

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO FINLAND

Vantaa, Finland

3 to 14 October 2022

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



Integrated
Regulatory
Review Service
IRRS



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**REPORT OF THE
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Mission dates: 3-14 October 2022
Regulatory body visited: Radiation and Nuclear Safety Authority (STUK)
Location: Vantaa, Finland

Regulated facilities, activities, and exposure situations in the mission scope:	<i>Fuel Cycle facilities, Radiation Sources in Industrial and Medical facilities, Waste Management facilities, Decommissioning activities, Transport of radioactive material, Emergency Preparedness and Response, Medical Exposure, Occupational Exposure, Public and Existing Exposure.</i>
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The number of recommendations, suggestions and good practices is in no way a measure of the status of the national infrastructure for nuclear and radiation safety. Comparisons of such numbers between IRRS reports from different countries should not be attempted.

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EXECUTIVE SUMMARY

At the request of the Government of Finland, an international team of senior safety experts met representatives of the Radiation and Nuclear Safety Authority (STUK) at its headquarters, from 3 to 14 October 2022, to conduct an Integrated Regulatory Review Service (IRRS) mission. This was the second full scope IRRS mission that Finland has hosted since IRRS programme began in 2006.

The purpose of this IRRS mission was to review Finland's national regulatory framework for nuclear, radiation, radioactive waste and transport safety. This IRRS mission is organized back-to-back to an ARTEMIS mission, scheduled for November 2022. The review assessed Finland's regulatory framework for nuclear and radiation safety against IAEA safety standards. The mission was also used to exchange information and experience between the IRRS team members and the Finnish counterparts in the areas covered by the IRRS.

The IRRS team consisted of 18 senior regulatory experts from 14 IAEA Member States, four IAEA staff members, and an observer. The Finnish counterparts for the mission were mainly from the regulatory body STUK but also from the ministries with regulatory responsibilities and functions regarding nuclear and radiation facilities and activities: the Ministry of Social Affairs and Health (MSAH) and the Ministry of Economic Affairs and Employment (MEAE).

The review covered the IRRS core modules 1 to 10: the responsibilities and functions of the government, the global safety regime, the responsibilities and functions of the regulatory body, the management system of the regulatory body, the activities of the regulatory body including authorization, review and assessment, inspection and enforcement, development of regulations and guides, and emergency preparedness and response. The review also included the optional module 11 on safety and security interface. Facilities reviewed included nuclear power plants, fuel cycle facilities, radiation source facilities, and waste management facilities. Activities and exposure situations reviewed included transport, decommissioning, occupational exposure, medical exposure, and public and existing exposure.

At the request of STUK, the IRRS mission included discussion during which members of the IRRS team and senior staff of STUK shared views and regulatory experiences regarding two policy issues: Regulatory Readiness for SMR Licensing and Deployment and Institutional Strength InDepth (role of stakeholders challenging the accountability of regulators and licensees).

In preparation for the IRRS mission, STUK conducted a self-assessment and prepared a preliminary action plan to address areas that were identified for improvement. The results of the self-assessment and supporting documentation were provided to the IRRS team as advance reference material for the mission. The IRRS team was impressed by the extensive preparation, thorough assessment, and dedication of STUK.

The review mission included a series of interviews and discussions with STUK, MEAE and MSAH staff, as well as advisory committees' chairpersons of the Nuclear Safety Advisory Committee and the Radiation Safety Advisory Committee. Senior members of the IRRS team met the representatives of the two ministries. Discussions were conducted with the ministries regarding the purpose of the mission, focussing mainly on responsibilities and functions of the government, national policies, and the regulatory framework for safety.

The IRRS team was extended full cooperation in the regulatory, technical, and policy discussions with the management and staff of STUK, in a very open and transparent manner. This enabled the IRRS team to develop a broad understanding of the regulatory framework resulting in recommendations and suggestions that should benefit nuclear and radiation safety for Finland.

The IRRS team also observed on-site inspections conducted by STUK at various facilities: DEKRA (industrial radiography), Helsinki University Hospital (radioisotope unit, comprehensive cancer centre), and Loviisa Nuclear Power Plant. The IRRS team members reported very favourably on the professionalism of STUK staff in the preparation and conduct of the inspections. During the site visits, open discussions took place with the management of the authorized parties, who indicated that STUK provides valuable feedback on the safety of the facility. STUK expertise was also commended.

The IRRS team concluded that Finland has a comprehensive and robust regulatory framework for nuclear and radiation safety covering facilities and activities. STUK has a strong culture of continuous improvement, and is a very mature and competent regulator which fulfils its statutory obligations without undue influence.

The IRRS team identified three good practices: the education and engagement with the media to enhance public outreach, a systematic approach for continuous monitoring of licensees' overall safety performance, and a public information system on radiation safety legislation.

The IRRS team highlights that many of the IRRS recommendations and suggestions were properly identified by the host in their self-assessment and are already being addressed through the initial corrective action plan prepared.

In the spirit of continuous improvement, the IRRS report includes several recommendations and suggestions, which, if addressed by the Government of Finland and STUK, should further enhance the overall performance of the regulatory system.

The government should:

- include all stages of the facilities life cycle into the legislation and expand it to encompass adequate provisions for closure of radioactive waste repositories;
- ensure adequate level of national competencies on radiation protection;
- strengthen its emergency preparedness and response to enhance coordination between organizations involved and ensure appropriate capacities in radiation measurements;
- separate responsibilities for operation and oversight of state-owned radioactive waste at the storage room leased to the state by TVO.

The regulatory body, STUK, should:

- continue to develop training and qualification programmes to ensure their systematic implementation;
- take the opportunity during ongoing legislation updates to enhance its regulation and guides;
- increase its oversight of radioactive material transport;
- expand its requirement for emergency exercises to all regulated facilities and activities, including transport.

To conclude, in inviting the IAEA to conduct this IRRS mission and providing a transparent and comprehensive self-assessment, the Government of Finland and the regulatory body STUK have demonstrated their commitment to continuous improvement, a basic principle for excellence in nuclear and radiation safety. This report, in particular its recommendations and suggestions, should be viewed in that context.

The IRRS team findings are summarized in Appendix V.

An IAEA press release was issued at the end of the IRRS mission.

