due to the dismantling of the nuclear facility, and to prevent radioactive materials from spreading into the environment during decommissioning.

Question 18 Does the regulatory framework include requirements for operating organizations of research reactors to establish and implement a commissioning programme?

Answer: Yes

Response:

In connection with the commissioning of a nuclear facility or its modifications, the licensee shall ensure that the systems, structures and components and the nuclear facility as a whole operate as designed. The procedures of the commissioning of the nuclear facility or its modifications shall be planned, and instructions shall be provided. At the commissioning stage, the licensee shall ensure that appropriate procedures are in place for the future operation of the nuclear facility. (STUK Y/1/2018 section 19). The detailed requirements for the commission is presented in Guide YVL A.5 chapter 4.

Question 19 Does the regulatory framework includes requirements for operating organizations of research reactors to develop operating instructions and procedures before operation commences?

Answer: Yes

Response:

The procedures of the commissioning of the nuclear facility or its modifications shall be planned, and instructions shall be provided. At the commissioning stage, the licensee shall ensure that appropriate procedures are in place for the future operation of the nuclear facility. (STUK Y/1/2018 section 19).

Question 20 Does the regulatory framework include requirements for operational limits and conditions (OLCs) of research reactors?

Answer: Yes

Response:

OLC shall include technical and administrative requirements for ensuring nuclear facility's safety operation in compliance with design bases and assumptions of safety analysis. (STUK Y/1/2018 section 22)

OLC's shall be defined and sent for approval as part of the operating license application (Nuclear Energy Degree (161/1988) section 36) and shall be kept up to date during operation and also during decommissioning.

Question 21 Does the regulatory framework include requirements pertaining to the operational safety of research reactors?

Answer: Yes

Response:

Safety assessments are required in all licensing phases (Nuclear Energy Degree sections 35, 36 and 36 a). Periodic safety reviews shall be done at least after every ten years if not otherwise set in the license conditions (Nuclear Energy Act section 7 e).

The requirements for

- safety of operation are given in section 20 of STUK Y/1/2018
- safety and fuel management are given in section 12 of STUK Y/1/2018
- operating experience are given in section 21 of STUK Y/1/2018
- condition monitoring and maintenance in section 23 of STUK Y/1/2018

Requirements for fire safety are presented in guide YVL B.8.

Question 21.1 What measures are place for the control over experimental devices and experiment personnel at research reactors, which may change from one research campaign to another?

Response:

According Nuclear Energy Act (990/1987 section 9) the operating organization (License holder) shall be under an obligation to ensure the safe use of nuclear energy. This obligation may not be delegated to another party. The licence holder shall ensure that the products and services of contractors and subcontractors which affect the nuclear safety of the nuclear facility meet the requirements of Nuclear Energy Act.

Research reactor shall have a managements system (YVL A.3), where guidance is given for all operations and also for internal document approvals. The requirements in YVL A.6 shall be followed during the operation.

If plant modifications are planned, the YVL A.5 shall be followed.

The only research reactor in Finland is under decommissioning phase, so there are not any research activities on-going at the facility.

Question 22 Does the regulatory framework include requirements for operating organizations of research reactors to develop and maintain the competence of personnel?

Answer: Yes

Response:

The licensee shall have an adequate number of qualified personnel suitable for their tasks. Only a person approved by the Radiation and Nuclear Safety Authority for the position in question may act as a nuclear facility operator in the control room of the facility. The licencee shall appoint the persons responsible for ensuring the emergency arrangements and security arrangements and safeguards of nuclear material. Only people approved by the Radiation and Nuclear Safety Authority specifically for each task may be appointed as the persons responsible and as their deputies. The licencee shall arrange adequate training for the maintaining and development of the expertise and skills of its personnel handling tasks relating to nuclear safety. The licence holder shall ensure that contractors and subcontractors whose activities affect the nuclear safety of the nuclear facility have an adequate number of qualified and trained personnel suitable for the tasks. (Nuclear Energy Act (990/1987), section 7i). More detailed requirements are given in guide YVL A.4.

Question 23 Does the regulatory framework include requirements for operating organizations of research reactors to conduct maintenance, calibration, testing, surveillance and inspection to ensure that SSCs important to safety are able to function in accordance with the design intent and with safety requirements?

Answer: Yes

Response:

The design, construction, operation, condition monitoring and maintenance of a nuclear facility shall provide for the ageing of systems, structures and components important to safety in order to ensure that they meet the design-basis requirements with necessary safety margins throughout the service life and

decommissioning of the facility. Systematic procedures shall be in place for preventing such ageing of systems, structures and components which may deteriorate their availability, and for the early detection of the need for their repair, modification and replacement. Safety requirements and applicability of new technology shall be periodically assessed in order to ensure that the technology applied is up to date, and the availability of the spare parts and the system support shall be monitored. OLC shall include technical and administrative requirements for ensuring nuclear facility's safety operation in compliance with design bases and assumptions of safety analysis. Operability and the effects of the operating environment shall be monitored by means of inspections, tests, measurements and analyses. Operability shall be checked in advance by regular maintenance, and provisions shall be made for maintenance and repairs in the event of any deterioration in operability. Condition monitoring and maintenance shall be planned, supervised and implemented so that the integrity and operability of systems, structures and components are reliably preserved throughout their service life. (STUK Y/1/2018 sections 5, 22 and 23).

The licensee shall sent a summary programme for periodic inspection, operational limits and conditions and a programme for the management of ageing when applying for operational license to STUK for approval. The documents shall be kept up to date during operation. The licensee shall have a quality management programme for the nuclear facility, where all instructions are given. (Nuclear Energy Act 990/1997 section 36)

Question 24 Does the regulatory framework include requirements for operating organizations of research reactors to establish and implement a radiation protection programme?

Answer: Yes

Response:

Section 2 a and Section 7 c of the amendment to the Nuclear Energy Act contain provisions regarding the limiting of the radiation exposure of the workers of the nuclear facility and the public in the surroundings of the nuclear facility.

Radiation exposure and emissions of radioactive substances shall be limited through layout design and component placement of the nuclear facility, material choices and planning of the working methods for operation and decommissioning of the facility and by using systems, structures, components, special radiation shielding and workers' equipment. (STUK Y/1/2018 section 7)

Radiation protection shall be performed according guide YVL C.2 "Radiation protection and exposure monitoring of nuclear facility workers.

Question 25 Does the regulatory framework include requirements for operating organizations of research reactors to establish and implement provisions for emergency preparedness and response?

Answer: Yes

Response:

The emergency arrangements have to set up based on STUK Y/2/2018. The planning of emergency operations shall be planned based on the radiation safety risks of facilities. More detailed requirements are given in guide YVL C.5. STUK can give a separate decision, where it is defined in detailed which requirements in YVL C.5 are applied for research reactor.

Question 26 Does the regulatory framework include requirements relating to the preparation for decommissioning of research reactors?

Answer: Yes

Response:

See responses to Regulation on Decommission of nuclear facilities. The same requirements are applied for the decommissioning of a research reactors.

Analysis

STRENGTHS FOR REGULATION OF RESEARCH REACTORS

S1	STUK has long experience in oversight of FIR research reactor, which will soon be dismantled. Spent fuel has been removed from the reactor, so oversight is concentrating to management of radioactive substances and waste management.
S2	STUK has good competences and experience of radiation protection and radioactive waste management from other facilities and activities. This is useful in regulating research reactor decommissioning.

OPPORTUNITIES FOR REGULATION OF RESEARCH REACTORS

O1	FIR research reactor is the first nuclear facility to be decommissioned in Finland. This gives a good opportunity to test our requirements and regulatory oversight before decommissioning of larger nuclear facilities.

THREATS FOR REGULATION OF RESEARCH REACTORS

T1	Research reactor is the first nuclear facility to be decommissioned in Finland. Spent fuel has been already removed from reactor site, but due to traditions and first-of-a-kind situation oversight might be over graded compared to safety significance.

CONCLUSIONS FOR REGULATION OF RESEARCH REACTORS

C1	Finnish regulatory framework fulfils IAEA standards. Reactor is in decommissioning phase and spent fuel removed from the site, which limits the scope of regulation.

Module: Regulation of Nuclear Power Plants

Findings

Question 1 Are provisions in place for the application of the graded approach to all regulatory activities pertaining to nuclear power plants (NPPs)?

Answer: Yes

Response:

National policy and strategy for safety

Safety Standards Series No. GSR Part 1 (Rev. 1) 2.4: "The national policy and strategy for safety shall be implemented in accordance with a graded approach, depending on national circumstances, to ensure that the radiation risks associated with facilities and activities, including activities involving the use of radiation sources, receive appropriate attention by the government or by the regulatory body."

With regard to the national policy and strategy for safety, see response to the primary question 1.1 of Module 1.

Safety Standards Series No. GSR Part 1 (Rev. 1) 2.5 "The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following: … (3) The type of authorization5 that is required for the operation of facilities and for the conduct of activities, in accordance with a graded approach; (8) Provision for the review and assessment of facilities and activities, in accordance with a graded approach; (10) Provision for the inspection of facilities and activities, and for the enforcement of regulations, in accordance with a graded approach;"

Safety Standards Series No. GSR Part 1 (Rev. 1) 4.3: "The objective of regulatory functions is the verification and assessment of safety in compliance with regulatory requirements. The performance of regulatory functions shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach. The regulatory process shall provide a high degree of confidence, until the release of facilities and activities from regulatory control, that: …"

Safety Standards Series No. GSR Part 1 (Rev. 1) 4.62: "The regulations and guides shall provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization. They shall also establish the criteria to be used for assessing compliance. The regulations and guides shall be kept consistent and comprehensive and shall provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach."

Safety Standards Series No. SSR-2/1 (Rev. 1) 4.15: "National and international codes and standards that are used as design rules for items important to safety shall be identified and evaluated to determine their applicability, adequacy and sufficiency, and shall be supplemented or modified as necessary to ensure that the quality of the design is commensurate with the associated safety function."

Nuclear Energy Act (990/1987) 7a § states that the safety requirements and measures for ensuring safety shall be graded and targeted so as to be commensurate with the risks in the use of nuclear energy.

Internal guide STUK 3.6 describes STUK's processes to prepare and manage STUK's regulations and regulatory guides as well as procedures when participating in the preparation of national or international legislation.

General safety requirements concerning NPP design are described in Regulation STUK Y/1/2018. Chapter 3 describes design related requirements, such as the defence-in-depth principle. Safety classification requirement is described in Section 4. Requirements set for and the actions taken to ascertain the compliance with the requirements of the systems, structures and components implementing safety functions and connecting systems, structures and components shall be commensurate with the safety class of the item in question.

Explanatory memorandum of STUK Y/1/2018 provides the reasoning behind the requirements. Among others, references to the IAEA, WENRA and ICRP safety standards are made.

Resources allocation

Safety Standards Series No. GSR Part 1 (Rev. 1) 4.5: "The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations

effectively. The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach. Thus, for the lowest associated radiation risks, it may be appropriate for the regulatory body to exempt a particular activity from some or all aspects of regulatory control; for the highest associated radiation risks, it may be appropriate for the regulatory body to carry out a detailed scrutiny in relation to any proposed facility or activity before it is authorized, and also subsequent to its authorization."

With regard to regulatory body's organizational structure, see response to the primary question 1 of Module 3.

With regard to regulatory body's management system, see response to the primary question 5 of Module 4. Graded approach is a key principle in Guide STUK 3.1 applied to all STUK's regulatory oversight activities.

Internal guide STUK 3.1 describes the regulatory control process of STUK, i.e., regulatory control related to radiation and nuclear safety. This guide provides the overall principles and practices to be followed in the regulatory control activities. Among others, the following principle is stated in the guide:

- Safety requirements and regulatory control shall be commensurate with the risks in the radiation practices and in the use of nuclear energy, considering both normal operation, disturbances and accidents. This principle is also called "graded approach".

STUK's strategy for 2018–22 include similar strategic targets, e.g.,

- cost-ware operations
- risk-informed and commensurable oversight
- flexible and efficient working methods

Design rules, quality of design, Reliability of items important to safety, Plant layout w.r.t activities for calibration, testing, maintenance, repair or replacement, inspection and monitoring, I&C systems

Safety Standards Series No. SSR-2/1 (Rev. 1) 5.29 "The analysis undertaken shall include identification of the features that are designed for use in, or that are capable15 of preventing or mitigating, events

considered in the design extension conditions. These features: ... (c) Shall have reliability commensurate with the function that they are required to fulfil."

Safety Standards Series No. SSR-2/1 (Rev. 1) 5.37-5.38: "The reliability of items important to safety shall be commensurate with their safety significance.

Safety Standards Series No. SSR-2/1 (Rev. 1) 5.42: "The reliability, redundancy, diversity and independence of support service systems and the provision of features for their isolation and for testing their functional capability shall be commensurate with the significance to safety of the system being supported."

Safety Standards Series No. SSR-2/1 (Rev. 1) 5.45 "The plant layout shall be such that activities for calibration, testing, maintenance, repair or replacement, inspection and monitoring are facilitated and can be performed to relevant national and international codes and standards. Such activities shall be commensurate with the importance of the safety functions to be performed, and shall be performed without undue exposure of workers."

Safety Standards Series No. SSR-2/1 (Rev. 1) 6.34-6.36: "Instrumentation and control systems for items important to safety at the nuclear power plant shall be designed for high functional reliability and periodic testability commensurate with the safety function(s) to be performed."

Regulatory guide YVL B.2 provides further requirements for the safety classification. With the help of safety classification, requirement levels are graded among systems, structures and components of the same type. Classification of the nuclear facility's systems, structures and components shall primarily be based on deterministic methods supplemented, and complemented by PRA (Guide YVL A.7) and expert judgement.

The quality management requirements applied to the systems, structures and components of different safety classes are given in Guides YVL A.3 "Leadership and management for safety". Section 3.5 states that the management system shall be developed and applied with consideration to the safety significance of the operation, and the quality of products and services shall be conformed with consideration to their safety significance.

More specific design requirements are given in various regulatory guides. It should be noted that each regulatory guide or its explanatory memorandum makes reference to relevant national and international standards.

Guide YVL B.1 describes overall design requirements. Chapter 4 describes the design requirements for ensuring the reliability of safety functions. Main principles affecting the reliability requirements of SSCs can be connected to the defence-in-depth concept and the design bases (operational occurrences and accidents to be taken into account).

Additional detailed requirements pertaining to the safety design of a nuclear power plant are given in the following Guides:

- YVL A.12 Information security management of a nuclear facility
- YVL B.3 Deterministic safety analyses for a nuclear power plant
- YVL B.4 Nuclear fuel and reactor
- YVL B.5 Reactor coolant circuit of a nuclear power plant
- YVL B.6 Containment of a nuclear power plant
- YVL B.7 Provisions for internal and external hazards at a nuclear facility
- YVL B.8 Fire protection at a nuclear facility
- YVL E.6 Buildings and structures of a nuclear facility
- YVL E.7 Electrical and I&C equipment of a nuclear facility
- YVL E.10 Emergency power supplies of a nuclear facility
- YVL E.11 Hoisting and transfer equipment of a nuclear facility
- YVL E.13 Ventilation and air conditioning equipment of a nuclear facility

Extent of regulatory control in the review of safety assessments

Safety Standards Series No. GSR Part 1 (Rev. 1) 4.33: "Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment [9], which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."

With regard to review and assessment related activities, see response to the question 1.2 of Module 6. Internal guide YTV 6.c describes the application of the graded approach.

Periodic safety reviews, evaluation of operating experience, Depth and scope of regulatory review

Safety Standards Series No. GSR Part 1 (Rev. 1) 4.39A: The regulatory body shall ensure, adopting a graded approach, that authorized parties routinely evaluate operating experience and periodically perform comprehensive safety reviews of facilities, such as periodic safety reviews for nuclear power plants [11]. These comprehensive safety reviews are submitted to the regulatory body for assessment or are made available to the regulatory body. The regulatory body shall ensure that any reasonably practicable safety improvements identified in the reviews are implemented in a timely manner.

Safety Standards Series No. GSR Part 1 (Rev. 1) 4.40: The regulatory body shall review and assess the particular facility or activity in accordance with the stage in the regulatory process (initial review, subsequent reviews, reviews of changes to safety related aspects of the facility or activity, reviews of operating experience, or reviews of long term operation, life extension, decommissioning or release from regulatory control). The depth and scope of the review and assessment of the facility or activity by the regulatory body shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.

With regard to review and assessment related activities, see response to the question 1.2 of Module 6.

Records of operation

Safety Standards Series No. SSR-2/2 (Rev. 1) 4.52: "The operating organization shall identify the types of record and report, as specified by the regulatory body, that are relevant for the safe operation of the plant. Records of operation, including maintenance and surveillance, shall be kept available from initial testing during the startup of each plant system important to safety, including relevant off-site tests. The records of operation shall be retained in proper archives for the periods required by the regulatory body. All records shall be kept readable, complete, identifiable and easily retrievable [3]. Retention times for records and reports shall be commensurate with their level of importance for the purposes of operation and plant licensing and for future decommissioning."

Guide YVL A.3 describes requirements concerning leadership and management for safety. Processes and functions of the management system are described in Section 6. Subsection 6.4, control of records, is based on IAEA GSR Part 2 Req. 8 "Documentation of the management system" as explained in the explanatory memorandum.

Integrated safety assessment

Safety Standards Series No. GSR Part 1 (Rev. 1) 4.46: "For an integrated safety assessment, the regulatory body shall first organize the results obtained in a systematic manner. It shall then identify trends and conclusions drawn from inspections, from reviews and assessments for operating facilities, and from the conduct of activities where relevant. Feedback information shall be provided to the authorized party. This integrated safety assessment shall be repeated periodically, with account taken of the radiation risks associated with the facility or activity, in accordance with a graded approach."

With regard to regulatory body's assessment activities, see response to the primary question 1 of Module 6.

Internal guide YTV 1.b describes the integrated safety assessment. "The results are evaluated three times a year at supervision meetings, and a summary of the evaluations is drawn up and checked to ensure that the measures taken - both by the licence holder and STUK - are adequate. The adequacy shall be assessed considering the safety significance of the target and any factors that may indirectly affect it, such as the technical complexity, uniqueness or first-time occurrence."

YTV 3.c.11

1. Licence holders shall carry out a safety assessment in accordance with YVL A.1 at the time of renewal of the operating licence and at the time of the periodic safety assessment (approximately every 10 years). The STUK safety assessment shall include a statement on the adequacy of the operational test activities and the basis for the statement.
2. The overall picture of the results of the supervision of the licensee's operational experience activities is documented three times a year in accordance with guide YTV 1.b (Supervision and assessment of safety of nuclear facilities).
3. The findings of the operational experience supervision are continuously documented.

YTV 3.c.11

Monitoring must systematically verify the licensee's ability to achieve results and impacts over time: learning from experience will be reflected in the licensee's ability to make the necessary changes to the facility, operations and culture that it deems necessary to avoid a repetition of the same faults and deficiencies. Key to success is the ability of the licensee's organisation to form an idea of the situation

and the ability of the whole organisation to improve. This means the ability to collect observations from all employees and areas, and the ability to screen and investigate observations with the priority and depth required for safety significance. It also means a commitment to improvement throughout the organisation, reflected in action that is targeted at the root causes of incidents, understood and implemented as planned.

I

nspection programme, regulatory inspections

Safety Standards Series No. GSR Part 1 (Rev. 1) 4.50: "The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach."

Safety Standards Series No. GSR Part 1 (Rev. 1) 4.52: "Regulatory inspections shall cover all areas of responsibility of the regulatory body, and the regulatory body shall have the authority to carry out independent inspections. Provision shall be made for free access by regulatory inspectors to any facility or activity, at any time, within the constraints of ensuring operational safety at all times and other constraints associated with the potential for harmful consequences. These inspections may include, within reason, unannounced inspections. The manner, extent and frequency of inspections shall be in accordance with a graded approach."

With regard to inspection activities, see response to the question 1 of Module 7.

Response of the regulatory body to non-compliances

Safety Standards Series No. GSR Part 1 (Rev. 1) 4.54: "The response of the regulatory body to non-compliances with regulatory requirements or with any conditions specified in the authorization shall be commensurate with the significance for safety of the non-compliance, in accordance with a graded approach."

With regard to regulatory body's enforcement policy, see response to the primary question 1 of Module 8.

Public information activities

Safety Standards Series No. GSR Part 1 (Rev. 1) 4.69: "Public information activities shall reflect the radiation risks associated with facilities and activities, in accordance with a graded approach."

With regard to regulatory body's public informational activities and consultation, see response to the primary question 8 of Module 3.

Question 2 Are provisions in place for authorization (licensing) of NPPs during the different phases of their life cycle?

Answer: Yes

Response:

The legislation (YEL 990/1987 and YEA 161/1988) pertaining the licensing process, especially related to the construction, operating and decommissioning licences, of nuclear facilities in Finland is described in the connection of the Core questions of the Module 5. The provisions for licensing of NPPs are further elaborated in the Guide YVL A.1 Chapters 3.1–3.10, 4.1-4.8 and 4.11, although these are mainly referring to the YEL 990/1987 and YEA 161/1988.

In addition, specific requirements for the authorization in the commissioning phase of an NPP are given in the Guide YVL A.5 Chapters 4 and 5, especially in Chapters 4.5 and 5.3. The requirements include e.g. the requirements or preconditions for the first fuel loading to the reactor, pre-criticality tests, criticality and low power tests as well as the power tests at different power levels (requirements 431-443 and 514-515a). The licensee shall fulfill the preconditions set and apply for STUK's permission to proceed in the commissioning.

Concerning modifications, the YEA 161/1988 Section 112 prescribes that the licensee shall obtain approval from STUK for modifications that influence safety and involve changes in the plans or documents approved by STUK before they are carried out. Further requirements are given in the Guide YVL A.1 Chapter 3.13.

Release from regulatory control and expiry of waste management obligation are prescribed in YEL 990/1987 Chapter 6 (especially Sections 27c-e and 32-34) and in YEA 161/1988 Section 84. Further requirements are given in the Guide YVL D.4 (e.g. in the Chapter 7.3).

STUK's oversight process and procedures for different authorization phases of the nuclear facilities are described in the Guide YTV 2.a.

Question 3 Does the regulatory body have requirements for the content of the safety analysis report to be submitted by the operating organization in support of a licence application for a NPP?

Answer: Yes

Response:

As presented in the answer to the Core Question ID 2 of the module 5, the YEA 161/1988 Sections 35, 36 and 36a define the deliverables to be submitted to STUK by the license applicant or the licensee when applying for a construction, operating or decommissioning license, respectively. More detailed requirements for the contents of these deliverables including e.g. the safety analysis report, Operational Limits and Conditions (OLC), quality management programme and plans for the emergency arrangements are given in the Guide YVL A.1 Annex A that also makes references to other relevant YVL Guides for more elaborated requirements.

In addition, according to STUK Y/1/2018 Section 3 the safety of a nuclear facility shall be assessed when applying for a construction license and operating license, in connection with plant modifications, and at Periodic Safety Reviews during the operation of the plant. In connection with the safety assessment it shall be demonstrated that the nuclear facility has been designed and implemented in a manner that meets the safety requirements. STUK Y/1/2018 Section 3 also considers e.g. the maintaining and revision of the assessment as necessary, as well as the reliability and uncertainty aspects of the relevant analyses.

Regarding the safety analysis report YEA 161/1988 Section 35 states that the safety analysis report shall include the general design and safety principles of the nuclear facility, a detailed description of the site and the nuclear facility, a description of the operation of the facility, a description of the behaviour of the facility during accidents, a detailed description of the effects that the operation of the facility has on the environment, and any other information considered necessary by the authorities.

Furthermore, according to the Guide YVL A.1 requirement A02 the safety analysis report shall include, among others, the safety objectives and principles of the nuclear facility, its design basis and other

criteria used in the design, a description of the facility's behaviour in transient and accident conditions and associated analyses and a summary of the results of the probabilistic risk assessment. In addition, the Guide YVL B.1 Chapter 6.1 gives more detailed requirements related to the description of the safety features of the nuclear facility (e.g. required contents of the system descriptions of the safety systems and safety assessments independent of the designer drawn up by the license applicant). The general requirements concerning the license applicant's or licensee's independent assessment of the acceptability of safety-significant products are given in the Guide YVL A.1 requirements 374-375.

The requirements for establishing the OLC are given in the Guide YVL A.1 requirement A22 (further requirements for the OLC are given in the Guide YVL A.6 Chapter 7.5) and the requirements for preparing the emergency plan are given in the Guide YVL A.1 requirements A06 and A24 (detailed requirements pertaining the emergency plan and in general the emergency arrangements are given in the Guide YVL C.5).

In addition, the Guide YVL A.1 requirements A05 and A21 require that the license applicant shall prepare a description of quality management or a quality management program, respectively, depending on the licensing phase in question. The description of quality management shall present e.g. the license applicant's and plant supplier's organizations and overall descriptions of the organizations' management systems. In turn, the quality management programme refers to a description of the management system and the structured procedures to be complied with during the commissioning and operation of the nuclear facility in respect of any functions with quality and safety implications. The general requirements pertaining to the management system and quality management are specified in the Guide YVL A.3.

Question 4 Are provisions in place for the regulatory body to review and assess information to be submitted by operating organizations of NPPs?

Answer: Yes

Response:

Review and assessment for nuclear facilities is covered by core questions of module 6. STUK is required and has the authority to review and assess information provided by NPP operating organizations. Review and assessment is performed over the whole lifecycle of a nuclear power plant.

For decision-in-principle STUK gives preliminary safety assessment. Basic design requirements and main safety features of each proposed alternative design, selected NPP sites and applicant's organization are reviewed.

For construction license STUK gives safety assessment on the acceptability of technical principles and requirements of the plant. Design criteria and conceptual design of the plant, safety relevant systems and systems integration are reviewed before STUK presents safety assessment including both deterministic safety analysis and probabilistic risk assessment. As an example, detailed requirements for probabilistic analyses are given in YVL A.7 and for deterministic analyses in YVL B.3.

During construction STUK reviews and approves the detailed design and oversights the manufacturing and construction. For operating license STUK gives safety assessment on the technical and organizational aspects of the as built plant. Final technical documentation is reviewed including modifications made during construction and commissioning.

Review and assessment process continues during commissioning and operation of a NPP. Periodic safety reviews, plant modifications and decommissioning require thorough review and assessment by STUK.

Question 5 Are provisions in place for a regulatory inspection programme for NPPs?

Answer: Yes

Response:

STUK has implemented Periodic Inspection Program for the inspection of nuclear power plants and nuclear facilities. The goal of the periodic inspection program is to ensure that STUK's oversight covers all relevant areas of nuclear safety and security in relevant intervals. The Periodic inspection program covers the whole lifecycle of the nuclear facility. The Periodic Inspection program consist of the following inspection programs (described in Guide YTV 4.a.1):

- Operation Inspection Program (KTO) is an inspection program for nuclear power plants and nuclear facilities that have received operation license
- Construction License Application Inspection Program (RKT) is an inspection program for nuclear power plants and nuclear facilities that have applied for construction license
- Construction Inspection Program (RTO) is an inspection program for nuclear power plants and nuclear facilities that are under construction

The periodic inspection program is based on annually planned pre-announced inspections, but additional, unannounced and reactive inspections can be added into inspection plan based on case-by-case consideration. Graded approach is used to optimize the periodic inspection program when defining the interval and scope of individual inspections and the need for additional inspections. Graded approach is also used when assessing severity of the inspection findings and defining possible enforcement actions (see module 8 core answers for more details).

In addition to periodic inspection program inspection types (KTO, RTO, RKT) there is also “lighter” inspection type called KV-inspection (Operation Surveillance inspection). The purpose of the KV-inspection is to inspect the licensee's activities as part of STUK's oversight work and document the inspection findings. The inspection scope is typically limited as such that the inspection could be carried in one working day. KV-inspections are typically used to supplement inspection activities under the Operation Inspection Program (KTO).

RTO and KTO inspection programs also cover the commissioning phase of the facility.

A similar inspection program is planned for the inspection of the facilities under decommissioning phase, however in NPP’s Finland this is not yet current issue. STUK oversight for decommissioning of nuclear facilities is described in YTV guide YTV 3.e.1.

This answer to primary question is dedicated to present KTO inspection program. See question 5.1 for description of RTO inspection program and module 7 core question 1.2 for description of RKT inspection program.

The objective of the KTO inspection programme is

- to verify that the facility is operated and maintained in accordance with the regulations, design criteria, and instructions issued in the licensee’s quality management system;
- to assess the licensee’s operations with a view to maintaining and upgrading safety, the consideration of safety in the management procedures, implementation of the licensee’s self-assessments, and active utilization of the gathered experience at all organizational levels;
- to acquire information to provide a basis for directing and enhancing STUK’s regulatory control

KTO inspection program consists of a total of 20 individual inspections. These inspections are divided into annual inspections and biennial inspections. Annual inspections consist of the following:

- Management system
- Plant maintenance
- Radiation protection
- Security
- Safety planning
- Safety features
- Emergency preparedness
- Annual outage

Biennial inspections consist of the following:

- Automation technology
- Human resources and competence
- Management and safety culture
- Waste disposal facilities
- Chemistry
- Mechanical engineering
- Interim storage of spent fuel
- Operation experience
- Plant operation
- Fire protection
- Use of PRA (Probabilistic Risk Assessment)
- Structures and buildings
- Electrical engineering
- Power plant waste handling
- Nuclear safeguards

Detailed descriptions of individual inspections are given in STUK internal Guide YTV 4.a.2 attachment 2.

An annual plan shall be drawn up specifying the inspections to be carried out in that year. The plan shall be submitted to the licensee. The overall scope of the inspection program is assessed based on the findings and experience gained in the oversight work, and if necessary, the scope and targeting of the inspection program could be adjusted. For example, the frequency of certain individual inspections could be adjusted from biennial to annual. Reactive and unannounced inspections could also be conducted based on case-by-case consideration.

The size of the RB's inspection team is typically 3-5 persons. Resident inspectors are recommended to take part to inspections however it is not necessary. Inspections are typically performed in 2 or 3 days depending on the inspection type and scope. The inspections are typically held at the plant site. However, because of the recent pandemic situation most of the inspections since March 2020 have been executed fully or partially (as so called "hybrid"-method) remotely using suitable teleconference software. Inspection results including possible requirements for remedial actions are consisted into inspection protocol, which is submitted to the licensee within a formal STUK decision.

As a conclusion STUK's periodic inspection provisions covers the expectations from GSG-13 chapter 4 and safety guide GS-G-1.3.

Question 5.1 What are the objectives and the scope of inspections conducted by or for the regulatory body during the construction stage of NPPs?

Response:

Section 109 of the Nuclear Energy Decree (12.2.1988/161) states that after the construction licence has been granted, the Radiation and Nuclear Safety Authority (STUK) controls the implementation of the facility project in detail.

During the construction stage of NPP's STUK is authored to inspect the safety related structures and components (mainly in Safety Classes 1 and 2) at manufacturers' premises and on site. These inspections include pressure equipment, pipes and their reassemblies, pumps, valves and other mechanical components are construction inspected prior to shipping to site as well as after installation is completed at site. Control of pressure tests at factory (for a component) and at site (for a system) is a part of the construction inspection. During construction inspections at manufacturer's facilities and on site STUK also oversees the operations of nuclear pressure equipment manufacturers and NDT/DT-testing organizations which STUK have approved to their duties. After installation phase it is reviewed by STUK that the Pre-Service Inspections (PSI) will be acceptably carried out applying qualified non-destructive inspection methods. Regulatory inspection methods are described in component specific YVL-guides YVL E.2, YVL E.3, YVL E.4, YVL. E.8 and YVL E.9. More detailed oversight is given in YVL E.3 Annex C.

The inspections carried out for safety related civil works are directed e.g. to concrete and steel structures and excavation of tunnels, Construction Inspection Program (RTO) has been established (described in internal Guide YTV 4.a.1). Individual inspections focus on different licensee's activities related to construction of a nuclear power plant. The contents of the inspections are planned in 6 months periods in order to adjust for different needs and project developments during construction phase. The purpose of STUK's Construction Inspection Programme is to verify that the operations of the construction licensee ensure high-quality construction and implementation in accordance with the approved designs while complying with the regulations and official decisions concerned. In particular, the Construction Inspection Programme assesses and controls the following issues:

- the licensee's general operations with a view to constructing the facility
- detailed procedures in the various fields of technology implemented for constructing the facility
- dealing with safety matters and consideration of safety in management procedures
- the licensee's expertise and use of expertise
- quality management and quality control.

The Construction Inspection Programme is divided into two main levels: the upper level assesses the licensee's main operations, such as project management and resources management, project control, dealing with safety issues and project quality management. The next level, known as the operation level, assesses, e.g., project quality assurance, training of the operating personnel, inspection procedures, utilization of the PRA, document management, radiation safety, and structure and component-specific inspections in the various fields of technology. Furthermore, the emergency response arrangements during construction, physical protection, fire protection and nuclear waste treatment are included in the Construction Inspection Programme within the scope STUK considers necessary. These topics can also be discussed during periodic inspection programme of the operating plant (plant sites including both operating units and units under construction).

In addition to the above-mentioned inspections, of which the licensee is informed in advance, STUK may carry out inspections without prior notice at its discretion based on case-by-case consideration.

Question 6 Are provisions in place for the enforcement of regulatory requirements at NPPs?

Answer: Yes

Response:

YEL (990/1987) section 64 states that if it is discovered in an inspection carried out by the Radiation and Nuclear Safety Authority or otherwise that, in order to secure the safe use of nuclear energy, to maintain appropriate security or emergency arrangements or to fulfill obligations under Finland's international contractual obligations in the field of nuclear energy, it is necessary to make changes in the construction of a nuclear facility or in the operation relating to its construction or use, STUK shall, upon consulting the license holder, oblige it to carry out the necessary changes within the time specified.

Prior to giving the order referred to in section 64, necessary for securing the safe use of nuclear energy, the Radiation and Nuclear Safety Authority shall request a statement from the Advisory Commission on Nuclear Safety mentioned in section 56, unless the change involved in the regulation is to be considered of minor financial significance, or such that its implementation must not be delayed.

If the provisions, regulations, or license conditions concerning safety, security or emergency arrangements laid down in Nuclear Energy Act (990/1987) or hereunder have not been observed in the use of nuclear energy, the Radiation and Nuclear Safety Authority shall issue, upon consulting the license holder, instructions to remove the defects or faults, and at the same time oblige the license holder to take the required measures within the time specified.

An authority may reinforce its order referred to in sections 64 or 65 by a conditionally imposed fine, or a threat to interrupt or limit the operation or to have the neglected obligation fulfilled at the expense of the neglecting party. The expenses of such a measure shall be paid in advance from the State funds, and can be collected from the neglecting party.

Having consulted the license holder, the Radiation and Nuclear Safety Authority may interrupt the operation or limit it, should a defect or fault referred to in Nuclear Energy Act section 64 or 65 cause immediate danger, or should there otherwise be justified cause for suspecting that the operation presents such a danger. Said operations may be interrupted or limited until the reason for the issuance of the provision no longer exists. STUK shall have the same right, if supervision hereunder cannot be implemented otherwise, or if the license holder has failed to comply with regulations issued by STUK, based on the provisions of this Act or issued under this Act, or if the license holder has failed to comply with its obligations under the Nuclear Liability Act.

Above mentioned regulatory body enforcement provisions regarding NPPs are prescribed in Internal Guide YTV 5.a, which presents a general view of the available enforcement actions and their mutual relations. See more detailed answers presented in the Core Question ID 1.1 of the module 8.

Question 7 Does the regulatory framework include requirements relating to fundamental safety functions, application of defence in depth at NPPs, and categories of plant states?

Answer: Yes

Response:

The concept of Defence in Depth is introduced into the legislation and regulation starting at the highest level. YEL Section 7b requires both functional and structural defence-in-depth to be applied: "*The safety of a nuclear facility shall be ensured by means of successive levels of protection independent of each other (safety principle of defence-in-depth). This principle shall extend to the functional and structural safety of the plant*." Section 7d of the Act requires consequences of the operational occurrences and accidents to be in relation with the frequency of the event: "*The design of a nuclear facility shall provide for the possibility of operational occurrences and accidents. The probability of an accident must be lower, the more severe the consequences of such an accident would prove for people, the environment or property.*"

As defined in the Nuclear Energy Decree, the initiating events are required to be classified according to their frequency of occurrence to operational occurrences ($f \geq 1/100$ years), class 1 design basis accidents ($1/1000 \leq f < 1/100$) and class 2 design basis accidents ($f < 1/1000$). The design extension conditions and severe accidents are discussed under the Primary Question 19. As per STUK regulation 1/Y/2018, *normal operating conditions shall refer to the planned operation of a nuclear facility*

according to the operating procedures. These also include testing, plant start-up and shutdown, maintenance and the replacement of nuclear fuel.

These fundamental principles are further elaborated at lower levels of legislation and regulations. Section 9 of the STUK regulation the Safety of a Nuclear Power Plant STUK Y/1/2018 defines five levels of defence in depth:

1. *prevention to ensure that the operation of the nuclear facility is reliable and deviations from normal operating conditions are rare;*
2. *control of deviations from the nuclear facility's normal operating conditions so that the facility is equipped with systems which are able to limit the development of operational occurrences into accidents and if required can bring the facility into a controlled state;*
3. *control of accident situations so that the nuclear facility is equipped with systems that function automatically and reliably to prevent severe fuel damage in postulated accidents and in design extension conditions; manually actuated systems can be used to manage accident situations if it can be justified from a safety perspective;*
4. *confinement of a release of radioactive substances in severe reactor accidents by equipping the nuclear power plant with systems which ensure the sufficient leaktightness of the containment in severe reactor accidents so that the limits for releases in severe reactor accidents are not exceeded*
5. *mitigation of the consequences by means of emergency arrangements to limit the public's exposure to radiation in situations where radioactive substances are released from the nuclear facility into the environment*.

Section 10 of the regulations elaborates the structural aspect of defence-in-depth: "*Structural defence-in-depth design shall prevent dispersion of radioactive substances into the environment by means of successive barriers which are the nuclear fuel and its cladding, the reactor cooling circuit (primary circuit) and the containment*." The section presents the further safety objectives for the barriers, e.g. that "*The probability of a fast growing crack in a primary circuit leading to an early or large release shall be extremely low*". These are further elaborated in YVL B.5 and YVL B.6.

The STUK regulation STUK Y/1/2018 section 11 sets the requirements for safety functions of the plant. For example, it is required that "In order to prevent accidents and mitigate the consequences thereof, a nuclear power plant shall be provided with systems for shutting down the reactor and maintaining it in a sub-critical state, for removing decay heat generated in the reactor, and for retaining radioactive materials within the plant. Design of such systems shall apply redundancy, separation and diversity principles that ensure implementation of a safety function even in the event of a malfunction." The requirements are then further elaborated in the YVL guides, especially in YVL B.1.

The STUK regulation STUK Y/1/2018 section 12 is dedicated for fuel storages and presents the similar high-level requirement of applying defence-in-depth on storages. Requirements concerning ensuring the safety functions YVL D.3. presents the requirements more in detail.

Question 8 Does the regulatory framework include requirements for operating organizations of NPPs to establish, implement, assess and continually improve a management system that integrates safety, health and environmental elements to ensure safe operation?

Answer: Yes

Response:

The requirement regarding Management System is stated in YEL (990/1987) Section 7j *Management system.* A nuclear facility shall have a management system. The management system of the nuclear facility shall take into account in particular the impact of the safety perceptions and attitudes of management and personnel on maintaining and development of safety, as well as systematic practices and their regular assessment and development.

YEL (990/1987) Section 9 prescribes as follows: It shall be the licensee's obligation to assure the safe use of nuclear energy. Regulation STUK Y/1/2018 Section 25, paragraphs 2 set out the requirements for ensuring operating organizations of NPPs have the prime responsibility for safety. *Organisations participating in the design, construction, operation and decommissioning of a nuclear facility shall employ a management system for ensuring safety and the management of quality. The objective of such a management system shall be to ensure that safety is prioritised without exception, and that quality management requirements correspond to the safety significance of the activity and function. The management system shall be systematically assessed and further developed.*

Section 25, paragraph 3 of Regulation STUK Y/1/2018 requires that the management system shall cover all organisational activities impacting the nuclear facility's safety. For each function, requirements significant to safety shall be identified, and the planned measures described in order to ensure conformity with requirements. The operating methods of the organisation shall be systematic and instructed.

The detailed requirements for integrated management system that meets the requirements of GSR Part 2, are presented in YVL Guide A.3 "*Leadership and Management for Safety".* Integrated Management system are mentioned in requirement 301. *A management system shall be planned and implemented to incorporate an organisation's operations, and it shall be continuously maintained and improved. The system shall be a well-balanced whole aligned with the goals of the organisation, which shall ascertain the fulfilment of nuclear and radiation safety requirements. Organisation shall integrate all management systems (integrated management system).* In requirement 302 are mentioned how to

establish a structure for the operating organization. *In the management system, the organisational structure and the responsibilities, authorities, and decision-making procedures of the personnel shall be defined, taking into account their safety implications. The organisational structure shall be justified.*

The requirement regarding Operating organization personnel is stated, in YEL (990/1987) Section 7i *"Personnel"*, that the holder of the licencee granting the right to use nuclear energy shall have a sufficient number of qualified personnel suitable for the related tasks. YVL Guide A.4 *"Organisation and personnel of a nuclear facility"* sets forth detailed requirements for personnel and individual competence. In requirement 304 are mentioned how to establish and document the functions, roles and responsibilities of staff*; The organisation structure, the duties, powers and responsibilities of the personnel and the procedures related to decision making shall be documented in an organisation manual or a comparable document, which shall be submitted to STUK for information.*

Regulation STUK Y/1/2018 Section 25, paragraphs 1 set out the requirements for ensuring *the continuing safety of the plant design throughout the lifetime of the NPP. When designing, constructing, operating and decommissioning a nuclear facility, a good safety culture shall be maintained. Safety shall take priority in all operations. The decisions and activities of the management of each organisation participating in the above mentioned activities shall reflect its commitment to operational practices and solutions that promote safety.*

Safety guides GS-G-3.1 (Application of the Management System for Facilities and Activities) and GS-G-3.5 (The Management System for Nuclear Installations) are more extensive than YVL Guide A.3 "*Leadership and Management for Safety",* but basically it contains similar requirements.

Question 9 Does the regulatory framework include requirements for operating organizations of NPPs to monitor and control all activities performed by vendors, contractors and suppliers?

Answer: Yes

Response:

Regulatory framework includes requirements for licensee to monitor and control all activities at NPP or NPP construction site. License holder is also required to monitor and control quality of design, and manufacturing of NPP equipment which are significant to safety. Graded approach is used.

According to Nuclear Energy Act (990/1987) 7i § The license holder shall ensure that contractors and subcontractors whose activities affect the nuclear safety of the nuclear facility have an adequate number of qualified and trained personnel suitable for the tasks.

Acc. to Nuclear Energy Act the license holder shall be under an obligation to ensure the safe use of nuclear energy. This obligation may not be delegated to another party. The license holder shall ensure that the products and services of contractors and subcontractors which affect the nuclear safety of the nuclear facility meet the requirements of this Act.

STUK regulation STUK Y/1/2018 requires that each organization participating in designing, constructing, operating and decommissioning of a nuclear facility, shall employ a management system for ensuring safety and the management of quality. The objective of such a management system shall be to ensure that safety is prioritised without exception, and that quality management requirements correspond to the safety significance of the activity and function.

The licensee shall commit and oblige its employees and the suppliers and subcontractors whose involvement affects the safety of the nuclear facility to adhere to the systematic management of safety and quality.

The licensee shall have a sufficient number of competent personnel suitable for the related tasks for ensuring the safety of the nuclear facility. The licensee shall have access to the professional expertise and technical knowledge required for the safe construction, operation and decommission of the nuclear facility, the maintenance of equipment important to safety, and the management of accidents.

General requirements for the management and control of suppliers and supply chains as well as purchases are given in Guide YVL A.3. Additional requirements are presented in other YVL Guides. Guide YVL A.4 requirements for organization and personnel, Guide YVL A.5 for Construction and commissioning. and Guide YVL B.1 includes requirements for safety design and design organizations.

Acc. to YVL A.3, 307, The licensee shall ensure operation in accordance with the objectives. The entire personnel, as well as the suppliers working at the nuclear facility, shall follow the management system and the procedures presented therein.

402, The licensee is obliged to ensure that the regulatory requirements and guides are complied with. This shall also be taken into account during the procurement of products and services having a bearing on the nuclear and radiation safety of the nuclear facility. It shall be ensured that organisations contributing to the plant delivery or plant modifications understand and comply with the delivery-related requirements. The licensee shall communicate the requirements to the product suppliers by

contractual means (contract documents) and ensure and control the fulfilment of the requirements throughout the supply chain.

Acc. to YVL, 811, During the operation of the nuclear facility, STUK will oversee the overall functionality of the management systems of the licensee and the organisation operating the facility and conduct, at its discretion, inspections focused on different fields of activity. Furthermore, STUK oversees the evaluation, carried out by the licensee and the organisation operating the nuclear facility, of the suppliers' and subcontractors' management systems and the control of operations.

318a, The licensee’s management system shall contain procedures to ensure the good safety culture of safety-significant suppliers, to assess the safety culture and to respond to its development needs.

606, The management system (of the licencee) shall have established procedures for the control of outsourced processes and activities.

624, Adequate quality requirements shall be established for products and services. Compliance with the quality requirements and achievement of the required quality level shall be ensured. There shall be adequately qualified personnel to specify the quality requirements and to control the products and suppliers.

633, The management system shall define procedures for the licensee to ensure that, when purchasing sets of equipment involving several fields of technology, the contractual relationships and responsibilities within the entire supply chain are unambiguously defined.

634, The licensee shall have in place procedures and competent personnel to assess, approve, control and guide suppliers of safety-significant products and services. The procedures shall cover the entire supply chain and lifetime stages of the product or service. The licensee shall also incorporate the oversight rights of authorities into the supervision procedures.

634b, The licensee shall ensure by follow-up audits in connection with delivery control that the operations of a safety-significant supplier comply with the requirements, that the supplier has capability

to deliver a product and service complying with the requirements and that the supplier complies with the imposed quality management requirements.

635, For all purchases, the documentation to be attached to a product and control during product manufacture shall be defined.

635a, The actions to assess, control and guide suppliers important for nuclear or radiation safety shall be planned. Competence essential for delivery shall be utilised in the planning. Supplier-specific measures concerning the supplier chain and the delivery shall be taken into account as a whole in the planning.

637, Suppliers shall draw up a delivery-specific quality plan for the supply of safety-significant products and services. Through the use of a quality plan, it can be ensured that a product supplier has correctly understood the requirements of quality management applicable to the delivery and demonstrates that the supplier has in place procedures to fulfil the requirements.

YVL A.3, Annex Quality plan content, gives specific requirements for quality plans and f.ex. th procedures for subcontractor supervision must be defined.

Acc to Guide YVL A.5, 309, The licensee shall ensure that safety-significant suppliers contributing to construction and plant modification projects have adequate competence and systematic procedures as regards their own deliveries and that the suppliers have the necessary operational prerequisites and that they follow the set safety requirements.

325, The licensee shall have in place procedures to regularly assess the functionality of interorganisational interfaces between own organisation and the supplier as well as in supplier organisations.

367, the licensee shall ensure that the organisations involved in the construction or plant modification project and who supply safety-significant products or services comply with the project's procedures for the management of non-conformances.

504, The licensee is responsible for the adequate supervision of design functions and designers.

Acc. to Guide YVL B.1, 308, if an organisation involved in the design of a nuclear facility and systems important to safety relies on subcontractors, it shall ensure that the subcontractor is capable of executing the assigned task, the safety requirements related to the subcontracted design task are communicated clearly and unambiguously, the subcontractor is duly briefed, instructed and supervised and its services used as appropriate, and the use of the subcontractor is transparent and documented in such detail as to allow an independent expert organisation to assess the design if necessary.

Question 10 Does the regulatory framework include requirements for operating organizations of NPPs to verify the safety of their NPPs?

Answer: Yes

Response:

The Finnish regulatory framework contains requirements for licensees to carry out periodic safety reviews (PSR) of operating NPPs. Periodic safety reviews are often carried out in parallel with renewal of the operation license.

The general requirements regarding PSR and operating license renewal are presented in Nuclear Energy Act (990/1987) Sections 7 e and 24.

Section 7 e:

Compliance with the requirements concerning the safety of a nuclear facility shall be reliably proven.

The overall safety of a nuclear facility shall be assessed at least at 10-year intervals. The overall safety of a facility performing large-scale disposal of nuclear waste shall, however, be assessed at least at 15-year intervals.

Section 24:

Licences, excluding the construction licence and the licence for decommissioning, shall be granted for a fixed term. When considering the length of the term, particular attention shall be given to the estimated duration of the operations and ensuring safety. The licence may include a provision that the licence shall expire if the operations are not started within a fixed period from the granting of the licence.

More detailed requirements are given in YVL Guide A.1, "Regulatory oversight of safety in the use of nuclear energy".

YVL Guide A.1 requirement 352 states the following:

The procedure to be followed when an application for the renewal of an operating licence for a nuclear facility currently in operation is filed is the same as that for filing an application for an operating licence for a new nuclear facility. The renewal of the operating licence always involves a periodic safety review of the facility.

According to Section 24 of the Nuclear Energy Act, the licence, excluding the construction licence, shall be granted for a fixed term, and when the length of the term is considered, particular attention shall be paid to ensuring safety and to the estimated duration of operations.

The length of the term of the operating licence is not defined in the legislation. In the application, the licensee shall make a proposal for the length of the term, justified by, among other things, the condition of the nuclear facility concerned and its foreseen operation. In the event that a licence to operate the nuclear power plant is granted for a term considerably longer than ten years, the licensee shall carry out a periodic safety review on the facility in accordance with Section 7 e of the Nuclear Energy Act, and submit it to STUK for approval within ten years of the date when the operating licence was granted or the previous periodic safety review was carried out. The periodic safety review of nuclear waste facilities shall be carried out at least every 15 years.

The renewal of the operating license always involves the same assessment than a periodic safety review of the facility. STUK assess in the periodic safety review the condition of the facility, paying particular

attention to the ageing management of the components, systems and structures. In STUK's assessment, the licensee's organizational capabilities to continue safe operation of the facility is also assessed.

If the outcome of the safety review indicates that the site is unacceptable and the deficiencies cannot be compensated to reach the criteria, and the continued operation of the nuclear power plant is thus no longer possible, as stated in STUK Y/1/2018 section 20a, the licensee is obliged to initiate measures for the decommissioning of the nuclear installation in accordance with the decommissioning plan and requirements referred to in Article 7g in Nuclear Energy Act and to apply for a licence for the decommissioning of the nuclear installation. The application for a licence shall be submitted in sufficient time to allow the authorities sufficient time to assess the application before the expiry of the licence for the operation of the nuclear installation.

Question 11 Does the regulatory framework include requirements regarding interfaces of safety with security and safeguards for NPPs?

Answer: Yes

Response:

This question has been answered under module 10 (Interfaces with nuclear security) in questions 1.4 and 1.5.

Question 12 Does the regulatory framework include requirements for a site evaluation to the extent that is appropriate for the potential hazards presented by NPPs?

Answer: Yes

Response:

Section 6 of the Nuclear Energy Act (YEL 990/1987) stipulates that the use of nuclear energy must be safe; it shall not cause injury to people, or damage to the environment or property. In the siting of a nuclear power plant, the aim is to protect the plant against external threats as well as to minimize any environmental detriments and threats that might arise from it. When applying for a decision-in-principle from the Government referred to in Section 11 of the Nuclear Energy Act, particular attention shall be paid to the suitability of the intended site of the nuclear facility and its effects on the environment, in accordance with Section 14(2) of the Nuclear Energy Act.

Radiation and Nuclear Safety Authority Regulation on the Safety of a Nuclear Power Plant (STUK Y/1/2018) Section 8 stipulates that *the impact of local conditions on safety and on the implementation*

of the security and emergency arrangements shall be considered when selecting the site of a nuclear facility. The site shall be such that the impediments and threats posed by the plant to its surroundings remain extremely small and heat removal from the plant to the environment can be reliably implemented. Section 14 titled "Protection against external hazards affecting safety" contains following binding requirements:

1. *The design of a nuclear facility shall take account of external hazards that may endanger safety. Systems, structures, components and access shall be designed, located and protected so that the impacts of external hazards deemed possible on nuclear facility safety remain minor. The operability of systems, structures and components shall be demonstrated in their design basis external environmental conditions.*
2. *External hazards shall include exceptional weather conditions, seismic events, the effects of accidents that take place in the environment of the facility, and other factors resulting from the environment or human activity. The design shall also consider unlawful and other unauthorised activities compromising nuclear safety and a large commercial aircraft crash.*

More detailed requirements are given in the YVL Guides. For site evaluation and external hazards most relevant YVL Guides are A.2 "Site for nuclear facility" and B.7 "Provisions for internal and external hazards at a nuclear facility".

YVL Guide A.2 requires that the siting of a nuclear power plant shall take into consideration external hazards to the plant that are caused by the environment and the conditions, industry, and population in the vicinity of the plant. Other factors to be considered in terms of legislation and technical aspects include the impact of the power plant project on the natural environment and land use, the social and economic effects, traffic arrangements and electrical connections to the national grid, cooling water solutions, and special factors relating to security of supply of electric power. Specific requirements and links to other regulations and laws about the land use, radioactive releases, populations and allowed activities in the vicinity of the nuclear facility are presented in the YVL Guide A.2. For radioactive releases YVL Guide A.2 has the requirement 419: *Guide YVL C.4 lays down the requirements concerning the preparation of analyses of the dispersion of radioactive substances and the assessment of radiation doses of the population during normal operation and under accident conditions. When assessing radiation doses of the surrounding population, the region's characteristics – hydrological, meteorological and natural – as well as the living conditions and habits of the population shall be considered.*

The license applicant prepares a report on the external hazards considered in the facility design and the methods of preparing against them. The range of hazards covers all natural phenomena assessed as possible at the facility site, as well as other external hazards affecting at the facility. The identification of hazards shall be site-specific. However, hazards which at least should be considered are listed in the YVL Guide B.7: earthquakes, high and low atmospheric temperature, high winds including tornadoes and downbursts, high and low air pressure as well as fluctuations of air pressure rain, snow, hail,

freezing, rain and splashes from sea or watercourses, atmospheric moisture, fog, mist, rime ice, frazil ice, lightning, drought, electromagnetic interference caused by solar flares, high and low sea water level, external floods, external events endangering seawater and raw water supply (e.g. algae, mussels, oil and other fouling chemicals), external fires and explosions, electromagnetic interference, hazards caused by flora and fauna, airplane crash. YVL Guide A.2 lists following hazards from human activities that at least need to be considered in licensing and siting process: land, sea and air transport, and pipelines, industrial facilities and storage facilities that may cause danger. Other hazards that are not specifically mentioned should be taken into account in the design if they are relevant as required by Radiation and Nuclear Safety Authority Regulation on the Safety of a Nuclear Power Plant (STUK Y/1/2018) and YVL Guide B.7.

Requirements regarding the airplane crash are presented in the YVL Guide A.11. In Finland, accidental large aircraft collisions are considered extremely improbable at nuclear facility sites, and in the regulatory framework they are considered mainly as acts of terrorism.

Combinations of external hazards are considered. When selecting design values as well as in applying the redundancy and separation principles, dependencies affecting the simultaneous occurrence of external events need to be taken into account.

The assessments of external hazards, including their combinations, shall be reviewed and, when necessary, updated at least every ten years in connection with periodic safety review carried out for renewal of the operating license or during the term of the license, and also if new relevant information turns up based on research or operating experience. In Finland operating licenses are granted for fixed term, usually ten or twenty years.

The nuclear facility is required to have in place procedures for the monitoring of external hazards affecting the safety of the facility. In addition, the nuclear facility is required to have the necessary measurement instruments for monitoring weather phenomena, the seawater level and the temperature.

It is worth noting that many severe hazards considered in IAEA guides are not considered separately in the Finnish regulatory framework, because they are not relevant in Finland due to geological and geographic conditions. For example, nuclear facilities are founded on hard crystalline bedrock and hazards related to soil instability are not relevant. Due to the flat topography of the sites, landslides, mudslides and avalanches are excluded. Significant seismic tsunamis are not considered possible in the Baltic region due to the shallow water and low seismicity. On the other hand, many hazards relevant in

Finland are considered only superficially in IAEA guides, for example sea ice, frazil ice, very low temperatures, long cold periods and snowstorms.

Question 12.1 What are the provisions in the regulatory framework relating to consideration of potential combinations of external natural and human induced events in site evaluations?

Response:

Combinations of external natural and human induced events are considered. YVL Guide B.7 Requirement 505 stipulates: *To be taken into account in selecting design values as well as in applying the redundancy and separation principles (YVL B.1) are dependencies affecting the simultaneous occurrence of external events.* When selecting design values for systems, structures and components important to safety that pertain to external events and conditions, at least phenomena whose estimated probability of occurrence at the site over one year is higher than 10^{-5} at a median confidence level are considered. Exceptional external events and conditions with an estimated frequency of occurrence less than 10^{-5}/year are considered as design extension conditions (DEC C events). Note that the DEC C events correspond roughly to the term Beyond Design Basis External Events used in IAEA documents.

Question 12.2 What are the provisions in the regulatory framework relating to consideration of multiple unit NPPs when assessing the feasibility of emergency plans in the frame of site evaluations?

Response:

The licensee shall prepare and maintain an emergency plan. The plan shall present a description of the planning, implementation and maintenance of emergency arrangements. Under Section 3, subsection 2, of Regulation STUK Y/2/2018, planning of emergency arrangements shall take account of simultaneous emergency situations occurring in all nuclear facilities in the site area and their potential consequences, especially the radiation situation on the site and in the surrounding area and the possibilities to access the area.

Emergency exercises shall be held during the operation of the nuclear power plant at least once a year, and more frequently when necessary if several reactors and plant types are located in the same plant site. The objective of these emergency exercises is to ascertain the appropriateness of the facilities, devices and equipment reserved for emergency situations; the suitability, compatibility and scope of the operating instructions and software; and the capability of the organisation to identify potential needs for modifications or improvements.

The annual emergency exercise shall cover a significant part of the emergency plans activities. The licensee shall ensure that all sectors are exercised over longer time spans. Simultaneous emergency situations of several nuclear facilities located at the same site area shall also be exercised. In addition,

situation exercises involving one or several sectors of emergency response shall be arranged to become acquainted with the performance of the tasks, improve co-operation and enhance operations. The threat of unlawful action shall be included in some of the exercises.

Question 12.3 What does the regulatory framework require regarding seismological data used for assessing the capability of a fault?

Response:

Requirements on site seismic assessments are set forth in Guide YVL B.7. Determination of the design basis earthquake is addressed in Req. 401 and consideration of the area's seismic history and local geology and tectonic in Req. 401a.

401. A design basis earthquake shall be determined for the nuclear facility. A design basis earthquake refers to facility site bedrock surface motion used as the basis for the nuclear facility's design. The design basis earthquake shall be so defined that in the current geological conditions the anticipated frequency of occurrence of stronger bedrock motions is less than once in a hundred thousand years (1·10-5/year) at a median confidence level.

401a.The methods used in the determination of the design basis earthquake shall be described and justified. The area's seismic history, regional and local geology and tectonics shall be considered in the determination.

However, in the Finnish regulatory framework there are no specific requirements regarding assessment of capability of a fault for the following reasons:

Seismicity in Finland and in the near regions is diffuse and earthquakes cannot be associated with known faults which could be observed on the surface. The geological and seismological conditions, including palaeoseismic and geomorphological data, has been analysed by an international expert group in connection with the recent probabilistic seismic hazard analyses for the Loviisa, Olkiluoto and Hanhikivi sites (Helsinki University of seismology reports S-63 and S-64).

Capable faults are considered in IAEA NS-R-3 (Rev. 1), paragraphs 3.5 – 3.7

3.5. The potential for surface faulting (i.e. the fault capability) shall be assessed for the site. The methods to be used and the investigations to be undertaken shall be sufficiently detailed that a reasonable decision can be reached using the definition of fault capability given in para. 3.6.

3.6. A fault shall be considered capable if, on the basis of geological, geophysical, geodetic or seismological data (including palaeoseismological and geomorphological data), one or more of the following conditions applies:

(a) It shows evidence of past movement or movements (significant deformations and/or dislocations) of a recurring nature within such a period that it is reasonable to infer that further movements at or near the surface could occur. In highly active areas, where both earthquake data and geological data consistently reveal short earthquake recurrence intervals, periods of the order of tens of thousands of years may be appropriate for the assessment of capable faults. In less active areas, it is likely that much longer periods will be required.

(b) A structural relationship with a known capable fault has been demonstrated such that movement of one could cause movement of the other at or near the surface.

(c) The maximum potential earthquake associated with a seismogenic structure is sufficiently large and at such a depth that it is reasonable to infer that, in the geodynamic setting of the site, movement at or near the surface could occur.

3.7. Where reliable evidence shows the existence of a capable fault that has the potential to affect the safety of the nuclear installation, an alternative site shall be considered.

Regarding NS-R-3 (Rev. 1) paragraphs 3.5-3.6 it should be noted that no seismic activity has been related to surface observations in Finland. Seismic events, even shallow ones, have not induced any visible scours at the surface during the seismological observation history, one old possibly seismicity induced land slide at Paltamo in 1626 is arguable.

Palaeoseismic studies indicate old land movements and post-glacial movements in the past, especially during the very fast rock uplift immediately after the last glaciation, but they are not representative of the current seismological regime. The known post-glacial faults are located in the northern part of country and addressed in the Helsinki University report for the Hanhikivi site (S-63). The topic has also

been investigated in connection with Posiva's project for final disposal of spent nuclear fuel. Current major (Magn. M3- M4) seismicity in Finland is not associated with known faulting. Very small movements at the surface can be recorded due to land uplift, seismicity is not common.

Question 13 Does the regulatory framework include requirements relating to the design of items important to safety for NPPs?

Answer: Yes

Response:

According to the STUK regulation 1/Y/2018 Section 4: "*The safety functions of a nuclear facility shall be defined and the related systems, structures and components classified on the basis of their safety significance.*

Requirements set for and the actions taken to ascertain the compliance with the requirements of the systems, structures and components implementing safety functions and connecting systems, structures and components shall be commensurate with the safety class of the item in question."

In the Guide YVL B.1, it is further required that the systems, structures and components required for each postulated initiating event shall be identified (YVL B.1 428). The nuclear facility shall be divided into systems, and each component or structure affecting operation or safety of the facility shall belong to a system (YVL B.2 302, 302a). Each systems shall be safety classified based on *"the facility's safety functions and the significance of the systems that perform them in terms of the reliability of these safety functions, with due consideration to ensuring safety by defence-in-depth*" (YVL B.2 304). Classification of components and structures is based on their functional and/or structural safety significance (YVL B.2 305,306). Each system, component and structure has to be assigned a safety class. The requirements and actions are then to be set according to the safety significance as described above; this is also further elaborated in YVL B.2 e.g. requirements 308 and 309.

The high level requirements that the nuclear facility is constructed, operated and decommissioned "*in conformity with the safety requirements and using approved plans and procedures*" are set forth in STUK regulation 1/Y/2018 (Sections 18- 20a). The chapter 3 of the guide YVL B.1 is dedicated to requirements concerning design management, i.e. requirement management, configuration control, quality and qualification plans, and so on. YVL B.1 requirement 311 states: "*A nuclear facility and the systems important to safety shall be designed by using design processes and methods appropriate for the required level of quality, and by applying the relevant safety regulations, guidelines and standards. The selection of the standards applied in design shall be justified in terms of suitability and coverage*." The principle is that each system important to safety are defined requirements before the actual design actions of respective life cycle phase (YVL B.1 312).

YVL B.1 section 3.8 Validation presents specific requirements for Qualification plans for systems. According to the requirement 362 "*Systems, structures and components important to safety shall be validated, i.e. it shall be demonstrated that they are appropriate for their purpose of use and fulfil the set safety requirements*". This also includes any ambient conditions which are to betaken into account as design basis: "*The design basis for all systems, structures and components of the nuclear power plant shall be the environmental conditions in which they are required to operate. Environmental conditions to be considered in the design shall include, as appropriate, vibration, temperature, pressure, electromagnetic effects, radiation, humidity, fluid properties and combinations of these conditions*" (YVL B.1 404). The qualification shall be drawn up for any type of system important to safety. Component specific requirements concerning qualification requirements are presented in YVL Guide E-series. The series also contains component related requirements tor testing during manufacturing and operation, maintenance, repairs and in-service inspections.

Testing is part of the validation (qualification). It is also required to be maintained during the whole lifecycle. Section 23 paragraph 2 of the STUK regulation states: "*Operability and the effects of the operating environment shall be monitored by means of inspections, tests, measurements and analyses. Operability shall be checked in advance by regular maintenance, and provisions shall be made for maintenance and repairs in the event of any deterioration in operability. Condition monitoring and maintenance shall be planned, supervised and implemented so that the integrity and operability of systems, structures and components are reliably preserved throughout their service life*."

The YVL B.1 406 also states: "*Systems performing safety functions shall be so designed as to ensure that their operability can be tested or otherwise verified during the operation of the plant under operational states and operating conditions as close as possible to the actual operational states and operating conditions for which they were designed. Components important to the operability of a safety function shall be accessible for inspection*."

Requirements for components and structures are partially deduced from the plant and system level functions: the format of defining the design requirements depends on the type of the component and the requirements for their design and manufacturing management are presented in YVL guides E-series. In addition, YVL A.3 contains requirements concerning ensuring the conformity of products and management of supply chain. As one example of component related requirements, Guide YVL E.9 states in paragraph 614: "*Construction plan shall give the pump design bases:*

- *highest allowable system pressure and temperature of the process system*
- *system flow requirement, pressure loss and back pressure*
- *available net positive suction head*
- *design basis operational, transient and accident conditions*
- *operability requirements*

- *loading and stresses exerted on the pump*
- *process, driving power and ambient conditions*
- *pump service life and number of start-ups during service life*
- *other service place-related pump requirements*."

And further on, paragraph 615 requires that "*The pump's design bases shall be determined in the scope of the requirements that have been set for the pump's operability in normal operation, during anticipated operational occurrences, postulated accidents, design extension conditions and severe reactor accidents*."

YVL E.9 Loadings and stresses shall be presented to the extent they are considered the pump's design bases. They typically include

- forces and moments exerted by piping and supports
- mechanical and thermal load fluctuations
- exceptional connection situations of the drive
- impact loading (accelerations caused by pipe breaks and seismic events)
- ambient conditions (temperature, humidity, radiation).

As per limits and loadings, defining the above design basis includes that. For pressure components, YVL E.4 states about service loadings and design loadings:

"*Design loadings, to be determined in accordance with the applicable standard, comprise design pressure, design temperature and other mechanical design loads which in combination with design pressure produce the highest primary stresses in normal operational conditions. (405)*

Service loadings relate to a nuclear power plant's design-basis normal operational conditions, anticipated operational occurrences and postulated accidents as well as to internal and external events. For each item of pressure equipment to be analysed, the service conditions shall be determined for those conditions and events where integrity or operability is required of the item of pressure equipment. (406)"

In general, Section 5 of the STUK regulation 1/Y/2018 requires considering aging phenomena of the whole lifecycle in the design, construction, condition monitoring and maintenance. In addition, "*Systematic procedures shall be in place for preventing such ageing of systems, structures and components which may deteriorate their availability, and for the early detection of the need for their repair, modification and replacement. Safety requirements and applicability of new technology shall be*

periodically assessed in order to ensure that the technology applied is up to date, and the availability of the spare parts and the system support shall be monitored." In addition, the Guide YVL A.8 sets more detailed requirements for aging management.

Both the internal and external hazards shall be taken into account in the design. STUK regulation 1/Y/2018 sets forth the high-level requirements in sections 14 and 15: "*The design of a nuclear facility shall take account of external hazards that may endanger safety. Systems, structures, components and access shall be designed, located and protected so that the impacts of external hazards deemed possible on nuclear facility safety remain minor. The operability of systems, structures and components shall be demonstrated in their design basis external environmental conditions.*

The design of a nuclear facility shall take account of any internal hazards that may endanger safety. Systems, structures and components shall be designed, located and protected so that the probability of internal hazards remains low and impacts on nuclear facility safety minor. The operability of systems, structures and components shall be demonstrated in the room specific environmental conditions used as their design bases."

The internal hazards to be considered are at least the following: *"fire, flood, explosion, electromagnetic radiation, pipe breaks, container ruptures, drop of heavy objects, missiles due to explosions or component failures, and other possible internal hazards. The design shall also consider unlawful and other unauthorised activities compromising nuclear safety*." Hence this covers also the potential harmful effects from system to another, in addition to the other requirements discussed above. The Guide YVL B.7 expands further on the protection against the internal and external hazards whereas Guide YVL B.8 is dedicated to fire protection requirements.

Also the Guide YVL B.1 contains some topical requirements concerning protection against hazards and spreading of faults especially in sections 5.2 I&C Systems, 5.3 Control rooms and 5.4 Electrical power systems, for example EMC protection. As for disturbances from the grid, requirements 5407 and 5408 state that: "*Plant-specific frequency and voltage variations caused by an external grid, and those caused by electrical components or failures of the plant, shall be analysed*.

Frequency and voltage fluctuations analysed according to the requirement 5407 shall not endanger the safety functions during normal operation, anticipated operational occurrences or accidents."

The requirement to separate the systems is based on the defence in depth and divitional separation requirements. Defence-in-Depth (DiD) is discussed in Primary Question 7. In addition to the STUK

regulation 1/Y/2018 presenting requirements on DiD also YVL B.1 elaborates them. Requirement 426 states that "*Independence between the levels of defence shall be based on the adequate application of functional isolation, the diversity principle and physical separation*". An example of separation requirements is: "The safety divisions hosting redundant parts of safety systems shall be located in different buildings or housed in dedicated compartments to separate them from the other safety divisions in the same building in order to prevent faults from spreading from one redundant system part to another as a result of internal events (e.g. fire, flood or dynamic effects) or external events.". Sections 4.3.1 and 4.3.2 set also other requirements related on independence of DiD levels and separation of systems and divisions. Especially the Guides YVL B.7 and B.8 also include requirements with the aim of achieving separation as they present detailed requirements for prevention of spreading of hazards.

Finally, regarding failure of equipment, regulation STUK 1/Y/2018 states: "*If inherent safety features cannot be utilized in ensuring a safety function, priority shall be given to systems and components which do not require a power supply or which, in consequence of a loss of a power supply, will settle in a state preferable from the safety point of view*."

Question 14 Does the regulatory framework include requirements relating to the potential for common cause failures and single failure criterion?

Answer: Yes

Response:

According to the STUK regulation 1/Y/2018 Section 11 Paragraph 5: "*Common cause failures shall only have minor impacts on nuclear power plant safety*." More concrete requirements follow from the fact that in the Finnish regulatory framework defines an event category DEC A to be a common cause failure in any safety system combined with an anticipated operational occurrence or class 1 postulated accident; see Primary Question 15. In addition, YVL B.1 requires that a common cause failure of any individual component type shall not prevent reaching a controlled state or safe state of the plant

However, there are also direct diversification requirements for some systems or functions in YVL B.1: reactor shutdown (446), residual heat removal (449), reactor protection system (5228a), heat sink (5102), emergency power supply (5426a) and preferably for the power distribution systems (451). In addition, YVL B.5 requires diversity principle to be "*applied in the design of the pressure control systems of the reactor cooling system to reduce the likelihood of common cause failures*" (402). Diversification of the isolation valves that are located in series is explicitly required by YVL B.6 (323).

YVL B.1 351 also requires failure tolerance analyses including common cause failure analyses: "*The fulfilment of the failure criteria of systems implementing safety functions and their support systems as*

well as common cause failures shall be assessed by means of failure tolerance analysis when designing the systems or their modifications. If necessary, analyses shall be performed in more detail in different stages of design." Further details on analyses are included in requirements 352 and 353.

The systems that are necessary for bringing the nuclear power plant to the controlled state in postulated accidents shall perform their function "*even if any individual component of a system providing the safety function is inoperable and even if any other component of a system providing the same safety function or of a supporting system necessary for its operation is simultaneously inoperable due to the necessity for its repair, maintenance or testing*" (STUK regulation 1/Y/2018). This is brought to on more detailed level for the main fundamental safety functions in YVL B.1 concerning reactor shutdown (445) and residual heat removal (448).

The single failure criterion is to be applied to several functions:

- limitation functions (YVL B.1 456, 445, 448, YVL B.5 416)
- systems required to reach a safe state after a postulated accident or DEC A (YVL B.1 455)
- diverse safety functions (see above DEC A related requirements)
- severe accident management systems (YVL B.1 456b, 5235a, 5426b, YVL B.5 420, YVL B.6 337)
- containment isolation mostly (YVL B.6, YVL B.1 456e)
- other various functions (YVL B.1 456a -d 5105, YVL B.6 316.
- fuel pool cooling (YVL D.3)

It is also required in YVL B.1 442 that "*The failure criterion shall be applied to the complete train of systems consisting of the safety system and all auxiliary systems that are needed to perform the safety function. Such auxiliary systems include equipment cooling and power supply, as well as the systems controlling such functions. The (N+2) or (N+1) failure criterion, as defined herein, shall be used as the failure criterion*."

Question 15 Does the regulatory framework include requirements relating to safety assessment and safety analysis of NPPs with, in particular, consideration of margins against cliff-edge effects and early or large radiological releases?

Answer: Yes

Response:

STUK regulation 1/Y/2018 section 3 paragraph 1 sets forth a requirement for safety assessments: "*The safety of a nuclear facility shall be assessed when applying for a construction license and operating license, in connection with plant modifications, and at Periodic Safety Reviews during the operation of the plant. It shall be demonstrated in connection with the safety assessment that the nuclear facility has*

been designed and implemented in a manner that meets the safety requirements. The safety assessment shall cover the operational states and accidents of the plant. The safety of a nuclear facility shall also be assessed after accidents and, whenever necessary, on the basis of the safety research results." Paragraph 5 sets a similar requirement for decommissioning phase of a nuclear facility.

According to the same section, "*The nuclear facility's safety and the technical solutions of its safety systems shall be assessed and substantiated analytically and, if necessary, experimentally*." It is also required that "*The analytical methods employed to demonstrate compliance with the safety requirements shall be reliable, verified and validated for the purpose. The analyses shall demonstrate the conformity with the safety requirements with high certainty. Any uncertainty in the results shall be considered when assessing the meeting of the safety requirements*."

YVL B.1 Chapter 3.6 Justification for the choice of design solutions expands on these and requires both deterministic and probabilistic methods to be applied. Detailed requirements concerning the deterministic safety analyses are given in Guides YVL B.3 and YVL B.5. Detailed requirements concerning the probabilistic risk assessment are given in Guide YVL A.7. YVL B.3 requirement 302 states that "*The scope of the analysed events shall provide a comprehensive assessment of the nuclear power plant's behaviour during incidents and accidents as well as releases and doses due to incidents and accidents*." The guide YVL B.3 also specifies that sensitivity analyses shall be performed if conservative analyses are performed whereas uncertainty analyses are to be combined to using best-estimate methodologies (409, 410). The guide YVL A.7 sets forth a direct requirement for assessing potential cliff-edges: "*The frequency of events exceeding the plant design bases and their impact on safety systems as well as potential losses of safety functions shall be analysed in the PRA. The analysis shall also take into account situations during which the minor exceeding of a design basis could result in significant impairment of safety, i.e. the so-called cliff edge phenomena. Cliff edge phenomena might be caused…."*

The Finnish regulatory framework defines event categories DEC A, DEC B and DEC C as design extension conditions with the acceptance criterion of avoiding the core melt. The even categories of these are discussed in Primary Question 15. Hence these event categories cover cliff-edge effects near the design basis.

Large and early releases are to be practically eliminated. According to the Nuclear Energy Decree Section 22b "*In order to limit the long-term restrictions, the limit for atmospheric release of caesium-137 shall be 100 terabecquerels. The possibility of exceeding the limit shall be extremely small.*

The possibility of a release occurring at an early phase of an accident and requiring population protection measures shall be extremely small."

On the level of YVL Guides, the "extremely small" refers to practical elimination. In YVL B.1 it is both required that evens leading to a release measures to protect the population in the early stages of the accident and vents leading to a large release to be practically eliminated (423, 423a). The requirement 424 also states that the frequency of the event shall not be the only justification to exclude it from consideration: "*Events to be practically eliminated shall be identified and analyzed using methods based on deterministic analyses complemented by probabilistic risk assessments and expert assessments. Practical elimination cannot be based solely on compliance with a cut-off probabilistic value. Even if the probabilistic analysis suggests that the probability of an event is extremely low, all practicable measures shall be taken to reduce the risk*."

YVL A.7 sets the probabilistic goals for practical elimination:

"*A nuclear power plant unit shall be designed in compliance with the principles set forth in Section 22 b of the Nuclear Energy Decree (161/1988) in a way that*

a) the mean value of the frequency of a release of radioactive substances from the plant during an accident involving a cesium-137 release (Cs-137) into the atmosphere in excess of 100 TBq is less than 5·10 -7/year;

b) the accident sequences, in which the containment function fails or is lost in the early phase of a severe accident, have only a small contribution to the reactor core damage frequency.

Release assessments shall take into account all of the nuclear fuel located at the plant unit. A spent nuclear fuel storage external to the plant unit is considered a separate nuclear facility that must meet the requirement laid down in item a"

In addition, YVL C.3 requirement 310 provides a related requirement concerning the analyses to demonstrate fulfillment of the release limits.

Question 16 Does the regulatory framework require that the design establish a set of operational limits and conditions for the safe operation of the NPP?

Answer: Yes

Response:

Operational Limits and Conditions (OLC) shall be submitted to STUK for approval when the licensee applies for the operating license as per YEA 161/1988 Section 36. The Section 36 states that the OLC shall at least define the limits concerning the process variables affecting safety of the nuclear facility, give operability requirements or operational restrictions in case of inoperability of the systems, structures or components (SSC) and give requirements for the testing of the SSC important for safety.

Further requirements are given in STUK Regulation STUK Y/1/2018 Section 22, which requires that the OLC of a nuclear facility shall include the technical and administrative requirements to ensure that the nuclear facility's operation is in compliance with the design bases and the assumptions of safety analyses. It also requires that the requirements for ensuring the availability of the SSC important to safety, as well as the limitations that are to be complied with when they are unavailable, shall also be included in the OLC.

In addition to the above mentioned, Guide YVL A.6 chapters 7.5 and 7.6 give more detailed requirements concerning the preparation, the contents and the practices pertaining to the OLC. Regarding the contents of the OLC these requirements include, among others, the process parameter limits that are critical in terms of the integrity of the barriers and the limits for the activation of protection and limitation systems. Also, the basic requirements for the safety systems to be complied with in different operational states, the operability requirements or restrictions, the actions to be taken in case of unavailability, and the time allowed to complete these actions shall be covered in the OLC. Furthermore, the chapter 7.5 gives requirements for the contents of the OLC regarding the periodic testing, inspection, surveillance, and preventive maintenance programmes for ensuring the operability of the SSC.

Question 17 Does the regulatory framework include requirements relating to consideration of postulated initiating events for the design of NPPs?

Answer: Yes

Response:

Under Section 3 of STUK regulation STUK Y/1/2018, it is stated that: *The nuclear facility's safety and the technical solutions of its safety systems shall be assessed and substantiated analytically and, if necessary, experimentally. The analyses shall be maintained and revised as necessary, taking into account operating experience from the plant itself and from other nuclear facilities, the results of safety research, plant modifications, and the advancement of calculation methods*."

Guide YVL B.1 requires that: "*The nuclear power plant design shall take into account events that may cause a deviation of the plant parameters from normal values and threaten integrity of the nuclear fuel or other barriers. Such events may be caused, for example, by a rupture in pressure equipment or piping; a component failure; a fault in the plant's operation or automatic control; or an internal or external threat*."

The Guide YVL B.3 concerns the deterministic safety analyses and states that the events to be analysed shall cover all categories and plant states. "*Analyses pertaining to the plant's behaviour as well as releases of radioactive substances and radiation doses caused by the releases shall cover the nuclear power plant's normal operational states, anticipated operational occurrences, postulated accidents, design extension conditions and severe reactor accidents. Examples of the events to be analysed are given in [4 and 5]*." (The references related to examples of events are IAEA documents (Safety Assessment for Facilities and Activities, General Safety Requirements. IAEA Safety Standards Series No. GSR Part 4 (Rev.1). IAEA, Vienna 2016, Deterministic Safety Analysis for Nuclear Power Plants. IAEA Specific Safety Guide No. SSG-2. IAEA, Vienna 2009))

According to the requirement: 302 "*The scope of the analysed events shall provide a comprehensive assessment of the nuclear power plant's behaviour during incidents and accidents as well as releases and doses due to incidents and accidents*." (302)

Question 18 Does the regulatory framework include requirements relating to consideration of design basis accidents for the design of NPPs?

Answer: Yes

Response:

According to Section 7 d of the Nuclear Energy Act (990/1987), "*the design of a nuclear facility shall provide for the possibility of operational occurrences and accidents. The probability of an accident must be lower, the more severe the consequences of such an accident would prove for people, the environment or property*."

As defined in the Nuclear Energy Decree, the initiating events are required to be classified according to their frequency of occurrence to operational occurrences ($f \geq 1/100$ years), class 1 design basis accidents ($1/1000 \leq f < 1/100$) and class 2 design basis accidents ($f < 1/1000$). The Decree's Section 22b also sets forth the dose constraints for all of the event categories:

"*The annual dose constraint for the member of the public arising from the normal operation of a nuclear power plant and other nuclear facility equipped with a nuclear reactor shall be 0.1 mSv. The*

annual dose constraint for the member of the public arising from the planned decommissioning of a nuclear power plant and other nuclear facility equipped with a nuclear reactor shall be 0.01 mSv.

As a result of an anticipated operational occurrence, the annual dose constraint for the member of the public shall be 0.1 mSv.

The annual dose constraint for the member of the public shall be 1 mSv in the Class 1 postulated accidents, 5 mSv in the Class 2 postulated accidents and 20 mSv in the design extension condition."

These criteria are then referred to when setting the requirements for systems performing safety functions in any of the event classes. These requirements have been referred to under Primary Question 14, hence hereby only an example is presented (requirement 448a):

"It shall be possible to accomplish decay heat removal from the reactor and containment in postulated accidents by one or several systems that jointly meet the (N+2) failure criterion and the 72-hour self-sufficiency criterion in such a way that the limits set forth for fuel integrity, radiological consequences and overpressure protection in class 1 or class 2 postulated accidents are not exceeded. If the decay heat removal systems or their auxiliary systems have passive components that have a very low probability of failure in connection with the anticipated operational occurrence or postulated accident, the (N+1) failure criterion may be applied to those components instead of the (N+2) failure criterion." Requirements concerning the other safety functions referred to are of the same format, i.e. reference is made to acceptance criteria.

The other acceptance criteria than doses are presented at the lower level, i.e. in YVL Guides. Guides YVL B.5 Chapters 4.2-4.4 and YVL B.3 set the criteria for pressure control and overpressure, e.g.: "*The acceptance criterion for the overpressure protection in postulated accidents is that the pressure of the object to be protected stays below 1.1 times the design pressure of the protected object*.(YVL B.3 615)".

Chapters 4.4 and 4.5 set the acceptance criteria for the nuclear fuel, for example (415):

In anticipated operational occurrences, the nuclear fuel shall fulfil the following conditions:

- *No melting shall occur in fuel pellets.*

- *Adequate cooling of the cladding shall be ensured. Cooling of the cladding is considered adequate if there is a 95% probability at 95% confidence level that the hottest fuel rod does not reach heat transfer crisis. Alternatively, it may be demonstrated that the number of rods reaching heat transfer crisis does not exceed 0.1% of the total number of fuel rods in the reactor.*
- *The probability of fuel failure caused by mechanical interaction between fuel and cladding shall be extremely low*.

There dedicated acceptance criteria for fuel in class 1 postulated accidents and in class 2 postulated accidents, that are set forth in the above mention Chapters of Guide YVL B.3.

Question 19 Does the regulatory framework include requirements relating to consideration of design extension conditions for the design of NPPs?

Answer: Yes

Response:

In the Finnish framework, design extension conditions are divided in three categories that shall be provided for in such way that a severe fuel failure is avoided (i.e. without core melt).

According to the Nuclear Energy Decree "*Design extension condition shall refer to:*

a. an accident where an anticipated operational occurrence or class 1 postulated accident involves a common cause failure in a system required to execute a safety function; [DEC A]

b. an accident caused by a combination of failures identified as significant on the basis of a probabilistic risk assessment; [DEC B] *or*

c. an accident caused by a rare external event [DEC C] *and which the facility is required to withstand without severe fuel failure.*"

The DEC A is a specific category where diversification of safety functions is expected in such a way that the diverse systems fulfil the single failure criterion (YVL B.1 e.g. req. 421b, 446, 448a,…) and are safety class 3 (YVL B.2).

In addition to the failure combinations recognized as significant based on probabilistic risk assessment, DEC B category shall include "such failure combinations or additional failures that emerge during the

initiating event, and could significantly affect the integrity of fuel, the radiological effects of the accident or primary circuit pressure shall be considered"

Severe accidents are considered a separate accident category to be taken into account in the design. According to the Nuclear Energy Act "*The release of radioactive substances as a result of a severe accident at a nuclear power plant shall not necessitate implementation of large-scale protective measures for members of the public or any long-term restrictions on the use of extensive areas of land and water*."

