Finland IRRS ARM Summary Report

Contents

Photo: STUK

Abbreviations

ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
AFI	Areas of Improvement
AIO	Authorized Inspection Organizations
AOO	anticipated operational occurrences
AP	Action Plan
AVI	Regional State Administrative Agency
BCP	business continuity plan
BSS	Basic Safety Standards
BWR	Boiling water reactor
BWROG	BWR Owners Group
CAF	Common Assessment Framework
CL	Construction Licence
COTIF	Convention concerning International Carriage by Rail
Cores	Consortium for Radiation Safety Research
DBT	Design Basis Threat
DEC	design extension condition
DiD	Defence in Depth
DiP	Decision-in Principle by the Government
DG	Director General of STUK
EIA	Environmental Impact Assessment
ELY	Centre for Economic Development, Transport and the Environment
EM	Ministry of the Environment
EPR	European pressurized water reactor
FEP	Features, Events and Processes
FINAS	Finnish Accreditation Service
FiR1	Research reactor at Otaniemi
FOAK	first of a kind
FPH	Fortum Power and Heat Oy (NPP utility)
FSAR	Final Safety Analysis Report
FROG	Framatome owner's group
FSIS	Finnish Security and Intelligence Service
FV	Fennovoima (a new nuclear power company)
GTK	Geological Survey of Finland
HAKE	Observation database of NRR (HAKE-Polarion)
HAL	STUK's Administration department
HEP	STUK's Human Resources Section
HERCA	Heads of Radiation Protection Authorities
HFE	Human Factors Engineering
HLW	High level waste
HUT	Helsinki University of Technology
ICAO-TI	Technical Instructions for the Safe Transport of Dangerous Goods by Air
ICRP	International Commission on Radiological Protection
ILW	Intermediate level waste
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organizations
INF	International Code for the Safe Carriage of Packaged Irradiated Nuclear Fuel, Plutonium and High-Level Radioactive Wastes on Board Ships

IRS	International Reporting System for Operating Experience
JYSE	Term of agreement for public contracts
KTO	Construction Inspection Programme
KV	Operation Surveillance
KYT	National research programme on waste management
LILW	Low and intermediate level waste
LLW	Low level waste
LUT	Lappeenranta University of Technology
MAF	Ministry of Agriculture and Forestry
MD	Ministry of Defence
MDEP	Multinational Design Evaluation Programme
ME	Ministry of the Environment
MEC	Ministry of Education and Culture
MEAE *	Ministry of Economic Affairs and Employment [former MEE]
MEE *	Ministry of Employment and the Economy [former name of MEAE]
MESH	previous synonym for Ministry of Social Affairs and Health
MFA	Ministry for Foreign Affairs
MI	Ministry of Interior
MoF	Ministry of Finance
MSAH	Ministry of Social Affairs and Health
MTI*	Ministry of Trade and Industry [former of MEE]
NordERF	Cooperation between Nordic NPPs
NORM	Naturally occurring radioactive material
NPP	Nuclear power plant
NRAP	national radon action plan
NRR	Nuclear Reactor Regulation department of STUK
NTI	Nuclear Security Index
NWSC	Nuclear Waste Safety Committee
OEF	Operational experience feedback
OL	Operation Licence
OLC	Operational limits and conditions
ONKALO	Underground rock characterization facility for spent fuel disposal at Olkiluoto
OSH	Occupational Safety and Health
OTKES	Safety Investigation Authority in Finland
Posiva	Posiva Oy (company for spent fuel disposal)
PRA	Probabilistic risk assessment
PSAR	Preliminary Safety Analysis Report
PSR	periodic safety reviews
PWR	Pressurized water reactor
RC	Review class
REILA	Working Group on regulation development of lifecycle of nuclear facilities
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
RKT	Construction Licence Inspection Program
RPAS	Remotely Piloted Aerial System
RPE	Radiation Protection Expert
RSC	Reactor Safety Committee
RSO	radiation safety officer
RTO	Construction Inspection Program
SA	severe reactor accidents
SAFIR	National research programme on nuclear safety
SAHA	Document and case management system
SAHARA	Safety as high as reasonably achievable

SAMMIO	STUK's online regulation and guidance service
SAR	Safety Analysis Reporting
SASS	safe state following a severe accident
SOLAS	Safety of Life at Sea
SSC	plant structures, systems and components
STAKONE	National Advisory Board of Radiation protection experts
STARE	System designed for creation and management of inspection reports related to nuclear facilities
STMA	Ministry of Social Affairs and Health Decree
STN	Advisory Committee on Radiation Safety
STO	STUK's Radiation Practices Regulation department
STUK	Radiation and Nuclear Safety Authority
StukA	Decree on Radiation and Nuclear Safety Authority
StukL	Act on Radiation and Nuclear Safety Authority
SätL	Radiation Act
THL	Finnish institute for health and welfare
TJNK	Advisory Committee on Nuclear Security
TSO	Technical Support organization
TTO	Authorized Inspection Organizations Inspection Program
Tukes	Finnish Safety and Chemicals Agency
TVO	Teollisuuden Voima Oyj (NPP utility)
VALO	STUK's Environmental Radiation Surveillance department
Valvira	National Supervisory Authority for Welfare and Health
VASARA	Radiation Practices Regulatory Control Information System
WENRA	Western European Nuclear Regulators' Association
VLLW	Very low-level waste
VnA	Government Decree
VNp	Government Decision
VTT	VTT Technical Research Centre of Finland
VTT CNS	VTT Centre of Nuclear Safety
VVER	Soviet designed pressurized water reactor
VYR	Nuclear Waste Management Fund
YEA	Nuclear Energy Decree
YEL	Nuclear Energy Act
YJH	waste management program
YMO	STUK's Nuclear Waste Regulation and Safeguards department
YTN	Advisory Commission for Nuclear Safety
YTO	STUK's Nuclear Reactor Regulation department
YTV	Guide Internal management system guide for nuclear safety
YVL	Guide Safety regulation issued by STUK subject to nuclear energy legislation (example YVL Guide A.1)

*) The Ministry of Economic Affairs and Employment (MEAE) (formerly the Ministry of Employment and the Economic (MEE)) was established in 2008 and the duties of the Ministry of Trade and Industry (MTI) were transferred to the new ministry. The MEAE (former called MEE) has been the contact authority since 2008.

https://www.stuk.fi/web/en/about-us/advisory-committees

SUMMARY

Finland is highly committed to nuclear and radiation safety. Finland is a signatory to all relevant international organizations, treaties and conventions and participates actively in international cooperation considering nuclear and radiation safety. Based on the peaceful use of nuclear energy, Finland has several bilateral agreements with other countries. As of 1 January 1995, Finland has been a member of the European Atomic Energy Community (EAEC or Euratom). Consequently, the agreements made by the EAEC are applied in Finland.

Finland recognizes the importance of international peer reviews and is committed to the continuous improvement of radiation and nuclear safety and security, as well as the enhancement of regulatory activities. Inviting an IRRS mission is a demonstration of that commitment.

In preparation for this mission, STUK, the Finnish Radiation and Nuclear Safety Authority, completed the IRRS Self-Assessment Questionnaires and prepared supporting documentation with input from other relevant stakeholders. The responses to the Self-Assessment provide a comprehensive picture of how Finland implements the relevant IAEA Safety Standards. The present report represents a summary of the Advanced Reference Material (ARM) that was compiled for the IRRS Mission.

The results of the IRRS Self-Assessment concluded that Finland has a strong, robust and up-to-date regulatory framework that aligns with IAEA Safety Standards. No safety-significant gaps were identified through the IRRS Self-Assessment. However, a number of Areas for Improvement (AFIs) to further strengthen the regulatory framework in Finland were identified and are provided in the initial IRRS Action Plan. A number of those improvements are already being carried out as part of the further development of STUK’s regulatory framework.

1. INTRODUCTION

In 2019, the Ministry of Economic Affairs and Employment, on behalf of Finland, requested an international peer review mission from the International Atomic Energy Agency's (IAEA) Integrated Regulatory Review Service (IRRS). The IRRS Mission to Finland will be held from 2 to 14 October 2022 at STUK's premises in Vantaa.

Finland previously hosted an IRRS Mission in 2012. An IRRS Follow-Up Mission took place in 2015 to assess the progress against the initial mission's findings. Both missions are documented in IAEA reports, which are publicly available on STUK's website (http://www.stuk.fi).

Finland is a member of the EU. Nuclear safety directive sets an obligation to invite and conduct a peer review mission every ten years. This obligation is also in the Nuclear Energy Act. This IRRS mission meets the obligations of the EU and national legislation.

Scope of the IRRS Mission 2022 to Finland

The scope of the IRRS 2022 mission covers STUK's entire area of supervision as based on the Finnish national legal framework for the safe use of radiation and nuclear energy, namely: responsibilities and functions of the Government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, patient protection, public and environmental exposure control, transport, waste management and decommissioning.

STUK's area of oversight addresses all Finnish nuclear facilities (NPPs, research reactors, waste management facilities, and fuel cycle facilities) and radiation practices (use of radiation in medical, industrial and research, environmental monitoring of radiation) and all related activities therein (e.g. transport, decommissioning). Planned exposures and emergency exposure situations are included in the scope.

Based on the above, the scope of the 2022 IRRS Mission comprises the review of the Finnish legal and regulatory framework for nuclear and radiation safety. All activities and facilities covered by STUK's remit are within the review's scope. Therefore, with reference to the IRRS guidelines (see Figure 1) the review covers modules 1-11.

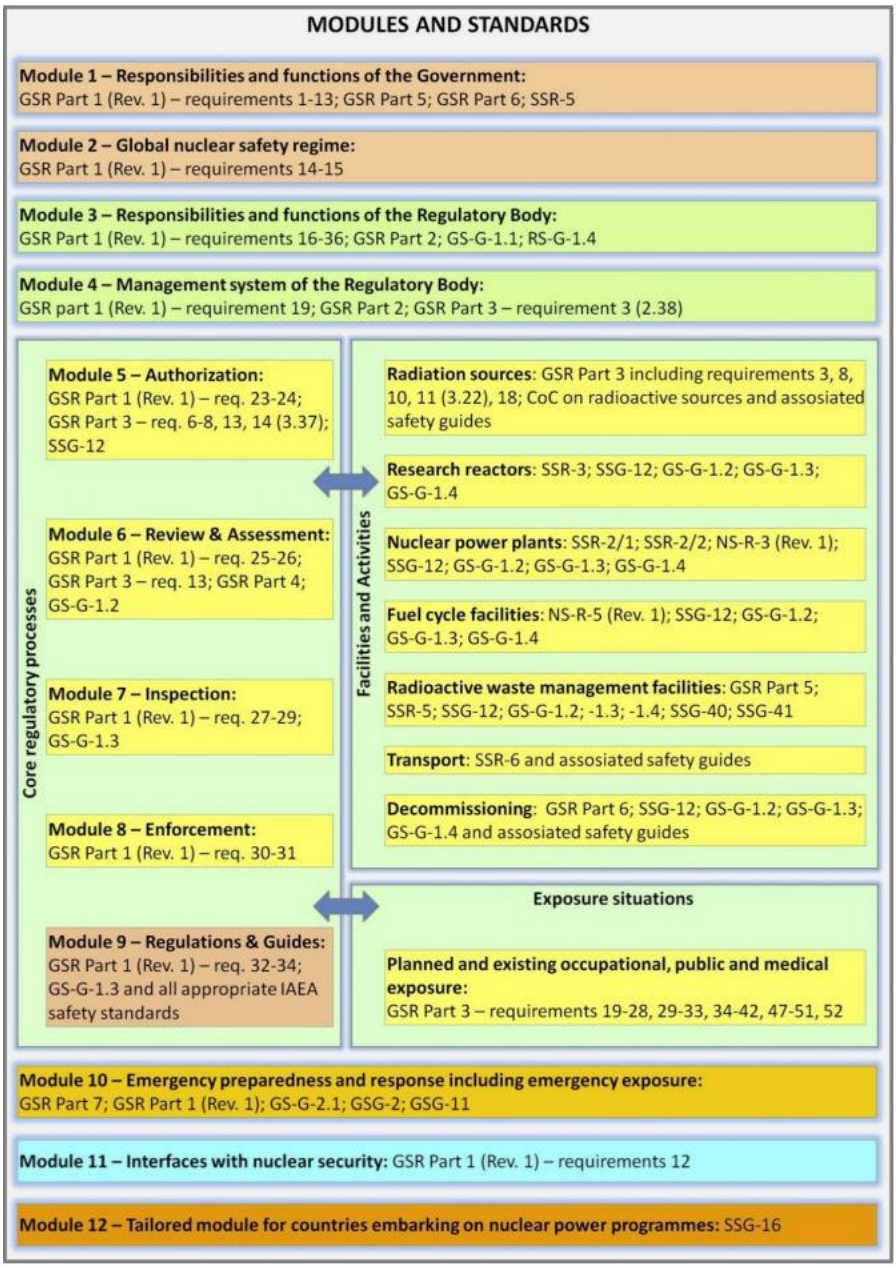

Figure 1. Structure of an IRRS Mission (Source: IAEA's IRRS Guidelines of 2018)

The IRRS Mission is full scope. However, areas related to the safety of Research Reactors are not fully included in the scope (only parts related to the decommissioning). The reasoning is that the only research reactor in Finland has been defueled and decommissioning is about to start. There are no plans to construct and operate research reactors in Finland.

1. RESPONSIBILITES AND FUNCTIONS OF THE GOVERNMENT

1.1 NATIONAL POLICY AND STRATEGY FOR SAFETY

In Finland, the policies and strategies for radiation and nuclear safety are mainly expressed through legislation, namely through the Nuclear Energy Act (YEL) for nuclear safety and through Radiation Act (SätL) for radiation safety. In addition, there is a policy paper on the national programme on waste management (Management of spent nuclear fuel and radioactive waste in Finland, 2022), and the Government is preparing a national climate and energy strategy. The Fundamental safety objective and Principles 1, 3 – 10 of the IAEA SF-1 have been addressed in the provisions of the legislation. In accordance with Principle 2 (Role of the Government), the legislation (adopted by Parliament) establishes a comprehensive legal and regulatory framework for the regulation of facilities and activities, including the establishment of STUK as an independent regulatory body. The legislation includes clear assignment of roles and responsibilities to the relevant ministries, licensees, and regulators to ensure the safe use of nuclear energy and use of radiation including emergency preparedness and response and existing exposure situations.

Finland has ratified all relevant international treaties and actively participates in conventions and other relevant international arrangements considering nuclear and radiation safety (see more Module 2).

To ensure expertise for radiation and nuclear safety, specific education is provided by universities. In addition to education, conducting research on nuclear and radiation safety is an essential part of maintaining and building expertise. YEL includes provisions on funding for nuclear safety research by collecting funds annually from the licensees of nuclear facilities. These funds are allocated to research programmes supporting and developing the competences in nuclear safety and nuclear waste management and creating preparedness for the regulator to be able to respond to emerging and urgent safety issues. National radiation safety research is coordinated through a programme comprising STUK and many Finnish universities, university hospitals and research institutes (Consortium for Radiation Safety Research, CORES network). Unlike to YEL, SätL does not include provisions for the funding of the radiation safety research. Funding is provided either by government budget or other sources (like EU research programmes). These funding sources have not been adequate to maintain a stable radiation research programme in Finland, and stakeholders (like STUK) are concerned about whether Finland will be able to maintain an adequate level of radiation protection expertise in the future.

YEL and SätL promotes licensees' undivided responsibility for safety, a graded approach to risk, leadership, and management of safety, including safety culture. Legislation also sets requirements for the human and financial resources of licensees. The graded approach has been incorporated into legislation in such a way that the risks associated with different types of facilities and activities have been considered in the regulatory control and in requirements set for the licensee.

1.2 ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

Legislative framework

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 current Constitution of Finland entered into force in March 2000. The Constitution stipulates how and by whom the acts, decrees and delegation of legislative powers can be issued. The Ministry of Economic Affairs and Employment (MEAE) is responsible for the legislation in the nuclear energy field and the Ministry of Social Affairs and Health (MSAH) for the radiation practices and existing exposure situations (acts and decrees). The Ministry of the Interior (MI) is the overall authority for national security, emergency preparedness and response, and rescue services. The legislative hierarchy is presented in Figure 2 below.

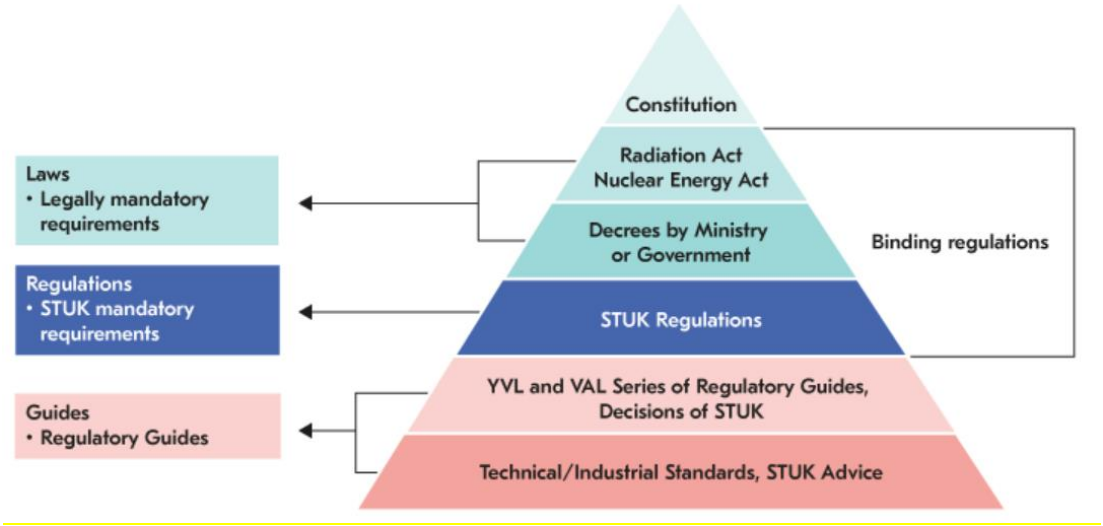

Figure 2. Legislative hierarchy in Finland

The Finnish legislation covers safety, security and safeguards. The graded approach has been taken into account in the legislation in such a way that the risks associated with different type of facilities and activities have been taken into account in licensing and other regulation. Among the safety principles, YEL and SätL stipulate governmental and regulatory frameworks, licensing procedures, provisions for human and financial resources, prime responsibility for safety, principles for continuous development and requirements to promote safety culture and the management of safety. In addition, provisions for nuclear waste management and safety research are set down in YEL. The Radiation Act (SätL) sets out provisions for radioactive waste management, but not for radiation protection research.

The ministries are responsible for the development and maintenance of the legislation. STUK is entitled to make proposals for developing legislation in its field of activity. According to the Nuclear Energy Act and Radiation Act, STUK has the authority to issue regulations and guides for radiation and nuclear safety, security and safeguards. STUK regulations and

YVL guides are reviewed and updated in a systematic manner described in the STUK management system.

Right of appeal on administrative decisions

The judicial powers are exercised by independent courts of law, with the Supreme Court and the Supreme Administrative Court as the highest instances. A decision by which an authority has ruled on an administrative matter or ruled an administrative matter inadmissible is eligible for judicial review by appeal. A decision relating solely to the preparation or enforcement of a matter is ineligible for review by appeal. An internal administrative order concerning the performance of a task or of some other measure is also ineligible for review by appeal.

A 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. Separate provisions concerning right of appeal are provided, for example in YEL section 75 a for a registered association or foundation whose purpose is to promote the protection of the environment, health or nature or the comfort of the living environment and in whose area of activity the environmental effects in question occur.

Appeals against the decision of an authority are made to a regional administrative court. A decision of an administrative court may be appealed to the Supreme Administrative Court, but usually a leave to appeal is required. Appeals against the decision of government plenary session are made directly to the Supreme Administrative Court. In certain cases, separate provisions are laid down by law on decisions for which an administrative review may be requested. No request may be made for a judicial review of such decisions by way of appeal before such an administrative review has been conducted. According to SätL section 196, certain decisions made by STUK are subject to an administrative review before an appeal to an administrative court is allowed.

An authority may also correct its erroneous decision upon a request or on its own initiative in certain circumstances provided by the Administrative Procedure Act.

Legislation and regulations for the use of Nuclear Energy

The current nuclear energy regulations are based on YEL (990/1987). The act has been amended several times over years it has been in force: most changes are minor and originate from changes to other legislation. In 2008, YEL was modified to bring it in line with the Constitution of 2000. In 2021, the MEAE decided to initiate a full renewal of the nuclear energy legislation. To support the renewal, STUK decided to initiate a full renewal of its regulations and guides. The Government should ensure that adequate resources are allocated to STUK and the ministry for completing the renewal on time and to the required level of quality.

The overall purpose of YEL is to ensure the safety, security and safeguards of the use of nuclear energy. The act sets general requirements for safety such as that utilising nuclear energy must be safe, and it places prime responsibility for safety on the licensees. It also sets general requirements and authority for regulatory oversight of nuclear safety. Together

with a supporting Nuclear Energy Decree (YEA, 161/1988), the scope of this legislation covers, for example:

- the construction and operation 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 and import of nuclear materials and nuclear waste as well as the export of nuclear waste and the export and import of ores containing uranium or thorium
- mining and milling activity for the production of uranium or thorium.

Nuclear Energy Decree that draws up, for instance, the administrative details for licensing and radiological acceptance criteria. STUK Regulations set mandatory requirements (e.g. general principles, fundamental technical requirements) for nuclear safety, on-site emergency preparedness, security and nuclear waste management. STUK's regulatory guides (YVL Guides) include detailed technical requirements, acceptable practices, guidance for licensee–STUK interaction and STUK's oversight activities in the area of the guide. YVL Guides are to be applied as such to new NPPs. Implementation at operating and plants under construction is considered on a case-by-case basis (with a so-called implementation decision issued by STUK). The 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 regulations.

STUK has issued following regulations on the safety of the use of nuclear energy:

- Radiation and Nuclear Safety Authority Regulation on the Safety of a Nuclear Power Plant (STUK Y/1/2018)
- Radiation and Nuclear Safety Authority Regulation on Emergency Arrangements of a Nuclear Power Plant (STUK Y/2/2018)
- Radiation and Nuclear Safety Authority Regulation on the Security in the Use of Nuclear Energy (STUK Y/3/2020)
- Radiation and Nuclear Safety Authority Regulation on the Safety of Disposal of Nuclear Waste (STUK Y/4/2018)
- Radiation and Nuclear Safety Authority Regulation on the Safety of Mining and Milling Operations aimed at Producing Uranium or Thorium (STUK Y/5/2016).

For more information on the regulations see Chapter 9. Safety and security interface are described in Chapter 11.

The licensing process for a nuclear facility includes the following phases: Decision in Principle (DiP), Construction licence (CL), Operating licence (OL) and Decommissioning licence. The Decision in Principle is done and licences for the construction, operation and decommissioning are granted by the Government. In addition to safety, many other essential issues are considered as part of licensing, and therefore the licensing decisions are made in Finland at the governmental level. However, STUK's statement on safety is a prerequisite before the Decision in Principle is made and the Construction licence, Operating licences and the Decommissioning licence can be granted.

Decision in Principle is required for a nuclear facility of considerable general significance. This is essentially a political decision: the government decides whether the planned use of nuclear energy is in line with the overall good of society. The decision can be applied for one

or more sites, the host municipality has the right of veto, and Parliament has the choice of ratifying or not ratifying the decision made by the Government. Public hearings are conducted in each licensing step and organized and managed by the MEAE as the licensing authority. STUK participates in public hearings.

For more information on the licensing of nuclear facilities, see Chapter 5.

Legislation and regulations for the use of radiation

The radiation safety legislation was fully reformed on 15 December 2018, when the SätL, the Government Decree on Ionizing Radiation (VnA, 1034/2018) and the Ministry of Social Affairs and Health Decree on Ionizing Radiation (STMA, 1044/2018) entered into force. The reformation was motivated by the must bring it in line with the Constitution of 2000 and to implement the EU BSS Directive.

The purpose of 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. The act applies to radiation practices, existing exposure situations and emergency exposure situations. The act also covers the exposure of the general public to non-ionizing radiation. However, the medical and occupational exposure to non-ionizing radiation is covered only in certain specific issues provided in the act.

A safety licence is required for the use of ionizing radiation (SätL, section 48) and other radiation practices (SätL, sections 141 and 148). Licences for the use of radiation are granted by STUK. Based on section 24 of the SätL, an undertaking must 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. For more information on the licensing of the use of radiation, see Chapter 5.

Regulated activities in the use of nuclear energy

There are two operating nuclear power plants in Finland: the Loviisa and Olkiluoto plants. The Loviisa plant comprises two PWR units (pressurized water reactors of VVER type), operated by Fortum Power and Heat Oy (Fortum), and the Olkiluoto plant two BWR units (boiling water reactors) and one PWR (EPR type), operated by Teollisuuden Voima Oyj (TVO). The operating reactors in Loviisa and BWR reactor units in Olkiluoto have been in operation for more than 40 years each. The operating licence for Loviisa 1 is valid until 2027 and until 2030 for Loviisa 2. The operating licence for Olkiluoto 1 and 2 is valid until 2038. The EPR type unit (Olkiluoto 3) started its operation is late 2021 and its operating licence is valid until 2038. Fortum applied for licence renewal for Loviisa 1 and 2 in March 2022 (licence to operate Loviisa 1 and 2 until 2050). The 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 waste. Posiva, a company jointly owned by Fortum and TVO, submitted an operating licence application for the spent nuclear fuel encapsulation plant and disposal facility at the end of 2021. The licensing process is ongoing and the start of operations is expected in 2025.

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 at the end of June 2015 and defuelled in 2021. VTT applied for a licence 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 licence in 2021. STUK's permission is required for the actual start of decommissioning and dismantling.

In addition, the is a nickel and zinc mine in Finland operated by a company called Terrafame. The company has applied for and received a licence from the Government to extract uranium. The production of uranium has not yet started due to other priorities in the company. The start of operations of the extraction facility requires a permit from STUK.

Regulated activities in the use of radiation and in activities causing occupational exposure to natural radiation

A total of 2,887 safety licences for the use of ionizing radiation were current at the end of 2021, in addition to three safety licences for aviation operations.

At the end of 2021, there were 1,477 current safety licences for the use of radiation in health care, 306 licences for veterinary practices and 1,104 current safety licences for the use of radiation in industry and research. Of these, 470 licensees used sealed sources and 705 used X-ray appliances. Altogether 63 high-activity sealed sources are in use.

A total of 13,660 occupationally exposed workers were subject to individual monitoring in 2021. Around 76,500 dose entries were recorded in the Dose Register maintained by STUK.

At the moment, there are more than 17,500 conventional workplaces in the national radon database. About 3,000 conventional workplaces with more than 12,000 radon measurements done in 2021 were included in the database. Radon concentrations in about 14% of conventional workplaces measured in 2021 were greater than the reference level of 300 Bq/m3. In those cases, STUK requires a reduction in radon exposure or additional investigations on working time radon exposure.

Roles and responsibilities of main stakeholders for nuclear and radiation safety, coordination between authorities

The licensees of nuclear energy and the use of radiation are responsible for safety throughout the lifetime of facilities and the duration of activities as prescribed by YEL and SätL. This responsibility is undivided and includes, where applicable, safety, security and safeguards as well as emergency preparedness and response to and liability for nuclear damage. The transfer of responsibilities for facilities or activities between different parties can only occur through a declared change, approved by STUK and/or the Government through procedures described in the legislation.

The Ministry of Economic Affairs and Employment (MEAE) has the supreme authority and highest directing power in supervising compliance with YEL. The ministry is responsible for preparing acts and decrees for the Government and Parliament, and it prepares nuclear facilities licensing 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 by the ministry. Furthermore, the ministry administrates the funding of the nuclear safety research.

The Ministry of Social Affairs and Health has the supreme authority and highest directing power in supervising compliance with the SätL. The ministry is responsible for preparing acts and decrees for the Government and Parliament.

The mission and duties of STUK are based on the Act on STUK (1069/1983) and the Decree on STUK (618/1997). STUK authority to control radiation and nuclear safety is further stipulated in YEL and SätL including the authority to issue binding regulations and regulatory guidance. STUK's independent regulatory position was enhanced in 2015 by an amendment of YEL, including clarification of the role of STUK's safety statement in the licensing process of nuclear facilities, and authority to issue binding regulations. In the Government structure, STUK reports to the MSAH. For more information on STUK as a regulatory body, see Chapters 1.3 and 3.

Other authorities also have responsibilities related to radiation practices and nuclear energy. Typical areas calling for coordination are environmental issues, security arrangements and emergency preparedness and response. In the areas of rescue services and security, the Ministry of the Interior (MI) is the overall authority. Off-site emergency plans required by 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 (406/2011).

In SätL, the responsibilities of a municipality's health protection authority (section 15), Finnish Customs (section 16), and the Finnish Safety and Chemicals Agency (section 17) are stipulated. Moreover, section 17 refers to other supervising authorities for which responsibilities have been stipulated in SätL. 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. These are described in more detail in Chapter 5.

1.3 ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The regulatory body and its independence

STUK is an independent governmental organization for the regulatory oversight of radiation and nuclear safety. The mission and duties of STUK are based on the Act on STUK (1069/1983) and the Decree on STUK (618/1997). STUK has no functions which would be in conflict with regulatory control. STUK's commercial service activities are organizationally separated from the safety oversight activities.

According to section 55 of YEL, STUK is responsible for the regulatory control of the safe use of nuclear energy. In addition, STUK is responsible for the regulatory control of security and emergency preparedness arrangements as well as regulatory control for the non-proliferation of nuclear weapons (safeguards). The supervisory rights and authorities of STUK are provided in Chapter 10 (sections 63-68) of YEL. According to SätL (section 14), STUK supervises compliance with SätL, unless otherwise provided elsewhere. The supervisory rights and authorities of STUK are provided in Chapter 20 of SätL.

STUK has legislative powers given in YEL and SätL. STUK issues regulations on the technical details of the principles and requirements laid down in YEL and specifies detailed

safety requirements concerning the implementation of safety level (YEL sections 7q and 7r). STUK also issues regulations based on SätL. STUK is also responsible for making proposals for developing legislation in its field of activity (Decree on STUK, section 1).

STUK's position in the Government structure

In the Government structure, STUK is under the Ministry of Social Affairs and Health. This means in practice that ministerial directions and guidance are provided to STUK by the MSAH and that STUK reports its activities and outcomes to the ministry (Annual Report of STUK, 2021, only in Finnish). STUK makes annual agreements with the ministry. These annual agreements include STUK's main goals, which are related to the Government's and ministry's main goals, STUK's commitments to general governmental goals (e.g. staff wellbeing, education, IT, good governance), and budgetary matters. Annual goals do not provide direction on STUK's regulatory activities (e.g. how much resources are allocated to an oversight activity, or how they are prioritized). How regulatory activities are focused and prioritized are fully at STUK's own discretion.

Decision-making

STUK is independent in its decision-making. No ministry or other party can make decisions on a matter that has been defined by law to be the responsibility of STUK. Its independence 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 supervisory activities (YEL, SätL) and the present organizational legislation (Act and Decree on STUK). At present, the independent role of the STUK in decision-making is not explicitly provided in legislation. STUK's independent position concerning its positions/statements and supervisory activities is being clarified with a renewed Act and Decree on STUK (currently in draft).

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). The Administrative Procedure Act (434/2003) includes provisions of disqualification (section 27 and 28). STUK has established guidance on addressing conflicting interests based on administrative rules and guidance provided by the government administration.

STUK's financial resources

Having adequate financial resources is a vital part of independence in ensuring that regulatory activities are conducted properly without financial pressure. STUK is independent in making decisions on its staffing (there is no must seek any approvals for staffing decisions from the ministry, or for decisions on the organization of STUK's activities).

The funding of STUK's activities is three-fold. The main part of STUK's funding comes from fees collected from licensees. This applies fully to the oversight of nuclear safety, and partly to the oversight of radiation practices. The rest of the STUK's funding comes from the Government budget and from the expert services. The table below presents the development of STUK's expenditure and financing between 2019 and 2021.

	2019 M€	2019 %	2020 M€	2020 %	2021M€	2021 %
Expenditure	41,5		38,9		38,0	
Financing						
- State budget	16,4	40 %	15,9	41 %	15,0	40 %
- Fees from safety surveillance	19,1	46 %	20,5	53 %	20,5	54 %
* Use of nuclear energy	18,4	44 %	19,6	50 %	19,7	52 %
* Use of radiation	0,75	2 %	0,9	2 %	0,8	2 %
- Expert services	4,4	11 %	2,1	5 %	2	5 %
- External funding for cost-shared projects	1,4	3 %	0,4	1 %	0,3	1 %

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 (predecessor of the MEAE) on the payment and payment bases of STUK's services subject to nuclear safety supervision (1285/1993, section 3). STUK has access to sufficient financial resources in nuclear safety oversight, which is net budgeted (covered by the fees based on actual costs and collected directly from the licensees). This has ensured STUK's full financial independence in the regulation of nuclear safety.

The fees for the supervision of radiation activities are based on the Decree of the Ministry of Social Affairs and Health on Fees for the Services of STUK (1167/2020) in addition to the State Payment Basis Act and Decree. Under section 189 of SätL, a supervision fee is also levied, which is a tax payable to the State. The radiation safety oversight is therefore no longer fully net budgeted since the reformation of SätL. Because of this development, STUK is no longer fully independent of the state budget and governmental guidance. The existing legislation and related practices may jeopardize STUK's access to sufficient financial resources for the proper and timely discharge of its assigned responsibilities.

STUK's human resources

Having adequate human resources is a vital part of independence in ensuring that regulatory activities and decisions are risk-informed and made in a professional manner. STUK has had access to adequate and competent human resources to fulfill its responsibilities. However, due to changes in the operating environment, access to adequate human resources may be challenging in the future. For instance, in-depth competence building in the field of radiation protection and emergency preparedness has been resting on radiation safety research. Due to limited and decreasing funding from the budget, STUK has not been able to carry on and fund radiation safety research as planned. STUK has been funding research activities from incomes originating from STUK's expert services. However, a reduction in income resulted in the discontinuation of this practice. In addition, there are possible new oversight activities for which STUK should be able to develop the needed competences early enough. For example, STUK currently finds it difficult to develop competencies for new reactor technologies like small modular reactors (SMRs) for budgetary reasons. There are also

several areas where STUK's competence relies on only one or a few competent experts. For example, STUK's competences in the oversight of nuclear waste management are thin. As also addressed earlier in the text, STUK's resources need to support the renewal of nuclear legislations, and STUK's regulations are limited and may jeopardize the renewal being completed on time and to the required level of quality.

To ensure the expertise of STUK's staff, STUK has a competence management system including annual discussions between managers and personnel, and training programmes. According to the proposed revision of the Decree on STUK (section 7), STUK would take care of training arrangements in order to maintain and develop the expertise and skills of its personnel. For more information on competence management, see Chapter 3.

1.4 RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

Responsibility for safety and compliance with regulations

The responsibility for the safety of nuclear facilities rests with the licensee as prescribed in section 9 of the Nuclear Energy Act. Accordingly, it is the licensee's obligation to assure safe use of 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 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.

The licensees retain prime responsibility for safety throughout the lifetime of facilities and the duration of activities in accordance with the YEL (sections 9 and 24). Transfer of responsibilities for facilities or activities between different parties can only occur through a declared change, approved by STUK and/or the Government through procedures described in YEL and Decrees.

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 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.
Regarding radiation practices, the licensee's responsibility for safety is prescribed in SätL (section 22). The licensee is responsible for the radiation safety of the practice and this responsibility cannot be transferred to another. The licensee is relieved from its responsibility only when the practice has ceased, and the safety license is withdrawn accordingly, or when the practice is transferred to another licensee who has obtained the required safety license for it. The licensee shall demonstrate safety through a safety assessment which shall be kept up-to date. The licensee is 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. In case of a radiation deviation (emergency exposure situation), the licensee shall assess the situation and take the measures necessary to ensure radiation safety.

Responsibilities related to existing exposure situations depend on the origin and nature of the situation. The licensee 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. If the licensee fails to fulfil its obligations, the licensee is unknown or the situation has arisen without the consent of the holder of the area, the State has a duty of care for these actions. In case of exposure to natural radiation, the responsible party (e.g. NORM-industry (Naturally Occurring Radioactive Material), producer of building material) or the employer (e.g. in case of aviation or radon in workplaces) is responsible to investigate the level of exposure or radon concentration if the exposure arising from natural radiation or the radon concentration can exceed the reference level. If the reference level is exceeded, the responsible party or employer, respectively, shall take measures to reduce the exposure. If such measures are not possible or are ineffective, a safety license shall be applied for the operations.

1.5 COORDINATION OF AUTHORITIES WITH RESPONSIBILITIES FOR SAFETY WITHIN THE REGULATORY FRAMEWORK

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. Separate provisions are laid down on executive assistance given by one authority to another. Typical areas calling for coordination are environmental issues, security arrangements as well as emergency preparedness.

According to section 55 of YEL and section 14 of SätL, STUK is responsible for the regulatory oversight of nuclear energy and of radiation practices. Other authorities also have responsibilities defined in YEL and SätL related to the use of radiation and nuclear energy. In SätL the responsibilities of a municipality's health protection authority (section 15), Finnish Customs (section 16), and the Finnish Safety and Chemicals Agency (section 17) are stipulated. Moreover, section 17 refers to other supervising authorities for which responsibilities have been stipulated in SätL. YEL Chapter 9 "Other legislation and cooperation between authorities" defines the interface in relation to the safety and security of the use of nuclear energy between STUK and other authorities. 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 the chapter 'Interface with safety and Security'. Also, many other governmental and local organizations and municipalities, have their own functions based on separate legislation as regards the construction and operation of facilities and conducting activities.

Official assistance and the authorities' right to obtain and disclose information is based on legislation. 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.).

Overseeing radon in homes, working environments and at public spaces has been identified as an interface between several supervisory authorities. Therefore, a working group has been established to develop regulation, practices and communication in the area of radon-cooperation. The working group also works as a steering committee of the 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 (ME), STUK, Regional State Administrative Agency (AVI), Building Control Authority and Association of Finnish Local and Regional Authorities.

1.6 SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE EXISTING OR UNREGULATED RADIATION RISK

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

SätL sets out a framework to reduce radiation exposure in existing exposure situations. During 2022, STUK and MSAH will draft a national action plan for identifying existing exposure situations and for the implementation of the measures referred to in the plan. For the identified situations, SätL defines the roles and duties of the different authorities. STUK is responsible for assessing the radiation exposure arising from the existing exposure situation and for the determination of the required measures, then the National Supervisory Authority for Welfare and Health (Valvira) draws up a plan for protective actions and the provision of guidance for individuals living or working in the area. 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 1 mSv per year.

A safety licence is also required for practices which repeatedly handle or store orphan sources, for example steel smelters using scrap metal. Further, any licensee shall immediately notify STUK if it suspects or knows of finding or melting of an orphan source or any significant contamination caused by such an orphan source. There are no legal requirements for monitoring for the purpose of detecting orphan sources. However, the metal recycling industry has arranged such monitoring for its own commercial interests. In addition, Finnish Customs conducts monitoring at the borders based on its responsibility to supervise imports and exports of goods, and it reports to STUK if unexpected radiation is detected.

1.7 PROVISIONS FOR THE DECOMMISSIONING OF FACILITIES AND THE MANAGEMENT OF RADIOACTIVE WASTE AND OF SPENT FUEL

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 its operations and for the costs incurred. Nuclear waste generated in Finland shall be handled, stored and permanently disposed of in Finland. 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. Later in 1991, a decision by a predecessor to MEAE launched more serious research and evaluation of the spent fuel disposal option within Finnish territory. These decisions also set her a long-term schedule for the implementation of nuclear waste management including the site selection and start of the operation of a spent fuel disposal facility. The policies, licensing system, regulatory control and definitions of responsibilities of waste management were set in nuclear energy legislation in 1988. The nuclear waste management policy has been described in detail in the updated Finnish National Programme.

The generators of nuclear waste are responsible for all nuclear waste management measures and their appropriate preparation, and for their cost. Spent fuel is considered to be nuclear waste. The State has the secondary responsibility if any producer of nuclear waste is incapable of fulfilling its nuclear waste management obligations. When the licensee's waste management obligations have ceased after 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.

Organizations engaged in a radiation practice shall take the measures necessary to render harmless any radioactive waste arising from their 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 also applies to undertakings utilizing natural resources containing radioactive substances. The State has the secondary responsibility if a producer of radioactive waste is incapable of fulfilling its management obligations.

As said above, licensees generating nuclear waste are responsible for all nuclear waste management measures and their appropriate preparation and are also responsible for the expenses incurred. Both of the current nuclear power plant operators, Fortum Power and Heat Ltd and Teollisuuden Voima Ltd (TVO), have their own low- and intermediate level waste (LILW) disposal facilities in operation at the nuclear power plant sites. Interdependencies of LILW management are managed within the management systems of the NPPs as the waste is managed and disposed of at the same site and same organization except for small amounts of waste that are sent abroad for processing and conditioning.

TVO and Fortum have formed a joint company, Posiva, to manage the disposal of the spent nuclear fuel, which is classified as nuclear waste. Both companies will have their spent fuel transferred to Posiva's encapsulation plant for packaging and disposal at Posiva's disposal facility. The operation of the facility is expected to start in the mid-2020s.

Fortum and TVO are also responsible for their own decommissioning projects at the end of their NPPs' lifecycles. The planned sites for decommissioning for both NPPs are brown fields with all radioactivity transferred to disposal facilities. The decommissioning wastes are planned to be disposed of in the planned extensions of the existing LILW disposal facilities. YEL requires that provisions for decommissioning of a nuclear facility shall be taken into account in its design. The decommissioning plan shall be updated regularly, at six years intervals. The licence for decommissioning shall be applied well in advance before the termination of a nuclear facility's operating licence. After permanent shutdown of the facility, it shall be decommissioned in accordance with the decommissioning licence granted by the government and a final decommissioning plan approved by STUK. The dismantling of the facility and other actions related to decommissioning shall not be unjustifiably postponed.

Every three years, Posiva compiles a waste management programme (YJH) for nuclear waste on behalf of TVO and Fortum, which are liable for the nuclear waste generated at their nuclear power plants. TVO and Fortum submit the programme to the MEAE for regulatory review as required by YEL. STUK reviews the programme and provides its statement to the MEAE. The most recent programme was submitted to the MEAE in September 2021 and covers the period 2022-2024. STUK is responsible for the governance of the safety-related implementation of the R&D work. The national research programmes on nuclear safety (SAFIR) and waste management (KYT) have been described in section 1.8 of ARM.

YEL addresses financial provisions for nuclear waste management. The basic goals of the financing system for radioactive waste management and decommissioning are to ensure that funds for future waste management are collected to ensure that assets are available, even in case of insolvency of the licensee. The mechanism is set so that the full waste management costs including costs of the 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). Every three years, the pertinent licence holders submit 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 €2.621 million.