I. INTRODUCTION

At the request of the Government of Finland, an international team of senior safety experts met representatives of the Radiation and Nuclear Safety Authority (STUK) from 3 to 14 October 2022 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the Finnish governmental, legal and regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Finland in September 2019. A preparatory meeting was conducted 13-14 April 2022 in hybrid mode to discuss the purpose, objectives, and detailed preparations of the review in connection with regulated facilities and activities in Finland and their related safety aspects and to agree the scope of the IRRS mission. Where specific facilities and / or activities would not be included in the scope of the IRRS mission, Finland undertook to provide explanation for the exclusion.

This mission will be followed by an Integrated Review Service for Radioactive Waste and Spent Fuel, Decommissioning and Remediation (ARTEMIS) mission scheduled from 27 November to 8 December 2022. To avoid unnecessary duplications between the IRRS and the ARTEMIS missions, the preparation and conduct of the IRRS mission were carried out in a coordinated manner with the ARTEMIS mission. Thus, the provisions for the decommissioning of facilities and the management of radioactive waste and of spent fuel, subject of Chapter 1.7, are to be reviewed by the upcoming ARTEMIS mission.

The IRRS team consisted of 18 senior regulatory experts from 14 IAEA Member States and 4 IAEA staff members and one observer. The IRRS team carried out the review in the following areas: 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, control of medical exposure, public and environmental exposure control, transport of radioactive material, waste management and decommissioning. In addition, policy issues were discussed, including: 1) Regulatory Readiness for SMR Licensing and Deployment and 2) Institutional Strength In-Depth (role of stakeholders challenging the accountability of licensees and regulator).

STUK conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of the STUK self-assessment and supporting documentation were provided to the IRRS team as advance reference material for the mission. During the mission the IRRS team performed a systematic review of all topics within the agreed scope through review of the Finnish advance reference material, conduct of interviews with management and staff from STUK and direct observation of STUK regulatory activities at regulated facilities. In addition, the Team Leads held meetings with the Ministry of Economic Affairs and Employment (MEAE) represented by Ms Liisa Heikinheimo, Mr Jorma Aurela, Ms Linda Kumpula, Ms Mirjami Tanner and Ms Hanna-Mari Kyllönen, and with the Ministry of Social Affairs and Health (MSAH) represented by Mr Taneli Puumalainen, Mr Mikko Paunio, Ms Helena Korpinen and Ms Samira Kudia.

All through the mission the IRRS team received excellent support and cooperation from STUK.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review Finnish radiation and nuclear safety governmental, legal and regulatory framework and activities against the relevant IAEA safety standards to report on effectiveness of the regulatory system and to exchange information and experience in the areas covered by the IRRS. The agreed scope of this IRRS review included all facilities and activities regulated in Finland. It is expected this IRRS mission will facilitate regulatory improvements in Finland and other Member States, utilising the knowledge gained and experiences shared between STUK and IRRS reviewers and the evaluation of the Finnish regulatory framework for nuclear and radiation safety, including its good practices.

The key objectives of this mission were to enhance the national legal, governmental and regulatory framework for nuclear and radiation safety, and national arrangements for emergency preparedness and response through:

- a) providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;
- b) providing the host country (regulatory body and governmental authorities) with a review of its regulatory technical and policy issues;
- c) providing the host country (regulatory body and governmental authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;
- d) promoting the sharing of experience and exchange of lessons learned among senior regulators;
- e) providing key staff in the host country with an opportunity to discuss regulatory practices with IRRS Team members who have experience of other regulatory practices in the same field;
- f) providing the host country with recommendations and suggestions for improvement;
- g) providing other states with information regarding good practices identified in the course of the review;
- h) providing reviewers from Member States and IAEA staff with opportunities to observe different approaches to regulatory oversight and to broaden knowledge in their own field (mutual learning process);
- i) contributing to the harmonization of regulatory approaches among states;
- j) promoting the application of IAEA Safety Requirements;
- k) providing feedback on the use and application of IAEA safety standards;

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IRRS TEAM

At the request of the Government of Finland, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 13 to 14 April 2022. The preparatory meeting was carried out by the appointed Team Leader Ms Sylvie Cadet-Mercier, Deputy Team Leader Ms Andrea Kock and the IRRS IAEA Team representatives, Mr Miguel Santini and Mr Hilaire Mansoux.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of STUK represented by Petteri Tiippana, Director General, other senior management and staff. It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides:

- Nuclear power plants;
- Fuel cycle facilities;
- Radioactive waste management facilities;
- Radiation sources facilities and activities;
- Decommissioning;
- Transport of radioactive materials;
- Control of medical exposure;
- Occupational radiation protection;
- Public and environmental exposure control;
- Selected policy issues.

The FIR-1 RR in Finland is defueled and in the initial stages of the decommissioning process. Hence, the review of the regulatory functions for research reactors was removed from the scope.

The STUK counterparts made presentations on the national context, the current status of STUK and the self-assessment results to date.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in Finland in October 2022.

The proposed composition of the IRRS team was discussed and tentatively confirmed. Logistics including meeting and workplaces, counterparts and Liaison Officer identification, proposed site visits, lodging and transportation arrangements were also addressed.

The STUK Liaison Officer for the IRRS mission was confirmed as Ms Kaisa-Leena Hutri-Aspholm and Ms Pirjo Vastamäki was appointed deputy Liaison Officer.

STUK provided IAEA with the advance reference material (ARM) for the review at the end of June 2022. In preparation for the mission, the IAEA review team members reviewed the Finnish advance reference material and provided their initial impressions to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

The relevant IAEA safety standards and the Code of Conduct on the Safety and Security of Radioactive Sources were used as review criteria. The complete list of IAEA publications used as the references for this mission is provided in Appendix VIII.

C) CONDUCT OF THE REVIEW

The initial IRRS team meeting took place on Sunday, 2 October 2022 in Vantaa, directed by the IRRS Team Leader and the IRRS Team Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS programme. The understanding of the methodology for review was reinforced. The agenda for the mission was presented to the IRRS team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

The host Liaison Officer was present at the initial IRRS team meeting, in accordance with the IRRS Guidelines, and presented logistical arrangements planned for the mission, including the proposed interview schedule between the reviewers and the counterparts.

The IRRS entrance meeting was held on Monday, 3 October 2022, with the participation of the Deputy DG Liisa Heikinheimo, Senior Specialist Linda Kumpula from the Ministry of Economic Affairs and Employment (MEAE) and the Medical Counsellor Mikko Paunio, from the Ministry of Social Affairs and Health (MSAH), STUK senior management and staff. Opening remarks were made by Ms Heikinheimo and Mr Paunio. Ms Sylvie Cadet-Mercier, IRRS Team Leader gave a presentation on the expectations for the mission. Petteri Tiippana, Director General of STUK gave an overview of the Finnish context, STUK activities and the results of the pre-mission self-assessment.