In addition, Nuclear Energy Act requires that "*in order to limit the long-term restrictions, the limit for atmospheric release of cesium-137 shall be 100 terabecquerels. The possibility of exceeding the limit shall be extremely small. The possibility of a release occurring at an early phase of an accident and requiring population protection measures shall be extremely small*." The term "extremely small" refers to practical elimination which is specifically mentioned in the guides YVL A.7 and B.1, for example. There are probabilistic goals as well as deterministic requirements set for assessing and designing practical elimination means in the YVL guides, especially in the two mentioned.

Requirements for systems design for design extension conditions and severe accidents are set in Radiation and Nuclear Safety Authority Regulation on the Safety of a Nuclear Power Plant STUK Y/1/2018 and YVL Guides, most specifically in YVL B.1 but the other B-series guides contain some requirements as well. As stated above, a DEC A is an category aims for diversification of systems performing safety functions in anticipated operational occurrences and class 1 postulated accidents.

Requirements for systems necessary for mitigation of DEC B and DEC C are less strict than for DEC A: no additional single failure needs to be postulated and systems performing safety functions can be "EYT" (not safety classified). YVL B.1 and YVL B.2 set the the requirements for the systems, e.g. "*It shall be possible to carry out the removal of residual heat from the reactor outside the containment in rare external events (DEC C) so that that the limit values set for fuel integrity, radiological consequences and overpressure protection are not exceeded under design extension conditions. Systems needed in the events shall be stationary and meet the self-sufficiency criterion. Measures related to the use of the systems and conducted at the plant site shall not require the use of vehicles during the first eight hours. Components designed for use shall be accessible even if any individual route or hatch were blocked by an external obstacle. It is not necessary to apply the single failure criterion to the arrangements*."

According to the STUK Y/1/2018 “the systems needed for reaching and maintaining a controlled state and the monitoring of the progress of an accident and the plant’s status in severe reactor accidents in a nuclear power plant shall be independent of the systems designed for normal operation, anticipated operational occurrences and postulated accidents. The leaktightness of the containment during a severe reactor accident shall be reliably ensured.” Also, “The nuclear power plant shall be designed so that it can be reliably brought into a safe state after a severe reactor accident.” YVL guides present the more detailed requirements for the system design: the systems required for reaching the controlled state shall be single failure tolerant and be classified to SC3 in addition to the above. Reaching the safe state (i.e. final depressurisation of the containment) can be performed non-classified systems but it shall be be demonstrated they are either qualified to severe accident conditions or repairable (YVL B.6).

The default is the power plant units to have their own safety functions for any given accident class. However it is recognised some sharing may be necessary or even beneficial, and hence YVL B.1 req 411 states that “*If shared structures, systems and components important to safety are designed for nuclear power plant units and fuel storage facilities located at the same plant site, it shall be demonstrated that the solution is beneficial for the plants’ safety. Fault propagation through shared structures, systems and components shall be prevented. The functions needed by each unit shall, when necessary, be implemented also in the event of a transient or accident occurring simultaneously at the plants*.”

Question 20 Does the regulatory framework include requirements relating to consideration of internal and external hazards for the design of NPPs?

Answer: Yes

Response:

Regarding the external events, see answer to QID 12.

Radiation and Nuclear Safety Authority Regulation on the Safety of a Nuclear Power Plant (STUK Y/1/2018) Section 15 titled “Protection against internal hazards affecting safety” has the following requirements:

1. *The design of a nuclear facility shall take account of any internal hazards that may endanger safety. Systems, structures and components shall be designed, located and protected so that the probability of internal hazards remains low and impacts on nuclear facility safety minor. The operability of systems, structures and components shall be demonstrated in the room specific environmental conditions used as their design bases.*
2. *Internal hazards to be considered include at least fire, flood, explosion, electromagnetic radiation, pipe breaks, container ruptures, drop of heavy objects, missiles due to explosions or component failures, and*

other possible internal hazards. The design shall also consider unlawful and other unauthorised activities compromising nuclear safety.

YVL Guide B.7 includes more specific requirements regarding the internal hazards. In the chapter 3.2, titled "Protection of the nuclear facility against internal hazards", more detailed list of internal hazards that at least have to be considered is presented and specific requirements for different internal hazards are given. Design, layout and classification requirements for individual internal hazards are also given in other YVL Guides as presented in the YVL Guide B.7 requirement 319.

Question 20.1 What are the requirements relating to the specifities of multiple unit plant sites regarding external hazards?

Response:

Radiation and Nuclear Safety Authority Regulation on the Emergency Arrangements of a Nuclear Power Plant (STUK/Y/2/2018) Section 3 about the design basis for the planning of emergency arrangements has a requirement:

2. Planning shall take account of a simultaneous threat to nuclear safety occurring in all nuclear facilities in the site area and their potential consequences, especially the radiation situation on the site and in the surrounding area and the opportunities to access the area.

YVL Guide B.7 Requirement 108 stipulates: *The following general principles apply to solutions implemented for protection against internal and external hazards*:

…

- *The possible simultaneous effect of external events on parallel and diverse (sub)systems, several systems, structures and components, several nuclear power plant units and other nuclear facilities located on the same site, the regional infrastructure, material deliveries from outside the plant site and the implementation of countermeasures is taken into account.*
- *The sufficiency of personnel and other resources is ensured considering the use of shared equipment and personnel at several nuclear power plant units and other nuclear facilities located on the same site.*

YVL Guide B.7 Requirement 302 stipulates: *The site area layout design shall take into account the possibility of simultaneous accidents at several facility units.*

Question 20.2 What are the requirements relating to the margin against external hazards?

Response:

The general principles are presented in the requirement 503 of the YVL Guide B.7:

The following general principles shall be followed in selecting design values for systems, structures and components important to safety that pertain to external events and conditions:

a. Design values shall include an adequate margin in relation to the peak values measured at the facility site and in its vicinity.

b. In determining design values, at least phenomena whose estimated probability of occurrence at the site over one year is higher than 10^{-5} at a median confidence level shall be considered.

c. *If it can be reliably demonstrated that an external event or condition does not affect the probability of occurrence of a certain postulated accident, the design value regarding the external event or condition in question can be chosen for the systems required for the management of the postulated accident so that its maximum probability of exceedance in one year is 10^{-4}.*

d. *The safety significance of systems, structures and components important to safety shall be considered in selecting their design values, and the adequacy of the design values shall be justified.*

More extreme events are considered as design extension condition events as required in the requirement 506 of YVL Guide B.7.:

Exceptional external events and conditions with an estimated frequency of occurrence less than 10^{-5}/year shall be considered design extension conditions (DEC C events). The licence applicant/licensee shall present and justify external phenomena considered as DEC C events. In selecting the phenomena and their magnitude, the limit values for core damage and large release frequency presented in Guide YVL A.7 shall be taken into account. To be incorporated in the DEC C design values is a justified marginal in relation to the observed maximum values of the phenomena analysed.

The margin in relation to measured peak values for both the design values and DEC -values is required because of the uncertainties in frequency estimations. When evaluating the adequacy of the margin the

at least the following are considered: uncertainties related to frequency estimation, safety relevance of the consequences and cliff-edge considerations.

In Finland PRA/PSA for seismic events and other external events is mandatory according to YVL Guide A.7. Both deterministic and probabilistic considerations are used in evaluating safety margins against external events.

Question 21 Does the regulatory framework include requirements relating to the design of the reactor core and associated features for NPPs?

Answer: Yes

Response:

Section 10, paragraph 3 subparagraph a) of the Regulation on Nuclear power plant safety (STUK Y/1/2018) sets the fundamental requirements for fuel integrity: the probability of fuel failures during normal operating conditions and anticipated operational occurrences shall be low, and the rate of fuel failures shall be limited and fuel coolability not endangered in postulated accidents. Section 12 paragraph 3 requires that damage to the cladding of the fuel rods during handling (and storage) must be prevented. A more detailed guidance to the phenomena and processes of deterioration of fuel elements to be taken into account in setting the fuel design limits and performing fuel analyses together with the acceptance criteria is provided in the YVL Guide B.4 “Nuclear fuel and reactor”. Sections 4.2 and 4.3 of YVL B.4 deal with normal operation, section 4.4 with anticipated operational occurrences and section 4.5 with design basis and design extension accident conditions. SSR-2/1 Requirement 44 about maintaining a geometry that allows for adequate cooling and the insertion of control rods is included in the YVL B.4 sections mentioned above.

Inherent stability of the reactor core is required in Section 11 paragraph 1 of STUK Y/1/2018 specifically mentioning a negative combined effect of feedback parameters. This is repeated in a more detailed form in the YVL Guide B.4 requirement 303. Section 16 paragraph 1 states that a nuclear facility shall contain equipment that provides information on the operational state of the facility and any deviations from normal operation. Specific requirements for nuclear instrumentation are detailed out in YVL Guide B.1 “Safety design of a nuclear power plant” requirements 5215 and 5216. The instrumentation shall provide information for determining the core power distribution and thermal margins, as well as detecting any abnormal conditions.

The requirement for control rods to endure the wear and stresses of normal operation and retain their capability to absorb neutrons is stated in YVL Guide B.4 requirement 410. YVL Guide B.4 requirement 304 and 306 limit the amount of positive reactivity that may be introduced by the malfunctioning of reactivity control systems or weakening of the efficiency of neutron absorbers.

The fundamental requirement for the capability to shut down the reactor and maintain subcriticality also if any individual component is inoperable and another component is under repair, maintenance or testing is set in Section 11 paragraphs 3 and 4 of STUK Y/1/2018. According to YVL Guide B.1 requirements 445 and 445a there shall be a shutdown system based on solid neutron absorbers (control rods), which is capable of shutting down the reactor and maintaining it subcritical in operational and accident conditions so that the acceptance criteria for fuel integrity are not exceeded. One stuck control rod, and a single failure and maintenance or repair in reactor protection I&C initiating shutdown must be taken into account. Requirement 446 calls for a diverse shutdown system fulfilling the single failure criterion, and requirement 447 for the possibility to shut down the reactor also in design extension conditions. Requirement 454 concerns keeping the reactor subcritical in all possible temperatures also without the control rods.

YVL Guide B.4 requirement 509 and 510 state that during shutdown and refueling inadvertent criticality of nuclear fuel in a nuclear reactor shall be prevented primarily by technical means, and that during refueling neutron flux and the possible boron concentration of the coolant shall be monitored.

Safety guide NS-G-1.12 (Design of the Reactor Core for Nuclear Power Plants) was used as a reference when writing YVL Guide B.4. Some issues in NS-G-1.12 are covered by other YVL Guides, such as YVL Guide B.1 and YVL Guide B.3 “Deterministic safety analyses for a nuclear power plant”.

Question 22 Does the regulatory framework include requirements relating to the design of the reactor coolant systems for NPPs?

Answer: Yes

Response:

In Radiation and Nuclear Safety Authority Regulation on the Safety of a Nuclear Power Plant (STUK Y/1/2018) section 10 are set requirements for physical barriers to the release of radioactive material to the environment. Reactor coolant system (RCS) being one of these physical barriers the requirements for this are set in paragraph 3 b). The purpose of the requirements is that RCS is designed, manufactured, installed and operated in such a way that probability of fast fracture that can lead to early release or large release is extremely low. To achieve this, it is required that RCS is designed and manufactured in compliance with high quality standards, that inspections (NDT testing) can be performed to detect any faults, that RCS withstands loads from operational states and accidents with sufficient margins, that RCS is protected from overpressure, that water chemistry conditions in RCS are such that they do not result in mechanisms that threaten integrity of RCS and that there is reliable leak detection system.

More detailed requirements are given in guides YVL B.5 and YVL E.3. For example, break preclusion and leak-before-break principles can be used in the design of RCS and if these principles are not applied, then pipe whip restraints and other structures shall be used to limit the effects of RCS pipe break. Also detailed requirements for overpressure protection and water chemistry are given in guide YVL B.5.

Requirement, that nuclear power plant shall have systems to remove residual heat from reactor, is given in Regulation STUK Y/1/2018 section 11 paragraph 3. More detailed requirements for design of systems are given in guides YVL B.1 and B.5. According to guide YVL B.1 requirement 5101, nuclear power plant must have systems to remove residual heat from reactor to ultimate heat sink in operational and accident states and that meet the design requirements (redundancy, separation and diversity) given in section 4 of guide YVL B.1. To control primary coolant inventory, nuclear power plant must have coolant volume control system that fulfills single failure criterion (YVL B.1, 5105). It is also re-quired that nuclear power plant has an emergency core cooling system to compensate leakages from RCS (YVL B.1, 5108, 5109 and 5111). Design basis for this system is break of largest pipe in RCS (YVL B.5 305).

To clean primary coolant from radioactive substances, nuclear power plant must be equipped with a cleaning system and that this system is de-signed to operate in all operational states (YVL B.5 507).

Question 22.1 What are the requirements relating to the heat transfer to an ultimate heat sink?

Response:

As said in the answer to primary question 22, according to guide YVL B.1 requirement 5101, nuclear power plant must have systems to remove residual heat from reactor to ultimate heat sink in operational and accident states. In case the primary heat sink is unavailable, it is required that the design also includes a second ultimate heat sink (YVL B.1, 5102). This second ultimate heat sink must fulfill so called 72 hour self-sufficiency criterion: the system must be able to function for the first 24 hours without any material replenishments (water, fuel, etc.) and for the following 48 hours the necessary material reserves must be at the plant site. Similar requirement existed in YVL guides already but after Fukushima accident it was written more clearly.

Question 23 Does the regulatory framework include requirements relating to the containment structure and the containment system for NPPs?

Answer: Yes

Response:

The requirement regarding the containment as part of the functional defense-in-depth principle is stated in Section 9, paragraph 2 of the Regulation on Nuclear power plant safety (STUK Y/1/2018). It is

required that a nuclear power plant shall be equipped with systems ensuring sufficient leak-tightness of the containment in severe reactor accidents, so that the release limits stipulated in Section 22(b) of Nuclear Energy Decree (161/1988) are not exceeded. Section 10, paragraphs 3 and 4 of STUK Y/1/2018 set out the requirements for ensuring structural integrity of the containment.

Detailed requirements are set out in the YVL Guide B.6 “Containment of a nuclear power plant”. Requirement 301 of YVL B.6 specifies the basic functions of the containment, and it is essentially the same as requirement 54 of Safety Standards Series No. SSR-2/1. The provisions for leak-rate testing, integrity and reaction-force protection of the containment penetrations presented in Requirement 55 of SSR-2/1 are set out in the YVL B.6 requirements 314, 317, 318 and 319. Requirements corresponding to Requirement 56 of SSR-2/1 on containment isolation are included in Section 3.6 of YVL B.6. Requirements for airlocks and hatches providing access and sealability are given in YVL B.6 Section 3.5.

The detailed requirements for managing containment pressure and temperature in accident conditions are presented in Section 3.8 of YVL Guide B.6. Combustible gases and energetic phenomena are addressed in Section 3.9. These requirements are not a repetition of the Requirement 58 of SSR-2/1, but the YVL Guide requirements meet the same level of safety (with the exception of 6.28B). The requirements of YVL B.6 are supplemental to YVL B.1 “Safety design of a nuclear power plant”, since most of the requirements for safety functions, such as failure tolerance, diversity and self-sufficiency, are presented in YVL B.1.

The safety guide NS-G-1.10 has been acknowledged as a type of model guide during development of the YVL Guide B.6. However, NS-G-1.10 is more extensive because many of the topics covered by the guide are distributed in several YVL Guides within the Finnish regulatory framework. For example, YVL Guide E.6 “Buildings and structures of a nuclear facility” includes requirements for structural materials, structural analyses and inspections of the containment. Section 6.7 of YVL E.6 provides a list of applicable standards for design, manufacturing and quality control of containment structures.

Question 23.1 What are the requirements relating to the prevention of the loss of the structural integrity of the containment?

Response:

According to the Regulation on Nuclear power plant safety (STUK Y/1/2018), Section 10, paragraph 3, the containment shall be designed to maintain its integrity during anticipated operational occurrences and, with a high degree of certainty, during all accident conditions. This includes severe reactor accidents with core melt. Pressure, radiation and temperature loads, radiation levels on plant premises, combustible gases, impacts of missiles and short-term high energy phenomena resulting from an

accident shall be considered in the design of the containment. It is also required that the possibility of losing the containment function as a result of reactor pressure vessel failure shall be extremely low (RPV rupture with high primary pressure shall be ruled out by the design).

Section 10, paragraph 4 of Regulation STUK Y/1/2018 requires that a nuclear power plant shall be equipped with systems to ensure the stabilisation and cooling of molten core material generated during a severe accident. The possibility of direct interaction of molten core material with the load bearing containment structure shall be extremely low.

Question 23.2 What are the requirements relating to features to restore the capability to remove heat from the containment?

Response:

Paragraph 8 of Section 11 of the Regulation on Nuclear power plant safety (STUK Y/1/2018), which concerns safety functions, requires that a nuclear power plant shall have systems for reaching and maintaining a controlled state during a severe reactor accident. These systems shall be independent of the systems designed for normal operation, anticipated operational occurrences and postulated accidents. The function of containment heat removal in a severe accident shall be single-failure tolerant, so that no failure of any single component may result in the loss of the function. By design provisions, containment heat removal shall be ensured for the self-sufficiency time of 72 hours without water, fuel or any other material replenishments external to the plant site. (YVL B.6 337)

It is not required to use dedicated SAM systems for reaching and maintaining a safe state following a severe accident (SASS). Reaching safe state after a severe accident refers to permanent decrease of the containment pressure close to atmospheric pressure and stable cooling of the core debris. However, if the safe state is to be reached without independent SAM systems, the restorability, operability and capability of the non-independent systems to withstand the expected post-accident conditions has to be demonstrated. A typical example is a design in which the long-term cooling of the core debris relies on the restoration of emergency core cooling systems. (YVL B.6, 304a, 340b, 340c).

A nuclear power plant is expected to withstand rare external hazards, such as exceptional weather conditions and seismic events, with no severe damage to the reactor core. In rare external events, the containment heat removal shall be ensured by stationary (permanently installed) systems fulfilling the 72-hour self-sufficiency criterion (YVL B.1 450a). In addition, it is required that the operation of these systems at the plant site do not necessitate the use of vehicles for the first eight hours, and that the necessary components of the systems are accessible even if any individual route or hatch were blocked by an external obstacle.

To summarize, the existing design requirements for permanently installed containment heat removal systems consider rare external events, as well as foreseeable severe accident scenarios up to the time when core debris has continuous cooling and containment pressure is permanently close to atmospheric pressure. Thus, no additional requirements for the "safe use of non-permanent equipment" are necessary.

Question 24 Does the regulatory framework include requirements relating to the design of instrumentation and control systems for NPPs?

Answer: Yes

Response:

Req. 59: NPPs shall have equipment that provides information on the operational state of the facility and any deviations from normal operation (Y/1/2018 Section 16, item 1). Detailed requirements of which instrumentation is needed to monitor the parameters of the plant are given mainly in YVL Guide B.1 Section 5.2.3. and in several other YVL Guides (e.g. C.6: radiation monitoring, E.4: leak detection)

Req. 60: NPPs shall have first and second defense-of-depth level to ensure that the operation of the nuclear facility is reliable and deviations from normal operating conditions are rare (Y/1/2018 Section 9, item 2). Operational control system is explicitly required (YVL Guide B.1 Section 5.2.4)

Req. 61: NPPs shall have third defense-of-depth level to control the accident situations with automatically functioning systems (Y/1/2018 Section 9, item 2, Section 16 items 2 and 3). A protection system is explicitly required (YVL Guide B.1 5228).

Req. 62: NPPs shall provide necessary inspections, tests and maintenance to ensure that the systems important to safety are available as detailed in the design basis requirements (STUK Y/1/2018 Section 23), including the instructions for maintenance (STUK Y/1/2018 Section 20, item 2a). It shall be possible to periodically test the functionality of protection system, back-up protection system and control systems for severe accidents. In addition, the protection system shall be testable during the operation, ensuring the safety during the tests (YVL Guide B.1 Section 5.2.5)

Req. 63: Instrumentation and control equipment in safety class 2 and the equipment needed by the operators to restore and maintain the controlled state shall be primarily based on nuclear industry standards. In safety class 3, international I&C standards shall be used (Guide YVL E.7 311, 312).

Software in safety class 2 & 3 shall be developed and implemented by nuclear industry standards, but in safety class 3, applicable standards for safety-critical software may be applied as well (Guide YVL E.7 602, 602a). Additional detailed requirements on related to practices for the development and testing of safety classified computer systems' hardware and software are given in Guide YVL E.7 Section 4: Quality control in manufacturing, Section 5: Qualification and tests of I&C equipment and systems and Section 6: Qualification of software.

Req. 64: NPPs shall include different defense-in-depth levels for plant normal operation and control of deviations, and control of accident situations. These levels shall be as independent of one another as is reasonably achievable (Y/1/2018 Section 9, item 3). Failures of operational control systems shall not prevent the functionality of protection system (YVL B.1 Section 4.3.1) and failures of the operational control systems shall not degrade the plant state during the accidents (YVL B.1 Section 5.2.7). No network-based data transfer from other control systems are allowed to protection automation (A.12 Section 4.1 405d)

Req. 65: NPPs shall have a control room where the majority of the user interfaces required for the monitoring and control of the nuclear power plant are located (STUK Y/1/2018 Section 16, item 3a). YVL B.1 requirements 5209-5211, 5309-5312 give more specified requirements for enabling operating activity in the control room in all operational situations to maintain and bring the plant back to safe state. STUK Y/2018 §15 requires that systems, structures and components are protected according to their safety significance, this applies to control room as well as other SSC. B.1 requirement 5305 specifies requirements concerning protection of control rooms.

Req. 66: NPPs shall have a supplementary control room independent of the main control room to shut down the nuclear reactor and remove the decay heat from the fuel (STUK Y/1/2018 Section 16, item 4). More specific requirements relating to the independence and operating capability of the supplementary control room (emergency control room) are given in YVL B.1 section 5.3.3 requirements 5315 - 5318. YVL B.1 5305 specifies requirements concerning protection of control rooms, including supplementary control room.

Req. 67: Under Section 4(6–9) of Regulation STUK Y/2/2018, to manage emergency response operations, there shall be an emergency response centre, which shall be able to maintain proper working conditions during an emergency situation, and which shall also be available during prolonged power failures. There shall be a designated centre outside the site area from which to direct the plant's emergency response operations, if the emergency response centre is not available. There shall be reliable communication and alarm systems in place to manage emergency response operations for the purposes of internal and external communications of the nuclear power plant. The licensee shall ensure that there are automatic data transmission systems in place to send information essential in terms of the emergency operations to the emergency response centre of the Radiation and Nuclear Safety Authority.

In order to prepare for emergency situations, the nuclear power plant shall have premises, equipment, accessories and devices for the management, situation assessment, alerting, communications, data transfer and recording, planning and repair, fire protection, assembly and decontamination of personnel, first aid, dose monitoring as well as radiation measurements and laboratory activities to facilitate the operation of the emergency organisation.

Question 24.1 What are the requirements relating to margins vis-à-vis external hazards for the design of the control room?

Response:

The basis for the design of the systems against external hazards in general are in the Section 14 of STUK Regulation 1/Y/2018. The general principles as well as the detailed requirements regarding the protection of NPPs against external hazards are given in the Guide YVL B.7. The design requirements of the NPP systems are given in the Guide YVL B.1 where the design of the control room is concerned particularly in Chapter 5.3.1 and the ventilation systems in Chapter 5.5.1.

Guide YVL B.1 requirement 5305 states that the control room (as well as the emergency control room) shall be protected to permit working without protective equipment during normal operation and under accidents and threat conditions. Fire protection, protection against flooding, lighting, air conditioning and ventilation, noise abatement, radiation protection and access control shall be considered.

Guide YVL B.1 requirement 5511 states that the control room (as well as the emergency control room) shall be provided with isolating and filtering devices controlling supply air, and with measuring instruments to detect concentrations of radioactive and toxic substances. The storage and transportation of hazardous materials, threats and accidents on the plant site and in its surroundings shall be considered in the design.

Also, the requirement 456d of the Guide YVL B.1 relates the matter stating that systems necessary for maintaining safe working conditions in the control room shall satisfy the (N+1) failure criterion.

Question 24.2 What are the requirements relating to the design of emergency response facilities on the site?

Response:

Under Section 4(6–9) of Regulation STUK Y/2/2018, to manage emergency response operations, there shall be an emergency response centre, which shall be able to maintain proper working conditions during an emergency situation, and which shall also be available during prolonged power failures. There shall be a designated centre outside the site area from which to direct the plant's emergency response operations, if the emergency response centre is not available. There shall be reliable communication and alarm systems in place to manage emergency response operations for the purposes of internal and external communications of the nuclear power plant. The licensee shall ensure that there are automatic data transmission systems in place to send information essential in terms of the emergency operations to the emergency response centre of the Radiation and Nuclear Safety Authority.

In order to prepare for emergency situations, the nuclear power plant shall have premises, equipment, accessories and devices for the management, situation assessment, alerting, communications, data transfer and recording, planning and repair, fire protection, assembly and decontamination of personnel, first aid, dose monitoring as well as radiation measurements and laboratory activities to facilitate the operation of the emergency organisation.

More specific requirements relating to the premises, equipment, accessories and devices are given in Guide YVL C.5 paragraph 3.10.

Question 25 Does the regulatory framework include requirements relating to the design of the emergency power supply for NPPs?

Answer: Yes

Response:

In Regulation section 11 sentence 6: A nuclear power plant shall have off-site and on-site electrical power supply systems to cope with anticipated operational occurrences and accidents. It shall be possible to supply the electrical power needed for safety functions using either of the two electrical power supply systems.

In sentence 4 demand (N+2) redundant safety systems: …the most important safety functions necessary to bring the plant to a controlled state and to maintain it must be ensured in postulated accidents even if any individual component of a system providing the safety function is inoperable and even if any other component of a system providing the same safety function or of a supporting system necessary for its operation is simultaneously inoperable due to the necessity for its repair, maintenance or testing.

There shall be two separate, independent grid connections from the off-site grid to each of the redundant sections of the on-site power distribution system. Also, the NPP must be able to supply from the main generator to the NPP own systems in case the connection to the off-site grid is lost, as island operation. YVL B.1 5417 and 5402.

In YVL B.1 provision for DEC situation: The design of on-site emergency power supply shall provide for a common cause failure in the supply system during operational occurrences and class 1 postulated accidents when offsite electrical power supply is lost. The provisions can be implemented by complying with the diversity principle in the emergency power supply system, for example, or by designing an independent emergency power supply system in accordance with the diversity principle (5426a).

In YVL B.1 The power supply to the systems designed for managing severe reactor accidents shall be independent of all the other power supply units and power distribution systems of the plant (5415).

To assure the proper operation of components important to safety requiring uninterruptible power supply, the electrical power supply to such components shall be ensured by means of reliable battery-backed systems that secure an uninterrupted supply of power in the event of a disruption in the supply of alternating current power. The battery sets supplying loads important to safety shall be dimensioned to provide at least two-hour discharge time under the highest conceivable load and for severe accident management systems shall be dimensioned to provide a 24-hour discharge time.

Question 25.1 What are the requirements relating to the design of the alternate power source?

Response:

In case that all primary emergency power supply sources are lost it is design extension condition (DEC). For these cases in Regulation STUK Y/1/2018 section 11 sentence 7a: "*The nuclear power plant shall be so designed that, if necessary, it can be reliably brought into a safe state after an anticipated operational occurrence, a postulated accident or a design extension condition*." Consequently, the DEC power sources are needed.

In YVL B.1 the design of on-site emergency power supply shall provide for a common cause failure in the supply system … The provisions can be implemented by complying with the diversity principle in the emergency power supply system, for example, or by designing an independent emergency power supply system in accordance with the diversity principle. (B.1 5426a) So the emergency power sources,

and DEC power sources can be combined if sufficient diversity and independent principles have been applied.

For alternate power source (or independency power source) DEC A design requirements and acceptance criteria shall be applied. This mean that N+1 failure criterion shall be applied.

In addition of DEC systems, there shall be systems needed for reaching and maintaining a controlled state and the monitoring of the progress of an accident and the plant's status in severe reactor accidents (SA) in a nuclear power plant shall be independent of the systems designed for normal operation, anticipated operational occurrences and postulated accidents. The nuclear power plant shall be designed so that it can be reliably brought into a safe state after a severe reactor accident. (Regulation STUK Y/1/2018 section 11 sentence 8 and 9)

In order to manage SA, an on-site emergency power supply system shall be available that fulfills the (N+1) failure criterion and is independent of systems designed for normal operation, anticipated operational occurrences, postulated accidents and design extension conditions. (B.1 5426b) So the own SA power sources are needed. DEC and SA power sources can be combined, if this will not undermine the ability of the SA systems to perform their primary SA function in case the conditions evolve into a severe reactor accident. (B.1 431)

The on-site emergency power supply systems shall fulfill the 72-hour self-sufficiency criterion in postulated accidents and design extension conditions. (5427)

The on-site emergency power supply systems shall be dimensioned to start, switch on, receive loads and supply electrical power reliably even under extreme load conditions (e.g. start-ups or short circuits in power distribution sub-systems). (5431)

More detailed requirements regarding the equipment used for emergency power supply at nuclear power plants are specified in Guide YVL E.10.

Question 25.2 What are the requirements relating to situations where the alternating current (AC) power sources are lost?

Response:

To assure the proper operation of components important to safety requiring uninterruptible power supply, the electrical power supply to such components shall be ensured by means of reliable battery-backed systems that secure an uninterrupted supply of power in the event of a disruption in the supply of alternating current power (B.1 5441).

The battery sets supplying loads important to safety shall be dimensioned to provide at least two-hour discharge time under the highest conceivable load and for severe accident management systems shall be dimensioned to provide a 24-hour discharge time (B.1 5443 and 5444).

Addition of this electrical design requirements there are plant level design requirements 451: The design of a nuclear power plant shall provide for the loss of the power distribution network caused by an electrical transient or prevent it. The event shall primarily be prevented in accordance with the general DEC A design principles with electrical power distribution systems that fulfill the diversity principle and (N+1) failure criterion as well as by separating the severe reactor accident management systems from other systems. If the situation is managed through additional arrangements deviating from this, the DEC B design criteria shall be applied to the additional arrangements. Design extension condition acceptance criteria for fuel integrity, radiological consequences and overpressure protection shall be applied to the event.

Question 25.3 What are the design requirements relating to the use of non-permanent equipment regarding electrical power supply?

Response:

The Finnish regulations are based on the fact, that all electric power sources and distribution networks are permanently installed in advance. The old NPPs have been upgraded in some special cases with some small mobile aggregates, e.g. to supply emergency response center, severe accident valves or weather tower.

Question 26 Does the regulatory framework include requirements relating to the design and performance of supporting systems and auxiliary systems of NPPs?

Answer: Yes

Response:

Req. 70 relates in the general requirements for systems design that is addressed in the Guide YVL B.1. Requirement 5505 states that reliable cooling systems shall be provided for spaces that house heat-

producing equipment, for which a maximum temperature limit has been specified in order to deliver the required performance. Also, based on the requirement 442 the failure criterion shall be applied to the complete train of systems consisting of the safety system and all auxiliary systems (such as cooling) that are needed to perform the safety function. The requirements for the failure criteria are given in requirements 456 (functions for mitigating the consequences of AOOs) and 456 b (active components and systems for reaching and maintaining the controlled state). Finally, the requirement 5507 states that safety divisions shall have separate ventilation and air conditioning systems. The requirements 311 and 312 in the Guide YVL B.2 state that the safety classification of a support system shall follow the safety system in case the support system is necessary for the safety function.

Req. 71 is addressed in the Guide YVL C.6, Chapter 3, particularly in the requirements 301 and 302. Requirement 301 states that NPPs shall have radiation monitoring systems both stationary and portably/locally installed, whereas requirement 302 relates to accident monitoring systems that shall be at the NPPs as well. Means for analyzing the radioactive samples shall also be available. The basis of these YVL Guide requirements is in the Section 24 of the STUK Regulation Y/1/2018.

Req. 72 is not present in the Finnish legislation as such but the general requirements regarding all NPP systems are given in the chapter 4.1 of the Guide YVL B.1, especially Requirement 442 addressing the failure criteria (see above in Req. 70). Also the safety classification requirement in the Guide YVL B.2 related to the safety system/function itself (see above in Req. 70) would concern compressed air systems. The compressed air systems are in the minority at the Finnish NPPs, especially related to systems important to safety.

Req. 73 is addressed in the Guide YVL B.1, Chapter 5.5, particularly in the requirement 5502 in which is stated that ventilation and air conditioning systems shall maintain and ensure such ambient conditions in all the rooms of a nuclear power that the components and structures important to safety are kept in good condition and operate flawlessly. The requirement 5501 relates the matter as well as it concerns radioactivity control by means of ventilation (prevent, reduce and limit).

Req. 74 is addressed in the Guide YVL B.8, particularly in the requirements 308 (principles of fire protection), 309 (prevention), 310 (detection and extinguishing), 311 (preventing fire growth and spread), 311a (fire protection concept), 349–354 (fire compartmentation) and 397 (smoke control systems). The basis of these YVL Guide requirements is in the Section 15 of the STUK Regulation Y/1/2018.

Req. 75 is addressed in the requirement 398 (emergency lighting) of the Guide YVL B.8.

Req. 76 is addressed in the Guide YVL E.11 that gives requirements for the hoist and transfer equipment for NPPs. The requirement 510 states that hoisting functions and routes shall be designed in such a way that 1) the handling of heavy loads above the fuel is avoided, 2) the transfer of heavy loads on top of equipment important to safety is avoided, 3) the transfer of heavy loads can be performed such that collision of loads is avoided, 4) the transfer of heavy loads can be performed such that tangling of loads is avoided and 5) the integrity of the storage pools and the fuel (including water purity) is not jeopardised. Requirement 511 states that safe heavy load handling areas shall be defined and shown in the construction plan and requirement 512 that the seismic design of the hoisting device unit shall be performed according to Guide B.7. Requirement 523 (YVL E.11) concerns the safety equipment and functions of the hoisting devices (protective devices for stopping the movement, speed limiters, limit switches, indications for fastening and load weight etc.). The basis of these YVL Guide requirements is in the Sections 14 and 15 of the STUK Regulation Y/1/2018.

Question 27 Does the regulatory framework include requirements relating to the design and performance of steam supply system, feedwater system and turbine generator for NPPs?

Answer: Yes

Response:

There is no requirement with the exact wording referring to the systems listed. However, it is considered that the aim of the requirement included int the Finnish regulatory framework.

The Guide YVL B.5 sets the requirements for pressure control and overpressure protection of a nuclear power plant. It is stated that primary circuit pressure control shall designed *to ensure that pressure can be maintained within the limits required for the normal cooling of the reactor during normal operation and anticipated operational occurrences*. This concerns any system or component that has an impact on pressure control. In addition, it is required that "*provisions shall be made for normal operational conditions and anticipated operational occurrences by means of systems intended for pressure control to ensure that it will not be necessary to use safety valves to restrict pressure increase in the primary circuit*."

For events less frequent, it is required that "*The primary and the secondary circuits shall be provided with several redundant safety valves. Redundant safety valves protecting the same item shall be set to open in succession to ensure that no more valves than required are opened to relieve overpressure*."

In the Finnish framework, the steam supply system, feedwater system and turbine generator an considered to be not safety classified and hence not relied on performing the safety functions in accident conditions which are expected to be of safety class 2 and fulfil the failure criterion N+2 . Even the limitation systems for anticipated operational occurrences are required to be of safety class 3 and single failure tolerant. However, the systems mentioned are to be taken into account in deterministic analyses of anticipated operational occurrences:

"*Anticipated operational occurrences shall be analysed as follows:*

1. All plant systems operate according to design, with the exception of the failure or operator error analysed as the initiating event and the consequences of the initiating event. The most penalising failure in accordance with the (N+1) failure criterion shall be assumed for systems which limit the development of operational occurrences into accidents."

The demonstration of overpressure protection function for accidents is to be performed by dedicated analyses with specific assumptions that are described in Guide YVL B.3 Chapter 4.3.5.

As for the turbine missiles, they are considered to be treated as an internal hazard. There are requirements concerning protection from missiles, not only turbine missiles. STUK regulation 1/Y/2018 section 15 "*Internal hazards to be considered include at least fire, flood, explosion, electromagnetic radiation, pipe breaks, container ruptures, drop of heavy objects, missiles due to explosions or component failures, and other possible internal hazards. The design shall also consider unlawful and other unauthorised activities compromising nuclear safety*."

YVL B.7 requirement 307 elaborates these to be taken into account in the site layout: "*The site area layout shall be designed in such a way that the danger caused by missiles generated by the failure of a turbine, generator or other heavy rotating machines to safety functions implemented by systems, structures and components important to safety is very low. Hazard assessment shall include all facilities at the same site area or in its immediate vicinity."*

Question 28 Does the regulatory framework include requirements relating to the design of fuel handling and storage systems for NPPs?

Answer: Yes

Response:

The Nuclear Energy Act (YEL 990/1987) section 7 h states that a nuclear facility shall have premises, equipment and other arrangements to ensure the safe handling and storage of nuclear material and waste. The Nuclear Energy Decree (YEA 161/1988) sets requirements for the plans for fuel management at the various application stages (sections 24, 32, 34, 34 a 38). The level of detail of the plan required depends on the stage. The Decree also states when it is allowed to bring fuel to the nuclear power plant under construction (110 a). In addition, it states that STUK shall oversee that the

fuel is designed, fabricated, stored, handled, used and transported safely and according to the legislation (section 114 and 115).

The requirements regarding the safety of fuel handling and storage are stated in Section 12 of the Radiation and Nuclear Safety Authority Regulation on the Safety of a Nuclear Power Plant (STUK Y/1/2018) and in Section 15 of the Radiation and Nuclear Safety Authority Regulation on the Safety of Disposal of Nuclear Waste (STUK Y/4/2018) as applicable. The deference-in-dept principle shall be applied to the storage of nuclear fuel. Redundancy, separation and diversity principles shall be applied when storing nuclear fuel in water pools. Residual heat removal from the fuel storage in pools has to be ensured for three days independently of the off-site supply of electricity and water in a situation caused by a rare external event or a disruption in the on-site electrical distribution system. The storage conditions are required to be such that the leak-tightness and the mechanical endurance of the fuel assemblies is not substantially degraded during the planned storage period. The damage to the cladding during handling and storage must be prevented with a high degree of confidence. In addition, the possibility of criticality or a severe accident is required to be extremely low. In section 10, paragraph 3 a) of STUK Y/1/2018 it is additionally stated that the probability of fuel failures shall be low during normal operating conditions and anticipated operation occurrences. And further, it is state that in postulated accidents, the rate of nuclear fuel failures shall remain low and fuel coolability shall not be endangered.

Detailed requirements are set out in the YVL Guides. YVL Guide E.2 specifies the requirements for the acceptance of the design, manufacture, receiving and operation of nuclear fuel and control rods used in the reactor, as well as the requirements for the inspections and repairs to be carried out during and after operation. The Guide shall be applied to a nuclear facility at every phase of its life cycle, starting from the design until the decommissioning of the facility starts.

The requirements for handling and storage of nuclear fuel are detailed in Guide YVL D.3. The guide addresses dry storage of fresh fuel, storage of fresh and spent fuel in storage pools adjacent to reactors, storage of spent fuel in separate storages, transfers of nuclear fuel, as well as encapsulation of spent fuel for disposal and the encapsulated fuel. In addition, it addresses the planning, design, construction, use and decommissioning of the aforementioned functions and the necessary facilities and systems. However, the transport of spent nuclear fuel via public roads is covered elsewhere (in YVL D.2). Guide YVL D.3 also set requirements for the decontamination of transfer cask and other contaminated objects (para.461).

Paragraph 499 requires that provisions are made for leaking rod which shall be sealed in gas-tight canisters or containers if necessary.

YVL Guide B.4 shall be applied to the design of the reactors, reactivity control systems, nuclear fuel as well as fuel handling and storage systems of nuclear facilities. Section 4 states requirements for the nuclear fuel. It covers the general design criteria as well as detailed criteria for the various operational conditions ranging form normal operational conditions through anticipated operation occurrences and postulated accidents to design extension conditions. Section 5 details the requirements for preventing a criticality accident and section 6 covers the regulatory oversight by STUK.

Detailed requirements for hoisting and transfer equipment at a nuclear facility are given in YVL Guide E.11. This guide applies to the hoisting and transfer equipment used for handling nuclear fuel. The design of the hoisting functions and hoisting device units shall ensure adequate criticality prevention, nuclear fuel cooling and radiation protection, and that the probability of nuclear fuel damage is minimal.

Question 28.1 What are the requirements relating to the prevention of fuel uncovering for reactors using a water pool system for fuel storage?

Response:

According to section 10 paragraph 3 STUK Y/1/2018 the coolability of the fuel shall not be endangered in postulated accidents. Further in section 11 paragraph 3 it is stated that a nuclear power plant shall be provided with systems for removing decay heat generated in the reactor, and for retaining radioactive materials within the plant. Design of such systems shall apply redundancy, separation and diversity principles that ensure implementation of a safety function even in the event of a malfunction. Paragraph 7 states that a nuclear power plant shall have the necessary components and procedures for securing the removal of residual heat from the nuclear fuel in the reactor for a period of three days independently of the off-site supply of electricity and water in a situation caused by a rare external event or a disruption in the on-site electrical distribution system.

Section 12 states that when storing nuclear fuel in water pools, the cooling of the fuel shall apply redundancy, separation and diversity principles that ensure the implementation of the function even in the event of a malfunction. It also sets requirements for the electricity supply and removal of residual heat for which the facility shall have necessary components and procedures to ensure it for three days in a situation caused by a rare external event or a disruption in the on-site electrical distribution system.

Detailed requirements for nuclear fuel storage pools and nuclear fuel cooling are stated in section 4.5.2 in YVL Guide D.3. Section 4.5.3 states the requirements for cooling of spent fuel in the encapsulation plant. Paragraph 477a sets detailed requirements for the design of the pool structures, tube and pool connections, and cooling system. It is required that the maximum amount of nuclear fuel with maximum amount of decay heat generation can be cooled in all situations and that coolant shall not

boil in normal conditions and operational occurrences. It shall be ensured that an inadvertent discharge of the pool or excessive water level drop that would endanger the fuel cooling is not possible. The diversity principle shall be applied, and a secondary ultimate heat sink shall be provided, that shall fulfil the 72-hour self-sufficiency criterion. (YVL D.3 479-479a). Paragraphs 483-486 states the requirement for ensuring the cooling in various accident conditions including severe reactor accident (para 483), events involving a combination of failures (para 484), rare external events (para 485), loss of the plant's internal electricity distribution (para 486). Paragraph 485 states that measures to ensure cooling and conducted at the plant site shall not require the use of vehicles during the first eight hours. Further, the components designed for this use shall be accessible even if any individual route or hatch is blocked by an external obstacle. Paragraph 486 sets the requirement for a sufficient inventory of water and fuel, and the capability to recharge the DC batteries to enable the cooling arrangements for a period of 72 hours.

Question 28.2 What are the requirements relating to the monitoring and control of parameters representative of the spent fuel pool conditions during operational states or accident conditions?

Response:

According to section 10 STUK Y/1/2018 structural DiD shall be implemented and the design shall prevent dispersion of radioactive substances into the environment. Paragraph 3 further states that the nuclear fuel, the reactor, the primary circuit, the cooling circuit (secondary circuit) of a pressurised water reactor removing heat from the primary circuit, the water chemistry of the primary and secondary circuit, the containment and the safety functions shall be designed so as to meet the safety objectives in order to limit the spread of radioactive substances caused by fuel failures although the probability of fuel failure shall be low during normal operating conditions and AOO and the rate of nuclear fuel failures shall remain low and fuel coolability shall not be endangered in postulated accident. Paragraph 3b states requirements for ensuring primary and secondary circuit integrity and for verifying leak-tightness.

Section 12 of STUK Y/1/2018 states that the DiD principle shall be applied in the storage of nuclear fuel. When storing nuclear fuel in water pools, the cooling of the fuel shall apply redundancy, separation and diversity principles that ensure the implementation of the function even in the event of a malfunction. Further, a nuclear facility shall have the necessary components and procedures for securing the removal of residual heat from the nuclear fuel in the storage pools for a period of three days independently of the off-site supply of electricity and water in a situation caused by a rare external event or a disruption in the on-site electrical distribution system. Paragraph 2 states that nuclear fuel storage conditions shall be maintained such that the leak-tightness or mechanical endurance of fuel assemblies is not substantially degraded during the planned storage period.

Furthermore, paragraph 1 in section 16 of STUK Y/1/2028 states that a nuclear facility shall contain equipment that provides information on the operational state of the facility and any deviations from normal operation.

Guide YVL D.3 paragraph 463 states that nuclear fuel storage pool shall be equipped with a pool water radioactivity monitoring system. Furthermore paragraph 463 states that the nuclear fuel storage pool shall be equipped with a purification system, which can be used to remove impurities and radioactive substances from the water and paragraph 464 sets requirements for the monitoring system which shall be done according to requirements 301 and 314 of the Guide YVL C.6. with stationary radiation monitoring systems and instruments.

Guide YVL D.3 paragraph 477a states that the structures, tube connections, connections to other pools and water volume of nuclear fuel storage pools and the nuclear fuel cooling system shall be designed so as to ensure that the maximum decay heat generated by the nuclear fuel can be cooled in all situations, that the coolant shall not boil in normal conditions and operational occurrences. It further requires that inadvertent discharge of the storage pool or excessive water level drop to a level that would endanger nuclear fuel cooling or the necessary radiation protection is not possible and that the storage pool structures withstand the thermal load of normal conditions, operational occurrences and accidents.

Guide YVL D.3 paragraph 4102 states that any leak of nuclear fuel storage pools shall be detected and localised with sufficient accuracy for the purpose of repair. In addition, YVL Guide B.1 section 5.2.3 sets requirements for the instrumentation and section 5.2.4 for the operation I&C systems. Paragraph 5213 states that the instrumentation shall be designed to give accurate and reliable input data to the I&C systems performing safety functions. Paragraph 5214 states that a nuclear power plant shall have instrumentation that the operator can use to monitor the plant's status and the execution of safety functions in order to restore the controlled state and maintain it in anticipated operational occurrences, postulated accidents and design extension conditions DEC A. Paragraph 5223 states that the nuclear power plant shall be provided with reliable systems for monitoring and controlling the functioning of the reactor and the plant systems during normal operational states. Specific requirements for monitoring the water level or the temperature of the cooling water have not been identified in addition to the more general ones mentioned here.

According to Section 24 of STUK Y/1/2018 and Section 28 of STUK Y/4/2018, the radiation levels of nuclear facility rooms and the activity concentrations shall be measured. The releases of radioactive substances from the facility shall be monitored, and the radiation doses to the public in the vicinity shall be assessed.

Paragraph 518 of Guide YVL D.3 states that the storage conditions of spent nuclear fuel shall be designed so that the condition of nuclear fuel assemblies, nuclear fuel racks or nuclear fuel storage pools will not significantly deteriorate during the storage period. By choosing suitable materials and

controlling the chemical properties of the cooling water, corrosion of nuclear fuel assemblies, storage racks, and storage pool liners shall be kept as low as reasonably achievable.

Guide YVL B.5 section 5 sets detailed requirements for the water chemistry of the primary and secondary circuits of an NPP. These also apply to spent fuel pools in connection to the reactor pool. Specific requirements concerning separate fuel pools at e.g. the intermediate storage facility do not exist. Therefore, the requirements of YVL B.5 section 5 are also applied to such storage pools. Many of these requirements are based on IAEAS's guide SSG-13. Paragraph 518 states that a sampling programme shall be in place for monitoring the chemistry parameters and activity concentrations in the primary and secondary circuit. Paragraph 516 requires the analysis and measurement method for monitoring the limit values for activity in the coolant water to be sufficiently sensitive and accurate. Furthermore paragraph 521 states that the plant shall have a sampling system to deliver representative samples for on-line analysers and measurements as well as for grab sampling during different operational states and their changes. A system shall be in place allowing primary coolant sampling during accident conditions.

Question 29 Does the regulatory framework include requirements relating to optimal operator performance and human factors for the design and safe operation of NPPs?

Answer: Yes

Response:

Consideration of human factors is required by the STUK Regulation Y/1/2018 Section 6 Management of human factors relating to safety. This section requires that human factors relating to safety shall be controlled with systematic procedures throughout the entire life cycle of the nuclear facility and that human factors shall be taken into account in the design of the nuclear facility and in the planning of its operations, maintenance and decommissioning. It is also required in Section 6 that human factors management shall aim at both enabling high quality human performance and avoidance of human errors.

STUK YVL guide B.1 requirements 458a and b demand that an HFE-program and related task analyses shall be used in the design of new NPPs. Task analyses and the consequent analysis of staffing result in specification of the number and competence requirements for the operating staff. In addition, task analysis results are required to be used in the design of division of responsibility between the human operators and the automation system as required by requirement YVL B.1 5207. The HFE program scope shall contain also plant and equipment layout as it is not limited to control room design as it was previously. This is enforced also in STUK internal design evaluation guideline YTV 3.a.4 which outlines for which design projects an HFE program shall be required. YVL A.6 739 requires that the Operational Limits and Conditions document shall specify the minimum staffing levels for the NPP control room area and on the plant site. YVL B.1 requirement 5208 requires that sufficiency of the time available for operator response shall be justified by the means of task analysis which means that

decision times shall be considered in the design of human-system interfaces within the NPP. YVL B.1 5210 and 5211 requires that the operators in the control room shall have access to clearly presented and reliable information on the status of the nuclear power plant, and an overview shall be presented.

The HFE program required in YVL B.1 458 shall contain an Operating Experience Review which will ensure that relevant operating experiences from the point of view of human factors will be considered in the design of the NPP. YVL B.1 307 requires that the design organizations shall have the required resources and competences in place. The licensee shall ensure the adequacy of the resources and level of competence. But currently, it is not required directly that the competences include experience from operating similar plants to ensure as early as possible active involvement in the design process.

STUK Regulation Y/1/2018 Section 16 Safety of monitoring and control requires that an NPP must contain the equipment which provide information on the operational state of the facility and deviations from normal operation. The same section also requires that in the NPP automatic systems shall actuate safety systems as required and that the automatic systems shall be capable of maintaining the plant in a controlled state long enough to provide operators with sufficient time to initiate manual actions. YVL B.1 5207 and 5208 require that in the design of user interface considers sufficiency of the time available for operator response.

An HFE program required in YVL B.1 458a and b shall be such that it provides assurance that operator actions will be implemented as planned and as required to maintain safety of the plant in all conditions.

An HFE program required in YVL B.1 458a and b shall contain a Functional analysis and allocation activity which ensures that human capabilities, e.g. proper reaction times are considered in allocating tasks for human operators. And as required in YVL B.1 5208 first analyses shall demonstrate that design fulfills the requirements of human factors and secondly HFE verification and validation as required in HFE program shall provide assurance of the fulfillment of requirements.

YVL B.1 5305 requires that the control rooms etc. shall be protected to permit working without protective equipment during normal operation and under accidents and threat conditions. Due consideration shall be given to e.g. fire protection, protection against flooding, lighting, air conditioning and ventilation, radiation protection. YVL B.1 5316 requires that a safe passage shall be provided from the main control room to the emergency control room.

YVL B.1 requirement 5302 requires that due consideration shall be given to human factors and organizational circumstances right from the outset when designing the control room operations or modifications affecting the control room.

YVL B.1 requirements 458a and b and YVL B.1 5303 require that human factors verification and validation activity shall be conducted to ensure the appropriateness of control room design.

YVL B.8 375 requires that the nuclear facility shall feature an adequate number of appropriate, sufficiently spacious, and easy-to-use access routes to enable safe exit from the facility and that relevant other national requirements e.g. fire protection shall be fulfilled.

STUK regulation Y/2/2018 §4 requires that a reliable communication and alarm systems shall be in place to manage emergency response operations for the purposes of internal and external communications of the nuclear power plant.

YVL C.5 361 requires that the control rooms, emergency response centre and the facilities of the technical support group shall be equipped with redundant alarm and communications systems to alert those in danger at the site area and in the immediate vicinity of the plant, to launch operations in an emergency situation and to keep in touch with the command and operational units of the emergency organization, rescue operations command centre and STUK.

Question 30 Does the regulatory framework include requirements relating to radiation protection in design for NPPs?

Answer: Yes

Response:

Under Sections 6 and 7 of the Radiation Act (859/2018), exposure to ionising radiation arising from a nuclear facility's operation shall be kept as low as reasonably achievable (optimisation principle, ALARA) and the radiation doses of workers or individuals of the population shall not exceed the dose limit (principle of limitation). In addition, the dose limits of radiation exposure to an individual of the population from the operation of a nuclear facility are laid down by Chapter 3 a of the Nuclear Energy Decree (161/1988). Even if the dose limits and constraints were not exceeded, it is not justifiable to not implement a design option that would essentially reduce occupational or public dose.

STUK Y/1/2018 section 7 states that radiation exposure and emissions of radioactive substances shall be limited through layout design and component placement of the nuclear facility, material choices and planning of the working methods for operation and decommissioning of the facility and by using systems, structures, components, special radiation shielding and workers' equipment.

The general requirements for the design process and organisation are given in Guide YVL B.1.

According to Section 35 of the Nuclear Energy Decree (161/1988) the preliminary safety analysis report shall be submitted to STUK when an application for a construction license is filed. The general requirements for the content of the preliminary safety analysis report (PSAR) are given in Guide YVL A.1.

The nuclear facility's PSAR or the associated topical report shall give a summary of the most important radiation protection-related design features by which the optimisation principle in radiation protection is implemented at a nuclear facility. In the PSAR or in a separate topical report submitted with it, a procedure shall be described that takes into account structural radiation safety requirements during the various phases of the nuclear facility's design process. In addition, the description shall include a plan of the involvement of radiation safety experts in reviews made during the various phases of design and in decision-making affecting the implementation of radiation protection. The radiation safety experts and their qualification as well as the tools and calculation methods used shall also be stated.

In the PSAR the applicant and licensee shall present an analysis of the radioactive releases and radiation exposure of the population arising from the normal operation of and anticipated operational occurrences and accidents in the facility. The reports must also demonstrate that the radiation exposure arising from the operation of a facility is as low as reasonably achievable and that radioactive releases to and radiation levels in the environment are limited by employing the best available techniques.

The design process shall take into account the operation of a nuclear facility including commissioning, normal operation, anticipated operational occurrences, potential accidents and plant decommissioning. Decommissioning-related requirements to be taken into account during the design of a nuclear facility are given in Guide YVL D.4. Many of the design solutions considered useful for decommissioning are important also from the viewpoint of radiation protection and waste management during operation.

The nuclear facility's organizational structure and operations shall be planned to continuously implement radiation protection in accordance with regulations, facility-approved instructions and the ALARA principle. The radiation safety of the nuclear facility's workers is looked after for the facility's entire lifetime.

Related YVL-guides:

- Guide YVL C.1 provides detailed requirements to the design of a nuclear facility's structural radiation safety.
- Guide YVL C.2 provides detailed requirements to the radiation protection and radiation exposure monitoring of nuclear facility workers.
- Guide YVL C.3 provides detailed requirements to be satisfied by the applicant and licensee regarding the reduction of radioactive releases from a nuclear power plant as well as the radiation measurements, sampling systems and laboratory determinations used for monitoring the radioactive releases from the plant.
- Guide YVL C.5 contains detailed requirements on how a nuclear power plant licensee shall plan, implement and maintain emergency arrangements.
- Guide YVL C.6 provides detailed requirements to the design of radiation monitoring systems of a nuclear facility.
- Guide YVL C.7 provides detailed requirements applicable to the licence applicant and licensee for the radiological monitoring of the environment of a nuclear facility.

There are no specific requirements for NPPs used for cogeneration of heat or power, because there hasn't been such powerplants in Finland. Nonetheless the current requirements to prevent the dispersion of radioactive substances, requirements for structural defence-in-depth design, requirements to ensure primary and secondary circuit integrity and verify leak-tightness should be enough to prevent dispersion of radioactive substances outside the NPP's circuits even in a case of cogeneration plant. The requirements related to this topic can be from guide YVL B.5 and STUK Y/1/2018 section 10.

Question 31 Does the regulatory framework include requirements relating to design features to facilitate radioactive waste management and decommissioning of NPPs?

Answer: Yes

Response:

A nuclear facility shall have premises, equipment and other arrangements to ensure the safe handling and storage of nuclear material required by the facility as well any nuclear waste generated during operation and decommissioning. (Nuclear Energy Act 990/1987 section 7h) A nuclear facility shall have adequate storage space both for unconditioned and conditioned waste. (YVL D.4 450)

Radioactive waste shall be sorted, categorized according to its characteristics, handled and packed in an appropriate manner in terms of its storage and disposal, and stored safely. Limiting values shall be set for each class, which the waste package used for the waste in question shall meet in terms of the operational safety and long-term safety of the nuclear waste facility. Acceptability criteria shall be defined for the waste and waste packages. Radioactive waste that can be disposed of in a repository shall be conditioned and packed in accordance with the disposal requirements. Radioactive waste that cannot yet be disposed of in a repository shall be safely processed and stored until disposal. (STUK Y/1/2018 section 13)

The planning and implementation of the processing and storage of operational waste shall be carried out with due consideration given to potential dependencies between different waste management stages. The generation of waste that needs to be stored or disposed of shall be limited by means of repair work and maintenance planning, decontamination and volume reduction. The bringing of any unnecessary objects and materials into the controlled area shall be avoided. Where possible, the working methods shall be so selected that the amount of waste generated remains small and the further processing of the waste generated is facilitated. (STUK Y/1/2018 section 13, YVL D.4 443)

Different waste streams, liquid wastes with different chemical composition, activity concentration or radionuclide composition are in general not allowed to mix. The liquid wastes can be immobilized, dried or absorbted in suitable medium. The temporary storage of contaminated oils, chemicals and other similar fluids or sludges shall be resistant to corrosion and fit for the purpose in other regards as well. Non-immobilised waste of this kind may only be stored for long time periods in exceptional cases, such as when ageing them for clearance from regulatory control (YVL D.444-446)

The solid waste shall be packed into containers that facilitate their transfer, prevent the spreading of radioactive contamination and reduce the fire risk associated with the waste. Efforts shall be made to reduce the volume of waste by means of sorting, compaction, cutting or decontamination, for example. Decontamination could be used if it significantly reduces the risks of the spreading of radioactive material or enables clearance from regulatory control. Decontamination should not cause any significant occupational exposure. (YVL D.4 447-449)

The radioactivity and other properties of waste shall be determined and recorded such as to ensure the availability of the necessary information concerning the waste packages that are to be disposed of, or any waste that is to be stored for a prolonged period of time.

The radiation exposure of workers arising from waste management actions shall be limited, the spreading of radioactive materials inside the facility and into the environment shall be prevented, and preparedness for operational occurrences and accident conditions shall be maintained. (YVL D.4 402)

Decommissioning of a nuclear facility shall be taken into account already in the design phase of a nuclear facility. The design of a nuclear facility and its operation shall take account of the decommissioning of plant units so that it is possible to limit the volume of nuclear waste for disposal accumulating during the dismantling of units, and radiation exposure to workers due to the dismantling of the nuclear facility, and to prevent radioactive materials from spreading into the environment during decommissioning. (Nuclear Energy Act 990/1987 section 7g, STUK Y/1/2018 section 17).

One design target of a nuclear facility should be to make the decommissioning easier. Materials shall be selected to be easy to clean and to minimize the generation and spreading of radioactive materials. It shall be possible to remove large components, decontaminate systems and handle activated components. It is also should be possible to use plant's own structures and systems for decommissioning, (YVL D.4 436)

Radiation exposure and emissions of radioactive substances shall be limited through layout design and component placement of the nuclear facility, material choices and planning of the working methods for operation and decommissioning of the facility and by using systems, structures, components, special radiation shielding and workers' equipment (STUK Y/1/2018 Section 7). More detailed requirements are presented in YVL guide C.3 *Limitation and monitoring of radioactive releases from nuclear facility*.

Question 32 Does the regulatory framework include requirements for operating organizations at NPPs to establish and implement a commissioning programme?

Answer: Yes

Response:

YEA 161/1988 Section 110 states that different phases of the commissioning of a nuclear facility are allowed to be commenced only after STUK has confirmed based on e.g. detailed plans and documents required for each phase that the factors impacting on and the regulations concerning safety have been appropriately taken into account. Here, the detailed plans and documents refer e.g. to the plans related to the commissioning. STUK Y/1/2018 Section 19 and the Guide YVL A.5 Chapter 4 further elaborate this topic.

STUK Y/1/2018 Section 19 requires that in the commissioning of a nuclear facility the licensee shall ensure that the systems, structures and components and the facility as a whole operate as designed. Furthermore, the procedures of the commissioning shall be planned, and instructions shall be provided. Thus, for the commissioning of a nuclear facility, a detailed plan shall be drawn up on how to demonstrate the operational compliance of the facility's systems, structures, and components with the

design bases. The commissioning measures shall be planned in advance so that they can be implemented in a controlled manner without endangering safety.

Guide YVL A.5 requirements 409-410 require preparation and submission to STUK for approval of a commissioning plan which shall contain for example information of the organizations involved in the commissioning with their areas of responsibilities, structure of the commissioning-related documentation, a list of test programmes to be drawn up for commissioning testing and conditions for phase-to-phase progress and other hold points for testing. Related to the hold points during the nuclear commissioning phase, STUK specifies the power levels on which there shall be hold points necessitating STUK approval before raising the power. This specification is done in connection with the review of the commissioning documents as per the Guide YVL A.5 requirement 515a.

Further detailed requirements concerning actual testing programmes of a specific system or a phase are given in the Guide YVL A.5 Chapters 4.3-4.5. These include e.g. the requirements regarding the objective of each test programme and the acceptance criteria for each test.

As mentioned above, by means of commissioning tests, the licensee demonstrates that the entire plant and, in particular, the systems important in terms of safety are compliant with the design bases. In addition to demonstrate the systems' intended operability under normal operating conditions, the commissioning shall be done, as far as possible, under those transient and accident conditions in which the systems are required to function as per the Guide YVL A.5 requirement 428. In addition to these demonstrations, one purpose of the commissioning is to gather basic data on the operational properties of systems, structures, and components as per the Guide YVL A.5 requirement 406 for the reference and for the future assessments.

The commissioning shall be divided into phases (e.g. first testing in a cold state, then in a hot state with the normal design parameters and, finally, in the nuclear testing done after the loading of the fuel) and prior to proceeding from one phase to another, the prerequisites for the continuation shall be assessed based on the results of the preceding phase as per the Guide YVL A.5 requirements 411-412. In addition to presenting essential test results of the phase in question, a summary of the observations made during the testing as well as an assessment of the appropriateness of the testing performed in the phase concerned and any necessary changes to the operation of the plant shall be assessed and presented as per the Guide YVL A.5 requirement 448.

Specific requirements related to the prerequisites and authorization of the first fuel loading, criticality and initial power increase are given in the Guide YVL A.5 in the requirements 429-431, 432-436 and

437-438, respectively. These include among others the assessment of the results of the previous commissioning tests and phases to demonstrate fulfillment of the acceptance criteria. Furthermore, before starting the operation and on completion of the commissioning testing, the licensee shall assess the testing results as a whole according to the Guide YVL A.5 requirement 449.

STUK Y/1/2018 Section 19 requires that during the commissioning, the licensee shall ensure that appropriate procedures are in place for the future operation of the nuclear facility. It is further required to use facility's operating and testing procedures during commissioning tests when possible to validate them as per the Guide YVL A.5 requirement 404. More detailed requirements regarding the abnormal and emergency operating procedures' verification and validation are given in the Guide YVL A.6 requirements 716-717.

Also, instructions shall be in place for procedures applied during commissioning as per the Guide YVL A.5 requirement 408. This includes e.g. the necessary administrative instructions for processes regarding the work and change control and, in general, the plant status management. Further requirements related to the control of the status of components and systems are given in the Guide YVL A.6 Chapter 5.6, which are applicable during the commissioning as per Chapter 2 of the Guide.

STUK Y/1/2018 Section 23 paragraph 2 requires condition monitoring and maintenance to be planned, supervised and implemented so that the integrity and operability of systems, structures and components are reliably preserved throughout their service life including construction and commissioning phase. A specific requirement regarding the plan for maintenance during commissioning is given in the Guide YVL A.5 requirement 410.

The licensee organization shall have adequate human resources and competence for the facility's commissioning and operation in good time before the start of commissioning and the licensee's personnel shall participate in the commissioning testing to familiarize themselves with the facility and its systems as per the Guide YVL A.5 requirements 328 and 407. This especially concerns the facility's operating personnel. During commissioning it shall also be ensured by the licensee that the structure, functions and duties of the licensee's organization as well as the number and competence of the necessary personnel are adequate to ensure the safe operation of the facility (Guide YVL A.5 requirement 402). The specific requirements concerning the different functions of the licensee's organization and their implementation are given in the YVL Guides in question (e.g. emergency arrangements in the Guide YVL C.5 etc.).

Since activities relating to the nuclear facility's construction, commissioning and operation by several different organizations partly take place at the same time, the responsibilities of the organizations shall be clearly and unambiguously specified and detailed so that no unsolved or unclear matters remain between the different organizations and their functions. Also, the transfer of responsibilities between organizations shall be planned and controlled. The licensee shall have procedures to regularly assess the functionality of interorganizational interfaces between own organization and the supplier as well as in supplier organizations. The requirements related to these topics are given in the Guide YVL A.5 in the requirements 320, 320a, 325 and 409.

The requirements regarding systematic procedures for identifying and correcting deviations and management of non-conformances are given in STUK Y/1/2018 Section 25 paragraphs 4 and 4a and in the Guides YVL A.3 Chapter 7.5 and YVL A.5 Chapter 3.6, which are applicable during commissioning.

The requirements discussed above are also applied to the modifications of a nuclear facility where applicable in accordance with STUK Y/1/2018 Section 19 and the Guide YVL A.5 Chapter 2.

Question 33 Does the regulatory framework include requirements relating to the management of operational safety at NPPs?

Answer: Yes

Response:

Finnish regulatory framework covers the expectations from above mentioned Safety Standards Series No. SSR-2/2 requirements. See the answers below:

Safety policy

Section 7 f of the Nuclear Energy Act (990/1987) stipulates that safety shall take priority during the construction and operation of a nuclear facility. YVL Guide A.3 chapter 3.4 lays out requirements 322-325 regarding licensee's safety and quality policy. Furthermore, YVL Guide A.6 requirement 301 stipulates that in decision-making related to the operation of a nuclear power plant, the first priority shall be given to safety.

Operation limits and conditions

Section 22 of the Radiation and Nuclear Safety Authority Regulation on the Safety of a Nuclear Power Plant (STUK Y/1/2018) stipulates that the Operational Limits and Conditions of a nuclear facility shall include the technical and administrative requirements for ensuring the nuclear facility's operation in compliance with the design bases and the assumptions of safety analyses. Furthermore, YVL Guide A.6 chapter 7.5 lays down more detailed requirements regarding operating limits and conditions.

Performance and safety related activities

Section 25 of the Radiation and Nuclear Safety Authority Regulation on the Safety of a Nuclear Power Plant (STUK Y/1/2018) stipulates that the management system shall cover all organizational activities impacting the nuclear facility's safety. For each function, requirements significant to safety shall be identified, and the planned measures described in order to ensure conformity with requirements. The operating methods of the organization shall be systematic and instructed. Personnel shall be encouraged to perform responsible work, and to identify, report, and eliminate factors endangering safety. Personnel shall be given the opportunity to contribute to the continuous improvement of safety.

Section 6 of the STUK Y/1/2018 stipulates that human factors relating to safety shall be controlled with systematic procedures throughout the entire life cycle of the nuclear facility. Human factors shall be taken into account in the design of the nuclear facility and in the planning of its operations, maintenance and decommissioning in a manner that supports the high-quality implementation of the work and ensures that human activities do not endanger plant safety. Attention shall be paid to the avoidance, detection and correction of human errors and the limiting of their effects.

Section 20 of the STUK Y/1/2018 stipulates that the control and supervision of a nuclear facility shall utilise written procedures that correspond to the existing structure and the operational state of the nuclear facility.

Guide YVL A.6 requirement 516 stipulates that the risks related to nuclear and radiation safety associated with the execution of the work shall be identified in connection with work planning, and they shall be managed systematically. Regarding NPP operating organization's operation shifts, guide YVL A.6 requirement 418 stipulates that care shall be taken to ensure that the workload, participation in training, and the human factors related to the duration of the shifts, shift rotation, and rest periods do not affect the teams' ability to perform safety-related work.

Regarding the use probabilistic assessment is decision-making, guide YVL A.3 requirement 326 stipulates that the principles of observing risk-based decision-making and safety significance shall be described in the management system. Furthermore, guide YVL A.8 requirement 710 stipulates that the assessment of the comprehensiveness of the maintenance of a SSC, shall be based on a probabilistic risk assessment.

Monitoring and review of safety performance

Guide YVL A.3 requirement 702 stipulates that the licensee shall ensure the systematic and continuous monitoring of safety indicators in order to ensure maintaining the level of safety

and improving it where necessary. Requirement 709 stipulates that the licensee shall carry out regular self-assessment of their own work performances against pre-defined criteria.

Guide YVL A.3 chapter lays down requirements regarding handling on non-comformances and corrective and preventive actions.

Guide YVL A.6 lays down requirements regarding monitoring of safety related issues. For example, requirement 504 stipulates that general surveillance shall be carried out during the control tours of the nuclear power plant facilities. The objectives and locations as well as the limit values to be monitored shall be defined for the control tours. Any non-conformances observed during the control tours shall be reported. Any observations suggesting a risk to safety shall be reported to the shift team in the control room without delay.

Control of plant configuration

Guide YVL B.1 chapter 3.3 contains several requirements (319-330b) regarding configuration management in nuclear facilities. For example, requirements 319 and 326:

319: *Licensee's management system shall define the processes and procedures applied in configuration management related to the construction and operation of a nuclear facility*.

326: *All changes between baseline configuration levels shall be made in accordance with pre-determined change management procedures.*

Management of plant modifications

Guide YVL A.8 chapter 8 lays out requirements (801-810) regarding licensee's management of plant modifications.

YVL A.8 requirement 804: *The licensee shall assess the safety impact of the modification at the planning stage. The modification may not compromise the safety of the nuclear facility or the preconditions for the condition monitoring or maintenance of SSC*.

YVL A.8 requirement 808: *The licensee shall ensure by means of training that the effects of the modification on the operation, condition monitoring and maintenance of the SSC and the nuclear facility concerned are communicated to the operation and maintenance organisations.*

Management of temporary modifications are covered in Guide YVL A.6, which there are given several requirements (530-534). The requirements state that temporary modifications shall be designed, evaluated, and executed in accordance with specific plant procedures and shall be clearly documented and identified. The number of temporary modifications must be as low as possible and the duration of a temporary modification shall be minimised. The temporary modifications shall be periodically reviewed to determine whether they are still needed

Equipment qualification

YVL Guide A.8 requirement 404a stipulates that the qualification of SSC shall be periodically renewed if in-service condition monitoring cannot provide sufficient information on the maintained operability of the SSC, including fatigue and earthquake resistance.

Guide YVL A.6 lays down requirements for monitoring the operability of safety related items.

Requirement 501 stipulates that *the operation shift team shall monitor the state of the nuclear power plant on a regular basis by using the control room screens and measurements,*

testing the operability of components, and performing inspections and control tours of the plant facilities.

Requirement 734 stipulates that *the periodic testing, inspection, and surveillance programmes for ensuring the operability of systems, structures, and components subject to operability requirements, as well as the testing frequency, staggering, operational state, and the related instructions; shall be specified in the Operating limits and Conditions (Tech Specs).*

Ageing management

Radiation and Nuclear Safety Authority Regulation on the Safety of a Nuclear Power Plant (STUK Y/1/2018) Section 5 stipulates:

1. *The design, construction, operation, condition monitoring and maintenance of a nuclear facility shall provide for the ageing of systems, structures and components important to safety in order to ensure that they meet the design-basis requirements with necessary safety margins throughout the service life and decommissioning of the facility.*
2. *Systematic procedures shall be in place for preventing such ageing of systems, structures and components which may deteriorate their availability, and for the early detection of the need for their repair, modification and replacement. Safety requirements and applicability of new technology shall be periodically assessed in order to ensure that the technology applied is up to date, and the availability of the spare parts and the system support shall be monitored.*

Furthermore, STUK has a dedicated Guide YVL A.8, *Ageing management of a nuclear facility*, which lays down more detailed requirements for licensee's ageing management activities. YVL Guide A.8 lays down requirements regarding licensee's ageing management program as following:

301. The licensee shall describe ageing management as part of the management system of the nuclear facility.

302.The licensee shall define an ageing management programme for the nuclear facility comprising the functions, duties and responsibilities for assuring the operability and technological conformance of systems, structures and components (hereinafter 'SSC', see the definition below) related to the safety of the nuclear facility throughout their service life.

Reports and records

Radiation and Nuclear Safety Authority Regulation on the Safety of a Nuclear Power Plant (STUK Y/1/2018) Section 5 stipulates:

4. Operational measures concerning the nuclear facility, as well as events having an impact on safety, shall be documented so that they can be verified and assessed afterwards.

Guide YVL A.9, *Regular reporting on the operation of a nuclear facility*, requirement 305 stipulates that the licensee shall store the measurement results based on which the reports have been drafted for a minimum of ten years. The reports shall be stored until the facility has been decommissioned.

Guide YVL A.3 chapter 6.2 "Document management" lays out general requirements (612-615) on document management. According the requirements, the documents shall be managed by systematic procedures and the document management procedures shall be described. The independence principle shall be applied when drawing up, reviewing, and approving a document.

Long term operation

There are no dedicated requirements regarding long term operation of NPPs in Finnish regulatory framework. However, Guide YVL A.1 requirement 302 requires licensee to carry out periodic safety

reviews in regular intervals. Possible applications for long term operation to extend original plant operating life are handled in STUK same way as normal operation license renewals.

Many of the Guide YVL A.8 requirements regarding licensee's ageing management (see answer above) are relevant to long term operation management as well.

Question 34 Does the regulatory framework include requirements for operating organizations at NPPs to develop and maintain the competence of personnel?

Answer: Yes

Response:

Regulations concerning the personnel and of the expertise required for the use of nuclear energy are laid down in YEL, YEA and STUK Y/1/2018. More detailed requirements are presented in Guide YVL A.4.

According to YEL Section 7 i, *the holder of the licence giving the right to use nuclear energy shall have an adequate number of qualified personnel suitable for their tasks*. Furthermore, *the licence holder shall arrange adequate training for the maintaining and development of the expertise and skills of its personnel handling tasks relating to nuclear safety.*

YEA Section 125 sets qualification requirements for person to be accepted as a responsible manager. According to Guide YVL A.4 Requirement 356 *the performance of managers and supervisors and their professional development in their positions shall be assessed on a regular basis. Individual needs-based development programmes shall be designed and implemented for managers.*

According to STUK Y/1/2018 Section 25, *significant functions with respect to safety shall be designated. The competence of the persons performing these functions shall be verified.* According to Guide YVL A.4 Requirement 310 *the licensee shall, at regular intervals, assess the work performance of the individuals holding positions that require a specific approval and evaluate the need to develop their competence and duties.* These positions comprise e.g. responsible manager, persons in charge and control room operators. According to STUK Y/1/2018 Section 20, *the control room of the nuclear power plant shall be constantly manned by a sufficient number of operators aware of the status of the nuclear power plant, systems and components.* For control room operators, detailed requirements concerning competence and training are presented in Guide YVL A.4 Annex E.

According to Guide YVL A.4 Requirement 321 *the competence development programmes of a nuclear facility shall comprise basic, continuing, and refresher training based on the principle of continuous improvement of competences. An induction programme shall be prepared for the nuclear facility recruits to help them become familiar with their duties and working environment.* According to Guide YVL A.4 Requirement 320 *the licensee shall make active use of the various means to develop the competences of the personnel.*

Question 35 Does the regulatory framework include requirements relating to operational safety programmes to be established and implemented by operating organizations of NPPs?

Answer: Yes

Response:

Requirement 17: Consideration of objectives of nuclear security in safety programmes

Requirements regarding minimizing potential conflicts between operating organization's safety and security objectives are covered in the YVL Guide B.1 "Safety design of a nuclear power plant" and A.11 "Security of a nuclear facility.

Guide YVL B.1 requirement 409 states:

In the design, due account shall be taken of security aspects to minimise potential conflicts between safety and physical protection considerations. Due consideration shall be given to cybersecurity in the design of a nuclear power plant. Specific requirements pertaining to security arrangements are provided in Guide YVL A.11 and those pertaining to information security in Guide YVL A.12.

Guide YVL A.11 requirements 309 and 309a state:

309

Nuclear-security related requirements shall be taken into account in all phases of the nuclear facility's life cycle and, later, during plant improvements, refurbishments and modifications.

309a.

Nuclear security design shall take place simultaneously with other designing of the plant or its systems and structures. The design process shall proceed logically, taking into account the following nuclear security aspects:

- *fundamental principles and tasks*
- *design bases and requirements*
- *interdependencies between systems design and components design*
- *definitions, technical specifications and functional descriptions*
- *documentation needs.*

Requirement 19: Accident management programme

Requirements regarding operating organization's accident management programmes are covered in regulatory framework.

See answer for question 35.1 for more detailed description.

Requirement 21: Management of radioactive waste

Requirements regarding management of radioactive waste are covered in regulatory framework.

Basic requirements are given in Radiation and Nuclear Safety Authority Regulation on the Safety of Disposal of Nuclear Waste (STUK Y/4/2018). More detailed requirements are given in YVL Guide D.4, Predisposal management of low and intermediate level nuclear waste and decommissioning of a nuclear facility.

Requirement 22: Fire safety

Requirements regarding management of fire safety are covered in covered in regulatory framework.

Detailed requirements are given in Guide YVL B.8, Fire protection at a nuclear facility.

Requirement 23: Non-radiation-related safety

In STUK's regulatory framework there are no requirements on licensee's non-radiation-related safety issues of NPPs. For example, occupational safety and health in nuclear power plants is under regulation of Regional State Administrative Agencies, not STUK.

Requirement 24: Feedback of operating experience

Requirements regarding management of operation experience feedback are covered in regulatory framework.

Basic requirements are given in section 21 of Radiation and Nuclear Safety Authority Regulation on the Safety of a Nuclear Power Plant (STUK Y/2/2018). More detailed requirements are given in Guide YVL A.10, Operating experience feedback of a nuclear facility, and A.3, Leadership and management for safety.

Question 35.1 What are the provisions in the regulatory framework dealing with accident management programmes of operating organizations of NPPs?

Response:

In the Finnish regulatory framework, there are no explicit requirements for so called accident management programme. However, the requirements for the emergency arrangements (according to YEL 990/1987 Section 3 paragraph 7 the emergency arrangements mean advance preparation for accidents or events impairing safety at the nuclear facility or in its site area) practically include the

requirements set for the accident management programme in the SSR-2/2. Furthermore, the accident management is also taken into account in the design requirements of a nuclear power plant and its systems as per the Guide YVL B.1 Chapters 4 and 5. In addition, there are also other specific requirements in the Finnish regulation related to the accident management such as needed resources, training and operating procedures. These are further discussed below. Accordingly, the referenced requirements in SSR-2/2 are considered fulfilled.

In high level, YEL 990/1987 Section 7d states that the design of a nuclear facility shall provide for the possibility of operational occurrences and accidents. This is further elaborated e.g. in STUK Y/1/2018 Section 9 paragraph 5 which requires that the necessary measures to bring a situation, such as an accident situation, under control or to prevent harmful effects of radiation must be planned in advance. These required plans and measures are described e.g. in the licensee's administrative instructions, in the emergency operating procedures, in the severe accident management guidelines and in the emergency plan. These licensee's documents shall be kept up-to-date at all times and reviewed regularly according to the Guide YVL A.6 requirements 701 and 718 and STUK Y/2/2018 Section 8 paragraphs 4 and 6.

STUK Y/2/2018 gives requirements related to the emergency arrangements of nuclear power plants. The basis for the planning of the emergency arrangements is to ensure that emergency situations are quickly brought under control and that timely action is taken to prevent or limit radiation exposure to the public as per Section 3. In addition, the planning shall take into account concurrent threats to nuclear safety or accidents affecting all nuclear facilities in the site area and their potential consequences and the fact that the emergency situation could continue for a prolonged period. STUK Y/2/2018 Section 8 gives requirements for the maintenance and development of preparedness to act. These include e.g. requirements concerning emergency training of the personnel, annual emergency exercises and the regular evaluation of the emergency arrangements. Guide YVL C.5 gives detailed requirements for the emergency arrangements. The emergency arrangements are further discussed in the connection of the answer to the QID 37.

STUK Y/1/2018 Section 20 paragraph 3 requires that for accidents appropriate procedures for the identification and control of those shall be available. Further requirements are set in the Guide YVL A.6 Chapter 7.2, which requires the preparation of the emergency operating procedures covering postulated accidents and design extension conditions as well as the preparation of the guidelines for managing severe accidents to mitigate the consequences of those. The detailed requirements for these procedures and guidelines in the Chapter 7.2 include e.g. that the field actions defined in the procedures and guidelines shall be drawn up. There are also requirements for e.g. the verification and validation of the procedures and guidelines.

STUK Y/1/2018 Section 25 paragraph 8 requires that the licensee shall have a sufficient number of competent personnel suitable for the related tasks for ensuring the safety of the nuclear facility, which is applicable for all conditions including accidents. In addition, the licensee shall have access to the professional expertise and technical knowledge required for the management of accidents. Requirements for the regular training and practicing of the licensee's personnel for the use of the emergency operating procedures and guidelines for severe accidents are set in the Guide YVL A.4 in the requirements 328-330. These also include e.g. the practicing of the measures specified in the procedures and guidelines for restoring the critical safety functions. The requirements especially concern the operating personnel but also the technical support personnel present at the facility where applicable. It is also required in the Guide YVL A.4 requirement E29 (Annex E) that the annual refresher training of the control room operators shall include the plant's operation in transients and accidents.

As discussed above, the regulatory requirements also take into account concurrent accidents affecting all units in multiple unit NPP sites. Guide YVL A.3 requirement 506 requires that the nuclear facility's organisation shall be able to function and to ensure the safe operation under all circumstances, including operational occurrences and simultaneous accidents at one or several plant units. Furthermore, personnel resources shall be planned so that they are also sufficient during prolonged accidents. The Guide YVL A.4 requirement 303 requires the demonstration of these organizational capabilities by the licensee. Also, in multifacility site the functions needed by each unit shall, when necessary, be implemented also in the event of a transient or accident occurring simultaneously at the plant units as per the Guide YVL B.1 requirement 411.

Requirements related to the protection of the control rooms and other rooms needed under accident conditions are given in the Guide YVL B.1 5305 and 5306 of which the former also requires due consideration of e.g. lighting and radiation protection aspects of the rooms. Specific requirements related to the emergency response facilities or premises are given in the Guide YVL C.5 351-356. These include e.g. the possible loss of electricity and the so called 72-hour self-sufficiency criterion to be taken into account. 72-hour self-sufficiency criterion means that that the system to which the criterion is applied must be able to perform its function for a minimum of 72 hours so that for the first 24 hours no material replenishments (such as filling the water or fuel tank of the system) are needed, and for the following 48 hours provisions and material reserves exist at the plant site to arrange the necessary material replenishments for the system. 72-hour self-sufficiency criterion regarding necessary components and procedures for securing of the residual heat removal in general is given in STUK Y/1/2018 Sections 11 (paragraph 7) and 12 (paragraph 1b).

The control room system's or ensemble's appropriateness shall be demonstrated using the plant simulator including also accident conditions before the first fuel loading and before implementation of significant modifications (Guide YVL B.1 5303). Regarding the emergency arrangements the licensee shall demonstrate the appropriateness of those with an emergency exercise before the first fuel loading as per STUK Y/2/2018 Section 7 paragraph 2.

Question 35.2 What are the provisions in the regulatory framework dealing with arrangements made by the operating organization to ensure fire safety at the NPP?

Response:

Section 15 of the Regulation on the Safety of a Nuclear Power Plant (STUK Y/1/2018) states that the design of a nuclear facility shall take account of internal hazards, including fire. Section 3 of the Regulation on the Emergency Arrangements of a Nuclear Power Plant (STUK Y/2/2018) states that emergency arrangements shall be consistent with […] fire protection […] and emergency plant and rescue plans prepared by the authorities. More detailed guidance is given in Guide YVL B.8 "Fire Protection at a Nuclear Facility"

Section 3.5.3 of YVL B.8 covers operational fire protection. Operational fire protection readiness consists of a designated plant fire brigade at the plant or in its immediate vicinity, plant personnel and off-site fire brigades, and the equipment needed to carry out operations. The plant fire brigade shall consist of at least one full-time fire foreman and three full-time fire fighters (1+3). Five-minute response time is required at all times. There are also training requirements set for fire fighters.

Operation with the plant fire brigade and the regional fire and rescue services shall be planned, instructions provided and co-operation exercises conducted. Nuclear facilities shall be provided with equipment facilitating the use of a communication system generally in use by the authorities. For command responsibility the Rescue Act (379/2011) and the Government Decree on Rescue Services (407/2011) apply.

Control room and the fire brigade shall be equipped with displays and printers for the fire detection system to identify fire locations.

Question 35.3 What are the provisions in the regulatory framework dealing with operating experience programmes of operating organizations of NPPs?