Regarding radiation practices (uses of radiation sources and licensees for practices involving exposure to natural radiation), SätL provides for the decommissioning of facilities, radiation sources and the management of radioactive waste. Radioactive waste shall be considered from the planning stage of a practice so as to minimize its generation and to take it into account in the justification and optimization of the practice as a whole. The licensee is responsible for ensuring that radiation waste generated is rendered harmless: 1) Disused sources shall be managed by returning them to the manufacturer or supplier, or by delivering them to the long-term storage at Olkiluoto LILW disposal facility at the NPP site through a private waste management company and 2) the facility shall be cleaned from radioactive substances. The licensee shall furnish a security for the costs arising from rendering radioactive waste harmless and any possible environmental clean-up measures if the safety licence is granted for a practice specified in SätL. The State has a subsidiary duty of care in cases where the licensee fails to meet its duty of care. STUK shall ensure that these tasks of the State are carried out.

1.8 COMPETENCE FOR SAFETY

The basic professional education and research is done in Finnish universities and research centres, such as the VTT Technical Research Centre of Finland.

Nuclear safety

According to YEL, the holder of a licence granting the right to use nuclear energy (licensee) shall have a sufficient number of qualified personnel suitable for the related tasks (YEL 7i). Significant functions with respect to safety within nuclear power plants must be designated, and the competences of the persons working in such positions must be defined and verified. The licensee shall evaluate and develop the performance of its 22rganization and individuals and identify and evaluate the risks associated with the 22rganization's performance regularly. Further, the potential safety impacts of significant 22rganizational changes are to be evaluated in advance. The expertise and competencies of the licensees are reviewed and assessed by STUK in different licensing steps and inspected periodically within inspection programmes.

YEL was amended in 2003 to ensure funding for long-term nuclear safety and nuclear waste management research in Finland. Money is collected annually from the licensees to a special fund. One aim of the research is to ensure that the authorities have sufficient and comprehensive nuclear safety expertise as well as novel safety assessment tools at their disposal when needed. (YEL 53a). The related national safety research programmes are called SAFIR and KYT. They have an important role in maintaining and building competence for all essential organizations involved in the use of nuclear energy.

The national education system for the university level studies (MSc, PhD) in nuclear engineering and sciences is based on the education programs of Lappeenranta University of Technology (LUT), Aalto University and the University of Helsinki. These universities have a strong tradition of providing education programmes with nuclear- (and other relevant topic area in engineering and sciences) specific content. In general, the funding of these programmes relies on two main sources: about a half is from the basic national funding driven by the Ministry of Education and Culture (MEC). The rest is acquired from various competitive sources of funds (such as the European Commission, Academy of Finland, etc.) by each of the universities.

The Government has established together with parties involved in the use of nuclear energy a specific training programme for nuclear safety (YJK-course). In October 2010, the Ministry of Economic Affairs and Employment (MEAE) 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 the 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 (Survey of Competence in the Nuclear Energy Sector 2017–2018 in Finland). The studies indicated that Finland has adequate national infrastructure (e.g. education institutions with needed training structures and degree programmes needed by the nuclear sector) to develop the competences needed by its nuclear energy sector now and in the future. However, certain competence areas remain as

an item of special interest. The MEAE is committed to keeping the competence survey up-to-date and the review is repeated at regular intervals.

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 (Nuclear Energy Research Strategy, 2014). The formulated strategy addresses seven themes aiming to ensure that internationally high-quality Finnish expertise and research will safeguard the safe, sustainable and competitive use of nuclear energy and promote business opportunities. The strategy has been implemented among other things through the national nuclear and waste management research programmes SAFIR and KYT. Up-to-date research infrastructure is seen as a key asset for high-level nuclear safety research, and significant investments have been made in VTT's Centre for Nuclear Safety and LUT's thermohydraulic laboratory. The investments in the infrastructure go not only to national infrastructure but also to some foreign research infrastructure (Finland ownership of 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

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

For the education and training of radiation protection experts, the current curricula of different Finnish universities cover most parts needed, but no formal curricula have been established leading to the qualification of a radiation safety expert in the fields of industry, research and education. Cooperation between universities and colleges was established with the support of the Ministry of Social Affairs and Health for this purpose in 2019, and the work is still ongoing. The formal curricula are essential to ascertaining the availability of the radiation safety experts of the future.

Radiation safety officers' training and qualifications are given by colleges, universities and commercial training service providers. There are 13 fields of expertise in industrial, educational, medical and veterinary practices and the use of nuclear energy. Training courses have been available in most of the fields, but the availability of the training is a matter of concern in some of the fields due to the limited number of potential participants.

In the field of the medical and veterinary use of radiation, the training of medical physicists has already included the training of a previous radiation safety officer stipulated in SätL (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 the universities acts as coordinator 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 a 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 doctorate 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 the medical physicist examination.

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

In Finland, a national network (Cores) and programme for radiation protection research has been established. It consists of universities, university hospitals and VTT Technical Research Centre of Finland. The network is coordinated by STUK. This network does not have its own funding and is dependent on external money whose availability and continuation is uncertain. To ensure the continuation of radiation protection research and national expertise, more stable funding would be needed (see also Chapter 1.3).

For the competence of STUK's staff, see chapters 1.3 and 3.3 for more information.

1.9 PROVISION OF TECHNICAL SERVICES

Most 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). STUK approves a dose measurement service (SätL section 60).

STUK maintains the national metrological standards necessary to ensure the reliability of radiation measurements (SätL section 14). STUK also 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 (SätL section 14).

1.10 CONCLUSIONS AND ACTIONS

Finland has a mature and well-established national framework for safety in the use of nuclear energy and radiation practices. Policies for safety are established mainly through legislation. Roles and responsibilities for safety have been clearly allocated to ministries, licensees and authorities. STUK is a competent and independent safety regulator.

The radiation legislation and regulations were reformed in 2018. The implementation of the new legislation revealed some immediate needs to correct/clarify/change some of the provisions of SätL These are expected to be adopted by Parliament in 2022 in conjunction with the adoption of a new Act on STUK. Also, further needs for improvement have been identified. As 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.

The preparation of the total revision of the Nuclear Energy Act underlying legislation and regulations has started. Binding requirements will be presented in YEL, YEA and STUK regulations are according to the principles laid down in the Finnish Constitution. One of the key principles of the comprehensive legislative reform is that Finland will continue to ensure compliance with international agreements, commitments and best practices related to the safe use of nuclear energy. The public consultation of the draft act is expected to take place in 2024. The review by the Government and Parliament will be in 2025–2026. The enactment of the act is expected in 2027.

Finland broadly complies with the IAEA requirements related to module 1. For further enhancement of the national framework for safety, the following actions have been identified as a result of the self-assessment:

- The Government should evaluate future resource and competence needs and make provisions that ensure adequate competences for STUK and other stakeholders.
    - The Government should carry out an assessment of the current level of expertise, education and future needs of radiation protection competences in Finland
    - The Government should evaluate the effectiveness of education services for radiation protection officers and experts (RPO and RPE) and the coverage in different fields of radiation practices.
    - The Government and STUK should steer national R&D programmes so that they are developing the needed competences.
    - The Government should ensure continuous basic funding for radiation protection research.
- The Government should ensure that STUK is able to participate and contribute in a timely and effective manner to the overall renewal of the Nuclear Energy Act (including STUK regulations and guidelines).
    - The Government should ensure an adequate budget for STUK to ensure adequate staffing resources for Nuclear Energy Act renewal

2. GLOBAL NUCLEAR AND RADIATION SAFETY REGIME

2.1 INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Finland is highly committed to nuclear and radiation safety. Finland is a signatory to all relevant international organizations, treaties and conventions and participates actively in international cooperation considering nuclear and radiation safety. Based on the peaceful use of nuclear energy, Finland has several bilateral agreements with other countries. As of 1 January 1995, Finland has been a member of the European Atomic Energy Community (EAEC or Euratom). Consequently, the agreements made by the EAEC are applied in Finland. The full list of the organizations, treaties, agreements and conventions to which Finland is a party is shown in the Annex 2.

Finnish experts participate actively in international cooperation on R&D tasks, drafting safety standards and guidelines. Finland has members on each of the IAEA safety standard committees. The IAEA safety standards and WENRA-harmonised safety reference levels are addressed when developing Finnish legislation, regulation and requirements.

The Finnish Government has requested several international peer reviews concentrating on the safe use of nuclear energy. Finland has also been active in making Finnish experts available in international peer reviews.

In addition, STUK has bilateral cooperation arrangements with several foreign regulatory bodies, which generally cover the exchange of information on safety regulations, operational experiences, waste management, etc. STUK is participating actively in European and international cooperation in the field of nuclear and radiation safety, safeguards and security as well as the safety of waste management.

International cooperation plays a significant role in the development of the regulatory competence and framework for emerging technologies in the use of nuclear energy and radiation. STUK is responsible for contributing to international cooperation in its field of activity, and for taking care of international control, contact and reporting activities, as enacted or prescribed. STUK annually allocates and uses approximately 16 person years for international activities (average number in 2019 just before COVID-19).

To enhance its effectiveness and efficiency, STUK has recently established a new organisational unit responsible for coordinating its international activities. International cooperation covers close collaboration with the other governmental organizations and ministries of Finland, participation in international meetings and workshops, and also the provision of international expert services for the organizations or regulators, which are paid to STUK.

2.2 SHARING OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

Nuclear facilities

STUK analyses both domestic and foreign operational experiences 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 regulations and regulatory guides.

STUK has made arrangements for receiving and collecting information from other states and relevant authorized parties. STUK actively disseminates lessons learned 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 the European Clearinghouse on Operating Experience Feedback for Nuclear Power Plants.

STUK gathers information directly from its cooperation with other regulators, especially with regulators and plants of Sweden, France and Russia with similar operating plants (BWRs, VVERs, EPR) to 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. STUK participation in international co-operation in the field of nuclear facilities is reported in the annual report on oversight.

One of the leading principles of YEL laid down in section 7 a is continuous improvements and consideration of 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 regulatory oversight (see modules 5-8). 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. All the three nuclear accidents – TMI, Chernobyl and Fukushima - have led to enhancement of nuclear safety requirements. After the TMI accident in 1979, systems to manage severe accidents were required in Finland, the Chernobyl Accident 1986 led to requirements in safety culture and the TEPCO Fukushima Daiichi accident in 2011 led to enhancement of requirements concerning extreme external conditions, and criteria for the design goals were made more stringent (YEA section 22b).

STUK requires that all incidents at the Finnish facilities and activities are reported to STUK without delay (STUK's Guide YVL A.9). STUK's Guide YVL A.10 includes detailed requirements on operational experience feedback (OEF) at nuclear facilities.

As per regulatory requirements, licensees of nuclear facilities must examine all operational events, which have safety significance, using a sophisticated root cause analysis method. Operational events at other nuclear power plants and foreign operational occurrences must be systematically screened and assessed as well, from their applicability and significance for the nuclear facilities in Finland. Based on the analysis, corrective actions are planned and implemented by the licensees. 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. The failure register is also utilized in updating probabilistic risk assessments (PRA). The utilization of operating experience is also reviewed and evaluated in connection with periodic safety reviews.

International practices, OEF and results of the research and development are considered when the act, its underlying regulations and YVL guides are developed and updated. The current status/up-to-date references such as IAEA Safety Standards are 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 the public, media and users of radiation about changes in regulatory work and guidance, and other current issues.

STUK has recently developed a process for managing regulatory experience from various sources. This process has been in pilot use in the 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.

Radiation practices

SätL requires STUK to use inspection findings and other observations pertaining to radiation safety to develop regulatory control and to report on them to undertakings, authorities and any other parties concerned to the necessary extent to promote safety. All regulatory decisions, inspection findings, actions of enforcement and radiation safety deviations are recorded in VASARA (Radiation Practices Regulatory Control Information System) in a systematic manner. VASARA enables the analysis of statistics, for example of different types of inspection findings and safety deviations in different types of activities and facilities. The analysis of inspection findings is used for targeting regulatory control, for example in 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.

Moreover, in the field of radiation safety, STUK participates actively in Nordic regulators' groups and HERCA in which regulatory experience and lessons learned are shared. Participation in other international co-operation is reported in the Annual Report on Radiation Practices.

SätL 130 § requires undertakings to report radiation safety deviations to STUK, and SätL 131 § requires that radiation safety deviations be investigated, and that measures required to prevent similar deviations be implemented. STUK S/6/2019 requires that the safety assessment be reviewed in the light of experience gained from other similar operations, the results of safety studies and technological developments.

2.3 CONCLUSIONS AND ACTIONS

Finland is a signatory to all relevant international organizations, treaties and conventions and an active member in international radiation and nuclear safety co-operation. STUK's experts participate actively in all IAEA safety standards committees. Finland invites peer review missions and contributes to peer review missions in other countries. According to the governmental programme, Finland is globally influential. In its role, STUK aims at enhancing effectiveness in international cooperation with recently established organizational units. STUK works in close collaboration with the other governmental organizations and ministries of Finland; participation at international meetings and workshops, as well as the provision of international expert services for the organizations or regulators which are paid to STUK, are well managed and coordinated.

In conclusion, the requirements 14 and 15 of GSR Part 1 are complied with. STUK has enhanced the management of the regulatory experience from various sources and experimented with them at nuclear safety and nuclear waste management departments. For further use, STUK should ensure that a systematic regulatory experience feedback process is effectively implemented in all STUK regulatory departments. This process should be integrated into STUK's management system and lessons learned should be shared more systematically with other stakeholders.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

3.1. ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND ALLOCATION OF RESOURCES

According to section 5 of StukA (618/1997), organization and decision-making authority within STUK can be decided by STUK's Director General. STUK's Director General has the authority to decide on STUK's organizational structure and the management of STUK's resources without any consent from outside STUK. This also ensures that STUK's organizational structure and use of resources supports both effective and efficient regulatory activities, and decisions on the structure and resources can be made without undue influence from outside. The Director General of STUK is appointed by the Government of Finland for a fixed period of time (typically 5 years).

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

1) regulatory control of safety of the use of nuclear energy, emergency preparedness, physical security and nuclear materials
2) regulatory control of the use of radiation and other radiation practices
3) monitoring the radiation situation in Finland, and maintaining of preparedness for abnormal radiation situations
4) maintaining of national metrological standards in the field
5) research and development work for enhancing radiation and nuclear safety
6) informing on radiation and nuclear safety issues, and participating in training activities in the field
7) producing expert services in the field
8) making proposals for developing the legislation in the field, and issuing general guides concerning radiation and nuclear safety
9) participating in international co-operation in the field, and taking care of international control, contact or reporting activities as enacted or defined.

STUK's current organization (see Figure 3) reflects the most significant duties of STUK, namely regulatory oversight of radiation practices and nuclear energy, and environmental radiation surveillance. The organization, duties and resource management are described in more detail in STUK's Management System (Guide STUK 2.1 and Guide STUK 2.2). The organizational structure and resources are periodically evaluated (e.g. strategy, annual plans, management reviews) and needs for changes may be identified. Changes are carried out following Guide STUK 2.2, which has a chapter on the management of organizational changes. Resource planning is an essential part of annual planning.

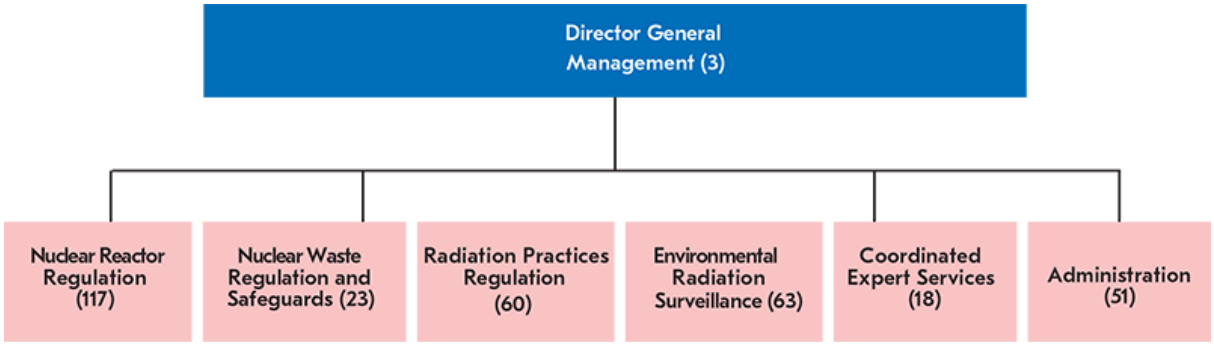

Figure 3. STUK's organization December 2021

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 the implementation of regulatory activities according to the processes (see module 4). Another prerequisite for the practical implementation of a graded approach is naturally staff competence. The number of staff in different organizational units (in Figure 3) is in proportion to the risk-informed oversight. In addition to the graded approach, staffing considerations take into account the volume of regulated activities and the possibilities that increased staff numbers could have on regulatory effectiveness. The use of resources in different areas is illustrated in Figure 4.

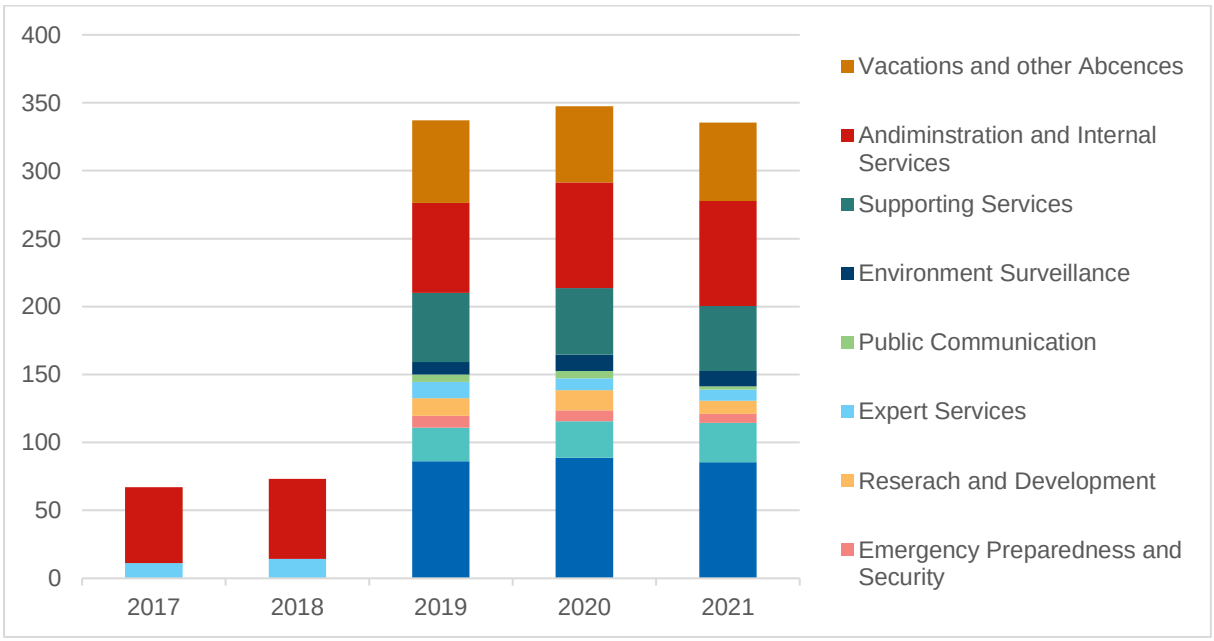

Figure 4. Use of resources in 2021

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

The foundation of the independence of STUK is given in legislation. Legislation describes STUK's governmental position, regulatory duties, regulatory powers and financial arrangements to ensure the conduct of regulatory activities. The current StukL (1069/1983) on STUK was given in 1983 and the StukA (618/1997) in 1997. The responsibilities and rights of STUK as regards the regulation of the use of radiation and nuclear energy are provided in detail in the Radiation (SätL) and Nuclear Energy (YEL) Acts. The powers provided for STUK in the legislation enable it to intervene in any facilities or activities that present significant radiation risks.

According to the legislation, STUK is a governmental organization for the regulatory control of the use of radiation and nuclear energy. The legislation defines no other responsibilities or duties, which would be in conflict with regulatory control. In the governmental structure, STUK is administratively under the Ministry of Social Affairs and Health. No ministry can take for its decision-making a matter that has been defined by law to be the responsibility of STUK. STUK has a duty to operate and regulate interim storage for state-owned radioactive materials (discussed in Chapter 5.5). Conflicting responsibilities are divided between STUK departments to establish functional independence. However, this arrangement is not optimal and re-arrangement should be evaluated.

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

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 (39/1889), the 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 (39/1889), section 40, concerning malfeasance.

In addition to what is described in the legislation, STUK's Management System addresses the expectations and gives more detailed guidance to ensure independence at all levels of STUK's activities. The competence of STUK's staff is an important prerequisite for ensuring independence in decision-making and oversight activities from organizations or bodies charged with responsibilities for the promotion or application of nuclear or radiation-related technologies. 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 regulated stakeholders. If STUK uses subcontractors for any work, the requirement for independency is included in the contracts. Procedures for this are further discussed in section 3.4.

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 8. No provision

in the legislation nor in the STUK Management System documents refers to costs to the licensee as a factor hindering STUK from exercising its authority to intervene in case of significant and acute radiation risks. However, STUK applies a graded approach in its 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.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

The number of staff at STUK at the end of 2021 was 349. The distribution of staff to different organizational units at STUK level can be seen in Figure 3.

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, which also covers the strategic aspects of staffing and competence. The implementation of strategy is ensured by a specific programme ('effective regulator change programme' and detailed goals are included in STUK's annual plan). The implementation of the strategy is followed up by the Executive Management team at least twice a year, and the strategy is also assessed on an annual basis and, if needed, changes can be made. The annual planning covers all regulatory activities as well as actions from the strategic 'Effective regulator change programme'.

STUK's competence and human resource needs (See also Module 1, chapters 1.3 and 1.8) 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 and avoidance of unnecessary costs to licensees 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 Ministry of Finance (MoF) and this has affected STUK's radiation safety research activities but not directly regulatory oversight activities.

Budget cuts and the 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 also finds it difficult to develop competencies for new areas/technologies (e.g. SMRs). See also Module 1 (Chapter 1.3).

To maintain a clear vision and status of staff turnover, STUK updates its human resource plan annually as a part of the annual planning process. Training, staff rotation and recruiting plans are established and finalized typically at the end of each year. Furthermore, STUK maintains a mid-term staff forecast for a 5-year period to evaluate the effects of retirements, fixed-term contracts and long-term leaves/absences, and to estimate recruitment needs in near future. Since staffing is fully at the discretion of STUK's Director General, plans do not must be discussed or agreed with the ministry in annual agreements between STUK and the ministry.

According to Guide STUK 5.1, Human Resource Policy, competent, co-operative and motivated people are a fundamental success factor 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

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). The training system consists of training content designed based on, for example, competence needs, strategic goals, 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. The management of competences is also discussed in section 4.4.

The introduction of new employees is conducted according to a specific process (Guide STUK 5.8). The aim of the introduction process is to support a proficient start for the newcomers to STUK and to ensure that the common STUK knowledge, shared practices and procedures are presented and adopted by the newcomers.

STUK encourages its personnel to develop their professional skills and to expand their competence to new tasks as well. STUK may grant leave of absence for the purpose of working for a certain period for another employer such as ministries, other governmental organizations or international organizations (e.g. IAEA). In these cases, working elsewhere develops competence in STUK-related tasks but does not endanger STUK's independence as a regulator, and the execution of the unit's tasks does not become considerably more difficult as a consequence. The exchange of civil servants within the Finnish administration as well as with international organizations is also encouraged by the Finnish Government. A specific case is the medical use of radiation where working periods at hospitals have helped staff to keep up with the rapid technical development in this field. In this case, the worker shall not participate in the regulatory activities of the hospital in question for a certain time period after the working period.

The qualification requirements for inspectors and other staff of Radiation Practices Regulation are presented in Annex 2 of Guide SKV 12.4 and for inspectors of Nuclear Reactor Regulation and Nuclear Waste Regulation and Safeguards in Guide YTV 6.b. STUK has developed a comprehensive system for competence management and qualification processes for nuclear facility inspectors. However, systematic implementation still needs further work.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

Legislation provides possibilities for STUK to liaise with stakeholders, contract expert organizations (section 4 of StukL) and have advisory bodies. STUK has four advisory committees that have been defined in the legislation. STUK's advisory committees are laid down in StukA section 2. The Advisory Committee on Nuclear Safety and the Advisory

Committee on Nuclear Security are defined in YEL section 56 and the Advisory Committee on Radiation Safety in section 18 in the SätL. The composition, quorum, term and tasks of the safety and security committees are defined in associated government decrees.

STUK´s advisory committees help STUK to function as a regulatory, research and expert organization in such a way that the activities are in balance with society´s expectations. Advisory committees have no decision-making authority on any of STUK's regulatory activities, and are purely in an advisory role to the Director General and the Executive Management Team. Topics discussed at advisory committee meetings are related mostly to the implementation of STUK's strategic goals. Members of the committees are nominated by STUK. They serve for two years. Meeting minutes are published on STUK's website.

For large licensing steps in authorization processes (Decision in Principle, Construction, Operating and Decommissioning licence steps for nuclear facilities), STUK is obliged to request a statement from the Advisory Committee on Nuclear Safety (YTN). In addition, STUK asks for statements from YTN on new safety regulations, major facility modifications or other areas it deems necessary. For licensing purposes, STUK must attach YTN's statement to STUK's statement and safety assessments submitted to the MEAE. The duties of YTN are described in the decree and members of the committee are proposed to the Government by the MEAE, typically after consultation with STUK. The term of office of the Committee is three years. YTN has two subcommittees, one for nuclear safety and one for waste safety. Subcommittee members are international experts. Meeting minutes of YTN and subcommittees are published on STUK's website.

The Advisory Committee on Radiation Safety (STN) makes statements on planned, existing and, emergency exposure situations as well as other matters relevant to radiation safety and other matters covered by SätL, makes statements on draft radiation safety legislation and regulations, follows the development and research in the field, promotes national and follows international co-operation and makes initiatives to competent authorities on necessary measures for radiation safety. The duties of the STN are described in the decree and members of the committee are proposed to the Government by the MSAH, typically after consultation with STUK. The term of office of the Committee is three years. Meeting minutes are published on STUK's website.

The Advisory Committee on Nuclear Security (TJNK) assesses threats in the nuclear field and provides consultancy 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 duties of TJNK are described in the decree and members of the committee are proposed to the Government by the MEAE, typically after consultation with STUK. The term of office of the Committee is three years. Meeting minutes are published on STUK's website.

Members of the Advisory committees are nominated by the Government, and they must conform to the Administrative Procedure Act (434/2003), the which specifies the principles of independency and grounds for disqualification.

In addition to advisory commissions, STUK uses expert organizations to support its regulatory functions. The process for contracting and conditions for the use of external organizations are described in STUK's Management System (Guides STUK 8.11 and STUK 2.11). STUK's main support organization in Finland is VTT Technical Research Centre of Finland. STUK and VTT have a framework contract and rules on cooperation to ensure

independent advice and to avoid conflict of interest. This is necessary since VTT is also used by the licensees in Finland. In addition to VTT, STUK uses other organizations in Finland and abroad, mostly in the area of nuclear safety. The advice and assistance from external organizations does not have a formal status and does not relieve STUK of its assigned responsibilities. The independence and possibilities of conflicting interests are addressed in the course of contracting.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

STUK has a long tradition and has gained good experience in stakeholder interactions with excellent results through arranging several types of meetings, seminars and workshops with users of nuclear energy and radiation, as well as with professional bodies and decision-makers. In addition, users of nuclear energy and radiation are also actively given information on radiation protection, new regulations and the reasons for them in different types of guidance material, other publications and on the STUK website.

STUK has established both formal and informal mechanisms for communication between itself and authorized parties to ensure possibilities for professional and constructive liaison. Based on the experience and stakeholder feedback, liaison, and communication work very well between STUK and the authorized parties.

The formal and most frequently used mechanisms are through correspondence between STUK and authorized parties, and inspections of the authorized activities and organizations. It is also possible for STUK to invite authorized parties to a formal meeting. Formal mechanisms are described in detail in STUK's Management System. The informal mechanisms consist of informal meetings and discussions between individuals at different levels of the organizations, as well as seminars and workshops with authorized parties.

Both mechanisms allow possibilities for frank and open discussions to foster mutual understanding on safety-related issues. Authorized parties are also given the chance to be heard when regulatory decisions are made prior to issuance, and to participate in the regulations update process before they enter into force.

STUK is a governmental body, and the Administrative Procedure Act (434/2003) is applied in all its activities. This act lays down provisions on the foundations of good administration and on the procedure to be applied in administrative matters. These include provisions on hearing the views of parties in regulatory decisions (for example, a decision on a safety licence 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".

The legislation requires and the STUK management system reiterates that STUK's decisions and requirements have 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 the basis for possible requirements set for the authorized parties is included in the decision or presented in a separate justification memorandum, which is attached to the decision and is submitted to the authorized parties. STUK has also 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.

To evaluate stakeholder interactions, feedback is also collected via questionnaires and surveys.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

The regulatory control activities of STUK are based on legislation, including the Act of Administrative Procedures (434/2003), YEL and SätL. STUK's activities and decisions must be justified, making a reference to the relevant provisions in legislation and regulations. The obligations of STUK presented in the legislation are implemented through the management system. STUK's managements system policies and procedures must be observed in all regulatory processes. Acts, decrees, regulations and guides are publicly available for applicants, licensees and authorized parties.

The implementation of STUK's Management System in all regulatory activities is the prerequisite for the stability and consistency of regulatory control. Each employer is responsible for seeing that his/her activities are conducted according to the Management System. Training on the Management System is provided for new employers and information on modified procedures is given to the staff.

A change or update to STUK regulations and regulatory guides is done in accordance with process described in Guide STUK 3.6. The preparation process of STUK regulations includes internal consulting and hearing the stakeholders and relevant advisory committees, which in part ensures that requirements remain stable to the extent necessary, and changes are introduced only after thorough consideration.

STUK's management system includes comprehensive guidance for decision-making. In most cases, consistency is supported by having different managerial or coordinative roles as part of the process. A hearing process is applied prior to decision-making, enabling authorized parties to raise concern on subjectivity if needed. Decision-making education and training are part of inspector qualification programme, and short training courses are provided regularly to inspectors to ensure consistency in decision-making.

3.7. SAFETY RELATED RECORDS

Provisions for establishing and maintaining adequate and retrievable records relating to the safety of facilities and activities are set in the legislation and regulatory guides. Information related to the safety of the facilities and activities must be submitted to STUK for information or approval in different stages of the lifetime of the facility or activity. Information produced and submitted in different stages of the lifetime (for example design, construction and operation in case of nuclear energy) is stored over the lifetime of the facility and can be utilised before and during the decommissioning of the facility. Information is archived and maintained in STUK registers following the regulations on information management. It is expected that the licensees will also store the information during the lifetime of the facility.

STUK has established and maintains several registers for its regulatory purposes. These include registers for sealed radioactive sources and radiation generators (VASARA database), for occupational doses (Dose register), registers for maintaining information related to the safety of facilities and activities and their decommissioning (SAHA and VASARA database), a register on radon (RAMI and Ratikka database) and NORM-industry (NAMIT database), accidents and non-routine releases (SAHA and VASARA database), and a register for waste and spent fuel inventories). In addition to registers at STUK, it is required that licensees also keep the data in their own registers.

STUK publishes annual reports on the results of its oversight of the use of nuclear energy, radiation practices and environmental surveillance (Regulatory oversight of nuclear safety in Finland, Annual Report 2020, STUK-B 267, May 2021; Environmental Radiation Monitoring in Finland Annual Report 2020, STUK-B 268; June 2021; Radiation practices: Annual Report 2020, STUK-B 276). When compiling the reports, information in the registers is utilised. The same information is also utilised in the periodic safety reviews conducted for nuclear facilities.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

The Decree on STUK defines STUK's tasks. One of the tasks is to inform about radiation and nuclear safety matters and participate in training activities in the area (section 1 of the Decree on STUK). STUK's Management System (Guide STUK 1.1) describes STUK's values, and one of the values is openness. In addition, Guide STUK 1.1 provides STUK's communication policy highlighting the following principles:

- Communication belongs to all of us and enables the implementation of STUK's basic mission and strategy. We are an open, listening and humane conversationalist. We actively provide people with correct and clear radiation safety information.

STUK utilizes the internet to inform the public and interested stakeholders about nuclear and radiation safety in general, risks related to radiation and use of nuclear energy, safety requirements, the roles and responsibilities of STUK, STUK's organization, current activities and operating experience, significant regulatory decisions taken, events and publications and safety research. STUK web pages can be found (www.stuk.fi) in Finnish, Swedish and English. STUK is active on social media (LinkedIn, Facebook and Twitter). STUK also encourages its individual staff members to be active on social media. Particular attention is paid to serving different type of media due to their access to a wider audience. STUK serves public media and is transparent in its communication. In addition, STUK utilizes different means to communicate with public and interested stakeholders:

- Communication with authorized parties is conducted via correspondence, meetings and seminars and personal contacts
- STUK organizes and participates in training courses on nuclear and radiation safety matters (e.g., training for media people, training on radiation protection, training for customs officers, e-learning courses on radon measurements, training on regulatory requirements for licensees, vendors and subcontractors and other stakeholders)
- Press releases are published on safety-significant event at nuclear facilities or in the use of radiation or the most significant existing exposure situations such as radon or observations of elevated radioactivity in environmental surveillance
- Regular reports on radiation and nuclear safety are published quarterly and annually
- STUK also has organized meetings and seminars with the residents of the municipalities living in the vicinity of the nuclear power plants. The purpose of these meetings has

mainly been to interact with the public and present the results of annual oversight and the safety assessments of the nuclear power plants
- For communication during emergencies STUK has established lists of contact points for relevant licensees, authorities and ministries in Finland and abroad. Communication is practised in annual emergency exercises.

STUK consults with interested parties (public, advisory bodies, licensees, ministries, other authorities, etc.) when drafting new regulations. STUK communicates actively with other authorities (e.g., security, emergency preparedness) to enhance co-operation.

3.9. CONCLUSIONS AND ACTIONS

STUK's organisational structure is tailored to discharging its responsibilities and performing its functions effectively in a manner commensurate with the radiation and nuclear risks associated with facilities and activities. So far, STUK has a sufficient number of competent staff and its human resources are allocated for the effective discharge of its regulatory responsibilities and performance of functions, using a graded approach. STUK is legally, institutionally, financially and politically independent. STUK has well-established liaison with advisory bodies and support organizations. STUK ensures with different instruments that its regulatory control and decisions are stable and consistent. Legal provisions and STUK's regulations and guidelines specify the requirements for recording and archiving documentation regarding the construction and operation of nuclear facilities, supervisory activities, occupational doses, and inventories of radioactive sources, waste and spent fuel. STUK actively communicates with all interested parties in matters relating to radiation and nuclear safety and security in an open, transparent, understandable and timely manner.

In conclusion, the requirements 16-36 of the GSR Part 1 are complied with. However, there is still room for improvement. Accordingly, the following needs for actions have been identified:
- The Government should evaluate possibilities to organize state-owned radioactive waste management in a manner in which STUK does not have operating role.
- Action identified for module 1: the Government should ensure an adequate budget for STUK enabling the maintenance and development of its competencies also covering possible new activities needed based on long-term scenario assessments.
- STUK needs to ensure that the process for competence management is fully implemented (for example implementation of training programmes, full implementation of the nuclear safety inspector qualification programme)

Good practise

STUK has improved 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. STUK considers this good practice.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

The framework for all work performed by STUK and its employees is the Management System. The Management System comprises all activities of STUK, ensures implementation of a strong safety culture, STUK’s Mission Statement, and that STUK fulfills its legal obligations. In addition to the Management System, STUK’s strategy and annual target plans represent key instruments for responsibilities and leadership for safety.

Guide STUK 2.6 explains the structure of STUK’s organization. The Rules of Administration (Guide STUK 2.1) provide the functional responsibilities of organizational units and directors, and decision-making rules. The Rules of Administration are confirmed based on section 5 of StukA (618/1997).

STUK uses a Management by Results System. The focus of the annual planning process is not only in goals but also in the quality and effectiveness of the work. Resources are allocated to different areas of regulatory activities and other activities based on the detailed work time recording system, and the real time used is followed and assessed. One part of annual planning is human resource planning, and all departments prepare HR plans for the coming years, including a long-term one for the next five years. The follow-up of activities and the evaluation of achieved results are also covered by the Management by Results System. Objectives and timelines as well as resource allocation for all goals and activities are also determined (Guide STUK 2.2).

A graded approach is implemented in the planning process and in developing and allocating STUK’s resources in various regulatory activities in the fields of nuclear energy and the use of radiation and other radiation practices. The prioritization of activities and the most important objectives are set out in the strategy and included in annual target plans. The conduct of work at STUK is guided by the Management System Manuals, which are a comprehensive set of orders and guides that give instructions for all STUK’s operations, including both administration and professional work. The principle of a graded approach is key to STUK Guide 3.1 (Regulatory activities of STUK).

Legislation defines matters on which STUK makes decisions. The Rules of Administration STUK 2.1 gives a list of matters and defines by whom the decisions must be made. In matters of principle and wide scope, the decision-maker is usually the Director General or a head of department. All relevant information is gathered and used when a decision is being prepared. An essential part of the decision-making 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 STUK 9.2. Preparation of documents, Chapter 4.3.).

4.2. MANAGEMENT FOR SAFETY

STUK established its first comprehensive Quality Management system in 1997-98 covering all its activities Since the 1970s, special management guidance has been issued both at STUK level and at departmental level. The current Management System means an integrated system of core and support processes, the organizational 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 (Guide STUK 1.3). Key principles and goals for safety, quality and information security are outlined in STUK's Safety-, Quality- and Information security policy (Guide STUK 1.1).

STUK´s mission is to is to protect people, society, the environment and future generations from the harmful effects of radiation. Ensuring fulfillment of the mission is the primary goal in both strategic and annual planning processes, which are described in Guide STUK 2.2. The time span for STUK's strategic planning has been five years and the goal is to prepare and, if necessary, transform STUK so that it can proactively respond to future challenges and hence continue to fulfill its mission, now and in the future. The strategy is based on an analysis of the changes and drivers in the operating environment, expected developments in the regulated areas and resource needs. The strategy includes a vision, mission, set of values, strategic goals addressing needs for change in different areas of operations, as well as the monitoring and evaluation of the implementation of the strategy (followed up on a yearly management cycle by the STUK Executive Management Team).

STUK's management uses a performance management system that ensures that it achieves the goals set for it. The performance management system includes the control of operations, evaluation of the results achieved and systematic development of operations including the safety aspect. Annual Performance targets address strategic and operational goals and are accompanied by schedules and available financial and human resources. Guide STUK 2.2 gives instructions for the strategic planning, annual planning of activities, evaluation of achieved results and systematic development of activities.

Senior management has assigned responsibilities in their respective departments to individuals for being responsible for the development, application and maintenance of management system and quality management. STUK´s management system procedures include procedures for continuous improvement (Guide STUK 1.3) such as the follow-up of the metrics of processes, handling of non-compliances and other findings, corrective actions procedures and handling of customer feedback.

In addition to the internal assessment work, STUK also conducts external assessments. STUK could participate in a more focused way on international cooperation (e.g. OECD/NEA) work to learn from other regulators' experience (see recommendation module 2).

4.3. THE MANAGEMENT SYSTEM

The functions and responsibilities of STUK and regulatory safety goals are stipulated in Finnish legislation (e.g. SätL (859/2018), YEL (990/1987), StukL (1069/1983), and StukA (618/1997)).

STUK's key principles and goals for safety, quality and information security are written in the Safety-, Quality- and Information security Policy of STUK (Guide STUK 1.1). The directors have committed themselves to following the quality policy requirements and expect 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 graded approach principle is described in Management System guides regarding regulatory activities.

STUK´s organizational structure is described in Guide STUK 2.6, which also provides guidance on changing and evaluating STUK's organizational structure. Accordingly, some reviews have been conducted after organizational changes in STUK in recent years. However, in some cases, the process of organizational change has been long and could be more efficient by for instance more timely and efficient engagement of people in the process.

The Rules of Administration (Guide STUK 2.1) describe the powers of certain roles and the functional responsibilities of organizational units and directors, and decision-making rules. These rules are confirmed based on section 5 of StukA (618/1997). Corresponding documents of the departments prescribe decision-making powers in different situations.

Regulatory decision-making emphasizes understanding the substance of the issues, applying a graded approach to risk, and ensuring consistency with the mission of STUK. Essential bases for the decisions and statements are documented. Requirements presented in connection with the decisions are proportional to the safety relevance and shall increase the quality and safety. A decision can be changed if additional arguments presented later give good reason for a new decision (Guide STUK 9.2). Regulatory activities are recorded (in the document and case management system SAHA and VASARA) for traceability of decision-making. 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). 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; the same type of procedure is included and implemented in nuclear safety regulatory activities. The decisions and procedures of STUK are open to publicity, if not otherwise decided by legal grounds (Act on the Openness of Government Activities (621/1999).

All procedures of STUK were defined and described for the first time in 1998. At the beginning of the 21st century, processes were identified and process descriptions were published. STUK's processes are described in the STUK Management System Manual. For example, Chapter 3 describes STUK's core processes. Departmental Management System manuals describe the procedures for core processes and subprocesses.

The processes are described and developed taking into account interfaces between organizational departments and interfaces with external stakeholders. For example, several departments might have similar procedures in regulatory activities, so they develop mutual process description and guidelines for this matter. The expectations of stakeholders are included when STUK's strategy, action programmes for core processes and annual plans are prepared.

Documentation of the management system includes strategy, mission, vision, values, policy statements, the goals of STUK, planning and reporting documents, guides and instructions as well as documentation of all management procedures such as risk management or competence management. The Management System Manuals are a comprehensive set of orders and guides. Processes are described in the Integrated Management System IMS tool, and also in the detailed guides and instructions of departments.

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. All documentation sent outside STUK is electronically signed (Guide STUK 9.7), which means it cannot be modified afterwards. All electronically incoming material in STUK is automatically saved in PDF/A format, which means that documents are blocked from being modified.

Instructions for the revision of the Management System guides are given in Guide STUK 1.4.

STUK´s Quality Manager is responsible for the coordination, development and improvement of STUK´s management system. Every department nominates their own responsible quality persons. STUK´s quality and development team consists of persons from the departments responsible for quality and STUK´s Quality Manager (placed in the Support Unit of the Administrative Department).

4.4 MANAGEMENT OF RESOURCES

The Human Resources Unit coordinates STUK's competence management process (Guide STUK 5.2) and takes care of the centralized competence development planning, training coordination and evaluation. In annual planning, all departments prepare a human resource plan for the coming year and also a long-term one for the next five years.

The competencies required in STUK are compiled into competence profiles: STUK's competence profiles combine its 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 his/her duties. When new staff are recruited, the targeted competence requirements are defined for each duty in question.

STUK has identified and defined key leadership competencies, and in 2021 work continued on defining managerial competencies. The development of leadership, management and supervisory work is systematic and based on defined competencies, 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.