During the IRRS mission, a review was conducted for all review areas within the agreed scope with the objective of providing Finland and STUK with recommendations and suggestions for improvement and where appropriate, identifying good practices. The review was conducted through meetings, interviews and discussions with STUK, MEAE and MSAH staff, visits to facilities and direct observations and direct observations of regulatory inspections at authorized facilities.

The IRRS team performed its review according to the mission programme given in Appendix II.

The IRRS exit meeting was held on Friday, 14 October 2022. The opening remarks at the exit meeting were presented by Mr Petteri Tiippana and were followed by the presentation of the results of the mission by the IRRS Team Leader Ms Sylvie Cadet-Mercier. The official closure of the mission was made by Ms Anna Bradford, IAEA, Director, Division of Nuclear Installation Safety of the IAEA.

An IAEA press release was issued at the end of the mission.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

In Finland the policy and strategies for nuclear safety and radiation protection are expressed in legislation mainly through the Nuclear Energy Act (YEL) for nuclear safety and through the Radiation Act (SätL) for radiation safety. In addition, there is a policy document on the national programme on waste management (Management of spent nuclear fuel and radioactive waste in Finland, 2022), and the Government has issued a national climate and energy strategy in June 2022.

The objective of the YEL is to ensure that use of nuclear energy is safe for the overall good of society, and to prevent the proliferation of nuclear weapons. The Act lays down provisions on the general principle for the use of nuclear energy, the implementation of nuclear waste management, the licensing and control of the use of nuclear energy, and the competent authorities. As a result of recommendations identified in the 2012 IRRS mission amendments were made to the Act in 2015 to increase the independence of STUK. Lately this Act was amended in 2016 to include changes in the management of nuclear waste funds and the funding of safety research to promote expertise in Finland. Additional changes were included that Government when making a decision in principle, and the licensing authority, when giving a licence, are now obliged to take into account STUK's statement based on its safety assessment. The Act is under renewal for instance to enable a more flexible licensing processes of the nuclear reactors foreseen in the future. The public consultation of the draft Act is expected to take place in 2024. The review by the Government and the Parliament will be in 2025-2026 and the enactment of the Act is expected in 2027.

Supporting the YEL there is a Nuclear Energy Decree (YEA) which contains provisions for instance on the administrative details on licensing process and radiological criteria.

The objective of the SätL is to protect human health against detriments caused by exposure to radiation. It also aims to prevent and reduce environmental and other detriments of radiation. The SätL was renewed in 2018 to transpose the European Basic Safety Standards Directive and to bring it better in line with the Constitution which entered into force in 2000.

YEL and SätL have assigned the prime responsibility for safety on the authorised parties. The legal framework fosters leadership, and management of safety, including safety culture, and a graded approach to management of risk of facilities and activities. The graded approach has been included 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 safety requirements for authorised parties.

The IRRS team is satisfied that Finland has a clear national policy and strategy for safety consistent with Requirement 1 of GSR Part 1.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Finnish Constitution is the cornerstone of all legislation and exercise of public power. It contains provisions on governmental organization, and checks and balances between the top government branches and fundamental civil rights. The current Constitution 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 use of nuclear energy. The ministry also steers the general planning and implementation of nuclear waste management originating from the use of nuclear energy. The nuclear waste management fund is operated by the ministry.

The Ministry of Social Affairs and Health (MSAH) is responsible for the legislation of radiation practices and existing exposure situations.

The Ministry of Interior is the overall authority for national security, emergency preparedness and response and rescue services.

STUK legislation, YEL and SätL establish STUK as the radiation and nuclear safety authority. STUK is the regulatory body that undertakes licensing review and assessment, oversight of safety, security and safeguards matters,

authorization of radiation practices and activities, the establishment of qualification requirements and enforcement. YEL and SätL empower STUK to issue regulations and guides for radiation and nuclear safety, nuclear security, and safeguards.

The mission and functions of STUK are established under the STUK Act. The IRRS team was informed that the renewal of the Act is in progress to be approved by the Parliament. The draft Act states explicitly that STUK has an independent status in its positions and supervisory activities related to its field of activity. It also includes a new responsibility for STUK for assessing and making recommendations on national arrangements concerning preparedness for radiological emergencies.

The current licensing process of nuclear installations in Finland distinguishes the stages of Decision-in-Principle, Construction, Operation, and Decommissioning. The license for a nuclear facility is granted by the Government.

While there has not been any application for the release of a facility from regulatory control, there are no adequate legislative provisions for this stage. The upcoming decommissioning of the research reactor will require understanding of the end point for when the site and facility are considered to be safe for use without restrictions or a need for radiation control.

Furthermore, the IRRS team was informed that there is no separate site licensing step in the current licensing process. Instead, the site evaluation is conducted stepwise in the Decision in Principle phase and later during the construction license phase. The IRRS team considers that there may be advantages of considering a separate licensing stage for site selection and approval. This could allow a timely identification of suitable sites for potential nuclear facilities (e.g., SMRs), using bounding design assumptions, without the need for pre-selection of a specific SMR technology. This licensing stage would allow timely in-depth environmental, geological, hydrological and meteorological studies as well as assessments of external hazards.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: There is no licensing phase for release of nuclear facilities from regulatory control upon completion of decommissioning.

In addition, no specific stage for site evaluation is included in the legislation; this has been recognized in the ARM and is included in the action plan.