Response:

Radiation and Nuclear Safety Authority Regulation on the Safety of a Nuclear Power Plant (STUK Y/1/2018) section 21 requires that safety significant operational events shall be investigated for the purpose of identifying the root causes as well as defining and implementing the corrective measures. Opportunities for safety improvements that are identified from operating experience, safety research and technical developments shall be assessed and implemented to the extent regarded as justified on the basis of the principles laid down in Section 7 a of the Nuclear Energy Act.

More detailed requirements regarding licensee's operation experience programmes are given in YVL Guide A.10, Operating experience feedback of a nuclear facility. Guide YVL A.10 requirements 302 and 307 state the following:

302: *The licensee shall put in place documented procedures to help to systematically identify, select for further processing, investigate and save operating experiences*.

307: *Where appropriate, the licensee shall maintain liaison with the organisations involved in the design and construction of the nuclear facility (manufacturers, research organisations, designers). The objective is to exchange operating experience feedback and secure advice in case of equipment failures and abnormal events.*

As a conclusion regulatory framework fulfils expectations from SSR-2/2 requirements 5.27 and 5.32.

Question 36 Does the regulatory framework include requirements for operating organizations of NPPs to establish and implement a radiation protection programme?

Answer: Yes

Response:

The grounds for the protection of a worker's health against the harmful effects of ionising radiation are regulated by the Radiation Act and the Government Decree on Ionising Radiation and the Ministry of Social Affairs and Health Decree on ionising radiation issued thereunder. Regulations regarding radiation safety published by STUK complement the requirements of the Radiation Act and decrees issued thereunder. The application of the Radiation Act in the use of nuclear energy is regulated in the Nuclear Energy Act.

Chapter 12 of the Radiation Act regulates the arrangement of radiation protection for workers, the bases of radiation exposure monitoring and medical surveillance, and responsibilities of the responsible party and employer to protect its own and outside workers engaging in radiation work. Guide YVL C.2 applies to the radiation protection and radiation exposure monitoring of nuclear facility workers.

The operational unit responsible for implementing radiation protection in practice and for co-ordinating related functions shall be established within the nuclear facility's operating organisation or such a unit shall be made available to it. The radiation protection manager of the plant acts as the unit's head. Tasks and responsibilities relating to the implementation of radiation protection shall be described in the facility's management system. Unforeseen conditions burdening the radiation protection function, e.g. unplanned maintenance outages, shall be taken into account in the operations and resources management of a radiation protection unit. The unit shall be capable of operation at all times of the day, where necessary. Guide YVL C.2 paragraph 4 provides more detailed requirements for the operation of the radiation protection organization.

The nuclear facility shall have a written programme (the ALARA action programme) to keep doses low. The programme shall include both short-term and long-term plans and measures to limit the doses of occupationally exposed workers. The action programme shall take into account from the overall viewpoint of radiation protection e.g. the facility's operation, water chemistry, plant modifications, materials, decontamination, nuclear waste management, testing and inspections etc. The programme shall include dose constraints for the highest individual annual dose and collective dose (manSv/GW) that shall not be exceeded based on the principle of continuous development. The ALARA action programme shall be kept up-to-date.

The nuclear facility shall have necessary instructions to implement radiation protection. They shall include at least the following:

- radiation protection principles and the organisation responsible for implementing them
- organising radiation protection training
- regulations for procedures in the controlled and supervised areas
- classification of radiation workers
- medical surveillance of radiation workers
- radiation measurements in the controlled and supervised areas
- monitoring of individual radiation exposure
- real-time dose monitoring
- decontamination of workers
- radiation work permit procedure

- work planning process for maintenance and modifications important to radiation protection
- radiation protection procedures for unexpected and urgent repairs or maintenance during power operation
- use requirements for personal protective equipment
- procedures to ensure the implementation of the ALARA principle
- procedures for radiation protection quality control.

The nuclear facility shall also have the necessary detailed instructions listing practices in radiation protection and radiation measurement as well as information on instruments for measuring or analysing radiation. These instructions shall be incorporated in the facility's management system. The radiation protection instructions shall be kept comprehensive, up-to-date and they shall be regularly evaluated as defined in the nuclear facility's management system. Activities in accordance with in the radiation protection instructions shall be evaluated as part of the facility's quality management. Guide YVL C.2 paragraph 4.5 provides more detailed requirements for the radiation protection instructions.

In the nuclear facility area, dose rates shall be measured as well as the airborne radionuclide concentration and surface contamination (surface activity) systematically determined. Based on the results of the measurements, work sites are divided into controlled and supervised areas. The area outside the controlled and supervised areas is uncategorised in terms of radiation protection. The zone classification at nuclear facilities does not apply to radon. Guide YVL C.2 paragraph 5 provides more detailed requirements for the radiation conditions-based area and zone classification of a nuclear facility.

Guide YVL C.5 requirement 340. states that, when the emergency situation has been terminated and the immediate measures necessary for limiting a radiation hazard and bringing a source of radiation under control have been performed, the dose limits stipulated shall apply to protection work and other measures seeking to mitigate the consequences of the accident. If the Government decides in accordance with Section 137 of the Radiation Act to shift to an existing exposure situation, the reference values confirmed by the Radiation and Nuclear Safety Authority based on Section 140 of the Radiation Act shall be applied in terms of occupational exposure.

Question 37 Does the regulatory framework include requirements for operating organizations at NPPs to establish and implement provisions for emergency preparedness and response?

Answer: Yes

Response:

The Nuclear Energy Act (990/1987) and Decree (161/1988) present the most important basic requirements for a nuclear power plant's emergency arrangements. Radiation and Nuclear Safety Authority Regulation on the Emergency Arrangements of a Nuclear Power Plant (STUK Y/2/2018) sets forth the general regulations concerning nuclear power plant's emergency arrangements. According to Section 9 (1–2) of the Nuclear Energy Act (990/1987), the licence holder shall be under an obligation to ensure the safe use of nuclear energy. It shall be the licence holder's obligation to carry out such security and emergency arrangements and other arrangements necessary for the limitation of nuclear damage which do not rest with the authorities.

According to Section 3(7) of the Nuclear Energy Act (990/1987), emergency arrangements mean advance preparation for accidents or events impairing safety at the nuclear facility or in its site area or other places or vehicles where nuclear energy is used. Preparation also applies to exceptional situations that require the intensification of preparedness to act in order to ensure the safety level of the plant. Guide YVL C.5 contains detailed requirements on how a nuclear power plant licensee shall plan, implement and maintain emergency arrangements.

Guide YVL C.5 requirement 302:

The emergency plan shall describe the measures to be initiated in emergency situations, and it shall include the instructions on how to carry out these measures. The emergency plan shall include at least the following:

- the classification of emergency situations and the description of events and accidents on which it is based
- the emergency response organisation
- the alarms, notifications and communications arrangements
- emergency situation management and performance of situation assessments
- the safety of workers and radiation protection
- the radiation measurements undertaken at the nuclear power plant, site area and precautionary action zone during an emergency situation
- provision of information to the public
- the premises, equipment and accessories

- termination of emergency situations and recovery measures
- actions to ascertain the causes of the emergency situation and to learn from the emergency situation
- measures pertaining to the licensee's rescue operations
- the emergency response organisation's instructions for emergency situations
- a description of how emergency preparedness is maintained.

In the Finnish regulatory framework, there are no explicit requirements for so called accident management programme. This is explained in the answer to the question 35.1.

Question 38 Does the regulatory framework include requirements relating to NPP operations?

Answer: No

Response:

Operating procedures

Radiation and Nuclear Safety Authority Regulation on the Safety of a Nuclear Power Plant (STUK Y/1/2018) section 20 requires:

2a. The control and supervision of a nuclear facility shall utilise written procedures that correspond to the existing structure and the operational state of the nuclear facility. Written orders and related procedures shall be provided for the maintenance and repair of components.

3. For operational occurrences and accidents, appropriate procedures for the identification and control of circumstances shall be available.

More detailed requirements regarding operating procedures are given in chapters 7.1 and 7.2 of Guide YVL A.6, Conduct of operations at a nuclear power plant.

Operation control rooms and control equipment

According to Section 16(1) of STUK regulation STUK Y/1/2018, a nuclear facility shall contain equipment that provides information on the operational state of the facility and any deviations from normal operation.

According to Section 16(3a) of STUK regulation STUK Y/1/2018, in order to control the nuclear power plant and enable operator actions, the nuclear power plant shall have a control room, in which the majority of the user interfaces required for the monitoring and control of the nuclear power plant are located. The scope of monitoring and control duties performed outside the control room shall be designed according to their feasibility.

According to Section 16(4) of STUK regulation STUK Y/1/2018, the nuclear power plant shall have a supplementary control room independent of the main control room and the necessary local control systems for shutting down the nuclear reactor and for removing decay heat from the nuclear fuel in the reactor and the spent nuclear fuel stored.

More detailed requirements regarding control rooms (main control room and emergency control room) are given in chapter 5.3 of Guide YVL B.1, Safety design of a nuclear power plant.

Requirement 28: Material conditions and housekeeping

Guide YVL A.6 requirement 504, 521 and 522 stipulates the following:

504. General surveillance shall be carried out during the control tours of the nuclear power plant facilities. The objectives and locations as well as the limit values to be monitored shall be defined for the control tours. Any non-conformances observed during the control tours shall be reported. Any observations suggesting a risk to safety shall be reported to the shift team in the control room without delay.

521. A standard of cleanliness and order shall be maintained in the nuclear power plant facilities.

522. A marking system shall be maintained at the nuclear power plant according to which all systems, structures, and components of the nuclear power plant are identified and marked.

Regarding foreign material exclusion management, YVL B.1 requirement 5217 requires monitoring instrumentation in the primary circuit to detect any loose objects. However, there are no specific requirements for foreign material exclusion policy in regulatory framework, and that is a deviation from the SSR 2/2 requirement 28 - 7.11:

Req 28 - 7.11.

An exclusion programme for foreign objects shall be implemented and monitored, and suitable arrangements shall be made for locking, tagging or otherwise securing isolation points for systems or components to ensure safety.

Requirement 29: Chemistry programme

Requirements regarding power plant water chemistry and radiochemistry are given in Guide YVL B.5, Reactor coolant circuit of a nuclear power plant. The requirements cover expectations from SSR-2/2.

Requirement 30: Core management and fuel handling

According to Section 63(1)(3) of the Nuclear Energy Act (990/1987), the Radiation and Nuclear Safety Authority is authorised to require that the nuclear fuel or the structures and components intended as parts of the nuclear facility be manufactured in a manner approved of by the Radiation and Nuclear Safety Authority (STUK).

According to Section 114 of the Nuclear Energy Decree (161/1988), the Radiation and Nuclear Safety Authority (STUK) shall see to it that nuclear fuel is designed, fabricated, stored, handled and used pursuant to the relevant instructions and regulations. Nuclear fuel cannot be placed in the reactor until STUK has accepted the fuel for use.

Section 12 of Regulation STUK Y/1/2018 and Section 15 of Regulation STUK Y/4/2018 set forth regulations for the handling and storage of fuel.

YVL Guide B.4 presents criteria and detailed requirements to ensure and demonstrate the fulfilment of the requirements of Regulation STUK Y/1/2018 during the design of the nuclear power plant, reactor core and nuclear fuel.

YVL Guide E.2 specifies the requirements for the acceptance procedure for the procurement and operation of nuclear fuel and control rods.

Question 38.1 What measures are planned to improve compliance with these requirements?

Response:

A requirement for licensees to implement policy for managing foreign materials should be added into regulatory framework.

SSR 2/2 Req 28 / 7.11

Req 28 - 7.11.

An exclusion programme for foreign objects shall be implemented and monitored, and suitable arrangements shall be made for locking, tagging or otherwise securing isolation points for systems or components to ensure safety

Question 39 Does the regulatory framework include requirements for operating organizations at NPPs to conduct maintenance, calibration, testing, surveillance and inspection activities to ensure that items important to safety are able to function in accordance with the design intent and with safety requirements?

Answer: Yes

Response:

Requirements regarding surveillance, testing and maintenance of NPP's systems, structures and components are included in regulatory framework. Section 23 of Regulation STUK Y/1/2018 lays out the following requirement:

2. *Operability and the effects of the operating environment shall be monitored by means of inspections, tests, measurements and analyses. Operability shall be checked in advance by regular maintenance, and provisions shall be made for maintenance and repairs in the event of any deterioration in operability. Condition monitoring and maintenance shall be planned, supervised and implemented so that the integrity and operability of systems, structures and components are reliably preserved throughout their service life.*

More detailed requirements regarding licensee's surveillance and maintenance equipments important to safety are presented in Guide YVL A.8, *Ageing management of a nuclear facility*, chapter 7, *Condition monitoring and maintenance*:

- Sub-chapter 7.1 gives out requirements for condition monitoring (requirements 701 – 707)
- Sub-chapter 7.2 gives out requirements for maintenance (requirements 708 – 717)
- Sub-chapter 7.3 gives out requirements for condition monitoring and maintenance programmes and instructions (718 – 722)

Requirements regarding licensee's operation organization surveillance and testing of SSCs are presented in Guide YVL A.6, chapter 5. These requirements include the following:

- 501. The shift team shall monitor the state of the nuclear power plant on a regular basis by using the control room screens and measurements, testing the operability of components, and performing inspections and control tours of the plant facilities.
- 503. The nuclear power plant shall have in place a periodic testing programme for ensuring the reliable operation and condition of structures, systems, and components related to the safety of the plant.
- 523. A nuclear power plant shall have in place a work management system for the administrative management of work assignments

In Guide YVL A.6, there is also few Operational Limits and Conditions (OLS) requirements, which are related to this topic. Requirement 734 requires that OLC should include:

- the process parameter limits that are critical in terms of the integrity of barriers, derived from the analyses serving as the design basis;
- the limits for the activation of protection and limitation systems;

- the basic requirements for safety systems to be complied with in different operational states, limit values, allowed deviations, operability requirements, the actions to be taken, and the time allowed to complete these actions;
- the periodic testing, inspection, and surveillance programmes for ensuring the operability of systems, structures, and components subject to operability requirements;
- the testing frequency, staggering, operational state, and the related instructions;
- any preventive maintenance giving rise to inoperability;
- the administrative requirements;
- the justifications for the requirements specified above.

In addition, YVL A.6 requirement 727 states that any in-service preventive maintenance and testing shall be optimised and justified by means of a PRA.

Guide YVL E.3 in Chapter 12 gives requirements to operation and periodic inspection of pressure equipment. The licensee is required to define working principles and guidelines to periodic inspections of nuclear facility's pressure equipment. Periodic inspections shall be performed in accordance with the Pressure Equipment Act 1144/2016. STUK approves the plans for annual periodic inspections and they shall be conducted by STUK, an authorised inspection body or the licensee's in-house inspection organisation,

Guide YVL E.5 gives requirements to periodic in service inspections with NDT to pressure equipment of nuclear facility. Testing procedures, equipment and personnel shall be qualified. STUK approves the qualifications, periodic inspection plans and results.

Guide YVL E.11 gives requirements to periodic inspections of hoisting and transfer equipments in nuclear facility. Licensee is required to prepare in-service inspection programme. STUK supervises the in-service inspections of hoisting device units and load-lifting attachments.

As a conclusion regulatory framework fulfils expectations from SSR-2/2 requirements 8.1-8.24. Also, the main expectations from IAEA Guide NS-G-2.6 are covered in legislation.

Question 39.1 What are the provisions in the regulatory framework regarding maintenance and testing of non-permanent equipment to be used for accidents more severe than design basis accidents at NPPs?

Response:

In Finnish regulatory framework accident management is strongly based on fixed equipment. YVL Guide B.1 requirement 455b states that "*provisions shall be made to enable the repair and servicing of the systems needed for maintaining the safe state"*, which practically applies only to fixed equipment.

The scope of requirements for non-permanent equipment to be used in accident conditions is therefore limited to general level. In Radiation and Nuclear Safety Authority Regulation on the

Emergency Arrangements of a Nuclear Power Plant (STUK Y/2/2018), there are presented general requirements regarding emergency preparedness training and maintenance of equipment as following:

STUK Y/2/2018 Section 4: *10. Licensee's management system and organisation shall ensure maintenance and development of the emergency arrangements.*

STUK Y/2/2018 Section 8: *3. The licensee shall draw up at least a three-year training plan to ensure that training is given on all aspects of preparedness to act at regular intervals.*

STUK Y/2/2018 Section 8: *5. Facilities and equipment reserved for emergency situations shall be available and maintained in operational condition at all times.*

More detailed requirements are given in YVL Guide C.4, *Emergency arrangements of a nuclear power plant*, requirements (354, 358, 360, 404, 411) as following:

354. In exceptional circumstances, there shall be preparedness to use mobile equipment to ensure electrical and water supply and other functions. The emergency plan and related supporting procedures shall provide comprehensive instructions on the utilisation of the equipment, but also training needs to be arranged.

358. The emergency organisation shall have an adequate amount of personal protective equipment available for emergency situations. There shall be a sufficient stock of the consumables required for the decontamination of persons and equipment. Equipment and consumables shall be stored and placed appropriately in such a way that they are quickly available for the various teams.

360. A record shall be kept on the quantity, location and operability of the premises, equipment and accessories.

404. The facilities used in emergency situations shall have the necessary equipment available such that prompt action can be taken without delay. The operability of all facilities, equipment and devices shall be regularly verified. The alarms as well as communication and data transfer connections shall be tested regularly at least once a month according to a separate programme. Defects, disturbances and deficiencies detected in the testing or otherwise shall be fixed without delay. The significance of the defects and weaknesses detected shall be assessed to identify potential improvement needs. Devices intended for emergency situations shall also be tested during exercises.

411.The annual emergency exercise shall cover a significant part of the emergency plans activities. The licensee shall ensure that all sectors are exercised over longer time spans. Simultaneous emergency situations of several nuclear facilities located at the same site area shall also be exercised. In addition, situation exercises involving one or several sectors of emergency response shall be arranged to become acquainted with the performance of the tasks, improve co-operation and enhance operations. The threat of unlawful action shall be included in some of the exercises.

Question 40 Does the regulatory framework include requirements relating to the preparation for decommissioning at NPPs?

Answer: Yes

Response:

The licence applicant and the licence holder shall prepare a plan for the decommissioning of the nuclear facility. In the design stage of a nuclear facility, a decommissioning plan shall be established that at least defines the decommissioning strategy, the implementation stages with timetables, an outline of the dismantling, waste management solutions adopted, and the end state of the facility site. If the plan involves a prolonged period of monitored storage prior to the dismantling of the facility, this shall be justified by considerations such as radiation protection optimization, co-implementation of the decommissioning with other nuclear facilities at the same site, or the commissioning of disposal facilities (Nuclear Energy Act 990/1987 section 7 g, Guide YVL D.4 404).

A nuclear facility's operating licence application shall include a sufficiently detailed decommissioning plan commensurate with the type and state of the facility (Guide YVL D.4 404). Unless otherwise provided in the licence terms, the licence holder shall also, during the operations requiring a licence, present on a regular basis, at least at 6-year intervals, an update to the plan for the decommissioning of

the nuclear facility for assessment by the Radiation and Nuclear Safety Authority (Nuclear Energy Act 990/1987 section 7 g). Decommissioning plan updates shall be sent to the MEAE for approval. The MEAE is asking statement on the decommissioning plan from STUK.

The final decommissioning plan shall be sent to STUK for approval as part of the application for decommissioning license (Nuclear Energy Degree 161/1988 section 36 a).

During the decommissioning of a nuclear facility the decommissioning plan shall be kept up to date and sent to STUK for approval (Nuclear Energy Act 990/1987 section 7 g).

The licensee under nuclear waste management obligation is responsible on the decommissioning costs. In Finland there is a national waste management fund, which covers spent nuclear fuel and nuclear waste management and decommissioning costs in the situations where the licensee would not be unable to pay the activities by itself. The licensee pays annually fee to the state nuclear management fund, which is based on waste management scheme presented by the licensee and approved by the MEAE. The waste management scheme is updated after every three years if not otherwise required by the MEAE. The nuclear waste management fund covers always the costs caused by the handling of existing nuclear waste amount at current price level and by using currently available technologies. (Nuclear Energy Act 990/1988 Section 9 and Chapter 7)

Plans for radioactive waste management shall be presented as part of the decommissioning plan. In addition, licensee must preset the radioactive waste management plans after every three year in a nuclear waste management plan sent to MEAE for approval. STUK give a statement on the plan. (Nuclear Energy Act 990/1988 section 28). During the reviews of plans it is ensured by the authorities that the plan is consistent with the national radioactive waste management policy and fulfills all relevant safety requirements related to nuclear waste management and decommissioning. Decommissioning license can only be granted if the radioactive waste management plans are acceptable.

The licensee shall have a sufficient number of competent personnel suitable for the related tasks for ensuring the safety of the nuclear facility. The licensee shall have access to the professional expertise and technical knowledge required for the safe construction, operation and decommission of the nuclear facility, the maintenance of equipment important to safety, and the management of accidents. (STUK Y/1/2018 section 25 paragraph 8)

The licensee is required to report on the progress of the decommissioning project to STUK regularly. (Guide YVL D.4 711)

When the decommissioning of a nuclear facility has been brought to completion and all waste has been removed from the site, the licensee shall submit to STUK for approval an application for the clearance of the site and any buildings therein (Nuclear Energy Act Section 33). In case of a general procedure, the application shall state the results of the survey demonstrating that the surface activity contamination levels specified in the legislation are not exceeded. In case of a case-specific procedure, the application shall also include a report demonstrating that the dose constraints set in legislation are not exceeded in the future use of the site and its buildings. The licensee shall provide also a summary of the implementation of the decommissioning for STUK for approval. (Guide YVL D.4)

When the decommissioning of the nuclear facility has been completed and after STUK has approved the above-mentioned documents, A licensee shall apply for an order on the expiry of his waste management obligation with the MEAE (Nuclear Energy Decree section 84). After approval this application the decommissioning has been bought to competition and the licensee shall notify STUK of the cessation of the use of nuclear energy (Nuclear Energy Decree section 120). In addition, licensee has to keep records on radioactive waste generated from its operations and report yearly to STUK about the unconditioned, stored and disposed radioactive waste volumes and activities (Guide YVL D.4 419-422).

Analysis

STRENGTHS FOR REGULATION OF NUCLEAR POWER PLANTS

S1	Finland has implemented the first principle of the Vienna declaration in legislation (Nuclear Energy Decree § 22b), and STUK has included in the regulatory guides more detailed and concrete interpretations for the principle (e.g. Guides YVL A.7 Probabilistic risk assessment and risk management of a nuclear power plant, YVL C.3 Limitation and monitoring of radioactive releases from a nuclear facility).
S2	Competent and experienced staff.
S3	Multidisciplinary in-house resources covering all main regulatory activities
S4	Competent and experienced technical support organization (VTT) to support regulatory oversight, review and assessment.
S5	Overall safety assessment for focusing regulatory oversight supported. Oversight information from various topics collected in a database tool. Assessment and decision on re-focusing regulatory activities done in every four months.

WEAKNESSES FOR REGULATION OF NUCLEAR POWER PLANTS

W1	STUK's expertise concerning non-water-cooled technologies is not as extensive as its expertise of light water technology.
W2	Nuclear legislation and requirements do not fully take into account new reactor types (e.g. SMRs).
W3	Regulatory procedures and guidance do not fully support graded approach in all regulatory activities, yet.
W4	Foreign material exclusion is not explicitly required, even if a general requirement for maintaining cleanliness and order in the nuclear power plant facilities exists. General requirement for material conditions and housekeeping is presented in YVL guide A.6, req. 521). STUK is starting a renewal of the Regulations and Guides. In the renewal it will be ensured that also the new goal setting requirements cover all the necessary aspects.

OPPORTUNITIES FOR REGULATION OF NUCLEAR POWER PLANTS

O1	Increased risk informed grading enables better focusing of limited resources to risk significant areas
O2	Development of nuclear legislation and regulatory requirements enables more streamlined licensing of various reactor types and better risk informed utilization of limited resources.
O3	Increased use of digitalization and tools could enhance regulatory work.
O4	STUK could increase co-operation and enhance wider utilization of multidisciplinary resources.

THREATS FOR REGULATION OF NUCLEAR POWER PLANTS

T1	The present requirements have been written for large light water reactors that are meant for electricity production and are situated in relatively remote areas. The present requirements may be challenging for other technologies or business models that may emerge e.g. with deployment of SMRs.
T2	Budget cuts in government funding.
T3	Loss of competence in certain special areas in the future (motivation, funding, availability of experts).
T4	Re-focusing of regulatory oversight and activities may lead to gaps in nuclear safety. A follow-up process needs to be developed.
T5	New goal-oriented legislation and requirements may lead to subjectivity in review and assessment.

CONCLUSIONS FOR REGULATION OF NUCLEAR POWER PLANTS

C1	Upcoming renewal of the regulations and regulatory guides enables more risk-informed and flexible way for oversight and highlights the responsibility of the licensees. At the same time, care must be taken not to neglect safety significant areas and to avoid subjectivity in review and assessment.

C2	SMRs are an emerging technology, not yet fully covered by the present legislation and regulations or by STUK's expertise. STUK is preparing for potential license applications by building its competence and taking SMRs into account in the renewal of the regulations and regulatory guides.
C3	The development of methods, tools and procedures related to graded approach has progressed well. However, further development is still needed to cover all main regulatory activities.
C4	STUK's overall safety assessment concept has proven to be a good platform for cross-disciplinary discussions and for supporting decisions making. It also provides means for the identification, categorization and tracking of regulatory issues.

Module: Safety Requirements for Disposal of Radioactive Waste

Findings

Question 1 Has the regulatory body established regulatory requirements for the development of different types of disposal facilities for radioactive waste and set out the procedures for meeting the requirements for the various stages of the licensing process?

Answer: Yes

Response:

In Finland, radioactive waste disposal is regulated with Nuclear Energy Act (YEL) 990/1987, Nuclear Energy Degree (YEA) 161/1988, STUK regulation Y/4/2018 on nuclear waste disposal, and binding Guides STUK YVL D.4, D.5 and D.7. Most of the radioactive waste to be disposed is produced in nuclear facilities and is nuclear waste. Therefore, it has been appropriate that the waste disposal legislation has been centralized under the nuclear waste legislation. In Finland, non-nuclear waste that cannot be returned to manufacturer or supplier will be disposed primarily to the existing nuclear waste facilities (cf. Radiation Act 859/2018 Section 80; STUK Y/4/2018 Section 1 Subsection 2).

YEA 161/1988 Section 6 identifies extensive disposal as:

"*Extensive final disposal* of nuclear waste, as referred to in paragraph 5, Section 3 Subsection 1 of the YEL 990/1987, means final disposal if it is intended that the disposal facility contain an amount of nuclear waste in which the total activity of radioactive materials, excluding natural uranium, thorium and depleted uranium, is higher than 1 TBq or the alpha activity, excluding natural uranium, thorium and depleted uranium, is higher than 10 GBq. (732/2008)"

On the extensive disposal of different waste types STUK Y/4/2018 Section 31 Subsection 5 states:

“The depth of the waste emplacement rooms shall be selected appropriately as regards the waste type and local geological conditions. The aim shall be that impacts on the long-term safety of above-ground events, activities and environmental changes will remain minor and that intrusion into the waste emplacement rooms will be difficult.”

On the non-extensive disposal STUK Y/4/2018 Section 31 Subsection 6 states:

“If nuclear waste referred to in the YEL is disposed of in a facility constructed in the ground, the disposal shall be planned and implemented according to the requirements of this regulation while taking into account the limited activity of the waste. Only very low-level waste, the total activity of which does not exceed the limits laid down in Section 6(1) of the YEA, can be placed in a facility constructed in the ground”.

In accordance with the Finnish regulatory framework, Governmental licensing of a nuclear facility is stepwise (Decision in Principle, Construction License, Operating License, Decommissioning License). In addition to authority actions needed making these decisions, these steps also imply turning points to regulatory oversight. The emphasis of regulatory oversight is different at an early stage than at a mature stage of a disposal project. The general conditions for granting a license are prescribed in the YEL 990/1987, Sections 18-20.

In case of very low-level waste facility (non-extensive disposal), the licensing authority is STUK as stated in YEL 990/1987 Section 16 Subsection 2. STUK grants license of operation on basis of an application. The application shall be supplemented with environmental impact analysis and safety analysis report.

Question 1.1 Does the regulatory body engage in dialogue with waste producers, the operators of the disposal facility and interested parties to ensure that the regulatory requirements are appropriate and practicable?

Response:

According to the YEL 990/1987 Section 55, STUK is responsible for the regulatory control of the safety of the use of nuclear energy. The rights and responsibilities of STUK are provided in the YEL Sections 55 and 63. The regulatory activities include authorization, review and assessment, inspection and enforcement, development of regulations and guides, national registers and inventories, *information and public communication*.

MEAE and STUK are engaged in dialogue with waste producers and other interested parties officially and unofficially. MEAE and STUK make decisions in terms of their rights and responsibilities. In accordance e.g. with the Administrative Procedure Act (APA) 434/2003 Section 35 and 36, before a decision is made licensee or other interested parties are heard in one or several hearings. Legislation amendments and facility licensing stages include diverse hearings and calls for statements from the interested parties. Demands for rectifying mistakes in an effective decision can be submitted to the Ministry or STUK in writing as laid down in Chapter 8 of the APA 434/2003. Furthermore, decisions may be appealed to Administrative Courts within 30 days from notification of the decision. More unofficial interaction between regulatory body and interested parties occur in meetings where e.g. license holder clarifies its intentions to meet the regulatory requirements or concerns of interested parties are heard. In the case of official decisions, the complete documented interaction is recorded to regulator registry. In the case of unofficial meetings, the minutes are usually kept by licensee or an interested party (e.g. municipality).

STUK is responsible communicating with the public and media on radiation and nuclear safety. STUK aims to communicate proactively, openly, timely and understandably. A prerequisite for successful communication is that STUK is known among media and general public, and the information given by STUK is regarded as truthful. Communication is based on best available information. STUK's own web site is an important tool in communication. STUK also uses social media platforms for two-way public communication. Internal communication informs the personnel about STUK's activities, and this supports STUK's capability to communicate with public.

The management of STUK highlights the need for a competent workforce. Costs of the regulatory oversight are invoiced from the licensees. This guarantees State budget independent financing of the oversight work. Furthermore, national nuclear safety research (KYT, SAFIR) programmes play an important role in the competence building for all essential organisations involved in nuclear energy. The funding of the programmes according to the YEL 990/1987 (Sections 53 d and 53 e) comes from the license holders, and one of the roles of programmes is to ensure the availability of experts and tools for regulatory oversight. The Finnish policy is to participate in the international discussion on developing safety standards and to adopt or adapt new safety requirements into national regulations.

Question 1.2 Does the regulatory body set conditions for each individual disposal facility, including its development, operation and closure and carry out such activities as are necessary to ensure that the conditions are met?

Response:

The licensing of disposal facility is stepwise process. The first step is the Decision in Principle made by Finnish Government and ratified by Parliament (YEL 990/1987 Section 11). The next step is the Licensing of Construction made by Finnish Government. The following step is the Licensing of Operation made by Finnish Government (YEL Section 16). Each license is based on licensee

application and must be supplemented with a set of justifying attachments. At each stage, STUK evaluates the operational and long-term safety, makes its statement for Government, and has a “safety veto” to Governmental decisions to be made.

The legislation does not specify individual types of facilities (but makes distinction between extensive and non-extensive disposal) and assigns the safety assessment to the period of time needed to ensure the safe disposal (see Response 1).

According to STUK Y/4/2018 Section 4 “The long-term safety of the disposal of nuclear waste shall be assessed based on the applicable principles when selecting the disposal site and applying for a decision in principle. It shall also be assessed when applying for a licence for operations for a very low level waste disposal facility, a construction licence and operating licence for a disposal facility and a decommissioning license for a nuclear waste facility as well as during the periodic safety assessments. Furthermore, the safety assessment shall be updated prior to the permanent closure of the disposal facility and the termination of the waste management obligation. The assessment of long-term safety at different stages shall demonstrate that the disposal has been designed and implemented in accordance with the safety requirements. *The safety assessment shall cover the period of time following the closure of the facility which is required for the purposes of ensuring the safety of disposal*”.

In regard of operational safety STUK Y/4/2018 Section 3 states: “The safety of operation of a nuclear facility shall be assessed when applying for a construction license and operating license, in connection with plant modifications, and at Periodic Safety Reviews during the operation of the facility.”

STUK Y/4/2018 Section 8 states that “Disposal shall be implemented in stages, with particular attention paid to aspects affecting long-term safety. The planning of the construction, operation and closure of a disposal facility shall account for the reduction of the activity of nuclear waste through interim storage, the utilisation of high-quality technology and research data, and the need to develop an understanding of the performance of the barriers and long-term safety through investigations and monitoring.”

Guide STUK YVL D.5 addresses the extensive disposal of nuclear waste and radioactive waste (cf. STUK Y/4/2018 section 1, subsection 2) in repositories constructed inside the bedrock. YVL D.5 chapter 4.1 further specifies that implementation of nuclear waste disposal will occur in phases (disposal concept, characterization, RD&D, construction, disposal, closure, potential post-closure monitoring). These phases can be partially parallel, but they shall be scheduled with due regard to long-term safety. For example following aspects should be considered: 1) reduction of the activity and heat

generation in waste prior to disposal, 2) introduction of the available technique or a technique that is becoming available, 3) acquisition of adequate experimental knowledge of the disposal site and other factors affecting long-term safety, 4) potential surveillance actions related to ensuring the long-term safety or to non-proliferation of nuclear materials, 5) need for preserving the retrievability of the disposed waste canisters, 6) aim of preserving the natural features of the host rock and other favourable conditions in the repository, and 6) aim of limiting the hazards and other burdens to future generations due to long-term storage of waste.

The HLW disposal site investigations in Finland were launched with Government's Policy Decision of 1983. In accordance with this decision, Teollisuuden Voima Oy (TVO) launched R&D program for selecting a disposal site by the end of year 2000. Proponent applied DiP for Olkiluoto repository in May 1999. The DiP was ratified by Parliament in May 2001. This DiP requires excavations of research facilities and underground RD&D activities at the site. The DiP remains effective 15 years from the ratification. In 2012, the proponent applied CL for the HLW disposal facility. In 2015, after review of application material the CL licence was granted. STUK made decisions on the licensee long-term safety case and the PSAR, which required improvements to those for the next licencing stage. During construction, a regular construction inspection program (RTO) is targeted to the licensee. Currently, the licensee is preparing its OL application for HLW disposal facility.

The LILW disposal facilities are operational in Olkiluoto and in Hästholmen. These facilities were licensed for operation in 1992 and 1998, respectively. The first FSAR and safety case update from Olkiluoto LILW repository was delivered in 2007. TVO is currently in the process of delivering the second FSAR and safety case updates of Olkiluoto LILW repository. The first FSAR and safety case update from Hästholmen was delivered in 2013. Due to disposal facility updates, Fortum produced updated safety case for Hästholmen LILW repository in 2018. Fortum delivered FSAR update in 2020, and this is currently being evaluated by STUK. Further safety case updates from both sites shall be made every 15 years. For both licensees, a facility specific operational inspection program (KTO) is targeted.

Currently, TVO is processing an application for a first VLLW disposal facility in Finland. The operation license for this facility will granted by STUK, and all safety justifications (including the long-term safety case) will be evaluated together with the application.

Question 2 Does the regulatory body require the operator to carry out safety assessment and develop and maintain a safety case, and to carry out all the necessary activities for site selection and evaluation, design, construction, operation, closure and, if necessary, surveillance after closure of a disposal facility, , in compliance with the regulatory requirements and within the legal and regulatory infrastructure?

Answer: Yes

Response:

YEL 990/1987 Section 9 identifies explicitly that the producer of nuclear waste is responsible for safe use of nuclear energy and is obligated to carry out such security and emergency arrangements and other arrangements necessary for the limitation of nuclear damage which do not rest with the authorities and shall be responsible for all nuclear waste management measures and their appropriate preparation, as well as for their costs.

In accordance with YEL Section 7e: "Compliance with the requirements concerning the safety of a nuclear facility shall be reliably proven. […] The overall safety of a facility performing large-scale disposal of nuclear waste shall, however, be assessed at least at 15-year intervals".

The overall safety assessment of a facility refers to whole safety documentation including operational and long-term safety (safety case refers specifically to long-term safety).

In regard of operational safety STUK Y/4/2018 Section 3 states: "[…] The safety assessment shall demonstrate that the nuclear facility has been designed and implemented in a manner that meets the safety requirements. The safety assessment shall cover the operation of the facility in accordance with the Operating Limits and Conditions as well as anticipated operational occurrences and accident situations."

According to STUK Y/4/2018 Section 4: "The long-term safety of the disposal of nuclear waste shall be assessed based on the applicable principles when selecting the disposal site and applying for a decision in principle. It shall also be assessed when applying for a licence for operations for a very low level waste disposal facility, a construction licence and operating licence for a disposal facility and a decommissioning license for a nuclear waste facility as well as during the periodic safety assessments. Furthermore, the safety assessment shall be updated prior to the permanent closure of the disposal facility and the termination of the waste management obligation."

STUK Y/4/2018 Section 31 indicates in 6 Subsections suitable properties for disposal site. Guide STUK YVL D.5 Chapter 4.3 gives more details, what are the expected properties of a suitable disposal site. STUK Y/4/2018 Sections 21 and 31 also give general boundary conditions for facility design, excavation, construction, and closure. STUK YVL D.5 Chapter 5.2.2 further specifies these prerequisites. STUK Y/4/2018 Section 32 describes in 5 Subsections expected properties of technical release barriers. Guide STUK YVL D.5 chapter 4.2 specifies in more detail the expected properties and safety functions of release barriers

STUK Y/4/2018 Section 33 requires that "In order to ensure the performance of the barriers, a research and monitoring programme shall be established and implemented for the operating stage of the disposal facility". Regarding the after closure surveillance YEL Section 34 states "[…] Should it become necessary after the disposal, the State has the right, at the disposal site, to take all measures required for the monitoring and control of the nuclear waste and for ensuring the safety of the repository". However, its assumed that a passive repository will not need long term monitoring.

Question 2.1 Does regulatory body require the operator to prepare and update a safety case and supporting safety assessment, as necessary, at each step of a disposal facility development, including operation and post-closure in compliance with legal and regulatory requirements and to be submitted to the regulatory body for approval?

Response:

According to YEA 161/1988 Section 24, the licensee shall report preliminary planned safety arrangements at DiP licensing step. In accordance with YEL 990/1987Section 12, STUK makes safety review on the DiP application material relevant to nuclear safety. According to YEA Section 35, the licensee shall deliver at the step of construction license application a PSAR for STUK's safety review. YEA Sections 36 and 36a declare that while applying operation or decommissioning license, the licensee shall deliver FSAR to STUK's for safety review.

In terms of long-term safety, STUK Y/4/2018 Section 37 states: "The safety case shall be presented when applying for a construction licence and operating licence for the disposal facility and when making substantial plant modifications. The safety case shall be updated during the periodic safety assessments of the disposal facility unless otherwise provided in the licence conditions. The need for updating the safety case shall be assessed before making modifications that concern the disposal system. Furthermore, the safety case shall be updated prior to the closure of the facility."

Furthermore, on long-term safety, STUK Y/4/2018 Section 4 says: "The safety assessment is presented in the safety case, which shall assess the evolution of the disposal system after the closure of the disposal facility and the related releases of radioactive substances by means of calculational analyses and other complementary considerations."

Guides STUK YVL A.1, D.5 and D.7 describe in more detail the documentation that needs to be delivered in STUK for acceptance at each step of a disposal facility development and for the periodic safety assessments.

Question 2.2 Does the regulatory body require that the safety case for a disposal facility describes all the safety relevant aspects of the site, the design of the facility, and the managerial control measures and regulatory controls?

Response:

There is a slight distinction between IAEA vocabulary and the Finnish context of the safety case as regards the overall safety of a facility.

YEA 161/1988 Sections 24, 32, 34 and 34a list several documents including several descriptions on financial securities, organization and managerial principles that need to be included to licence applications. YEA Sections 35, 36 and 36a lists several documents including e.g. Safety Analysis Reporting (PSAR/FSAR), facility administrative rules, quality management program, and safety and security arrangements that need to be delivered to STUK while applying a license.

In Finnish context, a Safety Analysis Reporting (SAR) covers e.g. descriptions of the site, overall design basis and safety requirements, operational systems, inventories, radiation protection, disturbance and accident analyses, detailed system descriptions, and a summary of long-term safety justifications. Safety Case refers specifically to the long-term safety of a facility, and to all those supporting reports used for justifying the long-term safety. Long-term safety case aims to justify all the safety relevant aspects of the site and designed facility.

Supporting information what is meant with “overall safety of a facility” can be found from the Responses 2 and 2.1. As indicated above, licensee managerial control measures are delivered in documented form to the regulatory body at each licensing step and periodic safety assessments. Regular regulatory oversight is implemented with authority decisions on required documentation delivered to regulatory body, and with construction and operation inspection programs (RTO & KTO). Further details on required documentation is also found from Guide STUK YVL A.1 Chapter 5. Inspection programs are outlined in Guide STUK YVL A.5 Sections 502, 503, 507, and STUK YVL A.6 Section 801.

Question 3 Does the regulatory body require the operator to develop (and demonstrate) understanding of the relevance, and its implications for, safety of the available options for the facility throughout the process of development and operation of a disposal facility for radioactive waste?

Answer: Yes

Response:

YEL 990/1987 Section 7a requires: “The safety of nuclear energy use shall be maintained at as high a level as practically possible. For the further development of safety, measures shall be implemented that can be considered justified considering operating experience and safety research and advances in science and technology”.

In accordance with STUK Y/4/2018 Section 3 Subsection 2: “The nuclear facility’s safety and the technical solutions of its safety systems shall be assessed and substantiated analytically and, if necessary, experimentally. *These assessments and justifications shall be maintained and revised as necessary, taking into account operating experience from the facility itself and from other similar nuclear facilities, the results of safety research, plant modifications, and the advancement of calculation methods.*”

Furthermore, STUK Y/4/2018 Section 8 Subsection 1 states: “Disposal shall be implemented in stages, with particular attention paid to aspects affecting long-term safety. *The planning of the construction, operation and closure of a disposal facility shall account for the reduction of the activity of nuclear waste through interim storage, the utilization of high-quality technology and research data, and the need to develop an understanding of the performance of the barriers and long-term safety through investigations and monitoring*.”

On taking operating experience and safety research into consideration in order to improve safety, STUK Y/4/2018 states in Section 25 Subsection 2: “For further safety enhancement, operating experience from the facility and from other nuclear facilities, the results of safety research and technical developments shall be regularly monitored and assessed.” The same Section continues with Subsection 3 that states: “Opportunities for improvements in technical and organisational safety, identified from operating experience, safety research and technical developments shall be assessed and implemented to the extent regarded as justified on the basis of the principles laid down in Section 7 a of the YEL”

Finally, taking into account the safety culture perspective, STUK Y/4/2018 Section 38 Subsection 1 states: “[…] Personnel shall be encouraged to perform responsible work, and to identify, report, and eliminate factors endangering safety. Personnel shall be given the opportunity to contribute to the continuous improvement of safety”.

Question 3.1 How does the regulatory body ensure that the implications for safety of the available design and operational options for the disposal facility are considered and taken into account at each major decision point?

Response:

Stepwise licensing process and periodic safety reviews encourages the licensee to develop its understanding and consider the possible available options for the facility throughout the life cycle of a disposal facility. Both licensing and periodic review steps result regulatory decisions where regulator sets requirements for improvements and further justifications. Furthermore, YEL 990/1987 Section 7 e states: "The overall safety of a facility performing large-scale disposal of nuclear waste shall, however, be assessed at least at 15-year intervals"

According to YEL 990/1987 Section 7 a (Guiding Principles): "The safety of nuclear energy use shall be maintained at as high a level as practically possible. For the further development of safety, measures shall be implemented that can be considered justified considering operating experience and safety research and advances in science and technology." The second Subsection of the same Section states: "The safety requirements and measures for ensuring safety shall be graded and targeted so as to be commensurate with the risks in the use of nuclear energy." YEL 990/1987 Section 7 f requires: "[…] the condition and operating experiences of any nuclear facility shall be systematically monitored and assessed." Finally, YEL 990/1987 Section 7 g states (among other things) that STUK shall issue further regulations on "taking operating experience and safety research into consideration in order to improve the safety of a nuclear facility".

In accordance with YEL 990/1987 Section 24 operating licences are granted always for a fixed term. The Regulation STUK Y/4/2018 Section 3 requires that "The safety of operation of a nuclear facility shall be assessed when applying for a construction license and operating license, in connection with plant modifications, and at Periodic Safety Reviews during the operation of the facility."

Based on YEA 161/1988 Section 35 the licensee shall present PSAR at the stage of construction license application. YEA 161/1988 Section 36 requires the licensee to present FSAR at the stage of operating license application, and Section 36 a requires the delivery of safety documentation while applying decommissioning (closure) of a nuclear facility.

In accordance with the STUK Y/4/2018 Section 37, licensee is obliged to present the long-term safety case at the construction, operation, and closure licensing steps. A licensee is also obligated to update its safety case for periodic safety reviews, and when making substantial plant modifications.

Question 4 Does the regulatory body require that the disposal facility is licensed (incl. sited, designed, constructed, operated and closed) in such a way that passive safety means are applied to the extent possible and that the need for actions to be taken after the closure of the facility is minimized?

Answer: Yes

Response:

YEL 990/1987 Section 7 h Subsection 3 requires: “The disposal of nuclear waste in a manner intended as permanent shall be planned giving priority to safety and so that ensuring long-term safety does not require the surveillance of the final disposal site.”

STUK Y/4/2018 Section 15 Subsection 1 states: “Ensuring the functions important to safety shall primarily be based on inherent safety features, alongside systems and components that do not require external power supply or which, as a consequence of a loss of power supply, will settle into a state preferable from the safety point of view.”

STUK Y/4/2018 Section 21 states: “The disposal facility shall be designed, constructed and operated in a manner that allows it to be closed without jeopardising long-term safety after its operation has ended.”

STUK Y/4/2018 Section 31 Subsection 1 requires: “The characteristics of the rock at the disposal site shall, as a whole, be favourable to the isolation of the radioactive substances from the living environment. Any area with a feature that is substantially adverse to long-term safety shall not be selected as the disposal site.”

STUK Y/4/2018 Section 30 states: “The long-term safety of disposal shall be based on long-term safety functions achieved through mutually complementary barriers so that the degradation of one or more long-term safety function or a foreseeable change in the bedrock or climate will not jeopardise the long-term safety.”

Legislation does not talk about passive safety but describes de facto the almost complete containment. It is assumed that a passive repository does not need long term monitoring.

Question 5 Does the regulatory body require the operator of a disposal facility to develop an adequate understanding of the features of the facility and its host environment and of the factors that influence its safety after closure over suitably long time periods (disposal system, safety case), so that a sufficient level of confidence in safety can be achieved?

Answer: Yes

Response:

On demonstration of a nuclear facility's compliance with safety requirements STUK Y/4/2018 Section 3 Subsection 3 states: "The methods employed to demonstrate compliance with safety requirements shall be reliable and suited to the purpose. The analyses shall demonstrate the conformity with the safety requirements with high certainty. Any uncertainty in the results shall be assessed and considered when assessing the meeting of the safety requirements."

STUK Y/4/2018 Section 36 Subsection 1 requires "The safety case and the methods, data and models used in it shall be based on high-quality research data and expert judgement, and they shall be documented in a traceable manner. The data and models shall be appropriate and correspond to the anticipated conditions at the disposal site and system during each assessment period." The same Section states in Subsection 2 that "The basis for calculational analyses shall be that the actual amounts of radioactive substances released and the actual radiation exposure shall be, with a high degree of certainty, lower than the results received from the safety analyses. The safety case shall separately assess the uncertainties included in the data, models and analyses and their significance."

STUK Y/4/2018 Section 31 declares several requirements on the site suitability and identifies that a disposal site cannot have substantially adverse features to long term safety. Section 32 gives long-term expectations for engineered barriers and requires compatibility of the barriers with each other. Section 33 requires setting up an operating stage research and monitoring programme to ensure the performance of the barriers. As indicated previously, STUK Y/4/2018 Section 4 requires that the long-term safety of the disposal of nuclear waste shall be fully assessed when applying e.g. a construction license.

The Guide STUK YVL D.5 gives more detailed instructions on the planning of the disposal method (Ch. 4) and compiling the safety case (Ch. 9).

Question 5.1 How does the regulatory body agree and approve the range of possible events and processes causing disturbances that it is reasonable to include in the safety case?

Response:

STUK Y/4/2018 Section 30 states on the long-term safety of the nuclear waste disposal that "The long-term safety of disposal shall be based on long-term safety functions achieved through mutually complementary barriers so that the degradation of one or more long-term safety function or a foreseeable change in the bedrock or climate will not jeopardise the long-term safety."

STUK Y/4/2018 Section 35 Subsection 1 identifies "[…] possible evolutions of the disposal system, including evolutions caused by rare events impairing long-term safety" and states that "The safety case includes, for example, calculational safety analysis based on the evolutions and the complementary considerations." STUK Y/4/2018 Section 11 emphasizes that radiation exposure caused by rare events shall be assessed where possible. (Further clarification of evolution/event definitions: see Response 8)

Guide STUK D.5 Sections 316, 316a, 317, and A04 further elaborates the possible FEP's to be considered. Section A04 says that "The scenarios used in assessing alternative evolutions of the disposal system shall be systematically created to cover any events and factors that may be of relevance to long-term safety and that may arise from:

a) external factors, such as climate changes, geological events or human actions;

b) radiological, mechanical, thermal, hydrological, chemical, biological and radiation-related factors internal to the disposal system; and

c) quality non-conformances in the barriers and the combined effects of all the aforementioned factors.

Guide STUK D.5 identifies a) base scenario (performance targets defined for each safety function are met), b) variant scenarios (declined performance of one or several long-term safety functions), and c) disturbance scenarios (rare events impairing long-term safety).

The regulatory body sets the above-mentioned minimum framework for licensee FEP and scenario considerations. Interaction between regulatory body and licensee occur during the stages between licensing steps. However, licensee presents its justifications for safety at each licensing step.

Question 6 Does the regulatory body require providing safety by means of multiple safety functions throughout all the disposal facility lifetime, including siting, design and operation, selection of the host environment, design of the facility engineered components and its operation?

Answer: Yes

Response:

YEL 990/1987 Section 7 b states: "The safety of a nuclear facility shall be ensured by means of successive levels of protection independent of each other (safety principle of defence-in-depth). This

principle shall extend to the functional and structural safety of the plant." In regard operational safety this requirement within a radioactive waste facility is comparable to a nuclear power plant. The operational defense-in-depth for nuclear waste facilities is further defined e.g. STUK Y/4/2018 Sections 13 and 14.

In terms of long-term safety of a geological disposal facility, it has been identified that nested engineered and natural barriers cannot be completely independent from each other. Therefore, STUK Y/4/2018 Section 30 defines long-term defense-in-depth as: "The long-term safety of disposal shall be based on long-term safety functions achieved through mutually complementary barriers so that the degradation of one or more long-term safety function […] will not jeopardise the long-term safety".

STUK Y/4/2018 Section 5 requires that systems, structures, and components implementing either operational or long-term safety functions shall be safety classified in accordance with their safety significance.

In terms of long-term safety, Guide STUK YVL D.5 sets more detailed requirements for natural and engineered barriers, and e.g. guidance (Sections 406, 408) is given for setting or considering appropriate safety functions for barriers.

Question 7 Does the regulatory body require that the engineered barriers, including the waste form and packaging, are designed, and the host environment is selected, so as to provide containment of the radionuclides associated with the waste, during the period when radioactive decay has not yet significantly reduced the hazard posed by the waste and in the case of heat generating waste when the waste produces heat energy in amounts that could adversely affect the disposal environment?

Answer: Yes

Response:

STUK Y/4/2018 Section 31 sets in 5 Subsections conditions that shall be taken into account while selecting the natural barrier for nuclear waste disposal. Requirements start from overall suitability of the site and focus down to successful selection disposal depth and implementation of disposal rooms.

STUK Y/4/2018 Section 32 set expectations for engineered barriers in 4 Subsections. The expectations take into account the type and activity of waste to be disposed. No explicit regulatory position is taken to the post-closure heat generation, but the overall expectations are set in Subsection 1: "The characteristics of engineered barriers shall be such that they effectively prevent the release of radioactive substances into the bedrock surrounding the underground emplacement rooms for a duration of time that is sufficient in relation to the half-life of the radioactive elements contained within

the waste. In the case of disposal of very low-level waste in the ground, the entry of radioactive substances into the environment must be prevented effectively. For short-lived waste, this period shall be at least several hundreds of years, and for long-lived waste, at least several thousands of years". The Section 32 Subsection 1b states: "Engineered barriers shall not be constructed of materials or combinations of materials that have a clearly unfavourable characteristic in terms of long-term safety or whose operability may be reduced under the conditions present in the emplacement rooms in a manner that jeopardises long-term safety of disposal."

However, any possibility to post-closure self-sustaining chain reactions of fissions shall be excluded with high certainty (STUK Y/4/2018 Section 32 Subsection 3).

The waste forms are identified in Guide STUK YVL D.5 as a requirement that radioactive materials shall be immobilized in the waste matrix (Section 406).

The legislation does not use the term containment. Instead phrases "[…] barriers shall be such that they effectively prevent the release of radioactive substances", or "[…] site shall, as a whole, be favourable to the isolation of the radioactive substances", and "long-term safety functions shall refer to functions achieved by the characteristics or processes of engineered and natural barriers that are intended to isolate the nuclear waste from the bedrock and the biosphere or to impede the migration of radionuclides" (Y/4/2018 Section 2 Subsection 1 paragraph 14) intend to describe almost complete radionuclide containment in relevant time scales.

Question 7.1 Does the regulatory body ensure that the requirements upon containment of radioactive waste on the early stages of facility planning/development (design)?

Response:

As indicated in the Response 7

STUK Y/4/2018 Section 31 Subsection 1 states on the disposal site that "The characteristics of the rock at the disposal site shall, as a whole, be favourable to the isolation of the radioactive substances from the living environment. Any area with a feature that is substantially adverse to long-term safety shall not be selected as the disposal site." The Subsection 4 requires that "The siting, excavation, construction and closure of underground rooms shall be implemented so that the characteristics of the rock deemed important in terms of long-term safety are retained, as far as possible."

STUK Y/4/2018 Section 32 Subsection 1 requires that "The characteristics of engineered barriers shall be such that they effectively prevent the release of radioactive substances into the bedrock surrounding the underground emplacement rooms for a duration of time that is sufficient in relation to the half-life of the radioactive elements contained within the waste." The Subsection 1 b states "Engineered barriers shall not be constructed of materials or combinations of materials that have a clearly unfavourable characteristic in terms of long-term safety or whose *operability* (N.B. in Finnish original: *performance*) may be reduced under the conditions present in the emplacement rooms in a manner that jeopardises long-term safety of disposal".

Guide STUK YVL D.5 Chapter 4 gives several more detailed requirements for planning of the disposal method.

In accordance with the STUK Y/4/2018 Section 8 Subsection 1 and Guide STUK YVL D.5 Section 402 the outlines of the disposal concept and suitable site shall be decided at an early stage of a final disposal project.

Question 8 Does the regulatory body require that the disposal facility is sited, designed and operated to provide features that are aimed at isolation of the radioactive waste from people and from the accessible biosphere, including consideration of both the natural evolution of the disposal system and events causing disturbance of the facility?

Answer: Yes

Response:

YEA 161/1988 Section 22 d Subsection 3 requires that the disposal of nuclear waste shall be so designed that the radiation impacts arising as a consequence of *expected evolution*:

a. the annual dose to the representative person remains below the value of 0.1 mSv; and

b. the average annual doses to other persons remain insignificantly low.

These constraints shall be applied over an assessment period, during which the radiation exposure of humans can be assessed with sufficient reliability, and which shall extend, at a minimum, over several millennia.

YEA 161/1988 Section 22 d Subsection 4 further requires that for assessment periods beyond several millennia the long-term averages of radioactive releases originating from disposed wastes shall below the maximum limits STUK confirms separately for each radionuclide (see Guide STUK YVL D.5 Sections 312-314).

As indicated in Response 5.1, instead of using term *expected* STUK Y/4/2018 Section 35 talks about (all) *possible evolutions* of a disposal system. Guide STUK YVL D. 5 defines *expected* evolution to cover both base and variant scenarios (STUK YVL D.5 Sections A05 and A05a) that need to be considered for a disposal system. Moreover, STUK Y/4/2018 Sections 11 and 35 discuss also about rare events while guide STUK YVL D.5 Section A05b assigns these to disturbance scenarios.

In accordance with STUK Y/4/2018 Section 11 Subsection 1 "The probabilities of rare events impairing long-term safety and their impacts on the disposal system and the long-term safety of disposal shall be assessed. The radiation exposure caused by them shall be assessed where possible. The probability of events causing significant radiation exposure shall be very low, and the widespread effects of the release of radioactive substances caused by them shall be low."

STUK Y/4/2018 Section 35 Subsection 5 states: "The depth of the waste emplacement rooms shall be selected appropriately as regards the waste type and local geological conditions. The aim shall be that impacts on the long-term safety of above-ground events, activities and environmental changes will remain minor and that intrusion into the waste emplacement rooms will be difficult".

STUK Y/4/2018 Section 32 Subsection 1 requires that characteristics of engineered barriers shall be such that that they effectively prevent at least several hundreds of years short-lived and at least several thousands of years long-lived radioactivity releases into the bedrock. Guide STUK YVL D.5 further defines this requirement in its Sections 410 - 411 a.

Expectations set for the disposal site (natural barrier) are discussed in STUK Y/4/2018 Section 31 as indicated in Responses 7 and 7.1. Section 31 Subsections 3 and 5 point also out the issues of the avoidance of exploitable natural resources at a successful site and other selections affecting the inadvertent human intrusion.

Question 8.1 What are the regulatory requirements for assessment of the human intrusion possibility, in case it may not be possible to provide sufficient assurance of isolation from the biosphere?

Response:

STUK Y/4/2018 Section 11 Subsection 2 requires that "The radiation exposure caused by inadvertent human intrusion into the emplacement rooms during the period following their closure shall be assessed."

Guide STUK YVL D.5 Section 316 a further refines by stating that "rare events impairing long-term safety caused by human actions to be considered shall at least include the boring of a medium-deep water well at the disposal site and core drilling or boring hitting a disposed waste package. In such a case, it is assumed that the existence of the disposed waste is not known and that the incident may occur 200 years following the closure of the disposal facility at the earliest."

As indicated in the Response 5.1, STUK Y/4/2018 Section 35 Subsection 1 identifies as well "rare events impairing long-term safety" and Guide STUK YVL D.5 Section A05 b states that for analyses of radionuclide releases disturbance scenarios shall be constructed for these events.

Based on Guide STUK YVL D.5 Section 317, The probability and importance to safety of the inadvertent human intrusion as well as the annual doses or activity releases arising from them shall be assessed where practicable. The possibility of radiation exposure that might imply deterministic effects shall be very low. This is analogously defined as in STUK Y/4/2018 Section 11 Subsection 1 on rare events: " […] The probability of events causing significant radiation exposure shall be very low, […]".

Question 9 Is an appropriate level of surveillance and control required by the regulatory body to be applied in order to protect and preserve the passive safety barriers to the extent that is needed in order to fulfil the functions assigned in the post closure safety case?

Answer: Yes

Response:

Passive safety barriers have been discussed earlier in Response 4. STUK Y/4/2018 Section 15 identifies *inherent safety features* that are primary ensuring the functions important to safety. STUK 4/Y/2018 Section 21 requires that operational activities do not jeopardize the post-closure safety. STUK YVL D.7 guides in detail activities of spent fuel disposal. About the scope the Section 201 states e.g.: "[…] technical design, manufacture, construction, installation, inspection, testing and verification of conformity of barriers intended for the disposal of spent nuclear fuel, and the monitoring of the impacts of their construction during construction and operation".

STUK Y/4/2018 Section 33 states “In order to ensure the performance of the barriers, a research and monitoring programme shall be established and implemented for the operating stage of the disposal facility.”

Guide STUK YVL D.5 Section 506 further specifies the coverage of the research and monitoring programme as follows: “During the construction and operation of the disposal facility, a research and monitoring programme shall be executed to ensure that the site and the rock to be excavated are suitable for disposal and to collect supplementary information about the safety-relevant characteristics of the host rock and the performance of the barriers. This programme shall at least include:

a. the characterisation of the rock volumes intended to be excavated;

b. the monitoring of rock stresses, movements and deformations in rock surrounding the

c. emplacement rooms;

d. the hydrogeological monitoring of the host rock surrounding the emplacement rooms;

e. the monitoring of groundwater chemistry;

f. the monitoring of the performance of engineered barriers; and

g. the monitoring of surface environment.

Guide STUK YVL D.5 Section 714 requires licensee to report the results of research and monitoring programme annually to STUK. Furthermore, Guide STUK YVL Section 706 states that licensee shall document its research and monitoring plans in its Safety Analysis Reportings (PSAR, FSAR, periodic updates). Its also required in Section 815 that a precondition for facility closure is that STUK has accepted, among other things, the final safety case that takes into account results received from operational research and monitoring programme.

Question 10 Does regulatory body require that disposal facilities are developed, operated and closed in a series of steps, each supported, as necessary, by iterative evaluations of the site, of the options for design, construction, operation and management, and of the performance and safety of the disposal system?

Answer: Yes

Response:

In accordance with YEL 990/1987 Sections 11, 16, 18, 19, 20, 20 a, and 21, licensing of a nuclear (radioactive) disposal facility is a stepwise process. The licensing process is described also in Response 1.2. Legislation describes the decision makers (government, parliament, community, STUK) and hold-points of each licensing step that intend to ensure at each step that YEL 990/1987 Section 5 ("The use of nuclear energy, taking into account its various effects, shall be in line with the overall good of society") is realized. Stepwise process requires also gradually increasing justifications for safety as licensing advances.

At a general technical level STUK Y/4/2018 Sections 4, 8, 22, 23, and 24 a set up requirements on stepwise implementation and gradually increasing management and justifications for safety. Guide STUK YVL D.5 Sections 402 and 403 outline in more detail the stepwise implementation of nuclear waste disposal. As indicated in the regulation a successful final disposal project starts from selection of disposal concept and site. The various stages of disposal shall be scheduled and implemented giving priority to safety.

Regulatory oversight has different emphasis at an early stage than at a mature stage of a disposal project. Before a Decision-in-Principle stage regulatory and independent technical review concentrates to credibility of justifications of selected disposal concept and characterized disposal site options.

Question 10.1 What are the regulatory measures for reviews, as well as transparency and public involvement in these activities at each step of the process for disposal facility development?

Response:

According to YEL 990/1987 Section 27 b, the Ministry of Economic Affairs and Employment (MEAE), together with STUK, is responsible of drawing up a national nuclear waste management programme. When drafting the programme, the public shall be reserved an opportunity to express their opinions.

At a pre-licensing STUK's oversight is based on YEL Section 55 Subsection 4 that states "The STUK may, upon request by anyone planning to use nuclear energy, check the plan drawn up by them and issue preliminary instructions on what should be taken into account with respect to safety, security and emergency arrangements."

YEL 990/1987 Sections 11-15 define the first licensing step, i.e. the Decision-in-Principle (DiP). For *extensive final disposal* an applicant shall apply DiP from the Government. Before a DiP decision can be made, the applicant shall publish an overall and environmental impact assessment reports of its

project. In accordance with YEL 990/1987 Section 13, MEAE shall take into account opinions of various stakeholders and general public. Before making the DiP, the Government shall ascertain that the municipality expresses its support for the project (Section 14), and STUK has delivered its affirmative safety assessment report (Section 14 a). The Governmental DiP shall also be ratified by the Parliament (Section 15).

In accordance with YEL 55 Subsection 5 “After Parliament has decided to leave in force a DiP relating to the construction of a nuclear facility of considerable general significance, the STUK may, on request of the holder of the DiP, carry out inspections on the nuclear facility and its systems, inspect and approve plans relating to devices and structures as well as inspect and oversee the manufacture of individual devices and structures. No work relating to structures affecting nuclear safety may, however, be started at the site before the granting of the construction licence. The structures and devices inspected and approved by the STUK may be used for the construction of a nuclear facility only if they comply with the construction licence”.

In accordance with YEL 990/1987 Section 23 a, “Before granting a nuclear facility construction licence and operating licence as referred to in this chapter, or a licence for decommissioning a nuclear facility, the MEAE shall reserve the public an opportunity to express their opinions in writing in the matter relating to the licence.” Legislation allows also to the applicant an opportunity to submit an explanation on the opinions.

The regulatory reviews during the licensing steps are based on YEA 161/1988 Sections 35, 36, and 36 a, and also to STUK Y/4/2018 Section 37.

Guide STUK YVL A.1 (Regulatory oversight of safety in the use of nuclear energy) provides (Section 201) “a summary of the obligations imposed on the licence applicant and the licensee, as well as the regulatory control measures to be taken by STUK in processing a licence application for the use of nuclear energy and at the different stages of the design, construction, commissioning and decommissioning of a nuclear facility.”

Guides STUK YVL A.1 (Sections A01 – A51), YVL D.5 (Sections 703a – 715), YVL D.7 (Sections 901 - 928) give further detailed instructions on documentation expected to be included to applications (DiP, Licenses), post-closure safety cases, safety analysis reports (PSAR, FSAR), periodic safety reviews (PSR), construction design documents, and e.g. regular reporting of construction and operational activities.

After licensing, based on YEA 161/1988 Sections 109, 111 and 112 b STUK has broad mandate to oversight disposal facility construction, operation and decommissioning (closure).

Question 11 Does the regulatory body require the safety case and supporting safety assessment for a disposal facility to be documented to a level of detail and quality sufficient to inform and support the decision to be made at each step and to allow for independent review?

Answer: Yes

Response:

STUK Y/4/2018 Section 3 requires demonstration of a nuclear facility's compliance with safety requirements, i.e. "the safety assessment shall demonstrate that the nuclear facility has been designed and implemented in a manner that meets the safety requirements. The safety assessment shall cover the operation of the facility in accordance with the Operating Limits and Conditions as well as anticipated operational occurrences and accident situations." Furthermore, "The safety assessment shall demonstrate that the decommissioning of the nuclear waste processing or storage facility and the final disposal of decommissioning waste have been designed and can be implemented in a manner that meets the safety requirements. The safety assessment shall cover activities pursuant to the plant's final decommissioning plan, including transients and accidents."

In regard of long-term safety STUK Y/4/2018 Section 4 requires that: "The safety assessment is presented in the safety case, which shall assess the evolution of the disposal system after the closure of the disposal facility and the related releases of radioactive substances by means of calculational analyses and other complementary considerations". STUK Y/4/2018 Sections 35, 36, and 37 set further requirements for the context of the safety case. Section 35 requires that compliance with the requirements shall be demonstrated by means of a safety case that shall study the possible evolutions of the disposal system, including evolutions caused by rare events impairing long-term safety. Section 36 makes requirements on the quality of the data and traceability of the documentation. Section 37 makes requirements, when a safety case or its update shall be presented for authority review. Guide STUK YVL D.5 Sections

A11, A11a, and A11b make specific expectations on consistency and clarity expected from the safety case.

Guide STUK YVL A.1 Chapters 5 and 6 set more detailed requirements what documents shall be submitted to STUK in connection with DiP or other licence applications, and details how documents shall be submitted to STUK. Document submission is also opened in Guide STUK YVL A.1 Chapter 3.12. Guide STUK YVL A.3 concentrates to leadership and management for safety. The Guide STUK YVL A.3 Section 620 requires: "The records generated during activities and the procedures pertaining to their management shall be defined. The records shall be specified, identifiable, readable, and easily traceable"

Question 12 Does the regulatory body require the site for a disposal facility to be characterized at a level of detail sufficient to support both a general understanding of the site characteristics, including its present condition, its probable natural evolution, possible natural events and also human plans and actions in the vicinity that may affect the safety of the facility over the period of interest, and a specific understanding of the impact of features, events and processes associated with the site a

Answer: Yes

Response:

STUK Y/4/2018 Section 31 is devoted to disposal site characteristics. Section 31 requires investigations and suitability, and states that some characteristics shall lead to exclusion of a site. STUK Y/4/2018 Section 35 makes requirements on demonstration of long-term safety of the release barriers including the site (natural barrier). Section 35 states that the site compliance with the requirements shall be demonstrated in the view of possible evolution (base and variant scenarios) and well as rare events (disturbance scenarios) – see Response 5.1.

Guide STUK YVL D.5 Sections 402 and 403 make requirements on selection and characterization of the disposal site, which may include the construction of an underground research facility. STUK YVL D.5 Sections 407 and 408 define in more detail favourable natural barrier properties that shall be considered when defining the long-term safety functions of the natural barrier. Guide STUK YVL D.5 Sections 411b, 412-416 set further conditions for successful candidate site and suitable locations of disposal rooms. The Section 412 includes more details on factors that should be considered as exclusion criteria.

The bedrock in Finland is with very few exceptions always crystalline hard rock that presents oldest parts of the continent. Potential volcanic activity or plastic deformation of disposal rooms are not issues in site suitability considerations.

Guide STUK YVL D.5 Section 704 requires compliance with requirements concerning long-term radiation safety, and the suitability of the disposal method and disposal site that shall be demonstrated within the safety case. The safety case shall include also scenarios (scenario analysis). More details of the long-term safety case content are given in Guide STUK YVL D.5 Chapter 9.

Question 13 Do the regulatory requirements provide for a disposal facility to be constructed in accordance with the design as described in the approved safety case and safety assessment?

Answer: Yes

Response:

In accordance with YEA 161/1988 Section 108 “The various phases in the construction of a nuclear facility cannot be commenced until the STUK has, on the basis of the documents mentioned in Section 35 and other detailed plans and documents, ascertained for each phase that all safety-related factors and safety regulations have been given sufficient consideration”.

YEA 161/1988 Section 109 states further: “After the construction licence has been granted, the STUK controls the implementation of the facility project in detail. The purpose of the control is to ensure that the conditions of the construction licence and the approved plans referred to in Section 35 are complied with and that the nuclear facility is also in other respects constructed in accordance with regulations issued on the basis of the YEL”.

In the view of long-term safety STUK Y/4/2018 Section 4 states: “[…] The assessment of long-term safety at different stages shall demonstrate that the disposal has been designed and implemented in accordance with the safety requirements. The safety assessment shall cover the period of time following the closure of the facility which is required for the purposes of ensuring the safety of disposal”.

Specifically in regard safety classified “Systems, structures and components performing long-term safety functions shall be designed, manufactured and installed so that their quality level, and the assessments, inspections and tests required to verify their quality level, are commensurate with the safety significance of the item in question” (STUK Y/4/2018 Section 5). Furthermore, YEL 990/1987 Section 55, Subsection 5 restricts this followingly: “[…] No work relating to structures affecting nuclear safety may, however, be started at the site before the granting of the construction licence”.

STUK Y/4/2018 Section 22 Subsection 1 states “The holder of the nuclear facility’s construction license shall ensure during construction that the facility is constructed and implemented in conformity with the safety requirements and using approved plans and procedures”.

On the operational stage STUK Y/4/2018 Section 24 states “The holder of the nuclear facility’s operating license shall ensure that the modifications to the nuclear facility are designed and implemented in conformity with the safety requirements and using approved plans and procedures”. If modifications are significant enough, the licensee shall also fulfil the requirement in STUK Y/4/2018 Section 37 “[…] The need for updating the safety case shall be assessed before making modifications that concern the disposal system […]”.

Guide STUK YVL A.5 gives more details on requirements and oversight of nuclear facility construction.

Question 14 Does the regulatory body require a disposal facility to be operated in accordance with the conditions of the licence and the relevant regulatory requirements so as to maintain safety during the operational period, and in such a manner as to preserve the safety functions assumed in the safety case that are important to safety after closure?

Answer: Yes

Response:

According to YEA 161/1988 Section 110, "The various phases in the commissioning of a nuclear facility cannot be commenced until the STUK has determined, on the basis of the documents mentioned in Section 36, and other detailed plans and documents required by STUK, for each stage, that sufficient attention has been paid to factors influencing safety, and regulations concerning safety. Similar requirements also apply to the restarting of a nuclear facility after a particularly substantial plant modification.

In accordance with YEA 161/1988 Section 111, "The STUK controls the operation of a nuclear facility to ensure that the operation of the facility is safe and complies with the licence conditions and the approved plans and that the operation also in other respects adheres to the YEL and to the regulations issued by virtue of the Act. The control of the operation of a nuclear facility also involves the maintenance, repairs, inspections and tests of the nuclear facility systems, structures and components".

In regard operational safety STUK Y/4/2018 Section 3 requires "The safety of operation of a nuclear facility shall be assessed when applying for a construction license and operating license, in connection with plant modifications, and at Periodic Safety Reviews during the operation of the facility. The safety assessment shall demonstrate that the nuclear facility has been designed and implemented in a manner that meets the safety requirements".

STUK Y/4/2018 Section 5 states: "The safety functions for the operation of the nuclear facility and long-term safety functions shall be defined, and the systems, structures and components performing them and related to them shall be classified. The classification shall take into account the use of the systems, structures and components on the basis of significance in terms of operational safety, long-term safety or both, if necessary".

I.e. nuclear facility is constructed and operated in accordance with approved plans that include division of nuclear facility to systems, structures and components. SSC's performing safety functions shall be safety classified, and STUK controls maintenance, repairs, inspections and tests of these. Guide STUK YVL A.5 gives more details on requirements and oversight of nuclear facility operation.

Question 15 Does the regulatory body require a disposal facility to be closed in such a way that supports the safety functions shown by the safety case to be important for the post-closure period?

Answer: Yes

Response:

YEA 161/1988 Section 112 b Subsection 1 states that STUK controls the decommissioning (closure) of a facility in accordance with the YEL 990/1987 Sections 55 and 63 to ensure that the decommissioning (closure) of the plant complies with licence conditions and approved plans and that the action is otherwise compatible with the YEL and the acts adopted pursuant to it. Control of decommissioning (closure) is also targeted at the maintenance, repairs, inspections and testing of nuclear facility systems, structures and components.

YEA 161/1988 Section 112b Subsection 2 states further that the key stages of decommissioning (closure) can be commenced only after STUK has determined, on the basis of the documents referred in Section 36 a, and other required detailed plans and documents that safety provisions have been adequately taken into account.

In accordance with STUK Y/4/2018 Section 21: "The disposal facility shall be designed, constructed and operated in a manner that allows it to be closed without jeopardising long-term safety after its operation has ended".

STUK Y/4/2018 Section 31 Subsection 4 requires further: "The siting, excavation, construction and closure of underground rooms shall be implemented so that the characteristics of the rock deemed important in terms of long-term safety are retained, as far as possible". Its also required in STUK Y/4/2018 Section 37 that "… the safety case shall be updated prior to the closure of the facility".

Question 16 Does the regulatory body require that waste packages and unpackaged waste accepted for emplacement in a disposal facility conform to criteria fully consistent with and derived from the safety case for the operational and post-closure safety of the disposal facility?

Answer: Yes

Response:

STUK Y/4/2018 Section 16 Subsection 1 requires that "Waste generated during the operation and decommission of a nuclear facility, the activity concentration of which exceeds the levels set by the Radiation and Nuclear Safety Authority (STUK), shall be treated as nuclear waste. Nuclear waste shall be sorted, categorised according to its characteristics, processed and packaged in an appropriate manner in terms of its storage and disposal, and stored safely".

According to STUK Y/4/2018 Section 16 Subsection 4: "Limiting values shall be set for each waste class, which the waste package used for the waste in question shall meet in terms of the operational safety of the nuclear facility and long-term safety. Acceptance criteria shall be defined for the waste and waste packages".

Furthermore, STUK Y/4/2018 Section 16 Subsection 5 states. "A licensee under a waste management obligation who intends to deliver nuclear waste to a handling, storage or disposal facility of another licensee shall ensure that the waste is handled and packed acceptably, taking into account the later stages of waste management".

Guide STUK YVL D.4 Section 402 requires predisposal sorting and classification, and conditioning and packing of low and intermediate level waste in accordance with disposal requirements. Furthermore, Guide YVL D.5 Section 603a states: "Criteria shall be defined for the nuclear waste and waste packages being disposed of, based on the operational safety of the disposal facility and the long-term safety of disposal which any waste brought into the disposal facility shall satisfy. Requirements pertaining to the criteria to be imposed on spent nuclear fuel are set out in Guide YVL D.3."

Question 17 Does the regulatory body require that a programme of monitoring needs to be carried out prior to and during the construction and operation of a disposal facility, and after its closure?

Answer: Yes

Response:

STUK Y/4/2018 Section 8 states among other things that "the planning of the construction, operation and closure of a disposal facility shall account for […] the need to develop an understanding of the performance of the barriers and long-term safety through investigations and monitoring".

STUK Y/4/2018 Section 33 requires that “In order to ensure the performance of the barriers, a research and monitoring programme shall be established and implemented for the operating stage of the disposal facility”.

Guide YVL D.5 Section 506 makes more detailed requirements on monitoring during disposal facility construction and operation as indicated in Response 9.

In terms of public safety during the operation, YEL 990/1987 Section 7c Subsection 4 refers to limits presented in Response 16. STUK Y/4/2018 Section 28 Subsection 1a makes the requirement: “The discharges of radioactive substances from the nuclear facility shall be monitored and their concentrations in the environment shall be measured”.

In terms of post-closure monitoring, YEL 990/1987 Section 32 Subsection 1 paragraph 3 states that after the STUK has confirmed the nuclear waste to be permanently disposed of in an approved manner “and the party with a waste management obligation has paid a lump sum to the State for the monitoring and control of the nuclear waste” then the disposal of nuclear waste is considered implemented. As soon as waste management obligation of a license holder has expired, The State shall be responsible of the possible post-closure monitoring and control.

Question 18 Does the regulatory body require that plans are prepared for the post-closure period to address institutional control and the arrangements for maintaining the availability of information on the disposal facility?

Answer: Yes

Response:

In accordance with YEL 990/1987 Section 34: “When the licence holder’s waste management obligation has ceased by virtue of Section 32, Subsection 1, paragraph 3, the ownership right to the nuclear waste is transferred to the State, which shall be responsible thereafter for the nuclear waste.

Should it become necessary after the disposal, the State has the right, at the disposal site, to take all measures required for the monitoring and control of the nuclear waste and for ensuring the safety of the repository”.

YEA 161/1988 Section 85 requires that the disposal site of nuclear waste and the prohibition on measures shall be entered in the real estate register, land register or list of titles. This also pointed out in STUK Y/4/2018 Section 34: “An adequate protection zone shall be reserved around the disposal facility as a provision for the prohibitions on measures referred to in Section 63, Subsection 1, paragraph 6 of the YEL”.

In accordance with Guide YVL A.5 Section 305 “The phases of the nuclear facility’s construction project shall be determined and the plans pertaining to them documented and maintained for the project’s entire life cycle”. In the view of disposal operations STUK Y/4/2018 Section 29 continues: “The licensee shall maintain a record of the disposed waste that includes waste package specific data on the waste type, radioactive substances, location within the emplacement rooms and other information deemed necessary by the authority. The waste records shall be submitted to the STUK in a format approved by it. The *STUK arranges the permanent keeping of records of information* concerning the disposal facility and disposed waste”. Guide YVL D.5 Sections 603 and 715 further refine the obligations on record keeping. According to Guide YVL D.5 Section 815, a precondition for the permanent closure of a disposal facility is that STUK has approved the plan concerning the closure, which shall include e.g. “a plan for the potential post-closure monitoring measures and a proposal for the restriction zone with prohibition on measures referred to in Section 85 of the YEA”.

Guide YVL D.1 Section 462 requires also: “As regards disposed spent nuclear fuel or other nuclear material, the operator shall retain the records (source documents, history file, general ledger and operating records as well as inventory change reports) up until the date when the waste management obligation is deemed to have expired and the accountancy obligation and responsibility for the materials have transferred to the state”.

Based on Governmental Degree on Archiving Institutes (832/1994) the permanent keeping of authority records is on the responsibility of National Archive. The National Archive has the best knowledge available on as permanent keeping of records as possible.

Question 18.1 How is it ensured that the plans are consistent with passive safety features and they form part of the safety case on the basis of which authorization was given?

Response:

Passive safety features and how those are expected to be taken into account in the justifications of long-term safety case are previously discussed in Responses 4 and 9.

YEL 990/1987 Section 7 h Subsection 3 states: “The disposal of nuclear waste in a manner intended as permanent shall be planned giving priority to safety and so that ensuring long-term safety does not require the surveillance of the final disposal site.”

STUK Y/4/2018 Section 30 states: “The long-term safety of disposal shall be based on long-term safety functions achieved through mutually complementary barriers so that the degradation of one or more long-term safety function or a foreseeable change in the bedrock or climate will not jeopardise the long-term safety.”

Guide YVL D.5 Section 408 lists properties of natural release barrier that should be considered as long-term safety functions. Also, the protection against human actions is mentioned. Inadvertent human intrusion is diminished primarily with siting (disposal depth, away from natural resources). Permanent keeping of records of information concerning the disposal site is written in legislation However, permanent keeping of records cannot be guaranteed on very extensive time scales.

Closure of a disposal facility in Finland is not yet topical. Extensive amounts of information are collected from each facility (under construction or in operation). The selection which information shall be permanently kept shall be made in future by latest when the ownership of waste is transferred to the State.

Question 19 Does the regulatory body require ensuring that safety is not compromised by the measures undertaken on accounting for, and control of, nuclear material in the design and operation of disposal facilities that are subjected to such agreements?

Answer: Yes

Response:

In accordance with Guide YVL D.1 Section 311: “Operators shall plan and implement any use of a nuclear facility with consideration to the control methods (e.g. non-destructive assays and remote monitoring) and control tools (cameras, seals and measuring instruments) employed by STUK, the European Commission and the International Atomic Energy Agency (IAEA) in such a way that the nuclear security arrangements and safety of the facility are not compromised”.

Question 20 Does the regulatory body require an integrated approach for the implementation of safety measures and nuclear security measures in the disposal of radioactive waste?

Answer: Yes

Response:

A holistic view on the overall radiation and nuclear safety is given in Guide YVL A.1 Section 110: "Nuclear and radiation safety comprises safety, security and emergency arrangements and nuclear safeguards at all stages of the use of nuclear energy. All the aforementioned are necessary for attaining the shared goal of protecting people, society, the environment and future generations from the harmful effects of ionising radiation. Safety, security and emergency arrangements, and nuclear safeguards all involve the common principle of assuring a level of safety as high as reasonably achievable. In the use of nuclear energy, safety, security and emergency arrangements, and nuclear safeguards measures shall be aligned by utilising similarities between them whilst avoiding potential conflicts as far as practicable".

STUK Y/3/2020 Section 3 Subsections 2 and 3 state on general planning criteria for security arrangements: "2. Security shall be consistent with the operation, fire safety and emergency response arrangements of nuclear energy. The objectives of nuclear safeguards and coordination of the arrangements shall be taken into account in the planning and implementation of security arrangements. 3. Furthermore, security arrangements shall be consistent with the special situational, emergency and rescue plans drawn up by the authorities".

Guide YVL A.11 Section 301a requires: "Security arrangements are part of overall safety and shall be coordinated with emergency response arrangements, nuclear and radiation safety and nuclear safeguards during threats and emergency situations". According to Guide YVL A.11 Section 608 states on exercises and training events: "The following requirements apply to the exercise methods and content: […] In the exercises, situations shall be included with a simultaneous accident and nuclear-security related threat".

From the viewpoint of management Guide YVL A.3 Section 105 requires: "In the management system, the consideration of factors affecting safety is ascertained by combining different management systems such as safety and quality management. Safety shall refer to nuclear and radiation safety, also covering safety, security and emergency response arrangements and nuclear safeguards at all stages of the use of nuclear energy". Guide YVL A.3 Section 301 further requires: "A management system shall be planned and implemented to incorporate an organisation's operations, and it shall be continuously maintained and improved. The system shall be a well-balanced whole aligned with the goals of the organisation, which shall ascertain the fulfilment of nuclear and radiation safety requirements. Organisation shall integrate all management systems (integrated management system). The management shall promote ways for the entire personnel to participate in the implementation of safety goals and continuous development of safety.

Question 21 Does the regulatory body require the safety of existing disposal facilities to be assessed periodically until termination of the licence?

Answer: Yes

Response:

As noted in Response 2, the YEL 990/1987 Section 7e requires: "[…] The overall safety of a facility performing large-scale disposal of nuclear waste shall, however, be assessed at least at 15-year intervals".

The same topic is further discussed in Response 3.1. In accordance with YEL 990/1987 Section 24 operating licences are granted always for a fixed term. The Regulation STUK Y/4/2018 Section 3 requires that "The safety of operation of a nuclear facility shall be assessed when applying for a construction license and operating license, in connection with plant modifications, and at Periodic Safety Reviews during the operation of the facility."

Based on YEA 161/1988 Section 35 the licensee shall present PSAR at the stage of construction license application. YEA 161/1988 Section 36 requires the licensee to present FSAR at the stage of operating license application, and Section 36 a requires the delivery of safety documentation while applying decommissioning (closure) of a nuclear facility.

In accordance with the STUK Y/4/2018 Section 37, licensee is obliged to present the long-term safety case at the construction, operation, and closure licensing steps. A licensee is also obligated to update its safety case for periodic safety reviews, and when making substantial plant modifications.

Question 21.1 How does the regulatory body ensure that safety is assessed when a safety significant modification is planned or in the event of changes with regard to the conditions of authorization?