STUK provides training for its personnel in order to achieve and maintain the required level of competence. It annually establishes a common training programme as well as dedicated training programmes of the departments.

4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

A process chart of STUK (Figure 5) as well as the most important process flow charts, i.e. core processes, supporting processes and general management processes, and definitions of processes can be found in the IT-tool IMS (Integrated Management System), where each process has information about process owners, 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 management or departmental directors.

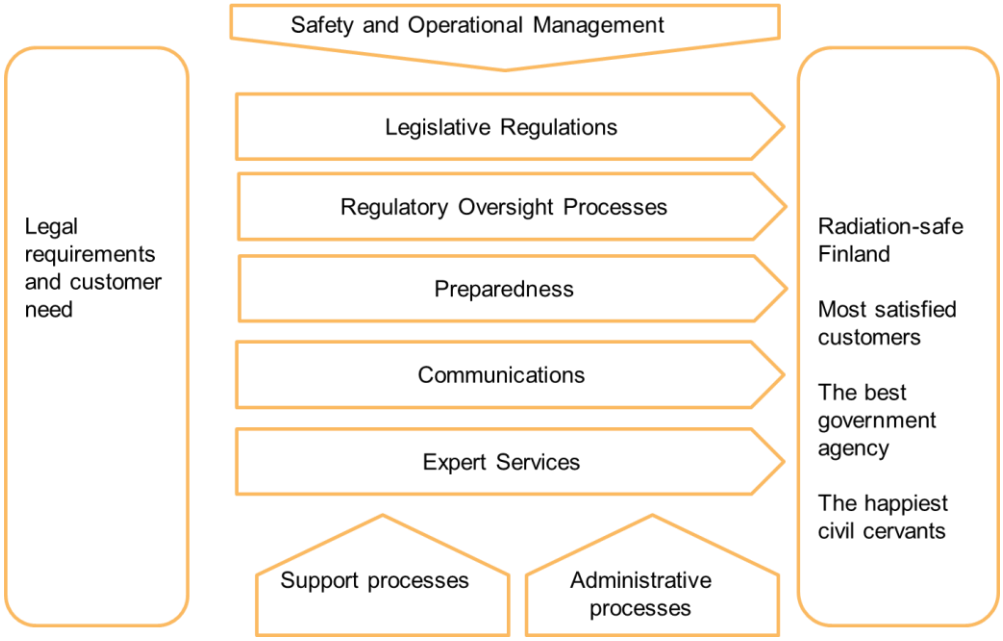

Figure 5. Process chart of STUK.

STUK's processes are described in more detail in the STUK Management System Manual. For example, Chapter 3 describes STUK's core processes and the other chapters supporting processes, including general management system processes such as procurement, administration and document management. The departmental Management System manuals describe the procedures for core processes and subprocesses, taking into account safety issues, and they also give guidance to STUK employees on how to tackle the requirements in legislation and how to impose these requirements on those running radiation or nuclear practices.

The control of carrying out processes, the evaluation of achieved results and the systematic development of activities are included in the Management by Results System.

Guide STUK 8.11 defines the control and organization of STUK´s procurement. The departments identify their procurement needs and prepare an annual procurement plan for their department, which is approved by the Director General. The departments are

responsible for the description and specification of the subject of the procurement, the technical and qualitative comparison of the tenders, and the supplier cooperation during the contract. Guide STUK 2.11, Management Reviews in STUK, also requires the evaluation of suppliers.

STUK's procurement team is responsible for monitoring the procurement and the implementation of the procurement plan with regard to the procurement for which the procurement team is responsible. The task of STUK's Procurement Cooperation Group is to monitor the implementation of the procurement as a whole.

Guide STUK 8.11 defines the principles of responsibility in the selection of suppliers. STUK's own tenders require that tenderers have duly fulfilled their social obligations, paid their taxes and social security contributions and complied with their legal obligations regarding environmental protection, occupational safety and working conditions. The Government's decision-in-principle on the promotion of sustainable environmental and energy solutions in public procurement also requires that environmental considerations be taken into account in public procurement.

There is a separate guideline for the procurement of technical support related to regulatory control (Guide YTV 8.d), which defines the measures for evaluating the supplier and supervising the execution of assignments.

4.6 CULTURE FOR SAFETY

The Safety-, Quality- and Information Security policy is outlined according to the STUK strategy. The mission of STUK is to protect people, society, the environment, and future generations from the harmful effects of radiation. The policy document Safety-, Quality- and Information Security Policy outlines key principles for STUK’s conduct of operations (Guide STUK 1.1) to support STUK in fulfilling its mission.

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 underlines the importance of safety in its daily operations and the commitment of STUK and all its employees to developing and maintaining a healthy safety culture and demonstrating safety as an overriding value through their actions.

STUK’s Safety Culture Programme was developed in 2019 and launched in 2020. The decision to establish a programme was made 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).The safety culture programme supports the development of a healthy safety culture in STUK. The programme presents key safety culture concepts and characteristics of a healthy safety culture. Furthermore, STUK’s Safety Culture Programme (2020-22) emphasizes three main topic areas as its ‘guiding stars’: 1) Vigilance and a Questioning attitude, 2) Sense of Responsibility and Assertiveness, and 3) Manageability of Work. The guiding stars set expectations for the behaviour and actions taken by STUK’s senior management, managers and specialists. Leadership and managerial work, as well as the behaviour and actions of the specialists, are continuously observed from the safety culture perspective, for example by conducting observation of daily life, by conducting personnel surveys and by collecting information from various other sources. The latest personnel survey was conducted in autumn 2021. Based on the results, STUK has a healthy safety culture. However, further

enhancement can be achieved by fostering a questioning attitude, ensuring a safe atmosphere for critical debates, addressing concerns raised on safety or work in general, and ensuring adequate resources (time) for tasks. Results have been discussed by STUK's Executive Management Team.

The Safety Culture Programme 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 the further development of specific activities supporting a healthy safety culture in STUK. In addition to specific development actions, the key aspects of a healthy safety culture are included in STUK's training programme 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 behaviour in relation to safety, are embedded and included in the objectives of, for example, various training events. Different training events are developed for different target groups and safety culture, organizational factors and leadership for safety, among other things, are addressed on various occasions.

4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

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, regular internal audits (Guide STUK 2.12) and external audits, regular management reviews at departmental level and also by STUK's Executive Management Team (Guide STUK 2.11).

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 also described in the following guides: STUK 2.12 Internal auditing, STUK 2.15 Risk management, STUK 2.13. Customer and stakeholder feedback. STUK 2.11 and STUK 1.3 describe methods of analyzing outputs or outcomes of the work done.

Assessment results are discussed in management reviews, the results of which are communicated, for example at department meetings, on the intranet and at staff meetings which STUK´s Executive Management Team arranges regularly.

To fully follow the continuous improvement of the PDCA cycle, it would be beneficial to further develop procedures for monitoring non-compliances related to the management system, and closing corrective actions. This is also related to the procedures of management reviews of departments. Also, learning from regulatory experience is related to these PDCA procedures.

4.8. CONCLUSIONS AND ACTIONS

STUK has implemented a policy document to demonstrate leadership for and commitment to safety by its senior management, including setting goals, defining individual and institutional expectations for continuous development and encouraging a questioning and learning attitude. A specific safety culture programme has been established to ensure that a healthy safety culture exists and is further enhanced at STUK.

To support STUK in fulfilling its mission and legal obligations, a detailed and integrated Management System has been implemented. The Management System lays down STUK's processes, roles, responsibilities, procedures, goals, strategies, plans and objectives. The Management System is comprehensibly documented, regularly reviewed (internally and externally), adapted and improved. It describes and defines STUK's organizational structure and lays down procedures for the management of organizational changes. With regard to the management of resources, STUK has established competence profiles for all positions, and these profiles are being utilised in staff training.

In conclusion, the requirements are complied with. However, there is still room for improvement. Accordingly, the *following needs for actions* have been identified:

- To harmonize STUK's regulatory oversight processes and to involve rules for processes and the roles of process owners in STUK's management system when appropriate, and accordingly to develop STUK's performance indicators further to be more visible to staff.
- To develop further the process for monitoring and closing internally corrective actions of non-compliances (also related to the procedures of learning from regulatory experience (module 2).

5. AUTHORIZATION

5.1. GENERIC ISSUES

Nuclear Facilities

The authorization process for nuclear facilities is based on requirements presented in YEL 990/1987 and YEA 161/1988. The construction, operating and decommissioning of a nuclear facility are not permitted without a licence and licences are prepared by the MEAE and granted by the Government. The authorization of different nuclear facilities including roles and responsibilities, types of authorization and related guides is described in more detail in the corresponding subsections 5.2-5.5 and 5.7. Subsection 5.2 Authorization of nuclear power plants is mostly applicable to other types of nuclear facilities, so the text is not repeated in subchapters 5.3-5.5.

Radiation practices

Licences for radiation practices are granted by STUK. The authorization of radiation practices is prescribed in section 48 of SätL. The authorization of radiation sources, as well as aspects of medical, occupational and public exposure related to authorization are discussed in sections 5.6, 5.9, 5.10 and 5.11.

If occupational or public exposure to natural radiation exceeds the reference level despite remedial actions, the undertaking must apply for a licence (SätL section 148) after which the activities are regulated similarly to the use of radiation sources (SätL section 149, 150).

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

According to YEL (990/1987) section 8, the use of nuclear energy without a licence is prohibited. According to YEL section 3, the use of nuclear energy cover, among other things, the construction, operation and decommissioning of a nuclear facility. The licensing process is led by the Ministry of Economic Affairs and Employment (MEAE) and the actual licences are granted by the Government as per YEL section 16. The process and conditions for granting a licence for a nuclear facility are prescribed in YEL and in YEA (161/1988).

For a nuclear power plant, the licensing process consists of four steps: Decision-in-Principle, construction licence, operating licence and decommissioning licence. This is illustrated in the Figure 6 below. Before a construction licence for a nuclear power plant can be applied for, a Decision-in-Principle (DiP) by the Government and subsequent ratification of the DiP by Parliament is required. The DiP process is prescribed in YEL Chapter 4 and in YEA Chapter 4. As said, the entry into force of the Decision-in-Principle requires ratification by Parliament. Parliament cannot make any changes to the Decision. It can only approve it or reject it as it is.

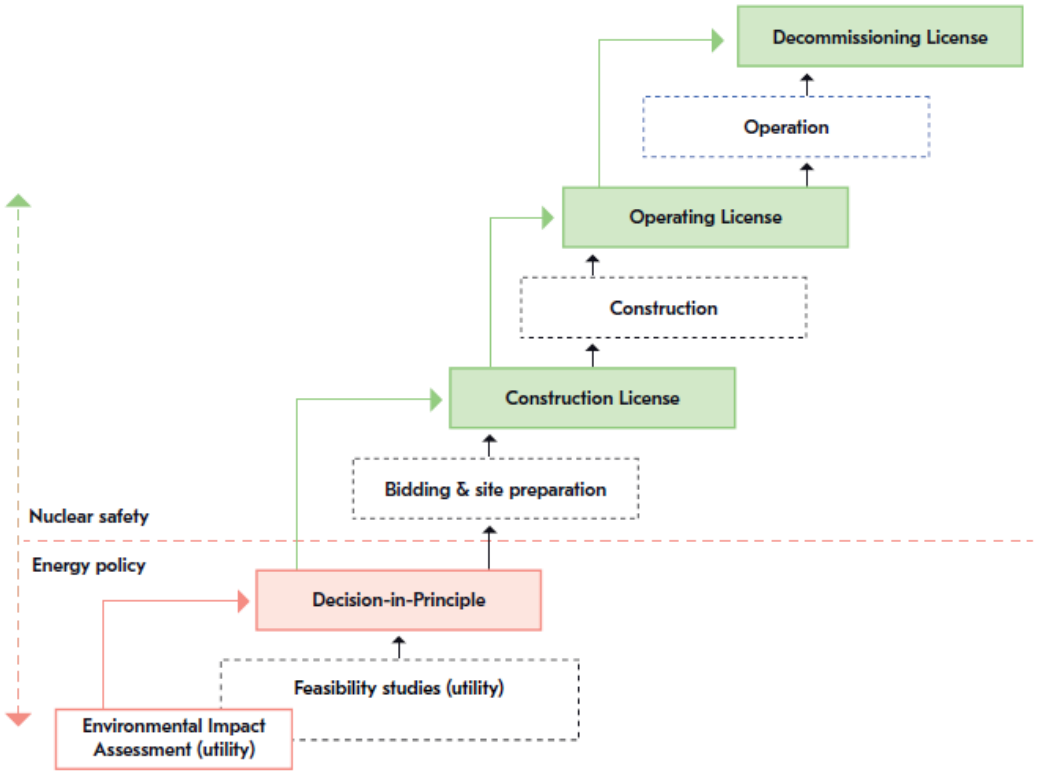

Figure 6: The four steps of licensing nuclear facilities. Decision-in-Principle is made by the Government and ratified by Parliament. Construction Licence, Operating Licence and Decommissioning Licence are granted by the Government.

The impacts of a nuclear power plant project on the environment are already studied and evaluated in the environmental impact assessment (EIA) that precedes the processing of the Decision-in-Principle (DiP) application. Later, the EIA is renewed prior to re-application for the operating licence. STUK gives its statement on the parts of EIA relevant to nuclear and radiation safety, nuclear security and safeguards (e.g. possible external hazards). In addition, STUK also participates in the EIA hearings when asked to do so by the Ministry.

A condition for granting the Decision-in-Principle is that the operation of the facility in question is in line with the overall good of society. There shall also be sufficient prerequisites for constructing the facility according to the Nuclear Energy Act: the use of nuclear energy shall be safe and it shall not cause harm to people, or damage to the environment or property and the arrangement for waste management shall be sufficient and appropriate. In addition, STUK's statement on safety including the preliminary safety assessment concerning the applicant, the proposed plant designs and the suitability of the plant sites are required before the decision-making as well as the consent of the host municipality. Regarding the safety assessment of the suitability of plant sites, there is no additional or separate authorization phase for site licensing in the Finnish regulatory framework. A public hearing is included in this licensing phase and managed by the MEAE. The stakeholders involved in the Decision-in-Principle process and their tasks are illustrated in Figure 7.

When a licence applicant is applying for a DiP from the Government, 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 YEL section 14. In the DiP phase, according to YEA section 24, the licence applicant shall supplement the application with, for example, a description of the suitability of the planned location for its purpose, taking account of the impact of local conditions on safety, security and emergency response arrangements, and the impacts of the nuclear facility on its immediate surroundings. STUK assesses the suitability of the sites proposed for the nuclear power plant for their purpose. The detailed requirements for the siting of a nuclear facility and its evaluation are given in STUK Guide YVL A.2.

The process of the construction, operating and decommissioning licences is prescribed in YEL Chapter 5 and in YEA Chapter 5. For the construction, operating and decommissioning licence application, the MEAE must request STUK's statement on safety including the safety assessment. The licensee is under obligation to ensure the safe use of nuclear energy as per YEL section 9. Therefore, YEA sections 35, 36 and 36a define the deliverables to be submitted to STUK for approval by the licence applicant or the licensee when applying for a construction licence, operating licence or decommissioning licence, respectively, for a nuclear facility. STUK issues a safety assessment and statement of safety on the licence application in question to the MEAE with STUK's safety assessment and evaluation of the documents required under either one of sections 35, 36 or 36a of YEA, as attached to the statement of safety. After receiving all statements for the construction, operating or decommissioning licence application, the Government will make its decision with the necessary conditions.

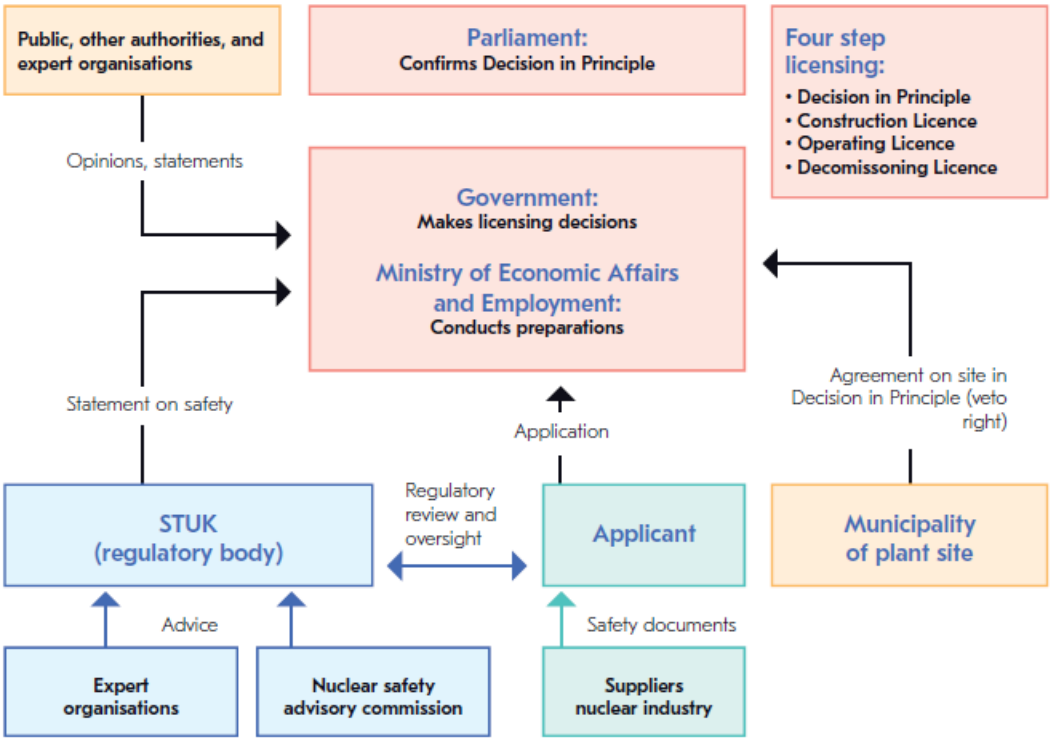

Figure 7. Stakeholders in the licensing process.

In all above-mentioned licensing phases, the necessary conditions are included in the licence as per YEL sections 14a and 25. STUK has the right of veto in all licensing phases. Further, the licensing authority shall take into account the conditions relating to safety as presented in the statement by STUK.

Operating licences are granted for a fixed term as per YEL section 24. The term of the licence depends on the facility. If the licence is granted for more than ten years, STUK typically proposes as a condition for the licence that the licensee carry out a periodic safety review by a certain deadline in accordance with YEL section 7e.

The licensing authority has the authority to cancel a licence wholly or partly if implementation of the general principles for the use of nuclear energy provided in YEL are essentially endangered as per section 26. When cancelling a licence, the same procedure is followed as when the licence was granted. In addition, if the licence terms or conditions are amended, the same procedure is complied with, where applicable, as in the case of a new licence as per section 25.

Concerning the licence applicant's or licensee's personnel, according to YEL section 7k, the licensee shall appoint a responsible manager and his or her deputy. The manager's task is to ensure that the provisions, licence conditions and regulations issued by STUK concerning the safe use of nuclear energy, security arrangements, emergency arrangements and 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 YEL section 7i, the licensee shall have an adequate number of qualified and competent personnel suitable for their tasks for ensuring the safety of the nuclear facility. Furthermore, the licensee shall appoint persons responsible for ensuring the emergency arrangements and security arrangements and safeguards of

nuclear material. The appointed persons shall be approved by STUK. STUK shall also approve the control room operators of a nuclear facility in accordance with section 7i. In addition, STUK approves the manufacturers of nuclear pressure equipment for their duties, and inspection and testing organizations for their duties pertaining to the control of pressure equipment at nuclear facilities in accordance with YEL section 60a.

In addition to the above-mentioned licensing process, there are also other authorization or hold points for nuclear facilities in the Finnish legislation. YEA sections 108 and 110 state that the various phases in the construction or commissioning 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, fresh nuclear fuel cannot be brought to the nuclear power plant until STUK has ascertained the licensee's preparedness to safely receive such fuel as provided in YEA 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 YEL sections 20 or 20a, respectively. The operation of a nuclear power plant is deemed to start from the first fuel loading.

Regarding the commissioning of a nuclear facility, STUK regulation (STUK Y/1/2018) section 19 requires that the procedures of the commissioning shall be planned, and instructions shall be provided. Thus, for the commissioning of a nuclear facility, a detailed plan and necessary procedures shall be drawn up by the licensee on how to demonstrate and ensure the operational compliance of the facility's systems, structures and components with the design bases and how to ensure that the nuclear power plant as a whole operates as designed. This also includes the organizational aspects. The commissioning measures shall be planned in advance so that they can be implemented in a controlled manner without endangering safety.

In accordance with STUK regulation (STUK Y/1/2018) section 22, the licensee shall operate the plant in compliance with the requirements and restrictions set in the Operational Limits and Conditions (OLC), and compliance with them shall be monitored and deviations reported. The licensee shall submit the OLC to STUK for approval when applying for the operating licence as per YEA section 36.

According to the STUK regulation (STUK Y/1/2018) section 23, the operability of the systems, structures and components important to safety and the effects of the operating environment on those 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. In addition, the requirements for ensuring the availability of systems, structures and components important to safety shall be included in the Operational Limits and Conditions as per STUK regulation (STUK Y/1/2018) section 22.

YEL section 7d states that the design of a nuclear facility must provide for the possibility of operational occurrences and accidents. According to STUK regulation (STUK Y/1/2018) section 20, there shall be appropriate operating procedures for the identification and control of operational occurrences and accidents. In addition to the emergency operating procedures, this also includes the severe accident management guidelines. Furthermore, in general the control and supervision of a nuclear facility shall utilize written procedures. At the commissioning stage, the licensee shall ensure that appropriate procedures are in place for

the future operation of the nuclear facility as per STUK regulation (STUK Y/1/2018) section 19.

YEA section 112 prescribes that modifications that influence safety and involve changes in the plans or documents approved by STUK require approval from STUK before they are carried out. This also means that the plans and documents such as the safety analysis report and other licensing documentation shall be kept up to date at all times. In addition, the licensee shall ensure that the modifications are designed and implemented in conformity with the safety requirements and using approved plans and procedures as per STUK regulation (STUK Y/1/2018) section 20. The modifications or changes must be implemented in a systematic and controlled manner as per STUK (STUK Y/1/2018) section 25.

According to YEL section 7f, safety shall take priority during the construction and operation of a nuclear facility. The licensee shall ensure that the products and services of contractors and subcontractors, which affect the nuclear safety of the nuclear facility meet the requirements of YEL as per section 9 of the act. In accordance with STUK's Guide YVL B.1 requirements 301-303, the licensee shall be responsible for ensuring that the nuclear facility is designed, constructed and operated in compliance with the safety requirements. The licensee shall also ensure the design integrity and safety of the facility during the design, construction, operation and decommissioning of the facility.

5.3. AUTHORIZATION OF RESEARCH REACTORS

The licensing and authorization process for research reactors is defined in YEL and YEA and is in principle the same as that used for other nuclear facilities like nuclear power plants and disposal facilities (see chapters 5.1 and 5.2) with the exception that a research reactor operated for the generation of nuclear energy with a thermal power lower than 50 MW does not require a DiP.

The conditions for granting a licence are prescribed in sections 18–20 a of YEL. The operating licences of a nuclear facility are granted for a fixed term. Construction and decommissioning licences do not have a fixed term. According to section 7e of YEL, periodic safety reviews of research reactors are required to be presented to STUK every 10 years.

Section 7a of YEL 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 infrastructure as for the regulation of power reactors YEL (990/1987 section 3), YEA (161/1988) and STUK's regulations: STUK Y/1/2018, STUK Y/2/2018, STUK Y/3/2018 and STUK Y/4/2018. STUK's regulation STUK Y/1/2018 section *1 Scope* defines what requirements are applied to research reactors.

STUK's YVL guides written for Nuclear Power Plants are applied to research reactors as appropriate (there are no research reactor-specific YVL guides). STUK prepares separate decisions (implementing decisions) on how the YVL guides are applied to a research reactor. During this process, STUK defines which YVL guides are applied to research reactors and how they are applied. Requirements, which are not relevant for the research reactor, can be excluded. Before deciding on the implementation, an evaluation of the position of the licensee is required. Currently these decisions are to be made for a research reactor in the decommissioning phase for STUK's YVL guides in series A, D and C.

It should be noted that the existing research reactor in Finland (FiR 1) was commissioned 60 years ago and has entered the decommissioning phase. A decommissioning licence was granted for FiR 1 research reactor in June (17.6.) 2021. The plan is to start the decommissioning in late 2022. There are no plans to build new research reactors in Finland, so there is currently no need to develop any research reactor-specific regulation or guidance.

5.4. AUTHORIZATION OF FUEL CYCLE FACILITIES

In Finland, the category of fuel cycle facilities covers three types of facilities: spent fuel interim storages, spent fuel encapsulation plants, and U3O8 production plants, also referred to as uranium extraction facility.

Spent fuel interim storages are operated as part of nuclear power plants, either on the same site as a separate building or in the same building as the nuclear power plant. The same regulatory framework is applied to spent fuel interim storages as for nuclear power plants and the same authorization and licensing are applied. Currently, a licence for spent fuel interim storage is covered by the same licence as for the nuclear power plant the storage is related to. The guiding requirements for spent fuel interim storage design and construction are described in STUK Regulation (STUK Y/1/2018) on the Safety of Nuclear Power Plants. The siting of spent fuel storage facilities follow the same principles as other fuel cycle facilities (cf. Summary 5.5 of this Module).

The other type of fuel cycle facility is an encapsulation plant. The purpose of this facility is to encapsulate spent nuclear fuel that has been stored in spent fuel interim storages in a disposal canister to be disposed of in an underground disposal facility. At the moment, the encapsulation plant and the disposal facility are under construction at Olkiluoto. In the Finnish regulatory framework, the same authorization and licensing requirements are applicable to encapsulation plants and disposal facilities as for any nuclear facility. Due to the specific features of encapsulation plants and disposal facilities, there are some additional requirements to be considered such as those related to post-closure safety and the construction and operation of the underground disposal facility.

In legislation, YEL and YEA are both applicable for encapsulation plants. Among STUK regulations, Regulation STUK Y/4/2018 is applicable to encapsulation plants. The major difference to other nuclear facilities is that that the long-term safety must be considered when authorizing or licensing an encapsulation plant and disposal facility.

Mining company Terrafame Ltd was granted a licence to produce U3O8 (yellow cake) by a government decision in February 2020. This licence became legally effective in June 2021 by a Supreme Administrative Court decision. The Government had granted the company a licence according to section 21 of YEA for ore enrichment operations, the purpose of which was to extract the uranium contained in the nickel ore mined from the company's mine. The company was also licensed for mining and ore enrichment operations to process up to 10 tonnes of uranium separated at another uranium plant at a uranium recovery facility. Prior to the Government's decision, the Ministry of Employment and the Economy had requested an opinion from the local municipality. In a statement approved by the council, the municipality had supported the granting of the licence under the conditions set out in the statement. The municipality had demanded that uranium-containing materials mined outside the mine could not be brought into the area for processing at the uranium plant. The Supreme Administrative Court prohibited the processing of uranium containing ore mined outside the mine in the facility.

Before uranium extraction activity can be started, the mining company will need a separate

STUK authorization to start the operation (in accordance with YEL section 16 subsection 2).

With the application of a graded approach to risk, regulation for this facility type is much lighter and simpler than other nuclear facility types. YEL (990/1987) 3 § 5 a) states 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 STUK's YVL guides are not applicable, except the YVL guides concerning safeguards (YVL guide D.1) and transport (YVL guide D.2).

The licensing of a uranium extraction facility is performed according to YEL section 21. There is only one licensing phase for this facility type instead of three licensing phases for nuclear facilities. The use of mining and milling operations aimed at producing uranium or thorium shall be initiated based on a granted licence after STUK's separate approval.

In addition to YEL, YEA is applicable to a uranium extraction facility. The requirements concerning uranium extraction facilities in STUK regulations 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 STUK regulation Y/5/2016 are set considering the low risk of uranium extraction facilities on nuclear and radiation safety.

Due to the nature of operations and time spans of operations, fuel cycle facilities (particularly spent fuel disposal facilities) may experience longer planned shutdown periods than have been seen for instance at nuclear power plants.

5.5. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

Nuclear facilities

The licensing process for nuclear waste management and other nuclear facilities is defined in legislation (cf. Chapter 5.2 of this module). The conditions for granting a licence are prescribed in the sections 18–20 a of YEL. The operating licences of a nuclear facility are granted for a fixed term, generally for several decades for disposal facilities. According to YEL section 7e, a periodic safety review is required to be presented to STUK every 15 years in the case of disposal facilities for nuclear waste.

Based on the section 16 of YEL, minor licences for spent fuel and nuclear waste management activities (near-surface disposal facilities for very low-level waste (VLLW), export, import, transfer and transport licences and licences for operations) are granted by STUK.

The currently licensed predisposal management of nuclear low- and intermediate-level waste (LILW) takes place at the NPPs under their operating licences and other provisions. The waste is segregated, treated, conditioned, packaged, monitored and stored, as appropriate, before being transferred to the site-specific disposal facilities. The LILW disposal facilities have separate operating licences both at the Olkiluoto and Loviisa NPPs.

Licence for decommissioning and waste management of the FiR 1 research reactor was granted in the licensing process.

The future operation of spent fuel disposal will also produce nuclear LILW. This waste is planned to be managed at the Olkiluoto NPP and disposed of at the existing LILW disposal facility. The disposal will need an update to the Olkiluoto LILW disposal facility licence.

Detailed requirements for predisposal waste management are given in STUK's YVL Guide

D.4 and the detailed requirements for the design and construction of (all) nuclear facilities in STUK's YVL Guides: YVL A.2, YVL A.5, YVL B.1, YVL B.3 and YVL D.3 (cf. chapters 5.2 and 5.4 of this module).

The spent fuel management facilities are nuclear facilities, either as an integrated part of a nuclear power plant or as separate facilities. All the present spent fuel management facilities in Finland are located on the NPP sites.

The description of siting procedures for the siting of spent fuel management facilities (including spent fuel storage facilities), is also applicable to facilities intended for the predisposal management of LILW at the NPPs and for the disposal of LILW or spent fuel. STUK's Guide YVL D.5 specifies the generic site suitability criteria for the disposal facilities.

Currently the closure of disposal facilities is authorized as an amendment to the disposal facility operating licence. The procedure to amend the operating licence is equivalent to the application of a new operating licence. The prerequisites for the closure are set in section 33 of YEL. An IRRS follow-up mission in 2015 proposed a new recommendation to amend the legislation to clarify that the decommissioning of a nuclear installation and closure of a disposal facility require a licence amendment. The decommissioning licence was introduced to the Finnish legislative framework at the beginning of 2018. Future work needs to be carried out for clarifying the licensing of the closure of disposal facilities.

Radioactive waste originating from the use of radiation

According to the section 48 of SätL prior authorization is required for all activities involving radioactive sources such as the use, manufacture, trade, holding and disposal of such sources. A safety licence is granted by STUK upon written application. The general conditions for granting a licence are laid down in SätL and the licensing procedure is prescribed in more detail in Annex 5 of VnA (1034/2018).

SätL section 83 states that it is not appropriate to store unnecessarily sealed sources no longer in use. When new sources are authorized for use, STUK requires the applicant to present a plan on measures to be taken when it becomes a disused source. According to SätL section 83, an undertaking is responsible for returning the disused sources subject to a safety licence to the manufacturer or supplier or for surrendering them to an operator holding a safety licence. Radioactive waste generated in radiation practices may be released from regulatory control according to exemption limits. Radioactive waste can also be aged by the undertaking if the exemption limits can be reached this way in a reasonable time. In the use of radiation minor discharges into the sewage system or into the open air within defined limits are allowed. The undertaking must keep a record of the discharges.

SätL section 80 specifies that the State shall ensure that the radioactive waste is rendered harmless where there is no operator of the kind. In that case, the operator is responsible for compensating the costs to the State. STUK takes care of rendering waste harmless on behalf of the State (section 32 of VnA 1034/2018).

TVO has leased a storage cavern to the State at the LILW disposal facility at Olkiluoto for the interim storage of radioactive waste from the use of radiation. The interim storage is operated by STUK's Department of Environmental Radiation Surveillance. The safety of the operations at the Olkiluoto storage is independently regulated by STUK's Department of Nuclear Waste Regulation and Safeguards. Most of this waste, including sealed sources, will be disposed of in the disposal facility. The disposal started at the end of 2016 based on revised operation conditions in 2012. A few high-activity sealed sources will need a different disposal route, which has not yet been determined.

Disused sources have been collected by a private business (Suomen Nukliditekniikka Ltd), which repacks them, as necessary, and then transfers them to the State´s storage at Olkiluoto. The handling of radioactive disused sources from other companies also requires prior authorization. Suomen Nukliditekniikka Ltd is currently the only company authorised for this and has been the main operator in collecting and repacking disused sealed sources.

5.6. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

Authorization process

The use of radiation requires a licence (safety licence). The licence is granted by STUK upon written 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. STUK grants a safety licence if the conditions for granting the licence are met.

Transparent guidance for implementation of requirements is available in SAMMIO (STUK's online regulation and guidance service). STUK's 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. The graded approach to this effect is built within the concept of licensing by means of categorization of practices and sources leading to different levels of licensing requirements.

The licensee shall carry out a safety assessment of the radiation practice if the practice is subject to a safety licence. In the safety assessment, the undertaking identifies the ways in which the practice can cause radiation exposure, considering any possible radiation safety deviations. In the safety assessment the magnitude of the occupational, public and medical exposure arising from the practices as well as the probability and magnitude of the potential exposure are assessed. Categorization of radiation practices shall be presented in the safety assessment. Applicant sends a safety assessment to STUK as a part of a new safety licence application. The safety assessment must also be reviewed regularly based on established categories of radiation exposure. A licence expires when the licensee states in writing that the use of radiation has ceased. In a case where radioactive sources have been used, the licensee shall provide sufficient evidence that radioactive sources or radioactive waste have been transferred to another licensee or returned to the supplier abroad.

The graded approach with respect to radiation risks of the practice is not fully applied in STUK's process for licensing radiation practices. The problem with the implementation of the graded approach has been identified and STUK is currently working on a project to identify situations where it should be possible to use the graded approach more extensively. However, it is already clear at this stage that the current practice (STUK's approach/policy) and internal guides do not provide sufficient means for processing licence applications based on assessed radiation risk. STUK's approach/policy in licensing and internal guides should therefore be updated in this respect. Based on the findings of the project, conclusions will be drawn on possible needs to revise SätL to support even further the application of a graded approach.

Requirements for and implementation of exemption and clearance

SätL and VnA (1034/2018) determine which practices or sources within practices are exempted from a safety license. In addition, STUK may exempt a radiation practice or radiation source provided that the generic exemption criteria established in SätL and VnA are fulfilled. The exemption values are given in STUK SY/1/2018. When the activity concentration, or the value of the activity used or possessed at any time, is less than or equal to the exemption value, a safety licence is not required. In case of sealed sources, only the exemption value for the activity is applied.

Reuse or recycling of radioactive material

Waste and other material deriving from radiation practices may be reused, recycled, utilized and disposed of in accordance with the Waste Act (646/2011), provided that the amount of radioactive substance it contains does not exceed the clearance level.

Sealed sources can be reused by another registrants and licensees with sufficient safety licence. The transferor of a sealed source subjected to safety licence shall ensure that the recipient has the required safety licence.

STUK checks the preconditions/requirements for the re-use of a radiation source during the licensing process.

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 to the legally binding EU legislation). STUK has been designated as the national contact point relating to the 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 the European Union. STUK submits the necessary enquiries and notifications, as prescribed in the above-mentioned Import/Export guidance, to the 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.

Because of the legally binding Council Regulation (1493/93/Euratom), transfers of radioactive sources within the European Union are regulated in a different way. The Regulation does not recognize IAEA source categorization; all sources above the exemption level are treated the same way. A holder of sealed sources that 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 authorization 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, Finnish Customs is responsible for seeing that imports and exports 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.

5.7. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

The decommissioning licence was added to YEL (990/1987) in 2018. The licensee of a nuclear facility must apply for a decommissioning licence from the Government. The required content of the decommissioning licence application is presented in YEL (990/1987) section 20a and in YEA (161/1988) sections 34a and 36a. The decommissioning licence can be granted by the Government if the requirements in the section 20a of YEL are fulfilled.

The licensee is responsible for the development of the decommissioning plan, implementation of the decommissioning project and decommissioning costs. The licensee is also responsible for all spent fuel and radioactive waste generated from its nuclear operations from waste handling to disposal.

The licensee shall have the sufficient number of competent personnel suitable for the related tasks for ensuring the safety of the nuclear facility. The licensee shall also have access to the professional expertise and technical knowledge required for the decommissioning of the nuclear facility, the maintenance of equipment important to safety, and the management of accidents (STUK Y/1/2018 section 25).

The preliminary decommissioning plan is required in the design phase of the nuclear facility, in a construction licence application. In the preliminary plan, the licensee must present the selected decommissioning strategy and justify it. In addition, the preliminary decommissioning plan shall at least define the implementation stages of the decommissioning with timetables, an outline of the dismantling, waste management solutions adopted, and the planned end state of the facility site. If the decommissioning 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 (YEL 990/1987 section 7g, STUK's YVL Guide D.4 404).

The next version of the decommissioning plan must be developed for the operating licence application. The plan must be based on the actual design of a nuclear facility. Detailed requirements on the content of the decommissioning plan during operation are presented in Guide YVL D.4 requirement 404. During the operation, the licensee must update the decommissioning plan at minimum every six years if not otherwise required in the licence conditions and send it to the MEAE for approval. STUK is asked to give a statement on the decommissioning plan. The licensee shall provide the final decommissioning plan for approval to STUK as part of the decommissioning licence application. (YEL 990/1987 section 7 g, YEA 161/1988 sections 33 a, 34 a, and 36 a) The licensee has a duty to ensure that the nuclear facility is dismantled according to the licence conditions set in the decommissioning licence, safety requirements and decommissioning plan approved by STUK (YEL section 7g).

Based on mandates given in YEL sections 55 and 63, STUK controls the decommissioning of the nuclear facility to ensure that the dismantling is done according to licence conditions, approved decommissioning plan and according to all relevant safety requirements presented in law, regulations and in STUK's YVL Guides. The regulatory oversight also contains the maintenance, repairs, inspections and tests of the systems, components and structures of a nuclear facility. The key steps of the decommissioning phases can be started after STUK has reviewed that all factors that influence the safety and all related safety requirements have been considered. STUK will review and authorize this based on documents listed in YEA section 36a and from the detailed planning documents provided by the licensee (YEA section 112b).

STUK has the right to require the licensee to correct its actions if the licensee is not fulfilling the licence conditions and/or safety requirements. If the licensee is not doing the corrective actions in given timeframes, STUK can set a penalty payment or interrupt the activities (YEL sections 65, 66 and 67).

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 (YEL 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 a case-specific procedure, the application shall 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 future use of the nuclear facility site and any buildings therein left undismantled shall be defined with the necessary restrictions, and the resulting radiation doses to the representatives of the most exposed group shall be assessed.

There are no requirements on controls and programmes for monitoring and surveillance of the optimization of protection and safety, and protection of the environment after the nuclear facility is released from the regulatory control as the limits of annual dose arising from the decommissioning are set so low (0,1 mSv) that the annual dose limit for the individual or the environment is not reached. Even in cases where the restrictions are not followed, the annual dose limit cannot be more than 1 mSv with high certainty and this is below the annual limit set for the individual. At the end of decommissioning, the licensee shall also provide a summary of the implementation of the decommissioning for STUK for approval (STUK's YVL Guide D.4 416, 713 and 718).

When the decommissioning of the nuclear facility has been completed and after STUK has approved the above-mentioned documents, the licensee shall apply for an order on the expiry of his waste management obligation with the MEAE (YEA section 84). After approval of this application, the decommissioning has been bought to completion and the licensee shall notify STUK of the cessation of the use of nuclear energy (YEA section 120).

The licensee under nuclear waste management obligation is responsible for the decommissioning costs. In Finland, there is a national waste management fund, which covers spent nuclear fuel, nuclear waste management and decommissioning costs, which means that society has a financial guarantee that nuclear waste management and decommissioning can be arranged under all circumstances. The licensee pays an annual fee to the state nuclear management fund based on the waste management scheme presented by the licensee and approved by MEAE. The waste management scheme is updated every three years if not otherwise required by MEAE. The nuclear waste management fund always covers the costs caused by handling all existing nuclear waste at the current price level and by using currently available technologies (YEL 990/1988 section 9 and Chapter 7).

The licensee shall define 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. The licensee shall define retention times of records, associated test pieces and testing materials. The recording media, manner of recording and storage conditions shall ensure readability for the duration of the retention period specified for each record. In specifying the retention period, the nuclear facility's life cycle and the long duration of nuclear waste management shall be considered. (STUK's Guide YVL A.3 620 and 621).

In radiation practices, STUK grants a safety licence upon application. The safety licence can be granted separately for different stages of the practice including decommissioning (SätL

section 48). A separate safety licence is required if the amount of radioactive substances in areas, premises and facilities prior to cleaning is greater than the clearance level (in addition to activity concentration values of materials, clearance levels may be issued to pertain to a particular type of or individual area, facility or structure and may also be expressed in other units than concentrations). After decommissioning, the remaining amount of radioactive substances shall not exceed the clearance level. The undertaking may not delay cleaning and decontamination without justification. If the amount of radioactive substances cannot be made lower than the clearance level through reasonable measures, the undertaking must present to STUK a plan of the measures concerning the premises (SätL section 83). If the costs arising from rendering radioactive waste harmless are estimated to be significant, the undertaking shall security for the costs (SätL section 54).

A plan for decommissioning premises must be presented to STUK, and the plan must identify the type and level of contamination, available cleaning methods and practices, and must assess the volumes and types of waste generated in cleaning and determining the possible waste management routes for the waste. The cleaning plan must present phases and schedule of actions, arrangements for the radiation protection of employees and the public, and documentation of actions. After the cleaning, the operator shall demonstrate that the desired end state has been achieved. (Regulation STUK S/5/2019 sections 32-34).