(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 2 para 2.5 states that <i>“The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following: (17) The criteria for release from regulatory control”.</i>
(2)	BASIS: GSR Part 1 (Rev. 1) Requirement 24: Paragraph 4.29 states that <i>“Different types of authorization shall be obtained for the different stages in the lifetime of a facility or the duration of an activity. The regulatory body shall be able to modify authorizations for safety related purposes. For a facility, the stages in the lifetime usually include: site evaluation, design, construction, commissioning, operation, shutdown and decommissioning (or closure). This includes, as appropriate, the management of radioactive waste and the management of spent fuel, and the remediation of contaminated areas. For radioactive sources and radiation generators, the regulatory process shall continue over their entire lifetime”.</i>
(3)	BASIS: GSG-13 para 3.86. states that <i>“Authorizations should be granted or denied in accordance with the governmental, legal and regulatory framework and should cover all stages of the lifetime of a facility or activity. For a nuclear facility, for example, this encompasses site evaluation, design, manufacturing, construction, installation, commissioning, operation, decommissioning (or closure) and subsequent release of the site from regulatory control”.</i>
(4)	BASIS: SSG-12 para 2.5. states that <i>“Licences and authorizations, as defined in para. 2.2, should be granted or denied in accordance with the national legal and governmental framework and should cover all stages of the lifetime of the nuclear installation, namely, site evaluation, design, construction, commissioning, operation, decommissioning and subsequent release of the site from regulatory control”.</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>control”.</i>
R1	Recommendation: The Government should incorporate a licensing phase for release of nuclear facilities from regulatory control upon completion of decommissioning.
S1	Suggestion: The Government should consider incorporation of the stage of site evaluation, in the Finnish legislation for nuclear facilities.

Currently there are no adequate provisions in legislation related to closure and institutional control of the radioactive waste final disposal facilities. Future work needs to be carried out for clarifying the licensing of the closure for disposal facilities. Further, provisions regarding closure of final disposal facilities are under discussion for possible inclusion in the next revision of the YEL.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: There are not adequate provisions for closure of waste disposal facilities included in the Nuclear Energy Act.

(1)	BASIS: GSR Part 1 Requirement 24, para 4.29 states that “Different types of authorization shall be obtained for the different stages in the lifetime of a facility or the duration of an activity. The regulatory body shall be able to modify authorizations for safety related purposes. For a facility, the stages in the lifetime usually include: site evaluation, design, construction, commissioning, operation, shutdown and decommissioning (or closure). This includes, as appropriate, the management of radioactive waste and the management of spent fuel, and the remediation of contaminated areas. For radioactive sources and radiation generators, the regulatory process shall continue over their entire lifetime”.
(2)	BASIS: SSR 5 Requirement 1 states that “The government is required to establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities shall be clearly allocated for disposal facilities for radioactive waste to be sited, designed, constructed, operated and closed. This shall include: confirmation at a national level of the need for disposal facilities of different types; specification of the steps in development and licensing of facilities of different types; and clear allocation of responsibilities, securing of financial and other resources, and provision of independent regulatory functions relating to a planned disposal facility”.
R2	Recommendation: The Government should expand the legislative framework to encompass adequate provisions for closure of radioactive waste repositories.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

STUK is established as the radiation and nuclear safety authority. As it was mentioned above, the STUK Act and Decree on STUK include provisions on the missions and functions of this regulatory body.

A new STUK Act and Decree are in the approval process to explicitly reinforce the independent role of STUK in its decision making in legislation. The draft Act includes the following provision:

- *The Radiation and Nuclear Safety Authority has an independent status in its positions and supervisory activities related to its field of activity.*

STUK is under the MSAH. This means that ministerial directions and guidance are provided to STUK by MSAH. STUK reports annually to the ministry. These annual reports include STUK’s main goals which are related to the Government’s and Ministry’s main goals.

STUK is independent in making decisions regarding its staffing.

STUK's funding comes from fees collected from licensees, from the Government budget and from expert services provided by STUK. The IRRS team was informed that STUK has access to sufficient financial resources for the supervision of nuclear facilities. The supervision of radiation facilities, since the amendment of SätL in 2018, is no longer fully covered by fees collected from licensees. Due to these changes STUK stated in the ARM that it is no longer fully independent of the state budget with regards to regulation of radiation practices.

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

Both YEL and SätL clearly set out legal responsibilities for nuclear and radiation safety.

Section 9 of YEL states that the responsibility for the safety of nuclear facilities rests with licensees. Sections 9 and 24 of YEL state that the licensees retain prime responsibility for safety through the lifetime of facilities and the duration of activities. 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.

SätL section 22 describes the responsibility of the licensee, stating that the licensee is responsible for the radiation safety of the practice and that this responsibility cannot be transferred.

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

In addition to the duties assigned to STUK for the regulatory oversight of nuclear safety and radiation protection, other authorities have responsibilities related to the use of radiation and nuclear energy as defined in YEL and SätL. In SätL there are responsibilities assigned to municipality's health protection authorities, Finnish Customs and Finnish Safety and Chemical Agency.

Both Acts contain provisions on the coordination and cooperation between the authorities responsible for safety and security.

Regarding radon surveillance and control in dwellings, workplaces and at public places several authorities have been given responsibilities. A working group has been established among these authorities to develop regulation, good practices, and communication regarding radon. The working group also serves as steering committee of the national radon action plan. It comprises members of the MSAH, National Supervisory Authority for welfare and health, Ministry of environment, STUK, Regional State Administrative Agency, Building Control Authority and association of Finnish local and regional authorities.

1.6. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE EXISTING OR UNREGULATED RADIATION RISKS

SätL provides a framework for the control of existing exposure situations. Several existing exposure situations have been identified in Finland, the main contributor being exposure to radon. An action plan to identify all existing exposure situations in the country is currently in preparation and has been drafted by STUK and MSAH. It is expected that this plan will be approved by the end of 2022. Reference levels for the exposure of the public and workers to radiation from natural radiation other than radon, space radiation or radiation from building materials is 0.1 mSv/y and 1 mSv/y respectively. The reference level for building materials intended for building construction is 1 mSv/y.

A radon reference level of 300 Bq/m³ has been established for existing workplaces, dwellings and public buildings and a radon reference level of 200 Bq/m³ has been established for new construction. As described in Chapter 1.5. a national radon action plan for the control of exposure to radon, prepared with the participation of several supervisory authorities, has been established.

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

This topic of Chapter 1.7 of the IRRS mission will be fully reviewed and reported in the upcoming ARTEMIS mission, as per the IRRS-ARTEMIS back-to-back specific and additional guidelines.

1.8. COMPETENCE FOR SAFETY

The education and research in the field of nuclear and radiation safety are organised and performed by Finnish Universities and research centres (including VTT Technical Research Centre).

In the case of nuclear safety, the Government has established together with parties involved in the use of nuclear energy a specific training programme for nuclear safety (YJK-course). In 2010 the 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. One of the key conclusions of the study, was that comprehensive high standard national competence is needed by the 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 outcome of the study concluded that Finland has an adequate national infrastructure to develop the competences needed by its nuclear energy sector currently and in the future. The MEAE is committed to keep the competence survey up to date and the review will be repeated at regular intervals.