Response:

The regulatory supervisory rights have been earlier dealt in Responses 10.1 and 13. In accordance with YEA 161/1988 Section 109: "After the construction licence has been granted, the STUK controls the implementation of the facility project in detail. The purpose of the control is to ensure that the conditions of the construction licence and the approved plans referred to in Section 35 are complied with and that the nuclear facility is also in other respects constructed in accordance with regulations issued on the basis of the YEL. A similar requirement applies to the operational stage of the facility project (YEA 161/1988 Section 111).

In regard of modifications, YEA 161/1988 Section 112 requires: “If the licensee intends to carry out modifications to the nuclear facility systems, structures, nuclear fuel or the way the facility is operated that influence safety and involve changes in the plans or documents approved by the Radiation and Nuclear Safety Authority (STUK), the licensee shall obtain approval from STUK for such modifications before they are carried out. Correspondingly, STUK shall approve measures related to the decommissioning of a nuclear facility. The licensee shall ensure that the documents mentioned in Sections 35 and 36 are revised accordingly”.

As indicated in Response 15, YEA 161/1988 Section 112 b gives separate attention to regulatory supervisory rights and facility compliance with the licensed plans at the facility decommissioning and closure stage.

The specific requirements concerning the long-term safety case have been previously dealt in Response 13. On the operational stage STUK Y/4/2018 Section 24 states “The holder of the nuclear facility’s operating license shall ensure that the modifications to the nuclear facility are designed and implemented in conformity with the safety requirements and using approved plans and procedures”. If modifications are significant enough, the licensee shall also fulfill the requirement in STUK Y/4/2018 Section 37 “…The need for updating the safety case shall be assessed before making modifications that concern the disposal system…”.

Question 21.2 Does the regulatory body require the operator, when new requirements are set down or are not met, to take reasonably practicable measures to upgrade the safety of the facility?

Response:

The requirement to upgrade the safety of the facility is based on YEL 990/1987 Section 7 a: “The safety of nuclear energy use shall be maintained at as high a level as practically possible. For the further development of safety, measures shall be implemented that can be considered justified considering operating experience and safety research and advances in science and technology”.

In regard STUK regulations and guides YEL 990/1987 Section 7 r states the following: “The STUK shall specify detailed safety requirements concerning the implementation of safety level in accordance with this Act”.

The regulatory body is obligated and engaged to update legislation in accordance with operating experience and safety research and advances in science and technology. This engagement includes also implementation of international treaties and review findings in national regulations as needed.

Legislation, regulations and guides are updated based on demand. Updated requirements are set in force based on hierarchy (Parliament, Government, STUK). Accordingly, responsible party in the regulatory body shall define how new requirements shall be applied for existing facilities.

In YEL 990/1987 and YEA 161/1988 a separate Annex on amendments made indicate how amendments come into force and how those shall be implemented. In regard of STUK regulations, STUK makes decisions how amended regulations shall be implemented in existing disposal facilities. In the case of updated guides STUK makes separate decisions for each disposal facility on the application of the updated guide.

Analysis

STRENGTHS FOR SAFETY REQUIREMENTS FOR DISPOSAL OF RADIOACTIVE WASTE

S1	The Finnish framework, legislation and regulations contains comprehensively provisions to address disposal of nuclear waste. The planning for the disposal of nuclear waste is covered from the design of the nuclear facility to the decommissioning phase. Disposal of nuclear waste must be considered already in the DiP phase. During operation the plans for disposal and R&D must be updated regularly every three years.
S2	Funding and financing of disposal is covered as part of radioactive waste funding and costs are evaluated regularly. The licensee has to evaluate the costs of nuclear waste management and decommissioning after every three years during the operation of the nuclear facility. The licensee has to pay to the nuclear waste management fund the liability amount defined by MEAE to cover the cost of the disposal of generated waste in cases where the licensee could be unable to pay the costs itself. The financing for the disposal generated waste of a nuclear facilities is ensured.
S3	Management (including disposal) of radioactive waste generated as a result of nuclear energy use has to be addressed as part of decommissioning planning. Nuclear facility licensee, having waste management obligation, is responsible for overall process from cradle to grave. This addresses in many situations the challenge with interdependencies.
S4	Finland is currently the most advanced country is disposal of spent nuclear fuel. This enables active regulatory participation and development of guidance, regulation and oversight parallel to progress of disposal solutions for nuclear waste.

OPPORTUNITIES FOR SAFETY REQUIREMENTS FOR DISPOSAL OF RADIOACTIVE WASTE

O1	Finland is currently the most advanced country in disposal of spent nuclear fuel. This sets an opportunity to be a pioneer in this area and to influence internationally, build competences and also create interest in the field of nuclear waste disposal.

THREATS FOR SAFETY REQUIREMENTS FOR DISPOSAL OF RADIOACTIVE WASTE

T1	Resources and competences are currently on adequate level but very narrow. It should be paid attention in the future that resources and competences are maintained. Challenge is also related on maintaining resources and competences between periodic safety reviews.
T2	Current design of LILW disposal facilities may not allow disposal of some fractions of decommissioning waste and some fractions of the state owned RAW. The design of the LILW disposal facilities needs to be developed and improved or other solutions for these fractions should be developed.

CONCLUSIONS FOR SAFETY REQUIREMENTS FOR DISPOSAL OF RADIOACTIVE WASTE

C1	Finland is currently the most advanced country is disposal of spent nuclear fuel and disposal of low and intermediate waste has been in use for a long time, therefore Finnish legislation contains comprehensively provisions to address disposal of nuclear waste. Funding and financing of disposal is covered as part of radioactive waste funding and costs are evaluated regularly.
C2	There are challenges in the use of set compliance criteria for the post-closure safety

Module: Safety Requirements for Occupational Exposure

Findings

Question 1 Has the government or the regulatory body established and enforced requirements to ensure that protection and safety is optimized for occupational exposure?

Answer: Yes

Response:

General

The very basics of The Radiation Act 859/2018 (SätL) (for which also the Nuclear Energy Act 990/1987 (YEL) refers in section 2 a) concerns the principles of justification, optimization and limitation (SätL sections 5-7).

The dose limits of workers and members of the public are given in VnA 1034/2018. This is stated in SätL section 10 and this section 10 is referred in the YEL section 2 a.

Nuclear safety

In the Nuclear Energy Act (YEL 990/1987) section 9 is stated the licence holder shall be under an obligation to ensure the safe use of nuclear energy. This obligation may not be delegated to another party.

Section 2 a of the Nuclear Energy Act (YEL) states how the Radiation Act (SätL) applies to the use of nuclear energy.

According to the section 2 a of the YEL the general principles of radiation protection as stated in the SätL sections 5-7 (justification, optimization and limitation) shall apply to the use of nuclear energy.

In the optimization of radiation protection, the dose limits under section 9 of the SätL shall be used (YEL section 7 c): *Dose constraints and constraints for potential exposure are set, taking into account the characteristic features of the practice, in such a way that the exposure is anticipated to remain below the constraint due to the optimization of radiation protection. A licence holder shall set radiation exposure dose constraints for nuclear facility workers and shall submit information about these constraints to the Radiation and Nuclear Safety Authority.*

STUK Y/1/2018 (Regulation on the Safety of a Nuclear Power Plant) states:

Radiation exposure and emissions of radioactive substances shall be limited through layout design and component placement of the nuclear facility, material choices and planning of the working methods for operation and decommissioning of the facility and by using systems, structures, components, special radiation shielding and workers' equipment. (Section 7)

According to the YVL Guide C.2 (Radiation Protection and Exposure Monitoring of Nuclear Facility Workers):

- The nuclear facility shall have a written programme (the ALARA action programme) to keep doses low. The programme shall include both short-term and long-term plans and measures to limit the doses of occupationally exposed workers. (Req. 309)

According to the YVL Guide C.1 (Structural Radiation Safety at a Nuclear Facility):

- A nuclear facility's Preliminary and Final Safety Analysis Report or the associated topical report shall give a summary of the most important radiation protection-related design features by which the optimisation principle in radiation protection is implemented at a nuclear facility. (Req. 302)
- Design shall take into account the operation of a nuclear facility including commissioning, normal operation, anticipated operational occurrences, potential accidents and plant decommissioning. (Req. 305)
- During the various design phases, collective doses shall be looked at and optimised by working tasks and worker groups. (Req. 307)
- With both the Preliminary and Final Safety Analysis Report, a topical report containing an assessment of the doses received by workers from plant operation shall be submitted for approval to the Radiation and Nuclear Safety Authority. (Req. 308)

Radiation safety

The principles of justification, optimization and limitation are set in (SätL sections 5-7).

The Government Decree on Ionizing Radiation (VnA 1034/2018) section 8 § states that the principle of justification concerning the occupational and public exposure are implemented so that the exposure of workers and public, the probability of exposure and the amount of exposure are kept as low as reasonably possible.

The dose limits for radiation workers, tor the public and for the students and apprentices are set in VnA sections 13 -15 and these are the same as those given in the Schedule III of GSR Part 3, with the following two exception: the effective dose for radiation workers is not allowed to be over 20mSv per single year, and for the students and apprentices the equivalent dose to the lens of the eye is not allowed to be over 15 mSv in a year.

According to the SätL section 25 the undertaking shall set in advance the dose constraints and potential exposure limits. In addition the SätL section 89 demands that the undertaking should estimate the radiation exposure and the means to reduce it. The latter also stipulates that the estimation should be updated if there are changes in that have effects on the occupational exposure.

SätL section 9 states that the dose constraints and constraints for potential exposure are set in such a way that the exposure is anticipated to remain below the constraint due to the optimization of radiation protection.

SätL section 48 states that a safety assessment pursuant to section 26 has to be drawn up for the radiation practice. SätL section 26 states further that the assessment includes identification of the ways in which the practice can cause radiation exposure, considering any possible radiation safety deviations. The assessment includes also the magnitude of the occupational, public and medical exposure arising from the practices as well as the probability and magnitude of the potential exposure. The measures to be taken to ensure radiation safety and the optimization of radiation protection and measures to prevent and prepare for identified radiation safety incidents are also presented in the assessment. In addition to the above, also the categorization of the radiation practice needs to be presented.

STUK has published guides on how to optimize protection and safety for occupational exposure. Example guide: *Radiation Safety in Cardiology 2018* (STUK-opastaa-Kardiologia.pdf)

Question 2 Has the regulatory body established and enforced requirements for the monitoring and recording of occupational exposures in planned exposure situations?

Answer: Yes

Response:

The points (a) – (f) refer to the corresponding points of GSR Part 3, paragraph 3.76.

(a)

SätL sections 89 and 90 state that in practices requiring a safety licence, the radiation exposure of workers and means to reduce it must be assessed before starting the work. The assessment must be adjusted if change affecting occupational exposure takes place in the practice. The worker's previous occupational exposure must also be investigated prior to the commencement of radiation work.

Radiation workers shall be classified into category A or B. The basis for this classification is an estimate on the exposure and potential exposure caused by the work. The classification must be carried out prior to the commencement of the radiation work and reviewed regularly based on radiological and medical surveillance. The classification must be reviewed also as part of reviewing the safety assessment referred to in SätL section 26.

SätL section 92 states that radiological surveillance must be conducted on a regular basis and it must allow for establishing that workers have been correctly classified; determining the radiation exposure to the workers; and an immediate observation of unforeseen deviations in factors with an impact on occupational exposure.

Individual monitoring shall furthermore be arranged for radiation workers belonging in category A. The individual monitoring shall be based on individual measurements performed by an approved dosimetry service. The measurements must be performed in one-month periods or for a working period, if the duration of the work is shorter than the one-month measurement period. In practice, often also for workers in category B individual monitoring is arranged, and in those cases monitoring period is usually 3 months.

The results of the radiological surveillance and individual monitoring must be recorded and followed regularly to ensure compliance with the requirements applicable to occupational exposure.

SätL section 101 states that the information from the individual monitoring of category A radiation workers referred to in section 20, subsection 2 shall be delivered to the workers' dose register on a regular basis. If the radiological surveillance has been carried out as the individual monitoring of category B radiation workers performed by a dose measurement service, the information specified in subsection 1 shall be delivered to the dose register regularly also for category B workers. When workers are exposed to radon or cosmic radiation, dose data must be submitted to the workers' dose register if individual monitoring has been organised for workers due to this exposure.

(b)

Previously mentioned safety assessment includes the magnitude of the occupational, public and medical exposure arising as well as the categorization of the radiation practice. The safety assessment will be reviewed before licencing and following operational changes. Appendix 5 of VNa states which information must be added to safety licence application. Point 4.5 states that the classification and numbers of radiation workers must be included to the application. Further, information on how the monitoring of exposure conditions, individual monitoring and health surveillance of category A workers are organised must be included.

(c)

SätL sections 60 states that STUK approves a dose measurement service until further notice or, for a special reason, for a fixed period of time. The approval requires:

1. the use of a documented dose measurement system compliant with the requirements laid down in SätL section 59: The measurements shall be performed with a method suitable for the purpose and proved reliable. The results of the measurements must be metrologically traceable to the International System of Units. The radiation meter or measuring instruments shall be appropriately calibrated.
2. the sufficient competence of the personnel;
3. an accredited quality system applicable to steering the practice, including the operation of the dose measurement service and the methods employed by it;
4. the necessary technical means for delivering the dose data to the workers' dose register.

VnA 1034/2018 section 55 provides more detailed information about the requirements on the dose measurement system and the information to be provided in an application.

The process is described in internal documentation in Guide SKV 6.4.

(d)

The information from the individual monitoring of radiation workers are delivered to the workers' dose register on a regular basis. When recording the information, all doses are reviewed using automatic data verification program and in more detailed when something unusual is found. The process is described in internal documentation in Guides SKV 3.8 and SKV 6.4.

(e)

SätL 20 states that STUK maintains a workers' dose register to ensure the health of radiation workers, emergency workers, emergency helpers and radiation safety. The register contains the identifying information of each worker and information on: their tasks; undertakings and the employers of outside workers; the methods employed for determining individual radiation doses; factors impacting radiation exposure; and the results of individual monitoring.

In addition, the register contains information on the methods and results of radiological surveillance insofar as they are employed in the determination of a worker's individual radiation dose.

SätL section 21 states that the information in the dose register is stored for as long as the worker is engaged in radiation work and, subsequently, until the person in question attains or would have attained the age 75 years, although until 30 years have elapsed from the termination of the radiation work. STUK may store the aforementioned information for longer than this for research purposes related to ensuring radiation safety.

(f)

As in point b was mentioned, Appendix 5 of VnA states which information must be added to safety licence application. This information is checked when processing the safety licence application and also later when inspections are carried out. Dose information is also reviewed as described in point d.

Nuclear safety

Chapters 9 and 12 of the SätL on radiation measurements and occupational exposure as well as SätL sections 20 and 21 on workers dose register applies to use of nuclear energy. Consequently, previously described procedures apply also to use on nuclear energy in addition to which the requirements are specified as follows.

According the requirement 308 of YVL Guide C.2 in addition to individual occupational doses, collective doses shall be monitored by task and worker group. The nuclear facility shall undertake measures if collective doses indicate a need to improve the radiation protection measures.

All workers in the nuclear facility's controlled area shall be provided with personal dosimeters and the radiation exposure of personnel working in the supervised area shall also be evaluated (YVL Guide C.2 requirements 702 ja 706). The nuclear facility shall have procedures and instructions in place to ensure continuous individual dose monitoring (YVL Guide C.2 req. 720).

Nuclear facilities shall report at least once a month the individual radiation doses of radiation workers to STUK's Dose Registry (YVL Guide C.2 req. 805).

In addition to a system that monitors individual occupational radiation exposure, the nuclear facility shall have a measurement system for the real-time monitoring of the accumulation of occupational radiation dose in the controlled area caused by external radiation (YVL Guide C.2 req. 737). The Final Safety Analysis Report (FSAR) describes the radiation conditions at a nuclear facility and the radiation protection and safety issues including radiation exposure control. The FSAR documents are approved by STUK and they shall be kept up-to-date at all times (YVL Guide A.1 req. 387).

Question 3 Has responsibilities been assigned to employers, registrants and licensees for the protection of workers against occupational exposure?

Answer: Yes

Response:

The very basics in the employees' radiation safety is set in SätL but the SätL section 3 also states the relations to elsewhere in Finnish legislation which includes e.g. Occupational Safety and Health Act (738/2002) which also sets requirements for both employer and employee.

In addition the very basics of SätL concerns the principles of justification, optimization and limitation (SätL sections 5-7). Thus the radiation work is not allowed at all without the optimization.

The undertaking's obligations (licensee's obligations) are set in the Radiation Act 859/2018 (SätL), chapter 5.

The undertaking is responsible for the radiation safety of the practice and this responsibility cannot be transferred to another.

In its capacity as an employer the undertaking is obligated to carry out the measures laid down in the SätL sections 88-101 to protect its own workers (SätL section 102). According to these the undertaking is responsible e.g. for organizing workers' radiation protection, obligated to investigate the occupational exposure and the means to reduce it. Undertaking is responsible to classification of the radiation workers (into category A or B), identify and differentiate the controlled and supervised areas. Undertaking is also responsible for the radiological surveillance and individual monitoring which must

allow for establishing that 1) workers has been correctly classified, 2) the radiation exposure to the workers is determined and 3) that the unforeseen deviations in factors impacting on occupational exposure has been observed. In addition, the undertaking is responsible to deliver the information from the individual monitoring of category A and B radiation workers.

The obligations of the employer of the outsider worker are stated in SätL section 103.

According to the SätL Section 3, the occupational health and safety and protection of workers is stated also in the Occupational Safety and Health (OSH) Act (738/2002), which e.g. in section 15 requires that the employers should provide the personal protective equipment, auxiliary equipment and other devices for use. In addition to OSH Act, the Radiation Act, section 23 requires that the undertaking shall implement the organization of the practice in such a way that the practice meets the requirements provided in Radiation Act and that radiation safety deviations are prevented with adequate effectiveness and that their consequences are as insignificant as possible.

When applying for a safety license, the undertaking shall include a description of the management system with the application. According to SätL section 29, the management system must describe the tasks, division of responsibilities and information flow relevant to radiation safety and security arrangements. It must also describe the measures to maintain and develop a good safety culture and the administrative and organizational arrangements to ensure radiation safety.

According to the SätL section 95 the undertaking’s responsibility is to provide the medical surveillance for a category A radiation worker. The medical surveillance includes a pre-employment examination by an occupational physician familiar with radiation and a follow-up examination at least every three years.

In SätL section 23 the undertaking has been obliged to ensure that it has the necessary expertise and Vna section 22 sets the requirements concerning the human resources. The training and supplementary training of radiation workers is set in SätL section 33 and 34.

A register of occupational exposures is kept by STUK (SätL Section 20). Responsible parties are obliged to give data on their workers to the register (SätL Section 101). According to SätL section 19, STUK maintains a register on the radon concentrations in dwellings, other premises used by people and workplaces.

The section 71 in SätL stipulates the undertaking to record-keeping. It states that the undertaking shall keep a record on the radiation sources held by the undertaking.

Records shall also be kept on training given to workers (SätL section 33). In SätL Section 12 it is set that the management of an organization is responsible to maintain and develop a good safety culture.

The dose limits for public are set in VnA 1034/2018 section 14. In same section it is also set that the limit concerns also the worker who is not a radiation worker.

SätL section 33 demands that the undertaking shall ensure that all workers have radiation protection education, training and induction to their duties required by the practices and the tasks.

In addition, the Occupational Safety and Health (OSH) Act (738/2002) sets the obligations of the worker (in chapter 4) which demands e.g that the employee is obliged to announce, without a delay, the employer if the employee of the faults the employee has found (faults in working methods, machines, PPE, etc.). According to SätL section 131, the undertaking must ensure that the radiation safety deviation, its causes and the resulting exposures are investigated. Records shall be kept of the incidents, the investigations, and the results of the investigations. The undertaking must ensure that the necessary corrective measures are taken to prevent similar occurrences. The operator shall inform STUK of the results of the investigations and corrective measures taken in the event of a radiation safety incidents.

Nuclear safety

The obligations of the licence holder are set in section 9 of the YEL. The licence holder shall be under an obligation to ensure the safe use of nuclear energy. This obligation may not be delegated to another party. The licence holder shall ensure that the products and services of contractors and subcontractors which affect the nuclear safety of the nuclear facility meet the requirements of the act.

Section 2 a of the YEL states how the SätL applies to the use of nuclear energy.

Chapter 12 of the SätL regulates the arrangement of radiation protection for workers, the bases of radiation exposure monitoring and medical surveillance, and responsibilities of the responsible party and employer to protect its own and outside workers engaging in radiation work.

In addition to Occupational Safety and Health Act (738/2002) the YVL Guide C.2 (req. 406) licence holder (radiation protection unit) shall ensure the availability of an adequate number of radiation monitoring instruments and protective equipment at the facility. The unit shall also ensure that these instruments and equipment are operable and used in accordance with the instructions given. An operational unit responsible for implementing radiation protection in practice and for co-ordinating related functions shall be established within the nuclear facility's operating organisation or such a unit shall be made available to it (YVL Guide C.2 req. 402).

Introductory radiation protection training aims at providing workers with knowledge about radiation legislation and the regulations issued under it as well as at providing them with the preconditions for correct working in the controlled and supervised areas as well as at furthering the accomplishment of radiation protection goals. In addition to introductory training, refresher training shall be given at regular intervals. Training programmes shall be prepared to develop and maintain the expertise of those holding positions vital to radiation protection. (YVL Guide C.2 reqs. 414, 417, 419).

The responsible party shall ensure that radiation workers are covered by medical surveillance for those engaging in radiation work (YVL Guide C.2 req. 606).

According to STUK Y/1/2018 section 25 when designing, constructing, operating and decommissioning a nuclear facility, a good safety culture shall be maintained. Safety shall take priority in all operations.

Question 4 Are there regulations/regulatory requirements/ that require workers to fulfil their obligations and carry out their duties for protection and safety?

Answer: Yes

Response:

In general, the employee's obligations are set in Employment Contracts Act 55/2001 chapter 3 where the basics is set in sections 1 and 2 which says that:

- "Employees shall perform their work carefully, observing the instructions concerning performance issued by the employer within its competence." And
- "Employees shall observe the care and caution required by their work duties and working conditions and apply all available means to ensure their own safety and the safety of other employees at the workplace."

"Employees shall notify the employer of any faults or deficiencies they may detect in the structures, machinery, equipment and work and protection implements of the workplace which may cause risk of accident or illness."

Also in Occupational Safety and Health (OSH) Act (738/2002), which e.g. in section 15 requires that the employers should provide the personal protective equipment, auxiliary equipment and other devices for use.

In SätL section 12 it is stated that the organisation which is responsible in ensuring the obligations laid down in the SätL, shall ensure that a good safety culture is maintained and developed within the organisation. That includes e.g. that the persons in all levels of the organization are aware of the radiation risks associated with their activities, follow the safe practices and participate in the continuous improvement of safety.

This matter is also discussed in the Act on Occupational Safety and Health Enforcement and Cooperation on Occupational Safety and Health at Workplaces (44/2006). Section 26 of the said Act states that:

"(In addition to what is otherwise provided, the issues to be handled in cooperation between the employer and employees include, among other things:

1. matters immediately affecting the safety and health of any employee, and any changes in those matters;
2. principles and manner of investigating risks and hazards at the workplace, as well as such factors generally affecting the safety and health of employees that have come up in connection with the investigation or a workplace survey carried out by an occupational health care organisation;
3. development objectives and programmes relating to workplace health promotion or otherwise affecting the safety and health of employees"

In the Occupational Safety and Health Act (738/2002), Section 18 it is stipulated that the employees shall avoid such harassment and other inappropriate treatment of other employees at the workplace which causes hazards or risks to their safety or health.

Further, the Occupational Safety and Health Act (738/2002), Section 19 states:

"Employees shall without delay inform the employer and the occupational safety and health representative of any such faults and defects they have discovered in the working conditions or working methods, machinery, other work equipment, personal protective equipment or other devices which may cause hazards or risks to the employees' safety or health". This informing obligation also applies to faults and defects that an employee has eliminated.

The requirement is given in Radiation Act, Section 33, which states that: "The undertaking shall ensure that all workers engaged in radiation practices or whose tasks otherwise require special expertise in radiation protection are in possession of the qualifications, radiation protection education and training and induction to their duties required by the practices and the tasks."

Though if there are reasonable grounds to suspect that a worker has received a radiation dose exceeding the worker's dose limit, the worker is obliged to participate in determining his/her own radiation exposure (SätL Section 105).

And according to the Occupational Health Care Act 1383/2001 chapter 3 section 13 it is stated that the employee is obliged to attend the health check.

Nuclear Safety

In addition to the Occupational Safety and Health Act (738/2002) the YVL Guide C.2 (req. 414) requires that in training and giving instructions, the worker's responsibility for taking care of their own radiation safety, and that of others, shall be highlighted.

Question 5 Is it regulated that employers and registrants and licensees cooperate to the extent necessary for compliance by all responsible parties with the requirements for protection and safety?

Answer: Yes

Response:

The radiation safety of employees is stipulated in SätL chapter 12 and further in SätL section 88 it is said that:

"The undertaking and the employer of an outside worker are responsible for the radiation protection of their workers engaged in radiation practices in accordance with the division of responsibilities provided in sections 102–104. Outside workers must enjoy a level of protection equal to the undertaking's own workers."

In SätL section 104 the undertakings obligations in the protection of an outsider worker are listed.

Nuclear safety

The use of nuclear energy is also subject to the SätL chapter 12 (sections 88-108).

The licensee shall give to outside workers, either directly or via their employer, all necessary information, and explanations on work site circumstances and on any changes in operation (YVL Guide C.2 req. 608).

Introductory training shall be given to all permanent and temporary workers of the nuclear facility working in the controlled area irrespective of their nationality (YVL Guide C.2 req. 415).

Question 6 Is it required that employers, registrants and licensees establish and maintain organizational, procedural and technical arrangements for the designation of controlled areas and supervised areas, for local rules and for monitoring of the workplace, in a radiation protection programme for occupational exposure in normal operation, in anticipated operational occurrences and accident conditions?

Answer: Yes

Response:

Nuclear safety

In the YVL Guide C.2 chapter 5 (reqs. 501-522) is defined radiation conditions-based area and zone classification of a nuclear facility. The main principles are as follows:

In the nuclear facility area, dose rates shall be measured as well as the airborne radionuclide concentration and surface contamination (surface activity) systematically determined. Based on the results of the measurements, work sites are divided into controlled and supervised areas.

Supervised area

If the effective dose in an area can exceed 1 mSv, or the equivalent dose to the eye (15mSv) or the equivalent dose to hands, feet or skin (50 mSv) per year, the area shall be classified as a supervised area at minimum.

Exposure conditions in the supervised area and, where necessary, individual radiation exposure shall be monitored according to the nature and extent of radiation exposure. Radiation sources in the area and the associated radiological danger shall be appropriately marked. The markings in the area shall indicate that the area is a supervised area.

Workers shall be provided with instructions on working in the supervised area, the use of radiation sources and the radiological danger associated with the sources. The outlines of the supervised area, radiological conditions and the adequacy of protective measures shall be regularly checked.

Controlled area

At least those rooms in the facility where the external dose rate can exceed 3 μSv/h or where a 40-hour weekly stay can cause an internal dose in excess of 1 mSv per year due to radionuclides originating from a nuclear facility shall be defined as a controlled area.

In the controlled area, special rules and procedures shall be followed, which aim to protect workers from ionising radiation and prevent the spreading of radioactive substances.

The attached appendix (Table A01) of The YVL Guide C.2 lists the limit values for surface contamination in the lowest zone of the controlled area as well as limits for when exiting the controlled area.

Zones of the controlled areas

The rooms in the controlled area shall be divided into zones based on external dose rate, surface contamination and airborne radionuclide concentration. There shall be at least three zones. The minimum zone classification of the facility is given in the attached appendix (Table A02) of the YVL Guide C.2.

The classification of an area into zones shall be clearly indicated by signs at the entrance. If the radiation situation changes, the signs indicating an area's classification shall be changed correspondingly.

An up-to-date record shall be kept of the zone classification of and radiation conditions in the nuclear facility's rooms. The record shall cover conditions during normal operation and the annual maintenance outage.

Access to the controlled area

Access to the controlled area shall be controlled. If the dose rate in a room can exceed 25 μSv/h, the room shall be locked or entrance controlled.

The spreading of contamination in the controlled area shall be restricted where necessary by keeping rooms locked and limiting access to them.

The use of dose monitoring devices shall be easy to verify.

At least protective overalls and shoe covers shall be used as protective clothing together with additional protective gear (protective gloves and shoes, respirators) required in a specific task.

Those leaving the controlled area shall be checked with a measuring instrument for surface contamination.

Measurement results exceeding the surface contamination limit shall be registered. Procedures shall be in place for the changing of contaminated protective clothing. Appropriately equipped personnel decontamination rooms shall be available at the nuclear facility for the elimination of surface contamination in workers.

Materials removed from the controlled area shall be measured for surface contamination.

Other requirements

An operational unit responsible for implementing radiation protection in practice and for co- ordinating related functions shall be established within the nuclear facility's operating organisation or such a unit shall be made available to it (YVL Guide C.2 req. 402).

The procedures to be followed in accident conditions are described in STUK Y/2/2018 (Emergency arrangements of a nuclear power plant) and in YVL Guide C.5 (Emergency arrangements of a nuclear power plant).

The inspection procedures are described in Guides YTV 4.a.1 (Inspection programmes for the control of nuclear facilities) and YTV 3.c.4 (Radiation safety).

Monitoring the radiation safety of nuclear power plants is part of the control of the operational safety of a nuclear power plant. The objective is to ensure that the total radiation exposure (collective dose) of both workers and the public from the use of a nuclear power plant is kept as low as practicable (ALARA). In addition, radiation exposure at individual level is kept well below the dose limits.

Radiation safety

To avoid duplication in in answers, see

- question 6.1 for classification of controlled areas (GSR Part paras 3.88-3.90)
- question 6.2 for supervised areas (GSR Part paras 3.91-3.92)
- question 6.3 for local rules, procedures and personal protective equipment (GSR Part 3 paras 3.93-3.95)
- question 6.4 for monitoring of the workplace (GSR Part 3 paras 3.96-3.98)

Regarding premises where radiation sources are used and stored the undertaking shall according STUK S/5/2019 Section 6 use inherent safety features as well as systems and equipment which set into a status beneficial for safety in case of an error shall be used primarily.

STUK has created forms for undertakings to use when applying for a new safety license or to modify an existing licence. The forms for the use of radiation are found in STUK www-pages (Lomakkeet - STUK). The forms are available in official languages (Finnish and Swedish). Occupation exposure specific forms include: *Order form for the employee dose report and radiation exposure monitoring document*, *Radiation worker health surveillance form* and *Forms for radon measurements in the workplace*.

Question 6.1 How is it ensured that employers, registrants and licensees establish and maintain organizational, procedural and technical arrangements for the designation of controlled areas in a radiation protection programme for occupational exposure in normal operation, in anticipated operational occurrences and accident conditions?

Response:

Nuclear safety

In the use of nuclear energy, the requirements are presented in the previous point (question 6).

In addition, a radiation work permit or instruction is required for work done in the controlled area if justifiable on radiation safety grounds. A permanent permit may be issued for routine and repetitive tasks. The methods and responsibilities for issuing the radiation work permit shall be defined in the facility's radiation protection instructions. If necessary, a radiation work permit for multi-phased work may be divided into different phases (YVL Guide C.2 req. 523).

The radiation work permit includes e.g. information about radiation conditions of work site, radiation protection measures or instructions and required protective equipments and estimation of the radiation exposure of workers.

The nuclear facility shall have instructions to implement radiation protection. They shall include at least the following (YVL Guide C.2 req. 422):

- radiation protection principles and the organisation responsible for implementing them

- organising radiation protection training

- regulations for procedures in the controlled and supervised areas

- classification of radiation workers

- medical surveillance of radiation workers

- radiation measurements in the controlled and supervised areas

- monitoring of individual radiation exposure

- real-time dose monitoring

- decontamination of workers

- radiation work permit procedure

- work planning process for maintenance and modifications important to radiation protection

- radiation protection procedures for unexpected and urgent repairs or maintenance during power operation

- use requirements for personal protective equipment

- procedures to ensure the implementation of the ALARA principle

- procedures for radiation protection quality control.

Radiation safety

Section 91 of the Radiation Act stipulates that working areas shall, where necessary, be classified as controlled areas and supervised areas. A controlled area must be delineated. Access to the area must be restricted to the individuals who have been appropriately instructed. Special arrangements shall furthermore be put in place for the purpose of protecting individuals from ionizing radiation and preventing the spread of radioactive contamination.

The special arrangements referred in Radiation Act Section 91 Subsection 2 are requirements for the undertaking. The undertaking shall have written instructions for working in controlled area, these instructions should include procedures for radiation protection during normal operation and procedures to limit the likelihood and magnitude of radiation exposure in the event of radiation safety deviation. The instructions and guidance shall also describe procedures for possible visit to the controlled area, such as: supervision of the visit by trained person, guidance and instructions to visitors before entering the controlled area, monitoring of the exposure conditions of visitors and recoding and monitoring of the radiation doses received, age restrictions and possible dose constraints.

In Government Decree on Ionizing Radiation (Vna) sections 35 and 36 states that

"*The identification and differentiation of the controlled and supervised areas must account for the nature of the practice and the magnitude of the radiation risk attributable to the practice.*

An area must be categorized as a supervised area if the effective dose to a radiation worker working there can be greater than 1 millisievert a year or the equivalent dose of the lens of the eye is greater than 15 millisieverts a year or the equivalent dose of the skin, hands, arms, feet or ankles is greater than 50 millisieverts a year.

An area in which working requires special measures for protection from ionizing radiation due to the radiation or contamination risk must be categorized as a controlled area."

“If the area carries a risk of the spread of radioactive contamination, necessary arrangements must be carried out for individuals’ arrival to and departure from the area and the delivery and removal of goods to and from the area.

A controlled area must have signs indicating the area’s classification, the nature of the radiation sources and the related hazards.

The undertaking must organize workers working in the controlled area training on the special characteristics of the workplace and the duties and provide the workers with the personal protective equipment necessary for radiation protection”

The basic requirements regarding markings and signings are given in Radiation Act Section 66 Subsection 2 and 3.

The undertaking shall ensure that the use and storage facility or place of a radiation source subject to a safety licence is marked with a sign indicating radiation hazard. The radiation source shall be marked with a sign warning of a radiation hazard if this is technically possible. In addition, the source shield or source container or storage shield of a radiation source containing a radioactive substance must have a label including the key information of the radioactive substance it contains and a marking indicating radiation hazard. What is provided in subsection 2 also applies to other radiation sources the safe use of which requires this.

More detailed requirements regarding markings and signs are given in STUK S/5/2019 Section 10:

The marking warning of radiation hazard referred to in section 66, subsection 2, of the Radiation Act, shall be placed at the doors of places where radiation is used and stored if the door is at the border of the controlled or supervised area. The marking shall be done in accordance with standard SFS-EN ISO 361. The marking may also be a marking of the intended use of the room, if the related radiation hazard is shown clearly in the marking.

Places of use and storage of radiation sources in which the design of radiation shielding is based on the estimate that no one stays in the room permanently shall be marked with a sign prohibiting people from staying in such rooms.

Fulfillment of undertaking's obligations regarding controlled areas is verified during authorization and inspection. The information about practices controlled and supervision areas shall be part of the safety licence application.

Government Decree on Ionizing Radiation, Annex 5 Details to be included in safety licence application

1. A safety licence application must include the following based on the quality and extent of the practice:

…

1.5 pictures and drawings of the areas and premises of the location where the practice is engaged in (including scale), which indicate the purpose of the areas and premises, the locations of the radiation sources, controlled and supervised areas, structural protections, including information on materials, passageways and the location of warning systems, fixed radiation control meters and access control points

STUK's quality guide SKV 3.4, *In-service supervision of radiation activities requiring a safety authorisation* Annex 2 *Issues to be covered by inspections* says that inspector shall verify regarding radiation premises that:

- *supervision and monitoring areas are adequately defined and adequately organised (locks, lights, markings, etc.)*

Chapter 16 in SätL considers the radiation safety deviations and emergency exposure situations. In section 129 it is stipulated that the undertaking must prepare for radiation safety deviations, thus the undertaking shall have an up-to-date plan of action for deviations. According to STUK/S/2/2019 section 2 the plan of action for deviations should include the site-specific procedures for dealing with a deviation, training and exercises on immediate measures to limit radiation exposure and the plan shall also include actions to identify the causes of the deviation and plan how to learn from the deviation.

Section 130 in SätL stipulates the immediate measures in a radiation safety deviation which states that the undertaking shall assess the situation and take the measures necessary to ensure radiation safety.

Question 6.2 How is it ensured that employers, registrants and licensees establish and maintain organizational, procedural and technical arrangements for the designation of supervised areas in a radiation protection programme for occupational exposure?

Response:

Nuclear safety

In the use of nuclear energy, the requirements are presented in the point (question) 6.

Section 2 a of the YEL states how the SätL applies to the use of nuclear energy.

Exposure conditions in the supervised area and, where necessary, individual radiation exposure shall be monitored according to the nature and extent of radiation exposure. Radiation sources in the area and the associated radiological danger shall be appropriately marked. The markings in the area shall indicate that the area is a supervised area. (YVL Guide C.2 req. 506)

Workers shall be provided with instructions on working in the supervised area, the use of radiation sources and the radiological danger associated with the sources. The outlines of the supervised area, radiological conditions and the adequacy of protective measures shall be regularly checked. (YVL Guide C.2 req. 507)

The radiation exposure of personnel working in the supervised area shall also be evaluated. (YVL Guide C.2 req. 706)

If transfers of material are made in the nuclear facility's supervised area or uncategorised areas that could entail an occupational dose deviating from regular background radiation in the area, workers shall be subject to personal dose monitoring considering the possibility of a work-related event leading to abnormal radiation exposure. (YVL Guide C.2 req. 708).

The nuclear facility shall have instructions to implement radiation protection. They shall also take into account supervised areas e.g.

- regulations for procedures in the controlled and supervised areas

- radiation measurements in the controlled and supervised areas

- monitoring of individual radiation exposure

- use requirements for personal protective equipment

- procedures to ensure the implementation of the ALARA principle

Radiation safety

The basic requirement for identification and differentiation of controlled and supervised areas is stipulated in Radiation Act Section 91 Subsection 1:

The controlled areas and supervised areas of working areas must be identified and differentiated. The basis for the differentiation is an assessment on the radiation exposure and potential exposure in the area.

Government Decree on Ionizing Radiation Section 37 sets following requirements for supervised areas:

A supervised area must have signs indicating the area's classification, the nature of the radiation sources and the related hazards, should it be necessary in terms of considering the hazard.

Special rules must be confirmed for the supervised area, should it be necessary in terms of considering the hazard.

The basic requirements regarding markings and signings are given in Radiation Act Section 66 Subsection 2 and 3.

The undertaking shall ensure that the use and storage facility or place of a radiation source subject to a safety licence is marked with a sign indicating radiation hazard. The radiation source shall be marked with a sign warning of a radiation hazard if this is technically possible. In addition, the source

shield or source container or storage shield of a radiation source containing a radioactive substance must have a label including the key information of the radioactive substance it contains and a marking indicating radiation hazard. What is provided in subsection 2 also applies to other radiation sources the safe use of which requires this.

More detailed requirements regarding markings and signs are given in STUK S/5/2019 Section 10:

The marking warning of radiation hazard referred to in section 66, subsection 2, of the Radiation Act, shall be placed at the doors of places where radiation is used and stored if the door is at the border of the controlled or supervised area. The marking shall be done in accordance with standard SFS-EN ISO 361. The marking may also be a marking of the intended use of the room, if the related radiation hazard is shown clearly in the marking.

Places of use and storage of radiation sources in which the design of radiation shielding is based on the estimate that no one stays in the room permanently shall be marked with a sign prohibiting people from staying in such rooms.

Fulfillment of undertaking's obligations regarding supervised areas is verified during authorization and inspection. The information about practices controlled and supervision areas shall be part of the safety licence application.

Government Decree on Ionizing Radiation, Annex 5 Details to be included in safety licence application

1. A safety licence application must include the following based on the quality and extent of the practice:

…

1.5 pictures and drawings of the areas and premises of the location where the practice is engaged in (including scale), which indicate the purpose of the areas and premises, the locations of the radiation sources, controlled and supervised areas, structural protections, including information on materials, passageways and the location of warning systems, fixed radiation control meters and access control points

STUK's quality guide SKV 3.4, *In-service supervision of radiation activities requiring a safety authorisation* Annex 2 *Issues to be covered by inspections* says that inspector shall verify regarding radiation premises that:

- *supervision and monitoring areas are adequately defined and adequately organised (locks, lights, markings, etc.)*

Question 6.3 How is it ensured by regulation that employers, registrants and licensees establish and maintain organizational, procedural and technical arrangements for local rules and procedures and personal protective equipment in a radiation protection programme for occupational exposure?

Response:

Nuclear safety

The use of nuclear energy must be safe and it shall not cause harm to people or damage to the environment or property (YEL section 6).

Releases of radioactive substances caused by the use of nuclear energy shall be restricted in compliance with the optimisation principle of radiation protection laid down in section 6 of the SätL. In the optimisation of radiation protection the dose limits under section 9 of the SätL shall be used (YEL section 7 c).

Section 2 a of the YEL states how the SätL applies to the use of nuclear energy.

The licence holder giving the right to use nuclear energy shall have an adequate number of qualified personnel suitable for their tasks (YEL section 7 i).

The radiation exposure of workers at the nuclear power plant and the nuclear waste facility during their work and the radiation exposure of the surrounding population shall be kept as low as practicable. The design and operation of the above-mentioned installations and activities shall be carried out in such a way that the radiation exposure of workers and the public can be limited in accordance with Sections 5 to 9 of the SätL. Occupational exposure in radiation work is regulated in Chapter 12 of the SätL and in Chapters 3 and 9 of the VnA (Government Decree on Ionizing Radiation) 1034/2018 on dose limits for radiation exposure of workers and reference levels of exposure from radiation emergencies.

Requirements for structural radiation safety are given in the YVL Guide C.1 (Structural radiation safety at a nuclear facility), which states e.g.:

- A nuclear facility's Preliminary and Final Safety Analysis Report or the associated topical report shall give a summary of the most important radiation protection-related design features by which the optimisation principle in radiation protection is implemented at a nuclear facility. (Req. 302)
- With both the Preliminary and Final Safety Analysis Report, a topical report containing an assessment of the doses received by workers from plant operation shall be submitted for approval to the Radiation and Nuclear Safety Authority. (Req. 308)
- At the design phase, the location of the nuclear facility's radiation sources and the amount of radioactive substances during normal operation shall be assessed. Radiation sources include e.g. the reactor and several systems connecting to it, spent fuel and radioactive waste. (Req. 401)
- In a room where work is done, components containing significant amounts of radioactive substances shall be permanently shielded. If it is not possible to use fixed shields, provision shall be made in the dimensioning and structures of the rooms for the use of mobile shielding. (Req. 404)
- Those nuclear facility's rooms where regular working is necessary shall be designed such that the external dose rate and the probability of the intake of radioactive substances are low. (Req. 406)
- The generation and spreading of radioactive substances at a nuclear facility shall be restricted in accordance with the radiation protection optimisation principle. The corrosion, activation and migration of substances significantly affecting occupational dose shall be kept low by the choice of materials and structural designs, surface treatment as well as water chemistry and purification systems design. (Req. 501)
- Parts and components of systems containing radioactive substances shall be located, as far as possible, in rooms such that workers are not unnecessarily exposed to radiation when operating, inspecting, maintaining and repairing them. Parts of systems containing considerable amounts of radioactive substances shall, as a general rule, be located in rooms of their own. Pipelines containing radioactive liquids shall be located away from clean piping and at a sufficient distance from components requiring maintenance. (Req. 503)

Requirements for radiation protection are given in the YVL Guide C.2 (Radiation protection and exposure monitoring of nuclear facility workers), which states e.g.:

- The nuclear facility shall have a written programme (the ALARA action programme) to keep doses low. (Req. 309)
- The nuclear facility's responsible manager is responsible for the nuclear facility's safe and reliable operation. The responsible manager manages activities relating to the nuclear facility's operation and maintenance as well as technical support at the facility. The responsible manager shall ensure sufficient resources and authority for the personnel implementing radiation protection. These resources shall be adequate already before the plant's commissioning. (Req. 401)
- According to Section 28 of the SätL and Section 2 a of the YEL, the responsible party shall appoint a radiation protection officer (RPO) and a deputy for them when necessary. The radiation protection officer is tasked with assisting the responsible party in the implementation of radiation protection.
- Under Section 33 of the SätL, the responsible party shall ensure that all workers engaged protection are in possession of the qualifications, radiation protection education and training and introduction to

their duties required by the practices and the tasks. The responsible party shall keep a worker-specific record on the radiation protection training and introduction for which it is responsible.

- The nuclear facility shall have instructions to implement radiation protection. (Req. 422)
- The nuclear facility shall have the necessary detailed instructions listing practices in radiation protection and radiation measurement as well as information on instruments for measuring or analysing radiation. These instructions shall be incorporated in the facility's management system. (Req. 424)
- In the nuclear facility area, dose rates shall be measured as well as the airborne radionuclide concentration and surface contamination (surface activity) systematically determined. Based on the results of the measurements, work sites are divided into controlled and supervised areas. (Req. 501)
- At least protective overalls and shoe covers shall be used as protective clothing together with additional protective gear (protective gloves and shoes, respirators) required in a specific task. (Req. 518)
- The radiation protection unit shall ensure the availability of an adequate number of radiation monitoring instruments and protective equipment at the facility. The unit shall also ensure that these instruments and equipment are operable and used in accordance with the instructions given. (Req. 406)

Radiation safety

On regulation STUK S/5/2019 Section 6 it is stipulated that engineer control solutions shall be primary option for radiation safety.

Section 6:

In premises where radiation sources are used and stored, structural solutions shall be used which allow the organization of activities in such a way that:

1) the potential exposure and the likelihood are as low as practically possible and exposure does not exceed the constrain for potential exposure;

2) the radiological safety deviation can be controlled;

3) after radiation safety deviation:

a. radiation sources shall be restored to safe state for employees and the members of the public;

b. radiation sources and the premises of use can be brought into safe state for allowing further use or processing;

c. operational and storage facilities can be decontaminated from radioactive substances that have såread in them.

Inherent safety features as well as systems and equipment which set into a status beneficial for safety in case of an error shall be used primarily.

In S/5/2019 Section 6 justification further clarifies the requirement:

The intention is that the prevention and management of radiological safety deviations should be based on good forward planning, where passive safety solutions for structures are always used as the preferred option where reasonably practicable.

More detailed requirements for engineering control solutions are given in S/5/2019 Annexes:

2) In-service acceptability criteria for medical X-ray imaging and fluoroscopic equipment, CT scan appliances and bone mineral density measurement appliances based on the attenuation of X-radiation;

3) In-service acceptability criteria for X-ray imaging and fluoroscopic equipment and the related auxiliary devices and equipment used in veterinary medicine;

4) In-service acceptability criteria for radiotherapy equipment and the related auxiliary devices and equipment;

5) In-service acceptability criteria for equipment used in nuclear medicine;

6) In-service acceptability criteria for radiometric measurement devices in industrial use;

7) In-service acceptability criteria for imaging equipment in industrial use;

Requirement to establish and make available local rules and procedure necessary for protection and safety is stipulated in SätL section 31 subsection 1:

The undertaking shall ensure that the radiation safety instructions concerning workers' tasks and other documents pertaining to workers' radiation safety are available to them.

Additionally, the undertaking shall establish necessary instructions and put in place special arrangements if it is needed to ensure radiation safety as stipulated in Radiation Act Section 91 Subsection 2:

A controlled area must be delineated. Access to the area must be restricted to the individuals who have been appropriately instructed. Access to as well as working in and visits to the controlled area must be controlled in accordance with the written instructions. Special arrangements shall furthermore be put in place for the purpose of protecting individuals from ionizing radiation and preventing the spread of radioactive contamination.

For all practices that require a safety licence, the undertaking shall appoint a radiation safety officer as stipulated in Radiation Act Section 28:

In practices subject to a safety licence, the undertaking shall appoint a radiation safety officer and, if necessary, deputy. The task of the radiation safety officer is to take care of the implementation of radiation protection as assistance to the operator.

The undertaking shall ensure that the radiation safety officer has sufficient authority to carry out the appointed tasks.

STUK issues more detailed regulations on the deputizing arrangements concerning radiation safety officers.

The undertaking shall provide for the employees who is working in controlled areas necessary personal protective equipment as stipulated in VnA Section 36 Subsection 3:

The undertaking must organize workers working in the controlled area training on the special characteristics of the workplace and the duties and provide the workers with the personal protective equipment necessary for radiation protection.

Tasks requiring the use of certain personal protective equipment shall only assigned to workers who are on the basis of medical advice capable of safely to use them. SätL section 96 sets prohibitions on assigning radiation work to persons who are unfit due to their medical condition for the work.

SätL section 96, subsection 1

If a worker, according to the assessment of an occupational physician familiar with radiation, is unfit for a task in which the worker is classified in category A, they may not be classified in this category or assigned to an equivalent task.

Basic requirements to ensure that all personal protective equipment is maintained in proper condition is stipulated in SätL section 30:

The undertaking shall establish quality objectives for practices subject to a safety licence and define and implement systematic measures with which to ensure the realization of the quality objectives (quality assurance) and the fulfillment of the requirements laid down in the law.

The undertaking shall draw up a quality assurance programme for the implementation of quality assurance. The programme must detail the quality assurance measures, their performance, performance intervals, action limits, measures for when the action limits are exceeded, and responsibilities for taking measures pursuant to the programme. In addition, the progamme must include instructions on performing the technical testing and checking of radiation sources and radiation appliances and other equipment as well as software and auxiliary devices with an impact on safety.

The results of the quality assurance must be documented. The quality assurance programme shall be reviewed on a regular basis and updated when necessary.

STUK issues more detailed regulations on quality assurance measures and their performance intervals and instructions as well as the documentation of results.

The undertaking needs also take account possible adverse effects from personal protective equipment (e.g. time to carry out radiation work takes longer). These effects shall be taken account in the safety assessment. Radiation Act section 26 states that the undertaking shall present measures in written safety assessment to ensure radiation safety.

Section 26 Safety assessment concerning radiation practices

In practices subject to a safety licence, the undertaking shall carry out a safety assessment concerning the radiation practice, which:

1. *identifies ways in which the practice can cause radiation exposure, considering any possible*
2. *radiation safety deviations;*
3. *assesses the magnitude of the occupational, public and medical exposure arising from the*
4. *practices as well as the probability and magnitude of the potential exposure;*
5. *presents measures to ensure radiation safety and the optimization of radiation protection;*
6. *presents measures to prevent and prepare for identified radiation safety deviations;*
7. *presents the categorization of the radiation practice….*

Additional requirements for safety assessment are given in STUK S/6/2019. Section 15 gives requirements on assessment of radiation exposure:

The safety assessment concerning radiation practices must present the following per worker and population group:

1) radionuclides, radiation types, radiation energies, and exposure pathways;

2) the key structural solutions and operational arrangements by which radiation exposure is limited; furthermore, in terms of these solutions and arrangements:

a) the estimated radiation dose and its key assessment criteria;

b) the number of persons exposed;

c) the applicable dose constraint and its selection criteria.

Question 6.4 How is it ensured that employers, registrants and licensees establish and maintain organizational, procedural and technical arrangements for monitoring of the workplace in a radiation protection programme for occupational exposure?

Response:

Regarding surface contamination STUK S/1/2018 section 3 sets requirements for determination of surface contamination, section 4 sets actions in response to surface contamination and in Annex 1 table 1 are the surface activity limits.

Section 3

As far as the surface contamination caused by radionuclides is concerned, a sufficient number of measurements shall be carried out to detect the contamination and prevent its dispersion.

Surface activity shall be determined from the amount of loose and attached radioactive substances. Surface activity shall be determined as the average activity over an area of 100 cm^2, if possible.

Section 4

Actions shall be taken to eliminate or isolate surface contamination if the surface activity at the place of use of radiation exceeds the limits specified in Table 1 of Annex 1.

The provisions of subsection 1 above shall not apply to the inner surfaces of fume cupboards and other similar processing facilities or contamination protectors that are used when working in contaminated areas.

If the workplace, tools or clothing cannot be sufficiently decontaminated, their use shall be restricted and the passage of radioactive substances into the body and their dispersion into the environment shall be prevented by other means.

STUK S/1/2018, ANNEX 1, Table Surface activity limits in the use of unsealed sources

Radioactive substance	**Workplaces and tools**		**Workers**	
	Controlled area (Bq/cm^2)	Supervised area (Bq/cm^2)	Clothes (Bq/cm^2)	Skin (Bq/cm^2)
Alpha emitters	4	0.4	0.4	0.2
Beta and gamma emitters	40	4	4	2

Nuclear safety

According to YVL Guide C.2:

- In the nuclear facility area, dose rates shall be measured as well as the airborne radionuclide concentration and surface contamination (surface activity) systematically determined. Based on the results of the measurements, work sites are divided into controlled and supervised areas. (Req. 501)
- Exposure conditions in the supervised area and, where necessary, individual radiation exposure shall be monitored according to the nature and extent of radiation exposure. Radiation sources in the area and the associated radiological danger shall be appropriately marked. The markings in the area shall indicate that the area is a supervised area. (Req. 506)
- Workers shall be provided with instructions on working in the supervised area, the use of radiation sources and the radiological danger associated with the sources. The outlines of the supervised area, radiological conditions and the adequacy of protective measures shall be regularly checked. (Req. 507)
- At least those rooms in the facility where the external dose rate can exceed 3 µSv/h or where a 40-hour weekly stay can cause an internal dose in excess of 1 mSv per year due to radionuclides originating from a nuclear facility shall be defined as a controlled area. (Req. 508)
- In the controlled area, special rules and procedures shall be followed, which aim to protect workers from ionising radiation and prevent the spreading of radioactive substances. (Req. 509)
- The limit values for surface contamination in the lowest zone of the controlled area as well as limits for when exiting the controlled area are listed in the appendix of the Guide YVL C.2 (Req. 510)

In addition to the rooms in the controlled area shall be divided into zones based on external dose rate, surface contamination and airborne radionuclide concentration. There shall be at least three

zones. (YVL Guide C.2 req. 511)

External dose rate, surface contamination or airborne radionuclide concentration may locally exceed the classification limit provided that access to the area in question is restricted by access barriers and visibly marked with signs indicating the radiation situation, potential stay limitations and the protective equipment required. Exceptional radiation sources shall be visibly marked. (YVL Guide C.2 req. 512)

The classification of an area into zones shall be clearly indicated by signs at the entrance. If the radiation situation changes, the signs indicating an area's classification shall be changed correspondingly. (YVL Guide C.2 req. 513)

An up-to-date record shall be kept of the zone classification of and radiation conditions in the nuclear facility's rooms. The record shall cover conditions during normal operation and the annual maintenance outage. (YVL Guide C.2 req. 514)

An operational unit responsible for implementing radiation protection in practice and for co- ordinating related functions shall be established within the nuclear facility's operating organisation or such a unit shall be made available to it. The radiation protection manager of the plant acts as the unit's head. Tasks and responsibilities relating to the implementation of radiation protection shall be described in the facility's management system. (YVL Guide C.2 req. 402)

According to Section 28 of the SätL and Section 2 a of the YEL, the responsible party shall appoint a radiation protection officer and a deputy for them when necessary. The radiation protection officer is tasked with assisting the responsible party in the implementation of radiation protection. (YVL Guide C.2 req. 401a)

According to Section 32 of the SätL and Section 2 a of the YEL, the responsible party shall use a radiation protection expert in the planning, implementation and monitoring of the radiation protection of workers and members of the public. According to Section 17 of the VnA on Ionising Radiation, the responsible party shall ensure that the radiation protection expert is closely involved in the radiation practice if the class of the occupational or public exposure is 1 or 2. (YVL Guide C.2 req. 401b)

Radiation safety

According to SätL section 92 exposure conditions must be regularly monitored in the control area and in the monitoring area. The monitoring shall enable:

1) establish that workers are correctly classified;

2) determine the radiation exposure of workers;

3) detect without delay any unforeseen abnormalities in the factors affecting occupational exposure.

STUK S/1/2018 stipulates that exposure conditions monitoring must include measurements or determinations to ensure that workers' exposure conditions have not changed. For activities with an

occupational exposure category of 3 and for medical X-ray and radiotherapy accelerator activities, the exposure conditions shall be determined by dose rate measurements at the start of the activity, and whenever it changes.

Thereafter, monitoring of the constancy of the exposure conditions is sufficient to monitor the exposure conditions. For other activities, the monitoring of exposure conditions shall include regular measurements of the dose rate of external radiation and the determination of the activity concentration of contaminating radionuclides in air and the determination of surface contamination by radionuclides, if the nature of the activity so permits.

The results of exposure monitoring must be recorded and monitored regularly to ensure compliance with the occupational exposure requirements. According to SätL section 93, workers shall be provided with the results of the individual monitoring concerning them without delay. Upon request, workers shall also be provided with the results of the radiological surveillance used to determine their individual radiation doses.

SätL section 32 states that for activities requiring a safety licence, the undertaking must use a radiation safety expert for the planning, implementation and monitoring of the radiation protection of workers and the general public, except for radiation activities that do not give rise to occupational exposure, exposure of the general public or potential exposure.

According to SätL section 14 STUK supervises compliance with the Radiation Act, unless otherwise provided. To obtain a safety license, which is granted by STUK, the undertaking must demonstrate that the activity complies with the principles of justification, optimization and protection of the individual, can be carried out safely and has been subject to a safety assessment (see primary question 1). STUK also inspects radiation activities to ensure the safety and legality (SätL section 176).

According to SätL section 30 the undertaking must set quality objectives for the activities requiring a safety authorisation and define and implement systematic measures to ensure that the quality objectives are met (quality assurance) and that the legal requirements are fulfilled.

The operator shall draw up a quality assurance programme for the implementation of quality assurance. The programme must specify the quality assurance measures, their implementation, performance intervals, deadlines, measures to be taken if deadlines are exceeded and responsibilities for the

implementation of the measures under the programme. In addition, the programme shall include instructions for the performance of technical testing and verification of radiation sources and equipment and other safety-related equipment, software and ancillary devices.

The results of quality assurance shall be documented. The quality assurance programme shall be regularly evaluated and, if necessary, amended.

Question 7 Are there regulatory requirements for employers, registrants and licensees to be responsible for making arrangements for assessment and recording of occupational exposure and for workers' health surveillance?

Answer: Yes

Response:

Section 102 of SätL states **undertaking's obligations in the protection of its own workers**. In its capacity as an employer, the undertaking is obligated to carry out the measures laid down in section 88–101 to protect its own workers. Section 88 of SätL states that outside workers must enjoy a level of protection equal to the undertaking's own workers.

Out of section 88-101 of SätL, the following sections deal with assessment and recording of occupational exposure and workers' health surveillance:

1) section 89 of SätL states that in practices requiring a safety licence, the radiation exposure of workers and means to reduce it must be assessed before starting the work. The assessment must be adjusted if change affecting occupational exposure takes place in the practice. The worker's previous occupational exposure must also be investigated prior to the commencement of radiation work.

More detailed regulations on prior investigation and assessment of the worker's radiation exposure are given in STUK S/1/2018, section 1 where it is stated that the worker's prior radiation doses shall be checked from the dose register to ensure that the radiation doses do not exceed the dose limit. If all of the worker's prior radiation doses cannot be obtained from the dose register, the prior doses shall be checked from the worker or his or her prior employer. The magnitude of the effective dose and equivalent doses in organs sustained by the worker shall be assessed.

2) section 92 of SätL states that radiological surveillance of controlled areas and supervised areas must be conducted on a regular basis. The surveillance must allow for determining the radiation

exposure to the workers as well as an immediate observation of unforeseen deviations in factors with an impact on occupational exposure. Individual monitoring shall furthermore be arranged for radiation workers belonging in category A. The individual monitoring shall be based on individual measurements performed by a dose measurement service. The measurements must be performed in one-month periods or for a working period if the duration of the work is shorter than the one-month measurement period. The results of the radiological surveillance and individual monitoring must be recorded and followed regularly to ensure compliance with the requirements applicable to occupational exposure.

Further provisions on the recording of the results of radiological surveillance and individual monitoring are given by VnA 1034/2018, section 38 according to which undertakings must record the following with regard to the results of the monitoring of exposure conditions: (a) the time of the monitoring or measurements; (b) the defined dose or the dose rates of external radiation, in which case the radiation types and energies or the radionuclide emitting the radiation must also be recorded; (c) the radioactive substance which caused the contamination, its surface activity as well as its physical state and chemical form; (d) the activity concentration of the radioactive substance in the air as well as its physical state or chemical form, should they be necessary for the calculation of doses; (e) the results of a worker's contamination measurement; (f) the duration of workers' exposure, should it be necessary for the calculation of the doses; (g) a note in the event that no external radiation, contamination or radioactive substance in the air is found; (h) record-keeping on the use of a dosemeter shared by several individuals which allows for assessing the radiation exposure of workers and deducing the need for individual monitoring.

3) section 93 of SätL states how the monitoring results must be reported. Workers shall be provided with the results of the individual monitoring concerning them without delay. Upon request, workers shall also be provided with the results of the radiological surveillance used to determine their individual radiation doses.

4) section 94 of SätL states that an established or suspected radiation dose exceeding the dose limit must immediately be reported to: (a) the worker in question; (b) the occupational physician familiar with radiation who performs the medical surveillance of a category A radiation worker; (c) STUK. The worker in question must also be immediately informed of any exposure exceeding the dose constraint.

5) section 95 of SätL states that a category A radiation worker must be provided with medical surveillance, which includes a pre-employment examination by an occupational physician familiar with radiation and a follow-up examination at least every three years. In the interim years, it shall be ensured that the worker informs the occupational physician familiar with radiation whether there have been any such material changes in the worker's state of health subsequent to the most recent medical examination which may have an effect on their capability to carry out radiation work. In the event that

there is a material change in the worker's state of health, the worker must undergo an extra medical examination performed by the occupation physician familiar with radiation. The occupational physician familiar with radiation must be provided with information on the workplace conditions relevant for the medical surveillance, the results of the worker's individual monitoring and any other information relevant for the medical surveillance.

6) section 96 of SätL states that if a worker, according to the assessment of an occupational physician familiar with radiation, is unfit for a task in which the worker is classified in category A, they may not be classified in this category or assigned to an equivalent task. If the worker has received a radiation dose exceeding the dose limit, they may not be assigned to radiation work before they have been deemed fit for radiation work. The worker has the right to submit the matter concerning them, referred to in subsection 1 and 2, to STUK for consideration. The employer must inform the worker of the said right.

7) section 97 of SätL states that if the worker has received a radiation dose exceeding the dose limit of workers, the measures deemed necessary by the exposed worker's occupational physician familiar with radiation must be carried out in addition to the medical surveillance laid down in section 95.

8) section 100 of SätL states that once a worker has notified the undertaking or, in the case of an outside worker, their employer of their pregnancy or of breastfeeding a child, the foetus and breastfed child must be protected in a manner equivalent to the protection of a member of the public. Radiation workers must be reminded of the importance of this notification.

According to VnA 1034/2018, section 41, the work of a pregnant worker must be organized in such a way that the foetus's equivalent dose is as low as practically possible and that it is no greater than one millisievert during pregnancy once the worker has informed the undertaking or, in the case of an external worker, the employer of their pregnancy. A breastfeeding worker assigned work which involves a risk of radionuclide intake or body contamination."

9) section 101 of SätL states that the information from the individual monitoring of category A radiation workers referred to in section 20, shall be delivered to the workers' dose register on a regular basis. If the radiological surveillance has been carried out as the individual monitoring of category B radiation workers performed by a dose measurement service, the information specified in subsection 1 shall be delivered to the dose register regularly also for category B workers.

According to VnA 1034/2018, section 42 states that in addition to what is provided in section 20 of the SätL, the following information is saved in the workers' dose register: (a) the first name, last name, personal identity code, gender and nationality of the worker, emergency worker and emergency assistant as well as the start and end date of the individual monitoring; (b) of an undertaking and the employer of an outside worker, the name, address and individual identification of the undertaking and the employer as well as the name of the employer's contact person; (c) information on the radiation practice and the quality of the exposure as well as the class of the radiation worker; (d) of the results of individual monitoring, the time of the measurement period as well as the result of the measurement or dose determination and, in terms of internal exposure, the information used for determining the dose; (e) of radiation safety incidents, the investigations pertaining to the exposure conditions and performed measures. If a worker's individual dose has been determined, the effective dose is saved as millisieverts, the equivalent doses of different parts of the body, in the case of unequally distributed radiation, as millisieverts and, in the case of an intake of radionuclides, the committed effective dose as millisieverts."

More detailed regulations of a technical nature on the organization of the radiological surveillance and individual monitoring at the workplace and on the determination of an individual radiation dose on the basis of the radiological surveillance are issued in STUK S/1/2018, Section 5-11.

Section 103 of SätL states **obligations of the employer of an outside worker**: (a) "investigate the worker's previous occupational exposure in advance pursuant to section 89, subsection 2, and assess the total radiation exposure to which the worker is exposed in the work of all undertakings in advance; (b) organize medical surveillance and special medical surveillance pursuant to section 95 and 97 for category A radiation workers; (c) consult an occupational physician familiar with radiation in accordance with section 97 in the event that a worker's radiation dose exceeds the dose limit; (d) for its part, ensure that the information to be registered and the results of individual monitoring are delivered to the workers' dose register in accordance with section 101; (e) for its part, ensure that an occupational physician familiar with radiation is provided with the reports and information specified in section 94 and section 95, subsection 2, and in section 95, subsection 4 for the purposes of performing medical surveillance of a worker.

Section 104 of SätL states **undertaking's obligations in the protection of an outside worker**: (a) "investigate an outside worker's previous occupational exposure and assess, in advance, the radiation exposure to which the outside worker is exposed due to work for which the undertaking is responsible and the means to reduce it pursuant to section 89; (b) in the practice for which it is responsible, organize the radiological surveillance and individual monitoring for an outside worker belonging in category A pursuant to section 92 and make sure that the information specified in section 20, subsection 2 is delivered to the dose register; (c) ensure that an outside worker belonging in category A has been organized the medical surveillance referred to in section 95 and the special medical surveillance referred to in section 97, and that the outside worker is medically fit for the assigned task in the practice for which the undertaking is responsible; (d)for its part, ensure that the information

referred to in section 95, subsection 4 is delivered to an occupational physician familiar with radiation. The undertaking and the employer may agree in writing that the employer takes care of the individual monitoring and the delivery of information to the dose register referred to in subsection 1, paragraph 3.

Section 105 of the Radiation Act (859/2018) states worker's duty to participate in the investigation of radiation exposure: "Where there is reasonable basis to suspect that the worker has received a radiation dose exceeding the dose limit of workers, the worker is obligated to take part in the investigation of the exposure to which they have been subject. A worker's duty to participate in a medical examination is laid down in section 13 of the Occupational Health Care Act (1383/2001).

Section 106 of SätL states that he fitness of a category A radiation worker for radiation work must be established prior to the commencement of working and at least once a year during the work. The capability to perform radiation work must also be established if the worker is found or suspected of receiving a radiation dose exceeding the dose limit of workers. The fitness for radiation work is determined by an occupational physician familiar with radiation on the basis of the worker's state of health, using the following categorization: 1) fit; 2) fit, subject to certain conditions; 3) unfit. The occupational physician familiar with radiation must provide the worker with a certificate on their fitness for radiation work and on the conditions for continuing radiation work in connection with the medical examination. The physician's certificate concerning the medical surveillance must indicate:1) the category referred to in subsection 2; 2) details on any possible restrictions in radiation work; 3) the date of the most recent review of health examination performed by an occupational physician familiar with radiation; 4) the validity of the physician's certificate.

Section 107 of SätL states that the occupational physician familiar with radiation must contact STUK if an observation made in the context of medical surveillance gives reason to believe the serious compromise of radiation safety. The physician may, non-disclosure provisions notwithstanding, provide STUK with the information needed to investigate the matter. In respect of personal data, the right to provide information is nevertheless limited solely to the data indispensable for the matter in question.

Section 108 of SätL states that the health records of a category A radiation worker maintained by occupational health care must include information on the worker's tasks and posts relevant for the medical surveillance. In addition, the documents must include the results of the medical surveillance conducted for the purpose of assessing the worker's fitness to be classified as a category A radiation worker prior to their current post. The information must be kept up to date for as long as the worker belongs in the category in question. Non-disclosure provisions notwithstanding, the information referred to in subsection 1 may be provided to STUK solely for the purpose of considering the matter referred to in section 96, subsection 3, or if such provision is necessary in terms of regulatory control. The occupational physician familiar with radiation must provide the undertaking or the employer of an

outside worker with the information on the medical surveillance of a worker necessary to fulfil the obligations laid down in SätL.

Nuclear safety

Sections 88-108 (chapter 12) of the SätL also apply to nuclear facilities in accordance with the YEL section 2 a.

The basic information is also given in the YVL Guide C.2 chapter 6 (Classification and medical surveillance of radiation workers) and chapter 7 (Monitoring of radiation exposure).

Question 7.1 How is it ensured that employers, as well as self-employed persons, and registrants and licensees are responsible for making arrangements for assessment of the occupational exposure of workers, on the basis of individual monitoring where appropriate, and to ensure that arrangements are made with authorized or approved dosimetry service providers that operate under a quality management system?

Response:

SätL section 102 states that the undertaking as an employer is obligated to carry out the measures laid down in section 88–101 to protect its own workers. In addition, section 88 states that the undertaking and the employer of an outside worker are responsible for the radiation protection of their workers engaged in radiation practices in accordance with the division of responsibilities provided in sections 102–104. Outside workers must enjoy a level of protection equal to the undertaking's own workers. According to SätL section 4 a sole proprietor is an undertaking if he/she carries out radiation activities. If he himself carries out radiation work, he is obliged under SätL section 88 to take care of his own radiation protection as provided for in SätL chapter 12.

According to SätL section 92 individual monitoring shall be arranged for radiation workers belonging in category A. The individual monitoring shall be based on individual measurements performed by a dose measurement service. The measurements must be performed in one-month periods or for a working period, if the duration of the work is shorter than the one-month measurement period. Often also for radiation workers in category B the individual monitoring is arranged similar way but with tree month measurement period.

Individual monitoring means by its definition in SätL section 4 that it is performed by approved dosimetry service. The requirements for approved dosimetry services are given in SätL sections 59 – 63 and include requirement for quality managements system.

In aviation, the dose assessments are made individually on the basis of flight hours and routes. The airlines are carrying out these dose assessments by themselves. The procedures are reviewed during the issuance of the safety licence and are monitored as part of the inspections.

Individual monitoring for radon exposure is based on the measurements which are approved by STUK. The approval is based on SätL section 64. The requirements are given in SätL section 59 and more detailed requirements in regulation STUK S/7/2021. The requirements include evidence for reliability of the measurements, uncertainty estimations, calibrations, and traceability. The approval is given up to five years period.

Nuclear safety

Sections 88-108 (chapter 12) and sections 59-65 (chapter 9) of the SätL also apply to nuclear facilities in accordance with the YEL section 2 a.

The basic information is also given in the YVL Guide C.2 chapter 7 (Monitoring of radiation exposure).

Question 7.2 How is it ensured that for any worker who usually works in a controlled area or who occasionally works in a controlled area and may receive a significant dose from occupational exposure, individual monitoring shall be undertaken where appropriate, adequate and feasible?

Response:

Section 92 of SätL states that radiological surveillance of controlled areas and supervised areas must be conducted on a regular basis. The surveillance must allow for determining the radiation exposure to the workers as well as an immediate observation of unforeseen deviations in factors with an impact on occupational exposure. Individual monitoring shall furthermore be arranged for radiation workers belonging in category A. The individual monitoring shall be based on individual measurements performed by a dose measurement service. The measurements must be performed in one-month periods or for a working period if the duration of the work is shorter than the one-month measurement period.

The results of the radiological surveillance and individual monitoring must be recorded and followed regularly to ensure compliance with the requirements applicable to occupational exposure.

Further provisions on the recording of the results of radiological surveillance and individual monitoring are given by VnA 1034/2018, section 38 according to which undertakings must record the following with regard to the results of the monitoring of exposure conditions: 1) the time of the monitoring or measurements; 2) the defined dose or the dose rates of external radiation, in which case the radiation types and energies or the radionuclide emitting the radiation must also be recorded; 3) the radioactive substance which caused the contamination, its surface activity as well as its physical state and chemical form; 4) the activity concentration of the radioactive substance in the air as well as its physical state or chemical form, should they be necessary for the calculation of doses; 5) the results of a worker's contamination measurement; 6) the duration of workers' exposure, should it be necessary for the calculation of the doses; 7) a note in the event that no external radiation, contamination or radioactive substance in the air is found; 8) record-keeping on the use of a dosemeter shared by several individuals which allows for assessing the radiation exposure of workers and deducing the need for individual monitoring.

More detailed regulations of a technical nature on the organization of the radiological surveillance and individual monitoring at the workplace and on the determination of an individual radiation dose on the basis of the radiological surveillance are issued in STUK S/1/2018, sections 5-11.

Nuclear safety

All workers in the nuclear facility's controlled area shall be provided with personal dosimeters. (YVL Guide C.2 req. 702).

The radiation exposure of personnel working in the supervised area shall also be evaluated. (YVL Guide C.2 reg. 706)

Question 7.3 How is it ensured that in cases where individual monitoring for any worker who usually works in a controlled area or who occasionally works in a controlled area and may receive a significant dose from occupational exposure, is inappropriate, inadequate or not feasible, the occupational exposure is assessed on the basis of the results of workplace monitoring and information on the locations and durations of exposure of the worker.

Response:

Section 92 of SätL states that radiological surveillance of controlled areas and supervised areas must be conducted on a regular basis. The surveillance must allow for determining the radiation exposure to the workers as well as an immediate observation of unforeseen deviations in factors with an impact on occupational exposure. The results of the radiological surveillance and individual monitoring must be recorded and followed regularly to ensure compliance with the requirements applicable to occupational exposure.

According to section 38 of VnA1034/2018, undertakings must record the following with regard to the results of the monitoring of exposure conditions: 1) the time of the monitoring or measurements; 2) the defined dose or the dose rates of external radiation, in which case the radiation types and energies or the radionuclide emitting the radiation must also be recorded; 3) the radioactive substance which caused the contamination, its surface activity as well as its physical state and chemical form; 4) the activity concentration of the radioactive substance in the air as well as its physical state or chemical form, should they be necessary for the calculation of doses; 5) the results of a worker's contamination measurement; 6) the duration of workers' exposure, should it be necessary for the calculation of the doses; 7) a note in the event that no external radiation, contamination or radioactive substance in the air is found; 8) record-keeping on the use of a dosemeter shared by several individuals which allows for assessing the radiation exposure of workers and deducing the need for individual monitoring.

According to Section 39 of VnA 1034/2018), the undertaking must carry out the measures necessary for the determining the individual dose of an outside worker belonging in class A working in a controlled area after each working period for the dose entry referred to in subsection 2. If the dose measured during a working period cannot be obtained from a dosemeter immediately after the working period, the dose in question must be determined through the monitoring of the exposure conditions. If the combined dose of different working periods cannot exceed six millisieverts a month, the worker's dose does not need to be determined separately for a period shorter than the measuring period. The undertaking must record the following on the results of the individual monitoring of an outside worker working in a controlled area after each working period: 1) the duration of the working period; 2) an estimate of the effective dose during the working period; 3) in the case of unevenly distributed radiation exposure, an estimate of the equivalent doses of various parts of the body; 4) in the case of internal exposure, an estimate of the intake of radionuclides or the committed effective dose.

Nuclear safety

All workers in the nuclear facility's controlled area shall be provided with personal dosimeters. (YVL Guide C.2 req. 702).

The radiation exposure of personnel working in the supervised area shall also be evaluated. (YVL Guide C.2 reg. 706)

In addition to a system that monitors individual occupational radiation exposure, the nuclear facility shall have a measurement system for the real-time monitoring of the accumulation of occupational radiation dose in the controlled area caused by external radiation. In real-time radiation exposure monitoring, teledosimetry shall be used, where necessary. (YVL Guide C.2 737)

The information yielded by the real-time dose measuring system shall be used to verify the reliable operation of the measuring instruments used for individual dose monitoring. (YVL Guide C.2 req. 738)

If the official dose measuring fails due to the dosimeter having been lost or due to some other exceptional event, the dose measurement data recorded by the real-time dose monitoring system may be utilised in radiation exposure assessment. The dose for such a monitoring period shall be reported to the Dose Registry as an estimated dose. (YVL Guide C.2 req. 739)

Question 7.4 How is it ensured that for any worker who regularly works in a supervised area or who enters a controlled area only occasionally, the occupational exposure is assessed on the basis of the results of workplace monitoring or individual monitoring, as appropriate?

Response:

Section 92 of SätL states that radiological surveillance of controlled areas and supervised areas must be conducted on a regular basis. The surveillance must allow for determining the radiation exposure to the workers as well as an immediate observation of unforeseen deviations in factors with an impact on occupational exposure. The results of the radiological surveillance and individual monitoring must be recorded and followed regularly to ensure compliance with the requirements applicable to occupational exposure.

Nuclear safety

All workers in the nuclear facility's controlled area shall be provided with personal dosimeters. (YVL Guide C.2 req. 702).

The radiation exposure of personnel working in the supervised area shall also be evaluated. (YVL Guide C.2 reg. 706)

Question 7.5 Are employers required to ensure that workers who could be subject to exposure due to contamination, including workers who use respiratory protective equipment are identified, and arrange for appropriate monitoring to the extent necessary to demonstrate the effectiveness of the measures for protection and safety and to assess intakes of radionuclides and the committed effective doses?

Response:

Section 2 of STUK S/1/2018 states that in the monitoring of exposure conditions, measurements or determinations shall be carried out to ensure that the workers' exposure conditions have not changed. In practices of occupational exposure class 3 and in health care X-ray practices and in the use of radiotherapy accelerators, the exposure conditions shall be determined by means of dose rate measurements upon commencement of the practices and whenever any changes are made to them. Thereafter, the monitoring of constancy is a sufficient means of monitoring the exposure conditions. In other practices, the monitoring of exposure conditions shall include regular measurement of the dose rate of external radiation as well as determination of the activity concentration of contaminating radionuclides in the air and determination of the surface contamination caused by radionuclides, if possible in view of the nature of the practices.

Section 3 of STUK S/1/2018 states that as far as the surface contamination caused by radionuclides is concerned, a sufficient number of measurements shall be carried out to detect the contamination and prevent its dispersion. Surface activity shall be determined from the amount of loose and attached radioactive substances. Surface activity shall be determined as the average activity over an area of 100 cm^2, if possible.

Section 4 of STUK S/1/2018 states that actions shall be taken to eliminate or isolate surface contamination if the surface activity at the place of use of radiation exceeds the limits specified in Table 1 of Annex 1. The provisions of subsection 1 above shall not apply to the inner surfaces of fume cupboards and other similar processing facilities or contamination protectors that are used when working in contaminated areas. If the workplace, tools or clothing cannot be sufficiently decontaminated, their use shall be restricted and the passage of radioactive substances into the body and their dispersion into the environment shall be prevented by other means.

Section 5 of STUK S/1/2018 states that if a worker is subject to external radiation exposure, the personal dose equivalent sustained by the worker shall be measured in individual monitoring. A

separate measurement shall be carried out for determining the equivalent dose to the lens of the eye if the dose to the lens of the eye cannot be assessed with a sufficient degree of accuracy based on other measurements carried out for the purpose of individual monitoring. The doses to the hands or the skin of fingers shall be assessed or measured whenever new working methods or radioactive substances are introduced if there is no sufficient prior knowledge of the exposure they cause in order to assesses the necessity of arranging individual monitoring. The doses to the hands or fingers shall also be determined when the worker starts working with unsealed sources.

Section 6 of STUK S/1/2018 states that if radionuclides have, or are suspected of having, ended up on the worker's skin or body, the activity present in the worker's body shall be determined by means of measuring equipment suitable for the purpose. The committed effective dose sustained by the worker shall be assessed based on the measurement result. The results of the measurement and the assessment shall be reported to the workers' dose register. The doses arising from internal radiation exposure shall be assessed or measured if new working methods or radioactive substances or materials containing them are introduced if there is no sufficient prior knowledge of the internal exposure they cause.

Section 7 STUK S/1/2018 states that when iodine isotopes in an easily volatile form are handled, the amount of radioactive substances accumulated in the worker's thyroid gland shall be monitored. If the amount of activity detected in the worker's thyroid gland exceeds 5 kBq, the resulting equivalent dose to the thyroid gland shall be determined and the result shall be reported in the workers' dose register.

Section 8 of STUK S/1/2018 states that in health care X-ray practices where the reading of the personal dosemeter when measured on the surface of the protective apron used by the worker may exceed 20 mSv per year, the undertaking shall assess the effective dose sustained by the worker. If the worker may become subject to skin contamination or exposure of the lens of the eye, hands, arms, feet or ankles, the equivalent dose to the exposed part of the body shall be determined. If the worker may become subject to internal exposure, the committed effective dose arising from internal radiation or the equivalent dose of the organs where the radioactive substance accumulates shall be determined.

Section 9 of STUK S/1/2018 states that if individual dosimetry cannot be carried out or no suitable method of measurement is available, the doses sustained by the worker shall be estimated computationally based on the measurement results of workers who were under individual monitoring, the results of the monitoring of exposure conditions, or by means of a reliable calculation method. The undertaking shall be responsible for carrying out the dose estimate. The estimated dose and the method of estimating shall be reported to the workers' dose register.

Section 10 of STUK S/1/2018 states that the values of ambient and directional dose equivalent and personal dose equivalent obtained as measurement results in the monitoring of exposure conditions and individual monitoring shall be compared against the values of the worker's dose limits. The computationally determined effective dose arising from radon, radioactive air contamination and other internal exposure shall be compared against the dose limit values.

Section 11 of STUK S/1/2018 states that as regards internal radiation exposure, the undertaking shall define intervals for the regular monitoring of radiation exposure. "

Nuclear safety

STUK S/1/2018 also applies to the use of nuclear energy.

According to the YVL Guide C.2:

- The nuclear facility shall have monitoring equipment for the detection of internal radioactivity in those working in the controlled area. The equipment shall be sensitive enough to detect with adequate accuracy from the upper body area such radioactive substances originating from nuclear facilities and emitting gamma radiation, which may, based on the level of radioactivity at the moment of measurement, cause an effective dose exceeding the recording level. (Req. 724)
- In addition, technical equipment and a calculation method shall be available at the nuclear facility for determining the internal dose caused by radionuclides originating from nuclear facilities. (Req. 725)
- A nuclide-specific measurement shall be conducted on workers assessed to be at risk from internal contamination due to the nature of their work. Workers from the nuclear facility's permanent staff and from contractors' staff shall be chosen for the measurement. The number of workers chosen shall be adequate to ensure representativeness of monitoring. (Req. 726)
- Exposure caused by internal radiation shall be assessed and determined, if necessary, whenever measurements to detect contamination of the skin and protective clothing of those leaving the controlled area or some other observation indicate that exceptional internal contamination is possible. (Req. 728)
- Internal dose shall be determined by a procedure approved by STUK and described in the licensee's documentation. (Req. 732)

Question 7.6 How is it ensured that employers, registrants and licensees maintain records of occupational exposure for every worker for whom assessment of occupational exposure is required under the regulations?

Response:

According to VnA 1034/2018, section 40, the results of the monitoring of exposure conditions must be stored for a minimum period of five years and for as long as the storage is necessary to ensure that the practice complies with the principles of optimization and limitation and for the development of the practice's safety and working methods. The results of a worker's individual monitoring must be stored in terms of the worker's entire time at work for as long as the worker is employed by the undertaking or the employer. Any information which is material in terms of determining the worker's individual dose, such as the results of thyroid gland and skin contamination measurements, must likewise be stored.

Nuclear safety

In addition to the VnA 1034/2018 the basic requirements are also given in the YVL Guide C.2 chapter 7 (Monitoring of radiation exposure) and chapter 8 (Reporting radiation doses to the Dose Registry).

Question 7.7 How is it ensured that records of occupational exposure for each worker are maintained during and after the worker's working life, at least until the former worker attains the age of 75 years, and for not less than 30 years after cessation of the work in which the worker was subject to occupational exposure ?

Response:

According to SätL, section 20, STUK maintains a workers' dose register to ensure the health of radiation workers, emergency workers, emergency helpers and radiation safety.

According to SätL, section 21, the information in the dose register is stored for as long as the worker is engaged in radiation work and, subsequently, until the person in question attains or would have attained the age 75 years, although until 30 years have elapsed from the termination of the radiation work. STUK may store the aforementioned information for longer than this for research purposes related to ensuring radiation safety. STUK maintains the workers' dose register and takes care of that the demands on Section 21 of SätL are fulfilled.

Question 7.8 How is it ensured that records of occupational exposure include: (a) Information on the general nature of the work in which the worker was subject to occupational exposure; (b) Information on dose assessments, exposures and intakes at or above the relevant recording levels specified by the regulatory body and the data upon which the dose assessments were based; (c) When a worker is or has been exposed while in the employ of more than one employer, information on the dates of employment

Response:

SätL section 20 states that STUK maintains a workers' dose register to ensure the health of radiation workers, emergency workers, emergency helpers and radiation safety. In terms of individual monitoring, the register contains the identifying information of each worker and information on:

1) their tasks;

2) undertakings and the employers of outside workers;

3) the methods employed for determining individual radiation doses;

4) factors impacting radiation exposure;

5) the results of individual monitoring.

In addition, the register contains information on the methods and results of radiological surveillance insofar as they are employed in the determination of a worker's individual radiation dose.