5.8. AUTHORIZATION OF TRANSPORT ACTIVITIES

IAEA SSR-6 Regulations for the Safe Transport of Radioactive Material are implemented in Finnish transportation regulations. Finnish national legislation on the transportation of dangerous goods is based on international agreements (e.g. European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO-TI), the International Maritime Organization (IMO), regulations concerning the International Carriage of Dangerous Goods by Rail (RID), the Convention concerning International Carriage by Rail (COTIF), and International Maritime Dangerous Goods (IMDG)) for all transportation modes. The requirements for the transportation of dangerous goods are given in the:

- Act on the Transportation of Dangerous Goods (719/1994)
- Government Decree on the Transportation of Dangerous Goods by Air (210/1997)
- Decree on the Transportation of Dangerous Goods in Packaged Form by Sea (666/1998)
- Government Decree on Driving Licences for Drivers of Dangerous Goods (401/2011)
- Government Decree on the Transportation and Temporary Storage of Dangerous Goods in a Port Area (251/2005)
- Government Decree on the Attestation of Conformity of Packaging, Containers and Bulk Containers Intended for the Transport of Dangerous Goods and on Inspection Bodies Performing Related Tasks (1208/2018)
- Government Decree on the Safety Adviser for the Transport of Dangerous Goods by Road and Rail (797/2019)
- Regulation of the Finnish Transport and Communications Agency on the Transport of Dangerous Goods by Road (TRAFICOM/443227/03.04.03.00/2020)

In terms of the Finnish Transport and Communications Agency on the Transport of Dangerous Goods by Rail (TRAFICOM/443235/03.04.02.00/2020) and for radioactive materials (Class 7), there are additional requirements presented in

- SätL (859/2018)
- Government Decree on Ionizing Radiation (1034/2018), sections 25, 26 and Annex 5
- Regulation STUK S/5/2019 Annex 11
- YEL (990/1987)

- YEA (161/1988)
- Guide YVL D.2

Competent authority approval is required only for B and C -type packages. It should be noted that there is no package design or manufacture in Finland, and practically all packages for which competent authority approval in Finland is required are of foreign origin. So, the approvals are done by validating the certificates given by the competent authorities in the country of origin of the packages. The document requirements for the package approval are listed in STUK's YVL Guide D.2 requirements 401-403.

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 (YEL section 8). A transport licence is not required if the transported nuclear material amount is small or natural uranium, depleted uranium or thorium, or the total activity is less than 1 TBq for nuclear waste not containing any nuclear material (YEA section 17). In the above-mentioned cases, a notification is needed by STUK for information about the transportation (YEA Chapter 17).

It is not allowed to start the transport operations of nuclear material or nuclear waste before STUK has approved the transport and security plans. The detailed requirements of the contents of the transport and security plans are specified in STUK YVL Guide D.2. STUK's approval of an emergency plan is required for consignments where the total activity is over 1000 TBq.

For radioactive sources, according to SätL (859/2018) the road and rail transport of high-activity sealed sources requires a safety licence. Annex 5 of the Government Decree on Ionizing Radiation (1034/2018) contains a list of information to be submitted in a safety licence application. The process of handling the safety licence is described in Guide SKV 3.2.

In addition to the safety licence requirement, each consignment of high-activity sealed sources must be notified to STUK prior to the transportation. Annex 11 to STUK regulation STUK S/5/2019 contains a detailed list of information required in the transport declaration/notification.

An application for the approval of shipments under special arrangements, as specified in the IAEA SSR-6, shall include all the information necessary to satisfy STUK that the 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.

5.9. AUTHORIZATION OF OCCUPATIONAL EXPOSURE

The Government Decree on Ionizing Radiation (VnA 1034/2018) section 8 states that the principle of optimization concerning the occupational and public exposure is 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, for the public and for the students and apprentices are set in VnA (1034/2018) sections 13–15 and these are the same as those given in the Schedule III of GSR Part 3, with the following two exceptions: the effective dose for radiation workers must not be over 20 mSv per single year, and for the students and apprentices the equivalent dose for the lens of the eye must not be over 15 mSv in a year. According to the SätL section 25, an undertaking shall set in advance the dose constraints and potential exposure limits. In addition, SätL section 89 demands that the undertaking estimate the radiation exposure and the means to reduce it. The latter also stipulates that the estimation should be updated if there are changes therein that affect occupational exposure.

SätL section 88 states that “The protection of other workers (others than radiation workers) is subject to what is laid down in this Act regarding the radiation protection of members of the public, unless otherwise provided elsewhere.” The dose limits for occupational exposure for workers who are not considered as radiation workers are the same as for members of the public. The dose limits for the public are set in VnA (1034/2018) section 14.

To ensure that radiation workers doses do not exceed the dose limit worker’s prior radiation, doses shall be checked by the undertaking from the dose register.

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.

Responsibilities for occupational exposure have been established in Finnish legislation. The principles of justification, optimization and limitation are stipulated in SätL sections 5 to 7. YEL (990/1987) refers in section 2a to these principles set out in SätL.

The undertaking’s obligations (licensee’s obligations) are set in SätL Chapter 5. The undertaking is responsible for the radiation safety of the practice and this responsibility cannot be transferred to another.

Section 51 of SätL lists items to be included in an application for a safety licence (see answer to question 5.6 for more details). More detailed requirements for safety licence applications are given in VnA Annex 5. Regarding occupational exposure, the application shall include the quality and extent of the practice:

- a report on the practice’s different work phases that are key to radiation safety, and the procedures complied with in them;
- a plan for radiation safety deviations;
- 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 to class A has been organized;
- the dose constraints complied with in the practice;

STUK has created forms for licensees to use when applying for a new safety licence 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 the official languages of Finland (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 (in the STUK e-service, also available in English).

In its capacity as an employer, the undertaking is obligated to carry out the measures laid down in SätL sections 88–101 to protect its own workers (SätL section 102). According to these, the undertaking is responsible, for example, for organizing workers' radiation protection, and is also obligated to investigate the occupational exposure and the means to reduce it. The undertaking is responsible for the classification of its radiation workers (into category A or B, except for workers exposed to radon only [SätL section 149]), and for identifying and differentiating the controlled and supervised areas. It is also responsible for radiological surveillance and individual monitoring, which must allow for establishing that 1) workers have been correctly classified, 2) the radiation exposure for the workers has been determined and 3) that the unforeseen deviations in factors impacting occupational exposure has been observed. In addition, the undertaking is responsible for delivering the information from the individual monitoring of category A and B radiation workers.

According to SätL section 95, the undertaking's responsibility is to provide medical surveillance for a category A radiation worker. This surveillance includes a pre-employment examination by an occupational physician familiar with radiation and a follow-up examination at least every three years. SätL section 20 states that STUK must maintain a workers' dose register to ensure the health of radiation workers, emergency workers, emergency helpers and radiation safety.

Regarding the protection of outside workers, SätL sections 102–104 stipulate 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."

The radiation workers are engaged in the optimization of protection and safety pursuant to SätL Chapter 2 in addition to SätL section 3, which refers to the Occupational Safety and Health Act 738/2002, which requires in section 18 that employees take precautions as necessary for maintaining the safety and health necessitated by the work and working conditions.

SätL section 23 obliges the undertaking to ensure that it has the necessary expertise, and VnA section 22 sets the requirements for human resources. The training and supplementary training of radiation workers is set in SätL section 33 and 34, and records shall be kept of training given to workers (SätL section 33). SätL section 33 also demands that the undertaking ensures that all workers have radiation protection education, training and induction to their duties required by the practices and tasks. Instruction and guidance must also be provided to the employees according to the Occupational Safety and Health Act 738/2002 section 14.

The requirements concerning a worker who is pregnant or breastfeeding are listed in SätL sections 100 and 134, VnA section 41 and the Employment Contracts Act (55/2001) section 9 by which the requirements from GSR Part 3 are fulfilled. These sections of the law(s) note that this individual should be protected in a manner equivalent to the protection of a member of the public. In addition, a pregnant worker's work should be arranged so that the equivalent dose for the foetus is as low as reasonably achievable and shall not exceed 1mSv for at least the remainder of the pregnancy. This individual should not also do work, which risks ingestion or contamination, and the employer is not allowed to terminate an employment contract on the bases of the employee's pregnancy.

SätL section 99 stipulates that a radiation worker must be at least 18 years old. A person of 16–18 years old may only engage in the use of radiation sources to the extent that is necessary for their education and training and the related work exercises. However, they should not be classified in category A or assigned to an equivalent task. 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/her training will work under supervision.

Protection of workers in existing exposure situations

The requirements for the protection of workers in existing exposure situations are included in SätL chapters 17 and 18 as well as in STMA 1044/2018 Chapter 5. An undertaking from whose practice an existing exposure situation arises is responsible for investigating the radiation exposure arising from it, 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 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). 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 issued by STUK, if the radiation dose arising from occupational exposure is higher than the reference level (SätL section 141).

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.

It was observed that investigation levels for occupational exposure as stipulated in GSR Part 3 para 3.46 a) and 3.94 b) are not currently implemented in Finnish legislation. 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/6/2022. The reference levels set in the STMA 1044/2018 section 19 are:'

- radon concentration in workplaces and buildings with high occupancy factors for members of the public: 300 Bq/m^3
- occupational exposure of radon: 500 000 Bq h/m3/year.

Continuous radon measurements ease the administrative burden on employers, because if radon concentrations during working hours can be kept low through ventilation, no radon remediation is needed. STUK supervises that the exposure does not exceed the reference level. Often radon concentrations are much lower during working hours. Therefore, if radon concentration is higher than 300 Bq/m3 in a 2-month screening measurement (indicating the average radon concentration during the measurement period) and the workplace has scheduled ventilation, supplementary radon measurement with continuous measurement instruments combined with the result of the 2-month screening measurement, this could indicate realistic radon concentrations during working hours.

According to SätL section 149, occupational exposure arising from natural radiation is subject to Chapter 12, if the occupational exposure arising from the practice or the radon concentration in the workplace exceeds the reference level despite the measures referred to in section 147. However, it is stipulated in SätL section 149 that the requirements for a private business (SätL section 35), classification of radiation workers (SätL section 90), an immediate observation of unforeseen deviations in factors with an impact on occupational exposure (SätL section 92.2), or medical surveillance (SätL section 95) shall not apply if solely the radon concentration in the workplace or the exposure arising from radon or cosmic radiation exceeds the reference level.

SätL section 149 states that an undertaking shall determine the radiation dose caused to a worker regularly if the radon concentration in workplace or the occupational exposure to radon or cosmic radiation exceeds the reference level. The results of the determination are subject to what is provided on the recording and follow-up of the results of radiological surveillance in SätL section 92, and what is provided on delivering information concerning individual monitoring to the workers' dose register in SätL section 101.

Nuclear safety

According to YEL (990/1987), the use of nuclear energy is subject to authorisation and includes the construction, operation and decommissioning of a nuclear facility. The authorisation is described in section 5.2 (Authorisation of nuclear power plants).

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 SätL. In the optimisation of radiation protection, the dose limits under section 9 of SätL shall be used.

A licensee shall set radiation exposure dose constraints for nuclear facility workers and shall submit information about these constraints to STUK (YEL 990/1987 section 7 c).

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 the operation and decommissioning of the facility and by using systems, structures, components, special radiation shielding and workers' equipment (STUK Y/1/2018 section 7).

Section 2 a of YEL describes how SätL is applied to the use of nuclear energy.

5.10. AUTHORIZATION OF MEDICAL EXPOSURE

Key arrangements for managing medical exposure in accordance with regulatory requirements are addressed in the licence application. These include issues such as the division of responsibilities, justification and optimization of medical exposures and competences. The applicant for a licence is solely responsible for demonstrating compliance with requirements.

The roles and responsibilities of various healthcare workers regarding the protection and safety of individuals undergoing medical exposures are defined in SätL sections 113 –116 and VnA 1034/2018 section 20. The requirements for the competence of health care workers in radiation protection are given in SätL sections 38 and 47 in addition to the general requirement of training and induction of workers in section 33. The licensee or applicant

demonstrates compliance with these regulations and that there are personnel for every role in the Management System document of radiation practices referred to in SätL section 29 during authorization.

During an authorization process, the proposed radiation safety officer must submit a qualification certificate of an appropriate field of medical exposure according to SätL sections 41 – 43. In addition, suppliers and service companies of medical equipment are also subject to authorization as their practice is considered to be a form of use of radiation according to SätL section 4.

If a medical physics expert or radiation safety expert is named, their qualification as a medical physicist can be verified from Valvira's (National Supervisory Authority for Welfare and Health) online registry service JulkiTerhikki (https://julkiterhikki.valvira.fi/). The same online registry service can also be used to verify designated responsible doctors' and dentists' qualifications.

General requirements concerning justification of the use of radiation are given in SätL sections 5 and 24 with further specified requirements on justification related to medical exposure given in sections 109 –111 and in more detail STUK regulation STUK S/4/2019 sections 2 – 4. These sections cover justification assessment, medical exposure in special circumstances, foetuses, children and asymptomatic individuals. General justification issues are considered during the authorization process. Patient-specific justification issues are not specifically considered during the authorization process apart from what is set out in the Management System document of radiation practices concerning roles and responsibilities.

The prime requirements for establishing dose constrains are given in SätL section 25. VnA sections 10–11 gives more detailed requirements regarding carers' and comforters' exposure to radiation, and section 9 gives requirements for optimization for a volunteer participating in a programme of biomedical research. The criteria for releasing patients are given in VnA 1034/2018 section 10 and 11 and further guidance for setting a relevant dose constraint is planned to be given in STUKs online regulation and guidance service SAMMIO. Dose constraints in general are documented in a safety assessment referred to in SätL section 26 which is confirmed by STUK during the authorization process or separately.

Requirements for the optimization of radiation protection in medical exposure are given in SätL section 112, which includes the employment of reference levels, which are not to be exceeded. The reference levels are issued by STUK in STUK S/4/2019. Deployment of diagnostic reference levels are not part of the authorization process but are covered by inspections.

Requirements for operational and design considerations are given in SätL sections 66,116 and 117 and in further detail STUK S/4/2019 and STUK S/5/2019 sections 15 and 16. Furthermore, the requirements for the reliability of radiation measurements are given in SätL section 59 and S/6/2018. Quality assurance must be organized according to SätL section 30 and STUK S/5/2019 and quality assurance procedures must be adequately described in the application for authorization. Requirements for the use of a medical physics expert in matters of optimization are provided in SätL section 32 and VnA 1034/2018 sections 19 and 20. The requirements for the prevention and minimizing of the consequences of unintended medical exposures also known as radiation safety deviations are given in SätL section 23 and, for preparedness for them, in section 129. More detailed requirements are given in STUK S/2/2018. In addition, there is a requirement according to SätL section 26 for safety assessment to include the identification of possible radiation safety deviations and magnitude of the potential exposure including potential medical exposure. The basic requirements for reporting radiation safety deviations are given in SätL sections 130 and

131. Safety assessment documents and a plan of action for radiation safety deviations are part of the authorization process according to SätL section 51 and VnA 1034/2018 Annex 5.

The requirements of radiation protection for pregnant and breast-feeding patients are given in STUK S/4/2019 sections 4 and 6. The requirements for a periodic radiological review of facilities in the medical exposure area are given in SätL section 118 and STMA 1044/2018 sections 11 and 12. Neither are part of the authorization process but rather subjects covered by inspections.

5.11. AUTHORIZATION OF PUBLIC EXPOSURE

General

The principles for the justification, optimization and limitation of public exposure are stipulated in SätL Sections 6–8. The responsibilities of the undertakings regarding the radiation safety of the practice are established in SätL section 22.

The dose limits for the public are set in VnA section 14 and these are the same as those given in Schedule III of GSR Part 3.

An undertaking shall establish dose constraints and constraints for potential exposure to optimize protection and safety. The constraints must be used so that exposure is anticipated to remain below the constraint due to the optimization of radiation protection. Values for constraints shall always be below applicable dose limits. When setting the constraints, the undertaking shall consider the possibility that a person may be exposed from multiple sources, so it is preferrable to set the dose constraint as a fraction of a dose limit. The undertaking shall establish dose constraints and constraints for potential exposure in advance, unless STUK has already established the constraints to be used in the practice. The information concerning the dose constraints and constraints of potential exposure must be delivered to STUK either as part of the granting of the safety licence or separately.

Visitors are considered as members of the public. Visitor access to areas like control areas, where they could be exposed to ionizing radiation or could spread radioactive contamination, shall be restricted. According to SätL section 91, an undertaking shall have written instructions and special arrangements to ensure individuals' safety.

Nuclear Safety

The authorization process for nuclear facilities is described in section 5.2.

In the preliminary and final safety analysis reports of the nuclear facility, 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 applicant and licensee shall derive limits for the release of radioactive substances from the nuclear power plant in such a way that the constraint for the dose to an individual as defined in section 22 b of YEA is not exceeded. If the radiation monitoring of the environment indicates that the radiation dose of an individual in the population may exceed the dose constraints, the release limits shall be redefined.

Radiation safety

SätL section 48 stipulates that the use of radiation requires a licence. Upon application, STUK grants a safety licence. Requirements for authorization and safety assessment are explained in Chapter 5.6 Authorization of radiation sources facilities and activities.

Discharges, exemption and clearance

The practices and sources exempted and sources cleared from regulatory control are explained in Chapter 5.6 Authorization of radiation sources facilities and activities.

Nevertheless, according to SätL section 127, STUK may authorize a discharge exceeding the limit value for a minor discharge if the public exposure is as low as reasonably achievable, taking into account the nature and extent of the activity, the means available to control emissions, and the predicted level of exposure from emissions is below the dose constraint. The plan concerning monitoring of discharges is set in STUK S/2/2019 section 6. It must detail a proposal on the dose constraint and limit values of public exposure and procedures for monitoring the discharges and the exposure caused by the discharges.

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 per year (STUK S/2/2019 section 6).

Apart from authorised limits for discharges, no other operational limits have been addressed in legislation or regulations.

More details of requirements on exemption and clearance are given in 5.6 Authorization of radiation sources facilities and activities.

Consumer goods

Section 68 of SätL prohibits the incorporation of radioactive substances into certain consumer goods such as personal ornaments, cosmetics and toys. 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, unless exempted. Section 27 of VnA defines exempted consumer goods and related practices, including the use of limited amounts of radioactive substances in fire detectors and lamps. STUK can exempt consumer goods and related radiation practices from a safety licence, if they fulfil the general exemption criteria stipulated in SätL section 50 and VnA section 28.

Monitoring programmes for public exposure

It is stipulated in SätL section 128 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.

Requirements on records and reporting to authority from discharges are set in SätL 127 and in STUK S/2/2019 sections 6-8 and STUK S/6/2022 sections 8-12.

Requirements for protection against existing exposure situations

For commercial activities causing exposure to natural radiation (SätL chapter 18), there are responsibilities for the estimation of public exposure. NORM-involving industries have a reference level for public exposure (STMA 1044/2018 section 26). The industries with potential NORM-occurrences must make an exposure assessment of the public according to STUK S/6/2022. If the exposure of the public could exceed the reference level, the responsible party must limit the exposure (SätL section 147). If the exposure of the public exceeds the reference level despite of measures to reduce the exposure, the responsible party must apply for a licence (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 reductions of exposures, which are already below reference levels are not actively enforced by the regulator.

The reference levels for indoor radon concentrations are:

- in houses and other buildings of high occupancy factors by the public: 300 Bq/m^3 (STMA 1044/2018 section 20)
- in new buildings: 200 Bq/m^3 (STMA 1044/2018 section 21).

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 of 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 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 exposure other than that arising from radon may not exceed the dose limit for members of the public.

According to SätL sections 138 and 139, preparation of a remediation plan for existing exposure situations is the responsibility of the licensee, owner of the contaminated area or the State. Details regarding how licensee drafts the plan shall be given by STUK. The responsibilities of the state regarding the remediation plan are given in VnA 1034/2018.

5.12 CONCLUSIONS AND ACTIONS

Nuclear safety

Finnish legislation on nuclear energy requires authorizations for all nuclear facilities. The legal requirements for the authorization process are established in Finland by YEL and YEA, further details are regulated in STUK regulations and STUK's YVL Guides. The legal basis covers the whole life cycle of nuclear facilities. The licensing process is well established and licences for nuclear facilities are granted by the Government. STUK's positive statement on safety is a prerequisite for the Government to issue a license. STUK can set conditions on safety to be taken into account in the license.

STUK fulfills expectations given by the IAEA and has recent experience in the licensing of different kind of nuclear facilities and well-functioning and proven processes and practices

for them. However, related to licensing of nuclear facilities, there is still room for improvement. Accordingly, the following actions have been identified:

Actions

- The overall renewal of Nuclear Energy legislation should consider the following aspects (related action is formulated in module 9):
    - the authorization model should enable 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)
    - ensure that STUK's oversight is proportionate to the safety significance and emphasizes licensee's responsibility, for instance authorization vs. notification and STUK's role in the authorization of responsible persons, control room operators and different organizations
    - there is not a separate approval of site-related design basis parameters prior to the construction licence phase of a nuclear facility. The licensing approach should ensure that site-related aspects are processed in a timely manner.
    - the renewal offers an opportunity to give more detailed, non-binding guidance on matters for which there is currently no unambiguous guidance, for instance the content requirements for Safety Analysis Report.
    - licensing and requirements for transfer from operation to decommissioning should be clarified.
- The government should ensure there is adequate funding for preparation of the authorization (incl. requirement levels) of new technologies like SMRs, and ensure that STUK is able to remain a competent authority despite financial challenges.

Radiation practices

SätL requires authorizations for all radiation practices. The legal requirements for the authorization process are established in SätL and VNa. The legal basis covers the whole life cycle of radiation practices and radiation sources. Classification of practices and sources are used as means to apply a graded approach to authorization. The licensing process is well established, and licences are granted by STUK. STUK can set conditions on safety to the license.

STUK fulfills expectations given by the IAEA. However, there is still room for improvement. Accordingly, *the following actions* have been identified:

- Investigation levels for occupational exposure as stipulated in GSR Part 3 para 3.46 a) and 3.94 b) are not currently implemented in Finnish legislation.
- There is no specific provision stating explicitly that persons under the age of 18 years are allowed access to a controlled area only under supervision. The corresponding provision in SätL states in more general terms that that a young person shall work under supervision.
- STUK should take appropriate measures to ensure the full implementation of paragraph 3.123 of the GSR Part 3 on establishing operational limits for radiation practices.
- STUK should complete the project to examine possibilities to enhance the application of a graded approach in the licensing of radiation practices, and to take appropriate measures to implement the measures in this respect. The findings of the project may identify needs for revising SätLso as to better support the application of a graded approach.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

Nuclear facilities

STUK always performs its review and assessment prior to any decision or authorization. Safety-related requirements for 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 YEL, YEA and STUK regulations. More detailed requirements are given in STUK's YVL Guides. The above-mentioned requirements are also the guiding principles in the review and assessment process of STUK.

YEL establishes general requirements for the 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), the graded approach and the defence-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 and at least every 15 years in case of nuclear waste disposal facilities.

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, the safety of nuclear waste disposal and mining and milling. According to section 7r of YEL, STUK issues detailed requirements (YVL guides), which specify the how to achieve the safe use of nuclear energy. STUK uses IAEA safety standards and security guidance and WENRA reference levels and safety objectives as a basis when developing national regulations and guides. However, some more detailed items included in IAEA requirements (e.g. SSR-2/2 Req. 28 para 7.11 concerning exclusion programme for foreign objects) are not explicitly included in STUK regulations or STUK's YVL guides, but they are covered by a more general requirement and taken into account in practice. 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.

The review and assessment process is one of STUK's core regulatory functions. The process is described in YTV guides, which are part of the management system. The YTV guides do not impose any additional requirements on nuclear safety. The requirements for nuclear safety are included in YEL, YEA, STUK regulations and STUK's YVL guides.

STUK's management system has several thematic internal guides concerning review and assessment. Guides deal with, for example, overall safety assessment of a nuclear facility (Guide YTV 1.b), review and assessment of system design (electr. and I&C), structural design, probabilistic and deterministic analyses, organizational performance, waste management, safeguards and so on. However, STUK does not currently have an internal

guide for reviewing a nuclear facility's process system design (under preparation), or for reviewing EIA.

STUK's review and assessment process is based on several general principles. A major legal principle in the Finnish framework is the licensee's ultimate responsibility for nuclear and radiation safety. It is essential that the licence applicant presents its safety assessment and statement on acceptability of design, plans and activities.

Another major principle is the use of a graded approach. In addition to the safety classification of systems, structures and components, possible factors in grading reviews and assessments include safety significance, whether the component, system, etc. is the first of its kind or already known, and the level of quality displayed by the licensee's safety assessment. Safety significance refers to how the failure of a piece of equipment or system impacts the safety function, or other possible consequences. Probabilistic Risk Assessment (PRA) is also used in safety significance determination. However, the graded approach is not limited to these factors in the review and assessment process.

The purpose of various safety assessments and their review as well as regulatory oversight as a whole is to ensure that a nuclear facility is designed and built, operated, decommissioned and, in the case of disposal facilities, closed in accordance with YEL and the regulations issued under it, and with the decisions issued by STUK. In addition, it also ensures that the obligations of international agreements are met.

STUK's review and assessment is targeted in particular at matters with actual safety significance. In practice, it is carried out using the aforementioned graded approach principle. Additionally, internal YTV guides determine the scope and target of each individual review and assessment process.

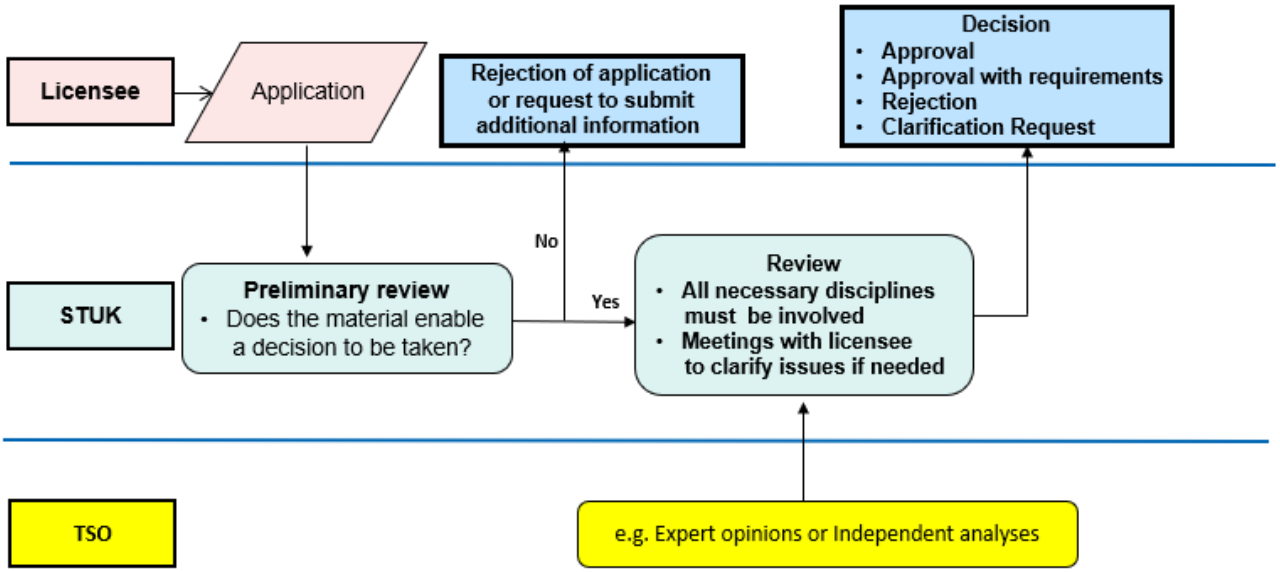

Figure 8. Review and assessment process of STUK

STUK's review and assessment process is presented in Figure 8 and discussed in detail in Guide YTV 8.a. The main principle in the review process is that STUK always evaluates whether the application fulfils all relevant requirements given in the regulations before any decision is made.

Before the actual review, a preliminary review is performed to clarify whether the licensee's application and its material enable conducting a meaningful review and assessment and a decision to be made. If the maturity of the application is not sufficient, it 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 held to clarify issues if needed. The relevant YTV guides steer the review and assessment work of each discipline. It is possible to include technical support organizations in the review and assessment process to give expert opinions or perform independent analyses. However, STUK shall always have enough competence to interpret and act on Technical Support Organization (TSO) results.

The final step in the review process is STUK's decision which, in practice, stands for approval, approval with requirements, rejection or a clarification request. STUK's decisions shall always have sound legal basis, STUK shall be able to justify its decisions and the decision-making process shall be consistent. Before the decision is made, a hearing of the licensee is conducted. At the hearing, the licensee is given a chance to comment on the content and the deadlines of possible requirements. The purpose of the hearing is not to answer the requirements but to correct possible factual mistakes or misunderstandings. The results of the hearing are documented in the presentation memorandum that provides justification for the decision.

The review and assessment process is based on different roles and assigned persons. The 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 it. Roles and responsibilities are presented in Figure 9.

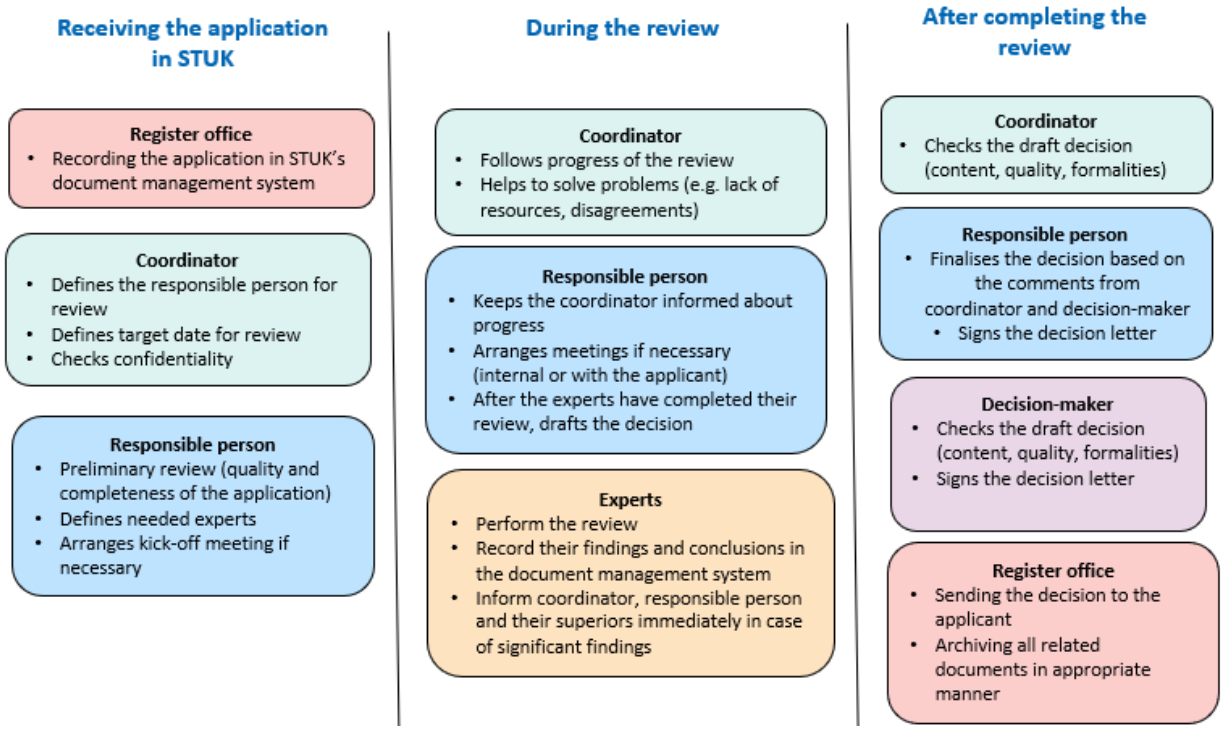

Figure 9. STUK's review and assessment process roles and responsibilities

STUK's review and assessment process is based on comprehensive support processes which include, for example, document management, decision-making and requirement management. All the review and assessment documents are stored in STUK's document management system called SAHA. In addition, SAHA enables monitoring of application processing times. The basic principle is that applications should be 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 2,500 applications concerning LO1&2, OL1&2 and OL3 NPPs.

Several different documents are related to the review and assessment process including the licensee's application documents, STUK's decision and related justification memorandum, review memoranda by the experts, possible communication with the licensee (emails, minutes of meetings, etc.) and other information related to processing the application (persons involved, dates, etc.). When the review and assessment process is finalized, a decision letter along with the justification memorandum and legal bases are delivered to the licensee. Memoranda by the experts are STUK's internal documents and not included in the decision. However, findings and conclusions presented in the expert memoranda provide input for the decision and justification memorandum.

STUK performs its review and assessment work mainly in-house, but co-operation with other regulatory bodies is undertaken whenever necessary.

Radiation practices

STUK's review and assessment of radiation practices is based on a review of the information received from the licence applicant in the safety licence application (or in the licensee's application for amendment of the safety licence). STUK's review and assessment focuses on the licence applicant's or licensee's 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). The process for review and assessment of a licence application is prescribed in internal Guide SKV 3.2.

The review and assessment are made against the mandatory requirements of SätL, Government Decrees (VnA 1034/2018 and STMA 1044/2018) and STUK regulations. The review and assessment subject to SätL for radiation practices and medical, occupational and public exposure are discussed in sections 6.6, 6.9, 6.10 and 6.11.

Graded approach

Section 7a of YEL 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 3.1 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. The following principles, among others, 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 a graded approach."

With regard to STUK's organizational structure and management system to facilitate the graded approach, see also Modules 3 and 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. This 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 when an unanticipated operating event or incident occurs. More detailed guidance for using the graded approach is given in topic-specific YTV guides. There is ongoing work to further develop more practical guidance to cover all main regulatory activities in accordance with STUK's strategy and oversight development programme.

For radiation practices, the application of a graded approach in regulatory control is addressed in SätL11 § as an overarching principle by stating that: "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." SätL also establishes a system of categorisation of practices, which affects, for example, the coverage and in-depth safety assessment conducted by the applicant, which is a key document for the review and assessment by STUK. The processes for licensing and the review and assessment are prescribed in Guide SKV 3.2, but it has been identified that there is still room for further application of a graded approach within these processes. A project to this effect has already been launched.

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

The availability/existence of internal manpower and organizational arrangements of STUK are discussed in subsection 1.3 of Module 1 and in subsection 3.1 of Module 3. Generally, STUK's competence and human resource needs are regularly evaluated, for example for the five-years strategy period and in annual plans. Factors considered in the planning include expectations of forthcoming authorization tasks (licensing steps for nuclear facilities) and retirements of senior experts.

Competences and training are discussed in subsection 1.8 of Module 1, in subsection 3.3 of Module 3 and subsection 4.4. of Module 4. 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.

The management carefully assesses the importance of different tasks and allocates resources to the essential tasks. The human resource plan is updated annually as a part of annual planning. The personnel are supported towards continuous development. Many of the most effective methods are considered as forms of on-the-job learning. The training system consists of training content designed based on, for example, the competence needs, strategic goals, contemporary topics and competence areas. Changes in competence needs (ageing staff, changes in STUK's operation or operating environment, etc.) are identified and considered when training plans are developed.

The availability of external independent resources for review and assessment including TSOs is discussed in subsection 3.4 of Module 3. STUK uses expert organizations to support it in its regulatory functions, including review and assessment. STUK's main support organization in Finland is VTT Technical Research Centre of Finland. STUK and VTT have a framework contract and rules on co-operation. In addition to VTT, STUK regularly uses other organizations in Finland and abroad.

The advisory body is discussed in subsection 3.4 of Module 3. STUK has four advisory committees defined in legislation: STUK's Advisory Committee, Advisory Committee on Nuclear Safety, Advisory Committee on Nuclear Security and Advisory Committee on Radiation Safety. Regarding review and assessment, the most relevant committee is the Advisory Committee on Nuclear Safety, which prepares statements in connection with the authorization processes (Decision in Principle, Construction and Operating licence steps for nuclear facilities).

Tools for review and assessment

Control of the documentation and assessment process for nuclear facilities is done through the electronic document management system SAHA, which covers, for example, the selection of a coordinator, recording and archiving submissions, task distribution, specification of intermediate actions, on-line monitoring of the review status, recording the STUK review/inspection reports and the justification of decisions made.

Control of the documentation and assessment process for use of radiation is done through safety licence management system VASARA where all the decisions and inspections protocols are stored for each of the licensees. The electronically signed decisions and protocols are handled in electronic document management system SAHA as described in the previous paragraph. Quality control for decisions made and protocols is done according to internal guides SKV 3.2 and 3.4. All the requirements STUK has issued for licensees and follow-up of the set time limits are also stored in VASARA.

The RAMI-database and stukasiointi.stuk.fi service are used to manage the occupational radon exposure supervision (described in Guide VALO 7.6).

The Polarion requirements management tool is used for several purposes for nuclear facilities: the planning of review and other regulatory activities, follow-up of activities, overall safety assessment of facilities, management of regulation including follow-up fulfilment of regulatory requirements, operating experience feedback, and the collection and analysis of observations made concerning licensees' activities.

Analytical tools are described in the corresponding subsection 6.2–6.11 below.

STUK does not operate any experimental facilities. The necessary experimental results can be obtained through the national research programmes or by contracting dedicated experiments to other organizations for regulatory support.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

Nuclear facilities

Relevant regulation and guidance for safety assessment by the licensees are described in the corresponding subsections 6.2–6.11. Internal Guide STUK 3.6 describes STUK's process of preparing regulation and regulatory guides. One of the requirements in this process is to align the requirements with the IAEA safety standards and with international good practices as far as possible. The availability of specific regulations/guidance on the scope and quality of deterministic and probabilistic safety analysis is discussed in subsection 6.2. In accordance with the legislation and Guide YVL A.1, STUK has the right to request any detailed information on each facility at its discretion.

Consistency in requirements set in decisions on safety assessment in various licensing/authorization documents is an obvious target for review and assessment. Some issues may arise due to revisions of regulation and regulatory guides. Regulation and regulatory guides have been revised over the past ten years. Even though the old and new requirements are similar at the overall level, there are differences in details, which has an impact on review and assessment activities in longer projects such as licensing Olkiluoto 3.

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 licence applicant shall carry out a safety assessment concerning the radiation practice if the practice is subject to a safety licence. STUK's website contains prepared forms and guidance on carrying out the safety assessment (www.stuk.fi/lomakkeet, available in Finnish and Swedish).

Review and assessment subject to SätL for radiation practices and medical, occupational and public exposure are discussed in sections 6.6, 6.9, 6.10 and 6.11.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

Nuclear facilities

STUK's performance of review and assessment is an integral part of the overall safety assessment process (see Guide YTV 1.b). The overall safety assessment of a licensee and the associated nuclear facility is divided into the following major assessment areas:

- Normal operation performance,
- Adequacy of the licensing basis,
- Management and maintenance of the licensing basis,
- Technical condition of the facility, and
- The performance of the organisation.

These major areas are further divided into sub-areas and each sub-area is regularly evaluated by the responsible unit at STUK. Inputs to the overall safety assessment include:

- Operating experience
- Oversight of refuelling and maintenance outages
- Inspections related to mechanical components and structures
- Section meeting conclusions
- Resident inspector reports
- Document reviews
- Plant modification reviews and assessments
- Periodic inspection programme findings and conclusions
- Nuclear material related inspections
- Any other observations made using the HAKE-system (see Guide YTV 3.d)

Review and assessments activities are therefore essential inputs to the overall safety assessment process and also take into account various assessments made within the overall safety assessment system. The requirement management system Polarion is used to register assessments/observations made in different connections and to indicate links between the issues. The status of the assessment areas and open issues are regularly followed in internal meetings (office meetings, section meetings, oversight project meetings).

The review and assessment process is based on similar principles during the whole life cycle of a nuclear facility. The development and updating of the safety analysis report especially requires comprehensive review and assessment by STUK during all licensing steps, periodic safety reviews, licence renewals due to expiration of the licence or power uprating and significant plant modifications. The scope of the regulatory review and assessment associated with the authorization of various nuclear facilities are discussed in detail in subsections 6.2–6.5 and 6.7. The authorization process is covered in detail in Module 5.

An essential part of the review process is to verify the comprehensiveness and quality of the licensee's safety assessment. Verification of the comprehensiveness and quality takes place in two stages: Before the actual review, as mentioned earlier, a preliminary review is performed to clarify whether the licensee's application and its material enable a review and decision to be made. If the maturity of the application is not sufficient, the application is rejected or additional information is requested to be submitted. In the actual review, the comprehensiveness and quality of the safety assessment are verified in detail.

Methods and degree of the verification depend on the context (e.g. "full-scope if related to the licensing of the facility), safety significance of the item (graded approach, see 6.1.1), type of the topic (e.g. deterministic/probabilistic analysis, human and organisation factors) and the technical areas (e.g. mechanical components, electrical systems, I&C). The methods of verification are described in the corresponding YTV guides with reference to the relevant STUK YVL guides and regulations (see e.g., Guide YTV 3.b.1 and STUK's YVL Guide B.3 with regard to deterministic safety analyses and Guide YTV 3.b.2 and STUK's YVL Guide A.7 with regard to probabilistic safety assessment).

According to STUK's YVL Guide A.1, the licensee shall duly review the conformance of the documents pertaining to safety-significant products before submitting the documents to STUK. The licensee shall assess the acceptability of safety-significant products and those conducting the acceptability assessment shall be independent of the product's design and implementation.

In addition to the formal communication with the licensees through the SAHA system, STUK's inspectors and the licensee's counterpart often organize meetings to discuss and clarify issues. Topic-specific meetings are the most important, but issues can also be discussed at management meetings, in connection to the periodic inspection programme and by resident inspectors.

Radiation practices

The review and assessment are made against the mandatory requirements of SätL, Government Decrees (VnA 1034/2018 and STMA 1044/2018) and STUK regulations. Internal guides SKV 3.2 and 3.4 discuss in more detail how the review and assessment are done and at which stage of the application or radiation practice. The licensee is obliged to review and revise the safety assessment at set intervals. Review and assessment subject to SätL for radiation practices and medical, occupational and public exposure are discussed in sections 6.6, 6.9, 6.10 and 6.11.

Based on SätL sections 145, 146 and 151, NORM-involving industries must 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 if exposure can exceed the reference level, measures must be taken in order to reduce the exposure. Based on SätL section 148, a licence 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 described 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. The plan of regulatory control related to natural radiation is updated annually. Targeted surveys and requests for reporting are used in order to increase awareness of the requirements in SätL. The in-house RAMI-database and stukasiointi.stuk.fi service for employers are used to manage radon in the usual workplaces (described in Guide VALO 7.6). For underground workplaces, e-forms are provided by STUK. The results of the regulatory control activities are reported in STUK's annual report online (e.g. Workplace radon concentrations in Finland - stuk-en - STUK, https://www.stuk.fi/web/en/stuk-supervises/practice-that-causes-exposure-to-natural-radiation/radon-at-the-workplace/stuk-s-monitoring-projects-at-workplaces) and in the public diary (Julkinen diaari - STUK).

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

STUK's review and assessment process is based on the same principles and requirements presented in section 6.1 during the whole life cycle of a nuclear facility including nuclear power plants. 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 the 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 licence, operating licence, possible plant modifications, periodic safety reviews, renewal of the operating licence and decommissioning. In addition to these, review and assessment are 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 to 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. Approval has to be obtained before they are carried out.

Decision-in-principle

Requirements related to decisions-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 decisions-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 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 an 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 licence 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 as needed. Based on the information provided, STUK will draw up a preliminary safety assessment of the application for a decision-in-principle.

Construction licence

When applying for a construction licence, the documents listed in section 35 of 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 licence application only after having approved the essential parts of each of these documents by a separate decision.