The MEAE created another working group in January 2013 to prepare a research strategy for nuclear energy until 2030. This strategy has been implemented through the national nuclear safety and waste management research programmes SAFIR and KYT.

In the field of radiation safety, a national network CORES and a programme for radiation protection research has been established. Unlike the study carried out in the nuclear safety field the last survey which focused on research and development infrastructures was performed for the MSAH about ten years ago. Due to limited scope of the study and time elapsed, it is not possible to state if existing national competences and infrastructures for radiation safety are adequate to cover current and future needs and if they can be maintained in the future in Finland.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Since the last survey on national competencies and infrastructure for radiation protection was performed 10 years ago and has not been updated, building and maintaining competences and infrastructure cannot be assured. This has been recognized in the ARM and is included in the action plan.

(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 11 states that <i>“The Government shall make provisions for building and maintaining the competence of all parties having responsibilities in relation to safety of facilities and activities”.</i>
(2)	BASIS: GSR Part 1 (Rev. 1) Requirement 11 para 2.35. states that <i>“The building of competence shall be required for all parties with responsibilities for the safety of facilities and activities /.../ competence shall be built in the context of the regulatory framework for safety, by such means as:</i> - <i>Technical training</i> - <i>Research and development work /.../”.</i>
R3	Recommendation: The Government should evaluate competencies and infrastructure needs on radiation protection and make provisions to cover current and future demands.

A formal curriculum for the education and training of Radiation Protection Experts (RPE) is established in the field of medical use of radiation. It is, however, not in place in the fields of the industry and research and nuclear power.

The National Advisory Board of the education of radiation protection experts (STAKONE) was set up in June 2020 to coordinate the RPE education in the universities in the fields of industry and research and nuclear power. The IRRS team was informed that the formal curriculum has not yet been established in these fields. The formal curriculum for the education would be essential to ensure that the RPE education is consistent in all universities. It would also foster adequate participation in the radiation protection courses.

In addition to the education and training, the RPE qualification requires working experience. The qualification is granted by STUK. With the absence of formal training, STUK has to evaluate the applicant's knowledge basis case by case.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The current Radiation Act requires a Radiation Protection Expert (RPE) in radiation practices and activities. The Government has not established necessary arrangements to ensure professional training to guarantee the availability of a sufficient number of qualified and experienced Radiation Protection Experts. This has been recognized as part of the ARM and is included in the action plan.	
(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 11 states that <i>“The government shall make provision for building and maintaining the competence of all parties having responsibilities in relation to safety of facilities and activities”</i>
(2)	BASIS: GSR Part 1 (Rev. 1) Requirement 11 para 2.36.c). states that <i>“The government shall make provisions for adequate arrangements for increasing, maintaining and regularly verifying the technical competence of persons working for authorized parties”</i>
R4	Recommendation: The Government should make the necessary arrangements to ensure the professional training of a sufficient number of qualified and experienced RPEs.

1.9. PROVISION OF TECHNICAL SERVICES

According to section 14 SätL technical services providing measurements for occupational, public, or medical exposures and for existing exposure situation require authorization by STUK. STUK has approved several measurement and dosimetry services. The IRRS team was informed that one of the nuclear facility operators operates their own dosimetry authorized by STUK. Due to lack of an external service provider, internal dosimetry service is provided by the regulatory body to ensure that this service continues to be available in the country.

STUK maintains the national metrological standards necessary to ensure the reliability of radiation measurements. STUK also prepares and implements an environmental radiation monitoring programme to monitor the amount of radioactive substances in the environment and the magnitude of the public exposure resulting from them.

1.10. SUMMARY

Finland has a clear policy and strategy for safety, mainly set out in legislation, supported by a clear framework for safety.

STUK has been established under the legal framework as the regulatory authority.

The IRRS team has made recommendations to address gaps in the current legislation to incorporate the stage of nuclear facilities from regulatory control upon completion of decommissioning and closure of radioactive waste repositories.

The IRRS team also has made recommendations to address gaps in evaluating competences and infrastructure needs on radiation protection and establishing arrangements to ensure the training of RPE in industrial, research and education fields.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Finland is highly committed to nuclear and radiation safety. It is a signatory to all relevant international organizations, treaties and conventions and participates actively in international cooperation in those issues. Finland has expressed political support to the Code of Conduct on the Safety and Security of Radioactive Source and its associated Guidance.

STUK, according to the Decree on Radiation and Nuclear Safety Authority, is responsible for contributing to international co-operation in its field of activity, and for taking care of international control, contact and reporting activities, as enacted or prescribed.

Finland has also several bilateral agreements for exchange of information on nuclear facilities and on notification of a nuclear or radiation emergency, with Sweden, Norway, Estonia, the Russian Federation, Ukraine, Denmark and Germany. Agreements relating to early notification of nuclear events and exchange of information on safety of nuclear facilities are in place with Denmark, Norway, Sweden, Germany, the Russian Federation and Ukraine.

In addition, STUK has a number of cooperation arrangements with several foreign regulatory bodies, which cover exchange of information on safety regulations, operational experiences, waste management etc. Such an arrangement has been made with several regulators.

STUK participates in all IAEA Safety Standard Committees and Commission on Safety Standards and WENRA. The IAEA safety standards and WENRA reference levels are addressed when developing legislation, regulation and requirements.

In the field of radiation safety, STUK participates actively in the Nordic regulator's group and HERCA.

To enhance its effectiveness and efficiency of international co-operation, STUK has recently established a new organisational unit responsible for coordinating its international activities. This unit manages regulatory cooperation, development of international projects, agreements, coordination with other regulatory bodies, and the overall coordination of activities with the IAEA, OECD/ NEA/, EC, etc. This unit is composed of 5 people plus the head of unit, dedicated full time to international cooperation.

The Finnish government has requested several international peer reviews concentrating on the safe use of nuclear energy. These peer reviews have been focused on regulatory activities and on the safety of nuclear facilities (IRRS, ARTEMIS), and in physical protection (IPPAS) as well as on the environmental surveillance program (EC). Finland carries out a self-assessment in the frame of topical peer reviews performed every six years requested by EURATOM Nuclear Safety Directive.

The Finnish government has planned to host an EPREV mission in 2024.

The IRRS team is satisfied that Finland is fulfilling international obligations and supporting international cooperation to meet the requirements of the GSR Part 1 (Rev. 1).