Further provisions on the information to be stored in the dose register are given by VnA section 42.

All the dose information is recorded to national workers dose register which STUK maintains. According to SätL section 60 approved dosimetry service need to have the necessary technical means for delivering the dose data to the workers' dose register. The approved dosimetry service delivers main part of the dose data to workers dose register on behalf of employer. The data is sent in the format which allows to set up obligatory fields in it. That ensures that all the required information mentioned in points a – c will be sent to workers dose register.

The dose data is also reviewed before recording it and there is specific automatic review program for that. In addition to this, the person using the review program checks manually the needed parts of the data. The data is also recorded manually from radiological monitoring documents and other comparable documents, but the same review program is used to those. The process is described in internal guides SKV 6.1 and SKV 3.8.

Question 7.9 How is it ensured that employers, registrants and licensees: (a) provide workers with access to records of their own occupational exposure; (b) provide the supervisor of the programme for workers' health surveillance, the regulatory body and the relevant employer with access to workers' records of occupational exposure; (c) facilitate the provision of copies of workers' exposure records to new employers when workers change employment; (d) make arrangements for the retention of exposu

Response:

According to SätL section 101 the information from the individual monitoring shall be delivered to the workers' dose register on a regular basis. The data in the register is visible through extranet for doctors carrying out workers' health surveillance, employers and responsible parties. The description of the extranet and procedure to get an access to it is in internal guide SKV 6.1. The guide SKV 6.1 includes also the measures taken to verify confidentiality.

So far individual workers are not able to get an access via extranet to their own dose data. They have a right to get all information which is recorded of them, but only by request. SätL section 93 states that employer must take care the workers are provided with the results of the individual monitoring concerning them without delay.

Question 7.10 How is it ensured that if employers, registrants and licensees cease to conduct activities in which workers are subject to occupational exposure, they make arrangements for the retention of workers' records of occupational exposure by the regulatory body or a State registry (e.g., National Dose Registry), or by a relevant employer, registrant or licensee, as appropriate?

Response:

Dose monitoring services send workers' occupational exposure data simultaneously to the employers and the workers' dose register. In the workers' dose register the doses are maintained according to SätL section 21: the information in the dose register is stored for as long as the worker is engaged in radiation work and, subsequently, until the person in question attains or would have attained the age 75 years, although until 30 years have elapsed from the termination of the radiation work. STUK may store the aforementioned information for longer than this for research purposes related to ensuring radiation safety.

Question 7.11 How is it ensured that programmes for workers' health surveillance: (a) are based on the general principles of occupational health ; (b) are designed to assess the initial fitness and continuing fitness of workers for their intended tasks ?

Response:

According to the SätL Section 3, the general basis for the medical surveillance of workers is the Occupational Health care Act (1383/2001). The Occupational Health Care Act (1383/2001) and regulations given under it enact in general terms the arranging of occupational health care for workers.

The undertaking shall ensure that radiation workers are covered by medical surveillance for those engaging in radiation work. According to SätL section 95 category A radiation worker shall be subject to health surveillance, including an initial examination by an occupational physician familiar with radiation and a follow-up examination at least every three years.

Every year when follow-up examinations are not done, care shall be taken to ensure that the worker informs the occupational physician if there have been any substantial changes in his state of health since the last medical examination which may affect the conditions for carrying out radiation work.

An additional medical examination by an occupational physician familiar with radiation shall be carried out if there is a substantial change in the worker's state of health.

The occupational physician shall be provided with the information on the conditions at the workplace, the results of the worker's personal dose monitoring and any other information necessary for monitoring the state of health.

According to Act on approval of medical doctor to be a doctor carrying out health checks of radiation workers in category A (Laki lääkärin hyväksymisestä luokkaan A kuuluvien säteilytyöntekijöiden terveydentilan seurannan suorittavaksi lääkäriksi (170/2017)), the doctor monitoring the health status must be an occupational health physician familiar with radiation and approved by Valvira.

An occupational physician familiar with radiation must demonstrate his or her familiarity with the health effects of radiation by successfully completing the training in radiation protection required for the task, organised by the Institute of Occupational Health or a university, for which the training organisation issues a certificate to the physician. The training in radiation protection covers the matters that must be included in the medical certificate, i.e. the worker is fitness to carry out radiation work.

For a category B worker, there is no need for health surveillance for radiation protection reasons.

Nuclear safety

The medical surveillance of radiation workers aims, among other things, to

- ensure their suitability for radiation work and that their health does not prevent it
- ensure that they are capable of using the protective equipment required in radiation work
- monitor their health during radiation work to detect in particular such potential changes that would prevent them to continue radiation work

- determine the health significance of exposure whenever it is established or suspected that exposure exceeds the dose limit or is otherwise exceptional (YVL Guide C.2 req. 607)

The nuclear facility shall keep a record of the medical examinations of category A workers. (YVL Guide C.2 req. 609)

The medical surveillance of workers participating in emergency situations is addressed in Guide YVL C.5.

Question 7.12 How is it ensured that if one or more workers are engaged in work in which they are or could be exposed to radiation from a source that is not under the control of their employer, the registrant or licensee responsible for the source make with the employer any special arrangements for workers' health surveillance that are needed to comply with the rules established by the regulatory body or other relevant authority , as a precondition for the engagement of such workers?

Response:

In SätL 104, in untertaking's obligations in the protection of an outsider worker, it is stipulated that the undertaking shall ensure that an outside worker belonging in category A has been organized the medical surveillance. See answers also to question 5.

Question 8 Are there requirements that employers, registrants and licensees provide workers with adequate information, instruction and training for protection and safety?

Answer: Yes

Response:

In SätL sections 33 and 34:

"*The undertaking shall ensure that all workers engaged in radiation practices or whose tasks otherwise require special expertise in radiation protection are in possession of the qualifications, radiation protection education and training and induction to their duties required by the practices and the tasks. The undertaking shall keep a worker-specific record on the radiation protection training and induction for which it is responsible.*"

Detailed regulations on the provision and content of the radiation protection training and induction are set in STUK/6/2019 sections 4 and 5. From which the 4th section sets requirements for the induction and the 5th section adds additional requirements for induction when using HASS.

Further in section 34:

"*The undertaking shall ensure that workers engaged in radiation practices are provided with sufficient and regular supplementary training on radiation protection. The undertaking shall keep a worker-specific record on the supplementary radiation protection training for which it is responsible.*"

In STMA 1044/2018 section 8 is stated that "*Workers engaged in radiation practices must be provided with supplementary radiation protection training in periods of at least five years. The supplementary training must focus on the special characteristics related to radiation safety in each duty and on the latest knowledge and changes impacting radiation safety in the radiation operations in question.*" The requirements concerning supplementary training are also set in STMA's Annex 5, supplementary training of worker engaged in radiation practices.

In addition to those above in SätL section 136 stipulates that "*The employer shall ensure that emergency workers are provided with adequate training at regular intervals on the health risks related to tasks in an emergency exposure situation and on protection against such risks.*"

In SätL section 146 it is stated that the results of an investigation concerning occupational exposure to radon or NORM shall be processed in the workplace in accordance with what is provided in section 27 of the Act on Occupational Safety and Health Enforcement and Cooperation on Occupational Safety and Health at Workplaces (44/2006).

If occupational exposure to radon or NORM requires limitation by adjusting working hours or working methods according to SätL section 147, information and instruction to relevant workers from the employer is an inherent part of the limiting measures. For occupational exposure to NORM, the actual use of limiting measures can be checked through inspections.

If the occupational exposure from radon or NORM is large enough to warrant licensing, the sections mentioned above for use of radiation are also then valid (SätL sections 148, 149).

Nuclear safety

SätL sections 33-34 and 136 and STMA 1044/2018 also apply to the use of nuclear energy.

In addition the YVL Guide C.2 states that

- The licensee shall give to outside workers, either directly or via their employer, all necessary information and explanations on work site circumstances and on any changes in operation. The licensee and employer of the outside worker shall ensure for their part forwarding the information to an occupational physician familiar with radiation. (Req. 608)
- Introductory radiation protection training aims at providing workers with knowledge about radiation legislation and the regulations issued under it as well as at providing them with the preconditions for correct working in the controlled and supervised areas as well as at furthering the accomplishment of radiation protection goals. The introductory training shall provide preconditions for consistent actions in accordance with safety aspects if unexpected situations occur at the workplace. In training and giving instructions, the worker's responsibility for taking care of their own radiation safety, and that of others, shall be highlighted. (Req. 414)
- In co-operation with radiation protection experts, personnel contributing to work planning shall ensure that work phases are reviewed or practised before their implementation at work sites that are challenging in terms of radiation protection. (Req. 421)

Question 9 Are employers, registrants and licensees required not to offer benefits as substitutes for measures for protection and safety?

Answer: Yes

Response:

Section 23 of the SätL lays down the criteria for organizing practices. According to the section the undertaking shall implement the organization of the practice in such a way that the practice meets the requirements provided in this Act and that radiation safety deviations are prevented with adequate effectiveness and that their consequences are as insignificant as possible. The undertaking shall implement such measures to improve radiation safety as can be considered justified in terms of their quality and costs as well as their improving impact. The rationale of section 22 states that the undertaking has the responsibility of taking care of the radiation safety measures. Special compensatory arrangements, or preferential consideration with respect to salary, special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits, shall neither be granted nor be

used as substitutes for measures for protection and safety. The employees have neither any justification to lay claim to such compensation.

Though in SätL section 98 it is stipulated that an employment relationship may not be terminated on the grounds that a worker has received a dose exceeding the worker's dose limit.

Occupational Health Care Act (1383/2001), Section 12 stipulates that:

"*The occupational health care that the employer has a duty to arrange as provided in Section 4 shall, in accordance with good occupational health care practice, include the following:*

3) making suggestions for action to improve the healthiness and safety of the work, to adapt the work to the needs of the employee if necessary, to maintain and promote the employees´ working capacity and functional capacity and to monitor the implementation of the suggestions for action;

5) monitoring and supporting the ability of a disabled employee to cope at work, having regard to the health requirements of the employee, provision of advice on rehabilitation and directing for treatment or medical or vocational rehabilitation;"

According to SätL section 14 STUK supervises compliance with the Radiation Act, unless otherwise provided. To obtain a safety license, which is granted by STUK, the undertaking must demonstrate that the activity complies with the principles of justification, optimization and protection of the individual, can be carried out safely and has been subject to a safety assessment (see primary question 1). STUK also inspects radiation activities to ensure the safety and legality (SätL section 176).

Question 10 Are employers, registrants and licensees, required to make special arrangements for female workers, as necessary, for protection of the embryo or foetus and breastfed infants?

Answer: Yes

Response:

SätL section 100 sets that once worker has notified the undertaking of their pregnancy or breastfeeding a child the foetus should be protected in a manner equivalent to the protection of a member of the public.

SätL section 100 also reminds that the radiation workers must be reminded of the importance of the notification of the pregnancy of breastfeeding of the child.

In SätL section 134 it is noted that protective actions that may result in exposure to radiation may not be assigned to pregnant or breastfeeding individuals

In VnA section 41 it is demanded that when a woman has announced her pregnancy, her work shall be arranged so that the equivalent dose of the foetus is as low as reasonably achievable, nor shall it exceed 1 mSv for at least the remainder of the pregnancy. In addition, worker who has announced that she is breastfeeding a child, should not be do work which has a risk to ingestion or contamination.

According to Section 9 of Chapter 7 of the Employment Contracts Act (55/2001), the employer is not allowed to terminate an employment contract on the basis of the employee's pregnancy.

According to SätL section 14 STUK supervises compliance with the Radiation Act, unless otherwise provided. To obtain a safety license, which is granted by STUK, the undertaking must demonstrate that the activity complies with the principles of justification, optimization and protection of the individual, can be carried out safely and has been subject to a safety assessment (see primary question 1). STUK also inspects radiation activities to ensure the safety and legality (SätL section 176).

Question 11 Are there requirements for employers, registrants and licensees to ensure that no person under the age of 16 years is or could be subject to occupational exposure?

Answer: Yes

Response:

Section 99 of the Radiation Act stipulates that a person under 16 years of age is not allowed to participate in the use of radiation sources.

STUK inspects radiation activities to ensure the safety and legality (SätL section 176).

Question 12 Are there regulations/regulatory requirements/ that require employers, registrants and licensees to make special arrangements for protection and safety for persons under 18 years of age who are undergoing training?

Answer: Yes

Response:

Section 99 of the SätL stipulates that a person performing radiation work shall have attained the age of 18 years. The Section further states that persons younger than this, but not less than 16 years of age, may participate in the use of radiation sources insofar as this is necessary for their vocational training.

VnA section 15 stipulates that the dose limit for young persons (16-17 years) is 6 mSv per year. For this reason, the premises where the young person works must be such that the dose limits cannot be exceeded. In some situations, the young person may therefore not be able to work in the control area at all.

There is no direct provision that a young person should only work in a controlled area under supervision, but the presumption is that a person involved in the use of radiation sources by virtue of his training will work under supervision.

STUK inspects radiation activities to ensure the safety and legality (SätL section 176).

Question 13 Has the regulatory body established and enforced requirements for the protection of workers in existing exposure situations?

Answer: Yes

Response:

Requirements for protection of workers in existing exposure situations are included in SätL chapter 17 and 18 as well as in STMA 1044/2018 chapter 5 and 6.

The undertaking from whose practice an existing exposure situation arises, is responsible for investigating the radiation exposure arising from it and for carrying out the protective actions and for cleaning the areas, facilities and structures used in the practice, and the environment, of radioactive substances (SätL section 138).

In existing exposure situations, the aim is to carry out the protective actions in such a way that occupational and public exposure remain below the set reference level (SätL section 140). The party having the work carried out shall immediately inform the workers involved of any exposure greater

than the reference level (SätL section 140). The reference levels for occupational exposure in protective actions in an existing exposure situation as effective dose is 1 mSv/y (STMA 1044/2018 section 16). The determination of the effective dose must take into account all routes of exposure except for exposure to radon (STMA 1044/2018 section 18). Protective actions must be taken in such a way that the effective dose due to radiation exposure remains below the reference level. However, a dose higher than the reference level may be accepted if achieving a dose lower than the reference level requires action that causes disproportionate disadvantages in relation to the benefit to be achieved (STMA 1044/2018 section 18).

The prerequisite for protective actions in an existing exposure situation is a safety licence, if the radiation dose arising from occupational exposure is higher than the reference level (SätL section 141).

Based on SätL section 142 the MSAH will draw up a national action plan for identifying existing exposure situations and for the implementation of the measured referred to in the plan. Drafting of the action plan has started in STUK in 2021 (KAVATTU-project). The national radon action plan is described in the responses to (IRRS) Primary Question 14 of Occupational Exposure, and Primary Question 17 of Public Exposure.

The reference level for occupational exposure to natural radiation other than radon or space radiation is 1 mSv/y (STMA 1044/2018 section 23). Exposure is defined as the addition of the effective dose to the effective dose due to natural background radiation.

See more details related to radon in workplaces in the response to Primary Question 14.

Based on SätL sections 145, 146 and 151, NORM-involving industries need to assess the exposure of workers prior to the commencement of work. This requirement is enforced by sending reminders to the relevant companies about their obligation. Based on SätL section 147 exposure needs to be limited if it can exceed the reference level. Based on SätL section 148, a license is required if the exposure will exceed the reference level despite limiting measures (at this point the industry will be regulated in a similar way as a radiation practice including the enforcement of regulatory requirement as prescribed in answers to questions of Module 8.).

Compliance with requirements in existing exposure situations, such as occupational radon and NORM exposure, is mainly verified by document inspections. STUK’s inspection processes related to

occupational exposure to natural radiation (other than cosmic radiation) is described in Guide VALO 7. Plan of regulatory control related to natural radiation is updated annually. Targeted surveys and requests for clarifications are used in order to increase awareness of the requirements in the Radiation Act. The results of the regulatory control activities are reported in STUK's annual report, in www (e.g. Workplace radon concentrations in Finland - stuk-en - STUK) and in public diary (Julkinen diaari - STUK).

According to SätL section 152 an employer engaged in aviation by virtue of a licence issued by the Finnish Transport Agency is obligated to investigate the radiation exposure arising from its practice, if the principal flight altitude is more than 8,000 meters. The duty to investigate also applies to anyone engaged in military aviation and State aviation as referred to in the Aviation Act (864/2014). If the occupational exposure arising from cosmic radiation can exceed 1 mSv per year for anyone of the crew, the undertaking shall plan the work shifts of the aircraft's crew in such a way that exposure to the most exposed individuals is limited.

According to SätL section 145 the party responsible for practice of aviation shall notify STUK prior to the commencement of the practice. Section 146 states further that radiation exposure arising from natural radiation shall be investigated.

According to SätL section 148 the practice in which the occupational exposure arising from cosmic radiation can exceed 1 mSv per year for anyone of the crew, is subject to a safety licence. In aviation when issuing safety licence, there is one exception to requirements compared to other radiation practices: in aviation there is no need for radiation safety officer. The radiation safety expert shall, however, be called upon, if necessary, in the manner provided in VnA Section 17.

Question 14 Has the regulatory body established a strategy for protection against Rn-222 in workplaces?

Answer: Yes

Response:

The strategy for protection against radon in workplaces is provided by SätL chapter 18, VnA 1034/2018 chapter 11, STMA 1044/2018 chapter 6, and STUK S/3/2019.

The reference levels set in the STMA 1044/2018 section 19 are:

- radon concentration in workplaces and buildings with public access: 300 Bq/m^3
- occupational exposure of radon: 500 000 Bq h/m^3/year.

The reference level for **radon concentration** applies in a workspace where the working time spent by employees is greater than or equal to 600 hours per year. Radon concentration is calculated as the annual average radon concentration during working hours. (STMA 1044/2018 section 19)

The **reference level for the occupational exposure** to radon is calculated as the sum of all exposure accumulated during the year in all workspaces. The reference level for the occupational exposure to radon does not apply if an employee only works in a workspace where the radon concentration is lower than the reference level for radon concentration in indoor air at the workplace. (STMA 1044/2018 section 19)

According to the SätL section 155 an employer shall investigate the radon concentration in a workspace or other place of work if the facilities are located:

1) in areas defined by STUK (Areas requiring radon measurements in workplaces - stuk-en - STUK);

2) on an esker or other gravel or sandy soil with good air permeability (maps in Finnish: https://www.stuk.fi/documents/12547/214083/Läpäisevät+maaperät+zoomkartta/0dc302ac-819a-8ef4-4095-213fec58a194?t=1550477368607);

3) wholly or partly underground;

4) an installation which distributes water or in a food establishment the water of which does not derive solely from a body of surface water and has contact with indoor air.

However, the investigation need not be carried out if none of the workers work in the workspace for more than 20 hours in a year or if the workspace is located on the second or upper floor of the building seen from the ground level, or if the floor and walls of the building are not in contact with the ground and the good ventilation of the space in between is apparent. (SätL section 155)

The radon concentration in workplace shall be measured on a regular basis if the workspace or other workplace is in an underground quarry or an underground mining site as referred to in the Mining Act (621/2011) (SätL section 155).

STUK’s inspection processes related to exposure to natural radiation such as occupational radon is described in Guide VALO 7. Compliance with requirements is mainly done by document inspections. These documents include e.g. results of the measurements of indoor radon concentrations and

information on working time and ventilation. Targeted surveys and requests for clarifications are used in order to increase awareness of the requirements in the Radiation Act. In-house RAMI-database and stukasiointi.stuk.fi -service for employers are used to manage radon in usual workplaces (described in VALO 7.6). For underground workplaces e-forms are provided by STUK.

In practice, radon remediation in most workplaces is usually successful and the occupational radon exposure will reduce below the reference level. Regulatory control by STUK supervises that the exposure do not exceed the reference level. Often radon concentrations are much lower during working hours. Therefore, if radon concentration is higher than 300 Bq/m^3 in 2 months screening measurement and workplace has scheduled ventilation, radon measurement with continuous measurement instruments could indicate realistic radon concentrations during working hours. Furthermore, if working time is less than 600 h/y, occupational exposure can be calculated based on working hours and radon concentrations for the most exposed workers. Decision on which working areas should be remediated or restricted access will be based on the exposure.

If the exposure is higher than the reference level and cannot be remediated (e.g. tunnels), workplace needs a safety licence from STUK as stated in SätL section 148. Practices are subject to a safety licence if the occupational exposure arising from the radon concentration in workplace continues to exceed the reference level despite the measures taken to correct it (SätL section 148). Among other issues, this means regular determination of dose of radiation employees are exposed to. The effective dose resulting from radon exposure is calculated in accordance with VnA 1034/2018 section 1.2 of Appendix 3.

Question 14.1 Are there any workplaces in the State in which exposure to Rn-220 is managed as an existing exposure situation?

Response:

According to SätL section 146, radiation exposure arising from natural radiation shall be investigated in the situations referred to in section 145, 151, and 153.

SätL section 145 states that prior to the commencement of the practice, the party responsible for it shall notify STUK of … 3) the management, use, storage and utilization of materials and waste containing natural radioactive substances in which the activity concentration of uranium-238, thorium-232 or their progeny is greater than one becquerel in a gram.

SätL section 151 states that anyone utilizing soil, rock or other materials occurring in nature or materials resulting from the use of these materials is obligated to investigate the radiation exposure arising from their practices, if the exposure arising from natural radiation can exceed the reference level.

Furthermore, SätL section 153 states that anyone who manufactures, imports or transfers a construction product as referred to in Regulation (EU) No. 305/2011 of the European Parliament and of the Council, laying down harmonized conditions for the marketing of construction products and repealing Council Directive 89/106/EEC, hereinafter the Construction Product Regulation, shall investigate the radiation exposure arising from the product, if the combined exposure resulting from the radioactivity of the construction products in the product's intended purpose of use can exceed the reference level.

According to SätL section 146, the party responsible for carrying out the investigation must immediately notify STUK of the investigation's results. No notification related to Rn-220 has been given to STUK. In case elevated Rn-220 level is detected, it will be managed as an existing exposure situation based on SätL chapter 17 and 18.

Elevated Rn-220 concentrations might occur in workplaces where substantial amounts of thorium-rich materials are stored or processed. In these cases, STUK may require measurement of Rn-220 or Pb-212 in the air of the workplace.

Question 15 Has the regulatory body or other relevant authority determined that the assessment of the exposure of aircrew is warranted?

Answer: Yes

Response:

According to SätL section 152 an employer engaged in aviation by virtue of a licence issued by the Finnish Transport Agency is obligated to investigate the radiation exposure arising from its practice, if the principal flight altitude is more than 8,000 meters. The duty to investigate also applies to anyone engaged in military aviation and State aviation as referred to in the Aviation Act (864/2014). If the occupational exposure arising from cosmic radiation can exceed 1 mSv per year for anyone of the crew, there are more requirements which are described in the response to Primary Question 13.

Question 15.1 Has the regulatory body or other relevant authority established a framework for the assessment and recording of doses received by aircrew from occupational exposure to cosmic radiation?

Response:

SätL section 149 states that If the occupational exposure arising from cosmic radiation can exceed 1 mSv per year for anyone of the crew all the measures must be taken which are obligatory also in other licenced radiation practices to ensure radiation safety of workers.

The undertaking shall determine the radiation dose caused to a worker regularly if the occupational exposure cosmic radiation exceeds the reference level 1 mSv. The results of the determination are subject to what is provided on the recording and follow-up of the results of radiological surveillance in section 92, subsection 4: the results of the radiological surveillance and individual monitoring must be recorded and followed regularly to ensure compliance with the requirements applicable to occupational exposure. And also, what is provided on delivering information concerning individual monitoring to the workers' dose register in section 101: information from the individual monitoring of radiation workers shall be delivered to the workers' dose register on a regular basis.

STUK S/3/2019 gives more detailed requirements for dose assessment in aviation: The determination period for radiation exposure of aircraft crews shall not exceed one calendar year. Radiation exposure must be determined as the effective dose. Radiation exposure must be determined by a suitable and validated calculation method. Validation shall be performed in accordance with international standards or otherwise in an appropriate and documented manner. The calculated free dose equivalent / free dose equivalent rate must not deviate from the measured or reference value by more than ± 30%. When flying at altitudes above 15 km, measuring equipment must be available to determine the radiation dose to workers.

SätL section 100 states that once a worker has notified the undertaking or, in the case of an outside worker, their employer of their pregnancy or of breastfeeding a child, the foetus and breastfed child must be protected in a manner equivalent to the protection of a member of the public. Radiation workers must be reminded of the importance of the notification. VnA 1034/2018 section 41 states further that the work of a pregnant worker must be organized in such a way that the equivalent dose to the fetus is as low as practicable and does not exceed one millisievert during pregnancy after the worker has informed the operator or, in the case of an outside worker, the employer.

Question 16 Has a framework been established for radiation protection of individuals in space-based activities?

Answer: Yes

Response:

In Finland, currently there are no space-based activities that send individuals into outer-space. If there would be such activities, the obligations for the undertaking laid down in the SätL would apply and the

authorization and supervision procedures would be considered on a case-by-case basis, considering the requirements of the SätL.

Analysis

STRENGTHS FOR SAFETY REQUIREMENTS FOR OCCUPATIONAL EXPOSURE

S1	Regulatory framework covers comprehensively occupational exposure in all exposure situations and provides mechanisms for their regulation.
S2	Long term experience in managing and regulating occupational exposures to natural radiation (radon in workplaces, NORM-industries, Air crew)
S3	National radon database is a valuable tool for e.g. research, risk communication and for targeting of radon supervision.
S4	STUK has a radon dosimetry laboratory which is valuable for assure quality control for radon measurements.

WEAKNESSES FOR SAFETY REQUIREMENTS FOR OCCUPATIONAL EXPOSURE

W1	There is no specific requirement to establish investigation levels as referred to in GSR Part 3 paragraphs 3.46 a) and 3.94 b). Such levels are addressed only on guidance level (Guide ST 1.6 Operational radiation safety).

OPPORTUNITIES FOR SAFETY REQUIREMENTS FOR OCCUPATIONAL EXPOSURE

O1	National radon action plan is extensive and has means to assess and control radon exposure.

THREATS FOR SAFETY REQUIREMENTS FOR OCCUPATIONAL EXPOSURE

T1	Funding for regulatory control on occupational exposure to natural radiation may not be assured for the future.

CONCLUSIONS FOR SAFETY REQUIREMENTS FOR OCCUPATIONAL EXPOSURE

C1	In general, the Finnish legislation and regulations are in compliance with the IAEA requirements on occupational exposure as prescribed in IAEA GSR Part 3.
C2	There is no specific requirement to establish investigation levels as referred to in GSR Part 3 paragraphs 3.46 a) and 3.94 b). Such levels are addressed only on guidance level (Guide ST 1.6 Operational radiation safety).
C3	Radon action plan is being implemented in collaboration with all relevant authorities.

Module: Safety Requirements for Predisposal Management of Radioactive Waste

Findings

Question 1 Does the regulatory body require the operator to carry out safety assessment and develop and maintain a safety case for a predisposal radioactive waste management facilities or activities, and to carry out all the necessary activities for site selection and evaluation, design, construction, operation, shutdown and decommissioning, in compliance with the regulatory requirements and within the legal and regulatory infrastructure?

Answer: Yes

Response:

The licensing process is defined in the legislation. There are four different licensing steps:

- Decision-in-Principle – made by the Government and ratified by Parliament
- Construction License – granted by the Government
- Operating License – granted by the Government
- Decommissioning License – granted by the Government.

The conditions for granting a license are prescribed in the sections 18–20 a of YEL (990/1987). The operating licence of a nuclear facility is granted for a fixed term, generally for 10–20 years. Construction and decommissioning license do not have a fixed term. In case the operating license is granted for a longer period than 10 years, or 15 years in case of disposal facilities for nuclear waste, a periodic safety review is required to be presented to STUK. At each licensing step the documentation defined in the section 35-36 a of YEA (161/1988) shall be submitted to STUK. The documentation shall include detailed demonstration of safety.

Before a construction license for a nuclear facility can be applied for, a Decision-in-Principle (DiP) by the Government and a subsequent ratification of the DiP by Parliament are required. The environmental impact assessment procedure shall be conducted prior to the application for the DiP. Also, the EIA report and the coordinating authority's statement on the assessment report must be annexed to the DiP application. A condition for granting the DiP is that the construction of the nuclear facility in question must be for overall good of society. Further conditions are as follows:

- The municipality of the intended site of the nuclear facility must be in favour of constructing the facility (the municipality has a veto right)
- No factors must have arisen which would indicate that the proposed facility could not be constructed and operated in a safe manner (STUK has a veto right).

The entry into force of the Government's DiP further requires ratification by Parliament. Based on established practice, Parliament does not make any changes to the Decision; it only approves or rejects it as such. In the construction and operating license application handling processes, the acceptance of Parliament and of the hosting municipality are no longer required.

According to the section 7 h of YEL (990/1987) a nuclear facility shall have premises, equipment and other arrangements to ensure the safe handling and storage of nuclear waste generated during operation and decommissioning. Guide YVL D.4 concerning the predisposal management of LILW and decommissioning of a nuclear facility requires that waste management facilities and systems constructed in the immediate vicinity of a new nuclear power plant or other nuclear facility may be treated as parts of the plant or facility concerned. The Guide YVL D.4 requires further that documents pertaining to the waste management facilities or systems constructed in the immediate vicinity of an operating nuclear facility may be presented as amendments or additions to the corresponding documents pertaining to the nuclear facility concerned, if the construction of the facility or system can be carried out under the operating license of that nuclear facility.

Question 2 Has an integrated approach to safety and security for predisposal management of waste been taken into account in the regulatory framework?

Answer: Yes

Response:

According to the paragraph 2 of the section 3 of STUK Y/3/2020 security shall be consistent with the operation, fire safety and emergency response arrangements of nuclear energy. The objectives of nuclear safeguards and coordination of the arrangements shall be taken into account in the planning and implementation of security arrangements.

Security arrangements for radioactive waste are similar to security arrangements of radioactive sources with similar activity levels as stated in SätL sections 81 and 67. Also arrangements for the facility and place where radioactive waste is stored, and the equipment and devices related to it need to be ensured to be used safely. This is stated in SätL section 66.

Question 3 Are there requirements to ensure the interdependencies between the steps in predisposal management of radioactive waste are taken into account, particularly the impacts on the anticipated disposal option?

Answer: Yes

Response:

Both operating nuclear power plants have their own LILW disposal facilities. Interdependencies of the steps in the waste management are considered in the NPPs' documentation. At the Loviisa NPP all the waste treatment, conditioning, handling, storing, transport and disposal operations are carried out at the NPP site by the personnel of the Loviisa NPP. Only the spent nuclear fuel will be transported for disposal from the Loviisa NPP site to Posiva's disposal facility at Olkiluoto. In case of the Olkiluoto NPP, all the waste management steps take place at Olkiluoto. The Decision in Principle concerning Fennovoima also includes an LILW disposal facility on the NPP site. Fennovoima has performed preliminary site characterizations for proposed locations of disposal facility at the NPP site and STUK has reviewed these results.

The spent fuel is stored in the interim storage facilities at NPP sites and is planned to be disposed of in deep bedrock. The spent fuel of Loviisa NPP and Olkiluoto NPP is planned to be disposed in Olkiluoto. The disposal plans, including spent fuel transfer and transport, encapsulation and disposal, have been adapted to all the fuel types in use in Olkiluoto reactor units 1 to 3 and in Loviisa units 1 and 2.

Posiva, the implementing organization for the spent fuel disposal of TVO and Fortum, is co-owned as a joint company by these NPP utilities. Even though Posiva is the implementer of the final disposal, the waste management obligations remain with the NPP utilities. NPP utilities make sure that the interdependencies between the different steps in spent fuel management are considered in their waste management plans. Fennovoima is responsible for the disposal of its own future spent fuel. Fennovoima started the EIA process for its own disposal site in June 2016 as required as a condition of the DiP. The choice of a site for the disposal of spent fuel will become relevant later, approximately in the 2040's.

STUK reviews the waste management from documentations provided in the connection of the DiP, license applications, periodic safety reviews and plant modifications. The waste management is included in the inspections programs that cover the whole life cycle of nuclear facilities.

Requirements for the low and intermediate waste management are given in the Guide YVL D.4. It is required that on the treatment and storage of LILW from NPPs requires that waste is treated, e.g. segregated, categorized and conditioned, in an appropriate way regarding its further management. The Guide YVL D.4 also provides for the consideration of the requirements of waste packages related to their disposal. These requirements may concern, e.g., the structure of the waste packages, their physical and chemical compositions, their resistance to external and internal loads and the amount and structural and chemical stability of radioactive substances in the waste packages.

Question 4 Do the regulatory requirements exist for a management system to all steps and elements of the predisposal management of radioactive waste?

Answer: Yes

Response:

According to section 38 of STUK Y/4/2018, organizations participating in the design, construction, operation and decommissioning of a nuclear facility or in closing of a repository shall employ a management system for ensuring safety and the management of quality.

Guide YVL A.3 sets general requirements for management systems regarding quality and safety management. Guide YVL A.3 refers to the ISO 9000:2015 definition of quality management according to which quality management consists of quality planning, quality control, quality assurance and quality improvement. Guide YVL A.3 adheres to IAEA Safety Requirements GSR Part 2 Leadership and management for safety. Requirements for quality management of system design are established in the Guide YVL B.1. Further requirements related to specific technical areas are presented in the corresponding technical guides.

Practices subjected to a safety licence must have a written management system for the radiation practice (SätL section 29). Management of radioactive waste independently or as a part of other practices requires a safety licence. Management systems describes the division of responsibilities, flow of information and significant tasks in terms of radiation safety arrangement. Establishment and maintain of a good safety culture and administrative and organizational arrangements aiming to ensure radiation safety are required to be described in the management system.

Question 5 Does the regulatory framework ensure that all radioactive waste is identified and controlled, and waste arisings are kept to the minimum practicable?

Answer: Yes

Response:

In the section 13 of STUK Y/1/2018 and in the section 16 of STUK Y/4/2018 it is set that waste generated during the operation and decommissioning of a nuclear facility, the activity concentration of which exceeds the limits set by STUK, shall be treated as nuclear waste.

According to the section 27 a of YEL (990/1987), the waste produced as a result of the use of nuclear energy must be kept as low as reasonable by practical means both in terms of its activity and the

amount of waste. The requirements for waste minimization are presented in Guide YVL D.4. This guideline emphasizes that the generation of waste must be decreased, i.e. by proper planning of repair and maintenance work and by means of decontamination, clearance and volume reduction practices. The Guide YVL D.4 also refers to sound working methods for waste minimization, e.g. volume reduction of waste, avoiding the transfer of unnecessary objects and materials in the controlled areas and by adoption of working processes which either create only small amounts of waste or in which the created waste is easily manageable.

STUK reviews the waste management from documentations provided in the connection of the DiP, license applications, periodic safety reviews and plant modifications. The waste management is included in the inspections programs that cover the whole life cycle of nuclear facilities.

Similarly, general principles are that radiation practices shall be organized in such a way that they generate as little radioactive waste as practically possible without compromising the practice's accordance with the principle of justification, optimization and limitation. This is stated on SätL section 78. Arrangements for the management of radioactive waste shall be presented within the safety licence application as stated in SätL 51. This includes both radioactive waste generated by the practice during its operations and discontinuing of the practice.

Question 5.1 Is it ensured within the regulatory framework that the siting, design, construction, commissioning, operation, shutdown and decommissioning of facilities in which waste is generated has been planned to keep the volume and radioactive content of waste arisings to the minimum practicable?

Response:

According to the section 17 of STUK Y/1/2018 and section 20 of STUK Y/4/2018 the design of a nuclear facility and its operation shall take account of the decommissioning of plant units so that it is possible to limit the volume of nuclear waste for disposal accumulating during dismantling.

According to the Guide YVL D.4 one of the design objectives of a nuclear facility shall be the facilitation of its eventual decommissioning. In the design of the facility the materials shall be so selected as to minimize the generation and spreading of radioactive materials and to facilitate the cleaning of surfaces. When the decontamination, dismantling, transfer, cutting and packing techniques used in the decommissioning of a nuclear facility are selected, an important selection criterion shall be that the radiation exposure of workers, the releases of radioactive materials and the waste volumes generated are kept as low as reasonably achievable.

Guide D.4 requires that the planning and implementation of the processing and storage of operational waste shall be carried out so that the generation of waste that needs to be stored or disposed of shall be limited by means of repair work and maintenance planning, and decontamination and volume reduction.

Guide YVL B.1 addresses the safety design of a nuclear power plant. It is required that in the design phase, solutions shall be preferred that can help restrict the accumulation of radioactive waste during the operation and decommissioning of the plant and facilitate the dismantling of the facility. In particular, attention shall be given to the selection of materials and system design, so that the effects of neutron activation can be limited, decontamination is facilitated and the future amount of radioactive waste remains as small as practically possible. The design shall include the facilities required for the processing and storage of radioactive waste generated during operation, and the treatment of radioactive waste generated in the decommissioning of the plant shall also be anticipated.

STUK reviews the waste management from documentations provided in the connection of the DiP, license applications, periodic safety reviews and plant modifications. The waste management is included in the inspections programs that cover the whole life cycle of nuclear facilities.

Question 5.2 Is it ensured within the regulatory framework that the reuse and recycling of materials has been applied to keep the generation of radioactive waste to the minimum practicable?

Response:

According to the section 27 c of YEL (990/1987) nuclear waste other than spent nuclear fuel may, regardless of its radioactive nature, be reused, recycled, recovered and disposed of in accordance with the provisions of the Waste Act (646/2011) if the amount of radioactive substances within it does not exceed the clearance level provided by the virtue of section 7 q, subsection 1, paragraph 28. Similarly waste originating from radiation practices be reused, recycled, utilized and disposed of in accordance with the Waste Act, provided that the amount of radioactive substance it contains does not exceed the clearance level referred to in SätL section 85.

If the amount of radioactive substances within the waste referred to in subsection 1 is greater than the clearance level, the operations referred to in subsection 1 will require the approval of the STUK.

Clearance levels are set in STUK SY/1/2018 issued by the virtue of section 7 q as referred above. In addition, Guide YVL D.4 provides nuclide group specific clearance levels for nuclear facilities.

STUK reviews the waste management from documentations provided in the connection of the DiP, license applications, periodic safety reviews and plant modifications. The waste management is included in the inspections programs that cover the whole life cycle of nuclear facilities.

Question 6 Are there requirements or approval procedures of the regulatory body for waste classification and characterization at various steps in the predisposal management of radioactive waste?

Answer: Yes

Response:

According to the section 13 of STUK Y/1/2018 and the section 16 STUK Y/4/2018 nuclear waste shall be sorted, categorized according to its characteristics, handled and packed in an appropriate manner in terms of its storage and disposal, and stored safely. Limiting values shall be set for each class, which the waste package used for the waste in question shall meet in terms of the operational safety and long-term safety. Acceptability criteria shall be defined for the waste and waste packages.

Guide D.4 requires that nuclear waste shall be appropriately sorted and classified in view of its further treatment, clearance, storage and disposal. Radioactive waste originating from radiation practices is in Finland disposed and stored n same facilities as nuclear waste. Same requirements apply to that waste.

STUK reviews the waste management from documentations provided in the connection of the DiP, license applications, periodic safety reviews and plant modifications. The waste management is included in the inspections programs that cover the whole life cycle of nuclear facilities.

Question 7 Are there regulatory requirements that the radioactive material for which no further use is foreseen, and with characteristics that make it unsuitable for authorized discharge, authorized use or clearance from regulatory control, is processed as radioactive waste?

Answer: Yes

Response:

According to section 3 of YEL (990/1987) nuclear waste means radioactive waste in the form of spent nuclear fuel or in some other form, generated in connection with or as a result of the use of nuclear energy; and materials, objects and structures which, having become radioactive in connection with or as a result of the use of nuclear energy and having been removed from use, require special measures because of the danger arising from their radioactivity.

Further in the section 13 of STUK Y/1/2018 and in the section 16 of STUK Y/4/2018 it is set that waste generated during the operation and decommissioning of a nuclear facility, the activity concentration of which exceeds the limits set by STUK, shall be treated as nuclear waste.

STUK reviews the waste management from documentations provided in the connection of the DiP, license applications, periodic safety reviews and plant modifications. The waste management is included in the inspections programs that cover the whole life cycle of nuclear facilities.

According to definitions in section 4 of SätL radioactive waste means radioactive substances or devices, goods and materials contaminated by radioactive substances for which there is no use or for which an owner cannot be found, and which shall be rendered harmless due to radioactivity. And rendering radioactive waste harmless means all the measures necessary to treat, isolate, emplace or restrict the use of waste in such a way that it will not result in detriments to human health or the environment.

The use of radiation requires a licence (safety licence), unless otherwise provided in Radiation Act (859/2018). Other radiation practices require a safety licence if separately laid down in the law (SätL section 48).

According to section 51 of SätL safety licence application shall include

8) the arrangements *for managing the waste and discharges containing radioactive substances generated by the practice during its operations and when discontinuing the practice*.

A safety licence requires the prior amending when according to VnA (1034/2018) section 25

8) a change in the practices in such a way that the amount or quality of the radioactive waste or the waste referred to in section 78, subsection 3 of the Radiation Act, or the arrangements concerning it, change from what was approved in the safety licence;

9) changing the practices in such a way that the discharges of radioactive substances or their quality change from what was approved in the safety licence.

Question 8 Are there regulatory requirements that the processing of radioactive waste is based on appropriate consideration of the characteristics of the waste and of the demands imposed by the different steps in its management?

Answer: Yes

Response:

The requirements for the processing of nuclear waste are set in the Guide YVL D.4. For liquid wastes it is required that in the event that liquid wastes are markedly different from other types of waste in terms of their chemical composition, activity concentration or radionuclide composition and their amounts are substantial, they shall, as a rule, be processed separately. In the event that a certain type of waste is only generated in small amounts, it can be mixed with other waste, provided that this does not complicate its further treatment or essentially degrade the properties of the end product.

When the treatment and conditioning methods for liquid waste are selected, due consideration shall be given to the requirements imposed by operational safety and final disposal. Such waste can be immobilized, i.e. mixed with a binding agent to form uniform strong or ductile products. Alternatively, liquid waste can be closed in a durable container after drying or absorbing in a suitable medium.

For the purpose of interim storage or disposal, solid waste shall be packed into containers that facilitate their transfer, prevent the spreading of radioactive contamination and reduce the fire risk associated with the waste. Efforts shall be made to reduce the volume of waste by means of sorting, compaction or cutting, for example.

STUK reviews the waste management from documentations provided in the connection of the DiP, license applications, periodic safety reviews and plant modifications. The waste management is included in the inspections programs that cover the whole life cycle of nuclear facilities.

Question 8.1 How it is ensured that the quantities, activity, physical/chemical nature of the waste, technologies available, storage capacity and availability of disposal facilities are taken into account in the decision-making on appropriate treatment options at each step, and how are these assessed by the regulatory body?

Response:

According to the section 7 h of YEL (990/1987) a nuclear facility shall have premises, equipment and other arrangements to ensure the safe handling and storage of nuclear waste generated during operation and decommissioning.

When applying the construction, operating or decommissioning license the applicant shall submit to STUK the preliminary safety analysis report, the final safety analysis report or safety analysis report as required in the sections 35, 36 and 36 a of YEA (161/1988).

According to the Guide YVL D.4 the safety analysis reports shall include

- a description of the processing and storage activities,
- a description of the waste to be processed and stored at the facility and a description of waste processing methods and the properties of the resulting waste packages
- a description of the criteria pertaining to the properties of the waste to be processed and stored that have been derived from safety requirements.

The descriptions shall be outlines in the preliminary safety analysis report and detailed in the final safety analysis report.

According to the Guide YVL D.4 waste that cannot yet be disposed of in a repository shall be safely processed and stored until disposal. It is required further that a nuclear facility shall have adequate storage space for both unconditioned and packed waste. The design shall take account of the need for repairs of the storage containers and rooms as well as potential failures and disruptions in the processing equipment and disposal activities.

STUK reviews the waste management from documentations provided in the connection of the DiP, license applications, periodic safety reviews and plant modifications. The waste management is included in the inspections programs that cover the whole life cycle of nuclear facilities.

Question 8.2 What requirements are there for dealing with any secondary waste created during processing?

Response:

General requirement for minimizing waste is set in the section 27 a of YEL (990/1987). The amount of nuclear waste generated in the use of nuclear energy shall be kept as small as reasonably achievable with practical measures with regard both to the activity and the amount.

According to the Guide YVL D.4 the planning and implementation of the processing and storage of operational waste shall be carried out with due consideration given to potential dependencies between different waste management stages. Account shall be taken that the generation of waste that needs to be stored or disposed of shall be limited by means of repair work and maintenance planning, and decontamination and volume reduction.

STUK reviews the waste management from documentations provided in the connection of the DiP, license applications, periodic safety reviews and plant modifications. The waste management is included in the inspections programs that cover the whole life cycle of nuclear facilities.

Question 9 Are there regulatory provisions to ensure that waste packages are designed and produced so that the radioactive material is appropriately contained both during normal operation and accident conditions that could occur in the handling, storage, transport and disposal of waste?

Answer: Yes

Response:

According to the Guide YVL D.4 a licensee who processes and packs waste for storage or disposal shall determine the technical requirements pertaining to the waste packages. These requirements shall satisfy the criteria defined by the licensee of the storage or disposal facility based on the safety of interim storage or the long-term safety of disposal. The licensee responsible for processing and packing the waste shall ensure that the waste packages comply with the requirements. Any waste packages that do not satisfy the facility-specific criteria may not be transferred to the storage or disposal facility without an approval by STUK.

For the purpose of interim storage or disposal, solid waste shall be packed into containers that facilitate their transfer, prevent the spreading of radioactive contamination and reduce the fire risk associated with the waste

In the design of the transfer equipment, due account shall be taken of the prevention of handling accidents

STUK reviews the waste management from documentations provided in the connection of the DiP, license applications, periodic safety reviews and plant modifications. The waste management is included in the inspections programs that cover the whole life cycle of nuclear facilities.

Question 10 Does the regulatory body require the waste to be stored in a manner such that it can be inspected, monitored, retrieved and preserved in a condition suitable for its subsequent management, taking due account of the expected period of storage and that prevents degradation of the waste containment?

Answer: Yes

Response:

According to the Guide YVL D.4 the storage conditions shall be such that the condition of the waste packages will not degrade during the planned storage period. Air humidity and temperature variations in the storage shall be limited where necessary. The condition of waste packages that are stored for a prolonged period of time shall be systematically monitored, and it shall be possible to remove degraded waste packages from the storage.

A licensee who stores waste for a prolonged period of time (e.g. for more than 10 years) shall have a condition monitoring programme for stored waste packages or unpacked waste in place to ensure that the characteristics of the waste remain consistent with the requirements pertaining to their safe interim storage and eventual disposal. The programme shall comprise the inspection of stored waste to a representative extent. Where necessary, the waste shall be returned for re-conditioning or packing.

STUK reviews the waste management from documentations provided in the connection of the DiP, license applications, periodic safety reviews and plant modifications. The waste management is included in the inspections programs that cover the whole life cycle of nuclear facilities.

According to STUK S/2/2018 section 3 waste packages need to have sufficient markings including a sign warning of ionizing radiation. The package must be marked with information necessary for the safe handling of the waste. This may include information of for example: 1) the radionuclide(s); 2) the activity or activity concentration and total volume; 3) the time of detection of the activity or activity concentration, the method of detection, and 4) the physical and chemical state of the waste; 5) the origin of the waste package.

This information must be presented waste batch-specifically in the records concerning radioactive waste, as stated in STUK S/2/2018 section 4.

Question 10.1 What requirements are there to make provision for protection of present and future generations, in accordance with the fundamental safety principles, when waste is stored for long periods of time?

Response:

The Finnish nuclear waste management policy is based on the ethical principle of avoiding transferring undue burdens to future generations. Disposal facilities for LILW are operational at the both existing NPP sites and are planned to also host decommissioning waste. At Olkiluoto preparations for licensing VLLW disposal in a near-surface facility were started by the end of 2018. The spent fuel from Loviisa NPP and Olkiluoto NPP is planned to be disposed of in Olkiluoto.

According to the Section 7 h of the YEL (990/1987) a nuclear facility shall have premises, equipment and other arrangements to ensure the safe handling and storage of nuclear material required by the facility as well any nuclear waste generated during operation and decommissioning.

Nuclear facilities shall be designed so that they can be operated safely during their lifetime. The safety shall be demonstrated in DiP and license applications. Additionally, according to the Section 7 e of YEL (990/1987) the overall safety of a nuclear facility shall be assessed regularly.

STUK reviews the safety demonstration from documentations provided in the connection of the DiP, license applications, periodic safety reviews and plant modifications. The safety of the waste storage is included in the inspections programs that cover the whole life cycle of nuclear facilities.

Question 11 Does the regulatory body require that waste packages and unpackaged waste accepted for processing, storage and/or disposal conform to criteria that are consistent with the safety case?

Answer: Yes

Response:

According to the Guide YVL D.4 a licensee who processes and packs waste for storage or disposal shall determine the technical requirements pertaining to the waste packages. These requirements shall satisfy the criteria defined by the licensee of the storage or disposal facility based on the safety of interim storage or the long-term safety of disposal. The licensee responsible for processing and packing

the waste shall ensure that the waste packages comply with the requirements. Any waste packages that do not satisfy the facility-specific criteria may not be transferred to the storage or disposal facility without an approval by STUK.

Furthermore it is required in the Guide YVL D.5 that criteria shall be defined for the nuclear waste and waste packages being disposed of, based on the operational safety of the disposal facility and the long-term safety of disposal which any waste brought into the disposal facility shall satisfy.

STUK reviews the waste management from documentations provided in the connection of the DiP, license applications, periodic safety reviews and plant modifications. The waste management is included in the inspections programs that cover the whole life cycle of nuclear facilities.

Question 12 Are there regulatory requirements that the safety case for a predisposal radioactive waste management facility should describe how all the safety aspects satisfy the regulatory requirements, including the site, design, operation, shutdown and decommissioning of the facility, and the managerial controls?

Answer: Yes

Response:

In the section 7 e of YEL (990/1987) it is set that the compliance with the requirements concerning the safety of a nuclear facility shall be reliably proven.

According to the section 3 of STUK Y/1/2018 and the section 3 of STUK Y/4/2018 the safety of a nuclear facility shall be assessed when applying for a construction license and operating license, in connection with plant modifications, and at Periodic Safety Reviews during the operation of the plant. It shall be demonstrated in connection with the safety assessment that the nuclear facility has been designed and implemented in a manner that meets the safety requirements. The safety assessment shall cover the operational states and accidents of the plant. The safety of a nuclear facility shall also be assessed after accidents and, whenever necessary, on the basis of the safety research results.

The nuclear facility’s safety and the technical solutions of its safety systems shall be assessed and substantiated analytically and, if necessary, experimentally.

The analyses shall be maintained and revised as necessary, taking into account operating experience from the plant itself and from other nuclear facilities, the results of safety research, plant modifications, and the advancement of calculation methods.

The safety of decommissioning a nuclear facility shall be assessed in connection with the updates of the decommissioning plan, when applying for a decommissioning license and at Periodic Safety Reviews during decommissioning. The safety assessment shall demonstrate that the decommissioning of the nuclear facility and the final disposal of decommissioning waste have been designed and can be implemented in a manner that meets the safety requirements. The safety assessment shall cover activities pursuant to the plant's final decommissioning plan, including transients and accidents.

According to the section 25 of STUK Y/1/2018 and the section 38 of STUK Y/4/2018 organisations participating in the design, construction, operation and decommissioning of a nuclear facility shall employ a management system for ensuring safety and the management of quality. The management system shall cover all organisational activities impacting the nuclear facility's safety. More detailed requirements for the management system are given in the Guide YVL A.3.

STUK reviews the waste management from documentations provided in the connection of the DiP, license applications, periodic safety reviews and plant modifications. The waste management is included in the inspections programs that cover the whole life cycle of nuclear facilities.

Question 13 Are there regulatory requirements ensuring that the safety case and its supporting safety assessment is documented in a level of detail and to a quality sufficient to demonstrate safety, to support the decisions made at each stage and to allow for independent review and approval?

Answer: Yes

Response:

The submission of documents to STUK is handled in the Guide YVL A.1. The licensee shall duly review the conformance of the documents pertaining to safety-significant products before submitting the documents to STUK. To demonstrate this, the licensee shall, at a minimum, provide the following information in the submitted document:

- the licensee's justified assessment of the product's acceptability;
- the scope and extent of the licensee's in-house inspection;
- the due execution of the process (e.g. design process) defined for the generation of the document concerned, including due execution of the verification and validation stages defined for the process; and

- the fulfillment of the safety requirements in the design documentation: the licensee's description on how the requirements of the YVL Guides, reference standards and any prior decisions on the matter issued by STUK have been met. If any non-conformances are detected in the due fulfillment of the safety requirements, their acceptability shall be justified in detail.

The requirements for the contents and modes of presentation of documents are given in the Guide YVL A.1. The covering letter or document shall state the factual justification of the operations presented. They shall include, among other things, the radiation and nuclear safety regulations specifically applicable to the matter concerned as well as potential deviations from them, complete with reasoning.

The facts presented, conclusions drawn and statements made in a document shall represent the best of the licensee's knowledge in the matter concerned. Any information that is of relevance for resolving the matter concerned, insofar as it is known to the licensee, shall be presented in its entirety. If, for example, the sender of the document is aware of research results that contradict with what is proposed, such results shall also be discussed in the application.

STUK reviews the waste management from documentations provided in the connection of the DiP, license applications, periodic safety reviews and plant modifications. The waste management is included in the inspections programs that cover the whole life cycle of nuclear facilities.

Question 13.1 How is it ensured by the regulatory body, that all documentation is clearly written and includes arguments justifying the approaches taken in the safety case and traceable from reference documents?

Response:

According to the Guide YVL A.1 the documents submitted to STUK shall be clearly structured. If the document makes reference to literature or research results, their bibliographic information shall be given. If the referenced material is not part of the public domain and is necessary for the processing of the matter, it shall be made available to STUK and, upon request, delivered to STUK's use.

Question 14 Does the regulatory body ensure that periodic safety reviews are undertaken and that any consequential safety upgrades required by the regulatory body have been undertaken?

Answer: Yes

Response:

According to the section 7 e of YEL (990/1987) the overall safety of a nuclear facility shall be assessed at least at 10-year intervals. The overall safety of a facility performing large-scale disposal of nuclear waste shall, however, be assessed at least at 15-year intervals.

The Guide YVL A.1 further requires that for the purpose of conducting a periodic safety review during the operating licence period, STUK shall be provided with safety-related reports similar to those provided when an application for the renewal of an operating licence is filed. These reports shall also include the licensee's assessment of the current safety status of the nuclear facility concerned, potential improvements, and the maintaining of safety in future.

According to the section 7 a of YEL (990/1987) the safety of nuclear energy use shall be maintained at as high a level as practically possible. For the further development of safety, measures shall be implemented that can be considered justified considering operating experience and safety research and advances in science and technology.

It is further required in the section 21 of STUK Y/1/2018 and in the section 25 of STUK Y/4/2018 that safety-significant operational events shall be investigated for the purpose of identifying the root causes as well as defining and implementing the corrective measures.

For further safety enhancement, operating experience from the facility and from other nuclear facilities, the results of safety research and technical developments shall be regularly monitored and assessed.

Opportunities for improvements in technical and organisational safety, identified from operating experience, safety research and technical developments shall be assessed and implemented to the extent regarded as justified on the basis of the principles laid down in Section 7 a of YEL (990/1987).

Question 15 Are there regulatory requirements for predisposal waste management facilities to be located and designed so as to ensure safety for the expected operating lifetime under both normal and accident conditions and for their decommissioning?

Answer: Yes

Response:

According to the section 8 of STUK Y/1/2018 and section 12 of STUK Y/4/2018 the impact of local conditions on operational safety and the feasibility to implement the arrangements for security and emergency arrangements shall be considered when selecting the site of a nuclear facility. The site shall

be such that the detriments and threats posed by the operation of the facility to its vicinity remain very low.

Question 16 Are there requirements that predisposal waste management facilities are constructed in accordance with the design as described in the safety case and approved by the regulatory body?

Answer: Yes

Response:

According to the section 7 f of YEL (990/1987) safety shall take priority during the construction and operation of a nuclear facility. The holder of a construction licence shall be responsible for the nuclear facility's construction in accordance with safety requirements.

According to the section 109 of YEA (161/1988) after the construction licence has been granted, STUK controls the implementation of the facility project in detail. The purpose of the control is to ensure that the conditions of the construction licence and the approved plans referred to in section 35 are complied with and that the nuclear facility is also in other respects constructed in accordance with regulations issued on the basis of YEL (990/1987).

It is further required in the section 18 of STUK Y/1/2018 and section 22 of STUK Y/4/2018 that the holder of the nuclear facility's construction license shall ensure during construction that the nuclear facility is constructed and implemented in conformity with the safety requirements and using approved plans and procedures.

Guide YVL A.5 states that STUK oversees the manufacturing, construction and installation of the nuclear facility and its safety-classified systems, structures and components in accordance with the procedures presented in the technology-specific YVL Guides.

Question 16.1 Are there regulatory provisions to ensure that the commissioning of facilities is carried out to verify that equipment, structures systems and components and the facility as a whole perform as planned?

Response:

According to the section 110 of YEA (161/1988) the various phases in the commissioning of a nuclear facility cannot be commenced until STUK has determined, on the basis of the documents mentioned in section 36, and other detailed plans and documents required by STUK, for each stage, that sufficient attention has been paid to factors influencing safety, and regulations concerning safety. Similar

requirements also apply to the restarting of a nuclear facility after a particularly substantial plant modification.

It is further required in the section 19 of STUK Y/1/2018 and section 23 of STUK Y/4/2018 that in connection with the commissioning of a nuclear facility or its modifications, the licensee shall ensure that the systems, structures and components and the nuclear facility as a whole operate as designed. The procedures of the commissioning of the nuclear facility or its modifications shall be planned, and instructions shall be provided. At the commissioning stage, the licensee shall ensure that appropriate procedures are in place for the future operation of the nuclear facility.

Detailed requirements for the commissioning are set in the Guide YVL A.5.

Question 16.2 Are there regulatory provisions to ensure that modification of a facility with significant safety implications that require a revision of the safety case are also subject to the regulatory controls and approvals?

Response:

According to the section 112 of YEA (161/1988) if the licensee intends to carry out modifications to the nuclear facility systems, structures, nuclear fuel or the way the facility is operated that influence safety and involve changes in the plans or documents approved by STUK, the licensee shall obtain approval from STUK for such modifications before they are carried out. Correspondingly, STUK shall approve measures related to the decommissioning of a nuclear facility. The licensee shall ensure that the documents mentioned in sections 35 and 36 are revised accordingly.

It is further required in the section 19 of STUK Y/1/2018 and section 23 of STUK Y/4/2018 that in connection with the commissioning of a nuclear facility or its modifications, the licensee shall ensure that the systems, structures and components and the nuclear facility as a whole operate as designed. The procedures of the commissioning of the nuclear facility or its modifications shall be planned, and instructions shall be provided.

According to the section 20 of STUK Y/1/2018 and the section 24 of STUK Y/4/2018 the holder of the nuclear facility's operating license shall ensure that the modifications to the nuclear facility are designed and implemented in conformity with the safety requirements and using approved plans and procedures.

STUK oversees the implementation of plant modifications with same methods as used in the connection of the construction as described in the Guide A.5.

Question 17 Is it required that the procedures for the operation of predisposal waste management facilities are documented and comply with national regulations and conditions imposed by the regulatory body?

Answer: Yes

Response:

According to the section 36 of YEA (161/1988) when applying for an operating licence, the applicant shall provide STUK

- the Technical Specifications, which shall at least define limits for the process quantities that affect the safety of the facility in various operating states, provide regulations on operating restrictions that result from component failures, and set forth requirements for the testing of components important to safety,
- a summary programme for periodic inspections.

It is further required in the section 20 of STUK Y/1/2018 and section 24 of STUK Y/4/2018 that the control and supervision of a nuclear facility shall utilise written procedures that correspond to the existing structure and the operational state of the nuclear facility. Written orders and related procedures shall be provided for the maintenance and repair of components. For operational occurrences and accidents, appropriate procedures for the identification and control of circumstances shall be available.

The Guide YVL A.6 handles the conduct of operations at nuclear power plants. It is applied also to the waste management facilities at the power plants. According to the Guide YVL A.6 the procedures and instructions described in the management system, and a sound safety culture, shall be followed in the operation of a nuclear power plant. Written instructions shall be prepared for any foreseeable actions affecting safety.

Appropriate practices shall be put in place for the preparation, revision, updating, review, validation, approval, and implementation of operating procedures with due regard to the purpose and special characteristics of each procedure.

All procedures relevant to the conduct of operations shall be submitted to STUK for information following the approval processing by the licensee.

Question 17.1 Do the regulatory requirements consider the maintenance of facilities to ensure safe performance?

Response:

According to the section 111 of YEA (161/1988) STUK controls the operation of a nuclear facility to ensure that the operation of the facility is safe and complies with the licence conditions and the approved plans and that the operation also in other respects adheres to the Nuclear Energy Act and to the regulations issued by virtue of the Act. The control of the operation of a nuclear facility also involves the maintenance, repairs, inspections and tests of the nuclear facility systems, structures and components.

It is further required in the section 23 of STUK Y/1/2018 and section 27 of STUK Y/4/2018 that operability and the effects of the operating environment shall be monitored by means of inspections, tests, measurements and analyses. Regular maintenance shall be used to ensure operability in advance. Overhaul and maintenance shall be prepared for in order to prevent the degradation of operability. Condition monitoring and maintenance shall be planned, supervised and implemented so that the integrity and operability of systems, structures and components are reliably preserved throughout their service life.

Question 17.2 Are emergency preparedness and response plans, if developed by the operator, subject to approval by the regulatory body?

Response:

According to the sections 35, 36 and 36 a of YEA (161/1988) that when applying for a construction, an operating or a decommissioning licence, the applicant shall provide STUK with preliminary plans for the arrangements for emergencies or plans for the arrangements for emergencies.

The regulation STUK Y/2/2018 addresses the emergency arrangements of a nuclear power plant. The regulation also applies to other nuclear facilities as required by the danger they pose.

According to the Guide YVL D.4 a nuclear facility or a nuclear facility being decommissioned shall have emergency response arrangements in place, the extent of which shall be commensurate with the foreseen accidents. The Guide YVL C.5 presents requirements for the planning and maintenance of emergency arrangements and action in an emergency situation.

The Guide YVL C.5 requires that the licensee shall obtain STUK's approval for the emergency plan and any amendments thereto and deliver the approved emergency plan and any amendments to the Rescue Department. The amendments to the emergency plan shall be submitted to STUK for approval prior to their implementation if the emergency plan or instructions and the actions to be taken in an emergency situation are essentially modified. Updates to the contact information of the emergency plan and minor changes or specifications to the operating instructions that do not change the content of activities may be submitted to STUK for information.

Question 18 Are any of the predisposal radioactive waste management facilities subject to agreements on nuclear materials accounting?

Answer: Yes

Response:

Loviisa NPP is counted as one material balance area entirely. As per the requirements of the Additional Protocol, the Loviisa NPP site comprises Hästholmen Island as a whole and extends to the main gate on the mainland.

At Olkiluoto there are four active material balance areas: Olkiluoto Unit 1, 2, 3 and interim storage for spent nuclear fuel. NPP site as per the requirements of the Additional Protocol currently comprises the fenced areas around the reactor units, the spent fuel storage and the storage for low- and intermediate-level waste, and the Olkiluoto 3 construction site.

Central interim storage for small-user radioactive waste at the Olkiluoto NPP site in connection of the LILW disposal facility is subject to nuclear materials accounting. In the storage there are mainly disused sealed sources. Some sources contain nuclear material.

Small quantities of nuclear materials are stored by STUK in the storage inside STUK office building, mainly materials no longer in use and hence taken into STUK's custody.

Question 18.1 How is it ensured that the system of accounting for and control of nuclear materials is implemented in such a way as not to compromise the safety of the facility?

Response:

According to the section 118 b of YEA (161/1988) the planning, construction and operation of a nuclear facility shall be implemented so that the obligations concerning the control of nuclear material,

as provided and defined in the Nuclear Energy Act and provisions issued thereunder, and in the Euratom Treaty and provisions issued thereunder, are met.

In the Guide YVL A.5 it is required that the arrangement of nuclear safeguards in accordance with Guide YVL D.1 shall be taken into account in construction.

The Guide YVL D.1 requires that the operator shall see to it that regulatory inspections can be carried out appropriately and without any undue delay. The operator shall allow the inspectors access to all areas subject to inspection unless such access needs to be restricted for reasons related to safety or security arrangements. In this exceptional case, the operator shall agree on substitute or alternative procedures with the authorities.

Analysis

STRENGTHS FOR SAFETY REQUIREMENTS FOR PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE

S1	National framework and implementation of radioactive waste management is well established. Recent changes to enable to use of nuclear facilities in management of radioactive waste from other streams has enhanced situation in predisposal management of radioactive waste.
S2	Waste management has been developed for a long time and nationally Finland has comprehensive competence and resources.
S3	In nuclear waste management NPP licensees operate radioactive waste management from cradle to grave. This makes it easier manage interdependencies and optimize overall waste management.

WEAKNESSES FOR SAFETY REQUIREMENTS FOR PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE

W1	Nuclear waste management and radioactive waste from other sources have separate legislation and regulations. Also, regulatory oversight is divided in different STUK departments. This has led to some differentiation of requirements and practices.

OPPORTUNITIES FOR SAFETY REQUIREMENTS FOR PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE

O1	National cooperation group on nuclear waste management (YETI) evaluated challenges of radioactive waste management and proposed several recommendations directed to MEAE, Ministry of environment, STUK and licensee's with waste management obligation. Cooperation group was very effective forum for cooperation and implementation of recommendations have strong opportunity to enhance radioactive waste management.

THREATS FOR SAFETY REQUIREMENTS FOR PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE

T1	-

CONCLUSIONS FOR SAFETY REQUIREMENTS FOR PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE

C1	Finnish regulatory framework and regulatory oversight fulfil IAEA safety requirements. However, in the Finnish system legislation divides radioactive waste in two categories depending if it is from nuclear activities or from other use of radiation. Consistency of requirements and regulatory oversight could be enhanced from this aspect.

Module: Safety Requirements for Public Exposure

Findings

Question 1 Has the government or the regulatory body established the responsibilities of relevant parties that are specific to public exposure; established and enforced requirements for optimization; and established and enforced requirements for dose limits?

Answer: Yes

Response:

General

Basic requirements for protection of public against exposure are in SätL section 6, subsection 1:

To optimize radiation protection, occupational exposure and public exposure to ionizing radiation shall be kept as low as is reasonably achievable, and medical exposure shall be limited to what is necessary to achieve the intended examination or treatment result and performance of the procedure (principle of optimization).

Dose constraints shall be used in the optimisation of radiation protection according to SätL section 9:

Dose constraints and constraints for potential exposure are set, taking into account the characteristic features of the practice, in such a way that the exposure is anticipated to remain below the constraint due to the optimization of radiation protection.

The dose constraints concerning occupational and public exposure are furthermore set in such a way that the combined amount of radiation doses arising from all practices subject to a safety licence is anticipated to remain below the dose limit.

Nuclear safety

Nuclear Energy Act (990/1987) Section 7c states that *the dose constraints for radiation exposure caused to the member of the public caused by a nuclear facility or other use of nuclear energy shall be laid down by government decree.*

Section 9 states that *the licence holder shall be under an obligation to ensure the safe use of nuclear energy. This obligation may not be delegated to another party.*

Radiation safety

As with the use of nuclear energy, the basic requirement for protection of the public is in section 6 of the SätL.

The principle of limitation is in SätL section 7: *In radiation practices the radiation dose of workers and members of the public may not exceed the dose limit.*

The limits for public exposure are in section 14 of VnA (1034/2018):

The effective dose of members of the public attributable to radiation practices may not exceed 1 millisievert a year.

The equivalent dose of the lens of the eye may not exceed 15 millisieverts a year.

The equivalent dose of skin may not exceed, as an average dose, 50 millisieverts a year on the most exposed skin area the size of a quadrat centimeter.

What is provided in subsections 1–3 also applies to a worker who is not a radiation worker, an emergency worker or an emergency assistant.

The responsibilities of licensees for radiation safety are established in SätL Section 22, subsection 1: *The undertaking is responsible for the radiation safety of the practice. This responsibility cannot be transferred to another.*

The undertaking must also limit public exposure described in SätL section 126 by taking care of in-service radiation safety of radiation sources and the facilities and places where they are used; preventing radioactive substances from spreading outside the facility and place where the practice is engaged in and more widely to the environment with adequate efficiency; and restricting members of the public from accessing the facility and place where the practice is engaged in, if necessary. The protective shielding and the practice must be planned and implemented in such a way that there is no need to carry out measures to ensure the radiation safety of members of the public in the surrounding areas of the facility and place under the supervision and control of the undertaking.

The responsibilities of licensees, of suppliers, and of providers of consumer products regarding products' radiation safety are given in SätL section 56:

The undertaking which manufactures, imports, brings to the market, offers, keeps for sale, sells or otherwise hands over radiation sources or accessories and other products related to the safety of a radiation practice (product) shall be able to demonstrate that the product is safe.

Requirements for the limitation of exposure in the optimization of radiation protection are given VnA (1034/2018) section 8:

The optimization of radiation protection referred to in section 6, subsection 1 of the SätL must, in terms of occupational exposure and public exposure, be implemented in such a way that the magnitude of the dose generated, the probability of the exposure and the number of the exposed individuals is kept as low as possible by practical measures in light of current knowledge and technology as well as economic and societal factors.

Regarding public exposure from products the requirements for optimization of protection and safety and enforcing requirements (The product's market surveillance) are given in SätL section 57:

Regarding public exposure, the market surveillance of products generating ionizing or non-ionizing radiation or containing radioactive substances is subject, unless otherwise provided elsewhere, to the Act on the Market Surveillance of Certain Products (1137/2016). The economic operator specified in the Act in question is the party subject to the demonstrating obligation referred to in section 56 of this Act.

If a product referred to in section 56 may cause a significant detriment to health, the regulatory authority may also prohibit a legal or natural person other than the undertaking referred to in section 56 from manufacturing, importing, exporting, transferring, placing on the market, offering, keeping for sale, selling or otherwise handing over the product.

Compliance with requirements in terms of health care equipment is provided for separately. Health care equipment generating non-ionizing radiation is furthermore subject to the requirements specified in chapter 8 and section 161 of this Act insofar as they cause public exposure.

The compliance of technical equipment used at work and construction products and the surveillance thereof is laid down separately.

According to the section 126 of SätL the undertaking shall limit public exposure by:

1) taking care of in-service radiation safety of radiation sources and the facilities and places where they are used as provided in section 66, subsection 1;

2) preventing radioactive substances from spreading outside the facility and place where the practice is engaged in and more widely to the environment with adequate efficiency;

3) restricting members of the public from accessing the facility and place where the practice is engaged in, if necessary.

The protective shielding and the practice must be planned and implemented in such a way that there is no need to carry out measures to ensure the radiation safety of members of the public in the surrounding areas of the facility and place under the supervision and control of the undertaking.

SätL section 127 gives requirements for undertaking regarding discharges and limit values:

The undertaking must limit the discharges of radioactive substances to the environment and the sewerage system to the absolute minimum. In any event, the amount of the discharge may not exceed the limit value for a minor discharge. A record must be kept of the discharges.

STUK may nevertheless authorize a discharge exceeding the limit value for a minor discharge if there is an absolute need for the discharge despite limiting measures [KV(1)] [AS(2]) *and the undertaking has drawn up a plan for the discharges and assessed the exposure caused by the discharges.*

STUK sets limit values for the discharge referred to in subsection 2 in such a way that the public exposure is as low as possible, accounting for the nature and extent of the practice and the means available for limiting discharges, and that the anticipated amount of exposure caused by the discharges is lower than dose constraint.

The undertaking must regularly provide STUK with information on the discharges referred to in the authorization granted by virtue of subsection 2 and on their monitoring.

The secretions of patients who have received a radioactive substance in medical use of radiation are not subject to subsection 1 and 2.

STUK issues more detailed regulations on the general limit values of minor discharges and more detailed technical regulations on the plan concerning discharges and their monitoring, discharge monitoring and record keeping and the delivery of the information for the purpose of implementing European Union legislation.

More detailed regulations for discharges are given in regulations S/2/2019 sections 4, 6-8 and in S/3/2019 sections 7-9.

Requirement for limiting the public exposure from patients that emit radiation is given in VnA (1034/2018) section 11.

In the event that medical exposure is attributable to a radiopharmaceutical or a sealed source implanted in the patient, the individual subject to the radiation exposure may not be discharged until the dose caused by the radioactive substance in the body to the comforter or members of the public is expected to remain below the dose constraint.

For activities causing exposure to natural radiation (SätL Chapter 18), there are responsibilities for the estimation of public exposure (SätL section 146). NORM-involving industries (SätL section 145 and section 151) have a reference level for public exposure (STMa 1044/2018 section 26). The industries with potential NORM-occurrences have to make an exposure assessment of the public according to regulation STUK S/3/2019. If the exposure of the public could exceed the reference level, the responsible party needs to constrain the exposure (SätL section 147). If the exposure of the public exceeds the reference level despite of measures to limit exposure, the responsible party needs to apply for a safety license (SätL section 148) after which the activities are regulated similarly to radiation practices (SätL section 150) using dose limits, dose constraints, optimization and safety assessments.

The optimization principle also applies to NORM-involving industries even when licensing is not required, although actual reductions of exposures which are already below reference levels are not actively supervised and thus not enforced in practice. NORM-involving industries have a responsibility to re-estimate the public exposure, if there are significant changes in the operation (e.g. changes in the raw material composition) which could lead to exposure exceeding the reference level (SätL section 146).

According to SätL section 14, STUK supervises compliance with SätL, unless otherwise provided elsewhere. A municipality's health protection authority supervises compliance with the reference levels of the radioactivity in household water referred to in section 154 and the radon concentration in dwellings and other premises used by people referred to in section 158, as well as the investigation obligation referred to in section 146, subsection 1, with regard to household water, dwellings and other spaces with public access (SätL section 15). The supervision carried out by a municipality's health protection authority is subject to the Health Protection Act. Compliance with the action level applicable to foodstuffs and animal feed and the prohibition to use radioactive substances referred to in section 68 is supervised by the authorities referred to in chapter 4 of the Food Act (23/2006) and the authorities referred to in chapter 4 of the Feed Act (86/2008) in terms of their respective branches of activity. The Finnish Safety and Chemicals Agency (Tukes) supervises the prohibition referred to in section 68 in terms of cosmetics and toys.

Measures for limiting radiation exposure to natural radiation are set in SätL section 147:

The party obligated to carry out the investigation referred to above in section 146 shall implement the measures to limit exposure to natural radiation, if the occupational or public exposure arising from the practice or the radon concentration in workplace or household water exceeds the reference level.

According to SätL section 48 subsection 3 a safety license is granted provided that:

1) *the radiation practice complies with the principles of justification, optimization and limitation;*

2) *a safety assessment pursuant to section 26 has been drawn up for the radiation practice;*

3) *the practice can be carried out safely;*

4) *the undertaking has the right to engage in a trade in Finland.*

The basic requirements for safety assessment are in SätL section 26:

In practices subject to a safety licence, the undertaking shall carry out a safety assessment concerning the radiation practice, which:

1) identifies ways in which the practice can cause radiation exposure, considering any possible radiation safety deviations;

2) assesses the magnitude of the occupational, public and medical exposure arising from the practices as well as the probability and magnitude of the potential exposure;

3) presents measures to ensure radiation safety and the optimization of radiation protection;

4) presents measures to prevent and prepare for identified radiation safety deviations;

5) presents the categorization of the radiation practice.

The safety assessment shall be prepared in writing and kept up to date.

STUK confirms the safety assessment either as part of granting the safety licence or separately.

STUK issues more detailed regulations on the content and preparation of the safety assessment.

More detailed regulations on the content and preparation of the safety assessment are in STUK S/6/2019 sections 13-17.

Basic requirement for safety license application are given in SätL section 51:

A safety licence application shall include:

1) information of the applicant;

2) the purpose of the practice and information on the facility or place where the practice is carried out;

3) the management system for the radiation practice;

4) the certificates verifying the qualifications of the radiation safety expert and radiation safety officer;

5) the safety assessment concerning the radiation practice;

6) a plan on the security arrangements;

7) information on the radiation sources, the related appliances and shieldings and on the maintenance arrangements concerning the sources and appliances;

8) the arrangements for managing the waste and discharges containing radioactive substances generated by the practice during its operations and when discontinuing the practice;

9) the quality assurance procedures complied with in the practice;

10) information other than what is specified in paragraphs 1 through 9 relevant to the safety of the practice.

Further provisions on the information to be provided in an application for a safety licence are given by government decree.

Contents of a safety license application are given in VnA (1034/2018) Annex 5.

Requirements for amending safety license are given SätL section 52.

STUK amends the conditions for a safety licence subsequent to its granting if material changes in the circumstances and special reasons due to them require the conditions to be changed for the sake of ensuring safety.

A substantial change to a practice requires prior amendment of the safety licence. In addition, STUK must be notified of any other changes to a practice subject to a safety licence.

Further provisions on changes to practices subject to an amendment of the safety licence or a notification are given by government decree.

Changes that are considered material changes in nature of a practice which require a prior amending of safety license are given in VnA (1034/2018) section 25. Changes to a practice subject to a safety license which shall be reported to Radiation and Nuclear Safety Authority within two weeks of change are given in VnA (1034/2018) section 26.

Question 1.1 Has the government or regulatory body established or approved constraints on dose and constraints on risk to be used in optimization of protection and safety for members of the public?

Response:

Nuclear safety

Constrains on dose for nuclear power plants are established in section 22 b § and for nuclear waste facilities in section 22 d § of the Nuclear Energy Decree (161/1998), (unofficial translation):

The constraint on the annual dose to the population from normal operation of a nuclear power plant and other nuclear installations with a nuclear reactor is 0.1 millisievert. For the planned decommissioning of a nuclear power plant and other nuclear installations with a nuclear reactor, the constraint for the annual dose to the general public is 0.01 millisievert.

In the event of an anticipated operational occurrence, the constraint on the annual dose to the population is 0.1 millisievert.

The constraint for the annual dose to an individual member of the population from an release shall be 1 millisievert for category 1 postulated accidents, 5 millisievert for category 2 postulated accidents and 20 millisievert for design extension conditions.

In the event of a severe accident in a nuclear power plant, the radioactive releases shall not give rise to a need for extensive protective measures for the population or to long-term restrictions on the use of large areas of land and water.

In order to limit the long-term effects, the limit value for the release of caesium-137 into the air is 100 terabecquerel. The possibility of exceeding this limit value must be very small.

The possibility of release requiring protective measures in the early stage of an accident must be very small.

The constraint for the annual dose to the population from normal operation and planned decommissioning of a nuclear waste facility is 0.01 millisievert.

Radiation safety

Basic requirements for establishing dose constrains and constraints for potential exposure are given in SätL section 25.

The undertaking shall establish the dose constraints and constraints for potential exposure to be used in the radiation practice in advance, unless STUK has established the constraints to be used in the practice in general by virtue of section 10. Constraints on the occupational exposure of an outside worker shall be established in co-operation with the employer of the outside worker.

The constraints for potential exposure of workers and members of the public must be established beforehand for such radiation safety deviations referred to in section 26, subsection 1, paragraph 1, which may result in significant radiation exposure.

The information concerning the constraints referred to above in subsection 1 must be delivered to STUK either as part of the granting of the safety licence or separately.

When establishing dose constraints and constraints for potential exposure it shall be taken into account the characteristics of the practice according to the requirements set in SätL section 9.

Dose constraints and constraints for potential exposure are set, taking into account the characteristic features of the practice, in such a way that the exposure is anticipated to remain below the constraint due to the optimization of radiation protection.

The dose constraints concerning occupational and public exposure are furthermore set in such a way that the combined amount of radiation doses arising from all practices subject to a safety licence is anticipated to remain below the dose limit.

Default dose constrain for public exposure from practices subject to safety license is given in regulation STUK S/6/2019 section 8:

The dose constraint for public exposure is 0.1 mSv. However, the dose constraint may be greater than this if it is shown to be justified in the safety assessments, excluding the situations referred to in section 9.

In STUK S/6/2019 section 9 are given dose constraints for public exposure resulting from discharges and waste:

The dose constraint for public exposure resulting from discharges and waste in radiation practices may not be greater than 0.1 mSv:

1) in discharges of radioactive substances to the sewerage system, waterways or the air;

2) in the reuse, recycling, utilization, or disposal of waste containing radioactive substances.

The STUK S/6/2019 section 10 gives dose constraints concerning the design and construction of facilities where radiation sources are used and stored.

The dose constraint concerning the design and construction of facilities where radiation sources are used and stored may not be greater than:

1) 6 mSv for a radiation worker in a supervised area;

2) 0.3 mSv for occupational exposure in an area other than a controlled or supervised area;

3) the dose constraint for public exposure referred to in section 8.

If there are several facilities in which radiation sources are used and stored, the space-specific dose constraints must be set in such a way that their maximum sum is equal to what is specified in subsection 1.

Constrains for potential for potential public exposure are given in STUK S/6/2019 section 12.

The potential public exposure from a one-off incident may not be greater than 10 mSv, excluding a highly unlikely incident or sequence of incidents with a realization probability that cannot be reduced through practical measures.

The potential public exposure from a one-off incident may not be greater than 1 mSv if there can be more than 100 exposed persons, excluding a highly unlikely incident or sequence of incidents with a realization probability that cannot be reduced through practical measures.

If the potential public exposure resulting from a one-off incident is greater than 0.3 mSv, the expected number of the incidents may not be greater than one in ten years.

Question 1.2 Has the regulatory body established or approved operational limits and conditions related to public exposure including authorized limits for discharges?

Response:

General

There are established limits for discharges from both nuclear facility and radiation practices.

Nuclear safety

According to Section 7 c of the Nuclear Energy Act, the maximum values of radiation exposure caused by a nuclear facility or any other use of nuclear energy on any member of the public will be provided for by Government decree. Limits on releases of radioactive materials from a nuclear facility, in order that they do not exceed the maximum values for radiation exposure provided by Government decree, shall be confirmed by STUK. Supervision of releases of radioactive materials shall be arranged so that compliance with limits as referred to in this section can be reliably established.

According to requirement 106 of the Guide YVL C.3, these release limits are specified in the Operational Limits and Conditions of the nuclear facility approved by STUK.

Radiation safety

Conditions to limit radiation exposure to members of the public are set in SätL 126:

The undertaking must limit public exposure by:

1) taking care of in-service radiation safety of radiation sources and the facilities and places where they are used as provided in section 66, subsection 1;

2) preventing radioactive substances from spreading outside the facility and place where the practice is engaged in and more widely to the environment with adequate efficiency;

3) restricting members of the public from accessing the facility and place where the practice is engaged in, if necessary.

The protective shielding and the practice must be planned and implemented in such a way that there is no need to carry out measures to ensure the radiation safety of members of the public in the surrounding areas of the facility and place under the supervision and control of the undertaking.

SätL section 127 gives requirements for undertaking regarding discharges and limit values:

The undertaking must limit the discharges of radioactive substances to the environment and the sewerage system to the absolute minimum. In any event, the amount of the discharge may not exceed the limit value for a minor discharge. A record must be kept of the discharges.

STUK may nevertheless authorize a discharge exceeding the limit value for a minor discharge if there is an absolute need for the discharge despite limiting measures and the undertaking has drawn up a plan for the discharges and assessed the exposure caused by the discharges.

STUK sets limit values for the discharge referred to in subsection 2 in such a way that the public exposure is as low as possible, accounting for the nature and extent of the practice and the means available for limiting discharges, and that the anticipated amount of exposure caused by the discharges is lower than dose constraint.

The undertaking must regularly provide STUK with information on the discharges referred to in the authorization granted by virtue of subsection 2 and on their monitoring.

The secretions of patients who have received a radioactive substance in medical use of radiation are not subject to subsection 1 and 2.

STUK issues more detailed regulations on the general limit values of minor discharges and more detailed technical regulations on the plan concerning discharges and their monitoring, discharge monitoring and record keeping and the delivery of the information for the purpose of implementing European Union legislation.

More detailed regulations for discharges are given in regulations STUK S/2/2019 sections 4, 6-8 and in STUK S/3/2019 sections 7-9.

Apart from authorised limits for discharges, no other operational limits have been addressed in the legislation or regulations.

For practices subject to a safety license the requirements for monitoring public exposure are given in SätL section 128.

In practices subject to a safety licence, the undertaking shall monitor public exposure based on regular assessments and, if necessary, measurements in the event that the public exposure is greater than one-third of the dose constraint applicable to the practice in question despite the measures limiting radiation exposure.

If public exposure must be monitored due to discharges, the undertaking shall, prior to the commencement of the activity, carry out a baseline environmental radioactivity study, in which

radiation measurements and determinations of radioactive substances determine the preoperational environmental radioactivity status.

STUK issues more detailed regulations of a technical nature on the arrangement of the monitoring referred to in subsection 1 and the performance of the baseline environmental radioactivity study.

Question 1.3 Has the government or regulatory body, where a public dose may be caused outside the territory or jurisdiction of the State in which the source is located, ensured that the assessment for radiological impact includes those impacts outside the territory or other area under the jurisdiction or control of the State?

Response:

General

Finland is party to the Convention on Environmental Impact Assessment in a Transboundary Context (SopS 67/1997), so-called Espoo Convention. The convention covers nuclear power plants; facilities producing, enriching or reprocessing nuclear fuel; and facilities for storage, handling and final disposal of radioactive waste.