According to YEA, when applying for a construction licence, 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 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
- 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
- A programme for determining the baseline environmental conditions of the nuclear facility
- A decommissioning plan

An applicant for a licence shall also provide STUK with any other reports considered necessary.

Operating licence

When applying for an operating licence, 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 (STUK) with the following:

- 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 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
- A decommissioning plan

When the application for an operating licence is made for a nuclear facility that has already been in operation, the documents mentioned in subsection 1 must 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 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 renewal of the operating licence

In accordance with section 24 of YEL, the licence, excluding the construction licence and licence for decommissioning, shall be granted for a fixed term. The renewal of the operating licence always involves a periodic safety review of the facility.

The renewal of the operating licence 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 licence, 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 licence 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 the maintenance of safety.

Decommissioning

See subsection 6.7.

Release from regulatory control

Release from regulatory control is covered by YEL section 27 c, YEA section 75 and STUK regulation STUK 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 licensee under a waste management obligation shall submit to STUK for approval an application for the clearance of the site and any buildings.

Operational experience feedback

Section 21 of Regulation STUK/Y/1/2018 states that operating experience and safety research shall be taking into consideration in order to improve safety.

STUK's YVL Guide A.10 sets forth the criteria and requirements for operating experience feedback, in particular in respect of the utilisation of the experiences gained from the construction and operation of nuclear facilities. See paragraphs in STUK's YVL Guide A.10 305, 306, 516, 517 and 606 for more detailed requirements.

Guide YTV 3.c.11 describes STUK's process for reviewing and assessing operational events at Finnish facilities and Guide YTV 3.c.12 at foreign facilities.

Competences of operating personnel

YEL section 119 states that STUK sees to it that the organisation available to the licensee is adequate and serves its purpose, that the persons participating in the use of nuclear energy meet the qualification requirements set, and that proper training has been arranged for them. The objective of organizational performance review is to ensure that the organizations of the licence holder and its key suppliers operate at all levels to ensure the safety of the facility. This is in accordance with section 25 of regulation STUK Y/1/2018 and section 38 of regulation STUK Y/4/2018. 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 periodic inspection programme. For the above issues, the procedures for supervision and inspection are described in Guide YTV 3.d.

Specific review and assessment methods and tools

STUK has available a basic set of computer codes for independent deterministic and probabilistic safety analysis (e.g. APROS, TRAB, TRACE, MELCOR, FINPSA, RISKSPECTRUM). These codes are used partly for maintaining adequate basic knowledge in STUK. However, STUK often hires external organizations (mainly VTT) specialized in performing safety analysis for performing audit calculations.

6.3. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS

Finland has one research reactor (Triga Mark II research reactor (250 kW)), FiR 1 (Finland Reactor 1), which has been an important nuclear energy testing and training site for Finland. It closed in 2015 and was in 2020. The Government granted a licence in 2021 to

decommission the reactor. Decommissioning is expected to be started in 2023. Currently Finland has no plans for building any additional research reactors.

STUK's review and assessment process for research reactors is based on the same principles and requirements as presented in sections 6.1 and 6.2 during the whole life cycle of the reactor, except the overall safety assessment (Guide YTV 1.b), which is not applicable to a research reactor. The reason for not using an overall safety assessment process for a research reactor is based on the graded approach.

The Safety Assessment of a research reactor is required in all licensing phases as part of the licence applications for construction, operation and decommissioning (YEA sections 35, 36 and 36 a). The content requirements of the Safety Analysis Report (PSAR and FSAR) are described in YVL A.1 Appendix A. In practice, the requirements are the same as for NPPs. According to YEA, the Final Safety Analysis Report (FSAR) shall be kept up to date.

Periodic safety reviews shall be done for research reactors at least after every ten years if not otherwise set in the licence conditions (YEL section 7 e).

STUK will review the Safety Analysis Report as part of the licence application and prepare its own safety review of the application. In addition, separate statement is also prepared for MEAE about the licence application. Changes to the Final Safety Analysis report shall be sent to STUK for approval separately. The documents provided for the periodic safety review are reviewed by STUK, and STUK's safety review is prepared. The result of STUK's review is sent as a decision to the licensee. The decision can have requirements for the licensee concerning timelines.

The document reviews are done against safety requirements presented in STUK's YVL guides. As STUK's YVL guides are written for NPPs, for a research reactor they are followed as appropriate. The graded approach principle is used to take account of the lower radiation risk of a research reactor compared to NPPs. For a research reactor, separate implementing decisions are made for STUK's YVL guide A-, C- and D-series, which will be the most important guides during the decommissioning phase. The decommissioning of Finland's only research reactor will start in late 2022.

The review and assessment of documents is done according to Guide YTV 8.a. The regulatory oversight of the research reactor is done according guides YTV 3.c.10, 3.c.16, 3.e and 3.e.1.

6.4. REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILITIES

STUK's review and assessment process for fuel cycle facilities is based on the same principles and requirements presented in section 6.1 and 6.2 during the whole life cycle of fuel cycle facilities.

In Finland, the category of fuel cycle facilities contains three types of facilities: spent fuel interim storages, encapsulation plant and a uranium extraction facility. Spent fuel interim storages are operated as part of nuclear power plants either on the same site in a separate building or in the same building as the nuclear power plant. The same procedures and requirements are applicable to the review and assessment of spent fuel interim storages as for nuclear power plants.

The purpose of an encapsulation plant is to encapsulate spent nuclear fuel that has been stored in spent fuel interim storages in disposal canisters to be disposed of in an underground disposal facility. At the moment, the encapsulation plant and disposal facility are under construction. In the Finnish regulatory framework, the same review and assessment procedures and legal and regulatory requirements are applicable to an encapsulation plant and disposal facility as for any nuclear facility. Due to the specific features of an encapsulation plant and disposal facility, some requirements are not applicable to encapsulation plants. However, there are some additional requirements that must be considered. These additional requirements consider post-closure safety, and the construction and operation of an underground disposal facility. The requirements are presented in STUK Y/4/2018 and in YVL guides D.5 and D.7.

In the legislation, YEL and YEA are both applicable to an encapsulation plant. Among STUK regulations, Regulation STUK Y/4/2018 is applicable to an encapsulation plant. The major difference compared to other types of nuclear facilities is that that long-term safety shall be considered when authorizing or licensing an encapsulation plant and disposal facility.

Mining company Terrafame Ltd was granted a licence to produce U3O8 (yellow cake) by a government decision in February 2020. This licence became legally effective in June 2021 by a Supreme Administrative Court decision. Before uranium extraction activity can be started, the mining company will need a separate STUK authorization to start the operation (in accordance with YEL section 16 subsection 2).

The regulation for this facility type is much lighter and simpler than for other nuclear facility types. YEL (990/1987) 3 § 5 a) states that the term ‘nuclear facility’ does not mean mines or milling plants intended for the fabrication of uranium or thorium. This means that most YVL guides are not applicable except the YVL guides concerning safeguards (Guide YVL D.1) and transport (Guide YVL D.2).

In addition to the Nuclear Energy Act, YEA is applicable to a uranium extraction facility. The requirements concerning uranium extraction facilities in STUK regulations are set out in STUK regulation Y/5/2016 on the Safety of Mining and Milling Operations Aimed at Producing Uranium or Thorium. The requirements in regulation Y/5/2016 are set considering the low risk of uranium extraction facilities to nuclear and radiation safety.

6.5. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

There are two operating geological disposal facilities for low- and intermediate-level waste (LILW) in Finland, at a depth of approximately 100 meters. The LILW disposal facility operated by Fortum Power and Heat Ltd since 1992 is in Loviisa. The other has been operated by Teollisuuden Voima Ltd since 1998 and is situated in Olkiluoto. 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 also includes a new near-surface facility for very low-level waste. The 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.

The Construction Licence Application for the Olkiluoto spent nuclear fuel encapsulation and disposal facility was submitted by Posiva, the implementer, to the authorities at the end of 2012, and the Government granted a construction licence in November 2015. The facility is currently being constructed and is expected to start operation around 2024.

STUK's review and assessment process is based on the same principles and requirements presented in section 6.1 during the whole life cycle of a nuclear facility including waste management facilities. Processes related to waste management facilities are documented in STUK's management system. The YTV guides contain a broad documentation where guides on the YTV 3 series (39 separate guides) concentrate on review and assessment.

The applications for a new licence or for the renewal of an existing licence include the documents required by YEA: Preliminary or Final Safety Analysis Reports; Probabilistic Risk Analysis Reports; Quality Assurance Programmes for Construction and Operation; Safety Classification Document, Operational Limits and Conditions Document (Technical Specifications); Programmes for Periodic Inspections; Plans for Physical Protection and Emergency Preparedness; Plans for Accounting and Control of Nuclear Materials; Administrative Rules for the Facilities; Programmes for the radiological baseline survey or the results of the radiological baseline survey; Programmes for Radiation Monitoring in the Environment of the Facilities; and Decommissioning Plans.

The design of the facility is described in PSAR and in FSAR. These reports are submitted to STUK for approval in connection with the applications for construction and operating licences. According to YEA, the FSAR shall be kept continuously up to date.

STUK Regulation (STUK Y/1/2018) requires that nuclear power plant safety and the technical solutions of its safety systems, including systems for spent fuel interim storage, shall be assessed and substantiated analytically and, if necessary, experimentally. Analyses should be maintained and revised if necessary, considering operating experience, the results of experimental research, plant modifications and the advancement of computational methods.

The safety assessments are reviewed by STUK with the support of independent safety analyses and/or by external experts to the extent deemed necessary by STUK. For the time being, the licences and related safety documents of the on-site spent fuel storages are attached to those of the respective NPPs, and the renewal review processes take place simultaneously.

The discussion above on the safety assessment of spent fuel interim storage is valid for the predisposal management of LILW because both activities are covered by the operating licences of the reactor units at the present NPPs and by STUK's Regulation (STUK Y/1/2018).

The licensee shall carry out a periodic safety review for the disposal of nuclear waste at least once every 15 years, unless otherwise stated in the conditions of the operating licence. The periodic safety review shall be conducted in compliance with the requirements of Guide YVL A.1, Regulatory control of the use of nuclear energy, where applicable. The periodic safety review for the predisposal management is carried out in connection with the periodic safety review of the NPPs every 10 years.

Regarding the disposal of spent fuel and LILW, compliance with long-term radiation protection objectives and the suitability of the disposal concept and site shall, according to STUK Regulation (STUK Y/4/2018), be justified by means of compliance with the long-term radiation protection objectives. Equally, the suitability of the disposal concept and site shall be justified through a safety case that addresses both the expected evolutions and unlikely disruptive events possibly impairing part of the multi-barrier long-term safety features.

Detailed requirements for the contents of the post-closure safety case are provided in Guide YVL D.5. The post-closure safety case shall include a description of the disposal system: quantities of radioactive substances; waste packages; buffer materials; backfill materials;

structures for isolation and closure; excavated rooms; the geological, hydrogeological, hydrochemical, thermal and rock mechanical characteristics of the host rock; and the natural environment at the disposal site. The post-closure safety case shall define the safety concept, barriers and safety functions together with their performance targets.

6.6. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

STUK grants a safety licence upon application if the radiation practice complies with the principles of justification, optimization and limitation. The licence may be granted separately for different stages of the practice.

When processing the application, STUK compares the content of the application with the requirements set out in SätL, VnA and STUK regulations. When comparing the content of the application for a new safety licence (or application for a complex amendment of a safety licence), STUK uses a checklist available in internal Guide SKV 3.2 (Annex 12). Furthermore, review and assessment of information relevant to safety concerning radiation practices are conducted during licensing and inspection processes described in internal guides. Furthermore, the licensee is obliged to revise the safety assessment at set intervals. The safety assessment shall also be revised, if this is not clearly unnecessary in terms of radiation safety, in connection with a change of 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. Transparent guidance for the implementation of requirements is available in the regulatory and guidance service for radiation legislation SAMMIO (https://sammio.stuk.fi). All the information related to safety licences is stored in the VASARA system.

The requirements for a safety assessment are set out in SätL and STUK S/6/2019. In practice, subject to a safety licence, an undertaking shall categorize its 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.

During an authorization process by the regulatory body, the justification of practices is evaluated. Unjustified uses of radiation are listed in SätL. STUK publishes an up-to-date list on its website of practices, which are generally considered justified.

According to SätL an 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 fulfilment of the requirements laid down in the law.

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 methods, such as surveillance questionnaire. The supervision ensures that the radiation legislation and 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 at risk with a graded approach, through a series of supervision projects.

The graded approach is not fully applied in the review and assessment of radiation practices. STUK has established a project to identify and implement ways to enhance the application of the graded approach in the review and assessment of radiation practices.

6.7. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

STUK's review and assessment process is based on the same principles and requirements presented in section 6.1 during the whole life cycle of a nuclear facility including decommissioning.

The licensee shall develop the preliminary decommissioning plan already in the design phase of the nuclear facility, which is reviewed and approved by STUK in the construction licence application phase. In the preliminary plan, the licensee shall present the selected decommissioning strategy and justify it, define the implementation stages with timetables, present an outline of the dismantling and adopted waste management solutions, and present the end state of the facility site.

The next version of the decommissioning plan must be provided for the operating licence application and the plan shall be based on the actual design of a nuclear facility. STUK reviews and approves it as part of the operating licence application.

During the operation, the licensee must update the decommissioning plan at minimum once every six years if not otherwise required in the licence conditions and sent to MEAE for approval (section 7 g, YEA 161/1988, sections 33 a, 34 a and 36 a). MEAE then requests a statement from STUK about the decommissioning plan.

The final decommissioning plan shall be sent to STUK for approval as part of the decommissioning licence application. STUK reviews the plan against relevant regulations and YVL guides and prepares a safety evaluation report and a statement for MEAE. After receiving the licence from the Government, the licensee can start the decommissioning of the facility. The licensee must follow the plan approved by STUK in decommissioning the nuclear facility. At this stage, the decommissioning strategy, end state and project phases including the methods used in decommissioning are finally approved by STUK. The final decommissioning plan must be kept up to date during the decommissioning of a nuclear facility (STUK's YVL Guide D.4 709).

The licensee shall assess the safety of a nuclear facility in connection with the updates of the decommissioning plan, when applying for a decommissioning licence (YEA 161/1988, sections 33 a, 34 a, and 36 a) 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. (STUK Y/1/2018 section 3 paragraph 5).

During the decommissioning of a nuclear facility, the licensee shall do the safety assessment according to licence conditions or at minimum after every 10 years (Guide YVL D.4 609). The licensee has a duty to ensure that the nuclear facility is dismantled according to the licence conditions set in the decommissioning licence, safety requirements and decommissioning plan approved by STUK (YEL section 7g). The licensee shall report the progress of the decommissioning to STUK on a regular basis. At the end of

decommissioning the licensee shall submit to STUK a summary of the implementation of the decommissioning.

Based on mandates given in YEL sections 55 and 63, STUK controls the decommissioning of the nuclear facility to ensure that the dismantling is done according licence conditions, approved decommissioning plan and according to all relevant safety requirements presented in law, regulations and in YVL safety guides. The regulatory oversight also contains the maintenance, repairs, inspections and tests of the systems, components, and structures of a nuclear facility. The key steps of the decommissioning phases can be started after STUK has reviewed that all factors that influence safety and all related safety requirements have been considered. STUK will review this based on documents listed in YEA in section 36a and from the detailed planning documents provided by the licensee (YEA section 112b).

STUK establishes a project for the regulatory oversight of the decommissioning project. The resources for the regulatory oversight of decommissioning can be found from the line organization of STUK. The coordination of the regulatory oversight of decommissioning projects is given to the Department of Radioactive Waste and Safeguards. The most critical competence areas for decommissioning are radioactive waste management, radiation safety and protection, organization and resources, security, safeguards and emergency arrangements. STUK currently has the required expertise in house.

The review and assessment of documents during decommissioning is done according to Guide YTV 8.a. The regulatory oversight of decommissioning is done according guides YTV 3.e and 3.e.1.

In radiation practices, when an undertaking is moving towards the decommissioning of an operation including the handling of unsealed sources, the safety licence must be reassessed (SätL sections 48 and 52). The cleaning of facilities requires a safety licence if the amount of radioactive substances prior to the cleaning is greater than the clearance level. The decommissioning of the operation often includes decommissioning of the associated radioactive sources and sometimes decontamination of the premises. A safety licence can be granted separately for different stages of the practice. If the licence for the use of radiation does not already include the decommissioning stage, the undertaking shall apply for a new safety licence or an amendment to the current safety licence before moving to the decommissioning phase. In the amendment of the safety licence, the undertaking shall estimate the amount of radioactive waste generated in the decommissioning and the arrangements for managing the waste.

During the decommissioning the undertaking shall clean the facilities and structures contaminated by radioactive substances in such a way that the remaining amount of radioactive substances does not exceed the clearance level (SätL section 85). The undertaking reports the results of the decommissioning to STUK. STUK withdraws the safety licence when the radioactive waste has been rendered harmless and radiation practice has been discontinued (SätL section 53).

6.8. REVIEW AND ASSESSMENT FOR TRANSPORT ACTIVITIES

Finland’s legislation concerning the transportation of dangerous goods is based on international agreements for different transportation modes. SSR-6 has been implemented into Finnish legislation and is followed as such. Additional requirements for Class 7 transportations are given in SätL, YEL and YEA.

In most modes of transport, STUK is the competent authority issuing approvals relating to the transport of radioactive material. There are a couple of situations where another authority is involved. For example, INF (International Code for the Safe Carriage of Packaged Irradiated Nuclear Fuel, Plutonium and High-Level Radioactive Wastes on Board Ships), classification is made by the Finnish Transport Safety Agency. STUK relies mainly on the competence of its staff in connection with the review and assessment of the content of safety licence 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.

The goal for the review and assessment process is that only transport operations meeting all the requirements set out in the regulations are approved. Applicants receive guidance from STUK before and during processing their application.

Familiarization with the internal guidelines is part of the processing of applications. This ensure that the conditions for approval of the transport operations are the same for all applicants. It has been found important to supplement and update the internal guidelines. There are changes in the field of action, for example through digitalisation, and legislation in this area is in the process of being reformed in Finland. The internal guidelines are presented in YTV 3.g.1 and SKV 5.2.

The resources for regulatory oversight of the transportation of Class 7 have been quite limited at STUK in recent years. The renewal of the Act on the Transportation of Dangerous Goods is ongoing. Reform of the act may result in more duties for STUK. With current resources, it might be difficult also to take care of new duties in this area.

6.9 REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE

STUK's review and assessment process is based on the same principles and requirements presented in sections 6.1. and 6.6.

Review and assessment procedures for occupational exposure in nuclear facilities is described in section 6.2 (Review and assessment for nuclear power plants).

The objective is to ensure that the total radiation exposure of both workers and the public from the use of a nuclear power plant is kept as low as reasonably achievable (ALARA). In addition, radiation exposure at individual level is kept well below the dose limits.

Section 2 a of YEL describes how SätL applies to the use of nuclear energy.

Section 51 of SätL and VnA Annex 5 list items to be in be included in the application for a safety licence (see answer to question 5.6 for more details). Regarding occupational exposure, the review and assessment addresses depend on the quality and extent of the practice:

- safety assessment
- a report on the practice's different work phases key to radiation safety and the procedures complied with in them;
- a plan for radiation safety deviations;
- 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 have been organized;
- the dose constraints complied with in the practice;

- technical specifications which show that the facility where the radiation sources are used and stored meet the in-service safety requirements set by STUK
- 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
- information on the quality system concerning the practice and procedures used in quality

Review and assessment of occupational exposure is focused on safety assessment. SätL section 26 stipulates the main requirements for undertakings' safety assessments. An undertaking shall carry out safety assessment concerning a 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.

Safety assessment regarding occupational exposure is confirmed by STUK if the licensee can adequately demonstrate safety. The confirmation of the safety assessment is addressed in Guide SKV 3.2. Annex 11.

Internal Guide SKV 3.4. Annex 2 lists items to be reviewed by inspections. On occupational exposure, the following shall be reviewed:

- undertakings' plan to manage radiation safety deviations and implementation of preparedness measures
- classification of areas (control areas and supervision areas) is done properly and arrangements for the areas are adequate (e.g. for access control, warning lights and signs, markings)
- classification of radiation workers has been carried out correctly (for category A and B workers)
- radiological surveillance and individual monitoring have been conducted properly
- medical surveillance has been provided for category A workers and medical surveillance is done by an occupational physician familiar with radiation
- there are sufficient radiation meters for the activity
- there is sufficient and suitable personal protective equipment available for workers
- working methods are such that the radiation exposure of workers can be kept as low as reasonably practicable
- exposure results are systematically monitored and a procedure is defined to clarify and correct the situation if exposure exceeds the reference level
- training, instruction and refresher training in the use of the equipment are provided

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. In practice, radon remediation in most workplaces is usually successful and the occupational radon exposure will be reduced below the reference level. STUK supervises that exposure does not exceed the reference level. Often radon concentrations are much lower 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. A decision on which working areas should be remediated or access restricted is based on exposure by the employer. If the exposure is higher than the reference level and cannot be remediated (e.g. tunnels), the 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 the workplace continues to exceed the reference level despite the measures taken to reduce exposure (SätL section 148). Among other issues, this means regular determination of the 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 Annex 3.

6.10 REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE

Key parts of the review and assessment for medical exposure take place during the authorization phase based on documentation provided by the applicant, including the safety assessment and description of the management system. Further, several detailed aspects are reviewed and assessed during inspections.

STUK assesses the justification of the type of medical use of radiation primarily during the authorization process. If the type of medical use of radiation is similar to that already practised and still considered justified, then the activity is generally regarded as justified. For new types of practices and programmes of biomedical research, documentation demonstrating the justification is reviewed. If necessary, stakeholder groups such as the Advisory Committee on Radiation Safety are consulted in the matter.

Verification of the patient-specific justification of medical exposures is a part of regulatory inspections. During inspections, it is checked that the undertaking has procedures in place to ensure that a justification assessment is carried out. It is checked that responsible doctors are available and whether their qualifications are adequate. It may be checked if and what kind of referral guidelines or any guidelines relating to medical exposure are in use. It also may be checked whether asymptomatic patients are examined and what the related criteria are. There is a lack of national referral guidelines and the criteria for examinations of asymptomatic patients are currently prepared with one-off project funding. Also, the documents of clinical audits, which are periodic radiological reviews conducted usually alternately by another unit within the undertaking’s organization and an independent third party, are reviewed during inspection for findings relating to justification of medical exposure, among other things. Human resources and adequate radiation protection training for personnel concerning the radiation practice are also assessed where appropriate.

The first part of the review and assessment of optimization of medical exposure is done when a regulatory authority reviews and assesses an undertaking’s safety assessment for a licence application or amendment of a licence. In the safety assessment, the undertaking shall present measures to ensure radiation safety and optimization of radiation protection. Typically, in safety assessment these measures are only set out at heading level. The actual implementation of the measures like key work phases and procedures to ensure radiation safety are verified during the inspection. The validity of the categorization of medical, occupational and public exposures set in the safety assessment are assessed during the inspections. These categorizations are elements for the application of a graded approach, for example medical exposure categorizations affecting the periodicity of clinical audits. Information on the quality system and quality management procedures is reviewed during authorization, and the quality assurance programme and its implementation are reviewed during inspection.

Additionally, during inspections it is reviewed and assessed whether the equipment is suitable for the operation and that the exposure from the operation is optimized. Also, it is checked during inspections or by other means that the determination of patient dose has

been done and that the dose is below diagnostic reference levels for those examinations for which the reference levels have been set.

Dose constraints for medical exposure of comforters and carers are set either in safety assessment or separately since they are not explicitly mandated to be included in the safety assessment. For biomedical research, dose constraints shall also be set and they are reviewed and assessed during the processing of safety assessment, either during authorization or separately.

The assessment of dose constraints set can be done during inspections. The review and assessment of source calibration are done during inspections by verifying that there has been acceptance testing, commissioning and periodic testing for all medical sources where modality-dependent dosimetric quantities have been measured in reference conditions. During inspections, it is assessed and ensured that calibrations related to radiation therapy have independent verification.

6.11 REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE

Nuclear Safety

The reviews and assessments performed by STUK for each stage of a nuclear facility, as described in section 6.2, also include review and assessment of the public exposures and monitoring programmes of licensees (for public exposure).

Reviews and assessments by STUK include the following topics

- A statement on the environmental impact programme and report for a new nuclear facility
- Preliminary safety assessment for a nuclear facility's application for a decision-in-principle includes assessment of the safety analyses, including the analysis of the environmental and public radiation doses caused by the worst-case scenario accident.
- In connection with the review and assessment of the preliminary and final safety analysis reports:
    - Identification of the release pathways of radioactive substances
    - Analyses of the dispersion of radioactive substances and the doses they given rise to
    - Special systems for reducing releases
- The functionality of the dispersion and dose calculation methods intended for accident conditions and their maintenance at the plant site during the construction and operation of the nuclear facility.
- The validity of the dispersion and dose analyses during the periodic safety assessment of the nuclear power plant.

Radiation practices

STUK's review and assessment process is based on the same principles and requirements presented in sections 6.1. and 6.6.

Section 51 of SätL and VnA Annex 5 list items to be included in an application for a safety licence (see answer to question 5.6 for more details). Regarding public exposure, the application shall include, depending on the quality and extent of the practice:

- a safety assessment
- a plan for radiation safety deviations;
- dose constraints complied with in the practice;

- technical specifications which show that the facility where the radiation sources are used and stored meet the in-service safety requirements set by regulatory body (STUK).
- 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 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;
- a plan on discharges.

Review and assessment of public exposure is focused on safety assessment. SätL section 26 stipulates the main requirements for undertakings' safety assessment. An undertaking shall carry out safety assessment concerning the 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.

Safety assessment regarding public exposure is confirmed by the regulatory body (STUK) if the licensee can adequately demonstrate safety. The confirmation of the safety assessment is addressed in Guide SKV 3.2. Annex 11.

Practices or sources exempted or cleared from regulatory control

Section 49 of SätL and section 27 of VnA determine which practices or sources within practices are exempt from a safety licence. Exemption values are given in STUK SY/1/2018 (the values are the same as in GSR Part 3).

In addition, STUK may exempt other practices from a safety licence provided that the criteria established in section 50 of SätL and section 28 of VnA are met. For an application for exemption, STUK reviews and assess that the criteria are met, including:

- exemption is the most appropriate alternative
- the practice is justified
- the practice is inherently safe
- the level of public exposure, except for low probability radiation safety deviations, is in the order of 10 µSv from artificial radionuclides and 1 mSv from natural radionuclides, at the most
- the level of public exposure for low probability radiation safety deviations is 1 mSv at the most.

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 established in STUK SY/1/2018 (the values are the same as in GSR Part 3). If the amount of the radioactive substance is greater than the clearance level, the reuse, recycle, utilization and disposal require an approval of STUK (section 84 of SätL). The same criteria as above for exemption is also applicable to clearance. For an application for such an approval, STUK reviews and assesses whether these criteria have been met.

Radioactive waste and discharges

In case of a practice involving radiation substances, STUK's review and assessment include, as appropriate (not all of these elements exist in all practices):

- plans for waste generation considering the principle of generating as little radioactive waste as practically possible (section 78 of SätL)
- consideration of waste and doses arising from waste management as part of the assessment of the justification of the practice and the optimization of protection (section 2 of VnA)
- arrangements for managing the waste and discharges containing radioactive substances generated by the practice during its operations and when discontinuing the practice (section 79 of SätL)
- furnishing security for rendering radioactive waste harmless (section 54 of SätL)
- consideration of waste (and doses arising from the management of waste) as part of the justification of and the overall optimization of protection within the practice (VnA 1034/2018, Section 2)
- arrangements for discharges and applicable limits values (section 127 of SätL)
- arrangements for carrying out a baseline environmental radioactivity study (especially in NORM activities involving discharges to the environment)

Monitoring and reporting

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 at regular intervals and the results are published. The average effective total annual dose to the Finnish population from all sources is estimated in the report "Suomalaisten keskimääräinen efektiivinen annos vuonna 2018". 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.

For activities causing exposure to natural radiation (SätL chapter 18), there are responsibilities for the estimation of public exposure. NORM-involving industries have a reference level for public exposure (STMA 1044/2018 section 26). The industries with potential NORM-occurrences must make an exposure assessment of the public to STUK according to STUK S/6/2022. If the exposure of the public could exceed the reference level, the responsible party needs to constrain the exposure (SätL section 147). STUK's inspection processes related to exposure to natural radiation is described in Guide VALO 7. Compliance with requirements is mainly done by document inspections. If the exposure of the public exceeds the reference level despite constraints, the responsible party must apply for a licence from STUK (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 already below reference levels are basically voluntary.

Industries dealing with NORM are required to provide characterization and exposure assessment of NORM, limitation of exposure (if needed) and licensing (if needed) to STUK. The regulator (STUK) 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 individuals to reduce their exposure and the associated health risks is available at the STUK website.

Consumer products

The deliberate mixing or adding of a radioactive substance to consumer goods and the import, export and transfer of such goods to Finland are subject to a safety licence. In addition to the general safety licence criteria set out in SätL section 51 and VnA Annex 5, the consumer goods justification and optimization are assessed against the specific criteria for consumer goods stipulated in VnA 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 licence 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.*

STUK assess the radiation safety of a product pursuant to the applicable product safety legislation or according to standards referred to in the Official Journal of the European Union (SätL section 58). In addition, in the assessment of a product's radiation safety, STUK pays attention to: international and national standards pertaining to product safety, any recommendations of the European Commission which contain instructions concerning the assessment of radiation safety, the guidance and recommendations issued by regulatory authorities, the codes of conduct concerning radiation safety and current information and technology.

Consumer products' authorization and exemptions are explained in Chapter 5.11 on the authorization issues for public exposure.

Responsibilities of the Government specific to existing exposure situations

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 Chapters 5 and 6. NORM-involving industries are also existing exposure situations in Finland. 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 levels for radon concentration in houses and other buildings of high occupancy factors by the public are 300 Bq/m3 (STMA 1044/2018 section 20) and radon concentration in new buildings: 200 Bq/m3 (STMA 1044/2018 section 21). The reference level for the exposure of the public to radiation from natural radiation other than radon or space 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 to natural radionuclides in a construction product. There are separate reference levels for construction products (STMA 1044/2018 section 24).

Pursuant to SätL section 142, MSAH draws up a national action plan for identifying existing exposure situations and implementing the measures referred to in the plan. In practice, STUK will draft a national action plan for MSAH in 2022 in the KAVATTU project. The action plan shall include measures to identify the existing exposure situations identified in Annex XVII to Council Directive 2013/59/Euratom (EU BSSD). VnA 1034/2018 section 49 provides that the national action plan shall take into account the factors that may cause radiation exposure:

1) activities that have ceased and have not been subject to regulatory control or have not been regulated in the way similar activities were at the time the plan was prepared;
2) emergency situations that have been transferred to the existing exposure situation;
3) activities for which the responsible operator cannot be identified;
4) naturally occurring radioactive substances in situations other than those provided for in SätL Chapter 18;
5) radioactive substances that have entered products intended for consumer use from the situations referred to in points 1 to 4, with the exception of foodstuffs, animal feed, domestic water and construction products.

The national action plan shall set out the procedures and responsibilities for identifying the situations referred above. Once an existing exposure situation has been identified, it will be managed according to the procedures laid down in SätL Chapter 17.

Justification for protective actions and optimization of protection and safety

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 measures in radon exposure situations. In principle, protection measures are always justified when the radon exposure or activity concentration is higher than the reference level. In activities that require a safety licence (see SätL section 148), the undertaking shall demonstrate that the practice subject to a safety licence is justified (SätL section 24). Radon mitigation or remediation are justified if radon exposure needs to be lowered.

Responsibilities for remediation

The evaluation of justification and optimization for protective or remedial actions and the optimization of protection and safety in existing public exposure situations are done by comparing the estimated doses to the reference levels. 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 chapters 5 and 6.

Public exposure due to radon indoors

The evaluation of indoor radon concentrations and exposure are regularly reported by STUK using the national radon database. According to SätL section 19, STUK maintains a register

on the radon concentrations in dwellings, buildings with high occupancy factors for members of the public and workplaces. Representative population sample surveys have been conducted in Finland and the latest sample survey of new buildings examined the indoor radon concentrations of new single-family houses. 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/m3.

Exposure due to radionuclides in commodities

According to SätL section 153, anyone who manufactures, imports or transfers a construction product 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 may exceed the reference level. STUK should be notified of the results.

For foodstuffs imported into the European Union, Council Regulation 733/2008/Euratom requires that Cs-137 be under 600 Bq/kg. According to Commission Recommendation 2003/274, the same value should also be applied to wild food products in the EU area. In case of a nuclear accident, the Commission can set limits for radioactive substances in foodstuffs (Council Regulation 2016/52/Euratom). In trade with non-EU countries, FAO and WHO Codex Alimentarius (CODEX STAN 193-1995, amended 2018) shall be followed unless a national or EU regulation applies. For animal feed, Council Regulation 2016/52/Euratom sets limits for both imported feed and feedstuff produced in the EU.

6.12. CONCLUSIONS AND ACTIONS

STUK has a well-working and proven review and assessment process, which fulfills the expectations given by the IAEA and is in line with WENRA reference levels as well as with other established international best practices. STUK's competent and experienced staff is capable of performing comprehensive review and assessment covering all areas of safety. Also, the development of methods, tools and procedures related to a graded approach have progressed well.

In conclusion, requirement 25 of GSR Part 1 (Rev. 1) are complied with and STUK's review and assessment processes are in line with GSG-13 (that has superseded GS-G-1.2) paragraphs 3.147–3.209. However, there is still room for improvement. Accordingly, the following actions have been identified:

Actions

- STUK should continue to develop further regulatory procedures, guidance and tools to fully support a graded approach in all regulatory activities.
- STUK should increase preparedness for the licensing, review and assessment of new reactor types (e.g. SMR).
    - Competence building of new technologies
    - Development of legislation and regulation
- MHSA should enable the establishment of a national referral guideline for diagnostic imaging.

Good Practice

Continuous Overall safety assessment. The overall safety assessment of operating nuclear facilities is carried out continuously and its results are used for focusing regulatory oversight.

Oversight information from various topics is collected in a database tool. The assessment of and decision-making for re-focusing regulatory activities are performed every four months. STUK's overall safety assessment concept has proven to be a good platform for cross-disciplinary discussions and for supporting decision-making. It also provides means for the identification, categorization and tracking of regulatory issues.

7. INSPECTION

7.1. GENERIC ISSUES

Nuclear facilities

The legitimacy of nuclear facility inspections has been described in YEL 990/1987. Section 55 (subsections 4 and 5) describes how inspections are activated before and after DiP. Section 65 gives STUK broad supervisory rights to inspect, control and have access to all places where nuclear safety-affected construction, manufacturing or operation take place, and to receive the necessary information related to these activities. These activities are described in more detail in guides STUK YVL A.1, A.3, A.4, A.5 and A.6 as also indicated in the Chapter 7.2 response. Construction and operational inspection programmes follow formal procedures. Inspections of activities are done on-site and end up in an inspection record assists STUK in its decision-making, including interactions with licensees before the record is finalized. Inspection programmes and their procedures, also for waste facilities, are described in more detail in Guide YTV 4.a.1. Inspections can be targeted broadly at licensee management, organization, personnel, documentation, processes, planning and activities. At major operational sites, STUK also has local offices and inspectors that have supervisory rights to make safety-related claims on waste management facilities (Guide YTV 4.b.1). STUK also has the right to make safety-reactive inspections at sites whenever these are considered necessary. STUK internal management system Guide YTV 3.e forms an overarching reference for how STUK implements its oversight of waste management facilities.

See more detailed summaries regarding inspection of nuclear facilities in chapters 7.2–7.5.

Radiation practices

According to SätL (859/2018) section 176, STUK has, for the purpose of the supervision of compliance with the act, the right to inspect facilities and activities that are subject to the act. This includes the right to access the facility in which the practice is being engaged in. According to section 11 of the Act, when supervising compliance with obligations, the regulatory authority accounts for risks related to the activity performed.

Section 182 of SätL (859/2018) states that STUK draws up an inspection programme concerning the inspections of practices subject to a safety licence. 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 kinds of inspections and other measures for supervision. Also in the guide, the suggested intervals for inspections of

different kinds of practices are presented. In addition, departments and units performing the inspections have more detailed and more frequently updated programmes for inspections.

The types of inspection are stated in Guide SKV 3.4. According to the guide the inspections can be announced beforehand, or they can be unannounced. Most of the inspections are programmed or planned but STUK also conducts reactive inspections.
When planning the inspection (who to inspect, what areas to concentrate on, type of inspection) a graded approach is applied. An annex to the guide suggests inspection intervals. Practices with higher risks are inspected more often. Most inspections are planned and conducted annually within thematic supervision projects. The topics of the projects are chosen based on the risks and possibilities for improvement and effectiveness.

Exposure to natural radiation

STUK's inspection processes related to exposure to natural radiation such as occupational radon and NORM exposure as well as exposure to radionuclides from construction materials is described in Guide VALO 7. Compliance with requirements is mainly done by document reviews, including the measurements done by the responsible party. Targeted surveys and requests for clarifications are used in order to increase awareness of employers and industry on the requirements in SätL.

STUK's inspection processes related to the radiation safety of aviation personnel is described in Guide SKV 7.4. The inspection focuses on the operator's measures to ensure the radiation protection of flight crew and the monitoring of radiation exposure.

7.2. INSPECTION OF NUCLEAR POWER PLANTS

STUK has established a periodic inspection programme for nuclear power plants and nuclear facilities. The goal of the periodic inspection programme is to ensure that STUK's oversight covers all relevant areas of nuclear safety, safeguards and security in relevant intervals. The programme is based on planned pre-announced inspections, but additional, unannounced and reactive inspections can be added to the inspection plan based on case-by-case consideration. The periodic inspection programme consists of three different programmes (RKT, RTO and KTO) that cover different phases of life cycles of nuclear facilities: RKT is for facilities preparing for construction, RTO is for facilities under construction, KTO is for operating facilities. All three inspection programmes share the same principles and guides regarding the conduct of individual inspections (Guide YTV 4.a.1). A similar inspection programme is planned for the inspection of the NPPs in the decommissioning phase, when it becomes relevant. The number of individual inspections in KTO inspection programme is usually about 20 per year per licensee. Individual inspections are conducted either annually or every two years. In case of RKT and RTO, the inspection plan is more flexible than in KTO. RTO and RKT inspections are planned every 6 months and the number, frequency and scope of individual inspections is defined based on the phase of the project and current activities in the facility in question.

The aim of KTO, RTO and RKT inspections is to assess the licensee/licence 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 the observation of practical activities, evaluation of pre-assigned tasks and other material related to the inspection area, as well as familiarization with the licensee's processes and operations. STUK's assessment of the fulfilment of safety requirements should be based on the evaluation and verification of practical activities.

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 the so-called “hybrid” method) remotely using suitable teleconferencing software. Experiences with remote and hybrid inspections have been largely positive, but they are unable to cope with all inspection areas. The typical size of an inspection team is 3–5 inspectors and the typical length of an inspection 2–3 days. TSO organizations and consultants could be used in assistant roles in inspections, but the inspection lead is always from STUK and protocols are signed by a STUK staff member. All the inspections are carried out according to a detailed plan and inspection results are presented in inspection protocol, which includes possible requirements for remedial actions. Inspection protocol is submitted to the licensee within a formal STUK decision. All inspections are documented in a database that is used to follow up the inspection findings. STUK’s inspection findings are also communicated directly with the licensee at the inspection exit meeting. Inspection results are followed up in the regulatory process and communicated among the regulator’s staff. In addition, the inspection findings are added to STUK’s 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.

STUK has modified the KTO inspection programme over the years. The latest changes were made in 2015, when the whole programme was re-assessed. According to updated internal guide, many of yearly conducted inspections are now carried out every two years. The inspections focusing on the most safety-significant areas are still carried out annually. In addition, reactive inspections can be carried out based on the oversight results, and proactive inspections can be added focusing on ongoing or incoming activities at the plant. The aim is to have a more flexible inspection programme to optimize its effectiveness and focus, and to be able to conduct inspections in areas and at times considered necessary.

In addition to periodic inspection programme inspection types (KTO, RTO, RKT), there is also a “lighter” inspection type called a 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 to document the inspection findings. The inspection scope is typically limited in that it could be carried in one working day. The inspection findings are reported to the licensee in an official manner (electrical protocol “STARE” format is used). 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 Programme (KTO). KV inspections can be used in all life-cycle phases of nuclear facilities.

In addition to periodic inspections, STUK issues YVL guides that require the 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 the status and compliance of safety-related systems, structures and components. The inspection process for mechanical components and structures of nuclear facilities is described in component-specific YVL guides (E-series), which give stipulations for the construction inspection (CI) of components. CI ensures that component has been manufactured, installed, modified or repaired in accordance with the approved construction plan and procedures, and that the inspections and tests have been carried out on them in accordance with the construction plan. Guide YTV 4.b.2 Annex 4 gives the grading scope and manner according to which the construction inspection is performed by STUK. During CI, a STUK inspector may enlarge the scope of inspection when shortcomings in manufacturing are discovered.

At present, STUK carries out inspections of mechanical components and structures mainly in safety classes 1–2. Lower safety classes are given by a decision of STUK to the responsibility of Authorized Inspection Organizations (AIO). Based on section 60a of YEL and STUK's YVL Guide E.1, STUK approves Authorized Inspection Organizations for 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 (Finnish Accreditation Service) 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 programme is to ensure that the activities of the AIO are high-quality and meet the regulatory requirements during the period of validity of the AIO licences. TTO inspection is described in Guide YTV 4.a.3.

At present, commissioning inspections of safety-classified electrical or I&C systems, equipment or cables are performed by the licensees as stated in STUK's YVL Guide E.7, Electrical and I&C equipment of a nuclear facility, Chapter 7.4. However, as stated in STUK's YVL Guide E.7 requirement 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 inspection of electrical and I&C systems' pre-inspection documentation.

A graded approach is applied in all regulatory inspection activities. The graded approach is, for example, used as a tool to optimize the periodic inspection programme when defining the interval and scope of individual inspections and the need for additional inspections. It is also used when assessing the severity of inspection findings and defining possible enforcement actions (see Module 8 core answers for more details).

STUK has resident (site) inspectors at the Loviisa and Olkiluoto nuclear power plants. Resident inspectors carry out oversight on a daily basis and report their findings to STUK headquarters. One of the main tasks of the resident inspectors is to publish weekly reports that summarize the most important events of the past week at the plant units. The resident inspectors often take part in periodic inspection programme inspections, and may also carry out YVL guide-based inspections of systems, structures and components. Currently (2021) there are 5 resident inspectors at Olkiluoto covering the inspection of Olkiluoto NPP units 1–3 and Posiva's final disposal facility construction activities. At Loviisa, there are currently 2 resident inspectors.

7.3. INSPECTION OF RESEARCH REACTORS

STUK has a specific internal guidance for the regulatory oversight of a research reactor (Guide YTV 3.c.16).