The IRRS team notes the proactive efforts of Finland's efforts is fulfilling international obligations and supporting international cooperation.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

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

STUK gathers information directly from its cooperation with other regulators, meetings of regulator groups: OECD/NEA/WG's, WENRA, IAEA and early information channels like IAEA/NEWS and WGPCNEWS as well as OECD/NEA Topical Databases. Moreover, in the field of radiation safety STUK participates actively in Nordic regulators' groups and HERCA in which regulatory experience and lessons learnt are shared.

STUK participates in international cooperation in the field of nuclear and radiation safety which is reported in the annual reports on oversight of nuclear safety and radiation practices.

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

For review and assessment of Operating Experience (OE) information abroad, STUK has an internal OEF Group for international events with a coordinator and team of 16 technical experts covering all expertise areas of Nuclear Reactor Regulation and Nuclear Waste Regulation and Safeguards Departments. The group meets monthly and based on the screening and expert assessment in STUK's own IRS database, decisions are made whether there is a need for review of the regulatory or licensee measures based on lessons learnt. The IRS report is categorised on the basis of actions taken (categories 1 to 3), or not needed (category 0).

The guide YVL A.10 provides detailed requirements and administrative procedures for the systematic evaluation of operating experiences of the nuclear facilities, and for the planning and implementation of corrective actions.

However, for radiation facilities and activities STUK has no systematic process in place to analyse the domestic and international operating experience. The IRRS team notes that they already have all the elements associated with the review and assessment of OE for those facilities, although there is room for improvement.

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Observation: For radiation facilities and activities, STUK does not have a systematic process in place to analyse the domestic and international operating experience.

(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 15 states that <i>“The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities”.</i>
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S2	Suggestion: STUK should consider establishing a systematic process to identify lessons from operating experience at the domestic and international level for radiation facilities and activities and promote their use by authorized parties.
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Concerning regulatory experience management, STUK has recently (2018/2019) developed a process for managing regulatory experience from various sources. This process has been established as a pilot project by the Nuclear Reactor Regulation and Nuclear Waste Regulation and Safeguards Departments. The aim is to improve regulatory processes, functions and regulation based on the experience, and to share lessons learned with interested parties. The future objective is to expand the pilot process to cover all STUK regulatory departments and to share the lessons learned with other stakeholders and include this procedure in STUK's integrated management system.

For radiation practices, STUK has developed a database called the VASARA system which records all regulatory decisions, inspection findings, actions of enforcement and radiation safety deviations in a systematic manner. Regulatory experience is collected through the VASARA system. However, the available information is not systematically assessed.

STUK has recognized in the ARM the need to ensure that a systematic regulatory experience feedback process is implemented in all the regulatory departments, and it is identified in its action plan.

The IRRS team recognizes the effort made by STUK in developing a process for the systematic recording and compilation of regulatory experience under its management system, however the process it is not fully completed. A suggestion on this topic is provided in Chapter 4.

2.3. SUMMARY

Finland has established sound processes to fulfil its international obligations in line with international agreements and cooperation, STUK is committed to support international cooperation at all levels.

It has successfully implemented the principles of continuous safety improvement using operating experience in nuclear facilities although room for improvement has been identified in radiation facilities and activities field.

STUK has developed and implemented a systematic process for the management of regulatory experience for the Nuclear Reactor Regulation and Nuclear Waste Regulation and Safeguards Departments although the process is not fully implemented at STUK. The IRRS team has further discussed this in Chapter 4.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

STUK's organization includes five departments under the authority of the Director General: the Department of Nuclear Reactor Regulation, the Department of Nuclear Waste Regulation and Safeguards, the Department of Radiation Practices Regulation, the Department of Environmental Radiation Surveillance, Coordinated Expert Services, and Administration. In total, there are 336 staff at STUK, 117 in nuclear reactor regulation, 23 in nuclear waste regulation and safeguards, 60 in radiation practices regulation, 64 in environmental radiation surveillance, 18 in coordinated expert services, 51 in administration, and 3 in the Director General's office. In accordance with GSR Part 1 (rev. 1) Requirement 16, STUK's resources are allocated in a manner that is consistent with the radiation risks associated with facilities and activities.

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 ensures that STUK's organizational structure and use of resources support both effective and efficient regulatory activities, and decisions on the structure and resources can be made without undue influence. STUK periodically evaluates this organizational structure and resources and identifies the need for any change. Changes are carried out following Guide STUK 2.2, which has a chapter on the management of organizational changes.

STUK's budget is mostly through fee-charging (cost recovering) operations and services that simultaneously support development and sustainability of STUK's competency. The IRRS team was informed that STUK has access to sufficient financial resources for the supervision of nuclear facilities. The supervision of radiation facilities, since the amendment of SätL in 2018, is no longer fully self-funded. While this has not impacted oversight activities directly, reductions of STUK budget have challenged the national competencies in radiation protection (see Chapter 1.3). The IRRS team recognised that adequate budget is vital for the independence of the regulatory body in ensuring its missions and functions. During the mission, the IRRS team identified that areas such as preparedness to regulate new technologies (e.g., SMRs) and renewal of nuclear energy legislation could be negatively impacted by the budgetary constraints. In the area of nuclear safety, nuclear power plant licensees also fund research through fees. A six-year research plan was recently issued by the government. A management group chaired by STUK directs this research. This body and funding may enable provisions for research resources to support the preparation for new technologies such as SMRs. STUK also relies on support from the Technical Research Centre of Finland (VTT) and other research organisations, which are available to provide independent research for nuclear safety facilities.

As noted in Chapters 3.2 and 5.1, STUK does not issue licences for nuclear facilities. The licensing process is led by MEAE, and the actual licenses are granted by the government. STUK provides its safety assessment to MEAE in support of this process. A decision in principle regarding a nuclear facility of considerable general significance must be ratified by the Parliament before the licensing process can be initiated. The licensing decision process is discussed in detail in Chapter 5.1. The IRRS team noted that there is only one person at the MEAE that is responsible for coordinating and preparing licenses for nuclear waste facilities. Given the current number of nuclear waste facilities as well as the ongoing licensing process for operation of the deep geologic disposal facility, there may be a future need for the government to consider assessing the resources needed for licensing nuclear waste facilities.