In the general provisions of Espoo convention (Article 2), it is stated that parties are required to take all appropriate and effective measures to prevent, reduce and control significant adverse transboundary environmental impact from proposed activities.

The Party of origin shall ensure that in accordance with the provisions of this Convention an environmental impact assessment is undertaken prior to a decision to authorize or undertake a proposed activity listed in Appendix I that is likely to cause a significant adverse transboundary impact.

Article 3 of the Espoo Convention also requires that the Party of origin shall … notify any Party which it considers may be an affected Party as early as possible and no later than when informing its own public about that proposed activity. The Espoo Convention also sets how exchange of information, consultations and possible disputes shall be handled.

Law on environmental impact assessment (252/2017) implements the articles of Espoo Convention in 28 §, 29 § and 30 §. Requirement for the content of the Environmental Impact Assessment program to include transboundary impacts is given in (VNA 277/2017) 3 § 5).

Question 2 Do relevant parties apply the system of protection and safety to protect members of the public against exposure?

Answer: Yes

Response:

Nuclear safety

According to Section 7 a of the Nuclear Energy Act (990/1987), *the safety of nuclear energy use shall be maintained at as high a level as practically possible. For the further development of safety, measures shall be implemented that can be considered justified considering operating experience, safety research and advances in science and technology.*

The safety requirements and measures for ensuring safety shall be graded and targeted so as to be commensurate with the risks in the use of nuclear energy.

According to requirement 302 of the Guide YVL C.3, *the limitation of radioactive releases to and radiation levels in the environment shall be implemented by employing the best available techniques.*

Radiation safety

The principle of optimization is set in SätL section 6. The requirement for optimizing and limiting radiation exposure to the public is given in SätL section 126:

The undertaking must limit public exposure by:

1) taking care of in-service radiation safety of radiation sources and the facilities and places where they are used as provided in section 66, subsection 1;

2) preventing radioactive substances from spreading outside the facility and place where the practice is engaged in and more widely to the environment with adequate efficiency;

3) restricting members of the public from accessing the facility and place where the practice is engaged in, if necessary.

The protective shielding and the practice must be planned and implemented in such a way that there is no need to carry out measures to ensure the radiation safety of members of the public in the surrounding areas of the facility and place under the supervision and control of the undertaking.

The basic requirements for radiation sources in-service radiation safety are given in SätL section 66.

Possible changes in conditions that could affect the exposure of the public are assessed with a safety assessment. Safety assessment is required for all licenced practices as given in SätL section 48 and it shall be prepared in writing and kept up to date as stipulated in SätL section 26. Detailed requirements for performance and revision of safety assessment are given in STUK S/6/2019 section 14:

The safety assessment concerning a radiation practice must be carried out prior to the commencement of the practice and it must be revised in terms of occupational, public, and medical exposure:

1) every two years, if the category of radiation exposure is 1;

2) every three years, if the category of radiation exposure is 2;

3) every five years, if the category of radiation exposure is 3.

The safety assessment must also be revised, if this is not clearly unnecessary in terms of radiation safety, in connection to a change of the practice, after a radiation safety deviation, and to account for experiences gained from other comparable practices, the results of a safety investigation, and the development of technology

Possible buildup and accumulation in the environment of radioactive substances from discharges during the lifetime of the activity causing exposure to natural radiation is considered in STUK S/3/2019 section 11 as follows: The dose must also take into account the dose from radioactive substances accumulating in the environment during prolonged operation.

Question 2.1 How does the government or regulatory body ensure and verify that registrants and licensees, for sources under their responsibility, establish and maintain the requirements of paragraph 3.127 (a)-(h)?

Response:

Nuclear safety

According to the Section 6 of the Nuclear Energy Act 990/1987 *the use of nuclear energy must be safe and it shall not cause harm to people or damage to the environment or property.* Further in the Section 7a it is required that *the safety of nuclear energy use shall be maintained at as high a level as practically possible.*

In the Section 19 concerning the construction of a nuclear facility it is mentioned that a licence for the construction a nuclear facility can be granted, if … *appropriate account has been taken of the safety of workers and the population when planning the operations in question, and if the applicant has the necessary expertise available.*

According to the Section 20 the license to operate may be granted, if … *appropriate account has been taken of the safety of workers and the population, and environmental protection, and if the applicant has sufficient expertise available and, in particular, the competence of the operating staff and the operating organisation of the nuclear facility are appropriate.*

Detailed requirements for leadership and management for safety are presented in YVL A.3 and those for organisation and personnel of a nuclear facility in YVL A.4.

Detailed requirements for the radiation protection of the public in the design phase of a NPP are in the Guide YVL C.1 and for the operation in the Guide YVL C.3. Requirements for NPPs are also applied to the waste facilities when applicable.

According to Section 7 a of the Nuclear Energy Act (990/1987), *the safety of nuclear energy use shall be maintained at as high a level as practically possible. For the further development of safety, measures shall be implemented that can be considered justified considering operating experience, safety research and advances in science and technology.*

Regulations concerning safety design are presented in YVL B.1, those concerning structural radiation safety in YVL C.1, and those concerning limitation and monitoring of radioactive releases from a nuclear facility in YVL C.3.

According to regulation 302 in YVL C.1 *A nuclear facility's Preliminary and Final Safety Analysis Report or the associated topical report shall give a summary of the most important radiation protection-related design features by which the optimisation principle in radiation protection is implemented at a nuclear facility.*

According to regulation 301 in YVL C.3 *The radiation exposure arising from the operation of a nuclear facility shall be kept as low as reasonably achievable. A nuclear facility and its operation shall also be so designed that the constraints specified in the Nuclear Energy Decree (161/1988) are not exceeded. Hence, mere compliance with the constraints is not enough; instead, efforts shall be made to keep the radioactive releases to and radiation levels in the environment arising from the operation of the plant as low as reasonably achievable.*

According to regulation 302 in YVL C.3 *The limitation of radioactive releases to and radiation levels in the environment shall be implemented by employing the best available techniques.*

According to regulation 401 in YVL C.3 *The applicant and licensee shall design the systems and components containing radioactive substances in such a way that releases of radioactive substances and the radiation exposure of the population living in the vicinity of the plant can be kept low as provided in requirements 301 and 302. The release pathways of radioactive substances shall be identified, and systems to effectively reduce releases shall be designed for collecting and purifying liquids and gases containing radioactive substances. Different radionuclides shall be accounted for in the design of the systems.*

Guide YVL B.1 set the requirements for the radiation protection during design phase of a NPP. Requirements for the radiation protection of the public during operation are in the Guide C.3. According to the Guide YVL C.3 there shall be instruments for measurements of radioactive discharges to the appropriate extent. The environment monitoring program in the vicinity of the nuclear facility shall be implemented according to the Guide YVL C.7.

Section 7 i of the Nuclear Energy Act requires that *the licence holder shall arrange adequate training for the maintaining and development of the expertise and skills of its personnel handling tasks relating to nuclear safety.*

The licence holder shall ensure that contractors and subcontractors whose activities affect the nuclear safety of the nuclear facility have an adequate number of qualified and trained personnel suitable for the tasks.

Section 24 of the STUK Y/1/2018 requires that *the releases of radioactive substances from the nuclear facility shall be monitored and their concentrations in the environment shall be measured. The radiation doses to the workers and the public in the surroundings caused by the operation or decommissioning of a nuclear facility shall be measured or otherwise estimated with due consideration given to external and internal radiation exposure.*

Detailed requirements for monitoring of radioactive releases are presented in YVL C.3 and for radiological monitoring of the environment of a nuclear facility in YVL C.7.

The quarterly and annual reports of radioactive releases and environmental monitoring are subject to requirement 305 of YVL A.9:

The licensee shall store the measurement results based on which the reports have been drafted for a minimum of ten years. The reports shall be stored until the facility has been decommissioned.

According to Section 7p of the Nuclear Energy Act *The planning of emergency arrangements for the use of nuclear energy shall be based on analyses of operational occurrence and accident conditions, and the consequences assessed on the basis of these analyses. In planning emergency arrangements for a nuclear facility, preparations shall be made for the release of a significant quantity of radioactive substances from the facility.*

The nuclear facility shall have persons trained in the planning of emergency arrangements and emergencies (emergency response organisation), whose duties shall be specified and who shall have access to the facilities, equipment and communication systems required for their duties. The emergency arrangements shall be coordinated with the emergency and preparedness plans drawn up by authorities taking into account the provisions of

the Rescue Act (379/2011).

Detailed requirements are presented in YVL C.5.

Radiation safety

The prime entity of policies, procedures and organizational arrangements for protection and safety relation to public exposure that will fulfill IAEA standards is given in SätL sections 12 (Safety culture and safety management), 23 (Criteria for organizing practices), 25 (Establishing dose constraints and constraints for potential exposure), 26 (Safety assessment concerning radiation practices) and 29 (Management system of radiation practices).

The principle of optimization is given in section 6 of SätL. The requirement for limiting radiation exposure to the public is given in SätL section 126:

The undertaking must limit public exposure by:

1) taking care of in-service radiation safety of radiation sources and the facilities and places where they are used as provided in section 66, subsection 1;

2) preventing radioactive substances from spreading outside the facility and place where the practice is engaged in and more widely to the environment with adequate efficiency;

3) restricting members of the public from accessing the facility and place where the practice is engaged in, if necessary.

The protective shielding and the practice must be planned and implemented in such a way that there is no need to carry out measures to ensure the radiation safety of members of the public in the surrounding areas of the

facility and place under the supervision and control of the undertaking.

The basic requirements for radiation sources in-service radiation safety are given in SätL section 66.

The undertaking shall ensure that a radiation source, the facility and place where it is used and stored, and the equipment and devices related to it are such that the radiation source can be used safely.

The undertaking shall ensure that the use and storage facility or place of a radiation source subject to a safety licence is marked with a sign indicating radiation hazard. The radiation source shall be marked with a sign warning of a radiation hazard if this is technically possible. In addition, the source shield or source container or storage shield of a radiation source containing a radioactive substance must have a label including the key information of the radioactive substance it contains and a marking indicating radiation hazard.

What is provided in subsection 2 also applies to other radiation sources the safe use of which requires this.

STUK issues more detailed regulations of a technical nature on the radiation safety during use referred to in subsection 1, the markings referred to in subsection 2 and 3, appliances' in-service acceptability requirements and other requirements pertaining to the use of the appliances.

Detailed requirements for undertakings regarding sources under their responsibility are given in regulation STUK S/5/2019.

- chapter 2: Premises where radiation sources are used and stored, sections 4-14,

- chapter 3: In-service acceptability criteria of radiation sources, sections 15-17 and appendix 2-8),

- chapter 4: Information and notifications concerning radiation sources as well as documentation of radiation sources, sections 18-23,

- chapter 5: Quality assurance actions related to radiation sources, sections 24-31

The undertaking shall establish and implement dose constrains for public exposure. STUK approves the set dose constrains during authorization. The basic requirement to establish dose constrain is set in SätL section 25.

More detailed requirements and default dose constrains for members of the public are given STUK S/6/2019 sections 9-10 and 12.

The basic requirements for undertaking regarding security arrangements are given in SätL section 67.

The undertaking shall protect radiation sources subject to a safety licence against illegal operation or loss or otherwise falling into the hands of third parties at their use and storage facilities. These security arrangements shall be adequate in terms of the risks related to the practice and the radiation sources and they must form a whole compatible with the measures concerning radiation safety. The security arrangements include, depending on the risks involved in the radiation sources:

1) *drawing up a plan on the security arrangements and keeping the plan up to date;*

2) *protecting the radiation sources with structural barriers and the presence of personnel;*

3) *the regular verification of the location of the radiation source;*

4) *the use of access control and other technical surveillance measures;*

5) *restricting access to materials concerning radiation sources and security arrangements.*

STUK issues more detailed regulations on the security arrangements and their determination in accordance with the radiation sources

Requirements for suitable and adequate resources are stipulated in SätL section 23.

The undertaking shall implement the organization of the practice in such a way that the practice meets the requirements provided in this Act and that radiation safety deviations are prevented with adequate effectiveness and that their consequences are as insignificant as possible. The undertaking shall implement such measures to improve radiation safety as can be considered justified in terms of their quality and costs as well as their improving impact.

The undertaking shall ensure that it has the expertise necessary in terms of the nature and extent of the practice at its disposal and sufficient financial and human resources for the safe implementation of the practice.

Further provisions on the requirements concerning the financial and human resources referred to in subsection 2 may be given by government decree.

STUK issues further technical regulations for the prevention of radiation safety incidents and the limitation of their consequences

More detailed requirements for in-service radiation safety are given in STUK S/5/2019 sections 6, 8, 9 11 and 15. Requirements for human resources are given in VnA section 22.

The basic requirements for training, supplementary training and induction of workers are given in SätL sections 33 and 34.

Section 33 Training and induction of workers

The undertaking shall ensure that all workers engaged in radiation practices or whose tasks otherwise require special expertise in radiation protection are in possession of the qualifications, radiation protection education and training and induction to their duties required by the practices and the tasks.

The undertaking shall keep a worker-specific record on the radiation protection training and induction for which it is responsible.

STUK issues more detailed regulations on the provision and content of the radiation protection training and induction referred to in subsection 1 when the training or induction is provided in the form of continuing training and supplementary training.

Section 34 Supplementary training maintaining professional skills

The undertaking shall ensure that workers engaged in radiation practices are provided with sufficient and regular supplementary training on radiation protection.

The undertaking shall keep a worker-specific record on the supplementary radiation protection training for which it is responsible.

Further provisions on regular supplementary radiation protection training and the content thereof are given by a decree of the Ministry of Social Affairs and Health.

More detailed requirements for induction of workers are given in regulations STUK S/6/2019 sections 4-5

The basic requirements for monitoring public exposure from authorized practices are given in SätL section 128.

SätL, *Section 128 Monitoring public exposure*

In practices subject to a safety licence, the undertaking shall monitor public exposure based on regular assessments and, if necessary, measurements in the event that the public exposure is greater than one-third of the dose constraint applicable to the practice in question despite the measures limiting radiation exposure.

If public exposure must be monitored due to discharges, the undertaking shall, prior to the commencement of the activity, carry out a baseline environmental radioactivity study, in which radiation measurements and determinations of radioactive substances determine the preoperational environmental radioactivity status.

STUK issues more detailed regulations of a technical nature on the arrangement of the monitoring referred to in subsection 1 and the performance of the baseline environmental radioactivity study.

The requirements radiation measurements regarding public exposure are given in STUK S/7/2021 sections 4-6

Section 4, The reliability of radiation measurements

The radiation meter shall be suitable for the measurement with the values, radiation types and radiation qualities of the quantity being measured. If the dose rate of the radiation being measured is pulsed, the measuring instrument and the measuring system shall be capable of measuring both continuous and pulsed radiation. Additionally, the radiation meter shall be suitable for the environmental conditions prevailing in its place of use.

The metrological traceability of a measurement result shall be capable of being substantiated based on the information provided in the calibration certificate of the measuring instrument and the description of the method of measurement used.

In order to demonstrate the metrological traceability of the measurement result of the field instrument, the calibration data referred to in section 14 of the field instrument may be given in the management system data of the instrument user instead of the calibration certificate.

An uncertainty assessment shall be conducted on the measurement results of measurements concerning radiation practices and radon concentration measurements of a workplace, housing unit or other occupied space.

The reliability, measuring instrument and measuring system of radiation measurements shall meet the requirements specified in Annex 1, Tables 1.1─1.4.

Section 5, Measurement quantities for occupational exposure and public exposure

The measurement quantities set out in Annex 1, Table 1.1 and 1.3 shall be used in radiation measurements conducted for monitoring exposure conditions and individual monitoring and in radiation measurements conducted to safeguard the safety of population.

Section 6, Radiation measurements conducted for monitoring exposure conditions and public exposure

In radiation measurements conducted for monitoring exposure conditions and public exposure, the effect of radiation on the response of the radiation meter shall be known.

If the dose rate in the measurements referred to in subsection 1 above may exceed the maximum capacity of the measuring instrument, the measuring instrument shall in such cases indicate overloading.

Requirements regarding records are given in SätL section 127 and in STUK S/3/2019.

According to SätL section 127, the licensee must have records of releases and provide regular information about the monitoring of authorized discharges. According to STUK S/3/2019 section 9 the report about monitoring of discharges must be done quarterly and it must contain the nuclide specific information about quantities and alto temporal variations.

Based on STUK S/3/2019 section 11, the monitoring of public exposure must take into account external and internal exposure and the exposure from radionuclides that are accumulated in the environment in long-term operations. The monitoring of public exposure must be planned and performed regularly so that short-term and long-term changes to public exposure are identified. The monitoring of public exposure must be done in a way that allows comparison to the results of radiological environmental baseline survey results.

The basic required for preparation for radiation safety deviations are set in SätL section 129.

In practices subject to a safety licence, the undertaking must prepare for radiation safety deviations. The undertaking shall have an up-to-date plan of action for the deviations.

STUK issues more detailed regulations on the plan for radiation safety deviations referred to in subsection 1.

The detailed requirements for the plan of actions are given in regulation STUK S/2/2018 sections 2 and 3.

Section 2 Plan for radiation safety deviations

The plans for radiation safety deviations shall include separate operating instructions for each place of use in the event of a radiation safety deviation.

The plan shall include training and exercises on the immediate actions to be taken to limit radiation exposure.

Additionally, the plan shall specify measures for determining the causes of a radiation safety deviation and for learning from it.

Section 3 Operating instructions for each place of use

In a practice of class 1 radiation exposure, each place of use shall have written operating instructions in place that are available to the workers. The operating instructions shall at least specify:

1) the immediate actions to be taken to limit radiation exposure, including:

a) identifying and limiting the radiation hazard area;

b) preventing outsiders from accessing the radiation hazard area;

c) the use of respirators if it is suspected that radioactive substances have entered into the breathing air;

d) prevention of the dispersion of contamination;

e) notifying the radiation safety officer of the radiation safety deviation;

f) prevention of the accumulation of radioactive iodine into the thyroid gland;

g) accelerating the decorporation of radionuclides;

h) removal of sealed source radiotherapy apparatus from the patient;

i) removal of the patient from the radiation beam;

2) the procedure for recording the course of events, including:

a) the measures carried out and the times thereof;

b) the names and contact information of the individuals who were exposed or otherwise involved in the radiation safety deviation and, concerning employees, the information referred to in section 42 of the Government

Decree;

c) detailed information concerning the exposure;

3) the procedure for reporting a radiation safety deviation:

a) to competent authorities;

b) to those involved in the radiation safety deviation;

4) the actions for determining the magnitude of the radiation exposure;

5) the urgent actions for assessing the state of health of those who were exposed;

6) instructions for informing the patient and his or her attending physician;

7) the procedure for obtaining advice from a radiation safety expert and medical physics expert if applicable.

In a practice of radiation exposure classes 2 or 3, each place of use shall have written operating instructions in place that are available to the workers, and at least the information referred to in paragraphs 1, 2, 3, 4 and 7 of subsection 1 shall be included in the operating instructions.

Requirements for the undertaking for the immediate measures and measures after radiation safety deviation are given in SätL sections 130 and 131.

Regulatory supervision

Regulatory supervision of the requirements as stipulated in GSR Part 3 paragraph 3.127 is similar as the regulatory supervision (authorization and inspection) as explained in answer to question 2.

Question 2.2 How is it ensured that the requirements paragraph 3.128 (a) - (d) of GSR part 3, for visitors to controlled and supervised areas, are complied with?

Response:

General

According to SätL visitors are members of the public. The definition is given in section 4:

42) members of the public means any persons other than workers, outside workers, emergency workers, emergency helpers or persons subject to medical exposure;

On SätL's justification it is clarified that visitors are considered to be members of public.

42) Job visitors and other visitors are members of the public.

The basic requirements for controlled and supervised areas are given in SätL 91:

The controlled areas and supervised areas of working areas must be identified and differentiated. The basis for the differentiation is an assessment on the radiation exposure and potential exposure in the area.

A controlled area must be delineated. Access to the area must be restricted to the individuals who have been appropriately instructed. Access to as well as working in and visits to the controlled area must be controlled in accordance with the written instructions. Special arrangements shall furthermore be put in place for the purpose of protecting individuals from ionizing radiation and preventing the spread of radioactive contamination.

Further provisions on the need and grounds for identifying and differentiating between areas and on the requirements concerning controlled and supervised areas are given by government decree for the purpose of implementing European Union legislation.

On section 91 justification obligations of the undertaking are further explained.

These measures are obligations of an undertaking operator. The undertaking's written instructions shall include, for work in the controlled area, instructions to ensure protection against radiation during normal work and procedures to limit the likelihood and magnitude of exposure in the event of a radiation safety deviation. The guidelines also describe procedures for possible visits to the controlled area, such as: supervision of the visit by a trained person, guidance and instructions to visitors before entering the controlled area, monitoring of the exposure conditions of visitors and recording and monitoring of the radiation doses received, age restrictions and possible dose constraints.

More detailed requirements for controlled areas are given in Government Decree on Ionizing Radiation (1034/2018) section 36.

If the area carries a risk of the spread of radioactive contamination, necessary arrangements must be carried out for individuals' arrival to and departure from the area and the delivery and removal of goods to and from the area.

A controlled area must have signs indicating the area's classification, the nature of the radiation sources and the related hazards.

The undertaking must organize workers working in the controlled area training on the special characteristics of the workplace and the duties and provide the workers with the personal protective equipment necessary for radiation protection.

And requirements for supervised areas are given in section 37.

A supervised area must have signs indicating the area's classification, the nature of the radiation sources and the related hazards, should it be necessary in terms of considering the hazard.

Special rules must be confirmed for the supervised area, should it be necessary in terms of considering the hazard

Nuclear safety

According to YEL section 2a, subsection 1, paragraph 8, Sätl 91 also applies to the use of nuclear energy. Visitors are not allowed to stay alone in controlled area, they shall have a host. NPPs have very detailed guides in radiation protection guidebook how to bring visitors into controlled area. The guide includes chapters such as the definition (tourist visitors and expert visitors), the age of the visitors, monitoring of radiation exposure, entering the controlled area, protective clothing, safety of the visitors and action in abnormal situations such as radiation exposure, contamination, sickness or accident.

The entrance to a nuclear facility is controlled as regulated in the regulations 415 - 417 of the Guide YVL C.1. According to requirement 513 of the Guide YVL C.2, *the classification of an area into zones shall be clearly indicated by signs at the entrance*.

Question 2.3 Where a source can give rise to external or internal exposure of members of the public, are there governmental or regulatory requirements in place to ensure that the provisions of paragraph 3.129 (a) - (b) and 3.130 (a) - (b) are complied with?

Response:

Nuclear safety

Requirement 601 of the Guide YVL C.1 states that during a nuclear facility's construction and operating licence phases, STUK reviews from the Preliminary and Final Safety Analysis Reports as well as the separate topical reports submitted with them the fulfilment of requirements concerning design requirements and radiation safety aspects in the systems design.

According to requirement 504 of the Guide YVL C.2, *In industrial radiography, the zone classification in the nuclear power plant's uncategorised area complies with STUK's guideline regarding industrial*

radiography. In the controlled area, industrial radiography induced radiation beams shall be taken into account by using unambiguous warning signs and access restrictions.

Requirement 508 of the Guide YVL C.2 requires that rooms *where a 40-hour weekly stay can cause an internal dose in excess of 1 mSv per year due to radionuclides originating from a nuclear facility shall be defined as a controlled area*. Therefore, they are not accessible to members of the public.

Radiation safety

The undertaking must limit public exposure described in SätL section 126 by taking care of in-service radiation safety of radiation sources and the facilities and places where they are used; preventing radioactive substances from spreading outside the facility and place where the practice is engaged in and more widely to the environment with adequate efficiency; and restricting members of the public from accessing the facility and place where the practice is engaged in, if necessary. The protective shielding and the practice must be planned and implemented in such a way that there is no need to carry out measures to ensure the radiation safety of members of the public in the surrounding areas of the facility and place under the supervision and control of the undertaking.

The use of radiation requires a safety licence. The basic requirements for safety licence and its granting are given in SätL section 48. Section 51 of SätL list main requirements for licence application.

The detailed requirements for safety licence application are given in VnA Annex 5.

The application shall for example include to the quality and extend of the practice:

- *1.4 technical specifications which show that the facility where the radiation sources are used and stored meet the in-service safety requirements set by the Radiation and Nuclear Safety Authority.*
- *1.5 pictures and drawings of the areas and premises of the location where the practice is engaged in (including scale), which indicate the purpose of the areas and premises, the locations of the radiation sources, controlled and supervised areas, structural protections, including information on materials, passageways and the location of warning systems, fixed radiation control meters and access control points.*

The requirements for amending a safety licence are given in SätL section 52.

STUK amends the conditions for a safety licence subsequent to its granting if material changes in the circumstances and special reasons due to them require the conditions to be changed for the sake of ensuring safety.

A substantial change to a practice requires prior amendment of the safety licence. In addition, STUK must be notified of any other changes to a practice subject to a safety licence.

Further provisions on changes to practices subject to an amendment of the safety licence or a notification are given by government decree.

The details on changes that require prior amending of a safety licence are given in VNa section 25. Changes that shall be reported to Radiation and Nuclear Safety Authority within two weeks are given in section 26

The SätL's sections 66 subsection 1 establishes the basic requirements for undertakings regarding in-service radiation safety: *The undertaking shall ensure that a radiation source, the facility and place where it is used and stored, and the equipment and devices related to it are such that the radiation source can be used safely.*

More detailed requirements for in-service radiation safety are given in regulation STUK S/5/2019 Radiation and Nuclear Safety Authority regulation on the in-service radiation safety of radiation sources.

Section 4 Protective shielding of premises where radiation sources are used and stored

Premises where radiation sources are used and stored shall be planned and implemented in such a way that the exposure caused to employees and the public is as small as possible, when reasonable actions are implemented, and that the dose caused does not exceed the dose constraint applicable to the place where the radiation source is used and stored.

The type of use of the radiation source and the use of premises surrounding the place where the source is used and stored shall be taken into account in protective shielding.

The adequacy of radiation shielding shall be re-evaluated if:

1) the radiation source changes or additional sources are added;

2) the type of use of the radiation source changes;

3) the use of premises surrounding the place where the source is used and stored changes in a way that might increase the exposure in work or public exposure.

The adequacy of radiation shielding shall be ensured by means of radiation measurements or other reliable methods after the shielding has been constructed or changed.

Section 5 Activation

The planning and implementation of premises for neutron sources and accelerators shall take into account the possible activation of structures, systems and other materials:

1) for occupational and public exposure;

2) the decommissioning of the premises and the quality, quantity and disposal of the radioactive waste generated.

Section 6 Structural solutions

In premises where radiation sources are used and stored, structural solutions shall be used which allow the organization of activities in such a way that:

1) potential exposure and its likelihood are as low as practically possible and the exposure does not exceed the limit for potential exposure;

2) a radiation safety incident can be controlled

3) after radiation safety incident:

a. radiation sources can be brought into a controlled state for the safety of employees and members of the public;

b. radiation sources and the premises of use can be brought into a safe situation allowing further use or processing;

c. the premises can be cleaned of any radioactive substances that have spread in them.

Inherent safety features as well as systems and equipment which set into a status beneficial for safety in case of an error shall be used primarily.

Section 7 Safety and alarm systems

Safety and alarm systems shall be placed in the place where radiation is used, in the space outside it, the control room, the control panel and the control device as appropriate, such as:

1) emergency buttons which end the generation of radiation when pressed;

2) safety switches which prevent the generation of radiation if the door or similar to the place of use is used or someone enters a specific area when the appliance is on;

3) acknowledging switches used to ensure that no one stays in the space where radiation is used before the radiation appliance is started;

4) alarm lights or some other method of detecting when the radiation appliance is in operation and when it is generating radiation.

When particle accelerators are used for isotope production and research, also safety, warning and measurement systems shall be used for releases, dose rate and pressure in the place of use and in order to ensure the safe status of the target, transmission line and hot cell.

The space where a high-activity sealed source and a particle accelerator are used shall be equipped with a warning light or other method referred to section 1, subsection 4, which is independent of the control system of the radiation source.

When the safety system referred to in subsection 1 has prevented the generation of radiation, operation may only be continued from the control unit or operating unit.

Section 11 Special requirements in relation to contamination

When unsealed sources are used and in other activities involving the risk of contamination, solutions shall be implemented in the spaces where radiation sources are used and stored which allow the organization of activities in such a way that during normal operation and in case of a radiation safety incident:

1) contamination can be removed from surfaces as easily as possible;

2) spreading of radioactive substances to indoor air in the place of use and to the other premises of the building can be restricted effectively;

3) releases of radioactive substances to the environment can be restricted effectively;

4) transfer of contamination outside the place of use with the employees can be restricted effectively;

5) waste generated in the operations can be processed safely.

Question 3 Does the regulatory body require relevant parties to ensure that all discharges of radioactive material to the environment are managed in accordance with the authorization?

Answer: Yes

Response:

General

Nuclear safety

Nuclear Energy Act (990/1987) sets a requirement that (7 c §) limit values for releases of radioactive substances from a nuclear facility shall be approved by the Radiation and Nuclear Safety Authority in such a way that dose constraints laid down by government decree are not exceeded. Monitoring of releases of radioactive substances shall be organised in such a way that compliance with the limit values can be reliably demonstrated.

According to requirement 606 of YVL C.3, STUK will oversee the radioactive releases and radiation levels in the environment by observing the release measurements, the dose analyses derived from these results and the environmental radiation monitoring performed by the licensee as provided in the Guides YVL C.3, YVL C.4 and C.7. The oversight of the release measurements and environmental radiation monitoring by STUK will be carried out by checking the measurement results reported to STUK as provided in Guide YVL A.9. STUK also controls the release measurements and environmental radiation monitoring by inspecting any repairs and modifications to the radiation monitoring systems and equipment, and by auditing the steps taken by the licensee to ensure reliable measurements. The actions of the licensee are assessed by means of inspections specified in the periodic inspection programme and, where necessary, by means of other on-site inspections.

STUK shall, to the extent necessary, monitor and oversee the environment of a nuclear facility to verify the reliability of measurements of radioactive releases and to ascertain the environmental impact of the facility. Detailed authority monitoring program is described in STUK's internal guide VALO 3.3.

Radiation safety

SätL section 51 requires safety licence application to cover the arrangements for managing the waste and discharges containing radioactive substances generated by the practice during its operations and when discontinuing the practice. Undertaking must attach a safety assessment to the safety licence application and estimate in safety assessment the doses from discharges and radioactive waste to public. Undertaking must keep record of discharges as set in SätL section 127. More detailed orders are given in STUK S/2/2019 section 6.

SätL section 128 stipulates that if public exposure must be monitored due to discharges, the undertaking shall, prior to the commencement of the activity, carry out a baseline environmental radioactivity study.

The basic requirements for discharges and their limit values in radiation practices are given in SätL section 127. For NORM-involving industries, information about discharges needs to be presented in the required exposure assessment (SätL section 146, STUK S/3/2019 section 3). If the limit for minor discharges would be exceeded, the industry needs to limit discharges and provide evidence of effectiveness of measures. If the discharges exceed the limit for minor discharge, the industry has to apply for a license and becomes regulated in the same way as radiation practices (described in the previous paragraphs).

If discharges from radiation practices exceed limits for minor discharges, undertaking must seek for authorization from STUK (SätL section 127). The undertaking has to draw up a plan for the discharges and assess the exposure caused by the discharges. The undertaking must every three months, always by the end of the month following each quarter, provide STUK with information on the discharges. This must contain the nuclide-specific quantities and temporal variation of the discharges. (STUK S/2/2019 section 8).

Question 3.1 How is it ensured that applications to the regulatory body for authorization to make discharges comply with the requirements of paragraph 3.132 (a) – (e) of GSR Part 3?

Response:

Nuclear safety

According to requirement 304 of YVL C.3 *in the preliminary and final safety analysis reports of the nuclear facility pursuant to Guide YVL A.1, the applicant and licensee shall present an analysis of the radioactive releases and radiation exposure of the population arising from the normal operation of and anticipated operational occurrences and accidents in the facility.*

Chapter 5 of the Guide YVL C.4 sets requirements for radiation dose assessment to the representative person, including requirements concerning exposure pathways considered.

Section 24(2)(6) of the Nuclear Energy Decree states that for each nuclear facility project, the application for a decision-in-principle from the Government shall be enclosed with *an environmental impact assessment report drawn up according to the Act on the Environmental Impact Assessment Procedure (252/2017).* A description of the effects of the nuclear facility on the environment must also accompany an application for a construction licence, as required under section 32(1)(7) of the Nuclear Energy Decree.

Radiation safety

According to SätL section 127 subsection 2 STUK may authorize a discharge exceeding the limit value for a minor discharge if there is an absolute need for the discharge despite limiting measures and the

undertaking has drawn up a plan for the discharges and their monitoring, and assessed the exposure caused by the discharges. Additionally SätL section 127 subsection 4, the undertaking must regularly provide STUK with information on authorized discharges and on their monitoring.The SätL section 128 stipulates that in practices subject to a safety licence, the undertaking shall monitor public exposure based on regular assessments and, if necessary, measurements in the event that the public exposure is greater than one-third of the dose constraint applicable to the practice in question despite the measures limiting radiation exposure. If public exposure must be monitored due to discharges, the undertaking shall, prior to the commencement of the activity, carry out a baseline environmental radioactivity study, in which radiation measurements and determinations of radioactive substances determine the preoperational environmental radioactivity status.

For practices that are subject to a safety license, a safety assessment is required for authorization. SätL section 26 stipulates that the undertaking shall carry out safety assessment concerning radiation practice, which:

1) identifies ways in which the practice can cause radiation exposure, considering any possible radiation safety deviations;

2) assesses the magnitude of the occupational, public and medical exposure arising from the practices as well as the probability and magnitude of the potential exposure;

3) presents measures to ensure radiation safety and the optimization of radiation protection;

4) presents measures to prevent and prepare for identified radiation safety deviations;

5) presents the categorization of the radiation practice.

Section 25 of SätL stipulates that the undertaking shall establish dose constraints and constraints potential exposure. STUK S/6/2019 sections 8 and 9 give additional requirements for dose constraints for public exposure:

STUK S/6/2019 Section 8 Dose constraints for public exposure

The dose constraint for public exposure is 0.1 mSv. However, the dose constraint may be greater than this if it is shown to be justified in the safety assessments, excluding the situations referred to in section 9.

Section 9 Dose constraints for public exposure resulting from discharges and waste

The dose constraint for public exposure resulting from discharges and waste in radiation practices may not be greater than 0.1 mSv:

1) in discharges of radioactive substances to the sewerage system, waterways or the air;

2) in the reuse, recycling, utilization, or disposal of waste containing radioactive substances.

More detailed requirements regarding assessment of radiation exposure are given section 15 of S/6/2019. These requirements include obligations for the undertaking to determine the characteristics and activity of the material to be discharged, significant exposure pathways and requirement to assess the doses from the radioactive waste and discharges to the representative person.

S/6/2019, section 15, Assessing radiation exposure

The safety assessment concerning radiation practices must present the following per worker and population group:

1) radionuclides, radiation types, radiation energies, and exposure pathways;

2) the key structural solutions and operational arrangements by which radiation exposure is limited; furthermore, in terms of these solutions and arrangements:

a) the estimated radiation dose and its key assessment criteria;

b) the number of persons exposed;

c) the applicable dose constraint and its selection criteria.

Public exposure must be assessed in terms of a representative person as referred to in the Radiation and Nuclear Safety Authority Regulation on Radioactive Waste and Discharges of Radioactive Substances in the Use of Unsealed Sources (STUK S/2/2019).

STUK S/2/2019 section 7 (unsealed sources) and STUK S/3/2019 section 8 (natural radiation) stipulate that for authorized discharges the plan concerning their monitoring shall include:

The plan concerning the discharges of radioactive substances referred to in section 127, subsection 2 of the Radiation Act must detail:

1) the grounds for the necessity the discharge;

2) a proposal on the dose constraint to be applied to the exposure caused to members of the public by the discharges, grounds included;

3) procedures for monitoring the discharges and the exposure caused to members of the public by the discharges;

4) a proposal on the limit values for the discharges.

For authorized practices the activities of discharged materials and exposure pathways are required in the safety assessment (STUK S/6/2019 section 15), but points and methods of discharge and characteristics of discharged materials are not specifically included as listed in paragraph 3.132 a).

Question 4 Does the regulatory body require that relevant parties ensure that programmes for source and environmental monitoring are in place and that the results are recorded and made available?

Answer: Yes

Response:

Nuclear Energy Act, Section 7c states that *Monitoring of releases of radioactive substances shall be organised in such a way that compliance with the limit values referred to in this section can be reliably demonstrated.*

The Radiation and Nuclear Safety Authority Regulation on the Safety of a Nuclear Power Plant (STUK Y/1/2018) presents the general safety provisions for nuclear power plants, and Section 24 of the regulation presents the requirements for radiation measurements and monitoring of releases of radioactive substances and assessment of radiation doses to the public. Section 24 also includes requirement that radiation doses and the releases from a nuclear facility and concentrations of radioactive substances in the environment shall be reported to the Radiation and Nuclear Safety Authority. Chapter 3 of this regulation includes the requirements for radiation exposure and releases of radioactive substances. Regulation STUK Y/4/2018 presents the provisions concerning the safety of disposal of nuclear waste, which also apply to separate processing and storage facilities for nuclear waste that are not a part of a nuclear power plant.

Requirements for the source monitoring programs are given in YVL C.3. Section 5 of YVL C.3 gives the requirements for release measurements. These requirements include monitoring during normal operations (YVL C.3 section 5.2) and abnormal releases ((YVL C.3 section 5.3).

Regulatory oversight of source monitoring program is discussed In YVL C.3 Section 6. The regulatory oversight includes review of the plans during the application for a decision-in-principle. During the construction of a nuclear facility, STUK will assess and verify that the systems necessary for limiting and monitoring of releases of radioactive substances are implemented in compliance with the plans and designs presented to STUK. During the operation of the nuclear facility, STUK will oversee the radioactive releases and radiation levels in the environment by observing the release measurements, the dose analyses derived from these results and the environmental radiation monitoring performed by the licensee. STUK will continue to oversee the monitoring of radioactive releases from the nuclear facility throughout the decommissioning of the facility.

Requirements for the Assessment of radiation doses to the public in the vicinity of a nuclear facility are given in YVL C.4. Section 6 of YVL C.4 give requirements what document shall be submitted to STUK regarding dose assessment and section 7 discusses how regulatory oversight shall take place.

Requirements for Radiological monitoring of the environment of a nuclear facility are given in YVL C.7. Chapter 3 gives the requirements for environmental baseline study and chapter 4 requirements for environmental radiation surveillance. Chapter 5 gives requirements for reporting the results of environmental monitoring. Chapter 6 of YVL C.7 gives requirements for the applicant or licensee what documents on the contents of the monitoring programs shall be submitted to STUK for review and approval. Regulatory oversight and approval of the environmental monitoring programs and their results is discussed in chapter 7.

Licensee reporting requirements are discussed in addition to beforementioned YVL C.3, YVL C.4 and YVL C.7 in YVL A.9. Contents and reporting period for Environmental radiation safety reports is given in Chapter 3.4. Regulatory oversight of the reports is discussed in Chapter 4 of YVL A.9.

STUK publishes a summary of the results of licensee’s source and environmental monitoring and public dose assessments in its yearly reports (Regulatory oversight of nuclear safety in Finland : Annual report 2020; Monitoring of radioactivity in the environment of Finnish nuclear power plants : Annual report 2020). Licensee’s full reports are available per request as stipulated in 621/1999 Act on the Openness of Government Activities.

According to SätL section 127, the licensee must provide regular information about the monitoring of authorized discharges from radiation practices to the regulator. According to regulations STUK S/3/2019 section 9 and STUK S/2/2019 section 8 the report about monitoring of discharges must be done quarterly and it must contain the nuclide specific information about total quantities and also temporal variations.

For authorized discharges from both unsealed sources (STUK S/2/2019 section 9) and natural radiation (STUK S/3/2019 section 11), the monitoring of public exposure must take into account external and internal exposure and the exposure from radionuclides that are accumulated in the environment in long-term operations. The monitoring of public exposure must be planned and performed regularly so that short-term and long-term changes to public exposure are identified. The monitoring of public exposure must be done in a way that allows comparison to the results of radiological environmental baseline survey results.

Question 4.1 How does the regulatory body ensure the provision for an independent monitoring programme; for assessment of public exposure due to authorized sources and practises; for maintaining records of discharges; and for verification of compliance?

Response:

Provisions for an independent monitoring program around nuclear facilities are given in Nuclear Energy Act, § 7 c, stating that *The Radiation and Nuclear Safety Authority shall, to the extent necessary, monitor and oversee the environment of a nuclear facility to verify the reliability of measurements of radioactive releases and to ascertain the environmental impact of the facility*.

YVL C.7 states that (requirement 707) STUK will perform independent regulatory monitoring in the environment of the nuclear facility during the operation of the nuclear facility by taking and analysing samples from the environment of the nuclear facility to a necessary extent.

STUK's internal guide VALO 3.3 describes the independent monitoring program around nuclear power plants. The results of the independent monitoring program are made public in annual reports (Monitoring of radioactivity in the environment of Finnish nuclear power plants : Annual report 2020).

Responsibilities for national level radiation monitoring program are given in SätL 14 § according to which STUK acts as the institute responsible for executing the environmental monitoring programs set

in EURATOM article 35. Also according to SätL 14 § STUK is responsible for setting up and running a monitoring program that monitors the radioactive substances in the environment and determines radiation doses to the population.

Assessment of the total public exposure due to authorized sources and practices in Finland on the basis of monitoring data provided by registrants and licensees and with the use of data from independent monitoring and assessments is done in regular intervals and the results are published. The average effective total annual dose to the Finnish population from all sources is estimated in the STUK publication STUK-A263 Suomalaisten keskimääräinen efektiivinen annos vuonna 2018 (The average effective dose received by Finns 2018).

Records of discharges as reported by the licensees, results of monitoring programs of the licensees and results of assessments of public exposure are stored in regulatory authority's electronic document data base, in physical document library and in published yearly reports. The quarterly and annual reports of radioactive releases and environmental monitoring are subject to requirement 305 of YVL A.9:*The licensee shall store the measurement results based on which the reports have been drafted for a minimum of ten years. The reports shall be stored until the facility has been decommissioned.* Regulatory authority's own environmental monitoring program data and results are stored in laboratory databases and in published yearly reports.

YVL C.4, Chapter 7 gives requirements for Regulatory oversight by the Radiation and Nuclear Safety Authority for the control of public exposure:

- STUK issues a statement on the environmental impact programme and report for a new nuclear facility. The statement focuses attention on radioactive releases caused by the nuclear facility and radiation exposure to the population during operation and in the event of an accident.
- STUK compiles a preliminary safety assessment for the nuclear facility's application for a decision-in-principle; it assesses the safety analyses for the proposed plant option, including the analysis of the environmental radiation doses caused by the worst case scenario accident.
- STUK inspects the plans for meteorological measurements on site and close to the plant when processing the construction licence application for a nuclear power plant. When processing the operating licence application, STUK checks the documents relating to the meteorological measuring system for the plant as part of the final safety analysis report. For this, STUK may use the expertise of other authorities, such as the Finnish Meteorological Institute and the Finnish Environment Institute.
- STUK assesses the reports on the area's meteorological conditions, the mesoclimate and water areas in connection with the checking of the preliminary and final safety analysis reports. For this, STUK may also use the expertise of other authorities.
- STUK assesses the analyses of the dispersion of radioactive substances and the doses they give rise to in connection with the checking of the preliminary and final safety analysis reports.

- During its supervision of the construction and operation of the nuclear facility, STUK inspects the functionality of the dispersion and dose calculation methods intended for accident conditions and their maintenance at the plant site.
- During its supervision of the nuclear power plant's operation, STUK inspects the use and maintenance of the weather measurement system at the plant site.
- STUK inspects the validity of the dispersion and dose analyses during the periodic safety assessment of the nuclear power plant.

According to SätL section 176, once a mining authority has granted an exploration permit referred to in section 9 of the Mining Act for the location and exploration of a deposit containing uranium or thorium, STUK shall have the right to monitor and supervise the exploration area and its environment to the extent necessary so as to ensure radiation safety. STUK is furthermore entitled to necessary observing and supervision when some other mining mineral is being excavated and processed pursuant to the mining permit referred to in section 16 of the Mining Act, and the practice has or may have an effect on the environment's radiation safety.

Question 4.2 Does the regulatory body publish or make available results of source and environmental monitoring programmes and assessments of doses from public exposure?

Response:

Nuclear power plant licensee's source monitoring results are presented in yearly reports "Regulatory oversight of nuclear safety in Finland". The results of authority's independent monitoring program together with comparisons with licensee's own source and environmental monitoring program results are published in yearly reports "Monitoring of radioactivity in the environment of Finnish nuclear power plants".

Results of national environmental monitoring conducted by STUK are made available in real time on STUK's public web pages stuk.fi and in yearly reports "Environmental Radiation Monitoring in Finland". Dose rate monitoring network data and airborne radioactivity monitoring data is available through Open Data portal and these data are made available through Commission's EURDEP portal and for Council of the Baltic Sea States members.

Assessment of the total public exposure due to authorized sources and practices in Finland on the basis of monitoring data provided by registrants and licensees and with the use of data from independent monitoring and assessments is done in regular intervals and the results are published. The determination of the average annual radiation dose to Finns is discussed in STUK publication STUK-A263 Suomalaisten keskimääräinen efektiivinen annos vuonna 2018 (The average effective dose received by Finns 2018).

Question 4.3 How does the regulatory body ensure that registrants and licensees comply with requirements of para. 3.137 (a) -(h) of GSR Part 3?

Response:

Nuclear safety

Section 7c of the Nuclear Act states that *monitoring of releases of radioactive substances shall be organised in such a way that compliance with the limit values referred to in this section can be reliably demonstrated.*

Section 24 of the Regulation STUK Y/1/2018 states that *the releases of radioactive substances from the nuclear facility shall be monitored and their concentrations in the environment shall be measured.*

The detailed requirements for the radiological monitoring of the environment of a nuclear facility are presented in YVL C.7. The requirements for the quarterly and annual reporting are presents in requirements 501 – 503 and for the abnormal situations in requirements 414 – 416 of the YVL C.7.

Requirements concerning radiation dose assessments are presented in regulations 501 – 545 of the YVL C4.

Radiation Safety

The undertaking shall assess the exposure from their practice to the member of the public in the safety assessment. The basic requirements for safety assessment are in SätL section 26:

In practices subject to a safety licence, the undertaking shall carry out a safety assessment concerning the radiation practice, which:

1) identifies ways in which the practice can cause radiation exposure, considering any possible radiation safety deviations;

2) assesses the magnitude of the occupational, public and medical exposure arising from the practices as well as the probability and magnitude of the potential exposure;

3) presents measures to ensure radiation safety and the optimization of radiation protection;

4) presents measures to prevent and prepare for identified radiation safety deviations;

5) presents the categorization of the radiation practice.

The safety assessment shall be prepared in writing and kept up to date.

STUK confirms the safety assessment either as part of granting the safety licence or separately.

STUK issues more detailed regulations on the content and preparation of the safety assessment.

Detailed regulations on the assessing radiation exposure are given in STUK S/6/2019 section 15.

The safety assessment concerning radiation practices must present the following per worker and population group:

1) radionuclides, radiation types, radiation energies, and exposure pathways;

2) the key structural solutions and operational arrangements by which radiation exposure is limited; furthermore, in terms of these solutions and arrangements:

a. the estimated radiation dose and its key assessment criteria;

b. the number of persons exposed;

c. the applicable dose constraint and its selection criteria.

Public exposure must be assessed in terms of a representative person as referred to in the Radiation and Nuclear Safety Authority Regulation on Radioactive Waste and Discharges of Radioactive Substances in the Use of Unsealed Sources (STUK S/2/2019).

Adequacy of safety assessment is verified during the authorization for new safety license and during the amendment of safety licence.

For practices subject to a safety license the requirements for monitoring public exposure are given in SätL section 128.

In practices subject to a safety licence, the undertaking shall monitor public exposure based on regular assessments and, if necessary, measurements in the event that the public exposure is greater than one-third of the dose constraint applicable to the practice in question despite the measures limiting radiation exposure.

If public exposure must be monitored due to discharges, the undertaking shall, prior to the commencement of the activity, carry out a baseline environmental radioactivity study, in which radiation measurements and determinations of radioactive substances determine the preoperational environmental radioactivity status.

STUK issues more detailed regulations of a technical nature on the arrangement of the monitoring referred to in subsection 1 and the performance of the baseline environmental radioactivity study.

For practices where are discharges from the use of unsealed sources the monitoring of public exposure shall comply STUK S/3/2019. This requirement is given at STUK S/2/2019 Section 9:

The monitoring of public exposure resulting from the discharges must comply with the provisions in the Radiation and Nuclear Safety Authority Regulation on Practices that Cause Exposure to Natural Radiation S/3/2019.

Requirements for monitoring of public exposure from natural radiation are given in STUK S/3/2019 Section 11.

SätL section 127 gives requirements for undertaking regarding discharges and limit values:

The undertaking must limit the discharges of radioactive substances to the environment and the sewerage system to the absolute minimum. In any event, the amount of the discharge may not exceed the limit value for a minor discharge. A record must be kept of the discharges.

STUK may nevertheless authorize a discharge exceeding the limit value for a minor discharge if there is an absolute need for the discharge despite limiting measures and the undertaking has drawn up a plan for the discharges and assessed the exposure caused by the discharges.

STUK sets limit values for the discharge referred to in subsection 2 in such a way that the public exposure is as low as possible, accounting for the nature and extent of the practice and the means available for limiting discharges, and that the anticipated amount of exposure caused by the discharges is lower than dose constraint.

The undertaking must regularly provide STUK with information on the discharges referred to in the authorization granted by virtue of subsection 2 and on their monitoring.

The secretions of patients who have received a radioactive substance in medical use of radiation are not subject to subsection 1 and 2.

STUK issues more detailed regulations on the general limit values of minor discharges and more detailed technical regulations on the plan concerning discharges and their monitoring, discharge monitoring and record keeping and the delivery of the information for the purpose of implementing European Union legislation.

More detailed regulations for discharges are given in regulations S/2/2019 sections 4, 6-8 and in S/3/2019 sections 7-9.

Requirements for record keeping from discharges from unsealed sources are given in STUK S/2/2019, Section 4, subsection 3:

Records must be kept of the discharge of radioactive substances to be able to demonstrate compliance with the discharge limit values and so that the information referred to in section 8 can be determined.

Section 7 Limit values for minor discharges

The limit values for minor discharges of radioactive substances into the sewerage system as referred to in section 127, subsection 1 of the SätL are:

1) the activity of the waste delivered at any one time from a single place of use is, at maximum, equal to the exemption value or, if different radionuclides are discharged, their activities meet condition 1 of the Annex;

2) the activity of the waste delivered during a month from a single place of use is, at maximum, 10 times the exemption value or, if different radionuclides are discharged, their activities meet condition 2 of the Annex.

The limit value for a minor discharge in the effective dose received by members of the public from a discharge of radioactive substances into the open air is 10 µSv a year. The undertaking must determine the dose as the calculated dose received by the representative person as a result of measured or otherwise reliably determined discharges.

Section 8 Discharges and the plan concerning their monitoring

The plan concerning the discharges of radioactive substances referred to in section 127, subsection 2 of the SätL must detail:

1) the grounds for the necessity the discharge;

2) a proposal on the dose constraint to be applied to the exposure caused to members of the public by the discharges, grounds included;

3) procedures for monitoring the discharges and the exposure caused to members of the public by the discharges;

4) a proposal on the limit values for the discharges.

Section 9 Provision of information concerning discharges and their monitoring

The Radiation and Nuclear Safety Authority must be provided with the following information on the discharges of radioactive substances referred to in section 127, subsection 2 of the SätL every three months, always by the end of the month following each quarter:

1) the nuclide-specific quantities of the discharges;

2) the temporal variation of the discharges.

STUK shall be notified of radiation safety deviations where significant increase in dose rate or concentrations of radionuclides in environment that is attributed to authorized practice. The requirement for reporting is stipulated in SätL 130 subsetion 2:

The undertaking responsible for the radiation safety deviation and the authority which becomes aware of the radiation safety deviation shall immediately notify STUK of:

1) the radiation safety deviation due to which the radiation safety of the workers or members of the public at the facility and place where the radiation is used or its surroundings may be compromised;

…

4) any significant spreading of a radioactive substance indoors or in the environment;

5) any other abnormal observations and information which may be of material significance in terms of radiation safety.

More detailed requirements of the notification to STUK about radiation safety deviation are stipulated in STUK S/2/2018 section 5.

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Based on STUK S/3/2019 section 11, the monitoring of public exposure must take into account external and internal exposure and the exposure from radionuclides that are accumulated in the environment in long-term operations. The monitoring of public exposure must be planned and performed regularly so that short-term and long-term changes to public exposure are identified. The monitoring of public exposure must be done in a way that allows comparison to the results of radiological environmental baseline survey results.

For the sections 7-11 of STUK S/3/2019, the regulator will demand any missing information and can check the validity of information through inspections, if needed.

According to SätL Section 126, authorized practices need to plan for radiation safety measures and operate in a way that does not require actions in the environment to ensure radiation safety of the public. Therefore, environmental monitoring is not required from authorized practices unless they have authorized discharges to the environment.

SätL Section 23 requires that the undertaking has necessary capability for to prevent and to mitigate all radiation safety deviations:

The undertaking shall implement the organization of the practice in such a way that the practice meets the requirements provided in this Act and that radiation safety deviations are prevented with adequate effectiveness and that their consequences are as insignificant as possible. The undertaking shall implement such measures to improve radiation safety as can be considered justified in terms of their quality and costs as well as their improving impact.

Also, SätL Section 26 requires that the undertaking carries out safety assessment in which they present measures to ensure radiation safety and the optimization of radiation protection and present measures to prevent and prepare for identified radiation safety deviations.

More requirements for preparedness for radiation safety deviations are given in SätL Section 129.

The undertaking shall provide the regulatory body a safety assessment where they among other things, assess the doses from the practice to members of the public. When inspector reviews safety assessment they shall also review the adequacy of the assumptions made for the assessment of public exposure.

STUK publishes results from source monitoring and environmental monitoring programmes and assessments of doses from public exposure. Environmental radiation monitoring results are published as yearly reports and monitoring data is also available on stuk.fi web pages.

If someone requests documents which are not already in the published reports (if any), The Act on the Openness of Government Activities (621/1999) states on section 1:

Official documents shall be in the public domain, unless specifically provided otherwise in this Act or another Act.

Question 5 Are providers of consumer products required to ensure that consumer products are not made available to the public unless their use by members of the public has been justified, and either their use has been exempted or their provision to the public has been authorized?

Answer: Yes

Response:

RADIATION SAFETY

Prohibitions for the use of radioactive substances

SätL Section 68 sets prohibitions for the use of radioactive substances (in consumer goods):

Section 68 Prohibitions of use a radioactive substance may not be used deliberately in:

1) foodstuffs as referred to in the Food Act;

2) animal feed as referred to in the Feed Act;

3) cosmetic products as referred to in Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products;

4) jewellery and other equivalent personal accessories;

5) toys as referred to in the Toy Safety Act (1154/2011);

6) in the tracer tests carried out in water supply systems the water of which is used as household water.

Products falling under the scope of the aforementioned prohibition specified in subsection 1 may not be imported, exported or transferred. What is provided with regard to radioactive substances in subsection 1 and 2 also applies to practices in which the increase of radioactivity derives from the activation of consumer goods or the material used in manufacture of the consumer goods.

The exemption values of radioactive substances and radioactive materials are not applicable to consumer products. The requirement is laid down in STUK SY/1/2018 section 1.

Requirements for consumer good regarding manufacture, import, export an transfer are set in section 69 of SätL:

The deliberate mixing or adding of a radioactive substance to consumer goods other than those specified in section 68 and the import, export and transfer of such consumer goods to Finland is subject to a safety licence.

STUK notifies the competent authorities of other Member States of the European Union of the reception of an application pursuant to subsection 1. Said authorities will also be informed of the decision made and the basis for the decision, should the Member State in question make a request to this end.

What is provided with regard to radioactive substances in subsection 1 also applies to practices in which the increase of radioactivity derives from the activation of consumer goods or the material used in the manufacture of the consumer goods.

Authorization and exemption of consumer goods

Provision of consumer products requires authorization. The use of consumer goods require authorization if they are not exempted from it. All use of radiation requires a justification. Principle of justification is given in SätL Section 5:

Radiation practices and protective actions are justified if the overall benefits achieved exceed the detriment caused (principle of justification).

The specific requirements of justification of consumer good are written in VnA (1034/2018) Section 6.

The justification assessment concerning the manufacture, import and shipment of consumer goods causing exposure to ionizing radiation must include a review of:

1) the applicability of the consumer goods' characteristics and performance for the intended use.

2) the consumer goods' structure and technical properties with which the radiation exposure and potential exposure attributable to the goods can be minimized in conventional use and in any possible misuse.

3) the need for a safety license concerning the use of the consumer goods and a possible exemption from a safety licence;

4) the consumer goods' compliance with requirements.

5) the need for a requirement for rendering any radioactive waste attributable to the consumer goods harmless.

6) the appropriateness of the consumer goods' markings.

7) information and instructions to be provided to the consumer on the consumer goods' safe and appropriate use and on rendering radioactive waste harmless.

Consumer products are exempted from safety licence if … *9) they meet the criteria for an exemption from a safety licence pursuant to section 50, subsection 1 (SätL Section 49).*

Further provisions on practices exempt from a safety licence as referred to in subsection 1, paragraph 9 are given by government decree.

STUK issues more detailed regulations for the implementation of European Union legislation in terms of the insignificant amount of radioactivity (exemption).

The list of exempted practices is given by VnA Section 27.

Under section 49, subsection 1, paragraph 9 of the SätL, a safety licence is not required for:

1. *the use, manufacture, trade, installation, possession, safekeeping, import, shipment or storage of an appliance which produces ionizing radiation electrically, provided that the appliance operates with a maximum voltage of 30 kilovolts and does not cause, within a ten centimeter distance of the appliance's accessible surfaces, a greater dose rate than one microsieverts per hour.*
2. *the use of fire alarms and smoke detectors containing radioactive americium-241 isotope in the purpose they have been designed for or their resale and use or the possession, retention, storage, installation, maintenance or repair related to their use and resale; new fire alarms may nevertheless contain a maximum of 40 kilobecqurels of the americium-241 isotope.*
3. *for the use of a sealed source with radiation safety properties meant for educational use and contains a maximum of 40 kilobecquerels of the americium-241, strontium-90 or cesium-137 isotope as a teaching aid in schools, vocational schools and comparable institutions, provided that the educational institution has appointed a person in charge of radiation safety;*
4. *the use of lamps and igniters containing a maximum equal to the exemption value of a radioactive substance in the purpose they have been designed for or their resale and use or the possession, retention, storage, installation, maintenance or repair related to their use and resale.*

The detailed conditions for exemption for safety licence are given in VnA Section 28

The practice is safe in principle as referred to in section 50, subsection 1, paragraph 3 of the SätL if the workers do not need to be categorized as radiation workers and the effective dose of a member of the public is at most, excluding unlikely radiation safety incidents, of the magnitude of:

1. *10 microsieverts a year from artificial radioactive substances;*
2. *1 millisieverts a year from nature's radioactive materials.*

The effective dose to a member of the public in improbable radiation safety incidents may not exceed 1 millisieverts a year in a practice referred to in subsection 1, paragraph 1.

An assessment of a dose deriving from nature's radioactive materials accounts for the practice's addition to the dose deriving from the existing local background radiation.

Consumer products and radiation practice in general can be exempted from safety licence under a decision by the Radiation and Nuclear Safety Authority if full fills the requirements set in SätL Section 50:

STUK may exempt radiation practices other than those referred to chapter 13 or 14 from a safety licence, if exemption is the most appropriate alternative and:

1. *the radiation exposure and potential exposure caused the practice is insignificant enough not cause a health detriment;*
2. *the practice has been demonstrated to be justified;*
3. *the practice is inherently safe.*

The decision may include conditions necessary for ensuring safety.

The decision may be withdrawn if the prerequisites for exemption are not met or if the conditions for exemption have not been complied with and the deficiencies are not remedied within a prescribed period of time despite a request to do so.

Further provisions on the prerequisites for exemption from a safety licence are given by government decree for the purpose of implementing European Union legislation.

STUK grants authorization for consumer products to the public if the application for safety licence includes is justified (SätL Section 5) as stipulated in VnA Section 6, the application includes safety assessment and other information as listed in

SätL section 51 and in VnA Annex 5.

VnA Section 6, *Justification for consumer goods*

The justification assessment concerning the manufacture, import and shipment of consumer goods causing exposure to ionizing radiation must include a review of:

1. *the applicability of the consumer goods' characteristics and performance for the intended use;*
2. *the consumer goods' structure and technical properties with which the radiation exposure and potential exposure attributable to the goods can be minimized in conventional use and in any possible misuse;*
3. *the need for a safety license concerning the use of the consumer goods and a possible exemption from a safety licence;*
4. *the consumer goods' compliance with requirements;*
5. *the need for a requirement for rendering any radioactive waste attributable to the consumer goods harmless;*
6. *the appropriateness of the consumer goods' markings;*
7. *information and instructions to be provided to the consumer on the consumer goods' safe and appropriate use and on rendering radioactive waste harmless*

Authorization is granted if the application fulfills the requirements set for safety licence and its granting (SätL section 48). During the authorization the application is also review and assessed to see if consumer products could be exempted form safety licence. Requirements for exemption from safety license under the decision of STUK are given in SätL section 50.

Demonstration of product's radiation safety and assessment of radiation safety

Requirements for the undertaking regarding demonstration of a product's radiation safety are given in SätL section 56:

The undertaking which manufactures, imports, brings to the market, offers, keeps for sale, sells or otherwise hands over radiation sources or accessories and other products related to the safety of a radiation practice (product) shall be able to demonstrate that the product is safe.

Assessment of product's radiation safety shall be done according to the requirements set in section 58 of SätL.

The regulatory authority assesses the radiation safety of a product referred to in section 56 pursuant to the applicable product safety legislation or according to standards referred to in the Official Journal of the European Union.

In addition, the assessment of a product's radiation safety must pay attention to the following:

1. *international or national standards pertaining to product safety other than those mentioned in subsection 1;*
2. *any recommendations of the European Commission which contain instructions concerning the assessment of radiation safety;*
3. *the guidance and recommendations issued by regulatory authorities;*
4. *the codes of conduct concerning radiation safety;*
5. *current information and technology.*

If a product cannot be assessed in the manner referred to in subsection 1, the regulatory authority may assess the product's radiation safety according to what is provided in subsection 2. Furthermore, even if a product accords with the bases used for the assessment of a product's safety specified in subsection 1 and 2, the regulatory authority may pursue an action pursuant to chapter 3 of the Act on the Market Surveillance of Certain Products if the product nevertheless poses a risk to health.

Providers (the undertaking) of consumer goods is are responsible for radiation safety and this responsibility cannot be transferred to another (SätL section 22). Plan for appropriate arrangements for the servicing, maintenance, recycling or disposal of consumer goods are reviewed and assess and accepted in part of the authorization. Consumer goods review and assessment for authorization shall be according to the requirements set in VnA section 6. The justification of VnA section 6 further clarifies the requirements.

VnA Section 6, *Justification for consumer goods*

The justification assessment concerning the manufacture, import and shipment of consumer goods causing exposure to ionizing radiation must include a review of:

1. *the applicability of the consumer goods' characteristics and performance for the intended use;*
2. *the consumer goods' structure and technical properties with which the radiation exposure and potential exposure attributable to the goods can be minimized in conventional use and in any possible misuse;*
3. *the need for a safety license concerning the use of the consumer goods and a possible exemption from a safety licence;*
4. *the consumer goods' compliance with requirements;*
5. *the need for a requirement for rendering any radioactive waste attributable to the consumer goods harmless;*
6. *the appropriateness of the consumer goods' markings;*
7. *information and instructions to be provided to the consumer on the consumer goods' safe and appropriate use and on rendering radioactive waste harmless*

Justification of VnA Section 6

1. *The eligibility of a consumer product must be based on its fitness for its intended use, for example, a device intended as a smoke detector detects smoke and gives an appropriate alarm.*
2. *Possible misuse includes, for example, disconnecting a source of radiation in a consumer product and using it for other purposes.*
3. *It does not make sense that the use of a consumer product should require a safety authorisation. The starting point should therefore be that the use of the consumer product is safe enough to meet the conditions for exemption from control and can therefore be exempted from a safety authorisation.*
4. *Conformity refers both to the requirements for the radiation safety of a product under the Radiation Act and to the requirements laid down elsewhere in the Act for different types of consumer products, such as the ability of a smoke detector to detect and alarm against smoke.*
5. *For some categories of consumer products, there are systematic arrangements for the disposal of radioactive substances in discarded consumer products as part of organised recycling. This is the case, for example, for smoke detectors, where the raw materials are treated as electronic waste, a process which also includes the collection of radiation sources and their disposal as radioactive waste. Consumer products which are not covered by such arrangements and for which the disposal of the radioactive source as radioactive waste is the responsibility of the consumer are not considered eligible. In the event that the responsibility remains with the consumer, the quantity of radioactive material in the consumer product must be so small that it does not impose any constraints on the re-use, recycling, recovery or disposal of the products concerned.*
6. *Where radioactive material is present in consumer products, it shall be appropriately labelled on the consumer product.*
7. *Where radioactive material is present in a consumer product, this must be adequately disclosed in the instructions for the product, which must also include information on how the radioactive material is to be taken into account in the disposal of the consumer product.*

If the requirements or conditions of the authorization are not complied with, STUK will take appropriate enforcement actions (which are described in Module 9).

Question 5.1 How is it ensured that the design and manufacture of consumer products are subject to optimization of protection and safety?

Response:

The principle of optimization is set in SätL section 6 and it also applies to consumer products. SätL section 56 sets the requirement that the undertaking shall be able to demonstrate that the product is safe.

The undertaking which manufactures, imports, brings to the market, offers, keeps for sale, sells or otherwise hands over radiation sources or accessories and other products related to the safety of a radiation practice (product) shall be able to demonstrate that the product is safe.

Additionally, design and manufacture of consumer goods needs to be optimized for protection and safety for consumer goods to be justified. These criteria are stipulated in VnA section 6 and further clarified in justification of VnA section 6. Fulfilment of requirements for optimization are reviewed and assessed in safety assessment.

VnA Section 6, *Justification for consumer goods*

The justification assessment concerning the manufacture, import and shipment of consumer goods causing exposure to ionizing radiation must include a review of:

1. *the applicability of the consumer goods' characteristics and performance for the intended use;*
2. *the consumer goods' structure and technical properties with which the radiation exposure and potential exposure attributable to the goods can be minimized in conventional use and in any possible misuse;*
3. *the need for a safety license concerning the use of the consumer goods and a possible exemption from a safety licence;*
4. *the consumer goods' compliance with requirements;*
5. *the need for a requirement for rendering any radioactive waste attributable to the consumer goods harmless;*
6. *he appropriateness of the consumer goods' markings;*
7. *information and instructions to be provided to the consumer on the consumer goods' safe and appropriate use and on rendering radioactive waste harmless*

Justification of VnA Section 6

1. *The eligibility of a consumer product must be based on its fitness for its intended use, for example, a device intended as a smoke detector detects smoke and gives an appropriate alarm.*
2. *Possible misuse includes, for example, disconnecting a source of radiation in a consumer product and using it for other purposes.*
3. *It does not make sense that the use of a consumer product should require a safety authorisation. The starting point should therefore be that the use of the consumer product is safe enough to meet the conditions for exemption from control and can therefore be exempted from a safety authorisation.*
4. *Conformity refers both to the requirements for the radiation safety of a product under the Radiation Act and to the requirements laid down elsewhere in the Act for different types of consumer products, such as the ability of a smoke detector to detect and alarm against smoke.*
5. *For some categories of consumer products, there are systematic arrangements for the disposal of radioactive substances in discarded consumer products as part of organised recycling. This is the case, for example, for smoke detectors, where the raw materials are treated as electronic waste, a process which also includes the collection of radiation sources and their disposal as radioactive waste. Consumer products which are not covered by such arrangements and for which the disposal of the radioactive source as radioactive waste is the responsibility of the consumer are not considered eligible. In the event that the responsibility remains with the consumer, the quantity of radioactive material in the consumer product must be so small that it does not impose any constraints on the re-use, recycling, recovery or disposal of the products concerned.*
6. *Where radioactive material is present in consumer products, it shall be appropriately labelled on the consumer product.*
7. *Where radioactive material is present in a consumer product, this must be adequately disclosed in the instructions for the product, which must also include information on how the radioactive material is to be taken into account in the disposal of the consumer product.*

Question 5.2 How is it ensured that providers of consumer products ensure that consumer products are labelled, and clear and appropriate information and instructions are provided with each consumer product?

Response:

Markings on consumer products

For all radiation sources subject to safety licence it is required by SätL 66 that the radiation source is marked with a sign of a radiation hazard if this is technically possible. In addition, the source shield or source container or storage shield of a radiation source containing a radioactive substance must have a label including the key information of the radioactive substance it contains and a marking indicating radiation hazard. Additionally, in SätL section 66 subsection 3 it is stipulated that marking with radiation hazard is required for other radiation sources (e.g. consumer goods) if safe use requires this.

All consumer products shall fulfil obligations stipulated in Consumer Protection Act 22.7.2011/920 (Kuluttajaturvallisuuslaki). The Consumer Protection Act is applied to consumer goods which are manufactured, marketed, sold, or otherwise disposed of, imported, exported, transported through Finland or transmitted through Finland.

Regarding information and instructions Consumer Protection Act Section 9 requires:

Operators must provide consumers and persons treated as consumers with the necessary information in a clear and comprehensible way to enable them to assess the risks associated with consumer goods and services. The supervisory authority may require the operator to provide consumers, in an appropriate manner, with instructions, warnings or other information necessary to prevent or avoid the risk associated with the goods or services.

More detailed provisions on the provision of information necessary for consumers or persons treated as consumers concerning consumer goods and services may be laid down by a government decree.

Consumer Protection Act Section 12 requires that: A consumer product that does not bear the CE marking required by law may not be placed on the market.

Information and instructions on consumer products

SätL Section 73 sets obligation for manufacture or importer to provide information

When handing over a radiation source generating ionizing radiation, the manufacturer or importer shall provide the recipient with detailed information on the structure of the source and its properties having an impact on safety together with the source. A sealed source is also subject to a certificate demonstrating compliance with regulations.

The undertaking handing over a radiation source generating ionizing radiation to another is obligated to provide the recipient, in connection to the handing over, with any information and certificate and other information relevant to radiation safety in its possession, received from the manufacturer or importer as referred to in subsection 1.

Question 6 Has the government identified any existing exposure situations in the country that are of concern from the point of view of radiation protection?

Answer: Yes

Response:

Existing exposure situations are defined in SätL to be all exposure situations which are not emergency exposure situations or radiation practices (Sätl uses term radiation practices instead of planned exposure situations). Thus, there are many possible different types of existing exposure situations in Finland. They can be divided into two main types: situations where something has gone wrong or natural background radiation is unusually high (SätL Chapter 17), and on-going mainly commercial activities (SätL Chapter 18).

SätL Chapter 17 includes:

- Situations where exposure is caused by past activities which have not been regulated or regulated to lesser standards than today (e.g. mining waste from old mining activities)
- Emergency situations which have changed into existing exposures (e.g. nuclear accident fallout in the long term)
- Situations where the responsible operator cannot be identified in activities which would require licensing (e.g. contamination caused by orphaned sources where the owner is not found)
- Natural radioactivity in cases other than specified in SätL Chapter 18 (e.g. high background radiation areas)
- Consumer products resulting from radioactivity in the four cases above, excluding foodstuffs, animal feed, drinking water and construction products

SätL Chapter 18 includes:

- radon in workplaces, including underground
- radon in dwellings and public buildings
- constructions products
- NORM-involving industries
- aviation
- drinking water

According to SätL section 13, the MSAH has supreme authority and highest directing power in supervising compliance with the SätL. According to SätL section 14, STUK supervises compliance with the SätL, unless otherwise provided elsewhere. Furthermore, STUK prepares and implements an environmental radiation monitoring programme representing all members of the public to monitor the amounts of radioactive substances in the environment and the magnitude of the public exposure resulting from them.

Based on SätL section 15, a municipality's health protection authority supervises compliance with the reference levels of the radioactivity in household water and the radon concentration in dwellings and other premises used by people.

In ME coordinated KAJAK-project, Centre for Economic Development, Transport and the Environment is identifying, monitoring and remediating old mining sites based on chemical risks. STUK is involved as an expert on natural radiation and is making sure radiation aspects of old mining sites are considered. If existing exposure situations are identified, they are handled according to SätL Chapter 17.

According to SätL section 142 the MSAH draws up a national action plan for identifying existing exposure situations (of the SätL Chapter 17 -type) and for the implementation of the measured referred to in the plan. The national action plan shall set out the procedures and responsible parties for identifying the situations referred above. STUK will finalize a proposal on national action plan of identification of existing exposure situations for the MSAH during 2022 (KAVATTU-project).

VnA 1034/2018 section 49 defines the situations potentially causing exposure which should be included in the national action plan for existing exposure situations:

1) discontinued activities that have not been under regulatory control or that have not been regulated as similar practices at the time of preparation of the plan;

2) radiation emergency situations from which a transition to existing exposure situation has been made;

3) activities for which the responsible undertaking cannot be identified;

4) radioactive substances in nature in situations other than those provided for in Chapter 18 of the SätL;

5) radioactive substances, other than foodstuffs, feed, household water and construction products, released into the consumer products from the situations referred to 1) - 4).

Commercial activities involving NORM (SätL sections 145, 146, 151) are also existing exposure situations in Finland. Several industries (mining and milling, metallurgy, metal recycling, groundwater

treatment, abrasive minerals, pigment production) have been found to contain NORM. Thus far the exposure assessments have shown that either limiting measures are not required, or the limiting measures according to SätL section 147 are enough to keep effective doses below the reference levels. However, all industries have not yet delivered their exposure assessments and the regulator is continuing sending requests for missing data.

The undertaking from whose practice an existing exposure situation arises is responsible for investigating the radiation exposure arising from it and for carrying out the protective actions and for cleaning the areas, facilities and structures used in the practice, and the environment, of radioactive substances (SätL section 138).

If the undertaking is not identified or fails to fulfill its duty, and if the existing exposure situation has arisen with the consent of the holder of the area or the holder has been aware or should have been aware of the state of the area when acquiring it, the holder of the area must take care of the duty laid down in subsection 1 (previous paragraph) insofar as it is not clearly unreasonable (SätL section 138).

According to SätL section 139, the State takes care of the cleaning the areas, facilities, structures and the environment of radioactive substances to the extent that:

1) the undertaking or holder of the area does not within a reasonable period of time meet or cannot be expected to meet its duty of care specified in section 138; or

2) the undertaking responsible cannot be identified.

SätL section 139 stipulates that STUK assesses the radiation exposure arising from the existing exposure situation and determines the required measures, should there be a reason to suspect exposure higher than the reference level. Valvira draws up a plan on the measures and the provision of guidance for individuals living or working in the area. Unless otherwise determined by the principle of justification, Valvira may decide that the existing exposure situation does not require measures (SätL section 139).

It is set in SätL section 139 that Valvira draws up a plan on the measures and the provision of guidance for individuals living or working in the area. VnA 1034/2018 section 50 stipulates that the plan should include:

1) the objectives of the plan;

2) the areas and groups of people affected by the existing exposure situation;

3) the applicable reference levels referred to in SätL section 140;

4) the selected protection measures, optimised in terms of their implementation, scope and duration;

5) measures to provide individual and regional advice on the management of radiation exposure;

6) actions to provide advice and information to the exposed population on the potential health hazards and on the means available to reduce and monitor their own exposure;

7) the responsibilities for the measures and procedures for mutual coordination.

NORM-involving industries (SätL sections 145, 146, 151) are also existing exposure situations in Finland. For these industries, the responsibility of exposure assessment and limitation of doses is with the industry where NORM is formed, used, handled, stored or disposed (SätL sections 146, 147). If licensing is required (SätL section 148), industries are regulated as use of radiation.

According to SätL section 140 the aim in existing exposure situations is to carry out the protective actions in such a way that occupational and public exposure remain below the set reference level. The reference levels for existing exposure situations are set in STMA 1044/2018 chapter 5 and 6.

STMA 1044/2018 section 17 sets the reference level for population exposure in existing exposure situations other than commercial activities causing exposure to natural radiation which are listed in SätL Chapter 18. The reference level of effective dose for the population cannot be more than 10 mSv/y. The reference level can be less than 1 mSv/y if it refers to a significant area or other route or associated route of exposure. The reference level may not be less than 0.1 mSv/y if reaching it requires unjustifiably large or costly operations. As the radiation exposure decreases, the exposure reference level for the population must be reduced if a further reduction in radiation exposure is reasonably possible (STMA 1044/2018 section 17).

The reference level for occupational exposure in NORM-involving industries is 1 mSv/y for natural radiation other than radon or cosmic radiation (STMA 1044/2018 section 23). Exposure is defined as the addition of the effective dose compared to natural background radiation. The reference level for the exposure of the public to radiation from natural radiation other than radon or cosmic radiation is 0.1 mSv/y (STMA 1044/2018 section 26). Exposure is defined as the addition of the effective dose to the effective dose due to natural background radiation. This reference level does not apply to the exposure

of the public from natural radionuclides in a construction product. There are separate reference levels for construction products (STMA 1044/2018 section 24).

The legal and regulatory framework including provisions for management of existing exposure situations are presented in SätL chapter 17, VnA 1034/2018 chapter 10, and STMA 1044/2018 chapter 5. SätL section 141 stipulates that the prerequisite for protective actions in an existing exposure situation is a safety licence, if the radiation dose arising from occupational exposure is higher than the reference level referred to in SätL section 140.

For NORM-involving industries, the provisions for management come from SätL sections 145-149, 151 and 177-178. Industries are required to provide characterization and exposure assessment of NORM, limitation of exposure (if needed) and licensing (if needed). The regulator can demand the assessment, and in the case of non-compliance and risk of exposure, corrective actions and limitation or interruption of activities can be legally enforced.

Where the exposure situation involves naturally occurring radioactive substances that are not controlled as part of an activity requiring a safety licence, the plan shall also include measures to provide guidance and information on appropriate methods for monitoring activity levels and exposure and on protective actions.

Information on the potential health risks of exposure to existing situations and on the means for the individuals to reduce their exposure and the associated health risks is available in STUK www-pages.

Question 7 Has the government made provisions in its framework for protection and safety to identify those persons or organizations responsible for remediation of areas with residual radioactive material?

Answer: Yes

Response:

(see also response to the primary question 13 /occupational exposure)

The undertaking from whose practice an existing exposure situation arises is responsible for investigating the radiation exposure arising from it and for carrying out the protective actions and for cleaning the areas, facilities and structures used in the practice, and the environment, of radioactive

substances (SätL section 138). Provisions on the cleaning of areas, facilities and structures used in the practice are laid down in SätL section 83.

If the undertaking is not identified or fails to fulfil its duty, and if the existing exposure situation has arisen with the consent of the holder of the area or the holder has been aware or should have been aware of the state of the area when acquiring it, the holder of the area must take care of the duty laid down in subsection 1 (previous paragraph) insofar as it is not clearly unreasonable (SätL section 138).

According to SätL section 139, the State takes care of the cleaning the areas, facilities, structures and the environment of radioactive substances to the extent that:

1) the undertaking or holder of the area does not within a reasonable period of time meet or cannot be expected to meet its duty of care specified in section 138; or

2) the undertaking responsible cannot be identified.

In these cases, STUK assesses the radiation exposure arising from the existing exposure situation and determines the required measures, should there be a reason to suspect exposure higher than the reference level (SätL section 139). The National Supervisory Authority for Welfare and Health (VALVIRA) draws up a plan on the measures and the provision of guidance for individuals living or working in the area (SätL section 139). Unless otherwise determined by the principle of justification, VALVIRA may decide that the existing exposure situation does not require measures. Further provisions on the supervision of the measures pursuant to the plan are laid down separately.

The undertaking is obligated to compensate for any necessary costs incurred by the State due to the measures referred to in SätL section 139. SätL section 190 contains provisions on the charging of such costs. The costs are compensated for primarily with the furnishing security referred to in SätL section 54.

According to SätL section 54 the undertaking shall furnish a security for the costs arising from rendering radioactive waste harmless and any possible environmental clean-up measures if the licence is granted for: … 4) a practice which generates or may generate radioactive waste, or the waste specified in section 78, subsection 3 (NORM-waste), provided that the costs arising from rendering it harmless are substantial. However, a security need not be furnished if the practice concerns a radioactive substance with a shorter half-life than 150 days. The practice may not be commenced

before the security has been furnished. The State, a municipality or a joint municipal authority is not required to furnish a security.

VnA 1034/2018 section 29 stipulates that a security furnish shall be lodged for the activities referred to in SätL section 54, if the costs of decontamination of radioactive waste, measures necessary for radiation safety in waste management referred to in SätL section 78, subsection 3 (NORM-waste) or necessary environmental clean-up measures are estimated to exceed EUR 100,000.

Question 8 Does the government framework for protection and safety ensure a strategy for radioactive waste management is put in place to deal with any waste arising from the remedial actions?

Answer: Yes

Response:

First national programme for the management of spent nuclear fuel and radioactive waste in Finland was drawn up 2015. National programme is currently being updated, due by year 2021. National programme is based on Nuclear Energy Act (990/1987) and Radiation Act (859/2018). The national programme for the management of spent nuclear fuel and radioactive waste in Finland is drawn up as a single entity. It is drawn up jointly with the Ministry of Economic Affairs and Employment (MEAE), the Ministry of Social Affairs and Health and STUK.

The national programme is a plan to ensure that all spent nuclear fuel and radioactive waste generated in Finland is managed safely. The national programme sets out the general objectives, principles, estimated costs, quantities, locations and timetable for the management of spent fuel and radioactive waste. For waste arising from remedial actions shall be kept free storage space in the government-owned storage facility for radioactive waste. It shall be determined in advance with what funding the disposal of waste will be carried out. This type of waste is not generated on a regular basis and the quantities generated are not expected to be large. SätL Section 87 describes the National waste management policy and program as follows:

The Ministry of Social Affairs and Health draws up, in cooperation with STUK, a national programme for the waste management of radioactive waste outlining the general goals and principles of the waste management of radioactive waste as well as the amounts and locations of the waste, and an estimate of the costs and schedules of the waste management. When the programme is being drawn up, the public must be reserved a chance to express their opinion. The Ministry of Social Affairs and Health announces the commencement of the programme's preparation. The programme must be kept up to date. Further provisions on the programme are given by government decree.

Respectively YEL section 27 b describes the National waste management policy and program as follows:

A national nuclear waste management programme shall be drawn up of the national nuclear waste management policy and the management of spent nuclear fuel, presenting the general goals and principles of nuclear waste management, the amounts of nuclear waste, their sites as well as an estimate of the costs and schedule of nuclear waste management.

The national nuclear waste management programme shall be drawn up by the Ministry of Economic Affairs and Employment together with the Radiation and Nuclear Safety Authority. When drafting the programme, the public shall be reserved an opportunity to express their opinions. The Ministry of Economic Affairs and Employment shall publicise the start of the programme drafting.

The national nuclear waste management programme shall be updated on the basis of the assessments referred to in section 54a. Further provisions on the contents of the national nuclear waste management programme may be given by a government decree.

Question 9 Does the government make provisions for assigning responsibilities to the persons responsible for the planning, implementation and verification of remedial actions?

Answer: Yes

Response:

In VnA 1034/2018 section 50 it is states that the remediation plan shall include

1) goals of the plan

2) areas and groups of people affected

3) applied reference values

4) protective actions whose implementation and duration are optimized (considering e.g. other societal impacts)

5) how affected population is given advice on implementing protective actions

6) responsible parties and coordination

In VnA 1034/2018 section 51 implementation and review of the plan is discussed.

1) Responsible parties need to evaluate the effectiveness of implemented protective measures and also evaluate the needed protective actions

2) Evaluate the doses to the public and workers resulting from the implementation of the remediation plan

3) consider the need for additional protective actions to optimize remediation options and to reduce possible doses exceeding reference values

Valvira is responsible for verification of the implementation of the protective plan. A system for maintaining adequate records relating to the existing exposure situation and to actions taken for protection and safety is achieved through considering these factors when approving the remediation plan. Valvira has its internal procedures in place for record keeping.

The designation of responsibilities for planning and implementing remediation, including drawing up a remediation plan in accordance with SätL Section 139, is explained under Question 7.

Occupational exposure is in focus in the remedial action and the reference value for it is 1 mSv per year (STMA 1044/2018 section 16). SätL section 140 on reference levels in existing exposure situations stipulates that the aim in existing exposure situations is to carry out the protective actions in such a way that occupational and public exposure remain below the set reference level. The party having the work carried out shall immediately inform the workers involved of any exposure greater than the reference level. The setting of the reference levels must account for the principles of radiation protection and acceptability in terms of society. STUK confirms the reference levels for members of the public in an existing exposure situation. The prerequisite for protective actions in an existing exposure situation is a safety licence, if the radiation dose arising from occupational exposure is higher than the reference level (SätL section 141). SätL section 48 stipulated the safety licence and its granting. A safety licence is granted by STUK provided that the radiation practice complies with the principles of justification, optimization and limitation. The licence may include conditions necessary for ensuring safety. In addition, all the obligations of the undertaking/operator and the licensee under the SätL apply, such as the monitoring of exposure conditions and the obligation to report any radiation safety deviation.