The inspection programme for the operation of the research reactor has contained regular inspections in the following areas: security, safeguards, emergency arrangements, operation (includes also organizational aspects), radiation safety and radioactive waste management. The planning, performance, processing and reporting of inspections were carried out in accordance with NPP inspections as presented in this summary Chapter 7.2.

At the moment there are no operating research reactors in Finland. For the decommissioning phase of the Finnish TRIGA Mark II research reactor (250 kW), FiR 1, situated in Espoo, a similar kind of inspection programme is planned. STUK oversight for the decommissioning activities of nuclear facilities is described in Chapter 7.7.

7.4. INSPECTION OF 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 applicable to this facility. Once an operating licence has been granted for the encapsulation facility, the Operation Inspection Programme (KTO) will be applied.

7.5. INSPECTION OF WASTE MANAGEMENT FACILITIES

Inspections for predisposal management facilities (either during construction or operation) closely follow the inspection routines defined for NPPs. STUK makes annual decisions for each constructed or operated waste management facility. Decisions concern which topics series of inspections will focus on during the year. Some of the topics are not inspected every year while some are included annually, according to their safety significance. A special feature for operating predisposal facilities is the follow-up of the record keeping of managed waste. In the case of spent fuel storage facilities, oversight includes location verifications of each individual stored fuel bundle. The full traceability of each bundle is required at each step of the fuel cycle. Guide YTV 3.f is the overall internal reference of how to implement the national nuclear material oversight. Procedures related to the nuclear material inspections are described in Guide YTV 4.c.1.

Similarly, inspections of disposal facilities (either during construction or operation) imitate routines defined for NPPs. In accordance with the decided inspection programme, STUK targets inspections annually or every other year (operating LILW disposal facilities) at disposal facilities, according to safety significance. The record-keeping of disposed waste is followed up by local inspectors, and the licensee is obliged to report disposed inventories annually to STUK. Since the operating time of both LILW and high-level waste (HLW) disposal facilities is long (60 to 100 years) the ageing management of underground facility system, structures and components (SSC) has special emphasis.

With regard to the construction of waste disposal facilities, a natural barrier is a unique construction material that cannot be compared to the manufactured SSCs of facilities. Only qualified volumes of bedrock are chosen, and disposal rooms built are individually accepted for waste disposal. With regard to an HLW disposal facility, Guide YTV 3.e.3 describes in more detail the oversight process for acceptance of a natural barrier for long-term disposal. The oversight process covers review and assessment of the construction plans, interim hold points, and verification of the final result of activities.

The graded approach taking into account safety significance is applied to waste management facility inspections. Document reviews and on-site inspections are graded based on the safety classification of SSCs, and in terms of long-term safety (including concept, disposal method, safety argumentation, etc.). The implementation of the graded approach is clarified in Guides YTV 6.c, YTV 3.e.3, and YTV 3.b.4.

As a concluding remark, waste management facility inspections have documented process descriptions in the STUK management system, which is described in more detail in Chapter 7.2. STUK considers that the coverage of documented and actively implemented processes is in accordance with the IAEA requirements and guidance.

7.6. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

Inspections of radiation practices are part of in-service supervision, which also include other possible means of supervision such as different types of surveillance questionnaires and inquiries, as well as remote inspections. In-service supervision and its different means are targeted based on the safety significance of the practice and the expected impact on the reduction of risks and improvement of safety. In-service supervision is conducted through annually defined supervision projects. In selecting targets for inspections, the indicative inspection frequencies established are considered (every 3–8 years depending on the safety significance of the practice).

The inspection of radiation practices is based on STUK's management system Guide SKV 3.4: In-service oversight of radiation activities requiring a safety licence.

Inspections are done at the radiation facility as onsite inspection (announced and unannounced), reactive inspection and, when needed, re-inspections to confirm corrected non-compliances. Announced inspections onsite are agreed well in advance with the contact person of the undertaking notified to STUK. Unannounced inspections may be carried out without prior notice. There must always be a reason for unannounced inspection, for example, the reason may be a suspicion that the operation does not comply with the safety licence and that the deficiencies would not come to light during an inspection announced in advance.

An undertaking is asked to provide documentation beforehand to STUK or be prepared to present documentation during the inspection. Documentation usually requested is on quality assurance (SätL section 30), the management system of radiation practices (SätL section 29), safety assessment of radiation practice (SätL section 26), plan on radiation safety deviations (SätL section 129) and a list of familiarization and training of the workers engaged in radiation practices (SätL section 33). Depending on the scope of the inspection, other documentation may be requested as needed. If necessary, the undertaking is asked to make summaries, reports or measurements for the inspection, and send material in advance to STUK.

At an inspection of a radiation source facility or activity, the inspector verifies the following aspects:

- The undertaking takes responsibility for the safety of its operations in radiation practices and has sufficient resources for safe operations.
- Radioactive sources and devices and actions which cause exposure to radiation fulfil all licence requirements.
- The undertaking has a quality assurance process in place for radioactive sources and practices subject to a safety licence.
- Workers engaged in radiation practices or whose tasks otherwise require special expertise, for example on radiation protection, have adequate training, competence and instructions for using radiation sources. Training must be documented.
- The undertaking has adequate and up-to-date record-keeping on radiation sources.
- Disused sources and radioactive waste are handled appropriately.
- Security arrangements are adequate.

During the inspection, radiation measurements and wipe tests of radioactive sources are taken to the extent that is necessary, for example to verify the adequacy of radiation protection or the leak-tightness of the radiation source. Such measurements are the responsibility of the undertaking. The inspection report shall state the results of the measurements and, where appropriate, why the measurements were made.

The main findings of the inspection are discussed with the representative of the licensee (usually the Radiation Safety Officer) at the end of the inspection. A report of the inspection must always be drawn up and submitted without delay. The inspection report shall set out the main findings of the inspection and identify the necessary requirements for the undertaking. Annex 4 of Guide SKV 3.4 provides a template for the general structure of the inspection report.

7.7. INSPECTION OF DECOMMISSIONING ACTIVITIES

Inspections at the decommissioning phase of a nuclear facility are under development at STUK as the first decommissioning project (research reactor) is just starting. Inspection programmes and their procedures as presented in Chapter 7.2, are also implemented in the decommissioning phase of a nuclear facility as appropriate and described in more detail in Guide YTV 4.a.1. Guide YTV 3.e.1 describes the inspection activities related to decommissioning.

For the ongoing research reactor decommissioning project, an inspection programme was planned for shut-down state, which in this case covers the period before defueling of the fuel and the transition period after defueling and before actual dismantling. Inspections were targeted at areas, which were identified to contain the main radiation risks or, based on earlier inspection results, at areas, which were not totally fulfilling the safety requirements. The identified areas for the inspection programme were radioactive waste management, radiation safety, security, safeguards, emergency arrangements and organizational and competence management. The inspection programme is very similar to KTO inspections for operating nuclear facilities, but the main focus of the inspections is on the preparations for the decommissioning phase. In addition, there is an inspection plan developed for the dismantling phase. These “hold point” inspections are identified from the licensees’ decommissioning plan and are set to the most critical project phases (e.g. removing the fuel from the reactor, dismantling the reactor internals, dismantling the biological shielding). The graded approach was considered, when planning the inspection programme for the decommissioning of a research reactor.

The planned inspection activities are presented in a separate inspection plan, which is also communicated to the licensee. Inspections are done on-site and they end up in the inspection record upon which the STUK decision is based. The results are communicated to the licensee at the exit meeting of the inspection. STUK also has the right to make reactive inspections at a site whenever these are considered necessary.

7.8. INSPECTION OF TRANSPORT ACTIVITIES

STUK's inspection and access rights

Pursuant to the Act on the Transport of Dangerous Goods, STUK has the right to carry out inspections necessary to monitor compliance with national legislation. This includes the right to enter the places of manufacture, storage, sale, installation, repair, inspection, loading and transport of dangerous goods and packaging and containers intended for the transport of dangerous goods, temporary storage and the transport unit and to take the necessary samples and conduct research. Similar inspection and access rights have also been granted to STUK under SätL and YEL.

Scope of inspection

The scope of inspections performed by STUK is case-specific, considering the characteristics, particularly safety significance, of the object of inspection. The inspection of transport operations may be carried out separately from other uses of radiation or alternatively as part of a larger entity together with the supervision of other activities subject to a radiation safety licence. In inspections of transport operations, it is also possible to look at longer transport chains that combine several different modes and operators of transport. All the different stages of transport are inspected. Regarding the manufacture of packaging, it should be noted that there is no manufacture of packaging in Finland that requires competent authority approval, therefore the inspection of such packaging relies heavily on the approval prepared by the country of origin or another ADR country.

Inspections of individual transports focus on the detailed requirements for the driver, transport unit, load to be transported, labelling, documentation, loading and the safe handling of the cargo. On the other hand, instead of individual transport, operators can be inspected in a larger sample size. A larger inspection of the transport operator will also provide better information on the safety culture and the basics of safe transport operations, starting with the management system and quality assurance programme. Training and refresher training are important inspection topics as well as the security plan and practices related to the use of a safety adviser. The scope of inspections can be defined in advance using a checklist. The draft inspection report is most often used as a checklist. If necessary, more detailed transport checklists can also be used.

Inspection during operation

Inspections can be scheduled with the operator in advance, or they might be performed more dynamically as an unannounced inspection. A special feature of the inspections of transport operations is that some of the inspections must be carried out in co-operation with the Police, Customs and the Border Guard. In some cases, the inspection of transport operations can also be carried out together with the Finnish Transport and Communications Agency, especially in inspections of transport chains connecting different modes of transport. If STUK needs the above-mentioned authorities to support it during the inspection, it will do so by submitting a request for official assistance. In some cases, the inspection of the transport of radioactive material is, for example, an independent inspection by the Police or Customs, where STUK acts as expert support. Inspections may take the form of documentary checks or on-site inspections. During on-site inspections, the inspector will also interview the personnel performing the work in addition to the supervisors or responsible persons. In most cases, STUK carries out inspections of transport operations by an individual inspector. If it is necessary to use measuring equipment at the site, the inspection may also be carried out by several staff members, considering possible official assistance from another authority. The inspector must have sufficient skills for the mode of transport in question. This is ensured by STUK's internal training. In addition, some staff members must have completed ADR driving licence training and, where possible, be qualified as a safety adviser.

Administrative actions and follow up

After each inspection, a report is prepared, which is primarily a report on the content of the inspection. The inspection report must also be accompanied by the necessary decisions obliging the operator to bring its activities into line with the legislation. During the inspection, the subject of the inspection will be given the opportunity to express dissenting views if necessary. The hearing takes place on site during the inspection, where the main points to be recorded in the inspection report are discussed with the undertaking. The claims set out

in the decision always have a deadline. Monitoring is carried out, if necessary, by re-inspection and documentary inspection. The operator must notify STUK of the implementation of safety-related corrective measures. STUK may decide to suspend or restrict activities if the radiation activities do not comply with national legislation or may cause obvious health damage. Inspection results will be used to plan new priorities on inspection processes. They are also summarized annually and used to communicate with licensees to promote safe transport manners.

7.9 INSPECTION OF OCCUPATIONAL EXPOSURE

General

The principle of optimization is stipulated in SätL section 6 and the requirement to establish dose constraints and constraints for potential exposure are given in section 25. According to section 26, an undertaking shall carry out a safety assessment where they present measures to ensure radiation safety and the optimization of radiation protection.

The undertaking's safety assessment's appropriateness has been verified during the review and assessment process for authorization. During the inspection, the inspector verifies that the undertaking follows the procedures as presented in the safety assessment for the practice.

SätL section 22 stipulates 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.

If during the inspection it is found that there are deficiencies in radiation safety, and appointed radiation safety officers or other experts are unable to correct them, then the licensee is reminded of their prime responsibility for radiation safety. Additionally, the licensee can be ordered to correct the action. As stipulated in SätL section 178, STUK may decide on the discontinuation or restriction of the practice if the practice fails to comply with legislative requirements or may cause obvious health detriment.

The explanatory memorandum of SätL states in Section 22 that*: It is the responsibility of the undertaking to provide the necessary radiation safety measures and workers must not be given, nor are workers justified in demanding, any benefits to compensate for safety, such as special pay, insurance schemes, reduced working hours, days off, holidays or pension arrangements*. The fulfilment of this requirement is verified by discussions during the inspection.

Radiation protection and implementation of special arrangements for pregnant workers and underage persons is verified in inspections. SätL section 100 stipulates that once a worker has notified the undertaking of her pregnancy or that she is breastfeeding a child, the foetus should be protected in a manner equivalent to the protection of a member of the public. This is further clarified in VnA section 41, which requires that, when a woman has announced her pregnancy, her work shall be arranged so that the equivalent dose for the foetus is as low as reasonably achievable, nor shall it exceed 1 mSv for at least the remainder of the pregnancy.

In addition, a worker who has announced that she is breastfeeding a child, should not be involved in work, which poses a risk of ingestion or contamination.

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.

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.

SätL section 99 requires that: *A radiation worker must be at least 18 years of age. The radiation protection of an apprentice or student must be organized in the same manner as the radiation protection of a worker engaged in the radiation practices. A minor apprentice or student, who must be under the age of 18 but at least 16 years of age, may only engage in the use of radiation sources to the extent that it is necessary for their education and training and the related work exercise. They may not, however, be classified in category A or assigned to an equivalent task.*

Nuclear safety

Monitoring the radiation safety of nuclear power plants is part of the inspection of the operational safety of a nuclear power plant. The periodic inspection programme is described in section 7.2 (Inspection of Nuclear Power Plants).

Guide YTV 3.c.4 (Radiation Safety) describes the procedures for inspection of radiation safety at nuclear power plants. The criteria for the inspection are presented, for example, in STUK's YVL Guide C.2 Radiation protection and exposure monitoring of nuclear facility workers.

The objective is to ensure that the total radiation exposure of both workers and the public from the use of a nuclear power plant is kept as low as reasonably achievable (ALARA). In addition, radiation exposure at individual level is kept well below the dose limits.

Inspections include the following topics, among others:
- Operation of the radiation protection organization
- Radiation protection training
- Radiation protection guidelines
- Radiation conditions-based area and zone classification of a nuclear facility
- Radiation work permit
- Radiation work categories and medical surveillance of radiation workers
- Monitoring of radiation exposure
- Reporting radiation doses to the dose registry

Radiation safety

Guide SKV 3.4 In-service supervision of radiation activities requiring a safety authorisation and its Annex 2 Issues to be covered by inspections gives general guidance on issues that should be covered by inspections. Regarding occupational exposure, Annex 2 states that an inspector should verity that:
- the classification of workers performing radiation work in categories A and B is correct
- personal dose monitoring and monitoring of exposure conditions are satisfactorily organised
- the health surveillance of workers exposed to radiation is monitored and a radiological occupational physician is available to monitor the health of category A workers

- sufficient radiation meters and alarms suitable for the activity are available
- sufficient radiation protection and other protective equipment are available for staff
- working methods are such that the radiation exposure of workers can be kept as low as reasonably practicable
- occupational exposure results are systematically monitored and a procedure is defined to address and correct the situation if exposure exceeds the predicted level
- training, instruction and refresher training in the use of the equipment are provided
- work areas are appropriately divided into control and monitoring areas

The main requirements for occupational exposure are given in SätL sections 88 to 108.

According to the SätL section 3, the basis for the occupational health and safety and protection of workers is in the Occupational Safety and Health Act (OSH) (738/2002), which in section 15 requires, for example, that employers provide personal protective equipment, auxiliary equipment and other devices for use. In addition to OSH, SätL, section 23 requires an undertaking to organize the practice in such a way that it meets the requirements provided in SätL and that radiation safety deviations are prevented with adequate effectiveness and that their consequences are as insignificant as possible.

Occupational exposure to natural radiation

Compliance with requirements on existing exposure situations, such as occupational radon and NORM exposure, is mainly done through document inspections by STUK, which is described in Guide VALO 7. An employer shall investigate the radon concentration in a workspace or other place of work if the facilities are located as described in SätL section 155. Based on SätL sections 145, 146 and 151, NORM-involving industries must assess the exposure of workers prior to the commencement of work. These requirements are enforced by sending reminders to the employers or relevant companies about their obligation. Targeted surveys and requests for reporting are used in order to increase awareness of the companies/licensees of the requirements in SätL. The results of the regulatory control activities are reported in STUK's annual report, online (e.g. Workplace radon concentrations in Finland - stuk-en - STUK) and in the public diary (Julkinen diaari - STUK).

7.10 INSPECTION OF MEDICAL EXPOSURE

STUK prepares an inspection programme for inspections of activities requiring a safety licence, as prescribed in Chapter 7. The inspection programme may also include inspections based on surveillance questionnaires and on information and data from the undertaking, which do not include a visit to the site of the activity. Inspections can also be carried out to verify the completion of various phases activities such as the verification of the shielding of facilities or of the dosimetric accuracy of the treatment of equipment before it is used to treat patients.

The inspection of practices involving medical exposures is considered in STUK's management system guides:

- Guide SKV 3.4, In-service supervision of radiation activities requiring a safety authorisation (general guidance)
- Guide SKV 4.1, X-ray in healthcare
- Guide SKV 4.2, Nuclear medicine
- Guide SKV 4.3, Radiation therapy

The aim on in-service supervision is to ensure that undertakings operate safely and comply with legal requirements. This goal can be achieved not only through inspections but also through guidance and advice to the undertaking. Methods with the application of a graded approach for in-service supervision include

- Communications/media
- Surveillance questionnaire
- Request for clarification
- Onsite inspection (announced and unannounced)
- Reactive inspection
- Repeated inspection
- TLD dosimetry postal quality audit in intraoral radiology

The guidance on issues that must be covered at inspections is given in Guide SKV 3.4 Annex 2 Issues to be covered by inspections. Regarding medical exposure, it is written that an inspector must verify that:

- the undertaking has procedures in place to ensure that a justification assessment is carried out
- exposure from the activity is optimized
- the responsibilities of the referring doctor or dentist are defined
- the responsibilities of the doctor or dentist responsible for medical exposure are defined
- necessary medical physicist expertise and resources are available and used as required
- 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.

The calibration of sources and the dosimetry of patients are considered to be part of undertakings' quality assurance. Regarding quality assurance, Guide SKV 3.4 Annex 2 requires that the inspector verity that:

- there is a quality assurance programme for the activity, radiation sources and equipment related to the activity in accordance with section 30 of SätL and that it is being followed
- the activity complies with Chapter 5 of STUK Regulation STUK S/5/2019 (*Quality assurance measures relating to radiation sources*)

Annexes 4.1 to 4.3 of Guide SKV guidelines set out procedures and checklists on how to inspect different types of medical practices and medical devices. Here are examples of Guide SKV 4.1 annexes:

- Annex 1 Inspection of X-ray activities
- Annex 2 Inspection of screening activities
- Annex 3 Inspection of computer tomography
- Annex 4 C-arm inspection
- Annex 5 Inspection of fluoroscopy practices
- Annex 6 Plain X-ray equipment - measurement procedure
- Annex 7 Mammography equipment - measurement procedure
- Annex 8 Fluoroscopy X-ray machine - measurement procedure
- Annex 9 Computed tomography equipment - measurement protocol
- Annex 10 Panoramic tomography or dental X-ray CT equipment - measurement protocol
- Annex 11 Equipment and room specific data
- Annex 12 Patient dose collection for plain X-ray equipment
- Annex 13 Patient dose collection for mammography equipment
- Annex 14 Inspection report (template) - first inspection
- Annex 15 Inspection report (template) - periodic inspection
- Annex 16 Extremity CBCT device - measurement protocol

- Annex 17 Inspection of installation, maintenance, repair and testing of radiation equipment (list of questions to be asked during the inspection)

Guides SKV 4.1-4.3 are under revision. The guides will be merged into a single Guide SKV 4.1 (In-service supervision of radiation activities in healthcare).

Regarding radiation safety deviations (unintended medical exposure), Guide SKV 3.4 Annex 2 stipulates that the inspector must verify that, in accordance with the nature and extent of the activities, the undertaking has assessed the main risks associated with the activities and that procedures are in place to deal with radiation safety deviations that adequately address these risks. Also, the inspector must verify that the undertaking's plan in the event of a radiation safety deviation is in accordance with STUK Regulation S/2/2018.

The fulfilment of requirements for health professionals with responsibilities for medical exposure are checked during inspections. Applicable requirements are given in SätL as follows: section 33 (Training and induction of workers), section 38 (Qualifications of a medical physicist expert) and section 47 (Radiation protections skills in medical use of radiation). In the Decree of the Ministry of Social Affairs and Health on ionizing radiation (1044/2018), additional requirements are given: section 5 (Qualifications and competence of workers engaged in medical use of radiation) and section 9 (Qualifications of a physician or dentist responsible for medical exposure).

The basic requirements regarding the justification of medical exposure are given in SätL sections 109 (Justification assessment concerning medical exposure) and 101 (Justification of medical exposure in special circumstances). More detailed requirements are given in STUK S/4/2019 sections 2 to 4. As part of regulatory oversight, in 2019 and 2020 STUK examined the implementation of the conditions, i.e. guidelines and practices supporting the justification, for the justification of X-ray examinations at different sites. The report on the Implementation of the conditions for the justification of X-ray examinations: Healthcare surveillance report is available at: Röntgentutkimusten oikeutusarvioinnin edellytysten toteutuminen: Terveydenhuollon valvontaraportti (julkari.fi). Additionally, in 2021 STUK coordinated the assessment of the development of the referral guidelines for the Ministry of Social Affairs and Health. The final report of the working group for the Ministry of Social Affairs and Health, the report A Preliminary assessment of the development of the referral guidelines (STUK-B-273) is available at: Esiselvitys säteilylaissa tarkoitettujen lähettämissuositusten kehittämistä varten.

Justification assessment concerning the medical exposure of a foetus or breastfed child is a special focus of inspections. The regulatory requirement for these is given in STUK S/4/2019 section 4. Undertakings' conformity with requirements is typically verified by open discussions or by a review of their written procedures.

The basic requirements for optimization of medical exposure are stipulated in SätL section 112. Additional requirements are given in regulation STUK S/4/2019 sections 5 to 9. During inspection, the undertaking is asked to explain and show evidence of how it meets the optimization requirement (e.g. optimization of the radiation protection of medical exposure in children and breastfeeding individuals). STUK has carried out a study on the implementation of optimization in nuclear medicine imaging: Optimization in nuclear medicine imaging: Healthcare surveillance report:

In the inspections, the inspector shall verify that the undertaking has employed the diagnostic reference levels as stipulated in SätL section 112, for the purpose of optimizing radiation protection in medical exposure resulting from examinations and procedures. Diagnostic Reference levels are given in STUK Regulation STUK S/4/2019 annexes:

- 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

SätL section 25 stipulates that the undertaking shall establish dose constraints and constraints for potential exposure. The verification of the establishment of these constraints is done during authorization. During the inspections, it is verified that undertakings' procedures are such that exposure from the practice are below the set constraints. An example of this is the verification of the appropriateness of procedures for the release of patients who have radioactivity in their body due to medical treatment or procedure.

7.11 INSPECTION OF PUBLIC EXPOSURE

Nuclear safety

The inspection of discharges from nuclear power plants is part of the inspection of the operational safety of a nuclear power plant programme described in section 7.2. Guide YTV 3.c.4 (Radiation Safety) includes the procedures for inspecting limitation and the monitoring of radioactive releases from a nuclear facility. The objective is to ensure that the radiation exposure arising from the operation of a nuclear facility is kept as low as reasonably achievable. A nuclear facility and its operation shall also be so designed that the constraints specified in YEA are not exceeded.

Inspections include the following topics
- Release limits in the Operational Limits and Conditions (document review)
- Assessment of the target values for releases (document review)
- Radiation monitoring systems and equipment (document review, interviews, on-site observations)
- Release measurements, radiation levels and dose analyses (document review, interviews, on-site observations)
- Environmental radiation monitoring (document review, interviews, on-site observations)
- Repairs and modifications to the radiation monitoring systems and equipment (document review, on-site observations)
- Auditing the steps taken by the licensee to ensure reliable measurements

Radiation safety

Responsible parties' obligations regarding public exposure are explained in chapters *5.11 Authorization issues for public exposur*e and *6.11 Review and assessment for public exposure.*

The availability of personnel, qualifications and training of inspectors (training records) are defined in STUK's management system. The authority of inspectors is explained in Chapter 7.1 Generic issues.

Information on how STUK prepares and conducts inspection programmes and how inspections are carried out is explained in chapters 7.6 Inspection of radiation sources, facilities and activities and 7.10 Inspection of medical exposure. The inspection methods and procedures are similar to those for the inspection of public exposure.

The guidance on issues that shall be covered at inspections are given in the Guide SKV 3.4 Annex 2 Issues to be covered by inspections. Regarding radioactive waste, discharges and public exposure, it is stated that the inspector shall verify that:

- the practice is in accordance with Chapter 6 of STUK S/5/2019 (Decommissioning of radiation sources and operating facilities)
- appropriate records are kept of radioactive substances and radioactive waste that are decommissioned
- decommissioned radioactive substances and radioactive waste are not stored unnecessarily
- radioactive discharges from the operation are monitored in accordance with the conditions of the licence and that the quality assurance of the equipment used for monitoring is ensured.

Additionally, the inspector shall verify that radiation meters used to monitor public exposure are fit for purpose, have appropriate calibration and quality control has been performed as required.

When carrying out the on-site inspection, the inspector shall verify that the practice is in line with the safety assessment. Regarding public exposure, this means that inspector assesses the methods and procedures that the undertaking is using for the optimization of public exposure to achieve radiation protection goals, i.e. that doses from the practice are below dose constraints and constraints of potential exposure.

Consumer products

The in-service supervision of consumer products is done by market surveillance. Regarding public exposure, SätL 57 stipulates that 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). If a consumer product may cause significant detriment to health, the regulatory authority may also prohibit a legal or natural person other than the undertaking referred to in section 56 of SätL from manufacturing, importing, exporting, transferring, placing on the market, offering, keeping for sale, selling or otherwise handing over the product.

Graded approach in inspection of facilities and activities

The in-service supervision of undertakings is conducted in a risk-informed manner. Regarding public exposure, practices have been categorized as stipulated in VnA 1034/2018 section 16. Additionally, undertakings are obligated to establish dose constraints and constraints of potential exposure. The radiation exposure category of public exposure and constraints on public exposure can be used as indicators of public exposure risk. On-site inspections are focused on practices where the risk of public exposure is greatest.

Existing exposure situations

The inspection of remedial actions and protective actions in case of existing exposure situations is mainly done using a document review process by STUK. The inspection procedure related to natural radiation regulatory control by STUK is described in guides VALO 7.2 (Construction products) and VALO 7.7 (NORM), which are updated annually.

Public exposure to indoor radon in dwellings and other premises used by people, as well as radioactivity in household water are the responsibility of the local health protection authority and are supervised by Valvira.

7.12. CONCLUSIONS AND ACTIONS

Based on self-assessment and analysis, Finnish legislation and STUK's inspection process are in line with IAEA requirements concerning both the nuclear facilities and radiation practices. However, some areas for improvement have been identified.

On a general level, STUK has enough resources and these resources are fit for all necessary inspections. STUK can also obtain the necessary additional resources from approved inspection organizations for compliance inspections of the design and manufacture of the mechanical components and structures of nuclear facilities.

Inspections systematically and regularly cover all areas relevant to safety. The periodic inspection programme covers different phases of the life cycles of nuclear facilities as it contains specific inspection programmes for the construction, commissioning and operation phases.

- As areas for improvement, *the following items were listed in the initial action plan* for Module 7. Regarding Nuclear Facilities (YEL): STUK should develop a qualification programme for persons responsible for periodic inspections included in the programme.
- STUK should establish appropriate processes and methodologies to evaluate, control and enforce SätL provisions on licensee safety culture.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESSES

The procedures used in the enforcement of regulatory requirements are based on the mandate of the regulatory authorities given in legislation. Most enforcement tools and measures of STUK are provided in Chapter 10 of YEL and Chapter 20 of SätL.

STUK's enforcement policy and procedures are presented in Guide STUK 3.1 on a general level and in more detail in Guide YTV 5.a and Guide SKV 3.7. The choice of applied procedure is determined case-by-case based on the safety significance of the situation or matter in question, following the principle of a graded approach. The guides mentioned above take into account the Administrative Procedure Act (434/2003), for example section 6, which states that the acts of an authority shall be impartial and proportionate to the objectives sought and shall protect expectations that are legitimate under the legal order. In addition to administrative enforcement measures, it is possible to obtain assistance from police authorities in a situation where STUK interrupts an activity or limits it based on acute safety reasons (sections 67 and 68 of YEL and section 179 of SätL).

In certain cases, the act may also fulfil the characteristics of a radiation offence or an offence punishable under the Criminal Code (39/1889) under the criminal reference provision of SätL. 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. The prosecutor must request a statement from STUK before bringing a prosecution for an offence under SätL section 185.

All binding decisions can be appealed, either to STUK (e.g. a decision made by an individual inspector) or directly to the Helsinki Administrative Court. The written appeal shall be sent to Helsinki Administrative Court within 30 days of notification of the decision.

STUK ensures that the licensee effectively implements the remedial actions raised from the enforcement actions through document control, reporting, within the periodic inspection programme, inspections presupposed by STUK's YVL guides and SKV guides or other inspection activities.

Nuclear Facilities (YEL)

Enforcement measures enacted in sections 66 and 67 of YEL are: a conditional fine, a threat that the activity be interrupted or limited, and a threat that the work be done at the cost of the negligent organization.

In the most severe cases, the authority that has granted a licence may cancel it wholly or partially, if implementation of the general principles for the use of nuclear energy as laid down in YEL is essentially endangered (section 26 of the Nuclear Energy Act).

The applicable procedures in situations, which have minor safety significance are an oral notice and a request for action by a protocol made by the inspector. A written notice and an order for action by STUK's decision are used if there are factors aggravating the seriousness of the situation or matter.

Coercive measures are used to reinforce STUK's order by a conditionally imposed fine, a threat to interrupt or limit the operation or to have the neglected obligation fulfilled at the expense of the neglecting party.

The most often used enforcement is STUK's decision setting requirements on the licensee. In the decision, the nature of the deficiency is stated and a time limit is set for the required measures and for the implementation of the remedial actions.

Radiation practices (SätL)

The duty to carry out commensurate enforcement actions based on a graded approach when supervising compliance with obligations is mandated in SätL, section 11. When supervising compliance, 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 measure may have on the reduction of risks and the improvement of radiation safety.

The most important enforcement actions are (order here is based on the ascending sections of SätL):

- STUK may withdraw a radiation safety expert's approval or prohibit him/her 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).
- If STUK has exempted a practice from the need for a safety licence, 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 licence (section 53).
- STUK may withdraw the approval of other radiation measurements if the conditions for the approval are not met, if there are material deficiencies in the measurements or if the practice otherwise fails to meet the requirements laid down in this act and the deficiencies are not remedied within a prescribed period of time despite a request to do so (section 65).
- STUK or an individual inspector may obligate an undertaking to remedy its 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 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 an obligation to present documents.

STUK may also use the rights given in the Act on the Market Surveillance of Certain Products (1137/2016) when enforcing the sales of radiation sources for both occupational and public exposure (for example, sources used in industry as well as consumer products).

STUK may prohibit a legal entity or natural person from manufacturing, importing, exporting, transferring, placing on the market, offering, keeping for sale, selling or otherwise handing over a product that may cause significant detriment to health.

In addition to STUK's enforcement actions, the operator has the responsibility to remedy non-compliances on its own. These responsibilities include the implementation of such measures to improve radiation safety as can be considered justified in terms of their quality and costs as well as their improving impact, and the maintaining of an up-to date quality assurance system and safety assessment.

8.2. ENFORCEMENT IMPLEMENTATIONS

Nuclear facilities (YEL)

The applied procedures in non-compliances, which have minor safety significance are an oral notice and request for action through a protocol made by the inspector. An 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).

A 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 an oral notice could be used.

The use of a written request for action procedure has been limited to just a few cases in recent years. In most situations, an oral notice has been effective in handling minor deficiencies.

In case of more serious deficiencies, enforcement actions are implemented with a written decision by STUK. Through such a decision, STUK may require the 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 installation, for example: the installation must be shut down, the installation must not be started up or its power level or similar restrictions changed, before STUK has dealt with a separate application by the licensee.

According to section 66 of YEL, STUK may intensify its order referred to in section 64 or 65 with a conditional fine (see 14.12.1990/1113). Other coercive measures legislated in YEL are a threat to interrupt or limit the operation or to have the neglected obligation fulfilled at the expense of the negligent party. However, a conditional fine has never been used as an enforcement action at nuclear facilities in Finland. The use of a section 67-based threat to suspend operation has always been adequate, so it has not been necessary to put impose conditional fines.

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 licensee/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.

Enforcement actions are included in the basic training process of STUK inspectors.

Examples of recent enforcement actions at Finnish NPPs:

- Remark by a STUK inspector
    - During the commissioning test runs of the new emergency diesel generator, a STUK resident inspector became aware that the plant supplier had implemented modifications to the EDG turbocharger's dead-end port without a proper modification procedure. The STUK inspector sent the licensee an email ordering it to suspend the test runs until the unauthorized temporary installations were removed. The licensee also had to present STUK with the measures to prevent similar incidents in the future.
- STUK requires a licensee to execute necessary changes in the structure and operation of a nuclear facility (section 64 of YEL)
    - STUK decision 5/G43JEF/2020, 7/G43JEF/2020
    - In March 2020, a serious non-conformance was detected in primary circuit pressure relief valves at Olkiluoto 3. There was a complete break in one PSRV station’s pilot valve spindle and cracks in two other redundant PSRV-stations. STUK required the licensee (TVO) and plant supplier (Areva) to initiate various actions to improve the quality of the pilot valves. One of the required actions was to carry out modification planning to improve the pilot valve with design solutions and material choices that were not sensitive to environmental impact and thus improved the performance of the safety relief valve.

Radiation practices (SätL)

It is the inspector’s duty to follow through any binding enforcement action. These duties are described in internal guidance, such as Guide STUK 3.1 and Guide 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 guides STUK 3.1 and SKV 3.7 (for the use of radiation, Guide SKV 3.7 also applies to exposure to natural radiation). A summary of the enforcement actions and their basis 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 becoming aware of a deviation or suspicion of such a deviation. Used when more detailed information is needed.
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.
Obligation to correct a non-compliance			
		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 there is reason to suspect that the operator will not otherwise correct the deviation.
Suspension or restriction of operations			When the activity is not in accordance with SätL or may cause obvious adverse health effects.
Revocation of a safety licence			When the conditions for granting a licence are not met or the licensee has repeatedly or essentially violated the conditions of the licence or the provisions or regulations issued pursuant to SätL.
Revocation of a decision to exempt a practice from a 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.

In all cases described above, information is stored in VASARA (the licence registry). This information is used later when planning future inspections or other control of undertakings, or when assessing the need for a reactive inspection or other supervision. If a practice subject to a safety licence has been engaged in without a safety licence, in addition to a possible sanction under section 185 of SätL, the regulatory charge or the proportion that has not been collected is charged to the undertaking with an increase of 50 per cent. The subsequent collection of an increased regulatory charge can be affected within three years of the beginning of the year following the calendar year during which the payment obligation would have commenced. For example, in 2021 in 14 cases an increased charge was collected from industry/research operators.

In the most severe cases, the Criminal Code of Finland (39/1889) also applies directly. The Criminal Code (39/1889) includes punishments for a health offence, careless handling and the possession of radioactive material. Other infringements in the Criminal Code (39/1889) include a work safety offence, damage to the environment and an environmental infraction. STUK has made some requests for the police to investigate the illegal possession of radiation sources.

8.3. CONCLUSIONS AND ACTIONS

There are enforcement provisions available for STUK under YEL and SätL and other relevant legislation. There is an enforcement policy in place, and the graded approach is included when considering the response to a non-compliance.

In general, STUK complies with the IAEA requirements. Enforcement provisions in nuclear facilities and radiation practices have been considered adequate and no needs to change them have been identified.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

Process for development of regulations and guides including consultations with stakeholders and the public

The principles, requirements and associated criteria for safety upon which regulatory judgements, decisions and actions are based are laid down in legislation, which includes acts, decrees and STUK regulations. The requirements are legislated via different legislative instruments as is required and guided by the Constitution.

According to the Legislative Drafting Process Guide provided by the Ministry of Justice, consultations are an integral part of the drafting process. After regulatory drafting, the draft Government bill is circulated to stakeholders for comments. This procedure is also usually observed when consultation with stakeholders has been part of the preliminary preparation and regulatory drafting steps. Government draft proposals are sent to the Finnish Council of Regulatory Impact Analysis in Finnish according to normal request-for-statement procedure and concurrently circulated for consultation.

When comments are requested, a draft government proposal, draft decree or draft regulation, a memorandum including the reasons for the decree or regulation and any other material necessary for understanding the contents of the proposed legislation are appended

to the request. It is recommended to use Lausuntopalvelu.fi, a service for responding electronically to official consultation. The request for comments is submitted to all known key stakeholders and published to afford other interested parties an opportunity to comment as well.

According to the guide, a minimum of six weeks and, in extensive projects, a minimum of eight weeks shall be reserved for issuing comments requested concerning proposed legislation. The period is longer if it partly or entirely occurs during the holiday season. The period may for justified reasons also be shorter than mentioned above. In that case, reasons for the duration of the period shall be stated in the request for comments as well as in the government proposal and the presentation memorandum of a decree or regulation.

Comments received through the different methods for consultation during the drafting process are written down in the project documents, for example in a report of a working group set up for the preparation, minutes of meetings or separate memoranda. In bill drafting, a summary of the consultation and the received comments is presented in the reasons for the government proposal.

The guide can be found at http://lainvalmistelu.finlex.fi/en/

STUK has issued an internal guide STUK 3.6, which concerns the drafting process of STUK regulations and YVL guides. STUK regularly updates regulations and guides based on advances in science and technology, the results of safety research and analysis of operational experience. The guide STUK 3.6 states that the up-to-dateness of STUK's regulations and guides shall be checked at least every five year and if needed the updating process should be started.

STUK's oversight departments are responsible for the up-to-dateness and appropriateness of the safety requirements contained in the regulations and guides, as well as for the process for preparing the regulations and guides. STUK's oversight departments are also responsible for participating in drafting and commenting on the IAEA safety standards and security guidance and standardization work.

The update plans of regulations and guides are included in STUK's oversight departments' annual planning process. In recent years, there have been overall renewal projects for regulations and guides, both in the area of use of nuclear energy and radiation practices and in emergency and existing exposure situations.

The preparation process of a STUK regulation or guide starts with the preparation of the work plan. The background to and needs for update of a new regulation/guide are presented in the work plan including changes in national legislation or international safety standards. Also, regulatory experience and expert opinions from different stakeholders are taken into account.

There are four phases in the preparation process for STUK regulations and YVL guides:

- Draft L1 is the working group's first version of the regulation or guide for internal comments
- Draft L2 is circulated for external comments
- Draft L3 takes into account the external comments and is presented for the steering groups of relevant departments
- Draft L4 is internally approved. In case of STUK regulations and YVL guides within the scope of YEL, it is submitted to the relevant STUK advisory committee. The draft is finalized after the advisory committee statements.

The preparation process includes internal commenting and external commenting by stakeholders. Public participation is made possible through the websites where the drafts for external commenting are available. This is done via a specific web page, lausuntopalvelu.fi (maintained by the Ministry of Justice). 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 and stakeholders have had the possibility to send comments through STUK's website.

Prior to issuing the regulations within the scope of YEL, STUK hears the views of the licensees, the advisory committee referred to in YEL section 56, MEAE, MI, ME and the rescue authorities, as well as other authorities to the extent necessary.

The same procedures apply to amending radiation safety related regulations and guides as presented above concerning nuclear safety. According to Section 199 of SätL, prior to issuing regulations under the act, STUK gives 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.

Procedures for updating guidance texts in the SAMMIO guidance service (concerning radiation safety) 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 by 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 policy relevance must always be approved by the director of the department of Radiation Practices Regulation. There can also be an external consultation of stakeholders. After 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 into Swedish (and in the future also into English). Documents of the guidance texts are also saved in the case management system SAHA.

Feedback from users of SAMMIO is considered when updating guidance in SAMMIO, for example in cases where the users need more accurate guidance in applying legislation.

Use of the graded approach

The Administrative Procedure Act (434/2003) section 6 requires that the acts of an authority be proportionate to the objectives sought. This applies to all activities of an authority such as regulatory oversight (subjects and means), administrative decisions, drafting legislation and issuing guidance.

The graded approach has also been implemented in legislation in SätL and YEL, so reaches accordingly lower-level legislation and guides.

Some examples on the use of the graded approach in SätL legislation and regulations are listed on the next page (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, for example, the risks associated with radiation exposure and radiation sources
SätL 32 §	The Radiation Protection Experts (RPEs) will be used/must 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 depends on the classification of doses (E/3/2/1).
VnA 1034/2018 24 §	The requirements of licensing of sealed sources depend on the activity (classification) of the source.
VnA 1034/2018 25, 26 §	Whether a change of a licensed practice requires an application (beforehand) or notification (in 2 weeks) depends either on the classification on the practice, or other safety-related issues.
VnA 1034/2018 58 §	The content of the inspection programme (as per SätL 182 §) must depend on, for example, classifications and the experience gained from the observations made in previous inspections.
STUK 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.
STUK S/2/2018 6 §	Some radiation safety deviations can be reported yearly
STUK S/9/2021	Security arrangements depend on the risks of the practice.
STUK S/5/2019 7 §	Safety arrangement requirements depend on the potential dose.
STUK S/5/2019 8 §	Additional requirements for industrial radiography, if the occupational exposure category is 1 or 2.
STUK S/5/2019 9 §	Additional requirements if the occupational or public exposure category is 1 or 2 due to potential exposure
STUK S/6/2019 2 §	A deputy STV must be appointed when the radiation exposure category is 1.
STUK S/6/2019 Chapter 3	Dose constraints depend, for example, on the exposure category.
STUK S/6/2019 13, 14 §	The scope and review frequency of the safety assessment depend on exposure categories.

In 2013, the principle of the 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”.

At 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 risk they pose. The Regulation on the Safety of a Nuclear Power Plant is also applicable to the handling and storage of spent nuclear fuel. The sections that are applicable to low-power research reactors are mentioned separately. There are separate STUK Regulations for the Safety of Disposal of Nuclear Waste and for the Safety of Mining and Milling Operations Aimed at Producing Uranium or Thorium. There are also STUK regulations for nuclear security and emergency arrangements.

Regulation STUK Y/1/2018 section 4 describes the principles for the safety classification of systems, structures and components based on their safety significance. It also states that "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).

The regulatory requirements related to risk-informed safety management by licensees also affect regulatory oversight and therefore also make the regulatory actions more risk-informed. For example, the regulatory requirements related to the use of the graded approach in the management system are introduced in STUK's YVL Guide A.3 "Leadership and management for safety". In STUK's YVL Guide 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 life-cycle 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.