3.2 EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

The State Civil Servants' Act states that in appointing employees, STUK will ensure that no interests which might conflict with the proper performance of his or her duties exist, and that STUK staff are able to perform their duties with independence and integrity in all other respects. STUK staff must not handle matters concerning his or her former employer or a partner or competitor of his or her former employer which can compromise their impartiality. In addition to what is described in the legislation, STUK's management system addresses these expectations and gives additional guidance to ensure independence at all levels. The competence of STUK's staff is an important prerequisite for ensuring independence in decision-making and oversight activities. 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. STUK internal procedures provide additional guidance and criteria for

consideration when dealing with external stakeholders, in particular representatives of organizations subject to regulatory control, and issues that relate to an employee's personal interest. The independence of STUK and STUK's staff is also addressed in the training of all employees. As STUK provides some services (such as radon and other measurements), STUK's organization is structured so that its effective independence is not compromised as a result of providing these services. This is done by clear separation of regulatory activities and services to different organizational units. In addition, STUK's laboratories providing external services are regularly evaluated by independent external bodies such as the Finnish Accreditation Service FINAS.

STUK's right to intervene with regard to safety issues at regulated facilities is specified in legislation. 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 cases of significant and acute radiation risks.

According to the YEL and SätL, STUK has the authority to issue regulations and guides for radiation and nuclear safety, security and safeguards. However, as noted in Chapter 3.1, STUK does not grant construction or operating licences for nuclear facilities. STUK provides its assessment regarding fulfilment of the safety regulations to the MEAE. STUK's authority under the legislation is taken into consideration by MEAE and the government when determining whether to grant a licence. STUK's independent regulatory position was enhanced in 2015 by an amendment of the YEL, including clarification of the role of STUK's safety statement in the licensing process of nuclear facilities. However, 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 which is currently in draft and in the parliament process. While the legislation has not yet been completed, during discussions with the STUK staff and the MEAE, it was clear that STUK's positive safety finding would be necessary before the government would grant a licence to a nuclear facility. There has been no case in which a license has been issued without such a positive safety finding by STUK.

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 conflict with regulatory control. However, STUK has a duty to operate and regulate interim storage for a state-owned intermediate and low-level radioactive waste. The storage room is situated inside TVO's Olkiluoto low- and intermediate level waste disposal facility. These functions are performed by two different departments within STUK. Specifically, STUK's Environmental Surveillance Department operates the storage facility and STUK's Nuclear Waste Regulation and Safeguards Department provides oversight and performs inspections. While the separate departments provide some degree of separation of functions, this situation challenges the independence of the regulator given that STUK is both the operator and regulator of this facility.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: STUK has responsibilities as both the operator and the regulator for a storage room for state-owned low and intermediate radioactive waste at Olkiluoto, which has been leased to the State by TVO. This has been recognized in the ARM and is part of the action plan.

(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 4 states that <i>“The government shall ensure that the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making”.</i>
(2)	BASIS: GSR Part 1 (Rev. 1) Requirement 4 para 2.9 states that <i>“No responsibilities shall be assigned to the regulatory body that might compromise or conflict with its discharging of its responsibility for regulating the safety of facilities and activities.</i> <i>2.10. The staff of the regulatory body shall have no direct or indirect interest in facilities and activities or authorized parties beyond the interest necessary for regulatory purposes”.</i>
(3)	BASIS: GSR Part 1 (Rev. 1) Requirement 4 para 2.10 states that <i>“The staff of the regulatory body shall have no direct or indirect interest in facilities and activities or authorized parties beyond the interest necessary for regulatory purposes”.</i>
(4)	BASIS: GSR Part 5 Requirement 3 states that <i>“The regulatory body shall establish the requirements for the development of radioactive waste management facilities and activities The</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<i>regulatory body shall review and assess the safety case and the environmental impact assessment for radioactive waste management facilities and activities, as prepared by the operator both prior to authorization and periodically during operation...</i>
R5	Recommendation: The Government should separate responsibilities for operation and oversight of state-owned radioactive waste at the storage room leased to the state by TVO so that STUK no longer has responsibility for operating the storage room.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

STUK has a detailed process for long term planning to ensure appropriate staffing and competence. STUK establishes a competency strategy every five years with detailed goals established every year. Implementation is assessed every 6 months. To maintain a clear vision and status of staff turnover, STUK updates its human resource plan annually. This plan may include action for staff training, rotations, and recruiting plans. The process includes a systematic review by department and considers information from outside of STUK on what environmental factors may impact STUK's staffing and skill needs through activities such as international interactions and evaluation of the change in the numbers of licenses. 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. Potential use of external support (e.g., TSOs, consultants etc.) is considered as part of the annual resource planning. STUK has identified that when people have expertise in more than one area, this might not be addressed when allocating review and assessment tasks since the tasks are divided based on the department's identified competencies. STUK is continuing to refine the process to address issues such as this. Given the thorough nature of the process and the frequency of the evaluation, STUK's competency planning process is an area of good performance.

Less than 10% of STUK's staff is eligible for retirement, and during interviews the staff indicated that they have not identified increased attrition in the recent past. STUK has been successful in recruiting the staff necessary to fill vacant positions and cross training staff in some areas to build competencies. STUK does rely on contractors to supplement work. Provisions are in place to ensure appropriate competency of the contractors.

STUK does have qualifications programs in place for some areas that stipulate the necessary activities to become qualified. These programs include appropriate sign offs to document completion and allow tracking of qualifications progress. Chapter 7.1 addresses the qualifications of inspectors.

STUK does complete knowledge management activities such as archiving licensing documents, capturing the knowledge from staff that plan to retire, and discussion among technical experts. However, this information is not captured systematically to ensure that information that is related is connected, and there is not a centralized depository for capturing knowledge to ensure information sharing across STUK.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: STUK does not have a systematic process and centralized depository for knowledge management.	
(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 18 para. 4.13 states that <i>"a process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management ..."</i> .
S3	Suggestion: STUK should consider developing a systematic and centralized process for knowledge management and for sharing knowledge across STUK.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

STUK has four Advisory Committees to assist them to develop its functions as a regulatory, research and expert organization. Advisory committees have no decision-making authority on any of STUK's regulatory activities, and are purely in an advisory role. STUK's advisory committee provides advice to the Director General and the Executive Management Team. STUK's advisory committee members are appointed by the Director General. The other three committees can also provide recommendations to the government. Members of three advisory committees (the Advisory committees on nuclear safety, radiation safety, and nuclear security) are nominated by the Government, in consultation with STUK. Advisory committee positions are considered by STUK in decision making, and, should STUK revise its position based on such advice, or if STUK's decision is not in agreement with the advisory committee, these decisions are made available as part of the public record. Members of the committees must conform to the Administrative Procedure Act which specifies the principles of independence and grounds for disqualification based on a conflict of interest. As part of the nomination process, members must provide a statement of their experience as evidence of independence, and they are required to recuse themselves from topics that may create a personal conflict of interest.