Question 10 Has the government assigned responsibilities for review and establishing criteria for remedial actions to the regulatory body, or other relevant authority?

Answer: Yes

Response:

Section 26 of SätL covers the safety assessment concerning radiation practices. It stipulates that in practices subject to a safety licence, the undertaking shall carry out a safety assessment concerning the radiation practice, which: 1) identifies ways in which the practice can cause radiation exposure, considering any possible radiation safety deviations; 2) assesses the magnitude of the occupational, public and medical exposure arising from the practices as well as the probability and magnitude of the potential exposure; 3) presents measures to ensure radiation safety and the optimization of radiation protection; 4) presents measures to prevent and prepare for identified radiation safety deviations; 5) presents the categorization of the radiation practice. The safety assessment shall be prepared in writing and kept up to date. STUK confirms the safety assessment either as part of granting the safety licence or separately. STUK issues more detailed regulations on the content and preparation of the safety assessment.

It is stated in SätL section 138 that, if the undertaking is not identified or fails to fulfill its duty, and if the existing exposure situation has arisen with the consent of the holder of the area or the holder has been aware or should have been aware of the state of the area when acquiring it, the holder of the area must take care of the unless the responsibility is clearly unreasonable.

As stated in SätL section 138, provisions on the cleaning of areas, facilities and structures used in the practice are laid down in section 83 of SätL. The cleaning of the environment is subject to the reference levels referred to in section 140 of SätL. In SätL 140 $ it is stated that responsibilities for review and establishing criteria for remedial actions in existing exposure situation lie in the Ministry of Health and Social affairs.

Question 11 Has responsibilities for remedial actions been assigned to the person or organization responsible for carrying out the remedial action?

Answer: Yes

Response:

Please see answers to questions 7, 9 and 10.

According to SätL 22 §, the remedial actions referred to in this question are described in the safety license for remedial actions and in its evaluation. The responsibility for taking remedial actions falls to the safety license holder and these responsibilities cannot be transferred elsewhere.

Question 12 Does the regulatory body or other relevant authority take actions after the remedial actions have completed to review the work, identify responsibilities for post-remediation measures, impose restrictions, and review conditions in the remediation area?

Answer: Yes

Response:

According to VnA 1034/2018 section 51 The parties responsible for the execution of the plan referred to in VnA 1034/2018 section 50, must, in terms of their own areas of responsibility:

1) regularly evaluate the protective measures available for the achievement of the objectives and assess the effectiveness of planned and executed measures;

2) assess the radiation dose distribution of workers and members of the public resulting from the plan's execution in co-operation with the Radiation and Nuclear Safety Authority;

3) consider possible additional measures for the optimization of protection and for the reduction of any radiation exposures greater than reference values.

The National Supervisory Authority for Welfare and Health monitors the execution referred to in subsection 1 and reviews the plan if necessary.

According to SätL 139 National Supervisory Authority for Welfare and Health has the right to decide that the existing situation no longer warrants action.

Question 13 Does the regulatory body ensure that the person or organization responsible for post-remediation control measures establish and maintain, for as long as required by the regulatory body or other relevant authority, an appropriate programme, including any necessary provision for monitoring, to verify the long term effectiveness of the completed remedial actions for areas in which controls are required after remediation?

Answer: Yes

Response:

See answer to the question 12.

Also, SätL section 138 defines that the undertaking from whose practice an existing exposure situation arises is responsible for assessing the radiation exposure arising from it and for carrying out the protective actions and for cleaning the areas, facilities and structures used in the practice, and the environment, of radioactive substances. STUK will give more detailed instruction on how the assessment shall be performed.

Question 14 Has the government, in consultation with interested parties, ensured that arrangements are in place, as necessary, for the continuing control of exposure with the aim of establishing conditions for sustainable living?

Answer: Yes

Response:

SätL §139 states that The National Supervisory Authority for Welfare and Health draws up a *plan on the measures* and the provision of guidance for individuals living or working in an affected area.

In VnA 1034/2018, § 51 it is stated that the parties responsible for the execution of the *Plan on measures in an existing exposure situation* referred to in VnA 1034/2018, § 50, must, in terms of their own areas of responsibility:

1) regularly evaluate the protective measures available for the achievement of the objectives and assess the effectiveness of planned and executed measures;

2) assess the radiation dose distribution of workers and members of the public resulting from the plan's execution in co-operation with the Radiation and Nuclear Safety Authority;

3) consider possible additional measures for the optimization of protection and for the reduction of any radiation exposures greater than reference values.

The National Supervisory Authority for Welfare and Health monitors the execution referred to in subsection 1 and reviews the plan if necessary.

SätL § 140 states that in existing exposure situations, the setting of the reference levels must account for the principles of radiation protection and acceptability in terms of society. STUK confirms the reference levels for members of the public in an existing exposure situation. Also, VnA 1034/2018, §

45 states that during an emergency exposure situation, the reference level of members of the public must be reduced as soon as possible in terms of the situation.

VnA 1034/2018, § 50, 5) and 6), state that *Plan on measures in an existing exposure situation* shall detail measures for the provision of advice on radiation exposure management to individuals and regionally and measures for the provision of instructions and information to exposed members of the public on the possible detriments to health and the means available for the reduction and monitoring of their own exposure.

See the response to the PQ 10.

Question 15 Are there provisions in the regulations to ensure that the conditions prevailing after the completion of remedial actions, if the regulatory body or other relevant authority has imposed no restrictions or controls, shall be considered to constitute the background conditions for any new facilities and activities or for habitation on the land.

Answer: Yes

Response:

See the response to the PQ 10.

According to SätL section 139 National Supervisory Authority for Welfare and Health has the right to decide that existing exposure situation no longer warrants remedial actions. These new existing conditions would constitute the radiological background situation for new facilities and activities.

Question 16 Does the Government (through the regulatory body or other relevant authority) provide information on exposure due to radon and the associated health risks, including the increased risks due to smoking?

Answer: Yes

Response:

STUK, Valvira and ME have prepared information on exposure due to radon and the associated health risks, including increased health risks due to smoking in their www-pages. The information is actively provided to members of the public and other interested parties (schools, workplaces, central organizations, etc). STUK publishes free radon e-newsletter several times a year.

According to SätL section 19, STUK maintains a register on the radon concentrations in dwellings, other premises used by people and workplaces. Between years 2014 and 2020 there were approximately 42 700 radon measurements done in 28 400 dwellings. The radon database is slightly biased since more measurements are carried out in the areas known to have high radon concentrations. Radon concentrations only reported by STUK's laboratory are recorded and an unknown number of radon measurements by other radon laboratories is missing from the database.

From the most visited/popular www-pages of STUK (https://www.stuk.fi/aiheet/radon/radon-suomessa/pientaloasuntojen-radonpitoisuudet-suomen-kunnissa) more detailed areal information on radon concentrations in dwellings is available. Also national database containing statistical information on welfare and health in Finland https://sotkanet.fi/sotkanet/en/index includes indoor radon statistics.

Radon maps are presented in: Radon Suomessa kunnittain: https://www.stuk.fi/aiheet/radon/radon-suomessa/suomen-radonkartat/radon-suomessa-kunnittain.

The representative estimate of average radon concentration of Finland is based on a nationwide random sample survey carried out in 2006 (Mäkeläinen et al. 2009). The most recent estimate of the average population-based radon concentration in homes is 96 Bq/m^3 (in Siiskonen 2020). STUK reassessed the effective doses in Finland using the new radon dose conversion factors issued by the ICRP. The range of radon levels in dwellings in Finland is 10 – 40 000 Bq/m^3. By far the largest amount of ionizing radiation that Finns are exposed to comes from radon, and the home is the place where people are most exposed to radiation. The average effective radiation dose received by Finns is 5.9 millisieverts (mSv). Two-thirds of the radiation dose, 4 mSv, comes from indoor air radon.

It has been estimated that radon in homes is associated with about 300 lung cancer cases annually in Finland (Mäkeläinen 2010). However, this estimate will be updated in an epidemiological study conducted by STUK and University of Tampere. The manuscript (Auvinen, Kojo, Holmgren, Pätsi, et al.) was submitted in 2021.

Question 17 Where the radon levels are of concern for public health, has the Government (through the regulatory body or other relevant authority) established an action plan to control public exposure due to radon indoors?

Answer: Yes

Response:

National Radon Action Plan (NRAP)

Based on the requirements in the BSS and SätL, the national radon action plan (NRAP) to control exposure to radon indoors was drawn up and published in 2020. NRAP is included in SätL section 159 and VnA 1034/2018 section 54.

According to SätL section 5, radiation practices and protective actions are justified if the overall benefits achieved exceed the detriment caused (principle of justification). The principle of justification applies to protection actions in radon exposure situations. In principle, protection actions are always justified when the radon exposure or activity concentration is higher than the reference level.

The steering committee of NRAP includes representatives of MSAH (chair and the responsible body), ME, Valvira, regional health protection authority, regional occupational health authority, the Association of Finnish Local and Regional Authorities, local construction supervision, and STUK (coordinator, secretariat).

All the members in the steering committee of NRAP are responsible for dedicated aspects related to radon safety. The responsibilities are also indicated in the NRAP.

At the moment, the steering committee of NRAP is fixed termed until the end of 2021. However, the intention is to make a permanent working group of radon authorities which will continue to coordinate the implementation of the NRAP.

A country-wide strategy for communication to increase public awareness of radon levels and the associated health risk is included in the NRAP and the detailed annual plan has been drafted by STUK. The aim is that all radon authorities are involved in increasing radon risk communication.

NRAP was published in 2020 and implementation of the recommendations in it has been followed ever since. The direct impact on lung cancer reduction is not possible to see due to differences in smoking habits in different parts of the country. Instead other indicators to be followed have been suggested in NRAP:

Main objectives	Approaches (control responsibility[1])	Indicators
Reducing the number of cases of lung cancer caused by radon	Radon exposure in dwellings and other premises used by people (HPA) and workplaces (STUK) will be reduced. In addition, reducing smoking will contribute to the achievement of the target (Valvira, MSAH).	The extent of radon exposure and prevalence of smoking among the population and employees and related development.
Reducing radon exposure	Those undertaking construction projects will take into account radon risks in the design and construction solutions for new buildings subject to a permit (building control). Those undertaking construction projects take into account radon safety and carry out the necessary radon mitigation efforts in connection with renovation and remodelling subject to a building permit implemented due to other reasons (building control). It is essential that those undertaking construction projects are aware of the radon-related risks and hire designers and a contractor with awareness of radon. It is also key that, in connection with the permit process, the building control monitors that the risks related to radon have been appropriately taken into account in the project as part of the safety of construction to the extent required by e.g. construction safety. The owner/holder of the building will take measures to limit radon exposure if the reference levels found in dwellings and other areas exceed the reference values (HPA). The employer limits radon exposure at workplaces if radon concentrations exceeding the reference levels (STUK) have been found at the workplace. The responsible authority will provide advice and, if necessary, oblige the owner, holder or employer of the building to restrict the exposure.	Radon concentrations in new and existing buildings and the number and efficiency of radon mitigation.
Raising awareness of radon concentrations in indoor air	Residents of residential buildings or owners or holders of buildings will measure radon levels in single-family houses and dwellings on the lowest floors of blocks of flats across the country. HPA and STUK will provide more information about the need for measurements in residential buildings using the approaches mentioned in the risk awareness section. Employers or other parties responsible for premises measure radon concentrations at workplaces and other premises used by people as required by the SätL (STUK, OSH, HPA). Results of the radon measurements are comprehensively recorded in the national database (STUK, MSAH, OSH, HPA). The authorities have sufficient technical systems and the related viewing and access rights, technical interfaces and statutory rights. The supervisory authorities will be provided with adequate mutual access and disclosure rights and rights to receive data gathered in radon measurements from various agents (MSAH).	Impact metrics on radon control in construction, housing, other indoor areas and workplace. Number, representativeness and usefulness of radon measurements recorded in the national radon database.
Raising radon risk awareness	HPA, Valvira, STUK, OSH, MSAH, building control supervision and the Association of Finnish Local and Regional Authorities engage in effective and influential communications and training for various target groups. If necessary, instructions, guides or other material will be prepared to support the achievement of the target.	Results of radon risk awareness surveys.

[1] building control = municipal building control authority, MSAH Ministry of Social Affairs and Health, STUK =Radiation and Nuclear Safety Authority, HPA = municipal health protection authority, OSH = areas of responsibility of occupational safety and health, Valvira = National Supervisory Authority for Welfare and Health

In addition to the main objectives shown above, NRAP lists several recommended actions which should be taken in order to reduce radon risks. The actions are followed-up in the steering committee of NRAP several times a year.

NRAP should be updated every 5 years by the Ministry of Social Affairs and Health.

The National Radon Database and sample surveys on radon

Measurements of radon in dwellings done in STUK's laboratory are included in the national radon database. According to SätL section 19, STUK maintains the register on the radon concentrations in dwellings. STUK prepares radon maps and other interesting data, e.g. trends on radon concentrations in dwellings in STUK's annual reports. The radon database can be examined in www-pages described in the Primary Question 16.

Representative population sample surveys were conducted in Finland in 1991 and 2006 (Mäkeläinen et al. 2009). The study on radon during working hours and leisure time was carried out between 2000 and 2001 (Mäkeläinen et al. 2005). In it, radon measurements were carried out at homes and workplaces. The study also involved investigating how much time Finns spend in different kinds of indoor areas. Restricted sample surveys have been carried out in the Eastern Uusimaa in 1996, and in new houses in 2009 (Arvela et al. 2010) and 2016 (Kojo et al. 2016). The latest sample survey of new buildings (Kojo et al. 2016) examined the indoor radon concentrations of new single-family houses (building permit granted in 2013). As a conclusion, the newer the building the lower the radon concentrations were. In 5.6 % of the measurements, radon concentrations exceeded the reference level for new dwellings of 200 Bq/m^3. The results of the national surveys have been reported in the national or international reports and in STUK's www-pages.

Radon measurements

Protocols for radon measurement in dwellings: measurement season (Sept. 1st -May 31st) and duration ($\geq$2 months) are stated in STMA 1044/2018 section 20. Number of measurements and other instructions are published e.g. in STUK's www-pages about radon measurements (In Finnish) https://www.stuk.fi/aiheet/radon/radonin-mittaaminen/asuntojen-radonmittaus and in Sammio.stuk.fi.

STUK has a radon dosimetry laboratory (described in Guide VALO 6.5). STUK's radon alpha tract detection measurement laboratory is accredited by Finnish Accreditation Services (FINAS) (Guide VALO 4.7). In order to assure quality control for measurements, it is stipulated in SätL section 64 that measurements of ionizing radiation (includes radon measurements) carried out to determine occupational or public exposure and ensure safety in radiation practices or an existing exposure situation shall have the approval of STUK. Requirements for radon measurements are set in STUK S/7/2021.

STUK has prepared an e-training course for experts and other interested party making radon measurements Verkkokoulutus radonmittaajille.

Reference levels

It is stated in SätL section 144 that the setting of the reference levels for natural radiation must account for the principles of radiation protection and acceptability in terms of society. The reference level for public exposure for other exposure than that arising from radon may not exceed the dose limit for members of the public. The reference levels are:

- radon concentration in houses and other buildings of high occupancy by the public: 300 Bq/m^3 (STMA 1044/2018 section 20)
- radon concentration in new buildings: 200 Bq/m^3 (STMA 1044/2018 section 21)

Lower reference levels could be unreasonable due to geological conditions, climate and type of houses in Finland.

Radon prone areas

For new buildings and dwellings, the whole Finland is radon prone area. Therefore, communications about radon in new buildings or dwellings should not use the regional risk division since radon

concentrations can exceed reference level everywhere in Finland. The previous unofficial definition of "high-radon counties", is no longer used.

However, for workplaces and other premises used by people the definition of high radon-risk areas is used, According to SätL section 155 and 156, radon concentration at workplaces and other premises used by people must be determined in high radon-risk areas and buildings (see the response to Primary Question 14/ Occupational Exposure). The reason for existence of radon prone areas in relation with workplaces and other premises used by people is due to the graded approach and the fact that in these cases, the representative authority may require the radon measurements by the SL. Regarding dwellings, the obligation to limit and mitigate radon concentration is based on section 27 of the Health Protection Act and is bound to causing a health hazard. The Health Protection Act and does not directly require performing radon measurements in dwellings. Despite this, radon measurements are recommended in certain situations.

Radon mitigation

Techniques for the control and reduction of radon in existing buildings (corrective actions) was published in STUK-A252 and it is available via STUK's webpage (https://www.stuk.fi/web/en/topics/radon/radon-mitigation).

STUK has studied and evaluated the effectiveness of the techniques (STUK-A252, Holmgren and Kurttio 2016). The most effective techniques are activation of radon piping, radon fan and radon well which reduce radon levels by more than 70 % on average.

Information is provided to public and media on radon reduction measures regularly. STUK arranges annually radon remediation workshops for public (https://www.stuk.fi/web/en/topics/radon/radon-mitigation).

No requirements for measurements of radon at the time of sale of the buildings exists, but it is recommended by Ministry of the Environment to present radon measurement results in connection with selling real property.

Under section 4 of the Decree of the Ministry of the Environment on Foundation Structures (465/2014) issued pursuant to the Land Use and Building Act, the radon risks of a construction site must be

considered in the design and construction of a building. The Design of foundation section of the Strength and stability of structures chapter of the National Building Code of Finland (Ministry of the Environment 2018) has proposed that the adverse effects on indoor air quality from radon and other gases and impurities that are detrimental to health and comfort should be prevented with structures and/or actions that are applicable to the project under design. The guideline also indicates that the impact of the structure and/or action on the indoor air radon concentration can be determined by measuring the radon concentration in the indoor air after the construction work or action is completed.

Section 5 of the Decree of the Ministry of the Environment on the Indoor Climate and Ventilation of New Buildings (1009/2017) issues that indoor air may not contain physical factors (incl. radon) hazardous to human health. Section 21 Decree of the Ministry of the Environment on Indoor Air and Ventilation of New Buildings stipulates that a specialized designer must design the external and outdoor air flows of the building in such a way that the structures do not cause long-term moisture stress that damages the structures due to overpressure or the transfer of impurities to indoor air due to negative pressure. In accordance with their tasks, the main designer, specialized designer and building designer must plan the airtightness proofing of the building envelope and internal structures and stack effect management in such a way that the preconditions for proper ventilation can be ensured and the transfer of impurities in the structures, soil impurities and radon into indoor air is avoided and the transfer of moisture to the structures prevented.

Building Information Ltd. has published guidelines for radon prevention in new construction (Rt 103123, 2019). Radon concentration of indoor air is typically low in buildings with a crawl-space construction or a monolithic slab foundation and the sealing of pipe and wiring runs in the crawl space will usually suffice as a radon prevention measure. If ground-supported floor slab is laid in the buildings, radon prevention is carried out by installing radon piping, sealing the line between the foundation wall and the slab with rubber bitumen sealant membrane and sealing any penetrations. If the radon concentration is greater than 200 Bq/m^3, the radon piping is activated connecting a peak vacuum roof fan to its exhaust duct.

No radon measurements in new buildings are required, but it is recommended by Ministry of the Environment.

Radon is included in all relevant areas of education of building professionals. This originates from the fact that radon was included in the national building code of foundations in 2004. STUK has organized annually training courses for building professionals and the training materials is available e.g. in

https://www.stuk.fi/aiheet/radon/radonkorjaukset/radonkorjauskoulutuksen-materiaalit

Verkkokoulutus radonmittaajille

https://youtu.be/RziTgOgo0D8

In Finland, no certification system for companies offering corrective actions/preventive measures exists.

Question 17.1 Is there a need to include the control of public exposure to Rn-220 in the national action plan for radon?

Response:

There is no identifiable reason why Rn-220 should be included in the monitoring of public exposure. Measurements of thoron decay products were part of regular radon monitoring in mines from the 1970s until the 1990s, when they were discontinued as unnecessary (was never relevant in terms of radiation exposure). Occupational exposure to thoron and its decay products was investigated in the 1990s by measurements in workplaces where thorium-rich NORM materials were handled or stored. Even in these workplaces, the measured thorium concentrations were so low that the results did not warrant further action. Based on these observations, it was concluded that there is no reason to believe that there is a significant presence of thoron in dwellings, where thorium-rich materials are absent.

Low Rn-220 concentrations can, hence, be expected in Finnish homes and public buildings as the radioactivity of construction materials has been under regulatory control since 1991 and materials containing substantially elevated concentration of Th-232 has not been observed. Furthermore, rammed earth tiles or soil-floors are not used in Finnish buildings and no homes exist in caves.

Question 18 Has the regulatory body (or other relevant authority) established reference levels for radionuclides in commodities, such as construction materials, food, drinking water?

Answer: Yes

Response:

STUK supervises compliance with the radioactivity of **construction products** in Finland. Construction products are controlled based on the gamma radiation they emit. The reference level for exposure to gamma radiation from construction products is 1 mSv/year. VnA 1034/2018 section 53 specified the construction products for which an examination of the radiation exposure caused by natural radiation must be performed. The manufacturer, transferor or importer of the construction product is responsible

for assessing the need to examine radioactivity, performing an examination and related measurements, and notifying the STUK of the results of the report. STMA 1044/2018 section 24 lays down the reference levels for exposure to the population caused by construction products. STUK S/3/2019 sections 12–13 provide for the investigation of the exposure of the population caused by a construction product and related notifying. The provisions concerning the investigation of radiation exposure caused by a construction product also take into account the requirements of the Construction Products Directive.

For foodstuff imported into European Union, Council Regulation No 733/2008 requires that Cs-137 shall be under 600 Bq/kg. According to Commission Recommendation 2003/274, the same value should be applied also to wild food products in the EU area. In case of a nuclear accident, commission can set limits for radioactive substances in foodstuff (Council Regulation (Euratom) 2016/52). In trade with non-EU countries, FAO and WHO Codex Alimentarius (CODEX STAN 193-1995, amended 2018) shall be followed unless national or EU regulation applies.

For animal feed, Council Regulation 2016/52 gives limits for both imported feed and feedstuff produced in EU.

MSAH has issued decrees on the quality requirements and regulatory control for household water (1352/2015, hereinafter referred to as the *Household Water Decree)* and the Decree of the Ministry of Social Affairs and Health on the quality standards and regulatory control of on domestic water quality of the small entities (401/2001). The requirements laid down in an EU Directive (2013/51/Euratom) on the maximum levels of radioactive substances in household water are included in the Household Water Decree. The quality requirements for radioactivity are presented in Appendix 1, Table 3 of the Household Water Decree.

The municipal health protection authority monitors household water that is used or delivered to a water distribution area to be used as household water, amounting to at least 10 m^3 per day or serving the needs of at least 50 people. Under the Household Water Decree, water used as part of public or commercial activities or in food premises with their own wells or other water sources is also monitored.

The Health Protection Act (763/1994) defines the health requirements on the quality of water intended for human consumption. Council Directive (98/83/EC) of the European Union on the quality of water intended for human use, namely the Drinking Water Directive and Council Directive 2013/51/EURATOM have been implemented by the Household Water Decree. National legislation sets the maximum values for radioactivity in water intended for human consumption.

Valvira directs the implementation of the Health Protection Act and the decrees adopted pursuant to it at national level. Regional State Administrative Agencies (AVI) guide and supervise health protection in their areas of territories. Under the Health Protection Act, the surveillance of the quality of drinking water consists of self-surveillance of the operator and surveillance by the authorities. Planned surveillance by the authorities includes a plant-specific surveillance programme for surveillance of the quality of drinking water and a municipal surveillance plan defining the frequency of surveillance for inspections relating to the infrastructure, premises and operations of the plant. The municipal health protection authority shall issue the necessary orders to ensure the quality of domestic water meets the requirements of the national legislation. Water used as a part of public or commercial activities or at food premises having their own wells or other water sources are under the surveillance as well.

Valvira has prepared the national surveillance plan to guide the municipal health protection authorities in order to enable both the national harmonising of surveillance and the observance of local conditions.

Based on SätL section 15, a municipality's health protection authority supervises compliance with the reference levels of the radioactivity in household water and the radon concentration in dwellings and other premises used by people.

Analysis

STRENGTHS FOR SAFETY REQUIREMENTS FOR PUBLIC EXPOSURE

S1	Regulatory framework covers comprehensively public exposure in all exposure situations and provides mechanisms for their regulation.
S2	Long term experience in managing and regulating public exposures to natural radiation (indoor radon, building materials, drinking water)
S3	National radon database is a valuable tool for e.g. research, risk communication and for targeting of radon supervision.
S4	STUK has a radon dosimetry laboratory which is valuable for assure quality control for radon measurements.

WEAKNESSES FOR SAFETY REQUIREMENTS FOR PUBLIC EXPOSURE

W1	There is only little information easily available to the public about radioactivity of certain consumer products such as old glassware containing uranium and old camera-lenses containing thorium.
W2	At present, different authorities do not have the possibility to make direct use of one another's databases that contain data related to radon safety. In the future, the aim is to promote the access of other authorities to the data of the national radon database.
W3	There are shortcomings in the implementation of the requirements of GSR Part 3, par. 3.137: • Except for discharges, there is no specific legally binding requirement to maintain

	records of monitoring programme for public exposure. • There is no specific legally binding requirement to maintain records of estimated doses to members of the public. • Except for discharges, there is no specific legally binding requirement to make available to the regulatory body the results of the monitoring programme, including estimated doses to members of the public, at approved intervals. • Except for discharges, there is no specific legally binding requirement to establish operational limits related to public exposure and to report promptly to STUK any levels exceeding the operational limits.
W4	There is no specific legally binding requirement to maintain records of protective action taken in an existing exposure situation (Ref: GSR Part 3, par. 5.12 g).
W5	The SätL does not define a plan for protective action for existing exposure situation for the case where the undertaking from whose practice it arises from will take the action (Section 138 of SätL).
W6	STUK regulations do not explicitly require the determination of the characteristics and possible points discharge as required by GSR Part 3, paragraph 3.132. (Despite of this lack in the regulations, this information is de facto needed and required for carrying out an appropriate safety assessment referred to in SätL 26 §).

OPPORTUNITIES FOR SAFETY REQUIREMENTS FOR PUBLIC EXPOSURE

O1	National radon action plan is extensive and has new means to assess and control radon exposure.

THREATS FOR SAFETY REQUIREMENTS FOR PUBLIC EXPOSURE

T1	Funding for regulatory control on occupational exposure to natural radiation may not be assured for the future.

CONCLUSIONS FOR SAFETY REQUIREMENTS FOR PUBLIC EXPOSURE

C1	There is only little information easily available to the public about radioactivity of certain consumer products such as old glassware containing uranium and old camera-lenses containing thorium.
C2	Radon risk communication plan is being implemented.
C3	At present, different authorities do not have the possibility to make direct use of one another's databases that contain data related to public exposure to radon.
C4	There are shortcomings in the implementation of GSR Part 3 par. 3.137: Except for discharge monitoring, there are no specific legally binding requirements implementing the GSR Part 3 paragraphs 3.123 and 3.137 relating to the establishment of operational limits relating to public exposure, to report STUK any levels exceeding them and to maintain records of the results of the monitoring programmes and estimated doses to members of the public.
C5	There are no specific legally binding requirements implementing the GSR Part 3 paragraph 5.12 (f) relating to maintaining records relating to protective action taken in an existing exposure situation.

C6	Current provisions do not establish and define a plan for protective action in case where the action is taken by the undertaking from whose practice the situation arises (such provisions are in place only for the case where the action is taken by the State base on its duty of care).
C7	There is no specific legally binding for the determination of the characteristics and possible points of discharge as required by GSR Part 3, paragraph 3.132.

Module: Safety Requirements for Radiation Sources

Findings

Question 1 Is there a requirement for any person or organization intending to operate a facility or to conduct an activity to submit a notification, and as appropriate an application for authorization, to the regulatory body?

Answer: Yes

Response:

Any enterprise, corporation, foundation or institution as well as any employer or private entrepreneur about to conduct practice involving use of radiation is obliged to apply for authorization by the regulatory body according to SätL section 48. Definitions are in more detail defined in SätL section 4. There is no notification or registration process concerning the use of radiation. The application for a safety license is simultaneously the notification to the regulatory body in the meaning of para. 3.5 of GSR Part 3.

According to section 48 of SätL the use of radiation requires a licence (safety licence), unless otherwise provided in SätL. Other radiation practices require a safety licence if separately laid down in SätL.

STUK grants a safety licence upon application until further notice or, for a special reason, for a fixed period of time. The licence may also be granted separately for different stages of the practice. The licence may include conditions necessary for ensuring safety.

A safety licence is granted provided that:

1) the radiation practice complies with the principles of justification, optimization and limitation;

2) a safety assessment has been drawn up for the radiation practice;

3) the practice can be carried out safely;

4) the undertaking has the right to engage in a trade in Finland.

According to section 53 of the SätL STUK withdraws a safety licence when the radiation practice specified in the licence has been discontinued and the licensee has demonstrated in an acceptable manner that it has relinquished or rendered harmless the radiation sources specified in the licence and the radioactive waste generated in the practice and the waste referred to in section 78, subsection 3. STUK can also withdraw the safety licence if the prerequisites for granting it are not met or if the licensee repeatedly or essentially breaches the conditions for the licence or the provisions and regulations provided in the SätL or pursuant to it, and fails to remedy the deficiencies or its conduct despite a request to do so.

According to section 4 in SätL use of radiation means:

a) the use and manufacture of, trade in, installation, maintenance and remediation of radiation sources;

b) the possession, safekeeping, import, export, transfer and storage of radiation sources and radioactive waste;

c) the transport of radioactive substances and radioactive waste;

d) rendering radioactive waste harmless;

24) medical use of radiation means the use of radiation giving rise to medical exposure;

Question 1.1 Are there regulatory requirements that registrants and licensees notify the regulatory body of any intention to introduce modifications to any practice or source for which they are authorized, whenever the modifications could have significant implications for protection and safety?

Response:

There are regulatory requirements in SätL section 52 for licencees to apply for amendments to safety licence beforehand or notify the regulatory body of changes to practices or sources. These are specified in more detail in VnA (1034/2018) sections 25 and 26.

SätL Section 52 Amending a safety licence

STUK amends the conditions for a safety licence subsequent to its granting if material changes in the circumstances and special reasons due to them require the conditions to be changed for the sake of ensuring safety.

A substantial change to a practice requires prior amendment of the safety licence. In addition, STUK must be notified of any other changes to a practice subject to a safety licence.

Further provisions on changes to practices subject to an amendment of the safety licence or a notification are given by government decree.

VnA (1034/2018)

Section 25 Amending a safety licence

The following are considered material changes in the nature of a practice which require the prior amending of a safety licence:

1) a change in the holder of the safety licence;

2) a change due to which the class of the radiation exposure or radiation source changes from class 2 or 3 to class 1, or from class 3 to class 2;

3) a change of the radiation safety officer or some other significant change in the management system;

4) a change due to which the security referred to in section 54 of the Radiation Act would have to be changed or the high-activity sealed source specified in the security changes;

5) the start-up of a radiation source to be used for a therapeutical purpose;

6) the start-up of a radiation source other than a source referred to in paragraph 4 or 5 if the source differs, in terms of its radiation or radiation safety properties, from what is already in use in the practice pursuant to the safety licence or if its in-service radiation safety requires changes to structural protections or arrangements related to the place of use;

7) the use of the radiation source for a purpose other than for which the licence was issued;

8) a change in the installation where the practices are carried out;

9) a change in the practices in such a way that the amount or quality of the radioactive waste or the waste referred to in section 78, subsection 3 of the Radiation Act, or the arrangements concerning it, change from what was approved in the safety licence;

10) changing the practices in such a way that the discharges of radioactive substances or their quality change from what was approved in the safety licence.

Section 26 Notification of changes to a practice subject to a safety licence

The following changes to a practice subject to a safety licence must be reported to the Radiation and Nuclear Safety Authority within two weeks of the change:

1) a change in the contact details of the holder of the safety licence;

2) a change due to which the class of the radiation exposure or radiation source changes from class 2 or 1 to class 3, or from class 1 to class 2;

3) the start-up of a radiation source other than a source referred to in section 25, paragraphs 4–6;

4) a significant change to the quality assurance programme of radiotherapy;

5) a radiation source's removal from use;

6) the winding up of radiation practices in part or in full.

If a radiation source whose possession requires a safety licence is removed from use by relinquishment to another undertaking, the notification concerning the removal from use must include a certificate provided by the consignee on taking possession of the radiation source.

Question 2 Has the government or the regulatory body determined which practices or sources within practices are to be exempted from some or all aspects of regulatory control?

Answer: Yes

Response:

SätL and VnA determines which practices or sources within practices are to be exempted from some or all aspects of regulatory control. When value of the activity or the activity concentration used or possessed at any time, is less than or equal to the exemption value given in STUK SY/1/2018, a safety licence is not required under section 49, subsection 1, paragraph 2 of the SätL. In case of sealed sources, only the exemption value for activity is applied. Exempted practices are those in which the exposure is insignificant due to the safety features of the radiation appliance when appliances are not used in medical exposure or non-medical imaging exposure.

Practices in which the radioactive substance is derived from a permitted discharge of a radioactive substance and from radioactive waste or a radioactive material which has been reused, recycled, utilized or disposed of in a manner specified under section 84 of SätL, are exempted of regulatory control.

Exempted practices are also

- the transfer of a radiation sources (Note: the term "transfer" is defined in SätL as transfers from and to other EU Member State. Transfers of radioactive substances are regulated through mechanisms established by the Council Regulation (Euratom) No. 1493/93 on shipments of radioactive substances between Member States);
- the export of a radiation source which does not contain a radioactive substance,
- the transport of radioactive substances, excluding the road or rail transport of high-activity sealed sources
- the holding of health care or veterinary medicine X-ray equipment, provided that the holder has a safety licence for the use of equivalent appliance in the field of health care or veterinary medicine or for the installation, maintenance or remediation of such an appliance
- remediation or maintenance work of a radiation appliance which does not concern the appliance's parts producing radiation or shielding from radiation or any equivalent parts in a way that impacts safety

STUK may release practices from safety licence when they meet the criteria for an exemption according to SätL 50 and if exemption is the most appropriate alternative and the radiation exposure and potential exposure caused by the practice is insignificant enough not cause a health detriment. The practice is justified and inherently safe. The practice is safe in principle, as stipulated in VnA section 28, if the workers do not need to be categorized as radiation workers and the effective dose of a member of the public in a year is at most 10 µSv from artificial radioactive substances and 1 mSv from natural radioactivity. From improbable radiation safety incidents effective dose to a member of the public may not exceed 1 mSv a year.

Practices which don´t need authorization according to VnA 1034/2018 section 27 are:

1. The use, manufacture, trade, installation, possession, safekeeping, import, shipment or storage of an appliance which produces ionizing radiation electrically, provided that the appliance operates with a maximum voltage of 30 kilovolts. Appliance does not cause, within a ten centimeter distance of the appliance's accessible surfaces, a greater dose rate than one microsieverts per hour.
2. The use of fire alarms and smoke detectors containing radioactive americium-241 isotope in the purpose they have been designed for or their resale and use or the possession, retention, storage,

installation, maintenance or repair related to their use and resale. New ´,mfire alarms may nevertheless contain a maximum of 40 kilobecqurels of the americium-241 isotope.

3. For the use of a sealed source with radiation safety properties meant for educational use and contains a maximum of 40 kilobecquerels of the americium-241, strontium-90 or caesium-137 isotope as a teaching aid in schools, vocational schools and comparable institutions, provided that the educational institution has appointed a person in charge of radiation safety.
4. The use of lamps and igniters containing a maximum equal to the exemption value of a radioactive substance in the purpose they have been designed for or their resale and use or the possession, retention, storage, installation, maintenance or repair related to their use and resale.

Question 3 Has the government or the regulatory body ensured that only justified practices are authorized?

Answer: Yes

Response:

During authorization process by the regulatory body, the justification of practices is evaluated according to SätL section 24 and 48, and VnA (1034/2018) sections 2 and 7 and appendix 5 in addition to internal Guide SKV 3.2. Practice's compliance with principle of justification is thus ensured before granting the licence. Unjustified uses of radiation are listed in SätL section 68. Pertaining to section 24 of the SätL STUK provides an up to date list of practices, which are generally considered justified on its website (in Finnish, also available in Swedish, section of medical use of radiation incomplete): https://www.stuk.fi/stuk-valvoo/sateilyn-kayttajalle/hae-turvallisuuslupaa-tai-ilmoita-muutoksesta/oikeutettu-ja-oikeuttamaton-sateilyn-kaytto

Approved health screening programs which are assessed as justified are defined in Government Decree on Screening (339/2011).

Radiation Act

Section 24 Justification assessment concerning new types of or existing practices

The undertaking shall demonstrate that a new type of radiation practice subject to a safety licence is justified. The same applies to existing radiation practices if new important information on the efficiency, possible consequences or alternative methods or techniques of the practice is obtained.

STUK confirms the practice as justified either as part of granting the safety licence or separately.

Further provisions on the procedures to be followed in the justification assessment and the necessary explanations are given by government decree.

Section 48 Safety licence and its granting

The use of radiation requires a licence (safety licence), unless otherwise provided in this Act. Other radiation practices require a safety licence if separately laid down in the law.

STUK grants a safety licence upon application until further notice or, for a special reason, for a fixed period of time. The licence may also be granted separately for different stages of the practice. The licence may include conditions necessary for ensuring safety.

A safety licence is granted provided that:

1) the radiation practice complies with the principles of justification, optimization and limitation;

Government Decree on Ionizing Radiation (1034/2018)

Annex 5 Details to be included in a safety licence application

1. A safety licence application must include the following based on the quality and extent of the practice:

1.1 a report on the practice and its purpose, if the case involves a new type of practice;

1.2 a report on the justification for the practice should this be necessary according to section 24 of the Radiation Act;

Radiation Act

Section 68 Prohibitions of use

A radioactive substance may not be used deliberately in: 1) foodstuffs as referred to in the Food Act; 2) animal feed as referred to in the Feed Act; 3) cosmetic products as referred to in Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products; 4) jewellery and other equivalent personal accessories; 5) toys as referred to in the Toy Safety Act (1154/2011); 6) in the tracer tests carried out in water supply systems the water of which is used as household water.

Products falling under the scope of the aforementioned prohibition specified in subsection 1 may not be imported, exported or transferred.

What is provided with regard to radioactive substances in subsection 1 and 2 also applies to practices in which the increase of radioactivity derives from the activation of consumer goods or the material used in manufacture of the consumer goods.

Government Decree on Ionizing Radiation (1034/2018)

Section 2 Exposures to be accounted for in the justification assessment and the optimization of radiation protection

The justification assessment concerning a radiation practice and the optimization of radiation protection must take into account occupational exposure, public exposure and medical exposure.

The justification assessment of individual medical exposure does not account for occupational exposure and public exposure.

In an emergency exposure situation and an existing exposure situation, the justification assessment concerning a radiation practice and the optimization of radiation protection must take into account occupational exposure and public exposure prior to, during and after the protective measures.

The justification assessment and optimization of radiation protection referred to in subsections 1 and 3 must also take into account the waste generated as well as the radiation exposure arising from the related waste management.

Section 7 Statements and other reports on the justification of practices

As part of the justification assessment of a new type of radiation practice as referred to in section 24 of the Radiation Act, the Radiation and Nuclear Safety Authority requests, unless it is clearly not necessary for the resolution of the matter, a statement from:

1) the Advisory Committee on Radiation Safety;

2) the Data Protection Ombudsman, if the practice involves factors related to data protection;

3) key stakeholders (as necessary) on whom the intended practice may have an impact.

In addition, the Radiation and Nuclear Safety Authority requests, when necessary, a report from an expert institution or some other expert on the technology and safety of the appliance meant for practice referred to in subsection 1.

The undertaking must ensure that the Radiation and Nuclear Safety Authority has an opinion at its disposal for the purposes of the justification assessment referred to in section 24 of the Radiation Act from:

1) an ethics committee referred to in the Medical Research Act if radiation is intentionally directed at a human being within the said Act’s scope of application;

2) the National Institute for Health and Welfare on the assessment of a health care method, provided that the case concerns a new type of method which results in medical exposure which exposes a large number of members of the public or which results in a high degree of medical exposure.

The ethics committee hears experts on the medical radiological use of radiation in a matter referred to in subsection 3, paragraph 1.

…

Guide SKV 3.2 Processing of authorization

When considering an application for a licence for a new type of practice, the justification principle must be considered (e.g. a new type of equipment or laboratory to be introduced or a new type of practice). A list of activities already authorized is available on STUK's website. As a rule, when assessing the legitimacy of a practive, an opinion must be sought from independent bodies outside STUK, such as the Radiation Safety Advisory Board, in accordance with Section 7 of the Decree VnA 1034/2018. The preparer shall discuss the necessary opinions or reports with the head of the unit and the head of the STO during the preparatory phase.

Practices generally considered justified on STUKs website:

https://www.stuk.fi/stuk-valvoo/sateilyn-kayttajalle/hae-turvallisuuslupaa-tai-ilmoita-muutoksesta/oikeutettu-ja-oikeuttamaton-sateilyn-kaytto

Justified and unjustified use of radiation

Section 24 of the Radiation Act stipulates that the operator must demonstrate the justification of a new type of radiation activity requiring a safety authorization. The type of radiation use to be initiated is often similar to that which has already been carried out in Finland and which has been considered justified. The lists below are intended to help prospective operators to consider the need for a justification assessment when starting a new use of radiation.

The lists of authorized and non-authorized activities will be updated on the basis of the justification assessments carried out.

In general, justified uses of radiation

The following are the uses of radiation that are generally justified. "Generally" here means that there is nothing abnormal about the use of the radiation in question, for example, in terms of the purpose of the radiation, the radiation sources used, the radioactive waste or discharges from the activity, the working practices, or the activities related to radiation safety and security.

If the use of radiation is "normally justified", it is not necessary to consider the justification of the activity separately when starting the activity, unless there is something abnormal about it. However, the use of radiation must meet all the conditions for the granting of a safety authorization laid down in the Radiation Act.

In general, justified uses of radiation include:

- Use of radiation exempted from a safety licence (Section 49 of the Radiation Act)
- Use of radiation sources (sealed and open sources and devices containing them, as well as electrically emitting devices)

o Use in research when the radiation is not directed at a human being

o Use in the calibration and checking of radiation meters

o Use in education as a teaching, demonstration and training tool

o Trade, import, export and transfer

o Installation, maintenance, repair and manufacture

o Transport

- Use of sealed sources and electrically emitting devices

o Control and monitoring of industrial processes

o Quality control of raw materials, products and waste

o Analysis of material properties

o Industrial imaging and similar imaging where radiation is not applied to humans

o Irradiation of products, excluding foodstuffs

- Use of radioactive sources

o In tracer tests in industrial processes, except in water supply systems whose water is used for domestic purposes

- Treatment and disposal of radioactive waste[1)]
- Use of electrically emitting radiation equipment

o In the manufacture of radioisotopes

o Ion Implantation

o Veterinary imaging

o Security screening when radiation is not directed at humans

[1)] In the assessment of the justification for radiation activities, the waste generated and the exposure arising from its disposal must also be taken into account (Government Decree Article section 2, 4 part). Where a radiation activity is justified, the treatment and disposal of the radioactive waste resulting from that activity is also justified.

In general, justified non-medical exposure of a person resulting from research with health care equipment is described separately on the page on non-medical exposure of a person in imaging.

In general, the justified medical exposure will be completed here at a later stage. Section 113(3) of the Radiation Act provides that referring physicians and dentists must have at their disposal the referral recommendations for routine radiological examinations, procedures and treatments and information on the radiation doses resulting from such examinations, procedures and treatments.

Question 4 Has the government or the regulatory body established and enforced requirements for the optimization of protection and safety?

Answer: Yes

Response:

Requirements for optimization of protection and safety are given in SätL sections 6, 9, 10, and 25 and definitions of dose limit and dose constraint which are closely related to optimization of protection and safety are given in section 4. According to SätL section 48 safety licence is granted only if radiation practice complies with the principle of optimization. More detailed regulations are given in STUK S/6/2019 sections 6 -12. Radiation protection experts are according to VnA (1034/2018) section 18 to be used in setting and using dose constraints to optimize radiation protection.

Documented information related to optimization of protection and safety is to be confirmed by STUK in the safety assessment either as part of granting the safety licence or separately as according to SätL 26.

As a support for enforcing requirements for the optimization of protection and safety STUK publishes guidance series called “STUK Opastaa” aimed for different sectors of radiation users (In Finnish, some also in Swedish or English: https://www.stuk.fi/julkaisut/stuk-opastaa). These guides are often prepared as collaboration with volunteering professionals of each field and provide practical guidance for safe use of radiation.

On STUK’s regulation and guidance service Sammio (www.sammio.stuk.fi) guidance is given for the undertaking on how to implement requirements.

In addition, STUK communicates relevant matters such as requirements changed by the reform of radiation legislation by sending information or notifications directly for those concerned and by publishing e-newsletters (in Finnish: https://www.stuk.fi/stuk-valvoo/sateilyn-kayttajalle/uutiskirjeet-sateilyn-kayttajille/).

Radiation Act

Section 4 Definitions

For the purposes of this Act, the following terms have the following meanings:

2) dose limit means the radiation dose arising from ionizing radiation which may not be exceeded during a specific period of time;

3) dose constraint means a constraint on the individual radiation dose of a person other than a patient arising from ionizing radiation during a specific period of time, used to optimize radiation protection in radiation practices;

Section 6 Principle of optimization

To optimize radiation protection, occupational exposure and public exposure to ionizing radiation shall be kept as low as is reasonably achievable, and medical exposure shall be limited to what is necessary to achieve the intended examination or treatment result and performance of the procedure (principle of optimization).

Section 9 Dose constraints and constraints for potential exposure

Dose constraints and constraints for potential exposure are set, taking into account the characteristic features of the practice, in such a way that the exposure is anticipated to remain below the constraint due to the optimization of radiation protection.

The dose constraints concerning occupational and public exposure are furthermore set in such a way that the combined amount of radiation doses arising from all practices subject to a safety licence is anticipated to remain below the dose limit.

Section 10 Further provisions

Further provisions on the assessment of the radiation practices' and protective actions' compliance with the principle of justification, and on the optimization of radiation protection and on the calculation and determination basis for radiation exposure are given by government decree for the purposes of implementing European Union legislation.

The dose limits of workers and members of the public are given by government decree for the purposes of implementing European Union legislation.

STUK issues more detailed regulations on the general dose constraints applicable to specific radiation practices and radiation sources and on constraints for potential exposure and their use as well as on demonstrating the implementation of the justification and the optimization of radiation protection.

Section 48 Safety licence and its granting

The use of radiation requires a licence (safety licence), unless otherwise provided in this Act. Other radiation practices require a safety licence if separately laid down in the law.

STUK grants a safety licence upon application until further notice or, for a special reason, for a fixed period of time. The licence may also be granted separately for different stages of the practice. The licence may include conditions necessary for ensuring safety.

A safety licence is granted provided that:

1) the radiation practice complies with the principles of justification, optimization and limitation;

2) a safety assessment pursuant to section 26 has been drawn up for the radiation practice;

3) the practice can be carried out safely;

4) the undertaking has the right to engage in a trade in Finland.

Section 26 Safety assessment concerning radiation practices

In practices subject to a safety licence, the undertaking shall carry out a safety assessment concerning the radiation practice, which:

1) identifies ways in which the practice can cause radiation exposure, considering any possible radiation safety deviations;

2) assesses the magnitude of the occupational, public and medical exposure arising from the practices as well as the probability and magnitude of the potential exposure;

3) presents measures to ensure radiation safety and the optimization of radiation protection;

4) presents measures to prevent and prepare for identified radiation safety deviations;

5) presents the categorization of the radiation practice.

The safety assessment shall be prepared in writing and kept up to date.

STUK confirms the safety assessment either as part of granting the safety licence or separately.

STUK issues more detailed regulations on the content and preparation of the safety assessment.

STUK S/6/2019:

Section 6 Quantities of dose constraints and potential exposure

Dose constraints are provided for as an effective dose per year and the limits for potential exposure as effective dose resulting from a one-off incident.

The realization of an incident leading to potential exposure is reviewed as the expected number of incidents per person-year in terms of occupational exposure and per year in terms of public exposure. Person-year means the product of the number of potentially exposed workers and working years.

Section 7 Dose constraints for occupational exposure

The dose constraint for occupational exposure in radiation practices is 0.3 mSv, if the category of occupational exposure in the practice is 3. However, the dose constraint may be greater than this if it is shown to be justified in the safety assessments.

The dose constraint for occupational exposure in the practice of aviation is 6 mSv. However, the dose constraint may be greater than this in some restricted special circumstances in which the exposure cannot be limited to 6 mSv through reasonable means.

Section 8 Dose constraints for public exposure

The dose constraint for public exposure is 0.1 mSv. However, the dose constraint may be greater than this if it is shown to be justified in the safety assessments, excluding the situations referred to in section 9.

Section 9 Dose constraints for public exposure resulting from discharges and waste

The dose constraint for public exposure resulting from discharges and waste in radiation practices may not be greater than 0.1 mSv:

1. in discharges of radioactive substances to the sewerage system, waterways or the air;
2. in the reuse, recycling, utilization, or disposal of waste containing radioactive substances.

Section 10 Dose constraints concerning the design and construction of facilities where radiation sources are used and stored

The dose constraint concerning the design and construction of facilities where radiation sources are used and stored may not be greater than:

1. 6 mSv for a radiation worker in a supervised area;
2. 0.3 mSv for occupational exposure in an area other than a controlled or supervised area;
3. the dose constraint for public exposure referred to in section 8.

If there are several facilities in which radiation sources are used and stored, the space-specific dose constraints must be set in such a way that their maximum sum is equal to what is specified in subsection 1.

Section 11 Constraints for potential occupational exposure

The potential occupational exposure from a one-off incident may not be greater than 100 mSv, excluding a highly unlikely incident or sequence of incidents with a realization probability that cannot be reduced through practical measures.

If the potential occupational exposure resulting from a one-off incident is greater than 6 mSv, the expected number of the incidents may not be greater than one in ten person-years.

Section 12 Constraints for potential public exposure

The potential public exposure from a one-off incident may not be greater than 10 mSv, excluding a highly unlikely incident or sequence of incidents with a realization probability that cannot be reduced through practical measures.

Question 5 Are there regulatory requirements established for registrants and licensees to ensure the safety of radiation generators and radioactive sources?

Answer: Yes

Response:

Requirements for radiation generators and radioactive sources are set in chapter 10 of SätL. Undertaking needs to ensure that radiation generators and radioactive sources are used and stored in places where it can be done safely. Undertaking is responsible to store them in a manner so that they are protected against loss or otherwise falling into the hands of unauthorized persons or illegal operation. SätL 126 stipulates that undertaking must limit public exposure from radiation generators and radioactive sources. Undertaking must prevent radioactive substances from spreading outside the facility and more widely to the environment with adequate efficiency and restrict members of the public from accessing the facility.

Radiation safety of a product is ensured by licensees manufacturing or otherwise suppling them. In SätL section 56 the undertaking who manufacture, import, bring to the market, offer, keep for sale, sell or otherwise hand over radiation sources or accessories and other products related to the safety of a radiation practice or products, shall be able to demonstrate that the product is safe. The undertaking is responsible for demonstrating that the radiation source or radiation generator it supplies comply with

requirements of set out in STUK S/5/2019 Chapter 3 and Appendices 2-8. The undertaking supplying radioactive sources or radiation generators shall have a safety license which emphasizes its responsibilities for safety and security.

The manufacturer or importer is obligated to provide information on radiation generators and radioactive sources at the time of the handover as stipulated in section 73 of SätL. Also, when an undertaking is handing over a radiation generator or radioactive source to another undertaking, it is obligated to provide the recipient with certificate and other information relevant to radiation safety received from the manufacturer or importer. The undertaking shall also ensure that the transferee has sufficient safety licence to possess radioactive sources or radiation generators

STUK uses the inspection findings and other observations pertaining to radiation safety to develop regulatory control and reports on them to undertakings, authorities, manufacturers and other suppliers concerned in the extent as is necessary to promote safety (SätL section 183).

Medical radiological equipment is also subject to EU Regulations MDR 2017/745 and further to national legislation Act on Equipment and Supplies for Healthcare 719/2021 and Act on certain medical devices covered by EU directives 720/2021, thus a CE-marking is required.

Section 56 Demonstrating a product's radiation safety

The undertaking which manufactures, imports, brings to the market, offers, keeps for sale, sells or otherwise hands over radiation sources or accessories and other products related to the safety of a radiation practice (product) shall be able to demonstrate that the product is safe.

Question 6 Has the government ensured that arrangements are in place for regaining control over radioactive sources that have been abandoned, lost, misplaced, stolen or otherwise transferred without proper authorization?

Answer: Yes

Response:

The Finnish Customs is the responsible authority for detection and control, including the prevention of illicit trafficking, of nuclear and other radioactive materials in import and export transport traffic at the Finnish border crossing points such at major airports, harbors and land border crossing points.

In 2014 Finnish Radiation and Nuclear Safety Authority (STUK) and the Finnish Customs signed a bilateral agreement of cooperation and support on detection and control of nuclear and other radioactive materials at the Finnish border crossing points. The newest bilateral agreement of cooperation and support is updated on December 11th, 2020.

STUK supports Finnish Customs efforts by providing the necessary instrumentation for radiation detection (fixed radiation monitor system installations at major border crossing points, handheld radiation survey meters, radiation identification devices and mobile radiation detection systems at the Finnish Customs disposal) and by providing technical and scientific support both remotely and on-site when needed. All new detection systems are such that the STUK experts have remote access to their data.

STUK supports the Finnish Customs also in training and exercises. STUK and the Customs have developed a comprehensive training course on radiation protection as well as on detection and identification of nuclear and other radioactive materials, including the detection of orphan sources and detection of radioactive contamination in imported goods, as a part of the Finnish Customs

systematic CBRN training program.

According to internal guide STUK Emergency plan (VA 1) radiation safety incidents are classified into different levels of preparedness (incident to be clarified, enhanced preparedness and full preparedness) according to the level of STUK resources required to respond to the event. If necessary and required by the situation, the level of preparedness is may be raised or lowered as more information on the event and its safety significance is gained.

According to internal guide VA 1 orphan (abandoned, lost, stolen or found) high-activity source is handled as an incident to be clarified. If an orphan source is assumed to be melted, the incident is handled as enhanced preparedness. Both cases will be handled first by the officer on duty who receives the phone call and will be immediately transferred to the section head whose section is responsible on handling incidents with orphan sources.

According to section 86 of SätL practices which repeatedly handle, or store orphan sources are subject to a safety licence. Section 86 continues with paragraph 2 as follows: *The undertaking shall immediately notify STUK if it suspects or knows of the finding or melting of an orphan source or any*

significant contamination caused by such an orphan source. According to previous section of SätL only undertakings must notify STUK of the finding of an orphan source. There are not requirements for any other company than undertakings even if also they might find an orphan source. It is not clear in all cases who is the authority who should help the undertaking with the found source in the acute phase: STUK or rescue department. See answer to question 6.5.

The holder of a safety licence conferring the right to manufacture, safekeep, trade, export or import radiation sources shall deliver data on the radiation sources received, handed over and in its possession to STUK once every calendar year (SätL section 71). If STUK finds out that radiation sources have been handed over to an undertaking without a safety licence, STUK demands the undertaking to apply for a safety licence without delay (or seek for an amendment if the undertaking already has a licence but the radiation source in question is without licence). Furthermore, STUK is in contact with the licensee that handed over the radiation source to make sure that the licensee always checks that the undertaking has a safety licence (SätL section 72).

Question 6.1 Are there national strategies in place for gaining and regaining control over orphan sources?

Response:

According to section 86 of Sätl practices which repeatedly handle, or store orphan sources are subject to a safety licence. Section 86 continues with paragraph 2 as follows: *The undertaking shall immediately notify STUK if it suspects or knows of the finding or melting of an orphan source or any significant contamination caused by such an orphan source.*

Safety licence has been granted to three undertakings which repeatedly handle orphan sources (situation in Septemter 2021). STUK is also currently (September 2021) considering whether to require a safety licence for the treatment of orphan sources from one more company in the recycling metal sector, as the company regularly finds orphan sources (regularly means 1-2 times a year).

According to section 80 of SätL the State ensures that the radioactive waste is rendered harmless to the extent that an undertaking does not within a reasonable period of time meet or cannot be expected to meet its duty of care specified in section 79 of SätL. The State also carries out the measures referred to in subsection 1 if the origin of the waste is unknown or if the undertaking responsible for the duty of care is not found. In the event that there is no undertaking whose line of business includes rendering radioactive waste harmless or if an undertaking cannot return a disused radiation source to the manufacturer or supplier or transfer it to another undertaking, the State ensures that the radioactive waste is rendered harmless.

Section 32 of VnA 1034/2018 states that the Radiation and Nuclear Safety Authority ensures that the duties falling under the scope of obligations imposed on the State in section 80, subsections 1–3 of SätL are carried out. Responsibility for waste transfers to the State once the waste has been relinquished to the possession of the Radiation and Nuclear Safety Authority.

Radioactive waste means radioactive substances or devices, goods and materials contaminated by radioactive substances for which there is no use or for which an owner cannot be found (section 4 subsection 15 of SätL). Orphan source is radioactive substance for which an owner cannot be found so section 80 of SätL and section 32 of VnA 1034/2018 applies for orphan sources as well.

Question 6.2 How does the government or the regulatory body promote awareness among industry, health professionals, the public, and government bodies of the safety hazards associated with orphan sources?

Response:

For the metal recycling chain STUK has published poster "Be aware of radioactive sources in scrap metal". The poster gives advice on visual monitoring and radiation monitoring among recycled metal. The images on the poster show a range of different radiation shields, in order to help to recognize them when found among scrap metal.

STUK has also participated several times on Finnish recycling companies' education days to promote awareness with orphan sources and has at the same time handed out the poster for the representatives of the recycling companies.

STUK has published May 2021 a guide on sealed sources called "Lifecycle of sealed sources" (Umpilähteen elinkaari in Finnish). Guide gathers tasks and obligations associated with the use of sealed sources. Guide is intended to professionals responsible for sealed sources in their working place in industry, health care and government bodies. Guide sums up proper handling of sealed sources during their lifecycle. Guide informs professionals in order to prevent sealed sources from ending up orphan sources.

Question 6.3 Does the regulatory body has the authority to require those supplying or transferring radioactive sources or devices incorporating radioactive sources to provide the recipient with all relevant technical information to permit their safe management?

Response:

Obligations to provide information of radiation sources to their recipients are in sections 72 and 73 of SätL. Obligations are set to the transferor of radioactive sources.

A radiation source the holding of which is subject to a safety licence may be handed over only to an undertaking with the necessary safety licence. The transferor shall ensure that the recipient has the required safety licence. The recipient shall provide the transferor with a certificate on the reception of the radiation source.

Section 73 of SätL: When handing over a radiation source generating ionizing radiation, the manufacturer or importer shall provide the recipient with detailed information on the structure of the source and its properties having an impact on safety together with the source. A sealed source is also subject to a certificate demonstrating compliance with regulations.

The undertaking handing over a radiation source generating ionizing radiation to another is obligated to provide the recipient, in connection to the handing over, with any information and certificate and other information relevant to radiation safety in its possession, received from the manufacturer or importer as referred to in subsection 1.

STUK issues more detailed regulations on the content of the information referred to in subsection 1 and 2 and their provision.

Question 6.4 Does the regulatory body has the authority to monitor, or request other authorized bodies to monitor, at appropriate checkpoints for the purpose of detecting orphan sources?

Response:

According to section 16 of SätL the Finnish Customs is the responsible authority for detection and control of nuclear and other radioactive materials, including the prevention of illicit trafficking of such materials, in import and

export transport traffic at the Finnish border crossing points such as major airports, harbors and land border crossing points.

In 2014 STUK and the Finnish Customs signed a bilateral agreement of cooperation and support on detection and control of nuclear and other radioactive materials at the Finnish border crossing points. The newest bilateral agreement of cooperation and support is updated on December 11th, 2020.

STUK has raised awareness of orphan sources by publishing guidelines and guides for operators. No other incentive measures have been necessary, as the metal recycling industry has, due to commercial needs, independently acquired a comprehensive range of measuring equipment for the detection of sources and contamination.

Companies handling recycled metal use monitors for detecting radiation from scrap metal. Orphan sources are sometimes found among scrap metal. If orphan source is found, the undertaking shall immediately notify STUK if it suspects or knows of the finding or melting of an orphan source or any significant contamination caused by such an orphan source (section 86 of SätL).

Question 7 Has the regulatory body established requirements for protective actions and exercised regulatory control over protective actions, including for minimizing the likelihood of loss of control of radioactive sources?

Answer: Yes

Response:

Security arrangements for radioactive sources are planned to minimize the likelihood of loss of the control of sources. A radiation source the holding of which is subject to a safety licence may be handed over only to an undertaking with the necessary safety licence. The transferor shall ensure that the recipient has the required safety licence and the recipient shall provide a certificate on the reception of the radiation source as is stipulated in SätL section 72. Requirements for security arrangements are set in SätL section 67 and STUK S/9/2021. Radiation facilities have three levels of security (A, B or C) depending on the radiation sources. Security levels have different required actions, C being the lowest level. If a facility contains sources of more than one security level, the security arrangements shall be implemented in accordance with the source requiring the highest security level.

Section 67 Security arrangements

The undertaking shall protect radiation sources subject to a safety licence against illegal operation or loss or otherwise falling into the hands of third parties at their use and storage facilities. These security arrangements shall be adequate in terms of the risks related to the practice and the radiation sources and they must form a whole compatible with the measures concerning radiation safety.

The security arrangements include, depending on the risks involved in the radiation sources:

1) drawing up a plan on the security arrangements and keeping the plan up to date;

2) protecting the radiation sources with structural barriers and the presence of personnel;

3) the regular verification of the location of the radiation source;

4) the use of access control and other technical surveillance measures;

5) restricting access to materials concerning radiation sources and security arrangements.

Question 8 Are there provisions for effective mechanisms of communication established for making information on any incidents to government bodies, and national and international organizations?

Answer: Yes

Response:

STUK is responsible for informing government bodies and providing information internationally. National notification responsibilities are detailed in Ministry of Interior guide on radiation emergencies. For international notification, the responsibilities are set in the national implementation decrees for the international agreements, which define STUK as the National Competent Authority defined in the agreements.

Initial notification of government and national bodies is done in practice by the duty office of STUK. His procedures include the notification actions for these bodies. International notification, as well as provision of further information to national bodies, is done by STUK's emergency organization. In small cases where the organization is not in operation, this information is provided by the Emergency Preparedness unit of STUK. Arrangements and procedures for notification and the criteria and types of incidents to be notified are specified in the Emergency Manual of STUK.

Question 9 Has the regulatory body, in conjunction with other relevant authorities, specified requirements for acceptance and for performance, for any manufactured or constructed source, device, equipment or facility that, when in use, has implications for protection and safety?

Answer: Yes

Response:

The acceptability and performance criteria for radioactive sources, radiation generator and equipment are included in the requirements of quality assurance of SätL section 30. More detailed regulations are given in STUK S/5/2019 chapters 2, 3 and 5 and in appendices 2-8 which regulates the in-service radiation safety of radiation sources. These in-service acceptability criteria of appliances refer to the minimum requirements set for the performance of the appliance. Chapter 2 of STUK S/5/2019 sets out requirements for premises where radiation sources are used and stored. These premises shall be planned and implemented in such a way that the exposure caused to employees and the public is as small as possible, when reasonable actions are implemented, and that the dose caused does not exceed the dose constraint applicable to the place where the radiation source is used and stored. Furthermore, STUK S/5/2019 gives criteria for structural solutions (e.g. safety and alarm systems, marking of areas) and sets out requirements in relation to contamination or patient rooms. Chapter 3 sets out general requirements for radiation sources such suitability for use intended and markings on the radioactive source. There are requirements specified for medical radiation appliances and these are described in more detail in appendices 2-5. Acceptability criteria for a radiation appliance for industrial and research purposes are detailed in appendices 6-8.

Radiation appliance in health care and veterinary medicine shall include an acceptance inspection by regulatory authority in which the operation of the radiation appliance is ensured before commissioning the appliance, as stipulated in STUK S/5/2019 section 26.

STUK S/5/2019 has been identified for need of revision, which probably takes place in the coming years. The reason for the renewal of the regulation is the forthcoming amendments to Chapter 8 of the SätL concerning the radiation safety of the product. In addition, the annexes to this regulation are too specific about the characteristics of radiation equipment for which there is a standard. Medical radiological equipment is also subject to EU Regulations MDR 2017/745 and further to national legislation Act on Equipment and Supplies for Healthcare 719/2021 and Act on Certain medical devices covered by EU directives 720/2021.

SätL Section 30 Quality assurance

The undertaking shall establish quality objectives for practices subject to a safety licence and define and implement systematic measures with which to ensure the realization of the quality objectives (quality assurance) and the fulfillment of the requirements laid down in the law.

The undertaking shall draw up a quality assurance programme for the implementation of quality assurance. The programme must detail the quality assurance measures, their performance,

performance intervals, action limits, measures for when the action limits are exceeded, and responsibilities for taking measures pursuant to the programme. In addition, the programme must include instructions on performing the technical testing and checking of radiation sources and radiation appliances and other equipment as well as software and auxiliary devices with an impact on safety.

The results of the quality assurance must be documented. The quality assurance programme shall be reviewed on a regular basis and updated when necessary.

STUK issues more detailed regulations on quality assurance measures and their performance intervals and instructions as well as the documentation of results.

STUK S/5/2019 Section 15 General requirements

As a part of the safe use of radiation sources referred to in section 66, subsection 1, of the Radiation Act, the operator shall ensure that the in-service acceptability criteria specified in these requirements and other requirements applicable to radiation sources are met.

The radiation source and the equipment related to its use shall be suitable for the intended use.

An appliance generating radiation electrically may not be operated at values higher than what is necessary for the purpose and that are approved in the safety licence.

A sealed source must be labelled as "Radioactive", or, if this is not possible, equipped with the label for ionizing radiation in accordance with SFS-EN ISO 361:2015.

Section 16 In-service acceptability criteria for a medical radiation appliance

In addition to what is specified section 13, a medical radiation appliance shall meet the in-service acceptability criteria specified in this section.

The appliance shall meet the performance characteristics and safety properties specified by the manufacturer during operation.

A report shall be available at the place of operation of the appliance, indicating the in-service acceptability criteria and that these are met.

The in-service acceptability criteria are specified:

1. *for medical X-ray imaging and fluoroscopic equipment, CT scan appliances and bone mineral density measurement appliances based on the attenuation of X-radiation: in Appendix 2;*
2. *X-ray imaging and fluoroscopic equipment and the related auxiliary devices and equipment used in veterinary medicine: in Appendix 3;*
3. *radiotherapy equipment and the related auxiliary devices and equipment: in Appendix 4;*
4. *equipment used in nuclear medicine: in Appendix 5.*

Section 17 In-service acceptability criteria for a radiation appliance for industrial and research purposes

In addition to what is specified section 13, a radiation appliance for industrial and research purposes shall meet the in-service acceptability criteria specified in this section.

A radiation appliance for industrial and research purpose shall meet the radiation safety requirements specified in the applicable Finnish or international standard. Compliance shall be demonstrated with the applicable certificate.

If there is no standard referred to in subsection 2 applicable to a radiation appliance generating ionizing radiation:

1. *the doors, panels and hatches or similar acting as fixed structural protections of the appliance shall be equipped with safety devices which interrupt the generation of radiation when they are opened;*

2. *the appliance may only be started with a key, a code or a similar switch. The switch shall be such that radiation cannot be generated without it;*
3. *when the safety system has interrupted the generation of radiation, the appliance may not start without the operator's action;*
4. *the appliance shall be equipped with a pilot light indicating the generation of radiation or another means of indicating the generating of radiation;*
5. *electrical safety and warning systems shall be equipped with a safety circuit preventing the operation of the appliance in case of malfunction.*

The in-service acceptability criteria are specified:

1. *radiometric measuring devices: in Appendix 6;*
2. *industrial imaging equipment: in Appendix 7.*

Section 26 Acceptance inspection of a radiation appliance in health care and veterinary medicine

The quality assurance programme of the use of radiation in health care and veterinary medicine shall include an acceptance inspection in which the operation of the radiation appliance is ensured before commissioning the appliance. Also the reference performance values to be used in the monitoring of the appliance's operational capacity and performance characteristics shall be determined in the acceptance inspection.

Question 10 Has regulatory body, in consultation with the health authority, ensured that provisions are in place for ensuring protection and safety in the handling of deceased persons or human remains that are known to contain sealed or unsealed radioactive sources, , either as a result of radiological procedures for medical treatment of patients or as a consequence of an emergency?

Answer: No

Response:

The BSS Directive and the Finnish legislation do not contain a requirement equivalent to IAEA GSR Part 3 para 2.37. However, even without explicit requirement, the basic principle of optimization occupational and public exposure shall be applied to the handling of deceased persons or human remains that are known to contain sealed or unsealed radioactive sources. The principle of optimization is given in SätL section 6.

According to the SätL section 23, the undertaking shall implement the organizational practice in such a way that the practice meets the requirements set in SätL and that radiation safety deviations are prevented with adequate effectiveness, and their consequences are as insignificant as possible.

The undertaking shall have all the necessary instructions and procedures for their work, including having instructions and procedures for handling deceased persons and human remains that are radioactive. During regulatory oversight STUK has reviewed and assessed undertakings instructions for cremation and deceased patients.

STUK is participating in HERCA Medical Applications Workgroup, where work is conducted to gather European guidelines concerning cremation and handling of a deceased patient who has received radionuclide therapy. From this work, it is assessed if HERCA guidelines could be established.

Question 10.1 What measures are planned to improve compliance with these requirements?

Response:

STUK is considering establishing guidance in Sammio concerning cremation and the safe handling of deceased persons or human remains that are known to contain sealed or unsealed sources. The guidance would be established in consultation of relevant professional bodies.

Question 11 Has the regulatory body made provision for establishing, maintaining and retrieving a national register of radioactive sources and radiation generators?

Answer: Yes

Response:

STUK maintains register of safety licences containing information on radiation practices and the related undertakings, radiation safety officers, radiation sources and the facilities in which radiation practices are carried out.

All radioactive sources and radiation generators in accordance with section 19 of SätL are included to safety licence register except those with activities below exemption levels defined in STUK SY/1/2018 or which have been exempted separately in accordance with section 49 of SätL.

Information in the register of safety licences is kept up to date because a substantial change to a practice requires prior amendment of the safety licence. Also minor changes to a practice subject to a safety licence have to be notified to STUK (section 25 and 26 of VnA 1034/2018).

Licensees need to report STUK on all the HASS sources in their possession according to SätL section 71 and STUK S/5/2019 chapter 4.

Furthermore, the holder of a safety licence conferring the right to manufacture, safekeep, trade, export or import radiation sources shall deliver data on the radiation sources received, handed over and in its possession to STUK once every calendar year (SätL section 71).

Question 12 Are registrants and licensees required to maintain an inventory that includes records of radiation sources?

Answer: Yes

Response:

The undertaking shall keep a record on the radiation sources related to the safety licence. The requirement of inventory control is set in section 71 of SätL. The records must indicate the radiation sources held by the undertaking as well as the reception and handing over of the sources and their removal from the licence. A radiation source may be removed from the records five years after its handing over or removal from the licence. The records shall be kept up to date. These requirements are further specified in STUK S/5/2019, Chapter 4.

In addition, the holder of a safety licence conferring the right to use or hold high-activity sealed sources, the requirement is more stringent. They shall deliver data on the high-activity sealed sources in their possession to STUK once every calendar year. Detailed information to be presented is given in Appendix 9 of STUK S/5/2019.

The holder of a safety licence conferring the right to manufacture, safekeep, trade, export or import radiation sources shall deliver data on the radiation sources received, handed over and in its possession to STUK once every calendar year. The notification shall be made even if no receipts or transfers have taken place and the notifier has no radiation sources in its possession. Detailed information to be presented is given in Appendix 10 of STUK S/5/2019. Both of the above-mentioned notifications shall be submitted to STUK by the end of January of the following year.

According to SätL section 71, the undertaking must at regular intervals inspect the radiation source locations and verify that all the radiation sources and devices for which the responsible party is responsible, are accounted for and in proper condition. A radiation source the holding of which is subject to a safety licence may be handed over only to an undertaking with the necessary safety licence (SätL section 72). The transferor shall ensure that the recipient has the required safety licence.

Section 71 Record-keeping and notification obligation

In practices subject to a safety licence, the undertaking shall keep a record on the radiation sources related to the safety licence. The records must indicate the radiation sources held by the undertaking as well as the reception and handing over of the sources and their removal from the licence. A radiation source may be removed from the records five years after its handing over or removal from the licence. The records shall be kept up to date.

The holder of a safety licence conferring the right to manufacture, safekeep, trade, export or import radiation sources shall deliver data on the radiation sources received, handed over and in its possession to STUK once every calendar year.

In addition, the holder of a safety licence conferring the right to use or hold high-activity sealed sources shall deliver data on the high-activity sealed sources in its possession to STUK once every calendar year.

STUK issues more detailed regulations on the record keeping referred to in subsection 1 and on the information to be provided, referred to in subsection 2.

Section 72 Obligations of the transferor, recipient and transporter

A radiation source the holding of which is subject to a safety licence may be handed over only to an undertaking with the necessary safety licence. The transferor shall ensure that the recipient has the required safety licence.

The recipient shall provide the transferor with a certificate on the reception of the radiation source referred to in subsection 1.

The party which transports the radiation source shall notify STUK of the transportation subject to a safety licence prior to the start of the transport or the radiation source's arrival to Finland.

STUK issues more detailed regulations on the content of the notification referred to in subsection 3.

Question 12.1 Are registrants and licensees required to provide the regulatory body as required with appropriate information from their inventory records of radiation generators and radioactive sources?

Response:

Undertaking is responsible to keep record of all radiation sources subjected to safety license. Record keeping of radiation sources and radiation generators is stipulated in SätL section 71:

Section 71 Record-keeping and notification obligation

In practices subject to a safety licence, the undertaking shall keep a record on the radiation sources related to the safety licence. The records must indicate the radiation sources held by the undertaking as well as the reception and handing over of the sources and their removal from the licence. A radiation source may be removed from the records five years after its handing over or removal from the licence. The records shall be kept up to date.

Undertaking is obligated regularly confirm the location of the radioactive sources. For high-activity radioactive sources confirmation of the location needs to be recorded and done monthly. (SätL section 67 and STUK S/9/2021 section 7)

The verification of inventory of radiation generators and radioactive sources is mainly done during inspections. The general process of inspections is described in internal guide SKV 3.4: In-service supervision of radiation activities requiring a safety licence.

STUK supervises record keeping also by surveillance questionnaire. Undertakings are asked to check their safety license register information presented to them and report all alterations.

Question 12.2 Are registrants and licensees required to promptly notify the regulatory body with information regarding a radioactive source or radiation generator that is lost, missing or not under control?

Response:

Registrants and licensees possessing a radioactive source or radiation generator are responsible to be prepared in advance for radiation safety deviations. This includes for example scenarios in which radioactive source or radiation generator are lost, theft, missing or not under control. STUK must be notified immediately. The notification must be made by telephone or by any other means of

communication that enables the notifier to ensure that the message is received. Outside office hours, STUK must be contacted by calling the emergency exchange.

Section 130 of SätL lists measures that need to be done promptly.

The undertaking responsible for the radiation safety deviation and the authority which becomes aware of the radiation safety deviation shall immediately notify STUK of:

3) the loss, unauthorized use or holding of a radiation source subject to a safety licence;

This requirement is further specified in STUK S/2/2018. There is specified what information the notification must include, such name of the registrant or licensee, place of the event, information on the radiation generator, description of the event. The notification shall be confirmed in writing without delay. The written report must give an account of the causes and consequences of the abnormal incident (particularly of possible radiation exposure) and of the measures taken to prevent future corresponding incidents.

Question 13 Is it regulated that a radiation generator or a radioactive source is transferred only if the recipient possesses the necessary authorization?

Answer: Yes

Response:

According to SätL section 72 a radiation source the holding of which is subject to a safety licence may be handed over only to an undertaking with the necessary safety licence. The transferor shall ensure that the recipient has the required safety licence. The recipient shall provide the transferor with a certificate on the reception of the radiation source. The transferor shall also provide recipient with any information and certificate and other information relevant to radiation safety in possession of radiation source, received from the manufacturer or importer. This is stated in section 73 of SätL. The manufacturer or importer of a radiation source shall provide the recipient with detailed information on the structure of the source and its properties having an impact on safety together with the source.

Section 72 Obligations of the transferor, recipient and transporter

A radiation source the holding of which is subject to a safety licence may be handed over only to an undertaking with the necessary safety licence. The transferor shall ensure that the recipient has the required safety licence. The recipient shall provide the transferor with a certificate on the reception of the radiation source referred to in subsection 1. The party which transports the radiation source shall notify STUK of the transportation subject to a safety licence prior to the start of the transport or the radiation source's arrival to Finland. STUK issues more detailed regulations on the content of the notification referred to in subsection 3.

Section 73 Obligation to provide information

When handing over a radiation source generating ionizing radiation, the manufacturer or importer shall provide the recipient with detailed information on the structure of the source and its properties having an impact on safety together with the source. A sealed source is also subject to a certificate demonstrating compliance with regulations. The undertaking handing over a radiation source generating ionizing radiation to another is obligated to provide the recipient, in connection to the handing over, with any information and certificate and other information relevant to radiation safety in its possession, received from the manufacturer or importer as referred to in subsection 1. STUK issues more detailed regulations on the content of the information referred to in subsection 1 and 2 and their provision

According to section 84 of the SätL waste and other material deriving from radiation practices may be reused, recycled, utilized and disposed of in accordance with the Waste Act, provided that the amount of radioactive substance it contains does not exceed the clearance level referred to in section 85, subsection 2 of the SätL.

Sealed sources can be reused by another registrants and licensees with sufficient safety licence. According to section 72 of SätL and in more detail section 33 of the STUK S/5/2019 the transferor of a sealed source subjected to safety licence shall ensure that the recipient has the required safety licence. The transferor shall ensure that:

1) the useful life of the sealed source recommended by the manufacturer has not ended;

2) the sealed source and its shielding as well as the information and documentation supplied with the source meet the applicable requirements;

3) the leak tests referred to in section 28 of the SätL have been conducted for the sealed source;

4) the sealed source has a transport packaging which meets the applicable legal requirements.

STUK checks the preconditions/requirements for the re-use of a radiation source during the licensing process as described in the internal guide SKV 3.2 Safety authorisation procedure.

Question 14 Is it regulated that registrants and licensees in cooperation with manufacturers ensure that where applicable sealed sources are identifiable and traceable?

Answer: Yes

Response:

Sealed source must be marked permanently for identification on the shield of the sealed source and if technically possible on the sealed source, this is indicated in SätL section 70. Sealed source shall be marked with a sign warning of a radiation hazard, if this is technically possible. Also, the storage facility of radioactive sources shall be marked with radiation hazard signs as stipulated in SätL section 66.

Section 70 Identification of a sealed source

The manufacturer shall identify a sealed source the use of which is subject to a safety licence. The unique identifier must be marked with as permanent a method as possible on the shield of the sealed source. The unique identifier must furthermore be marked on the sealed source, if this is technically possible. If the marking of a sealed source is not technically possible, the identifying details must be indicated in the documents accompanying the sealed source.

The importer of the sealed source or the party responsible for its transfer to Finland must ensure that the source has been identified as previously described. An unidentified sealed source may not be used in, imported, or transferred to Finland.

Previous is described in more detail in STUK S/5/2019 sections 18 and 19:

Information about the radioactive substance

The shield or exposure container containing radioactive substance shall be marked with the radionuclide, activity and the activity's determination date.

In case of sealed sources, also the serial number or other identifier of the sealed source shall be marked.

Identification of sealed source and information concerning the identification of the source

The serial number of sealed source or other identifier of the source shall be presented in the certificate of compliance referred to in section 73, subsection 1, of the Radiation Act.

A high-activity sealed source shall be identified by means of a serial number assigned by the manufacturer.

Question 14.1 How does the regulatory body ensure that areas where radioactive sources are managed are marked by users with appropriate signs to warn workers or members of the public, as applicable, of the radiation hazard?

Response:

The areas used for managing radioactive sources need to be marked with a label warning of radiation hazard. Requirements are set out in SätL section 66 and STUK S/5/2019 section 10.

The undertaking shall ensure that a radiation source, the facility and place where it is used and stored, and the equipment and devices related to it are such that the radiation source can be used safely.

The undertaking shall ensure that the use and storage facility or place of a radiation source subject to a safety licence is marked with a sign indicating radiation hazard. The radiation source shall be marked with a sign warning of a radiation hazard if this is technically possible. In addition, the source shield or source container or storage shield of a radiation source containing a radioactive substance

must have a label including the key information of the radioactive substance it contains and a marking indicating radiation hazard.

STUK S/5/2019 section 10: *The marking warning of radiation hazard referred to in section 66, subsection 2, of the Radiation Act, shall be placed at the doors of places where radiation is used and stored if the door is at the border of the controlled or supervised area. The marking shall be done in accordance with standard SFS-EN ISO 361. The marking may also be a marking of the intended use of the room, if the related radiation hazard is shown clearly in the marking.*

Places of use and storage of radiation sources in which the design of radiation shielding is based on the estimate that no one stays in the room permanently shall be marked with a sign prohibiting people from staying in such rooms.

Different areas can be classified as controlled or supervised areas. Controlled areas and supervised areas must have signs indicating the areas' classification, requirement is set in VnA sections 36 and 37.

Markings and their adequacy are verified during inspections.

Question 15 Are registrants and licensees required to ensure that when radioactive sources are not in use they are stored in an appropriate manner for protection and safety?

Answer: Yes

Response:

Section 23 of SätL requires the undertaking to organize the practise so that the risk of an occurrence leading to exceptional exposure to radiation is adequately eliminated.

According to Sections 66 and 67 of SätL radioactive substances are to be used and stored in places in which they can be used safely and where they are prevented from falling into the hands of unauthorized persons. Storage facility or place of a radiation source subject to a safety licence need to be marked with a sign indicating radiation hazard. Undertaking is responsible to store radiation sources subject to a safety licence in a manner they are protected against loss or otherwise falling into the hands of third parties or illegal operation.

Requirements on structural shielding of a storage facility are described in more detail in STUK S/5/2019. Premises used for storage of radiation sources has be planned and implemented in such a way that the exposure caused to employees and the public is as small as possible and the dose caused by radiation sources does not exceed the applicable dose constraint. Premises need to be reassessed when the radiation source or the type of use of the radiation source changes or additional sources are added. Areas where radiation protection is based on the assessment that continuous presence isn´t allowed shall be marked with a sign prohibiting stay out in these places (section 10). Radioactive sources need to be stored apart from materials not related to the use of the radiation sources (section 13).

Security arrangements are set in STUK S/9/2021 (STUK Regulation on the security arrangements for radiation sources requiring a safety license). Security levels are three (A, B or C) depending on the radiation sources and they have different required actions. Level C is the lowest level of security arrangements.

SätL 66 In-service radiation safety

The undertaking shall ensure that a radiation source, the facility and place where it is used and stored, and the equipment and devices related to it are such that the radiation source can be used

safely.

The undertaking shall ensure that the use and storage facility or place of a radiation source subject to a safety licence is marked with a sign indicating radiation hazard. The radiation source

shall be marked with a sign warning of a radiation hazard if this is technically possible. In addition, the source shield or source container or storage shield of a radiation source containing a

radioactive substance must have a label including the key information of the radioactive substance it contains and a marking indicating radiation hazard.

What is provided in subsection 2 also applies to other radiation sources the safe use of which requires this.

STUK issues more detailed regulations of a technical nature on the radiation safety during use referred to in subsection 1, the markings referred to in subsection 2 and 3, appliances' in-service

acceptability requirements and other requirements pertaining to the use of the appliances.

Section 67 Security arrangements

The undertaking shall protect radiation sources subject to a safety licence against illegal operation or loss or otherwise falling into the hands of third parties at their use and storage facilities. These security arrangements shall be adequate in terms of the risks related to the practice and the radiation sources and they must form a whole compatible with the measures concerning radiation safety.

The security arrangements include, depending on the risks involved in the radiation sources:

1) drawing up a plan on the security arrangements and keeping the plan up to date;

2) protecting the radiation sources with structural barriers and the presence of personnel;

3) the regular verification of the location of the radiation source;

4) the use of access control and other technical surveillance measures;

5) restricting access to materials concerning radiation sources and security arrangements.

STUK issues more detailed regulations on the security arrangements and their determination in accordance with the radiation sources.

STUK S/5/2019 Section 4 Protective shielding of premises where radiation sources are used and stored

Premises where radiation sources are used and stored shall be planned and implemented in such a way that the exposure caused to employees and the public is as small as possible, when reasonable actions are implemented, and that the dose caused does not exceed the dose constraint applicable to the place where the radiation source is used and stored.

The type of use of the radiation source and the use of premises surrounding the place where the source is used and stored shall be taken into account in protective shielding. Providing reasonable justification for the applicable values of directional factors and times spent in the premises must be possible.

The adequacy of radiation shielding shall be re-evaluated if:

1) the radiation source changes or additional sources are added;

2) the type of use of the radiation source changes;

3) the use of premises surrounding the place where the source is used and stored changes in a way that might increase the exposure in work or public exposure.

The adequacy of radiation shielding shall be ensured by means of radiation measurements or other reliable methods after the shielding has been constructed or changed.