Related to authority inspections for pressure equipment, mechanical components and structures, YEL section 60 a stipulates that the equipment most important to safety is inspected by STUK, and the other safety-related items are inspected by authorized inspection organizations. This division is also defined in YVL guides.

Review and updating of the regulations and guides

The continuous safety assessment and enhancement approach is presented in Finnish nuclear legislation. YEL states that 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 implementation of safety improvements has been a continuing process at both Finnish nuclear power plants since the commissioning of the operating reactor units. Very similar provisions are presented in SätL regarding radiation practices and have been implemented accordingly.

STUK regularly updates regulations and guides based on advances in science and technology, results of safety research and the analysis of operational experience. The revision of the regulation considers international guidance such as IAEA standards and WENRA (Western European Nuclear Regulators' Association) safety reference levels. If there is no immediate need for corrections or updates (e.g. EU directives, new international requirements or the updating of pertinent national legislation) there are criteria in STUK's management system guidance (STUK 3.6) for the review and updating of the regulations. 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 of preparing the regulations and guides, the preparation and commenting of the IAEA guidelines and

standardization work. The Legal section is responsible for the legal aspects of the regulations and the renewal process of acts and decrees in STUK.

STUK has a system for periodic review and update of regulations and guides. Each regulation and guide shall be evaluated five years after publication. In recent years, there have been overall renewal projects of regulations and guides both in the area of use of nuclear energy and radiation practices.

The status of the regulations and regulatory guides is considered in the annual work planning and budgeting process. The preparation process includes internal hearings, external hearings of stakeholders and a review by STUK's relevant advisory committees. Public participation is made possible through the website of STUK or a specific web page, lausuntopalvelu.fi (maintained by the Ministry of Justice) where the drafts for external hearings and all the regulations are available, or by sending a specific request for comments from a chosen group of stakeholders.

Regulations and guides as a framework for the regulatory requirements and conditions

All legally binding legislative instruments (acts, decrees and regulations) are accompanied by rationales that further elaborate on their purpose and guide 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 memoranda of the issuer for decrees and regulations. The rationales are available publicly, most of them online.

STUK has issued such rationales (explanatory memorandums) for its own regulations. STUK has also had a strong influence on the rationales in Government's proposals and decree memoranda due to its participation in their development and its 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 to it in acts of Parliament. According to the Constitution of Finland (731/1999) section 80, 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 decree. The scope of such authorization shall be precisely circumscribed in an act. As a result of this, there is no general authority for STUK to issue regulations. STUK's authority to issue binding regulations is precisely defined both in YEL and SätL.

Guides are not legally binding. STUK, and the authorities in general, have authority to issue guidance in the field of their statutory tasks without special legal authorization.

In the field of nuclear energy, there are YVL guides that are issued by STUK. These guides do not perfectly fit the separation of legal rules and recommendatory guides. YVL guides have elements of both categories. New or updated YVL guides are applied as such to new facilities without a construction licence. Specific implementation decisions are issued to apply new or updated YVL guides to operating facilities or facilities under construction. The structural reform is planned when renewing YEL and the related regulations and guides. The need of revision of YEL is partly due to the dual function of YVL guides. The requirements included in the YVL guides are converted to legislation according to the requirements and guidance of the Constitution.

In the field of radiation safety and security, there are SätL, the Radiation Decree, and STUK's regulations. STUK has established a web-based regulatory and guidance service "SAMMIO" for radiation legislation. With this service, anyone can search for requirements from different levels of legislation and STUK regulations. The search result includes the individual requirement, its rationale and further guidance including STUK's expectations on its practical application. As it is an electronic 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. The ST guides are based on the old SätL (592/1991) that was repealed in 2018. The ST guides can be used as guides to the extent that they do not contradict the new SätL and subsequent legislation. The old ST guides are not legally binding.

Regulations and guides reflect IAEA safety requirements and best practices

STUK regularly updates regulations and guides based on advances in science and technology, the results of safety research and the analysis of operational experience. Legislation in Finland and STUK regulations and regulatory guides are regularly checked for compliance with international standards and recommendations (mainly EU, IAEA and WENRA). It is primarily the responsibility of STUK to undertake the appropriate screening and propose appropriate modifications or to implement the latest international developments. STUK regulations and YVL guides are benchmarked against IAEA requirements and WENRA reference levels.

Finland is a member of the EU and thus Euratom regulations, directives and decisions are followed in Finland. EU directives are implemented through Finnish legislation. EU Commission and Council regulations are directly applicable. STUK participates actively in the preparation of safety standards and recommendations of international organizations such as IAEA, ICRP, WHO, UNSCEAR, ILO, WENRA, OECD/NEA and of standardization organizations like IEC, CEN and ISO. International standards and recommendations are also used as references when preparing the Finnish safety requirements on nuclear and radiation safety (see above).

Finland is also a party to all relevant international conventions and agreements. These conventions and agreements are implemented through Finnish legislation.

Regulations and guides addressing specific authorization topics

This topic is discussed in chapters 9.2.–9.11.

Regulations and guides addressing all planned and existing exposure situations

This topic is discussed in chapters 9.2.–9.11.

Regulations and guides on specific review and assessment topics (Probabilistic Safety Analysis, Periodic Safety Review, Operating Experience Feedback, Severe Accident Management, ...)

This topic is discussed in chapters 9.2.–9.11.

Regulations and guides related to inspection and enforcement

According to the Constitution section 2, the mandate for an authority to inspect and enforce shall be prescribed in parliamentary acts. The legal basis for inspections, enforcement and coercive measures is in legislation (e.g. SätL, YEL, the Administrative Procedure Act and Act

on Conditional Fines). Guidance on practical implementation can be found in the internal guidelines such as STUK 3.1 and the guides of oversight departments.

Promotion of regulations

All regulations are published on STUK's website and the Finlex database. The publication of regulations is governed by the Act on Collections of Regulations of Ministries and Other State Authorities (189/2000). The department of Radiation Practices is in the process of reviewing its communication methods and priorities. Based on this work, the promotion of regulations will be enhanced. STUK also organizes events for licensees and other stakeholders to inform them about the new regulations.

STUK has published a web-based legislation, regulation and guidance service for licensees and other undertakings (sammio.stuk.fi). SAMMIO contains SätL and all decrees and STUK regulations issued under SätL. The service allows users to make searches by type of radiation practice, topic areas and free search words and to save the results of individual searches. The search results are shown as cards which include provisions, their rationales and further guidance on each provision. The guidance is being updated and supplemented continuously. Users of SAMMIO can send feedback to STUK, for example about the content.

STUK also has an internal database for YVL guide requirements, which has been used in the update of YVL guides and when making implementation decisions on how new or updated YVL guide requirements are implemented at operating nuclear facilities or facilities under construction. Each YVL guide requirement has also been given a set of attributes, which can be used for example to search different sets of requirements. This database with attributes has been shared with licensees so that they can use the information in database format for their own purposes. A similar database will be used in the overall renewal of regulations and guides. Added value will also be the links between different levels of legislation, regulations and guides since the structure and hierarchy will be changed in the renewal.

STUK sees these database tools for legislation, regulations and guides as good practice enhancing the systemic approach in renewal work and consistency in regulatory control.

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

The system of safety requirements for nuclear facilities (and NPPs in particular) as contained in legally binding documents (acts, decrees and regulations) and other STUK documents (YVL guides in particular) forms a basis for regulatory review and assessment, and subsequently for issuing authorizations. Safety requirements are also used as a basis in inspections and enforcement.

By virtue of section 7 q of YEL, STUK is authorized to issue more specific regulations on the technical details of the principles and requirements laid down in Chapter 2 a of the act. STUK has issued the following regulations for nuclear power plants under this authorization:

- Radiation and Nuclear Safety Authority Regulation on the Safety of Nuclear Power Plants (STUK Y/1/2018)
- Radiation and Nuclear Safety Authority Regulation on Emergency Arrangements of a Nuclear Power Plant (STUK Y/2/2018)
- Radiation and Nuclear Safety Authority Regulation on the Security in the Use of Nuclear Energy (STUK Y/3/2020)

- In addition, there is one regulation (STUK Y/4/2018) for disposal facilities and one regulation (STUK Y/5/2016) for mining and milling operations.

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 i.e. YVL guides.

There are 46 YVL guides in force and they have been organized into five topical areas:
- Safety Management of a nuclear facility
- Plant and system design
- Radiation safety of a nuclear facility and environment
- Nuclear materials and waste
- Structures and equipment of a nuclear facility.

Updates of three (STUK Y/1/2018, STUK Y/2/2018 and STUK Y/4/2018) out of five STUK regulations based on YEL 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 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 is pending the renewal of YEL.

After amending the nuclear safety legislation in 2008, the revision of all YVL guides was commenced to reflect the enhanced safety requirements and a new set of YVL guides was published in 2013. Since the renewal of YVL guides in 2013, nearly all IAEA Safety Requirements documents have been revised (for instance, due to the TEPCO Fukushima Dai-ichi accident IAEA updated several requirements documents). The updated WENRA Safety Reference Levels for Existing Reactors taking into account the lessons learnt and the insights from the EU stress tests were published in autumn 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, the new requirements of Council Directive (2014/87/Euratom) amending Nuclear Safety Directive (2009/71/Euratom NSD Directive) and BSS Council Directive (2013/59/ Euratom, EU BSSD) were also reviewed and their impact on Finnish nuclear safety regulations assessed.

The YVL guide update work began in 2017 to address the changes referred to above. In most of the YVL guides, only minor changes were needed and they are mainly clarifications. The update work was completed in February 2021. When the update of YVL guides was planned, a separate memorandum was prepared about the updates in IAEA safety standards after 2013 that should be taken into account in the updating work. Each YVL guide-specific work plan identified the needs for that particular guide. Each YVL guide has a specific rationale document (explanatory memorandum), which is published together with the updated guide. This memorandum describes the related international standards and their implementation in the guide (variations in the level of details in different guides).

During 2020, STUK participated in a work group steered by Finland´s Ministry of Economic Affairs and Employment (MEAE) on the development of the regulation of the life cycle of nuclear facilities. As a result, a final report was published, and in this report, the work group concluded that initiating overall nuclear energy legislation reform is necessary. This need partly arises from the lack of clarity in current legislation, but it is also caused by changes in the operating environment such as interests in deploying small modular reactors in Finland. Also, in 2020 the Constitutional Committee of Parliament required the Government to assess the legislation as a whole in relation to the reformed Constitution. In 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 aim of the renewal of the nuclear safety regulations and guides issued under YEL (990/1987) is to emphasize the licensee's responsibility, to focus the oversight based on risk-informed methods, and to make a clear difference between recommendations and binding requirements. The renewed binding requirements should be more goal-oriented, risk-informed and enabling different approaches, also taking into account the potential use of new technologies in Finland such as small modular reactors (SMRs). The project plan for the renewal was approved in January 2022. The overall renewal of both nuclear energy legislation and STUK's regulations and guides requires STUK's expertise and dedicated resources, and the Government should ensure adequate resourcing through STUK's budget.

Section 3 of STUK Y/1/2018 describes how the fulfilment of requirements related to safety is demonstrated. The safety of a nuclear facility shall be assessed when applying for a construction licence and operating licence in connection with plant modifications and at Periodic Safety Reviews during the operation of the plant. The safety assessment shall cover all operational states and possible accidents at the plant. In addition, safety shall be assessed after accidents and based on nuclear safety research, whenever necessary. There are requirements related to the safety design of a nuclear power plant in Chapter 3 of STUK Y/1/2018 and the STUK's Guides YVL A.1, A.3, A.5, A.6, A.7, A.11, A.12, B.2, B.3, B.4, B.5, B.6, B.7, B.8, C.1, C.3, C.4, C.6, E.6, E.7, E.10 and E.11. Guide YVL B.1 sets out requirements for the design of a nuclear power plant and systems important to safety, and specifies requirements in more detail than the design requirements set forth in STUK Y/1/2018. According to STUK's Guide YVL B.1 requirement 314, each design and implementation stage shall be reviewed before the stage is declared complete.

Section 11 of STUK Y/1/2018 defines requirements for safety functions. It covers requirements for design basis accidents, design extension conditions and severe accidents. It also includes reliability and failure tolerance requirements. More detailed requirements are presented, for example in STUK's Guide YVL B.1, B.3 and B.6. Section 9 of STUK Y/1/2018 defines requirements for the defence-in-depth principle. According to the defence-in-depth principle, a nuclear power plant shall be designed using multiple, successive mutually redundant structures and systems in order to prevent reactor damage and the detrimental effects of radiation. The 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. Safety functions in accordance with the defence-in-depth principle shall be based on five successive levels of protection: levels one and two are designed to prevent accidents, whereas the remaining levels are designed to protect the plant, its operators and the environment from the adverse effects of accidents. More detailed requirements are presented in STUK Guide YVL B.1.

Regulatory requirements and guidance on operation are described in Chapter 5 of STUK Y/1/2018 and in many YVL guides (at least YVL A.1, A.3, A.4, A.5, A.6, A.7, A.8, A.9, A.10, A.11, A.12, B.8, C.2, C.3, C.5). Guide YVL A.6 covers more detailed requirements on Operational Limits and Conditions, the monitoring of safety performance, operating procedures, accident management, modifications, maintenance, testing, surveillance and inspections. Designing plant modifications are mainly covered in STUK Guide YVL B.1. Requirements for personnel qualification and training are covered in sections 7 i, k and m of YEL, section 25 in STUK Y/1/2018 and STUK Guide YVL A.4. Requirements related to monitoring and control of activities performed by vendors, contractors and suppliers are covered in section 25 of STUK Y/1/2018 and STUK Guides YVL A.3 and A.5.

9.3. REGULATIONS AND GUIDES FOR RESEARCH REACTORS

The regulation for research reactors in principle follows the same legal and regulatory infrastructure as the regulation for power reactors (YEL section 3 “Obligations arising from activities requiring licensing”, YEA 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 paragraph 3 defines what requirements are applicable to research reactors i.e. pool-type research reactors with a maximum thermal output of 250 kW:

- Section 2 Definitions
- Section 3 Demonstration of compliance with safety requirements
- Section 4 Safety classification
- Section 5 Ageing management
- Section 6 Management of human factors relating to safety
- Section 7 Limitation of radiation exposure and releases of radioactive substances
- Section 8 Site safety
- Section 9 Defence-in-depth
    - 9(1)
    - 9(2)(1), (2) and (5)
    - 9(3), (4) and (5)
- Section 10 Engineered barriers for preventing the dispersion of radioactive substances
    - 10(1) and (2)
    - 10(3) subparagraph (a)
    - 10(3) subparagraphs (b)(i), (ii), (iv) and (v)
- Section 11 Safety functions and provisions for ensuring them
    - 11(1), (2) and (3)
- Section 12 Safety of fuel handling and storage
    - 12(2), (3), (4) and (5)
- Section 13 Safety of handling and storage of radioactive waste
- Section 14 Protection against external hazards affecting safety
- Section 15 Protection against internal hazards affecting safety
- Section 16 Safety of monitoring and control
    - 16(1), (2) and (3)
- Section 17 Taking the decommissioning into consideration in the design
- Section 18 Safety of construction
- Section 19 Safety of commissioning
- Section 20 Safety of operation
- Section 20 a Safety of decommissioning
- Section 21 Taking operating experience and safety research into consideration in order to improve safety
- Section 22 Operational limits and conditions
- Section 23 Condition monitoring and maintenance to ensure the safety of the facility
- Section 24 Radiation measurements and monitoring of releases of radioactive substances at a nuclear facility and estimation of radiation doses to the public and workers
- Section 25 Ensuring safety by management, organization and personnel
- Section 27 Transitional provision.

Section 7 a of YEL enables the use of the 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”. YVL guides are applied

to research reactors as appropriate (there are no specific YVL guides for research reactors) and defined precisely in STUK's implementation decisions. Risk significance and the life-cycle phase of a research reactor is taken into account when implementation decisions of revised YVL guides are prepared.

In Finland, there is only one research reactor (FiR1), which was commissioned 50 years ago and has entered the decommissioning phase. The plan is to start reactor dismantling in late 2022. The spent fuel has already been removed from the facility. There are currently no plans to build new research reactors in Finland.

9.4. REGULATIONS AND GUIDES FOR FUEL CYCLE FACILITIES

The Radiation and Nuclear Safety Authority Regulation on the Safety of a Nuclear Power Plant (STUK Y/1/2018) and Regulation on the Safety of Disposal of Nuclear Waste (STUK Y/4/2018) set out requirements concerning the handling, packing and storing of spent nuclear fuel and facilities performing these functions.

Specific guidance on spent fuel storage facilities is given in Guide YVL D.3 (17.3.2020), which contains references to various YVL guides that concern nuclear power plants. These YVL guides are valid for fuel facilities applying the graded approach principle. Guide YVL D.3 defines the primary requirements so as to meet the safety objectives for handling nuclear fuel and the storage thereof, including the safe management of spent nuclear fuel. These objectives concern:

- The prevention of criticality and damage to the fuel;
- Ensuring adequate cooling; and
- Ensuring that handling operations may not lead to load drops that may jeopardize the safety-related systems, components and structures of the facility.

The requirements for uranium extraction facility are set in the regulation on the Safety of Mining and Milling Operations Aimed at Producing Uranium or Thorium (STUK Y/5/2016). Mines and milling plants intended for the fabrication of uranium or thorium are not defined as nuclear facilities in YEL section 3 subsection 1 paragraph 5 a, due to the small amount of radioactive material handled in the facility and regulation for this facility is much lighter and simpler than for nuclear facilities.

The licensing of a uranium extraction facility is performed according to YEL section 21 (Other use of nuclear energy), which states that a licence 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.

Only two YVL guides are applied to the facility; Guide YVL D.1 concerning safeguards and YVL Guide D.2 concerning transport.

9.5. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

Spent fuel and Nuclear Waste

STUK Regulation on the Safety of Disposal of Nuclear Waste (STUK Y/4/2018) applies to the disposal of spent nuclear fuel and other nuclear waste at nuclear facilities to be constructed in bedrock and facilities constructed underground. The regulation is also applicable to nuclear facilities intended for the handling and storage of spent nuclear fuel and other nuclear waste that are not part of a nuclear power plant and of which the amount of spent nuclear fuel at any given time is not more than 100 tonnes of uranium. The regulation also applies to radioactive waste if it is handled or stored at a nuclear facility or disposed of in a disposal facility for nuclear waste.

Provisions on the handling and storage of spent nuclear fuel and other nuclear waste in a nuclear facility attached to a nuclear power plant or a separate nuclear facility, in which the amount of spent nuclear fuel at any given time is more than 100 tonnes of uranium, intended for the processing of spent nuclear fuel, are laid down in the Radiation and Nuclear Safety Authority's Regulation on the Safety of a Nuclear Power Plant (STUK Y/1/2018).

More detailed requirements for waste management are set in following YVL guides

- 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 a spent nuclear fuel disposal facility (13.2.2018)

Radiation practices

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. The undertaking must attach a safety assessment to the safety licence application and estimate in it the doses from discharges and radioactive waste to the public. The undertaking must keep a record of discharges as prescribed in SätL section 127. More detailed regulations are given in STUK S/2/2019 section 6.

It is possible to apply the Environmental Protection Act (527/2014) or Waste Act (646/2011) when the waste contains so little radioactive material that it is not radioactive waste within the meaning of SätL. Solid waste with activity levels of natural radioactive substances below the clearance levels in STUK SY/1/2018 may be treated in accordance with the Waste Act. Waste generated by activities exposing to natural radiation is not radioactive waste in accordance with SätL, even if the concentrations of natural radioactive substances are higher than the clearance levels. In this case, however, STUK's approval is required for the final disposal of the waste, even if it is not radioactive waste within the meaning of SätL. The manner of disposal is first selected in accordance with the Environmental Protection Act and Waste Act, and then the expected doses to workers and the public are estimated. The criterion for STUK's approval is that the perquisites for exemption from a safety licence defined in SätL and VnA 1034/2018 are fulfilled.

According to SätL section 54, an undertaking must provide 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.

Interface and consistency of YEL and SätL requirements on waste management

Provisions for nuclear waste management are set down in YEL. Radiation Act (SätL) sets provisions for radioactive waste management. The ministries (MEAE and MSAH) are (correspondingly) responsible for the development and maintenance of the legislation.

MEAE steers the general planning and implementation of nuclear waste management originating from nuclear facilities. MSAH has the supreme authority and highest directing power in supervising compliance with SätL.

Mining activities relevant to radiation protection may be licensed under SätL or YEL, depending on whether the process involves uranium extraction. This could possibly lead to different requirements for waste management even if the waste is similar.

Similarly, radiation sources, radioactive waste, various items that require decontamination and radioactive process samples could be regulated under SätL or YEL depending on whether radioactive material that is defined as nuclear material is present.

The Government and STUK should ensure that laws and regulations provide impartial safety provisions for radioactive waste from different origins (use of radiation and use of nuclear energy). The requirements could be harmonized as part of YEL reform. STUK should evaluate regulatory oversight practices on different areas and harmonize when unjustified difference is identified.

More details on the provisions for the decommissioning of facilities and the management of radioactive waste and spent fuel can be found in Chapter 1.7.

9.6. REGULATIONS AND GUIDES FOR RADIATION SOURCES APPLICATIONS

STUK has issued, for example, the following regulations that include issues for radiation source facilities and activities:

Radiation and Nuclear Safety Authority Regulation on exemption levels and clearance levels	STUK SY/1/2018
Radiation and Nuclear Safety Authority Regulation on a plan for radiation safety deviations and actions during and after radiation safety deviation	STUK S/2/2018
Radiation and Nuclear Safety Authority Regulation on the in-service radiation safety of radiation sources and on the decommissioning of radiation sources and facilities	STUK S/5/2019
Radiation and Nuclear Safety Authority Regulation on practices requiring a safety license	STUK S/6/2019
Radiation and Nuclear Safety Authority Regulation on measurements of ionizing radiation	STUK S/7/2021
Radiation and Nuclear Safety Authority Regulation on the security arrangements for radiation sources requiring a safety license	STUK S/9/2021

In addition to regulations and SAMMIO.stuk.fi, old ST guides (based on the repealed SätL 592/1991) are available on STUK's website and can be used as guidance if they are not inconsistent with current legal rules.

Radiation and Nuclear Safety Authority Regulation on exemption levels and clearance levels

This regulation includes exemption and clearance values for a limited number of radionuclides (not all listed in GSR Part 3 or the European BSSD). However, all the radionuclides that were used in Finland were included on the list. When the 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.

Also, a clearance level is given for surface contamination.

Radiation and Nuclear Safety Authority Regulation on the security arrangements for radiation sources requiring a safety licence

This regulation sets the security arrangement requirements for all radiation devices, including X-ray generators (used in, for example, industrial radiography). Required security arrangements are divided into three categories in line with IAEA SSS No. RS-G-1.9 and are based on either the total activity or the properties of a mobile X-ray device. Guidance for practical arrangements is given according to IAEA NSS 14 and IAEA NSS 11.

Radiation and Nuclear Safety Authority Regulation on the in-service radiation safety of radiation sources and on the decommissioning of radiation sources and facilities

This regulation includes the following requirements for:

- Premises where radiation sources are used and stored
- In-service acceptability criteria of radiation sources
- Information and notifications concerning radiation sources as well as documentation of radiation sources
- Quality assurance actions related to radiation sources
- Removing radiation sources and installations from use

There are also 12 appendices that give further requirements for:

1) Activity values of high-activity sealed sources;
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;
8) Information to be presented in the documentation for high-activity sealed sources;
9) Information to be presented in the notification on the receipt, transfer and possession of radiation sources;
10) Information to be presented in the notification on transport requiring a safety licence;
11) Intervals of quality assurance actions in X-ray operations, nuclear medicine and veterinary medicine;

12) Quality assurance actions of radiation sources in industrial use.

Further guidance on the implementation of these requirements is found in public section-specific rationale available, for example, at sammio.stuk.fi.

9.7. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

The basic requirements concerning the safe use of nuclear energy are set out in YEL and section 7 g provides general safety requirements for the decommissioning of a nuclear facility. According to section 33 of YEL, a nuclear facility is considered decommissioned when the Radiation and Nuclear Safety Authority (STUK) has confirmed that the quantity of radioactive materials remaining in the buildings and soil of the facility site complies with the requirements specified under this act.

The STUK Regulation on the Safety of a Nuclear Power Plant (STUK Y/1/2018) applies to the decommissioning of a nuclear power plant. The STUK Regulations on Security in the Use of Nuclear Energy (STUK Y/3/2020) and on the Emergency Arrangements of a Nuclear Power Plant (STUK Y/2/2018) apply to the decommissioning of a nuclear facility. The STUK Regulation on Exemption Values and Clearance Levels (STUK SY/1/2018) applies to the clearance from regulatory control of solid materials.

Guide YVL D.4, Predisposal management of low and intermediate level nuclear waste and decommissioning of a nuclear facility (15.12.2019), sets out the basic requirements for planning and implementing the decommissioning of a nuclear facility and for the sorting, processing, storage, activity determinations and record-keeping of the waste arising from decommissioning (hereinafter the processing and storage of decommissioning waste). The guide also addresses the clearance of nuclear waste, including recyclable material, arising from the operation and decommissioning of a nuclear facility, as well as the clearance of a decommissioned nuclear facility. It discusses the clearance procedures and the activity determination and record-keeping of the materials to be cleared.

Several other YVL guides issued by STUK are also applicable to the processing and storage of operational waste and to the decommissioning of nuclear facilities, and Guide YVL D.4 contains references to these applicable guides.

The decommissioning of facilities for radioactive sources is regulated in SätL section 83 and regulation STUK S/5/2019, Chapter 6.

The cleaning of the facilities requires a safety licence if the amount of radioactive substances prior to the cleaning is greater than the clearance level. The licensee must draw up a plan for the decommissioning. The contents of the plan are described in section 34 of regulation STUK S/5/2019 and are based on IAEA guidance (IAEA GSR Part 6, Requirement 11: Final decommissioning plan). Chapter 6 gives requirements for the following:

1) The ageing of radioactive material
2) The transfer of a sealed source to another operator
3) The decommissioning of contaminated facilities and activated structures and materials.

Clearance levels for radioactive materials and surface contamination are given in the STUK regulation on exemption levels and clearance levels STUK SY/1/2018.

9.8. REGULATIONS AND GUIDES FOR TRANSPORT ACTIVITIES

The Ministry of Transport and Communications is responsible for the development of legislation and requirements for the transport of all dangerous goods. The requirements of SSR-6 are incorporated into national regulations, which are based on the ADR, RID, IMDG Code and ICAO-TI. In the Act on the Transport of Dangerous Goods (719/1994), STUK is defined as the competent authority for the transport of radioactive materials. STUK oversees radioactive material transport in cooperation with the Police, Customs, Border Guard and the Defence Forces.

The Nuclear Liability Act (484/1972) applies to the transport of nuclear materials and nuclear waste. Nuclear liability is addressed in STUK Guide YVL A.1. STUK grants the licences for nuclear material and nuclear waste transports and, for these, a licence is needed with some exceptions (section 17 of 161/1988) for small quantities.

The requirements for the planning and assessment of security arrangements are set out in the Act on the Transport of Dangerous Goods and Nuclear Safety Authority Regulation on the Security in the Use of Nuclear Energy (STUK Y/3/2020).

Regulatory requirements for the transport of nuclear material and nuclear waste are given in Guide YVL D.2, Transport of nuclear materials and nuclear waste (15.5.2019). The requirements and procedures of the guide apply to nuclear material and nuclear waste transport in the Finnish territory as well as to vessels registered in Finland and transporting nuclear material or nuclear waste to or from Finland once they enter international waters/airspace. In international transport, the regulations valid in the countries of departure, transit and destination apply.

STUK has published two guides on the transport of radioactive material (non-nuclear radiation sources):

- Transport of Radioactive Material (based on ADR 2012, to be updated in 2022 or after the new Act on the Transport of Dangerous Goods has been published)
- Security Arrangements in the Transport of Radioactive Material (2015)

The transport of high-active sealed sources requires a safety licence (SätL section 4 and 48) and each consignment needs to be notified to STUK in advance. Annex 11 of regulation STUK S/5/2019 sets the information to be given in the notification.

The IAEA transport guidance documents are available on the STUK website; they have not been translated into Finnish or Swedish.

The Ministry of Transport and Communications is currently drafting an amendment to the Act on the Transport of Dangerous Goods.

9.9. REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE

In Finland, all basic requirements for the protection of workers are given in acts and decrees but not in regulations as in some other countries. Therefore, the relevant requirements in acts and decrees are also summarized below.

The basic requirements concerning protection of workers including limiting and assessing occupational exposure are set out in

- SätL Chapter 1 (General principles of radiation protection: justification, optimization, dose limitation), 4 (dose register), 5 (training and induction of workers, safety assessment, establishment of dose constraints), 12 (protection of workers in radiation practices), 16 (protection of workers in emergency exposure situations)17 (protection of workers in existing exposure situations) and 18 (occupational exposure to natural radiation)
- Government Decree on Ionizing Radiation (1034/2018) Chapters 2 (optimization of protection), 3 (dose limits), 7 (protection of workers in radiation practices), 9 (establishment and use of reference levels for occupational exposure in emergency exposure situations)
- STMA (1044/2018) Chapter 3 (supplementary training of workers), 5 (reference levels for existing exposure situations) and chapter 6 (reference levels for exposure to natural radiation)
- STUK regulation STUK S/1/2018 on the investigation, assessment, and monitoring of occupational exposure
- Regulation S/3/2019 on practices causing exposure to natural radiation.

Rationale for the aforementioned and further guidance are given in SAMMIO.

Occupational exposure in radiation practices and in the use of nuclear energy

The provisions of SätL on the protection of workers in radiation practices are also applied to the use of nuclear energy as detailed in Section 2 a of YEL.

The responsibilities of an undertaking and employer for the protection of workers in radiation practices in Chapter 12 of SätL include:

- The undertaking and employer of an outside worker are responsible for the radiation protection of their workers. Outside workers must have a level of protection equal to the undertaking’s own workers.
- Investigation obligation: in practices requiring a safety licence, the radiation exposure of workers and means to reduce it must be assessed before starting the work.
- Radiation workers must be classified into category A or B.
- The controlled areas and supervised areas of working areas must be identified and differentiated.
- Radiological surveillance of controlled areas and supervised areas must be conducted on a regular basis.
- The results of the radiological surveillance and individual monitoring must be recorded and followed regularly. Workers must be provided with the results of the individual monitoring concerning them, without delay.
- Medical surveillance must be carried out for category A radiation workers, and special medical surveillance if the dose limit has exceeded
- Prohibition to assign radiation work if the worker is unfit for the task and prohibition to dismiss

- A radiation worker must be at least 18 years of age. A minor apprentice or student (under 18 but at least 16 years of age) may only engage in the use of radiation sources to the extent necessary for their education and training and the related work exercise.
- During pregnancy or breastfeeding a child, the foetus and breastfed child must be protected in a manner equivalent to the protection of a member of the public.
- The information from the individual monitoring of category A radiation workers must be delivered to the workers' dose register on a regular basis. If the individual monitoring of category B radiation workers has been carried out by a dose measurement service, the information must be delivered to the dose register regularly, including for category B workers.
- Workers' duty to participate in the investigation of radiation exposure.

Chapter 5 of SätL contains further requirements for the protection of workers and assessing occupational exposure, including:
- the undertaking shall establish dose constraints and constraints for potential exposure;
- the undertaking shall carry out a safety assessment: identification and assessment of exposures, measures for the optimization of the protection and prevention of potential exposures.
- the undertaking shall ensure that radiation safety instructions concerning workers' tasks and other documents pertaining to workers' radiation safety are available to them;
- requirements on the training and induction of workers as well as supplementary training.

More detailed requirements for the provisions of SätL are given in VNa 1034/2018, including the numerical values for the dose limits.

STUK regulation S/1/2018 sets out the technical requirements for the investigation, assessment, and monitoring of occupational exposure, including:
- investigating and assessing the occupational exposure in advance (before starting a radiation practice;
- arrangements for radiological surveillance;
- determination of surface contamination;
- determination of individual dose, arrangements for individual monitoring in case of external and internal exposure;
- use of alarming devices
- transfer of information to the national dose register.

Occupational exposure in emergency exposure situations

Requirements for the protection of emergency workers and helpers are given in Chapter 16 of SätL and requirements for the establishment and the use of reference levels for occupational (and public) exposure are given in Chapter 9 of VNa 1034/2018. In emergency exposure situations, the aim is to carry out protective actions in such a way that occupational (and public) exposure remain below the reference level. Chapter 16 of SätL contains further requirements on the protection of workers and helpers in emergency exposure situations, including:
- designation of emergency workers in advance;
- radiological surveillance;
- medical surveillance;
- training and guidance.

Occupational exposure in existing exposure situations

Requirements for protection of workers in existing exposure situations are included in SätL Chapter 17 and requirements for the establishment and use of reference levels for

occupational (and public) exposure are given in Chapter 5 of STMa 1044/2018. 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 reference level for occupational exposure in an existing exposure situation is 1 mSv/y (STMA 1044/2018 section 16). A safety licence is required for protective actions in existing exposure situations if occupational exposure is higher than the reference level. In this case, all the provisions for occupational exposure in radiation practices apply.

Occupational exposure to natural radiation

The strategy for protection against occupational exposure to natural radiation, including radon in workplaces, is provided by SätL Chapter 18, VNa 1034/2018 Chapter 11, STMA 1044/2018 Chapter 6, and STUK regulation S/6/2022.

The reference levels for occupational exposure to natural radiation other than radon is 1 mSv/y (STMA 1044/2018 section 22 and 23). The reference levels for radon in workplaces set in the STMA 1044/2018 section 19 are:

- radon concentration in workplaces and buildings with public access: 300 Bq/m3
- occupational exposure of radon: 500,000 Bq h/m3/year.

Based on SätL section 147, exposure must be limited if it can exceed the reference level.

Based on SätL sections 145, 146 and 151, NORM-involving industries must assess the exposure of workers prior to the commencement of work.

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) in 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.

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).

Individual monitoring for radon exposure is based on measurements approved by STUK. The approval is based on SätL section 64. The requirements are given in SätL section 59 and more detailed requirements in STUK S/7/2021.

Based on SätL section 148, a safety licence is required if the occupational exposure to natural radiation, radon concentration in workplace or radon exposure of a worker will exceed the reference level despite limiting measures. In case of NORM industries and similar activities, this means that all the provisions on the protection of workers in radiation practices apply. The same also applies in the case of radon in workplaces and occupational exposure of aircraft crew to cosmic radiation but, in these cases, there are some exceptions to the requirements regarding, for example, the classification of workers, as well as on the practical means to monitor individual doses.

9.10. REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE

In Finland, all basic requirements for medical exposure are given in acts and decrees but not in regulations as in some other countries. Therefore, the relevant requirements in acts and decrees are also summarized in the below.

The division of responsibilities and obligations of health professionals in medical exposure is prescribed in sections 113–116 of SätL and the undertaking's responsibility for using a medical physics expert is prescribed in section 32. The use of medical physics expert is regulated in more detail in VnA 1034/2018 section 20.

The obligation to use diagnostic reference levels is set out in section 112 of SätL and the diagnostic reference levels are issued in STUK regulation on justification assessment and optimization of radiation protection in medical exposure (STUK S/4/2019) appendices 1–7. There are diagnostic reference levels for patients' radiation exposure in the computed tomography of adults, nuclear medicine, paediatric computed tomography, the cone-beam computed tomography of adults' head region, cardiology, conventional X-ray and conventional paediatric X-ray examinations.

Section 10 of VnA 1034/2018 provides for the optimization of a comforter's radiation protection. The criteria for the release of patients after radionuclide therapy are issued in VnA 1034/2018, section 11. The release is subject to a dose constraint established by the licensee in accordance with section 25 of SätL (the dose constraint shall be presented to STUK in the safety assessment of the practice or separately). The dose constraint for an individual taking part in medical research is stipulated in VnA 1034/2018 section 9. The use of dose constraints is also clarified in SAMMIO.

Training, education and competence in specialized areas are regulated in STMA 1044/2018 sections 5 and 9 and annex 4 in more detail.

The conditions of radionuclide treatment or other medical exposure are regulated in the STUK regulation on justification assessment and optimisation of radiation protection in medical exposure (STUK S/4/2019) sections 5, 6, 8 and 9.

Measures to minimize the likelihood of unintended and accidental exposures are regulated in STUK 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.

Periodic radiological reviews at medical radiologic facilities are issued in SätL section 118 and STMA 1044/2018 sections 11 and 12. Radiological facilities are required to have many different records based on regulations. These are covered in more detail in the self-assessment for medical exposure question 9.1.

Information given by the licensee to the person subject to medical exposure about the benefits and risks are regulated in SätL section 113 and 114. A physician or dentist giving the referral must ensure that, prior to the performance of the examination, procedure or treatment, 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 justification and optimization of medical exposure is regulated in SätL sections 5, 6, 109–112 and in more detail in the STUK regulation on justification assessment and optimization of radiation protection in medical exposure (STUK S/4/2019) sections 2–4 and 7.

According to SätL section 119, the estimated radiation dose for a foetus, and information about the examination, procedure or treatment relevant in terms of the radiation exposure must be recorded in the health records. More detailed regulations are issued in the STUK regulation on justification assessment and optimisation of radiation protection in medical exposure (STUK S/4/2019) sections 4, 6 and 8.

9.11. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE

In Finland, all basic requirements for the protection of members of the public are given in acts and decrees but not in regulations as in some other countries. Therefore, the relevant requirements in legislation are also summarized below.

The basic requirements concerning the protection of members of the public including limiting and assessing public exposure are set out in

- SätL Chapter 1 (basic principles: justification, optimization of protection, dose limitation), 5 (safety assessment, establishment and use of dose constraints), 10 (prohibition of use of radioactive substances in certain products, consumer products), 11 (clearance of materials, decommissioning of sources and facilities), 14 (non-medical imaging exposure), 15 (public exposure in radiation practices), 16 (public exposure in emergency exposure situations), 17 (public exposure in existing exposure situations), 18 (public exposure to natural radiation)

And more detailed requirements are given in:

- VnA 1034/2018 Chapter 2 (justification of a practice, optimization of protection), 3 (dose limits), 8 (provision of information and requesting consent in non-medical human imaging), 9 (establishment and use of reference levels in emergency exposure situations), 10 (national plan for the identification of existing exposure situations, plan for and implementation of protective actions in existing exposure situations), 11 (practices which require the investigation of public exposure to natural radiation, contents of national radon action plan)
- STMA 1044/2018 Chapter 5 (establishment and use of reference levels in existing exposure situations) and Chapter 6 (establishment and use of reference levels for natural radiation)
- Regulation STUK S/2/2019 on radioactive waste and discharges of radioactive substances in the use of unsealed sources
- Regulation STUK S/6/2019 on practices requiring a safety licence
- Regulation STUK S/6/2022 on practices causing exposure to natural radiation.
- Regulation STUK SY/1/2018 on exemption values and clearance values
- Health Protection Act (1994/763) section 27.

Further guidance and rationale for the binding requirements are given in legislation, and regulations are given in the SAMMIO database.

Public exposure from radiation practices

Dose limits for public exposure arising from radiation practices are regulated in VnA 1034/2018 Chapter 3. The values of the dose limits are the same as those in IAEA GSR Part 3.

Optimization of protection of members of the public in radiation practices and the establishment and use of dose constraints are regulated in SätL sections 6, 9, 10, 25, 123, 127 and 128. STUK regulation S/6/2019 states that the dose constraint for public exposure is

0,1 mSv unless a greater value is justified based on the safety assessment. However, a dose constraint exceeding 0,1 mSv is not allowed for release into the sewer system, bodies of water, the air or for the re-use, recycling, utilization or final disposal of materials arising from a practice. Optimization of protection shall be demonstrated in the safety assessment.

According to SätL 126, an 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.

According to SätL 127, 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.

Section 128 of SätL states 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, in which radiation measurements and determinations of radioactive substances determine the pre-operational environmental radioactivity status. Regulation STUK S/6/2022 on practices causing exposure to natural radiation gives more detailed requirements about the baseline environmental radioactivity study.

Requirements for external exposure and contamination in areas accessible to members of the public are set out in SätL sections 126 and 138. Provisions on the cleaning of areas, facilities and structures used in the practice are laid down in section 83.

Sections 84 and 85 of SätL provide for the clearance of material from radiation practices. The clearance values are given in STUK regulation SY/1/2018. The clearance criteria for clearing material on the basis of STUK's decision in individual cases are prescribed (based on a reference in section 84) in section 50 of SätL and section 28 of VnA 1034/2018. Both clearance values and clearance criteria are consistent with those in the IAEA GSR Part 3.

Public exposure from nuclear facilities

According to YEL section 7 c, STUK shall observe and monitor the environment of a nuclear installation to the extent necessary to ensure the reliability of measurements of discharges of radioactive substances, and to verify the environmental impact of the installation. Requirements for radiological monitoring of the environment of a nuclear facility are given in Guide YVL C.7. Chapter 3 gives the requirements for an environmental baseline study and Chapter 4 the requirements for environmental radiation surveillance. Chapter 5 gives requirements for reporting the results of environmental monitoring. Chapter 6 of Guide YVL C.7 gives requirements for the applicant or licensee concerning what documents on the contents of the monitoring programmes shall be submitted to STUK for review and approval. Regulatory oversight and approval of the environmental monitoring programmes and their results are discussed in Chapter 7.

In addition to aforementioned, licensee reporting requirements are also discussed in guides YVL C.3, YVL C.4 and YVL C.7 in YVL A.9. The contents and reporting period for environmental radiation safety reports are given in Chapter 3.4. The regulatory oversight of the reports is discussed in Chapter 4 of YVL A.9.

STUK publishes a summary of the results of licensees' 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). Licensees' full reports are available on request.

Consumer products and commodities

Regulations on consumer products and commodities are set out in SätL sections 68, 69 and 153.

The deliberate mixing or adding of a radioactive substance to consumer goods and the import, export and transfer of such consumer goods to Finland are subject to a safety licence. However, it is prohibited to use radioactive substances in foodstuffs, animal feed, cosmetic products, jewellery and other equivalent personal accessories, toys and in the tracer tests carried out in water supply systems, the water of which is used as household water. The same requirements also apply to goods where the increase of radioactivity derives from activation.

According to SätL section 153, any party that manufactures, imports or transfers a construction product, 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. The provision of the information and instructions is subject to Article 11, paragraph 6 of the Construction Product Regulation (EU Regulation 305/2011/Euratom). The Finnish Safety and Chemicals Agency (Tukes) supervises the labels, and STUK supervises compliance with the reference level of the public exposure. The two authorities cooperate in their supervision.

Public exposure existing exposure situations

An undertaking from whose practice an existing exposure situation arises is responsible for investigating the radiation exposure arising from it, for carrying out the protective actions and for cleaning the areas, facilities and structures used in the practice, and the environment, of radioactive substances.

However, according to SätL section 139, the State has a duty of care for 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; 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 (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 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).

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 remains below the set reference level. The reference levels for existing exposure situations are set in STMA 1044/2018 chapters 5 and 6.

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.

Public exposure to natural radiation

Regulations on radon indoors are set out in SätL Chapter 18 (sections 155–159), VnA 1034/2018 section 54, STMA 1044/2018 Chapter 6 (sections 19–21), and STUK S/6/2022 Chapter 5 (sections 15–24). According to SätL section 19, STUK maintains a register of the radon concentrations in dwellings, other premises used by people and workplaces. Sections 159 of SätL and 54 of VnA 1034/2018 provide for the establishment of the national radon action plan (NRAP) to control exposure to radon indoors, which was published in 2020.
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 other 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 factors 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)

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) provides that the adverse effects on indoor air quality from radon and other gases and impurities that are detrimental to health and comfort shall be prevented with structures and/or actions that are applicable to the project under design. The code 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 has been completed. Section 5 of the Decree of the Ministry of the Environment on the Indoor Climate and Ventilation of New Buildings (1009/2017) provides that indoor air may not contain physical factors (incl. radon) hazardous to human health. Building Information Ltd. has published guidelines for radon prevention in new construction (Rt 103123, 2019)
Requirements for responsibilities and requiring justification and optimization of remedial actions and protective actions in existing exposure situations and on reference levels for existing exposure situations are set out in SätL Chapter 17 (sections 138–142), VnA 1034/2018 Chapter 10 (sections 49–51), and STMA 1044/2018 chapters 5 and 6 (sections 15–26).

NORM-involving industries (SätL sections 145, 146, 151) also constitute existing exposure situations in Finland. For these industries, the responsibility of exposure assessment and limitation of doses lies with the industry where NORM is formed, used, handled, stored or disposed of (SätL sections 146, 147). If licensing is required (SätL section 148), the industries are regulated as radiation practices.

9.12. CONCLUSIONS AND ACTIONS

The legal framework for the use of radiation is based on the EU BSSD and GSR Part 3. STUK has a mandate to issue binding regulations based on SätL and YEL. Regulations needed for the use of nuclear energy and radiation are in place. In addition, the current system includes YVL guides for the use of nuclear energy. Regulations and guides are renewed as necessary via public consultation.

In conclusion, the requirements 32–34 in GSR Part 1 are complied with. However, there is still room for improvement. Accordingly, the following actions have been identified:

Actions

- Overall renewal of both nuclear safety legislation and STUK's regulations and guides requires STUK's expertise and dedicated resources, and the Government should ensure adequate resourcing through STUK's budget (will also be presented in Module 1).
- Project plans for STUK's renewal of STUK regulations and YVL guides and for MEAE's renewal of YEL and the decree should also consider the issues identified as opportunities in Module 5.
- Security Arrangements in the Transport of Radioactive Material (2015) should be updated according to the latest IAEA guidance (IAEA Nuclear Security Series No. 9-G (Rev. 1))
- Further guidance should be issued on the transport of radioactive material based SRR-6 and its complementary guides.
- Internal guidance on writing guidance text for the process of maintaining and updating SAMMIO should be further developed; the level of detail to give guidance on must be further specified
- The exemption/clearance levels for all the radionuclides in GRS Part 3 are not regulated. This can lead to an unnecessary regulatory burden when a licence would be required (e.g. Lu-176 as a calibration source)
- Not all the radionuclides are listed for a HASS-limit.
- There is no communication plan for the promotion of regulations and guides for operators.
- The introduction of notification or registration in the scope of SätL in line with graded approach should be considered.
- Internal guidance should be strengthened to further use graded approach in, for example, the authorization of radiation practices
- The Government and STUK should ensure that laws and regulations provide impartial safety provisions for radioactive waste of different origins (use of radiation and use of nuclear energy).
    - The Government and STUK should harmonize requirements as part of YEL renewal
    - STUK should evaluate regulatory oversight practices on different areas and harmonize when unjustified difference is identified.

Good practices

- STUK sees database tools (SAMMIO and Polarion) for legislation, regulations and guides as good practice, enhancing the systemic approach in the renewal work and consistency in the regulatory control.
- There are security requirements for radiation generators as well as radioactive material. This could be considered as Good Practice/Performance

10. BASIC PRIMARY RESPONSIBILITIES OF TH REGULATORY BODY (RB) IN EMERGENCY

10.1. AUTHORITY AND RESPONSIBILITIES FOR REGULATING ON-SITE EPR OF OPERATING ORGANIZATIONS

In Finland, STUK has a clear role as a national regulator for safety, security and safeguards at nuclear facilities. This integration into one single regulator has clear advantages.

STUK has in practice sole responsibility for the regulation and supervision of the emergency arrangements of operating organizations. However, in addition, regional emergency services are responsible for the preparation of external rescue plans for NPP sites concerning rescue actions in an emergency. These plans are approved by the State Regional Administrative Agency (AVI). STUK is entitled to take part in the planning and to give its expert opinion on the plan before its approval. STUK's authorities and responsibilities concerning the regulation and supervision of EPR arrangements are based on the Nuclear Energy Act.

10.2. REGULATIONS AND GUIDES ON ON-SITE EPR OF OPERATING ORGANIZATIONS

STUK has issued a set of requirements and guides that are baseline requirements. Operating organizations are fully devoted to bearing their responsibilities in case of emergencies. Their own initiatives for continuous improvements add value to existing requirements.

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.

Regulation STUK Y/2/2018 "Radiation and Nuclear Safety Authority Regulation on the Emergency Arrangements of a Nuclear Power Plant" gives the binding regulations. The Regulatory 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 threat caused by a nuclear accident at the facility or during transport.

10.3. VERIFYING THE ADEQUACY OF ON-SITE EPR OF OPERATING ORGANIZATIONS

Over the years, STUK has provided well-established regulation and inspection functions that cover EPR topics as part of regular oversight. Exercises, continuous improvements and learning from experiences are part of our regulatory culture.

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 fresh nuclear fuel is delivered to the site, the emergency arrangements shall be sufficient. Before 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 take part in the planning and evaluation work of the emergency exercises.

10.4. ROLES OF THE RB IN A NUCLEAR OR RADIOLOGICAL EMERGENCY

STUK's main role is to provide recommendations for protective actions in radiological and nuclear emergencies. This role is stipulated under section 46 of Rescue Act. In addition, STUK's responsibilities cover notifying, warning and reporting exceptional radiation situations and analyzing the safety significance of the situation. STUK also has an important informal role concerning communications towards the public.

Individual authorities have their own responsibilities during radiological or nuclear emergencies. For example, regional emergency services are in charge of the protection of the population while restrictions concerning traffic and the consumption of food and water are divided into several different authorities at different administrative levels. The current legislative framework is fragmented into separate laws appointing individual organizations or authorities. A coordinated structure for emergency response is therefore not clear.

10.5. CONCLUSIONS AND ACTIONS

STUK has established very strong regulatory requirements and oversight functions in order to verify that operating organizations are well-prepared for any emergencies. There is strong Finnish tradition to cooperate across administrative sectors and between the public and private sectors in preparedness and response functions. This tradition is manifested in day-to-day activities during the preparedness phase, and this is then put into practice in any real emergencies. We see, however, major room for improvements regarding response to complex threats cutting through the whole of society that may jeopardize effective response in radiological or nuclear emergencies. National co-ordination also needs updated legislation to achieve better co-ordination between different authorities on national, regional and local levels.

11. INTERFACE WITH NUCLEAR SECURITY

11.1. LEGAL BASIS

Finland has diverse legislation (laws, decrees, regulations and YVL guides) that takes into account nuclear safety, security, safeguards and interfaces between them. STUK as a "3S or one house authority" supervises all the nuclear and radiation legislation that the licensee must comply with. Legislation is revised on a regular basis to meet the changes in the operating environment. The last revisions of requirements entered into force in 2020-2021 (YEL as amended, STUK regulation on nuclear security and YVL guides (objective binding requirements) for physical security (A.11) and cyber security (A.12)). For example, a

licensee's security organization can now detect and respond to a drone (RPAS) threat based on the amended Nuclear Energy Act. STUK cooperates between different authorities and, as for nuclear security, there are sections in YEL and in Guide YVL A.11 that obligate the licensee to cooperate with authorities (such as the police), both in training and during a threat. Also, the commanding stakeholder in such events is defined in the Nuclear Energy Act.

Security arrangements are considered part of overall safety and are coordinated together with emergency arrangements and safeguards. The safety-security interface has been taken into account during the design, construction, operation and decommissioning of the nuclear facility as the legislation stipulates.

STUK oversees the fulfilment of the legislation through authorizations and decisions that are related, for example, to the licensee's organization, procedures and facility design. Another main oversight function is an inspection programme that contains inspections for the construction phase, preparation for operations and the operations phase. Some of the inspections are announced and some are unannounced. The last unannounced security inspection was conducted in August 2021.

The nuclear security regime has been reviewed with the help of the IPPAS mission that was previously conducted in 2009 (follow-up 2012). A new IPPAS mission was conducted in June 2022.

Finland was ranked third in the Nuclear Security Index (NTI) during the last two rounds of NTI assessment for nuclear security in both categories (theft and sabotage).

For the use of radiation sources that require a safety licence, SätL sets the main requirements for security arrangements. In addition to section 67, which lays down security arrangements, the most important articles from a security point of view are section 51, which defines the information to be provided in the application for a safety authorization, as well as sections 71 and 72 on the Record-keeping and notification obligation and Obligations of the transferor, recipient and transporter.

11.2. REGULATORY OVERSIGHT ACTIVITIES

The licensing of a nuclear facility can be divided into different steps, all of which require the licence applicant to fulfil strict requirements set by the legislation before the nuclear facility can be commissioned. Apart from licensing, STUK also authorizes certain aspects in the use of nuclear energy. For example, the person responsible for the nuclear security arrangements of the licensee must be authorized by STUK (NEA). If special temporary security arrangements are needed, STUK approves these in a decision-making process.

STUK has the right to inspect the nuclear facilities, issue requirements (regulations and objective binding YVL guides) and penalties to the licensee. These rights are stipulated in the legislation. If there is a need for powers that STUK does not have according to the Nuclear Energy Act, law enforcement must provide assistance. STUK cooperates closely with national authorities such as law enforcement, the Ministry of the Interior, CERT-FI, the military, Border Guard, Customs, etc.

In STUK, field inspections can be divided into three parts: regular-, unannounced- and reactive inspections. Reviews of licensees' documents are carried out daily to ensure that the instructions, manuals and other documents relating to the operation of a nuclear facility meet the requirements.

Resident inspectors who work at the nuclear power plant site are an important channel for gathering information about daily activities. They (certain resident inspectors) have also been trained for nuclear security-related topics with access to certain confidential information, further improving the safety-security interface.

Synergies of safety and security aspects are built into regulations and the implementation of regulatory oversight. To enhance systematic evaluation and to identify synergies in safety and security, together with Finnish nuclear facility licensees STUK initiated the development of probabilistic risk assessment (PRA) in security analyses and design. In the pilot project, fire-PRA was used to identify vital areas for nuclear security purposes. Currently, the use of PRA methods is required in STUK regulation on nuclear security. This is an example of using new systematic methods to enhance risk-informed security regulation, but also a means to integrate or evaluate the safety-security interface.

STUK has the right to issue requirements if the licensee does not meet the requirements set by the legislation. Penalty payments and orders for the temporary suspension of the operation of the nuclear facility are seen as the most extreme tools, should the licensee ignore the requirements deliberately.

STUK supervises compliance with SätL including security requirements by licensing, inspecting and enforcing. STUK draws up a yearly oversight plan, which takes into consideration the risk-informed approach. According to SätL (859/2018) section 67, security arrangements must 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. More detailed requirements for the security of radiation sources are established in Guide STUK S/9/2021, which is based on the IAEA Nuclear Security Series No. 11 Security of Radiation Sources.

11.3. INTERFACE AMONG AUTHORITIES

STUK provides a secretariat for STUK's Advisory Committee on Nuclear Security. The chair of the committee is from the Ministry of the Interior. This committee 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 Government Decree 1016/2016. The Commission has representatives from many authorities and meetings are held annually.

The Finnish Security and Intelligence Service (FSIS) is responsible for threat assessment for nuclear and radiation security. Based on threat assessment, STUK issues design basis threats (DBT) for such activities. FSIS uses other national security authorities (also internationals counterparts) in order to prepare the threat assessment. The responsibilities above are stipulated in YEA.

STUK is responsible for overseeing nuclear security and safety, other authorities have other responsibilities, and they must provide assistance to STUK on request based on the legislation.

11.4. CONCLUSIONS AND ACTIONS

YEL covers safety, security and safeguards and the responsibilities for them. The three domains are connected in practice, and especially in regulations and guides established by STUK. The overall approach has been to regulate the three areas in such a way that they are mutually supportive of each other and conflicts can be avoided.

Both SätL and YEL stipulate the responsibility for the licensee (safety, security and safeguards). This is a built-in approach. Both acts also stipulate STUK's powers for the oversight of safety, security and safeguards. According to the Nuclear Energy Act, STUK is a "3S" regulator responsible for the oversight of nuclear safety, security and safeguards.

STUK's safety, security and safeguards staff work closely together to harmonize safety, security and safeguards requirements and measures. Many documents are handled together to ensure the three domains do not conflict with each other.

The nuclear regime takes into account the interfaces of safety, security and safeguards to ensure there are no conflicts. In addition to the need-to-know principle, the security section is guided by the slogan: "need-to-share". This principle has been put into practice by training safety- and safeguards inspectors for security and conducting joint inspections. When updating the regulations, safety experts also assess confidential security requirements to ensure conflicts are avoided.

Good practice

Synergies of safety and security aspects are built into regulations and the implementation of regulatory oversight. To enhance systematic evaluation and identify synergies in safety and security, together with Finnish nuclear facility licensees STUK initiated the development of probabilistic risk assessment (PRA) in security analyses and design. In the pilot project, fire-PRA was used to identify vital areas for nuclear security purposes. Currently, the use of PRA methods is required in STUK regulation on nuclear security. This is an example of using new systematic methods to enhance risk-informed security regulation, but also a means to integrate or evaluate safety-security interfaces.

13. REGULATORY IMPLICATIONS OF THE COVID-19 PANDEMIC

Measures adopted by nuclear facility licensees

On March 6, 2020 STUK requested information from the licensees of the operating power plants on how they were prepared to possible worsening of the pandemic situation (still an epidemic situation at the time of the request). The licensees' answers were received on March 13 and March 17 from TVO (operator of Olkiluoto NPP) and Fortum (operator of Loviisa NPP), respectively. The licensees had identified critical functions/positions and listed the minimum number of the critical staff in different groups. During the pandemic, there have been no difficulties in fulfilling these requirements.

The Finnish nuclear research reactor was closed down permanently in June 2015. Core loading was changed so that the reactor is sub-critical in all situations. The reactor does not require any active control or cooling systems in shutdown mode. Operational personnel are not required to be present at the reactor all the time and the licensee, VTT, has evaluated the adequacy of operational and security personnel.

Other nuclear installations include operational nuclear waste disposal facilities that do not require active operations for safety. Current operational disposal facilities are at nuclear power plant sites and operated by nuclear power plant organizations (TVO and Fortum).

The licensees have closely followed the development of the situation and the suggestions and guidance from the Finnish Government and health authorities, and further instructed their own staff and suppliers on expectations of practices when entering the plant and the licensees' premises, as well as on suggestions for activity during free time. The licensees' instructions have been somewhat stricter than those given generally to the public in Finland, and this was already the case in the early phases of the situation. The actions include:

- restricting the number of people in the same room
- minimizing access to areas important to safety and operation
- requirements for protective measures (masks, testing, …)
- supporting remote work for those whose duties allow it
- restrictions on travelling both abroad and in Finland
- setting up company rules on temporary quarantines in the early phases of the situation for those who had been travelling abroad (also for persons coming from the Uusimaa region in Finland to the Olkiluoto site)
- checking that the people accessing the plants had not been in contact with patients diagnosed with COVID-19 infection or had come from abroad in the previous two weeks.

The licensees formed specific groups within their organizations that followed the development of the pandemic situation continuously in order to quickly react to changes and respond accordingly. Special measures to avoid spreading coronavirus among the NPP staff and especially among the control room staff were taken already from the early warnings of the virus. These measures have been tightened gradually with the changes in the national policies of the authorities.

Refuelling outages have been under evaluation, and the availability and need of external personnel and supplies has been discussed with the licensees regularly. Annual fuel exchange and a short maintenance period at Olkiluoto NPP were scheduled for spring/summer 2020, and these arrangements were re-evaluated because of the pandemic situation. Olkiluoto unit 2 outage was carried out as planned in May 2020 (only a refuelling outage with a duration of 8 days). The planned outage of Olkiluoto unit 1 was supposed to

be 25 days but it was shortened to 14 days due to action to restrict possible spreading of coronavirus among the plant personnel. The pressure test of Olkiluoto unit 1 reactor pressure vessel (RPV) required by STUK in the decision on periodic safety review in 2018 was postponed by one year. Postponing the pressure test of the RPV was accepted by STUK. Other changes to the Olkiluoto unit 1 outage were also reviewed and accepted by STUK, but there was no need for deviations, but rather changes to the implementation schedules. There were no other planned changes to the Loviisa NPP outages in August 2020, and the outages were carried out as planned in 2021.

Authority (STUK)

STUK has been in a continuous direct contact with the licensees. Most of the government employees had been working remotely for two years since mid-March 2020. However, continued oversight functions have been possible via digitalized systems. Concerning radiation and nuclear safety oversight, STUK has organized its regulatory functions so that most activities can continue normally but staff members are doing them remotely from home. This includes document reviews, decision-making, meetings with licensees, developing regulations, etc. On-site inspections continued in the most safety significant topics at the operating NPPs (Loviisa units 1 and 2 and Olkiluoto 1 and 2) and at the Olkiluoto 3 unit under commissioning, where there were no alternative options available. The objective was to minimize the travel needs and also the risk of spreading coronavirus to the site. Manufacturing inspections done abroad have been interrupted due to travel restrictions and instead inspections will be conducted later at the nuclear power plant sites in Finland. STUK has resident inspectors at the NPP sites and the objective has been to mainly use them for on-site inspections but, if needed, it will also be possible to send additional inspectors from the headquarters (case-by-case decision).

Information security matters have also been taken into account in remote communications by choosing appropriate channels and methods corresponding to the classification of information being transmitted. Remote inspections have been done in areas where it has been possible using teleconferencing software, taking into account the information security restrictions. Skype and Teams are used as the primary tools.

During the early phases of the pandemic, STUK also raised awareness of organizational factors in pandemic situation. the pandemic situation affects licensee organizations and may cause many cumulative changes in human performance and related risks such as:

- Temporary guidance (how to ensure that everybody has time to read it and make sure what the currently valid guidance is, …)
- Changes to plant modification/project implementation and schedules (dependencies needs to be taken into account, formal documentation, up-to-dateness of the plans and guidance, …) – for example, outages were shortened and some plant modifications/ tests were postponed by one year
- Lack of personnel (deputies with less experience might be used, …)
- Decision-making (many decisions due to many changes, overall picture of the effects of the decisions, is there enough time to do multidisciplinary decisions and discussion about risks, …)
- Information flow (fewer face-to-face meetings, possible misunderstandings and complications in teleconferencing, …)
- Mental loading (situation can be more stressful for some people and can affect work performance, …).

The conclusion was that, even when the staffing of control room personnel and other critical personnel groups was ensured, the situation required special attention from an organizational factor point of view. Rapid changes in routines, work processes and plans

were most common factors behind events and accidents (experience from history) but, in the end, there were no significant findings made in the oversight related to organizational factors. STUK also made plans for ensuring its internal and external communication activities and particularly its emergency response capabilities. STUK, for instance, followed the sickness absences of its staff to be able to react if needed. During the pandemic, there have been no challenges identified and sickness rates have been even lower than in previous years.

STUK's environmental radiation monitoring functions have been continued normally (sampling, measurements and laboratory functions).

One of the lessons learnt from the pandemic situation is that organizations must be prepared for different kind of hazards. There cannot be separate plans for every detail and a certain resilience is always a strength in an organization. Typically, business continuity plans (BCP) concentrate mainly on cyber threats, so one area for improvement is to widen the scope of BCPs, both for the licensees and the regulatory body in the case of a pandemic. Risk management is also typically an area for improvement, and it should also identify the main risks which must be prepared in BCPs.

Rapid changes in routines/work processes/plans are the most common factors behind events and accidents (experience from history)
Questions to be asked:

- Are there any changes in current work processes, guidance, resources, induction training, etc.
- Comprehensiveness of a licensee's decision-making and risk assessment
- Prerequisites for organizational functionality and human performance when discussing changes (documentation/guidance up-to-dateness, competences, induction training, adequacy of resources, preparedness for surprises/agreed procedures in those cases, …)

Measures adopted in case of radiation practices

- STUK organized its regulatory functions so that most activities could continue normally but staff members were doing them remotely from their homes. This included document reviews, authorization, decision-making, communication in regulatory issues with licensees, developing regulations, etc.
- The functions related to the authorization process were not affected. In specific cases concerning medical facilities, the authorization process was prioritized. Due to the increased need to use X-ray generators for examining patients, STUK adapted its procedures to respond to an urgent need for authorizations.
- The annual inspection plan was adjusted, but in a manner by which safety was not expected to be compromised, for example, inspections in radiotherapy were continued.
- The inspection process was adjusted, for example by conducting some inspections remotely in order to minimize the risk of spreading coronavirus to the sites.
- The capabilities of STUK for providing a full response in case of radiation safety deviations was maintained. For example, a scrap yard which found an orphan source was visited despite the restrictions on crossing provincial borders.

Other activities at STUK during pandemic situation

STUK also has plans for ensuring its internal and external communication activities and particularly its emergency response capabilities. STUK is, for instance, closely following the sickness rates of its staff to be able to react if needed (so far, the situation is very good and sickness rates has been even lower than in previous years).
STUK's environmental radiation monitoring functions are continuing normally (sampling, measurements and laboratory functions).

References

Main legislation

abbreviations	*acts and decrees*
StukL 1069/1983	Act on Radiation and Nuclear Safety Authority (1069/1983)
	Constitution of Finland (731/1999)
StukA 618/1997	Decree on Radiation and Nuclear Safety Authority
VnA 1034/2018	Government Decree on Ionizing Radiation
STMA 1044/2018	Ministry of Social Affairs and Health Decree on Ionising Radiation
	Nuclear Liability Act (484/1972)
SätL 859/2018	Radiation Act (859/2018)

Other national legislation

	Act on Collections of Regulations of Ministries and Other State Authorities (189/2000)
	Act on Conditional Fines (1113/1990)
	Act on Criteria for Charges Payable to the State (150/1992)
YVA 252/2017	Act on the Environmental Impact Assessment Procedure (252/2017)
	Act on the Market Surveillance of Certain Products (1137/2016)
	Act on Public Officials in Central Government (750/1994)
	Act on the Publicity of the Activities of Public Authorities (621/1999)
	Administrative Procedure Act (434/2003) (APA)
	Criminal Code of Finland (39/1889)
	Decree of the Ministry of the Environment on Foundation Structures (465/2014)
	Decree of the Ministry of the Interior on an External Rescue Plan Concerning Targets Causing Special Threat (406/2011)
	Decree of the Ministry of the Environment on the Indoor Climate and Ventilation of New Buildings (1009/2017)
	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)
	Decree on transportation of Dangerous Goods in Package form by Sea 666/1998
	Employment Contracts Act (55/2001)
	Environmental Protection Act (527/2014)
	Government Decree on the Advisory Committee for Nuclear Security (1016/2016), *in Finnish only*
	Government Decree on University Degrees and Specialization Training (794/2004)
	Health Protection Act (763/1994)
	Ministry of Interior Decree on Providing Information to Public in Occupational Health and Safety Act (738/2002)
	Rescue Act (379/2011)
	State Payment Basis Decree (211/1992)
	Waste Act (646/2011)

STUK regulations

abbreviations

STUK Y/1/2018	Radiation and Nuclear Safety Authority Regulation on the Safety of a Nuclear Power Plant
STUK Y/2/2018	Radiation and Nuclear Safety Authority Regulation on the Emergency Arrangements of a Nuclear Power Plant
STUK Y/3/2018	Radiation and Nuclear Safety Authority Regulation on the Security in the Use of Nuclear Energy
STUK Y/4/2018	Radiation and Nuclear Safety Authority Regulation on the Safety of Disposal of Nuclear Waste
STUK Y/5/2016	Radiation and Nuclear Safety Authority Regulation on the Safety of Mining and Milling Operations Aimed at Producing Uranium or Thorium
STUK SY/1/2018	Radiation and Nuclear Safety Authority Regulation on exemption levels and clearance levels
STUK S/1/2018	Radiation and Nuclear Safety Authority Regulation on the investigation, assessment and monitoring of occupational exposure
STUK S/2/2018	Radiation and Nuclear Safety Authority Regulation on the plan for radiation safety deviations and actions during and after radiation safety deviations
STUK S/2/2019	Radiation and Nuclear Safety Authority Regulation on radioactive waste and discharges of radioactive substances in the use of unsealed sources
STUK S/4/2019	Radiation and Nuclear Safety Authority Regulation on justification assessment and optimisation of radiation protection in medical exposure
STUK S/5/2019	Radiation and Nuclear Safety Authority Regulation on the in-service radiation safety of radiation sources and the decommissioning of radiation sources and places of use
STUK S/6/2019	Radiation and Nuclear Safety Authority Regulation on practices subject to a Safety License
STUK S/6/2022	Radiation and Nuclear Safety Authority Regulation on practices that cause exposure to natural radiation
STUK S/7/2021	Radiation and Nuclear Safety Authority Regulation on radiation measurements
STUK S/9/2021	Radiation and Nuclear Safety Authority Regulation on the security arrangements of radiation sources that require a safety license

EU legislation

abbreviations

NSD Directive	Council Directive 2009/71/EURATOM of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations (Nuclear Safety Directive)
	Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency
	Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas
	Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation
EU BSSD	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, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom
	Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom
	Council Directive 2003/122/Euratom of 21 February 2003 authorising Member States to take decisions under Directive 1000/105/EC on forest reproductive material produced in third countries
	Council Directive 2014/87/Euratom of 8 July 2014 amending Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations
	Council Regulation 1493/93/Euratom Council Regulation 1493/93/Euratom of 8 June 1993 on shipments of radioactive substances between Member States
	Council Regulation 733/2008/Euratom of 15 July on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station
	Council Regulation 2016/52/ Euratom of 15 January 2016 laying down maximum permitted levels of radioactive contamination of

food and feed following a nuclear accident or any other case of radiological emergency, and repealing Regulation (Euratom) No 3954/87 and Commission Regulations (Euratom) No 944/89 and (Euratom) No 770/90

EU Regulation 305/2011/Euratom

Regulation (EC) No. 305/2011/Euratom of the European Parliament and of the Council, laying down harmonized conditions for the marketing of construction product and repealing Council Directive 89/106/EEC

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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
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
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
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
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
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Guide STUK 1.1 Safety, quality and information security policy
Guide STUK 1.3 Description of STUK's management system
Guide STUK 1.4 Preparation and maintenance of management system guides
Guide STUK 1.5 Risk management policy
Guide STUK 2.1 Rules of Administration
Guide STUK 2.2 Performance management system
Guide STUK 2.3 Radiation and Nuclear Safety Authority Management Team
Guide STUK 2.5 Project activity
Guide STUK 2.6 Organisation
Guide STUK 2.9 STUK's working groups
Guide STUK 2.9 Appendix 1 STUK's permanent and temporary workgroups
Guide STUK 2.11 Management reviews
Guide STUK 2.12 Internal audits
Guide STUK 2.13 Processing of customer and stakeholder feedback
Guide STUK 2.14 Self-assessment of operations
Guide STUK 2.15 Risk management
Guide STUK 2.16 Deviations and initiatives
Guide STUK 2.20 Research and development
Guide STUK 3.1 Regulatory activities: oversight of compliance with legislation
Guide STUK 3.4 Investigation of events
Guide STUK 3.6 Regulations
Guide STUK 4.21 The principles of communications at the Radiation and Nuclear Safety Authority
Guide STUK 4.26 The principles of crisis communication at the Radiation and Nuclear Safety Authority
Guide STUK 5.1 Human resource policy
Guide STUK 5.2 Competence management at STUK
Guide STUK 5.7 Recruitment
Guide STUK 5.8 Work orientation

Guide STUK 6.12 Guide to good working communities
Guide STUK 8.11 Procurement guidance and orientation
Guide STUK 8.12 Low value procurements
Guide STUK 9.1 Information management
Guide STUK 9.2 Processing of an administrative matter
Guide STUK 9.3 Case management
Guide STUK 9.4 Openness of documents and handling of requests for information
Guide STUK 9.6 Processing of personal data (data protection)
Guide STUK 9.7 Electronic signing of documents in SAHA

Guide SKV 1.1 STO's management system
Guide SKV 2.1 STO organisation
Guide SKV 2.1 Appendix 1 STO organization and the duties of units
Guide SKV 2.5 Resolving Issues and Signing Documents
Guide SKV 2.5 Appendix 1 Cases decided and documents signed by
Guide SKV 3.2 Processing the safety licence
Guide SKV 3.3 Approval of the radiation safety officer's radiation protection training and examination
Guide SKV 3.4 In-service regulatory control in radiation practices requiring a safety licence
Guide SKV 3.5 Processing radiation safety deviations
Guide SKV 3.5 Appendix 2 Recording information on a radiation safety deviation
Guide SKV 3.5 Appendix 4 Processing radiation safety deviations to be reported as a summary
Guide SKV 3.7 Enforcement procedures in supervising the requirements of the Radiation Act
Guide SKV 3.7 Appendix 1 Template: Reminder to comply with a legal obligation
Guide SKV 3.7 Appendix 2 Template: Request for clarification (general)
Guide SKV 3.7 Appendix 3 Template: Recommendation when there is no radiation safety officer
Guide SKV 3.7 Appendix 4 Template: Clarification request when the name or business ID of the holder of the safety licence has changed
Guide SKV 3.7 Appendix 5 Template: Hearing on discontinuation or restriction of practice
Guide SKV 3.7 Appendix 6 Template: Decision on restriction of practice
Guide SKV 3.7 Appendix 7 Template: Decision of the inspector to suspend or restrict operations as an emergency measure
Guide SKV 3.7 Appendix 8 Template: Hearing on prohibition of sale of produce
Guide SKV 3.7 Appendix 9 Template: Decision on a ban on the sales and release of a product
Guide SKV 3.7 Appendix 10 Template: Hearing on the imposition of a conditional fine
Guide SKV 3.7 Appendix 11 Template: Decision on the imposition of a conditional fine
Guide SKV 3.7 Appendix 12 Template: Hearing on the imposition of a conditional fine and the imposition of a new one
Guide SKV 3.7 Appendix 13 Template: Decision on the imposition of a conditional fine and the imposition of a new one
Guide SKV 3.7 Appendix 14 Template: Decision on revocation of decision on restriction of practices
Guide SKV 3.7 Appendix 15 Template: Decision on amendment of decision on restriction of practices
Guide SKV 3.8 Regulatory control of workers' radiation doses and investigations into dose
Guide SKV 3.9 Recognition of the qualifications of a radiation safety expert
Guide SKV 4.1 Supervision of health care and veterinary practices
Guide SKV 4.1 Appendix 1 Postal supervision of intraoral x-ray equipment
Guide SKV 4.1 Appendix 2 Measurement practices for x-ray equipment in health care
Guide SKV 5.1 Regulatory control of trade, import, export and transfer of radiation sources

Guide SKV 5.1 Appendix 1 Request to the importing state for consent to import category 1 Radioactive sources or to import category 1&2 sources under exceptional circumstances
Guide SKV 5.1 Appendix 2 Request to the importing state for confirmation that the recipient is authorized to receive and possess category 2 radioactive sources
Guide SKV 5.1 Appendix 3 Notification to the importing state prior to shipment of category 1 or 2 radioactive sources
Guide SKV 5.2 Regulatory control of transport of radioactive substances
Guide SKV 6.1 Administration of the workers' dose register and disclosure of register data Administration
Guide SKV 6.4 Approval of the dosimetry service, dose measurements system and radon concentration measurements

Guide VALO 1.1 VALO's management system
Guide VALO 1.2 Description of the management system and management of the related documents
Guide VALO 3.1 National environmental radiation control
Guide VALO 3.1 Appendix 1 National Environmental Radiation Control Programme 2020-2022
Guide VALO 3.1 Appendix 2 Regulatory control of radioactive substances in the Baltic Sea (HELCOM-MORS)
Guide VALO 3.3 Environmental monitoring of nuclear power plants
Guide VALO 4.7 Radon handbook, Table of contents
Guide VALO 6.5 Airborne radon standards manual, Table of contents
Guide VALO 7.1 Radon regulatory control in conventional workplaces
Guide VALO 7.1 Appendix 2 Continuous radon measurements and number of measurements after radon mitigation
Guide VALO 7.1 Appendix 4 Indoor radon in water treatment plans
Guide VALO 7.1 Appendix 5 Further information for the employer
Guide VALO 7.1 Appendix 6 When the radon concentration measured at the workplace is higher than the reference level
Guide VALO 7.1 Appendix 9 Radon mitigation at workplaces – responsibilities of the employer and other operators
Guide VALO 7.1 Appendix 10 Use of respiratory protective equipment to reduce radon exposure
Guide VALO 7.2 Radon regulatory control of underground mines, excavation sites and tunnels
Guide VALO 7.2 Appendix 2 Instructions for the workplace: Radon in tunnel work
Guide VALO 7.3 Regular investigation of the radiation dose
Guide VALO 7.3 Appendix 1 Instruction for the employer: Regular investigation of the radon radiation dose
Guide VALO 7.4 Regulatory control of construction products
Guide VALO 7.5 Assistance in the regulatory control of radioactivity in water intended for human consumption
Guide VALO 7.7 Regulatory control of industrial practices causing exposure to natural radiation
Guide VALO 7.7 Appendix 4 Instructions for the investigation of natural radiation exposure – mining and underground excavation
Guide VALO 7.7 Appendix 7 Instructions for the investigation of natural radiation exposure
Guide VALO 7.7 Appendix 8 Instructions for the exposure assessment of workers

Guide YTV 1.a Regulatory oversight of safety in the use of nuclear energy

Guide YTV 1.b Overall assessment of the safety of nuclear facilities
Guide YTV 1.c International nuclear safety conventions and EU directives - YTO and YMO action and reporting
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Guide YTV 2.a Licences and approvals for nuclear facilities
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Guide YTV 2.d.1 Appendix 1 Diagram of when a separate manufacturer approval application is needed
Guide YTV 2.d.1 Appendix 2 Process diagram of manufacturer approval
Guide YTV 2.d.2 Approval and oversight of NDT and DT testing organisations
Guide YTV 2.d.2 Appendix 1 Assessment of approval procedure: NDT and DT of components and structures
Guide YTV 2.d.2 Appendix 2 Assessment of approval procedure: material manufacture-stage NDT or DT
Guide YTV 2.d.2 Appendix 3 Testing organisations
Guide YTV 2.d.3 Approval and control of authorised inspection organisations and the licensee’s in-house inspection organisations
Guide YTV 2.d.3 Appendix 1 Approval of an accredited inspection organisation and self-inspection organisation
Guide YTV 3.a.2 Monitoring of electrical and I&C systems and equipment
Guide YTV 3.a.2 Appendix 2 Review of the preliminary/final safety report’s architecture level documentation or conceptual plan
Guide YTV 3.a.2 Appendix 5 Pre-review of the final safety analysis report’s architecture level documentation
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Guide YTV 3.b.1 Deterministic safety anlayses
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Guide YTV 3.b.4 Long-term safety oversight
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Guide YTV 3.c.4 Radiation safety
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Guide YTV 3.c.6 Emergency arrangements
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Guide YTV 3.c.11 Assessment of events of Finnish nuclear facilities
Guide YTV 3.c.13 International Nuclear and Radiological Event Scale classification
Guide YTV 3.c.15 Calculation, assessment and use of nuclear safety indicators
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Guide YTV 3.d.2 Management system oversight
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Guide YTV 3.d.2 Appendix 2 Review of quality plans
Guide YTV 3.d.2 Appendix 3 Regulatory oversight of projects

Guide YTV 3.d.3 Oversight of human resources and competences
Guide YTV 3.e Regulatory control of nuclear waste management, decommissioning, uranium production and the disposal of radioactive material
Guide YTV 3.e.1 Oversight of nuclear facility decommissioning
Guide YTV 3.e.2 Preparing for nuclear waste management costs
Guide YTV 3.e.3 Regulatory supervision of construction of high-activity waste final disposal facility
Guide YTV 3.e.4 Regulatory control of technical barriers
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Guide YTV 4.a.1 Inspection programmes for the oversight of nuclear facilities
Guide YTV 4.a.1 Appendix 1 Process diagram of inspection programmes
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Guide YTV 4.b.2 Appendix 2 Examples of minor, ordinary and major deviations
Guide YTV 4.b.2 Appendix 3 Construction inspections as remote inspections
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Guide YTV 4.c.1 Appendix 1 Approval of international inspections
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Guide YTV 4.c.1 Appendix 3 Forms for safeguards verifications
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Guide YTV 6.c Appendix 1 Graded Approach assessment form
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Guide YTV 6.g Appendix 1 Monitoring of observations and measures concerning own operations at YTO and YMO
Guide YTV 7.a Organisation and tasks for the Nuclear Reactor Regulation department
Guide YTV 7.a Appendix 1 Nuclear Reactor Regulation, organisation chart
Guide YTV 7.a Appendix 2 Task descriptions of YTO sections and units
Guide YTV 7.a Appendix 5 Meeting procedures for YTO
Guide YTV 7.b Nuclear Waste Regulation and Safeguards (YMO); organisastion and tasks
Guide YTV 7.b Appendix 1 Nuclear Waste Regulation and Safeguards, organisation chart
Guide YTV 7.b Appendix 2 Tasks descriptions for YMO units
Guide YTV 7.b Appendix 5 Meeting procedures at YMO
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Guide YTV 8.c Regulatory oversight of modifications to nuclear facilities

APPENDIX 1 Organizations, treaties, agreements and conventions to which Finland is a party (related to Module 2: Global Nuclear Safety Regime)

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.
- The Comprehensive Nuclear-Test-Ban Treaty (FTS 15/2001). This treaty was ratified by Finland on January 15, 1999 but will not enter into force before it is ratified by all 44 states listed in Annex II of the Treaty.
- International Atomic Energy Agency (since 1958).
- Nuclear Energy Agency of the OECD (since 1976).
- International Energy Agency (since 1992).

Finland is a party to the following international conventions among others (the year when the convention entered into force for Finland is given in brackets):

- 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 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 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).
- Convention Relating to Civil Liability in the Field of Maritime Carriage of Nuclear Material; adopted in Brussels on 17 December 1971 (1991).
- The 1988 Joint Protocol Relating to the Application of the Paris Convention and the Vienna Convention; adopted in Vienna on 21 September 1988 (1995).
- 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).
- Nordic Mutual Emergency Assistance Agreement in Connection with Radiation Accidents; adopted in Vienna on 17 October 1963 (1965) Agreement on common Nordic guidelines on STUK-B 265 / MAY 2021 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).
- 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).
- Convention on Environmental Impact Assessments in a Transboundary Context (Espoo, 1991)

Bilateral Agreements made by Finland:

- The Agreement between the Government of the Republic of Korea and the Government of the Republic of Finland for Cooperation in the Peaceful Uses of Atomic Energy, entered into force on 1.1.2015 (FTS 5/2015).
- The Agreement with the Government of the Russian Federation and the Government of the Republic of Finland for Cooperation in the Peaceful Uses of Atomic Energy, entered into force on 6.4.2015 (FTS 32/2015).
- The Agreement on Cooperation in the Field of Peaceful Uses of Atomic Energy Between the Government of the Kingdom of Saudi Arabia and the Government of the Republic of Finland, entered into force on 3.6.2017 (FTS 48/2017).
- The Agreement with the Government of the United Kingdom of Great Britain and Northern Ireland and the Government of the Republic of Finland for Co-operation in the Peaceful Uses of Atomic Energy (FTS 16/69). Articles I, II, III and X expired on 20 February 1999.
- The Agreement with the Government of the Russian Federation (the Soviet Union signed) and the Government of the Republic of Finland for Co-operation in the Peaceful Uses of Atomic Energy (FTS 39/69). Articles 1, 2, 3 and 11 expired on 1.12.2004.
- The Agreement between the Government of the Kingdom of Sweden and the Government of the Republic of Finland for Co-operation in the Peaceful Uses of Atomic Energy 580/70 (FTS 41/70). Articles 1, 2 and 3 expired on 5.9.2000.
- The Agreement on implementation of the Agreement with Finland and Canada concerning the uses of nuclear materials, equipment, facilities and information transferred between Finland and Canada (FTS 43/84).

As of 1 January 1995, Finland has been a member of the European Atomic Energy Community (EAEC or Euratom). Consequently, the following agreements are applied in Finland:

- The Agreement between the Government of Republic of Finland and the Government of Canada and Canada concerning the uses of nuclear materials, equipment, facilities and information transferred between Finland and Canada (FTS 43/76).
- Substituted to the appropriate extent by the Agreement with the Government of Canada and the European Atomic Energy Community (Euratom) in the peaceful Uses of Atomic Energy, 6 October 1959, as amended.
- The Agreement between the Government of Republic of Finland and the Government of Australia concerning the transfer of nuclear material between Finland and Australia (FTS2/80).
- Substituted to the appropriate extent by the Agreement between the Government of Australia and the European Atomic Energy Community ty concerning transfer of nuclear material from Australia to the European Atomic Energy Community, 21 September 1981.
- The Agreement for Cooperation with the Government of the Republic of Finland and the Government of the United States concerning Peaceful Uses of Nuclear Energy (FTS 37/92).
- Substituted to the appropriate extent by the Agreement for Cooperation in the Peaceful Uses of Nuclear Energy with European Atomic Energy Community and the USA, 12 April 1996.
- The Agreement for Cooperation in the Peaceful Uses of Nuclear Energy Between the European Atomic Energy Community and the Government of Japan, 27 February 2006.
- The Agreement Between the European Atomic Energy Community and the Cabinet of Ministers of Ukraine for Cooperation in the Peaceful Uses of Nuclear Energy, 28 April 2005.

- The Agreement for Cooperation in the Peaceful Uses of Nuclear Energy Between the European Atomic Energy Community and the Government of the Republic of Kazakhstan, 4 December 2006.
- The Agreement for cooperation in the peaceful uses of nuclear energy between the European Atomic Energy Community (Euratom) and the Government of the Republic of Uzbekistan, 21.10.2003
- The Agreement for cooperation in the peaceful uses of nuclear energy between the European Atomic Energy Community (Euratom) and the Government of the Argentine Republic, 30.10.1997
- The Agreement between the Government of the Republic of South Africa and the European Atomic Energy Community (Euratom) for Cooperation in the Peaceful Uses of Nuclear Energy, 31.7.2013
- The Agreement between the European Atomic Energy Community (Euratom) and the Government of the United States of Brazil for cooperation concerning the peaceful uses of atomic energy, 24.6.1965