Section 10 Marking of places of use

The marking warning of radiation hazard referred to in section 66, subsection 2, of the Radiation Act, shall be placed at the doors of places where radiation is used and stored if the door is at the border of the controlled or supervised area. The marking shall be done in accordance with standard SFS-EN ISO 361. The marking may also be a marking of the intended use of the room, if the related radiation hazard is shown clearly in the marking.

Places of use and storage of radiation sources in which the design of radiation shielding is based on the estimate that no one stays in the room permanently shall be marked with a sign prohibiting people from staying in such rooms.

Section 13 § Special requirements for the storage of a radiation source

Radiation sources containing radioactive material shall be stored separately from goods and materials not related to the use of the radiation sources.

Question 16 Are registrants and licensees required to ensure that arrangements are made promptly for the safe management of and control over radiation generators and radioactive sources, including appropriate financial provision, once it has been decided to take them out of use?

Answer: Yes

Response:

When applying for safety licence, the application shall, according to SätL section 52, include the arrangements for managing the waste and discharges containing radioactive substances generated by the practice during its operations and when discontinuing the practice. Radioactive waste must be rendered harmless. Radioactive sources become radioactive waste once undertaking removes them from use and undertaking isn´t going to use them again.

After radiation generators and radioactive sources are removed from use, registrants and licensees must handle them appropriately and without unnecessary delay as stated in SätL section 83 subsection 6. Radioactive sources are removed from use by returning them to the manufacturer or supplier or by transferring them to another licensee with the safety licence for the reception, treatment and storage of radioactive waste. A source may be stored without returning or transferring it, provided that the source's half-life and activity is such that it can be aged safely.

SätL section 83 Decommissioning of radiation sources and facilities

The undertaking must be prepared to manage used radiation sources and radioactive waste generated by the practice as well as to clean the facilities used in the practice from radioactive substances.

The undertaking shall remove any radiation sources containing radioactive substance subject to a safety licence which have become obsolete by returning them to the manufacturer or supplier or by transferring them to another undertaking with the appropriate safety licence. A source may nevertheless be stored without returning or transferring it, provided that the source's half-life and activity is such that it can be aged safely.

The undertaking must clean any areas, facilities and their structures contaminated by radioactive substances in such a way that the remaining amount of radioactive substances does not exceed the clearance level referred to in section 85, subsection 2.

The cleaning requires a safety licence if the amount of radioactive substances prior to the cleaning is greater than the clearance level

If the amount of radioactive substances cannot be made lower than the clearance level with reasonable measures, the undertaking must present a plan on the measures concerning the area, facilities or structures to STUK.

The undertaking may not delay the performance of the measures referred to in subsection 2 and 3 without justification.

STUK issues more detailed regulations on decommissioning of radiation sources and facilities and on their cleaning.

SätL 54 requires registrants and licensees to furnish a security for costs arising from proper disposal or for possible environmental clean-up measures. Security is required if the undertaking has a high-activity sealed source (HASS) or if the total activity per nuclide of the radioactive material or radiation sources held by the undertaking at any time exceeds the activity of a high-activity sealed source of the same nuclide. The security must be furnished before high-activity source is purchased and it is checked during licensing phase. Activity values of high-activity sealed sources are set in STUK S/5/2019 Appendix 1.

The conditions for the security are specified in VnA (1034/2018) section 29:

The basic charge for a security in a practice referred to in section 54, subsection 1, paragraphs 1–3 of the Radiation Act is EUR 10,000. The surcharge is EUR 75 per payment unit.

The number of payment units is calculated by dividing the activity value of the high-activity sealed source in question, the activity value of the radioactive substance being held at any one time or the value of the nuclide-specific combined activity of sealed sources removed from use annually by the value of the activity of a high-activity sealed source provided under section 75, subsection 5 of the Radiation Act.

The Radiation and Nuclear Safety Authority may estimate and impose the additional fee to be smaller than what is provided in subsection 1 if the number of the payment units is greater than 2,000 payment units and the security would be clearly too big in proportion to the risks related to the practice. In such a case, however, the security may not be less than EUR 160,000.

A practice referred to in section 54, subsection 1, paragraph 4 of the Radiation Act is subject to the lodging of a security if the amount of the costs arising from rendering the radioactive waste harmless, the measures necessary in terms of radiation safety in the waste management of waste referred to in section 78, subsection 3 of the Radiation Act or any environmental clean-up measures is estimated to be greater than EUR 100,000.

Question 17 Does the government ensure that the use of ionizing radiation for human imaging for purposes other than medical diagnosis, medical treatment or biomedical research is subject to the system of protection and safety?

Answer: Yes

Response:

Protection and safety of non-medical imaging or the use of ionizing radiation for human imaging for purposes other than medical diagnosis, medical treatment or biomedical research is subject of SätL chapter 14 consisting of sections 120 through 125. Requirements given in mentioned sections cover periodical justification assessment of the practice as well as requirements for quality assurance, device's in service radiation safety and other requirements regarding medical exposure and requirements for setting dose constraints.

The undertaking must submit a report on the non-medical practice in question and an assessment of its justification when applying for authorization. STUK confirms the legitimacy of the activity as part of the granting of the safety licence or the decision on the licence modification.

On STUKs website there is a list of the non-medical exposure situations that STUK has so far assessed as generally justified (in Finnish and in Swedish: https://www.stuk.fi/stuk-valvoo/sateilyn-kayttajalle/toiminnan-valvonta/kuvantamisessa-henkiloon-kohdistettu-muu-kuin-laaketieteellinen-altistus). These include exposure situations such as tuberculosis screening, personal inspection, child abuse x-ray examinations and naval medical examinations with approved imaging methods associated with each situation and references to other legislations, regulatory guidance or scientific studies.

Radiation Act Section 120 Scope of application

This chapter contains provisions on non-medical imaging exposure to ionizing radiation.

Section 121 Justification assessment

The undertaking shall assess whether the practice referred to in this chapter is justified at least every five years.

Section 122 Imaging with a health care appliance

Any imaging carried out with a health care appliance is subject to section 30 with regard to quality assurance, section 66 with regard to the device's in-service radiation safety, and chapter 13 with regard to medical exposure.

The recording and storage of the information concerning the imaging is subject to what is provided in the Act on the Status and Rights of Patients (785/1992) on the drawing up and keeping of health records.

The imaged individual is not subject to the dose limits concerning members of the public in practices referred to in subsection 1.

Section 123 Dose constraint for other than health care appliance

The undertaking must set the dose constraint for the imaged person if the imaging is carried out by other than health care appliance.

The value of the dose constraint must remain significantly below the dose limit for the members of the public.

Section 124 Provision of information and requesting consent

The party requiring imaging must ensure that the individual to be exposed or their legal representative is provided with the appropriate information on the radiation exposure and possible health detriments caused by the imaging. The information must be given in the native language of the individual to be exposed or their legal representative or in a language they can justifiably be expected to understand.

The individual to be exposed or their legal representative is requested for a consent to the imaging, unless otherwise provided elsewhere. The opinion of an incompetent person to be exposed shall be determined whenever possible in relation to their age and level of development. If an incompetent person, based on their age and level of development, is able to give their consent to imaging, the consent of their legal representative is not required.

If the incompetent person is unable to give consent for the imaging, his or her legal representative will decide on the consent. The consent may be given and withdrawn in free-form. The imaging may not be performed if the existence of the consent required by law or its voluntary nature is unclear.

In imaging carried out by other than health care appliance, the provision of the information and the request for consent referred to in subsection 1 is ensured by the undertaking.

Further provisions on the provision of information concerning the radiation exposure and possible health detriments as well as the request for consent are given by government decree.

Section 125 Person inspection with a method causing radiation exposure

The competent authority gives a written order for a person inspection as referred to in the Coercive Measures Act (806/2011) or the Customs Act to be performed with a method that exposes the inspected person to radiation.

The consent referred to in above in section 124 is not requested in a person inspection performed based on the Coercive Measures Act or the Customs Act.

Question 17.1 What measures are planned to improve compliance with this requirement?

Response:

No response

Question 18 Has the government established a framework for safety that includes provision for controls on the import and export of radioactive sources?

Answer: Yes

Response:

SätL implements the provisions of the IAEA guidelines in imports and exports of radiation sources from and to outside the EU. Transfers within the EU are regulated through the Council Regulation 1493/93/Euratom. Import and export of high activity sources are also governed by International Atomic Energy Agency guidelines that Finland has agreed to observe ("Code of Conduct on the Safety and Security of Radioactive Sources", and "Guidance on the Import and Export of Radioactive Sources").

In VnA section 24 is stipulated that import and export of certain high activity sources require the approval of competent authorities in the country of origin and the destination country, together with the exchange of prior declarations and notifications between the countries. STUK will submit the necessary enquiries and notifications to competent authorities abroad when approval is sought for import or export of a high activity source. The approval decision will impose requirements, as necessary, concerning the special notifications or other measures that must be performed by the party securing approval (SätL section 76 and VnA section 24).

Transfer of radioactive sources in Category 1 and 2 is stipulated in SätL section 76. Activity values of high-activity sealed sources are set in STUK S/5/2019 Appendix 1.

A high-activity sealed source may only be exported to a state with adequate technical, legislative and administrative capabilities to manage the safety of the source and its use.

The undertaking shall ensure that the required departure and arrival notifications are prepared of sealed sources for the competent authorities of the country of origin and country of destination.

Shipments of radioactive material between EU Member States have been laid down in Council Regulation 1493/93/Euratom. According to Article 4 of the Council Regulation (Euratom) 1493/93, a holder of sealed sources or radioactive waste who intends to carry out a shipment of such sources or waste, or to arrange for such a shipment to be carried out, shall obtain a prior written declaration by the consignee of the radioactive substances to the effect that the consignee has complied, in the EU member state of destination.

Declarations on the export of high-activity sealed source is stipulated in VnA (1034/2018) section 24:

Prior to issuing a safety licence for the export of a high-activity sealed source belonging to class 1 or 2, the Radiation and Nuclear Safety Authority checks with the appropriate regulatory authority of the country of destination that said country has no impediment for the export and that the consignee is entitled to receive the source.

The notifications referred to in section 76, subsection 3 of the Radiation Act must be made with regard to the import and export of high-activity sealed sources belonging in class 1 or 2 source batch-specifically as stated in more detail by the Radiation and Nuclear Safety Authority in the safety licence.

Analysis

STRENGTHS FOR SAFETY REQUIREMENTS FOR RADIATION SOURCES

S1	Long continuous experience in regulation of uses of radiation sources (over 60 year) including comprehensive registers of sources including all sealed sources exceeding the exemption level (electronic data bases since 1980's).
S2	Effective mechanisms in place to ensure the continuous updating of source registry data including separate notifications from suppliers and receivers which are cross-checked and regular inspections where source inventories are verified.
S3	The new SätL provides comprehensive and effective mechanisms to address safety and security of sources and to emphasize the responsibility for safety of the licensee by various

	means including the conduct of a safety assessment, the use of Radiation Protection Experts and in advance planning for the management of sources when they become disused.
S4	Transparency of implementation of requirements by using SAMMIO.

WEAKNESSES FOR SAFETY REQUIREMENTS FOR RADIATION SOURCES

W1	STUK management system documents prescribe actions taken in case of orphan High Activity Sealed Sources or if an (orphan) source is melted but fails to describe explicitly the actions for other orphan sources.
W2	Despite that the responsibilities and roles of STUK and the Rescue Services are defined in legislation, the person or party confronted with an orphan source may not know which advise to follow.
W3	STUK regulations include some very detailed requirements on QC that cannot be fulfilled in all cases by the licensee.
W4	No specific provisions or guidance are in place addressing the handling of deceased persons or human remains that are known to contain sealed or unsealed radioactive sources.

OPPORTUNITIES FOR SAFETY REQUIREMENTS FOR RADIATION SOURCES

O1	STUK is revising its internal guide SKV 3.5 which provides a prompt opportunity to include the lacking guidance on the actions to be taken in case of an orphan source which is not a High Activity Sealed Source.
O2	Experiences gained in the application of new regulations (issued in 2019-2020) provides basis for improving the regulation.
O3	New means for regulatory control (remote inspection, questionnaires etc.) may help in further implementation of graded approach and better cost effectiveness for regulatory control.

THREATS FOR SAFETY REQUIREMENTS FOR RADIATION SOURCES

T1	New means for regulatory control (remote inspection, questionnaires etc.) may pose a challenge in gaining and maintaining inspector competence if it results in significant reduction of on-site inspections and diminishes related “learning by doing/seeing” possibilities.

CONCLUSIONS FOR SAFETY REQUIREMENTS FOR RADIATION SOURCES

C1	The legal framework, regulatory requirements, and arrangements for regulatory control for radiation sources and radiation sources facilities provides for the safety and security of radiation sources in Finland in a manner required by the IAEA Safety Standards.

C2	The self-assessment identified some possibilities for further improvement, mostly related to STUK processes and management system documents prescribing the management of orphan sources. Also, some minor possibilities for improvements in the new legislation were identified.
C3	The experience feedback from STUK regulations (issued in 2019-2020) can be exploited to improve the regulation.

Module: Safety Requirements for Transport of Radioactive Material

Findings

Question 1 In the context of paragraph 802 of SSR-6, does the Competent Authority for transport issue the necessary approval or validation certificates as appropriate?

Answer: Yes

Response:

a) Designs for:

i) Special form radioactive material

There is no manufacturing of special form material in Finland, so no specific guidance is written. The requirements that must be met are stated in Annex A, part 2.2.7.2.3.3 of the Regulation TRAFICOM/443227/03.04.03.00/2020. The requirements are the same as in the ADR agreement.

The general requirements for applications are stated:

Road: Annex A, part 6.4.23.8 of the Regulation TRAFICOM/443227/03.04.03.00/2020

Rail: Annex A, part 6.4.23.8 of the Regulation TRAFICOM/443235/03.04.02.00/2020

Air: Decree 210/1997, section 2. ICAO-TI: Part 6, chapter 7, 7.21.5

Sea: Decree 666/1998, Section 3. IMDG: Part 6, chapter 6.4.23.8

ii) Low dispersible radioactive material

There is no manufacturing of a low dispersible radioactive material in Finland, so no specific guidance is written. The requirements that must be met are stated in Annex A, part 2.2.7.2.3.4 of the Regulation TRAFICOM/443227/03.04.03.00/2020. The requirements are the same as in the ADR agreement.

The general requirements for applications are stated:

Road: Annex A, part 6.4.23.8 of the Regulation TRAFICOM/443227/03.04.03.00/2020

Rail: Annex A, part 6.4.23.8 of the Regulation TRAFICOM/443235/03.04.02.00/2020

Air: Decree 210/1997, section 2. ICAO-TI: Part 6, chapter 7, 7.21.5

Sea: Decree 666/1998, Section 3. IMDG: Part 6, chapter 6.4.23.8

iii) Fissile material excepted under SSR-6 para. 417(f)

There is no manufacturing of a fissile material in Finland, so no specific guidance is written. The requirements that must be met are stated in Annex A, part 2.2.7.2.3.5 of the Regulation TRAFICOM/443227/03.04.03.00/2020. The requirements are the same as in the ADR agreement.

The general requirements for applications are stated:

Road: Annex A, part 6.4.23.9 of the Regulation TRAFICOM/443227/03.04.03.00/2020

Rail: Annex A, part 6.4.23.9 of the Regulation TRAFICOM/443235/03.04.02.00/2020

Air: Decree 210/1997, section 2. ICAO-TI: Part 6, chapter 7, 7.21.5

Sea: Decree 666/1998, Section 3. IMDG: Part 6, chapter 6.4.23.9

iv) Packages containing 0.1 kg or more of uranium hexafluoride

There is no manufacturing of uranium hexafluoride in Finland, so no specific guidance is written. The requirements that must be met are stated in Annex A, part 6.4.6 of the regulation TRAFICOM/443227/03.04.03.00/2020. The requirements are the same as in the ADR agreement.

The general requirements for applications are stated:

Road: Annex A, part 6.4.23.6 of the Regulation TRAFICOM/443227/03.04.03.00/2020.

Rail: Annex A, part 6.4.23.6 of the Regulation TRAFICOM/443235/03.04.02.00/2020

Air: Decree 210/1997, section 2. ICAO-TI: Part 6, chapter 7, 7.21.1

Sea: Decree 666/1998, Section 3. IMDG: Part 6, chapter 6.4.23.6

v) Packages containing fissile material, unless excepted by SSR-6

For Packages containing fissile material, unless excepted by SSR-6, the requirements that must be met are stated in Annex A, part 6.4.11 of the regulation TRAFICOM/443227/03.04.03.00/2020. The requirements are the same as in the ADR agreement.

The general requirements for applications are stated:

Road: Annex A, part 6.4.23.7 of the Regulation TRAFICOM/443227/03.04.03.00/2020.

Rail: Annex A, part 6.4.23.7 of the Regulation TRAFICOM/443235/03.04.02.00/2020

Air: Decree 210/1997, section 2. ICAO-TI: Part 6, chapter 7, 7.21.4

Sea: Decree 666/1998, Section 3. IMDG: Part 6, chapter 6.4.23.7

vi) Type B(U) packages and Type B(M) packages

There is no manufacturing of type B(U) packages in Finland

Because Finland applies the ADR agreement, unilateral competent authority approval can be made by another ADR country. If Finland is the first ADR country in which the package is used (and it is manufactured in a non-ADR country), Finland will validate the certificate. See the definition of "Approval issued by STUK" in part 1.2 of Annex A of the TRAFICOM/443227/03.04.03.00/2020.

The general requirements for applications are stated:

Road: Annex A, part 6.4.23.4 of the Regulation TRAFICOM/443227/03.04.03.00/2020.

Rail: Annex A, part 6.4.23.4 of the Regulation TRAFICOM/443235/03.04.02.00/2020

Air: Decree 210/1997, section 2. ICAO-TI: Part 6, chapter 7, 7.21.2

Sea: Decree 666/1998, Section 3. IMDG: Part 6, chapter 6.4.23.4

Because Finland applies the ADR agreement, unilateral competent authority approval can be made by another ADR country. If Finland is the first ADR country in which the package is used (and it is manufactured in a non-ADR country), Finland will validate the certificate. See the definition of "Approval issued by STUK" in part 1.2 of Annex A of the Decree 369/2011.

There is no manufacturing of type B(M) packages in Finland.

The general requirements for application are stated:

Road: Annex A, part 6.4.23.5 of the Regulation TRAFICOM/443227/03.04.03.00/2020

Rail: Annex A, part 6.4.23.5 of the Regulation TRAFICOM/443235/03.04.02.00/2020

Air: Decree 210/1997, section 2. ICAO-TI: Part 6, chapter 7, 7.21.3

Sea: Decree 666/1998, Section 3. IMDG: Part 6, chapter 6.4.23.5

Additional guidance for B- type package approval is given in YVL guide D.2.

vii) Type C packages

There is no manufacturing of type C packages in Finland. The general requirements for application are same as presented in point vi) for B(U).

b) Special arrangements

According to part 6.4.23.3 of Annex A of the Decree 369/2011, the application has to include:

An application for approval of shipments under special arrangements shall include all the information necessary to satisfy STUK that overall level of safety in carriage is at least equivalent to that which would be provided if all the applicable requirements of the regulations were met.

The application shall include

- A statement of the respects in which, and the reasons why, the shipment cannot be made in full accordance with the applicable requirements of the regulations, and
- A statement of any special precautions or any special administrative or operational controls which are to be employed during carriage to compensate for the failure to meet the applicable requirements of the regulations

Road: Annex A, part 6.4.23.3 of the Regulation TRAFICOM/443227/03.04.03.00/2020

Rail: Annex A, part 6.4.23.3 of the Regulation TRAFICOM/443235/03.04.02.00/2020

Air: Decree 210/1997, section 2. ICAO-TI: Part 5, chapter 1, 1.2.1.3 and Part 1, chapter 6, 6.4

Sea: Decree 666/1998, Section 3. IMDG: Part 6, chapter 6.4.23.3

c) Certain shipments (SSR-6 para 825)

The transports for which an approval is required are listed in:

Road: part 5.1.5.1.2 of Annex A of the Regulation TRAFICOM/443227/03.04.03.00/2020

Rail: part 5.1.5.1.2 of Annex A of the Regulation TRAFICOM/443235/03.04.02.00/2020

Sea: Section 3 of the Decree 666/1998. IMDG: Part 5, 5.1.5.1.2.

Air: Section 2 of the Decree 210/1997. ICAO-TI: Part 5, chapter 1, 1.2.1.2

The general requirements for applications are stated in Annex A, part 6.4.23.2 of TRAFICOM/443227/03.04.03.00/2020 (road), Annex A, part 6.4.23.2 of the TRAFICOM/443235/03.04.02.00/2020 (rail), IMDG: Part 6, 6.4.23.2 (sea), ICAO-TI: Part 5, chapter 1, 1.2.2.1.

For nuclear material and nuclear waste transports, both a transport licence and an approval of transport plan are required. The use of nuclear energy is forbidden without a licence (Nuclear Energy Act section 8). It is not allowed to start the transport operations before STUK has approved the transport plan. The detailed requirements of the contents of the transport plan are specified in the YVL guide D.2.

d) Radiation protection programme for special use vessels

Road: Decree 194/2002:

Anyone who carries or temporarily stores radioactive materials shall have a radiation protection programme unless otherwise provided for in Annex A, chapter 1.7 of the Regulation TRAFICOM/443227/03.04.03.00/2020. The radiation protection programme shall indicate the measures of how to prevent and restrict radiation exposure caused by the transport or temporary storage of radioactive materials. These measures shall be proportional to the amount and likelihood of radiation exposure. Before undertaking any transport or storage operations, the radiation protection programme shall be submitted for information to STUK. Unless otherwise provided for in Annex A, chapter 1.7 of the Regulation TRAFICOM/443227/03.04.03.00/2020, the operator shall draw up a quality assurance programme to be applied in its operations to ensure the conformity of its operations:

1. for the transport of all radioactive substances in special form and of radioactive materials with low dispersibility;
2. for the design, manufacture, testing, documentation, use, maintenance, and inspection of all packages used for the transport and temporary storage of radioactive materials; as well as
3. for measures relating to the transport and temporary storage of radioactive materials. The quality assurance programme referred to in subsection 2 shall be based on requirements or instructions considered acceptable by

STUK in Finland. Upon request, the quality assurance programme shall be made available to STUK in Finland.

Further details of the programme are given in Annex A, chapter 1.7.2 of the TRAFICOM/443227/03.04.03.00/2020 (like ADR).

Similar requirements apply to the other modes of transport (IMDG; ICAO-TI; RID).

e) Calculation of radionuclide values that are not listed in SSR-6 Table 2

Competent Authority approval is required for the calculation of radionuclide values not listed in Table 2 in SSR-6 according Annex A, part 2.2.7.2.2.2 a) of the of the Regulation TRAFICOM/443227/03.04.03.00/2020 (road), TRAFICOM/443235/03.04.02.00/2020 (rail) .

f) Calculation of alternative activity limits for an exempt consignment of instruments or articles (see SSR-6 para. 403(b))

Competent Authority approval is required for Calculation of alternative activity limits for an exempt consignment of instruments or articles according Annex A, part 2.2.7.2.2.2 b) of the of the Regulation TRAFICOM/443227/03.04.03.00/2020, TRAFICOM/443235/03.04.02.00/2020 (rail).

Question 2 Does the competent authority for transport register serial numbers of transport packaging manufactured to an approved design?

Answer: Yes

Response:

There is not manufacturing of transport packages in Finland so currently no registers for serial numbers exists.

If someone would start manufacture transport packages in Finland, the manufacturer has to inform the competent authority about the registration number of the package according Annex A, part 6.4.23.19 of the of the Regulation TRAFICOM/443227/03.04.03.00/2020 (road). This is valid for all transportation modes.

Question 3 Does the competent authority for transport perform review and assessment of relevant information for determining whether the applicant for authorization or the authorized party complies with applicable regulatory requirements?

Answer: Yes

Response:

Competent Authority

The approvals relating to the transport of radioactive material are issued by STUK. A written application is sent to STUK. The application must contain all the information required by the relevant international agreement on each mode of transport and its national implementation. Finland has implemented ADR, RID, IMDG, ICAO-TI in its national legislation. In most of the modes of transport, STUK is the competent authority. There are a couple of situations where another authority is involved. For example, INF classification is made by the Finnish Transport Safety Agency.

The application is reviewed by relevant experts in STUK and the approval is issued if all the information is deemed sufficient. The decision is signed, depending on the matter, by section head, department head or director general of STUK. Before signing any decision, inspectors cross-check 10% of each other's decisions; 5% goes to the section head and 1% to the department head. The purpose of the practice is to promote consistent and good decision process.

STUK relies mainly on the competence of its staff in connection with the evaluation of the content of safety license applications. If a particular matter needs extra expertise, STUK can seek outside help.

When needed STUK is in contact with competent authorities in other countries, for instance the particular competent authority which has issued an original approval for a package design.

Administrative responsibilities

According to section 31 of the Administrative Procedure Act (434/2003), the competent authority must ensure an adequate and appropriate investigation of the matter by obtaining the information and explanations necessary for resolving the matter. According to the same paragraph, the party concerned, i.e. the operator, must provide an explanation of the application or notification he has sent and must otherwise contribute to the clarification of the case he has initiated. It is also the responsibility of the party to demonstrate that the conditions for granting a safety license are met. If there is a defect in the application or notification that prevents processing, the inspector (STUK) will send a supplementary request of information to the applicant.

The operator shall be consulted on the decision in advance if the decision is not taken in full compliance with the application or if specific restrictions or requirements are included in the decision.

Package approvals

For packages that are designed to contain non-nuclear material, the internal process (in STUK) is described in guide SKV 5.2. For packages that are designed to contain nuclear material, the internal process (in STUK) is described in guide YTV 5.3.1.

Regarding packages for which a competent authority approval is required (B and C -types), STUK reviews these issues from the package documents while granting the approval. It should be noted there are no package design or manufacture in Finland and practically all packages for which a competent authority approval is required, used in Finland are of foreign origin. The document requirements for the package approval are listed in YVL D.2 requirements 401-403.

High-activity sealed sources (non-nuclear material) – road and rail transports

In Finland, under the Radiation Act (859/2018) only road and rail transport of high-activity sealed sources requires a safety license. Annex 5 of the Government Decree on Ionizing Radiation (1034/2018) contains a list of the information to be submitted in a safety license application. The process of handling the safety license is described in STUK guide SKV 3.2.

In addition to the safety license requirement, each transport event of high-activity sealed sources must be notified to STUK prior to the transportation. Annex 11 to Regulation STUK S/5/2019 contains a detailed list of information required in the transport declaration/notification.

Nuclide specific limits for high-activity sealed source activity values can be found in STUK regulation no. S/5/2019. These limit values have been derived from the Council Directive 2013/59/Euratom. And origin for these high activity sealed source limits lies in the IAEA document *Dangerous quantities of radioactive material* (D-values) (EPR-D-VALUES 2006).

A safety license for the road and rail transport of high-activity sealed sources is granted provided that:

- the radiation practice complies with the principles of justification, optimization and limitation;
- a safety assessment pursuant to section 26 has been drawn up for the radiation practice;
- the practice can be carried out safely;
- the operator has the right to engage in a trade in Finland.

<u>Nuclear material and nuclear waste transports</u>

For nuclear material and nuclear waste transports, both a transport licence and an approval of transport plan and security plan are required. The use of nuclear energy is forbidden without a licence (Nuclear Energy Act section 8). The transport license is not required, if the transported nuclear material amount is small or natural uranium, deplete uranium or thorium or to the total activity is less than 1 TBq for nuclear waste not containing any nuclear material. (Nuclear Energy Degree section 17). In the above-mentioned cases a notification needs to be sent to STUK for information about the transportation (Nuclear Energy Degree chapter 17)

It is not allowed to start the transport operations before STUK has approved the transport and security plans. The detailed requirements of the contents of the transport and security plans are specified in the STUK YVL Guide D.2. STUK's approval of emergency plan is required for the transportations, where the total activity is over 1000 TBq.

Special arrangements

An application for approval of shipments under special arrangements shall include all the information necessary to satisfy STUK that overall level of safety in carriage is at least equivalent to that which would be provided if all the applicable requirements of the regulations were met.

The application shall include:

- A statement of the respects in which, and the reasons why, the shipment cannot be made in full accordance with the applicable requirements of the regulations;

- A statement of any special precautions or any special administrative or operational controls which are to be employed during carriage to compensate for the failure to meet the applicable requirements of the regulations.

Question 3.1 Does the competent authority for transport continue to review and assess as necessary, relevant information associated with the transport approvals during the validity period of the transport approvals?

Response:

High-activity sealed sources (non-nuclear material) – road and rail transports

Safety licenses issued under the Radiation Act (859/2018) for road and rail transport activities of high-activity sealed sources are in several cases approvals valid until further notice. For reasons justified during the application process, a temporary safety license may also be granted for these transport operations.

Safety licenses for road and rail transport of high-activity sealed sources are assessed in the same manner as all other safety licenses issued for the use of radiation. The process of inspections and other control actions performed by the competent authority are described in STUK guide SKV 3.4.

While issuing safety license applications for road and rail transport of high-activity sealed sources, a safety assessment covering all radiation activities is required. STUK confirms the content of the safety assessment as part of the approval decision for transport operations safety license. If the license holder makes changes in its activities subject to the license a notification/application must be submitted to STUK and the safety assessment must be updated. As a result, operations are evaluated regularly and always in connection with safety/security significant changes.

In addition to on-site inspections, the control activities of licensees also include documentary reviews. Based on the information collected, STUK sends requests of supplemental information to license holders to provide more detailed clarification, either for an individual incident or more broadly about arrangements affecting the safety of radiation operations.

The need for reassessment arises for a variety of reasons. For example, the influential factors might be the time intervals used as the basis for planning STUK's supervision strategy, abnormal events, the quality of applications and notifications received, and the monitoring of the implementation of binding instructions given to the license holder.

Nuclear material and nuclear waste transports

Nuclear materials and nuclear waste transports requires a transport license. Transport license can be granted by STUK for one transportation or to several transportations. If a license is applied for several transportations, the license is granted for a fixed time period. The typical license period is 5 years if the transportation is continuous activity like the fresh fuel transportations to NPP’s.

The transportation cannot be done until the transportation plan is approved by STUK. The transportation plan contains the detailed information on the transportation (e.g. time schedule, organization, route, detailed information on transported material, activity, chemical composition etc). Fulfilment of the safety requirements and requirements on transportation of dangerous goods (ADR) during the transportation is reviewed by STUK in this phase. In addition, security plan shall be delivered to STUK for approval and emergency plan, if the total activity of the transportation is over 1000 TBq.

STUK inspects selected transportations. Usually the licensee is notified before the inspection, but also unexpected inspections can be arranged.

Special arrangements

Transport with special arrangements is usually granted a safety permit for one transport event at a time. Where appropriate, a safety authorization may also be granted for series transport consisting of several repeated transports under arrangements approved in the decision. In the case of an individual shipment, the necessary restrictions are determined in the approval decision. Though, in the case of serial transport, monitoring and reassessment may be carried out as the transport series progresses.

Package approvals

There are no package design or manufacture in Finland and practically all packages for which a competent authority approval is required, used in Finland are of foreign origin. If there were manufacture of transport packaging in Finland for which the approval of the authority is required, supervision would be carried out in the same way as described above for other transport operations. Therefore, the control of packaging would also include reassessment on a regular basis and based on certain findings over time.

Question 4 Prior to issuance of approval of special arrangement shipments, is it required that the competent authority for transport is satisfied that conformity with some of the provisions of the regulations is impracticable and that the requisite standards of safety established by the regulations have been demonstrated?

Answer: Yes

Response:

An application for approval of shipments under special arrangements shall include all the information necessary (Regulation on the Transport of Dangerous Goods by Road (TRAFICOM/443227/03.04.03.00/2020) Annex A part 6.4.23.3) to satisfy STUK that overall level of safety in carriage is at least equivalent to that which would be provided if all the applicable requirements of the regulations were met.

The application shall include

- A statement of the respects in which, and the reasons why, the shipment cannot be made in full accordance with the applicable requirements of the regulations, and

- A statement of any special precautions or any special administrative or operational controls which are to be employed during carriage to compensate for the failure to meet the applicable requirements of the regulations

Question 5 Does the competent authority for transport carry out inspections of facilities and activities related to transport of radioactive materials to verify compliance with regulatory requirements and the conditions specified in any approvals?

Answer: Yes

Response:

Right to inspection, information, and investigation - Radiation Act

STUK have the right to:

- inspect and observe a practice referred to in this Act and circumstances that may result in harmful exposure to radiation and to access the facility in which the practice is engaged or in which the circumstances are manifested;
- inspect the fulfillment of the in-service requirements of the radiation sources used in the practice as well as the instruments, equipment and supplies with an impact on radiation safety;
- perform, free of charge, the tests and measurements required by the supervision take and obtain the necessary samples, photographs and other possible recordings, and to install the devices required by the supervision in the facility in which the practice is engaged in or in its vicinity;
- to obtain from the party engaged in the practice, non-disclosure provisions notwithstanding, information necessary for supervision and, in terms of personal data, the necessary information;
- investigate a radiation safety deviation or procedure observed in radiation practices which has or may have material relevance for the safety of the radiation practice; the investigator may also hear persons other than those employed by the undertaking, party to the matter being investigated or otherwise aware of it.

Right of inspection, information, and examination - Act on Transport of Dangerous Goods

The supervisory authorities provided for in the Act on Transport of Dangerous Goods have the right, within their sphere of operations, to carry out inspections necessary to supervise compliance with the

Act and the provisions and regulations issued thereunder as well as, in order to carry out the supervision, to have access to the places of manufacture, storage, sale, installation, repair, inspection, loading and transportation of dangerous goods and of the packaging and tanks used for their transport, to temporary storage places and to a vehicle transporting dangerous goods as well as the right to take the necessary samples and to carry out examinations.

Inspection program requirement - Radiation Act

The content of the inspection program referred to in section 182 of the Radiation Act must be of the kind that any control pursuant to it achieves, accounting for the risks resulting from the practice, adequate assurance of the safety of the radiation practice and of compliance with the provisions of the Radiation Act and the conditions provided in safety licenses.

The inspection program includes duties, regular inspections and inspections based on case-specific considerations announced and not announced in advance.

The inspection program may also include inspections based on control questionnaires and information and data received from the undertaking which do not include a visit to the location in which the practice is carried out.

The program specifies goal-oriented intervals for regular inspections, the grounds for conducting different types of inspections and the key content of the inspections. The program accounts for the categorizations of radiation practices referred to in section 27 of the Radiation Act (859/2018) and for experiences accumulated from observations made in previous inspections.

Inspection practices

In inspections carried out during transport operations, STUK often co-operates with other supervisory authorities. For example, roadside inspections are in practice carried out by the Police, for which STUK provides expert support. Other examples are the inspection of incoming and outgoing radioactive material in co-operation with Customs. The inspection can also be focused on transport chains connecting different modes of transport and several operators by working together with the Finnish Transport Agency.

In inspections of transport operations, it is natural to divide the objects of control into two groups based on legislation: license holders and class 7 transports exempted from a radiation safety license. STUK's inspections of transportations of radioactive non-nuclear materials are carried out according instructions given on STUK guides SKV 3.4 and SKV 5.2. More precisely high-activity sealed sources road and rail transports requiring a safety license are considered to belong to the scope of STUK guide SKV 3.4 that covers all license holders in the field on industry and research. Thus, transports exempted from the safety license procedure and matters related to transport packages are in the scope of STUK guide SKV 5.2.

The inspections of transportations of nuclear materials and nuclear waste are carried out according instructions given on YTV guide 3.g.1. In practice the regular inspections are mainly focused on transportations of fresh fuel to NPP's as there is not so much other transportations done in Finland so far. According current plans the transportations of spent nuclear fuel is starting at earliest in 2040's from Loviisa NPP to repository located in Olkiluoto. Nuclear wastes are mainly handled at NPP's. Only two transportations of nuclear waste (metal) for handling abroad has been done during last three years.

Question 6 Does the competent authority for transport make arrangements for assessments of radiation doses to persons due to transport of radioactive material, to ensure the system of protection and safety for transport complies with GSR Part 3?

Answer: Yes

Response:

Transport personnel handling class 7 dangerous goods in Finland are not automatically regarded as radiation workers. When the workers are classified as radiation workers, all regulations concerning radiation work will apply to them and the doses of the personnel will be monitored. The doses are recorded in the national registry. According to section 25 in the Radiation Act (859/2018), the undertaking shall establish the dose constraints and constraints for potential exposure to be used in the radiation practice in advance, unless STUK has established the constraints to be used in the practice in general by virtue of section 10 in the Act. Constraints on the occupational exposure of an outside worker shall be established in co-operation with the employer of the outside worker.

In the case of transport subject to a safety license, a clarification on radiation exposure under working conditions and information on the arrangements for monitoring radiation doses are required while issuing the application. According to the section 89 in the Radiation Act (859/2018), in practices requiring a safety licence, the radiation exposure of workers and means to reduce it must be assessed before starting the work. The assessment must be adjusted if change affecting occupational exposure takes place in the practice. The worker's previous occupational exposure must also be investigated

prior to the commencement of radiation work. These requirements are described in more detail in the STUK regulation on the determination, assessment, and monitoring of occupational exposure S/1/2018.

For shipments exempted from the safety license, these issues will be addressed as part of other control actions (*e.g.* on-site inspections, document inspections). It is the employer's responsibility to determine the exposure conditions and dose monitoring arrangements.

According to Government Decree on the Transport of Dangerous Goods by Road (194/2002), anyone who carries or temporarily stores radioactive materials shall have a radiation protection programme unless otherwise provided for in Annex A, chapter 1.7 of the Regulation TRAFICOM/443227/03.04.03.00/2020. The radiation protection programme shall indicate the measures of how to prevent and restrict radiation exposure caused by the transport or temporary storage of radioactive materials. These measures shall be proportional to the amount and likelihood of radiation exposure. Before undertaking any transport or storage operations, the radiation protection programme shall be submitted for information to STUK. Unless otherwise provided for in Annex A, chapter 1.7 of the Regulation TRAFICOM/443227/03.04.03.00/2020, the operator shall draw up a quality assurance programme to be applied in its operations to ensure the conformity of its operations.

Regulation of the Finnish Transport and Communications Agency TRAFICOM/443227/03.04.03.00/2020 states (like ADR) that if it is estimated that occupational exposure from transport activities readable effective dose either:

a) is likely to be between 1 mSv and 6 mSv per year:

a dose assessment program is required to monitor working conditions or as personal dose monitoring, or

b) is likely to exceed 6 mSv in a year:

personal dose monitoring is required.

Question 7 Does the competent authority for transport require appropriate action to be taken on discovery of a non-compliance?

Answer: Yes

Response:

<u>Actions in the treatment of an abnormal event</u>

Transportation of High-Activity Sealed Sources

In practices subject to a safety licence, the undertaking must prepare for radiation safety deviations. The undertaking shall have an up-to-date plan of action for the deviations.

In the event of a radiation safety deviation, the undertaking in a practice subject to a safety licence shall assess the situation and take the measures necessary to ensure radiation safety. The undertaking responsible for the radiation safety deviation and the authority which becomes aware of the radiation safety deviation shall immediately notify STUK of:

- the radiation safety deviation due to which the radiation safety of the workers or members of the public at the facility and place where the radiation is used or its surroundings may be compromised;

- any significant unplanned medical exposure;

- the loss, unauthorized use or holding of a radiation source subject to a safety licence;

- any significant spreading of a radioactive substance indoors or in the environment;

- any other abnormal observations and information which may be of material significance in terms of radiation safety.

The undertaking shall immediately notify any significant exposure arising from a radiation safety deviation and the reasons for it to:

- the exposed worker;

- the referrer and the physician responsible for medical exposure as well as the exposed individual or their legal representative, in terms of medical exposure;

- any other individuals exposed, insofar as possible.

If the radiation safety deviation requires rescue operations or protective actions from an authority, the undertaking shall take part in them.

The undertaking shall ensure that a radiation safety deviation and the reasons for it and the exposures arising from it are investigated. A record shall be kept of radiation safety deviations and their investigations and the results of said investigations. The undertaking shall implement the remedial measures required due to a radiation safety deviation, which prevent similar deviations. The undertaking shall notify STUK of the results of the investigation concerning the radiation safety deviation and of the remedial measures.

More detailed specifications for the notification, investigation and site-specific instructions for radiation safety deviations are given in STUK Regulation S/2/2018.

Transportation of nuclear materials and nuclear waste

The licensee shall report the transport-related special situations to the rescue services and/or the police upon detection and to STUK without delay. Unless restricted by authorities, the consignor shall be notified of any information relating to such special situations that the consignor needs to know to fulfill its responsibilities. (YVL D.2 318)

The Licensee shall made provision for special situations in transportation of nuclear materials or nuclear waste. In a special situation, immediate measures shall be taken to stop unlawful action, gain control of the special situation, and to mitigate and minimise the consequences. The operator shall assist the authorities in the event of special situations especially in matters relating to radiation safety. A record shall be kept of special situations and deviations, which are to be reported to STUK. The operator shall assist the authorities in the event of special situations, especially in mitigating and minimising radiation consequences and regaining control of stolen nuclear material or nuclear waste. (YVL D.2 338)

Remedying deficiencies detected in a practice

STUK or an individual inspector thereof may obligate an undertaking to remedy their practice to such a state that it meets the requirements laid down in the Radiation Act (859/2018), Nuclear Energy Act (990/1987), Nuclear Energy Degree (161/1988) and related STUK regulations. The undertaking may furthermore be obligated to implement such measures to improve radiation safety as can be considered justified in terms of their quality and costs as well as their improving impact. The implementation of

the measures shall be set a time limit. The decision may obligate the undertaking to notify the remediation of the deficiencies and the measures undertaken due to the decision.

Discontinuation or restriction of practice

STUK may decide on the discontinuation or restriction of a practice if the practice fails to accord with the Radiation Act (859/2018), Nuclear Energy Act (990/1987), Nuclear Energy Degree (161/1988) and related STUK regulations or may cause an obvious health detriment. In cases that are urgent in terms of safety an inspector may decide on the discontinuation or restriction of a practice.

According Radiation Act (859/2018) the inspector shall submit the matter without delay to STUK for decision. The inspector's decision is valid until STUK gives its decision in the matter, but in no case for more than 14 days.

For the transportations of nuclear materials or nuclear waste the operations may be interrupted or limited until the reason for the issuance of the provision no longer exists (Nuclear Energy Act 990/1987 Section 67).

STUK can also cancel the transportation licence of nuclear materials or nuclear waste wholly or partly if

1) the licence holder is violating the licence conditions or regulations

2) the licence holder is neglecting its financial provision obligation

3) the licence holder is dying or losing legal capacity or the corporation or foundation holding the licence being dissolved, otherwise discontinuing operations or going into bankruptcy.

Cancellation of a licence requires that a reasonable period of time has been allowed for the licence holder to correct the deficiency, where this is possible by means of the licence holder's actions. (Nuclear Energy Act 990/1987 Section 26)

Notices of conditional fine, enforced compliance and suspension

STUK may enforce a decision it has made or a prohibition it has given pursuant to the Radiation Act (859/2018) or Nuclear Energy Act (990/1987) with a notice of conditional fine or at the threat of having a neglected measure taken at the defaulter's expense or suspending the practice or prohibiting the use of the radiation source. STUK may impose a conditional fine to enforce a duty to provide information and obligation to present documents referred to in section 176, subsection 1, paragraph 4. The Act on Conditional Fines (1113/1990) lays down provisions on notices of conditional fine, enforced compliance and suspension. Section 185 of the Radiation Act sets out the grounds for imposing fines for a radiation violation.

Coercive means and consequences

The supervisory authority referred to in sections 5 and 6 of the Act on Transport of Dangerous Goods (719/1994) may enforce a prohibition or order issued under the Act by a conditional fine or the threat of ordering a measure to be performed at the defaulter's expense as provided for in the Act on Conditionally Imposed Fines (1113/1990).

Provisions concerning punishment for a crime committed against the Act on Transport of Dangerous Goods (719/1994) or provisions or regulations issued thereunder concerning the transport of dangerous goods are laid down in chapter 44, section 13, of the Penal Code (39/1889).

Provisions concerning punishment for impairment of the environment against the Act on Transport of Dangerous Goods (719/1994) or provisions or regulations issued thereunder are laid down in chapter 48, sections 1- 4, of the Penal Code.

Anyone who violates the provisions of the Act on Transport of Dangerous Goods (719/1994) or provisions or general or specific orders issued thereunder, shall be sentenced for an offence during the transport of dangerous goods to a fine.

STUK guidance for the enforcement actions

STUK's internal guidelines on administrative coercive measures are written in guide SKV 3.7 and in guide YTV 6.3. The necessary information is obtained, for example, through written requests for clarification and on-site inspections. If, in connection with the incident or otherwise, there is reason to suspect that the operator has committed a radiation violation, STUK submits a request for an investigation to the police. If necessary, STUK can influence the operator by imposing penalty payments or restricting approved operations via the safety license procedure.

Question 8 Has the competent authority for transport established or adopted regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based?

Answer: Yes

Response:

The “umbrella law” that covers all modes of transport is Act on Transport of Dangerous Goods 719/1994.

Different modes each have a government decree:

Road: Government Decree on the Transport of Dangerous Goods by Road 194/2002 and Regulation TRAFICOM/443227/03.04.03.00/2020, which gives the detailed provisions of ADR.

Rail: Government Decree on the Transport of Dangerous Goods by Rail 195/2002 and Regulation TRAFICOM/443235/03.04.02.00/2020, which gives the detailed provisions of RID.

Air: Decree on Transport of Dangerous Goods by Air 210/1997

Sea: Decree on the Transport of Dangerous Goods in Packaged Form by Sea 666/1998

In addition, transportations for nuclear materials and radioactive waste is regulated also in Nuclear Energy Act 990/1987 and Nuclear Energy Decree 161/1988. In addition, there is regulatory guide YVL D.2 “*Transportation of nuclear materials and nuclear waste*”.

Transportation of high-active shielded sources is regulated in the Radiation Act (859/2018) and Regulation STUK S/5/2019.

In the reform of national legislation, competent authorities and other actors in the field interact in steering and monitoring groups. STUK is an active member of the IAEA committees (incl. TRANSSC) and strives to promote radiation safety not only in the national field but also through an international co-operation network. In the development of national legislation, STUK mirrors Finnish regulations to the latest versions of international recommendations and contributes to ensuring that the regulations issued in Finland comply with binding international agreements. The Finnish Transport and Communications Agency has the largest role in the bodies preparing international agreements for individual modes of transport, and STUK seeks to support this work by participating in expert co-operation groups at the national level as a class 7 transport expert and supervisory authority. Binding draft laws and regulations are publicly open for comments before acts are presented to the government for approval.

Question 8.1 How does the competent authority for transport establish or adopt transport regulations and guides?

Response:

The implementation of international recommendations into national law takes place through a public procedure in which authorities and experts retain the opportunity to comment. The aim is to iterate the requirements as well as possible before they enter into force. STUK communicates its own findings on transport regulations to the IAEA through meetings of the Transport Committee (TRANSSC) and related technical expert meetings. In connection with mode-specific international agreements, STUK supports the Finnish Transport and Communications Agency in its work as a member of the bodies maintaining the agreements.

Question 9 Does the competent authority for transport require that persons engaged in transport receive adequate training?

Answer: Yes

Response:

Act on Transport of Dangerous Goods 719/1994 section 11 sets the requirements for the competences of the persons engaged in transport for all transport modes. Everyone participating into a transportation (packing, sending, shipping, loading, transporting, or unloading) of dangerous goods shall have a proper training or other competence for the work and regularly repeated continuing education unless the work is done under the immediate supervision of educated person. More detailed requirements on the content of the training are given in section 15. of decree 194/2002.

Employer should ensure the employees have proper training for the transportation and temporary storage of dangerous goods. Employer shall have records on the trainings and competences of the

employees. The records shall be maintained at least three years after the trainings. This information shall be shown to authorities, if required.

Special requirements are set for the competences of the employees working in duties related to air transportations (Act on Transport of Dangerous Goods 719/1994 section 11 a).

For the transportation of dangerous goods in road the driver needs a special driving license (ADR-driving license). (Act on Transport of Dangerous Goods 719/1994 section 11 b)

For transportations of nuclear materials and nuclear waste the persons contributing to the transport shall be given training in the properties of the transported material and the transport, nuclear security, and emergency preparedness arrangements, which also covers the procedure in special situations. Actions under special situations shall be practiced. The form, content, organization, and frequency of the exercises shall be planned in a risk-informed manner. The authorities in question shall be reserved the opportunity of participating in the training and exercises. (YVL D.2 325, 325 a and 339)

Among the authorities, training is most often provided in preparedness co-operation exercises. Exercises might be organized in the spirit of bilateral co-operation with one of STUK's co-operation authorities or in larger multi-authority exercises. The co-operation between the authorities also includes specific training events organized on request, for example, conscious training in the case of Class 7 transports that STUK can provide to the colleagues.

Question 10 Are adequate emergency arrangements in place for the transport of radioactive material?

Answer: Yes

Response:

Section 7 of the Act 719/1994 states the general responsibilities of operators regarding e.g. accidents: “The parties with an effect on the safety of the transport and temporary storage of dangerous goods, such as the packer, consignor, shipper, consignor, loader, carrier, operator and consignee hall for their part ensure the taking of measures necessary to prevent accidents as well as their harmful consequences to people, the environment and property.”

Section 11 if the Act states the general training requirements of staff. The requirements are further clarified in e.g. section 15 of the decree on Transportation of Dangerous goods in road 194/2002. Similar requirements are in place for all modes of transport.

The requirements for actions after road accidents are described in Section 34 of the decree 194/2002: "If an accident takes place during the transport of dangerous goods causing a danger of personal, environmental or property damage due to a leakage of the substance being transported or to another reason, the driver of the vehicle or the party in charge of the loading or unloading shall immediately report the 16 incident to the Emergency Dispatch Centre, give the necessary information to the rescue authorities and take the appropriate protective measures required by the situation.".

The rescue authorities have their own guidance on how to respond to accidents that include radioactive material ("TOKEVA, parts M1 and T7").

According to Section 33 of the decree 194/2002, the provisions of the Decree may be derogated from in urgent emergency operations if compliance with the provisions hampers the emergency operations.

The consignor is obligated to give relevant guidance to consignors according to sections 5.4.3 (standard ADR written instructions) and 5.4.1.2.5.2 (emergency arrangements appropriate to the consignment) of Annex A of the TRAFICOM/443227/03.04.03.00/2020. Similar provisions apply to the other modes of transport (IMDG; ICAO-TI; RID).

Rail: Regulation TRAFICOM/443235/03.04.02.00/2020, Annex A, 5.4.3 (standard ADR written instructions) and 5.4.1.2.5.2 (emergency arrangements appropriate to the consignment)

Sea: IMDG: Part 5, 5.4.1.5.7.2 and 5.4.3.2

Air: ICAO-TI: Part 5, chapter 4, 4.1.5.6.2

According to Section 130 of the Radiation Act (859/2018) The undertaking responsible for the radiation safety deviation and the authority which becomes aware of the radiation safety deviation shall immediately notify STUK of:

- the radiation safety deviation due to which the radiation safety of the workers or members of the public at the facility and place where the radiation is used or its surroundings may be compromised;

- any significant unplanned medical exposure;

- the loss, unauthorized use or holding of a radiation source subject to a safety licence;

- any significant spreading of a radioactive substance indoors or in the environment;

- any other abnormal observations and information which may be of material significance in terms of radiation safety.

The undertaking shall immediately notify any significant exposure arising from a radiation safety deviation and the reasons for it to:

- the exposed worker;

- the referrer and the physician responsible for medical exposure as well as the exposed individual or their legal representative, in terms of medical exposure;

- any other individuals exposed, insofar as possible.

If the radiation safety deviation requires rescue operations or protective actions from an authority, the undertaking shall take part in them.

Further provisions on reporting an observed or suspected defect or deficiency in a medical radiation appliance are laid down in the Act on Medical Equipment and Supplies.

More detailed specifications for the notification, investigation and site-specific instructions for radiation safety deviations are given in STUK Regulation S/2/2018.

An emergency plan, accompanied by a report justifying the measures presented in the emergency plan, shall be drawn up for a transport of nuclear materials or nuclear waste where the activity of the material transported exceeds 1,000 TBq. The requirements for the content of the emergency plan is described in YVL D.2 chapter 4.5. The requirement to inform STUK of any accidents or incidents during transport of nuclear materials or nuclear waste is stated in requirement 318 of STUK YVL Guide D.2. (YVL D.2 318, 356, chapter 4.5)

Analysis

STRENGTHS FOR SAFETY REQUIREMENTS FOR TRANSPORT OF RADIOACTIVE MATERIAL

S1	STUK is regulating safety, security and nuclear material safeguards (3S), which enhances the regulatory oversight of radioactive material transports.
S2	Radioactive material transport in Finland is quite standard practice and relies for example on transport casks approved in other countries. STUK has comprehensive competences for this type of regulatory work.

WEAKNESSES FOR SAFETY REQUIREMENTS FOR TRANSPORT OF RADIOACTIVE MATERIAL

W1	Requirements concerning transport on dangerous goods, and specifically related to radioactive material, are provided in three or more acts. It is difficult for transport companies providing service to Class 7 transportation to have clear view of all requirements. There is also risk that requirements differ between different areas.

OPPORTUNITIES FOR SAFETY REQUIREMENTS FOR TRANSPORT OF RADIOACTIVE MATERIAL

O1	-

THREATS FOR SAFETY REQUIREMENTS FOR TRANSPORT OF RADIOACTIVE MATERIAL

T1	Approval and certification of new type of cask or other similar situation can occur. In this kind of situation STUK does not have existing procedures or competences.

CONCLUSIONS FOR SAFETY REQUIREMENTS FOR TRANSPORT OF RADIOACTIVE MATERIAL

C1	Finnish regulatory framework and STUK's regulatory oversight fulfil IAEA standards requirements. Requirements for safe transportation of dangerous goods are provided in several acts, which hampers operators possibilities to have a clear view of all requirements.

OUTCOMES OF THE SELF-ASSESSMENT FOR INTERFACE WITH NUCLEAR SECURITY

Module: 11. Interfaces with nuclear security

Findings

Question 1 Have adequate infrastructural arrangements been established within the governmental framework to enable effective interfaces between safety and nuclear security and the State system of accounting for, and control of nuclear material?

Answer: Yes

Response:

Radiation practices:

Effective interfaces between safety and security of radiation sources have been established by SätL which covers both safety and security of radiation sources and establishes STUK as the regulatory authority for both aspects. Interphase between safety and security is specifically addressed in Section 67 of SätL which states that security arrangements shall be adequate in terms of the risks related to the practice and the radiation sources and they must form a whole compatible with the measures concerning radiation safety. Section 51 of SätL requires the submission of a a security plan to STUK for review in an application for a safety license. All provisions of SätL on regulatory control, e.g. STUK's right to inspect and enforce regulatory requirements, cover both safety and security aspects. Section 180 of SätL provides STUK official assistance from the police and the customs in enforcing safety or security related requirements of the SätL.

All small nuclear materials (e.g. uranium shields in gamma radiography) are covered in Nuclear Energy Act or Radiation Act.

YEL:

Nuclear Energy Act covers safety-security and safeguards in the use of nuclear energy. Interfaces are covered in more details in lower-level requirements, which is explained below. STUK oversees all three domains and they are all part of the licensing process. Section 7 of Nuclear Energy Act states that sufficient security arrangements are a prerequisite for the use of nuclear energy. Detailed requirements about safety-security and safeguards interface are given in Radiation and Nuclear Safety Authority Regulation on the Security in the Use of Nuclear Energy Y/3/2020 section 3, which states that security arrangements shall be consistent with the operation, fire safety and emergency response arrangements of nuclear energy. Nuclear safeguards shall also be taken into account in the planning and implementation of security arrangements.

Nuclear Energy Decree sections 24, 35 and 36, states that during the licensing process of a nuclear facility, several documents regarding security arrangements shall be delivered to STUK together with all the safety and safeguards-related documents that are required.

As said in Nuclear Energy Act section 55, STUK is responsible for the oversight of safe use of nuclear energy. This includes the oversight of both the emergency and security arrangements.

Question 1.1 Describe the extent to which the legal and governmental framework includes specific responsibilities for assessment of the configuration of facilities and activities for the optimization of safety, taking into account factors relating to nuclear security and the system of accounting for, and control of nuclear material.

Response:

Radiation Act:

For the undertaking there are several responsibilities taking nuclear security into consideration. First, the organization's management must maintain and develop a safety culture in its operations. Safety and security must be considered in all documents required by the Radiation Act: Safety assessment, management system, quality assurance program, preparedness plan and plan on security arrangements. These documents shall be included in safety license application.

The undertaking shall show the justification for a new type of radiation practice subject to a safety licence. The same applies to existing radiation practices if new important information on the efficiency, possible consequences or alternative methods or techniques of the practice is obtained. When assessing whether the use of a sealed source is justified, the possibility of using an appliance generating radiation electrically instead of a high-activity sealed source or some other alternative technology shall be considered.

The undertaking shall use radiation safety expert in the planning, for example when drawing up plan on the security arrangements. If the radiation safety expert has not sufficient expertise in security matters, other expertise shall be obtained (Section 23 of SätL states that "The undertaking shall ensure that it has the expertise necessary in terms of the nature and extent of the practice at its disposal and sufficient financial and human resources for the safe implementation of the practice.").

STUK supervises compliance with Radiation Act when it comes licensing and configuration of facilities. When supervising compliance with obligations pursuant to Radiation Act, the regulatory authority considers the risks associated with radiation sources and the impact that the supervising may have in the reduction of risks. The objective of regulatory measures is to keep radiation sources subject to a safety license under the supervising of the regulatory authorities throughout the source's entire life cycle. Small nuclear materials are accounted by Nuclear Energy Act but inspected by both safeguards and inspectors of radiation in industry unit.

Finnish Customs supervises, for its part, the import and export of radiation sources and radioactive waste, as well as the transit of radioactive waste through Finland's territory.

Nuclear Energy Act:

As explained under the question 1: STUK is "one house authority" covering safety, security and safeguards. Configuration of these three domains has also been explained under question 1 above (from the security point of view). Nuclear Energy Act requires the licensee to cover safety-security and safeguards aspects. The interfaces between security, safety and safeguards must be recognized as described above.

Question 1.2 Describe the extent to which the legal and governmental framework includes specific responsibilities for oversight and enforcement of arrangements for safety, nuclear security and the system of accounting for, and control of nuclear material.

Response:

Radiation Act:

STUK supervises compliance with Radiation Act and is solely responsible for oversight of safety and security aspect. STUK draws up an inspection programme concerning the inspections of practices subject to a safety license. The inspection program must be risk informed. The provisions of the SätL (Sections 174, 177, 178) authorizing STUK to enforce regulatory requirements can be used irrespectively whether the non-compliance is safety or security related.

According to the Police Act, the police must provide official assistance to another authority upon request, if so specifically provided. The police must also provide official assistance to another authority in order to fulfill the duty of supervision provided by law, if the authority requesting official assistance is prevented from performing its official duties.

In addition to what is provided with regard to the provision of official assistance in the Police Act (872/2011), the Police is obligated, upon request, to provide a regulatory authority with official

assistance in a matter pertaining the discontinuation and restriction as well as prohibition of a practice referred to in Radiation Act.

Regarding the import, export and transit of radiation sources and radioactive waste, the Customs provides official assistance for supervision compliance with and for the enforcement of Radiation Act.

Nuclear Energy Act

Nuclear Energy Act gives STUK the mandate and obligation to supervise the security arrangements as well as safety and safeguards in all phases of planning, construction, operation and decommissioning of a nuclear facility.

In STUK, field inspections can be divided into three parts: regular-, unannounced- and reactive inspections. Each office in the Nuclear Reactor Regulation and in Nuclear Waste Regulation and safeguards departments conducts their annual regular field inspections. Document reviews of licence holders' documents are carried out daily to ensure that the instructions, manuals and other documents relating to the operation of nuclear facility meet the requirements.

Resident inspectors who work in the nuclear power plant site are an important way to gather information about daily activities. They (certain resident inspectors) have also been trained for nuclear security related topics with access to certain confidential information. This is also safety-security interface that STUK has recognized, resident inspectors are mainly safety trained by default, but Nuclear Security Section of STUK has trained them for security. Resident inspectors participate also security inspections almost every time.

STUK has an internal group for nuclear security. This group is chaired by the Section Head of Nuclear Security and members of the group are from *safety, radiation safety, radioactive sources section, emergency preparedness* etc. covering all aspects and domains. This group ensures that different areas are taken into account.

When STUK establishes requirements, all relevant stakeholders are involved, and the requirements are cross-checked in order to avoid any contradictions. This also includes classified requirements.

Nuclear Energy Act gives STUK the mandate to have access and carry out measurements in premises that contains nuclear material in order to supervise the non-proliferation of nuclear weapons (Finland has no nuclear weapons, or large amount of such graded nuclear material that is suitable for WMD).

Nuclear Energy Decree states that the various phases in the construction of a nuclear facility cannot be commenced until STUK is certain that all safety-related factors and safety regulations have been given sufficient consideration. Section 35 of Nuclear Energy Decree defines the documents that is required to be submitted to STUK. These documents include preliminary plans for the arrangements for security and emergencies and a plan for arranging the safeguards control that is necessary to prevent the proliferation of nuclear weapons.

YVL-Guide A.11 Security of Nuclear Facility sets the actions that STUK shall take in supervision of security arrangements during all the different phases of nuclear facility license process (decision-in-principle phase, construction license phase, construction phase, operating license phase, commissioning phase, operation phase and decommission phase).

During decision-in-principle phase STUK reviews a plan to see if the nuclear power plant is protected against an aircraft crash in accordance with section 14 of STUK Y/1/2018. Also, the planned location of the nuclear facility shall be suitable for safety, security and emergency arrangements. A description of suitability of the location shall be submitted to STUK.

In construction license phase, preliminary plans for the security and emergency arrangements shall be submitted for approval. Purpose of these preliminary plans are to present the planning criteria, technical implementation and demonstration of adequacy for the security arrangements. Basically, the plans shall contain the following documents: preliminary security plan and a draft security standing order. Any changes made to the security plan and security standing order require approval from STUK.

During operation license phase security plan and security standing order shall be submitted to STUK for approval. Also, during this phase licensee shall submit guarding instructions, schedule for implementation of security arrangements and system level documentation to STUK. Inspections can be notified to the license holder beforehand but also surprise inspections will be made.

During commissioning phase STUK shall inspect the acceptability of nuclear security before the nuclear facility is taken into service by the means of both document inspections and site inspections.

In operation phase any changes that are made to the security standing order or to the security plan are subject to the STUK's approval before implementing any changes. STUK supervises the implementation of security alongside with other operations and periodic inspections are conducted during plant unit operation, refueling, maintenance and repair outages.

When the nuclear facility enters decommissioning phase security arrangements shall be kept adequate so that endangering of nuclear or radiation safety can be prevented.

Enforcement and sanctions are stipulated in Nuclear Energy Act: 69 § - 74 §

Question 1.3 Does the legal and governmental framework include specific responsibilities for the liaison with law enforcement agencies, as appropriate?

Response:

Radiation Act:

STUK does a lot of cooperation with the authorities. There is no need for Memorandum of Understandings between authorities, because the roles, functions and duties of different authorities are prescribed in the legislation, for example the police is required to provide assistance, if certain powers are needed. See e.g. Radiation Act Section 180: *In addition to what is provided with regard to the provision of official assistance in the Police Act (872/2011), the Police is obligated, upon request, to provide a regulatory authority with official assistance in a matter pertaining the discontinuation and restriction as well as prohibition of a practice referred to in this Act.*

With regard to the exchange of information: Notwithstanding non-disclosure provisions, the regulatory authorities referred to in Radiation Act shall have the right to obtain information necessary for carrying out its duties laid down in Radiation Act from another regulatory authority and to use samples acquired by another regulatory authority for the purposes of regulatory control. In respect of personal data, the right to obtain information is limited solely to the information absolutely necessary for regulatory control.

Notwithstanding non-disclosure provisions, the regulatory authority may disclose information received in the regulatory control purposes on the financial status, trade or professional secret, and exposure to radiation of a private individual or a corporation and of the state of a private individual's health to the other regulatory authorities referred to in this Act when they are performing the regulatory control laid down in Radiation Act, another authority which needs the information to perform an official duty in the field of radiation protection, and to the regulatory authorities of other Member States of the European Union for the purposes of supervision on implementation of the European Union's radiation legislation.

The regulatory authority may furthermore, non-disclosure provisions notwithstanding and for the purposes of statutory duties, disclose information on the holders of safety licenses and radiation sources and their locations to the Police and emergency authorities as well as to the authorities referred to in section 6 of the Act on the Transport of Dangerous Goods and ministries.

Nuclear Energy Act

Cooperation with other authorities is an important aspect for STUK and to the Finnish nuclear security regime. There is no need for Memorandum of Understandings btw. authorities, because at the law level security authorities (e.g. police) are required to provide executive assistance, if certain powers are needed. See e.g. Nuclear Energy Act Section 68: *A police authority **shall** provide executive assistance when needed in matters relating to supervision of the observance of this Act and the provisions issued hereunder.* As a practical example: in the past there have been "big demonstrations" next to nuclear power plant. These have been notified to license holder. According to DBT and requirements for the operator, they are required to protect the facility against such activities. First example: During these cases there has been request for the police to assist, which they have done. Second example: the operator is responsible for fresh nuclear fuel transport safety and security (also safeguards). They have requested assistance from police, which the police has provided. These examples explain the Finnish system from the security point of view.

Design Basis Threat (DBT) is used as a basis for the planning and assessment of the nuclear security arrangements for which the licensee is responsible. It is STUKs responsibility to define the DBT but STUK shall hear the Ministry of the Interior, license holder and the advisory commission mention in NEA section 56. It is the responsibility of Finnish Security and Intelligence Service (FSIS) to come up with the threat assessment relating to the use of nuclear energy.

In case when there's a reason to believe or during a situation when nuclear or radiation safety is endangered, a notification shall be made to the police authorities immediately. Responsibility of command shifts to the police authority when the police so notifies.

Should license holder's nuclear security officer detain a person, he or she shall be handed over the to the police without delay. Also, if a Remotely Piloted Aerial System (RPAS) is taken under custody by the security organisation, license holder shall hand over the RPAS to the police without delay.

With the help of annual health inspections done by the occupational health care, license holder shall make sure that the nuclear security officers and nuclear power plant operators than work in the control room are applicable to work in their positions and doesn't endanger nuclear or radiation safety. Should the occupational health care deem that the operator or nuclear security officer is unfit for the job, doctor has the right to notify STUK and license holder about the person. If the unfit person works as a nuclear security officer, a notification to the police authorities shall be made as well.

License holder shall periodically, however no less often than every four years, arrange an extensive nuclear security assessment where a team of external experts assess the license holders security arrangements and draw up a report about the results and measures planned on the basis of the reports.

In order to demonstrate the effectiveness of nuclear security, licensee shall draw up an exercise programme and hold exercises related to security at regular intervals. When drawing up this exercise programme, co-operation exercises shall be planned with the police authority and it's various police special groups.

STUK provides secretariat for National Advisory Commission on Nuclear Security. The chair of commission is from the Ministry of the Interior. This Commission gives statements for STUK on request and proposes activities to further enhance nuclear security. It is appointed by the Government and its duties are stipulated in Governmental Decree 1016/2016. The Commission has representatives from the Ministry of the Interior, Defence Forces, Border Guard, Customs, Finnish Security and Intelligence Service, Local police departments, Fire departments, and operators provide permanent experts. The Commission has annually 2-3 meetings.

The nuclear security regime has been reviewed accordingly, the last IPPAS mission was conducted 2009 (follow up 2012) and for 2020 a new IPPAS mission was requested, but it had to be postponed first to 2021 and then 2022 due the Covid-19 pandemic.

Finland has been ranked in the NTI (Nuclear Security Index) third during last two rounds of NTI assessment for nuclear security in both categories (theft and sabotage).

Question 1.4 Does the legal and governmental framework include specific responsibilities for the integration of emergency response arrangements for both safety related and nuclear security related incidents?

Response:

Radiation Act:

In case of a radiation safety deviation, the undertaking responsible for the radiation safety deviation and the authority which becomes aware of the radiation safety deviation shall immediately notify STUK of for example the loss, unauthorized use or holding of a radiation source subject to a safety license. If needed, STUK can request executive assistance from the rescue authorities according to Rescue Act, Section 50.

Use of Nuclear Energy:

These requirements are mainly found in YVL Guides and in STUK regulations. It should be noted that the Nuclear Energy Act states the following:

Operation of the nuclear facility shall not be started on the basis of the licence granted for it until:

1) the Radiation and Nuclear Safety Authority has ascertained that the nuclear facility meets the safety requirements set, that the security and emergency arrangements are sufficient, that the control necessary to prevent the proliferation of nuclear weapons has been arranged appropriately, and that the nuclear facility operator has arranged, in the manner provided, indemnification regarding liability in the event of nuclear damage;

Also, Guide YVL A.11, req. 301a. states: *Security arrangements are part of overall safety and shall be coordinated with emergency response arrangements, nuclear and radiation safety and nuclear safeguards during threats and emergency situations. [2021-02-12]*

Therefore, all the emergency arrangements shall be sufficient, no matter whether it's safety or security related incident.

Question 1.5 Describe the requirements and/or arrangements to ensure that safety and security measures are designed and implemented in an integrated manner so that security measures do not compromise safety and safety measures do not compromise security.

Response:

Radiation Act:

According to Radiation Act section 67, the security arrangements shall be adequate in terms of the risks related to the practice and the radiation sources and they must form a whole compatible with the measures concerning radiation safety. Also various other sections can be considered as contributing to the safety-security interface, for example section 71 states:

In practices subject to a safety licence, the undertaking shall keep a record on the radiation sources related to the safety licence. The records must indicate the radiation sources held by the undertaking as well as the reception and transfer of the sources and their removal from the licence.

and section 72 completes:

A radiation source the holding of which is subject to a safety licence may be transferred only to an undertaking with the necessary safety licence. The transferor shall ensure that the recipient has the required safety licence.

At the guideline level, for example, it is emphasized that radiation hazard signs should be used judiciously so that they warn of the radiation hazard appropriately, but do not increase interest in illegal activities.

Use of nuclear energy:

There are several requirements in order to design and implement security measures in a coordinated manner with safety and safeguards. Those requirements are referred below.

YVL Guide B.1, section 409 states that in the design of a nuclear facility, security aspects shall be taken into account to minimize conflicts between safety and physical protection. Due consideration also includes cybersecurity.

STUK 1/Y/2018 section 14 states that both the external safety hazards (such as extreme weather and seismic events) and unlawful threats (such as an airplane crash) shall be taken into consideration in the design of a nuclear facility.

As for the disposal of nuclear waste, STUK Y/4/2018, section 17 gives similar requirement for disposal facilities of spent nuclear fuel and waste,

Taking these into consideration, it can be concluded that the requirements take the safety-security interface into account without compromising other one.

Analysis

STRENGTHS FOR 11. INTERFACES WITH NUCLEAR SECURITY

S1	STUK is a 3S regulator having responsibility and resources to regulate safety, security, emergency preparedness and nuclear material safeguards in use of radiation and nuclear energy.
S2	Security is evaluated in integrated manner with safety during authorization of facilities and activities. Safety and security inspections are integrated or coordinated.
S3	Cooperation with other government agencies (e.g., police and other security organizations) is established in legislation. STUK has well-functioning co-operation with law enforcement authorities.
S4	STUK has enhanced safety-security interface by introducing new systematic methods for security risk assessment. STUK requires (Guide YVL A.11 Security of a nuclear facility) requires that nuclear security related risk analyses shall utilise PSA. STUK and utilities have agreed on performance of security risk analyses and licensees have performed Explosion PSAs. STUK has developed a tool for insider security analysis.

THREATS FOR 11. INTERFACES WITH NUCLEAR SECURITY

T1	International standards are not well integrated in 3S (safety, security, safeguards) or even in 2S (safety, security) perspective. There is a threat that Finland has to implement international standards that would force break up of well-integrated national framework.

CONCLUSIONS FOR 11. INTERFACES WITH NUCLEAR SECURITY

C1	Security interface is well managed in Finnish situation as STUK is competent regulator for safety, security and safeguards. Nuclear safety and security regimes are implemented in a joint legal and regulatory framework in Finland. STUK evaluates facility safety, security and nuclear materials safeguards in integrated manner throughout facility lifetime.
C2	STUK has enhanced safety-security interface by introducing new systematic methods for security risk assessment. As example PSA has been utilized in nuclear security risk analysis. Implementation of security PSA is candidate for a good practice (GP).

Enter the full name of your country	Finland
Give the full name(s) of the national body or bodies having responsibility for the regulatory oversight of nuclear and/or radiation safety.	• Regulatory body for the use of nuclear energy and radiation practices, Radiation and Nuclear Safety Authority, STUK • Supreme authority and highest directing power in supervising of Nuclear Energy Act, Ministry of Economic Affairs and Employment, MEE • Supreme authority and highest directing power in supervising of Radiation Act, The Ministry of Social Affairs and Health, MSAH
To whom (or to which body within the governmental organisational structure) is the above-named regulatory body (or bodies collectively) accountable?	• STUK is accountable to the Ministry of the Social Affairs and Health
List the type and number of Nuclear facilities (e.g. Nuclear Power Plants, Research Reactors, Nuclear fuel cycle facilities, waste management facilities, etc)	• There are currently two nuclear power plants operating in Finland: Loviisa and Olkiluoto plants. The Loviisa plant comprises two pressurised water reactor units (VVER-440) operated by Fortum Power and Heat Oy (FPH). Fortum submitted license renewal application to the Ministry in March 2022 to operate Loviisa 1 and 2 for additional 20 years. The Olkiluoto plant comprises two boiling water reactor units (BWR 75) operated by Teollisuuden Voima Oyj (TVO) and a third unit, a pressurized water reactor (EPR) received operating license in March 2019 and is in the commissioning phase. In addition, Fennovoima Oy (Fennovoima) has applied for a construction licence for one pressurized water reactor (AES-2006) at Pyhäjoki, and this construction licence application is currently under review. • Furthermore, there is a Triga Mark II research reactor, FiR 1 in Espoo. VTT Technical Research Centre of Finland Ltd (VTT) is the licensee. The reactor was permanently shut down in the end of June 2015 and defueled in 2020. VTT applied for a license for the decommissioning in June 2017. STUK gave its statement on VTT's application to the Ministry of Economic Affairs and Employment in April 2019 and the Government granted the license in 2021. Reactor is in decommissioning phase (spent fuel has been removed from the site), dismantling is expected to start earliest 2023. • Spent fuel from the nuclear power plant units is stored in interim pool type storages at the power plant sites (Olkiluoto and Loviisa) for tens of years until disposal. The interim spent fuel storages have already been in operation for about 30 years at both sites. • The spent nuclear fuel disposal: The construction

	licence for the encapsulation and disposal facility was granted by the Government to Posiva in November 2015 and the construction of the geological disposal facility started in Olkiluoto in December 2016. Posiva submitted the operating license application to Ministry at the end of 2021. Operation is expected to start in 2024-2025. Fennovoima started the Environmental Impact Assessment (EIA) of its own spent nuclear fuel disposal in summer 2016. • Geological disposal facilities for low and intermediate level waste have been in operation since the 1992 in Olkiluoto and 1998 Loviisa NPP sites. In the future, the Olkiluoto facility is planned to be extended for operational waste from the OL3 unit and decommissioning waste from all reactor units at Olkiluoto. The future at Olkiluoto includes also a new near-surface facility of the very low-level waste. Olkiluoto disposal facility is also the current route for radioactive waste originating from use of radiation in industrial, medical and research applications. The disposal facility in Loviisa will be extended for decommissioning waste from the Loviisa NPP units. Fennovoima has planned to build a geological disposal facility for its low and intermediate level waste at the Pyhäjoki site. • Uranium production facility: Terrafame company operates a nickel and zinc mine in Finland. Company has applied and received a license from the Government to extract uranium as a side product. Production of uranium has not yet started due to other priorities in the company. Start of operations of the extraction facility requires a permit from STUK.
List the type and number of radiation facilities. e.g. Medical (diagnostic/interventional radiology, dental), Waste management facilities, Industrial facilities (irradiation, well-logging, NDT), Mining and milling facilities, Research facilities, etc	• At the end of 2021, there were 1477 current safety licenses for the use of radiation in health care, 306 licenses for veterinary practices and 1104 licenses for the use of radiation in industry and research. These include (non-exhaustive list): • 1385 heath care or dental care x-ray practices • 13 radiotherapy practices • 27 nuclear medicine practices • 306 veterinary practices • 705 industrial or research practices using x-ray appliances • 470 industrial or research practices using sealed sources • 57 industrial or research practices using unsealed sources • 16 industrial or research practices using particle accelerators • 104 practices for import and export of radiation sources and trade in them • One underground tunnel facility with high radon levels has a safety license.

Enter the type and number of activities (e.g. transport of radioactive material, decommissioning, remediation activities, waste management activities such as radioactive discharge of effluents, etc	• Decommissioning of the research reactor: The reactor was permanently shut down in the end of June 2015 and defueled in 2021. VTT applied for a license for the decommissioning in June 2017. STUK gave its statement on VTT's application to the Ministry of Economic Affairs and Employment in April 2019 and the Government granted the license in 2021. STUK's permit is required for the actual start of decommissioning and dismantling. Spent fuel from the FiR 1 has been returned to the United States (late 2020) according to Foreign Research Reactor Spent Nuclear Fuel (FRR SNF) Acceptance Program of U.S. Department of Energy (DoE). VTT signed a contract with FPH on storage and disposal of operational and decommissioning wastes in Loviisa NPP site. Fresh nuclear fuel is transported by road to operating nuclear power plants approximately 4-6 times a year. Currently there are almost no transportation of spent fuel as it is stored in pool storages at the nuclear power plant sites. During recent years only few spent fuel rods have been shipped abroad for investigations. According to current plans the transportation of spent nuclear fuel from Loviisa to Olkiluoto starts in 2040's. Transportations of nuclear waste is also done very seldom as the storage and final disposal of nuclear waste is arranged in nuclear power plant sites. The spent fuel from research reactor was shipped permanently to USA in late 2020. The licensees of nuclear power plants are shipping the radioactive metal waste, mainly large components, abroad for melting approximately once in three years. The resulting radioactive waste is shipped back to Finland for disposal.
List and describe any facilities and activities not otherwise addressed above.	-
Enter the number of authorizations: • Issued • Renewed • Suspended or revoked in the last one year	• Fortum applied for license renewal for Loviisa 1 and 2 in March 2022 (license to operate Loviisa 1 and 2 until 2050). Licensing process is ongoing. • At both sites (Loviisa and Olkiluoto) there are interim storages for spent fuel as well as final disposal facilities for low and intermediate level nuclear wastes. Posiva, a joint company of Fortum and TVO, submitted an operating license application for the spent nuclear fuel encapsulation plant and disposal facility in the end of 2021. • Furthermore, there is a Triga Mark II research

	reactor, FiR 1 in Espoo. VTT Technical Research Centre of Finland Ltd (VTT) is the licensee. The reactor was permanently shut down in the end of June 2015 and defueled in 2021. VTT applied for a license for the decommissioning in June 2017. STUK gave its statement on VTT's application to the Ministry of Economic Affairs and Employment in April 2019 and the Government granted the license in 2021. STUK's permit is required for the actual start of decommissioning and dismantling. • STUK does authorizations that are given in YEL and YEA and described more in detail in STUK's YVL Guides (e.g. YVL A.1, YVL A.4, YVL E.1, YVL E.3, YVL E.5 and YVL E.12). In 2021 STUK approved e.g. several persons according to YVL Guides A.4, E.3, E.5 and E.12 (responsible persons of managers/ operators/ emergency/ pressure equipment manufacturers / testing organizations and pressure equipment operation). • 4 import licenses for import fresh nuclear fuel • 2 import licenses for other nuclear materials. At the end of 2021, the number of current safety licenses for the following practices was: • 4 for the transport of high-activity sealed sources: • 3 for the treatment of radioactive waste (for treatment which is not part of a practice from which the waste originates) • 3 for the repeated management of orphan sources • In 2021, 38 new licenses were issued, and 57 licenses were withdrawn for uses of radiation in industry and research. For medical and veterinary use of radiation 31 new licenses were issued and 83 licenses were withdrawn. In Finland, licenses are not renewed periodically but changes to licenses are subject to notification or prior amendment of the license, depending on the type of change.
Enter the number of: • planned inspections • Completed planned inspections • Unplanned inspections in the last one year	Nuclear facilities • periodic inspection programme (KTO inspections) • 2020: planned inspections Olkiluoto 19 ja Loviisa 18 • 2020: Completed planned inspections Olkiluoto 16 ja Loviisa 16 • 2020: Unplanned inspections Olkiluoto 0 ja Loviisa 1 • 2021: planned inspections Olkiluoto 17 (including 3 OL3-related inspections) ja Loviisa 19 • 2021: Completed planned inspections Olkiluoto 17 (including 3 OL3-related inspections) and Loviisa 19 • 2021: Unplanned inspections Olkiluoto 5 ja Loviisa 2 • additional (unplanned) reactive inspections (KV inspections) o 2020: Loviisa 2 and Olkiluoto 4. o 2021: Loviisa 2 and

	Olkiluoto 8. • programme of inspections related to the processing of the construction licence (RKT) • 2020: planned inspections 8 • 2020: Completed planned inspections 8 • 2020: Unplanned inspections 0 • 2021: planned inspections 7 • 2021: Completed planned inspections 7 • 2021: Unplanned inspections 0 • in 2020, inspections of components and structures at NPP sites and manufacturers, 2219 • planned inspections 0 • Completed planned inspections 2219 □ Construction, 606 □ Repair and modification, 757 □ Commissioning, 338 □ Periodic inspections of pressure equipment, 518 • Unplanned inspections 0 • in 2021, inspections of components and structures at NPP sites and manufacturers, 1946 • planned inspections 0 • Completed planned inspections 1946 □ Construction, 787 □ Repair and modification, 578 □ Commissioning, 143 □ Periodic inspections of pressure equipment, 419 • Unplanned inspections 0 • Posiva oversight (CIP Construction inspection program) • 2020: planned inspections 6 • 2020: Completed planned inspections 6 • 2020: Unplanned inspections 0 • 2021: planned inspections 6 • 2021: Completed planned inspections 6 • 2021: Unplanned inspections 0 Uses of radiation sources • For decades STUK has performed regular inspections at all licensed radiation sources facilities; the inspection frequency mostly varied between 2 – 8 years depending on the type of practice. Before 2019, the number of inspections was about 500 -700 annually. • The new SätL came into force in late 2018 and subsequent STUK regulations during 2019. Inspections to low-risk facilities were widely postponed as to give licensees time to adapt the new requirements. Inspections to high-risk facilities were less affected. In addition, new types of supervision projects (e.g., based on questionnaires) were initiated reducing the need for on-site inspections at low-risk facilities. About 200 inspections were conducted in 2019. • In spring 2020, inspections at radiation sources facilities were reduced to a minimum because of the COVID-19 situation. Only individual commissioning inspections of radiotherapy accelerators were carried out. In late 2020, on-site inspections of radiotherapy practices were carried out as normal and some on-site inspections and remote inspections were carried to other types of practices. About 100 inspections were conducted in 2020. • The

	COVID-19 situation continued in 2021. About 120 inspections to radiation sources facilities was conducted, mostly in health care facilities. However, several supervision projects based on questionnaires were conducted. For example, in case of industrial and research facilities, these projects resulted to over 200 written requests to the licensees for further action. Regulatory control of natural radiation • 2020: planned inspections 4 • 2020: Completed planned inspections 4 • 2020: Unplanned inspections 0 • 2021: planned inspections 3 • 2021: Completed planned inspections 3 • 2021: Unplanned inspections 0 On-site inspections are not regularly performed, since safety license is very rarely relevant for facilities related to natural radiation exposure. Instead, exposure is controlled mainly with a document control procedure and the data on regulatory control is recorded in the databases. Some inspections are made at NORM-facilities and legacy sites involving NORM.
List and briefly describe the national and international safety reviews and/or appraisals received by the regulatory body or State over the last three years	• Finland is a contracting party of Convention of Nuclear Safety (CNS) and Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management and thus Finland gets international peer review. In 2017-2018 Finland took part to ENSREGin Topical peer review concerning ageing management of nuclear power plants and research reactors. • IPPAS mission in June 2022 • VTT MIKES (National metrology institute) performs yearly audits on STUK's operations, year 2021 on the dosimetric laboratory, and SGS FIMKO performed an audit on x-ray equipment testing of the dosimetric laboratory. • FINAS (Finnish Accreditation Service) inspects every year STUK's accredited laboratory functions, also year 2021, and laboratory functions fulfill the requirements of ISO 10725:2017 standard.
List and briefly describe the ranks, roles, relevant qualifications, experience and numbers of staff engaged in all activities assigned to the regulatory body.	• At the end of 2021, STUK had 313 permanent and 23 fixed-term employees, a total of 336. • Women accounted for 42.4% of the permanent staff (41.7% in 2020). • 87.5% of STUK's permanent staff have a university degree and the share of STUK's personnel who have completed a master's degree or postgraduate education (doctors and licentiates) is 71.7%.
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Family name	Hutri-Aspholm

Job title	Development Manager (Principal Advisor)
Department	Nuclear Reactor Regulation
Organisation	Radiation and Nuclear Safety Authority of Finland (STUK)
Enter the date of completion of this self-assessment cycle.	30th April, 2022