The Finnish Advisory Committee on nuclear safety is an independent body giving recommendations to STUK and the Government concerning important topical safety issues and delivering statements on license applications and regulations. The Committee has two Subcommittees related to nuclear power plants and radioactive waste with non-Finnish experts with the exception of the Chair. These subcommittees provide an independent opinion based on knowledge and experience from foreign countries on the topics put in front of them to enrich the technical assessment delivered by the Advisory Committee to STUK or the Government. This also promotes international cooperation concerning the safe use of nuclear energy and further ensures independence of the committees given the limited independent expertise available and the strong culture of trust of the government within Finland. This demonstrates the importance and visibility given by Finland to external independent assessments. As such, this is an area of good performance.

STUK receives technical support from the VTT, Lappeenranta University of Technology, Aalto University (former Helsinki University of Technology), and from other support organisations or individual consultants. As noted in Chapter 3.3, potential use of external support (e.g., TSOs, consultants etc.) is considered as part of the annual resource planning. In general, STUK utilizes external support temporarily to complement its own human capacity (e.g., temporary peaks in workload) or to supplement STUK's own core competency (e.g., for specialized independent/external analysis). STUK's internal guides as well as contracts specify that the independence of the technical support organization must be taken into account. 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. The advice and assistance from external organizations does not have a formal status and does not relieve STUK of its assigned responsibilities.

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, and other publications on the STUK website. STUK has established both formal and informal mechanisms for communication between itself and authorized parties to ensure professional and constructive communications. The formal and most frequently used mechanisms are through correspondence between STUK and authorized parties, and inspections of the authorized activities and organizations. STUK also invites authorized parties to formal meetings. Informal mechanisms consist of meetings and discussions between individuals at different levels of the organizations, as well as seminars and workshops with authorized parties. STUK periodically sends surveys to its authorized parties to gather feedback on the regulatory process. Authorized parties are also given a 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. The legislation requires and the STUK management system reiterates that STUK's decisions and requirements must have a sound legal basis and the requirements set have to be commensurate with safety. The basis for the decision, evaluation

criteria, and scope of the review is included in the decision or presented in a separate justification memorandum and is provided to the authorized parties.

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. Currently, there are 5 resident inspectors at Olkiluoto covering the inspection of Olkiluoto NPP units 1–3 and Posiva’s final disposal facility and encapsulation plant construction activities. At the Loviisa NPP, there are 2 resident inspectors.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

Procedures for regulatory control are prescribed in relevant STUK guides and management system. These include process descriptions for the control of nuclear facilities, nuclear waste, nuclear material, and radiation practices. These include separate guides for all regulatory activities, such as establishment of regulatory requirements, licensing, review and assessment, and inspection and enforcement. STUK’s regulatory decisions are independently assessed by two persons, except for the decisions related to inspections at the facilities. However, some minor decisions concerning radiation practices can be approved by an individual inspector. In the management system for each type of decision, the responsibilities are defined. Those responsibilities are also defined in the electronic workflow in the document management system. The preparation process of regulations includes consideration of whether a change to the regulations is justified, soliciting internal and external comments, and hearings of relevant advisory committees. These processes ensure that requirements remain stable and changes are introduced only thorough careful consideration.

The following arrangements are in place to minimize subjectivity in decision making:

- Guidance and criteria on decision making are provided to STUK staff,
- The process of decision making involves two signatures in most cases,
- Hearing process applied prior decision making enables authorised parties to raise any concerns,
- STUK’s directors, section heads or application handling coordinators review decisions,
- Training of the inspectors to ensure consistency in decision making in relation to minor licensing matters concerning radiation practices, and
- Fairly detailed regulatory guides that present the legal basis for decision making.

There are some common areas of regulatory responsibility (e.g., waste, occupational exposure) where regulations and legislative requirements are contained in different regulations or legislation. STUK has initiated discussions among experts to identify and align the requirements in these areas. This creates the potential for divergent requirements for similar areas. The ongoing updates to legislation provide an opportunity to further align requirements in areas such as waste management and occupational exposure to avoid discrepant requirements in similar areas. For the area of radioactive waste management, the IRRS team suggests that the ARTEMIS mission address this issue.

3.7. SAFETY RELATED RECORDS

STUK establishes and maintains all records specified in GSR Part 1 (Rev. 1), Requirement 35. 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 and can be utilized before and during the decommissioning of the facility. Information is archived and maintained in STUK registers following the regulations on information management.

STUK utilizes several document depositories to maintain different types of records. STUK is considering how these systems of records can be streamlined.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

The Decree on STUK defines STUK's tasks. One of the tasks is to inform stakeholders about radiation and nuclear safety matters and participate in training activities. STUK's Management System describes STUK's values, and one of the values is openness. STUK is active on social media (LinkedIn, Facebook and Twitter). Particular attention is paid to serving different types of media due to their access to a wider audience. In addition, STUK utilizes different means to communicate with the public and interested stakeholders, including:

- Correspondence, meetings and seminars and personal contacts
- Press releases are published on safety-significant events at nuclear facilities or in significant existing exposure situations such as 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.
- For communication during emergencies, STUK has established lists of contact points for relevant licensees, authorities, and ministries in Finland and abroad.

STUK consults with interested parties (public, advisory bodies, licensees, ministries, other authorities, etc.) when drafting new regulations. STUK also publishes annual reports on the results of its oversight in the use of nuclear energy, radiation practices, environmental surveillance and nuclear non-proliferation. STUK communicates actively with other authorities (e.g., security, emergency preparedness) to enhance coordination.

STUK consults with the ministry of interior and advisory committees on security issues. For emergency preparedness related matters (regulations, emergency plans), STUK must ask for a statement from the ministry of interior as well as from the advisory committee for nuclear safety.

STUK goes beyond communicating on regulatory matters to educating and engaging stakeholders regarding radiation risks. This builds a common understanding of the relative risks of regulated activities and furthers deeper engagement among stakeholders. STUK utilizes the internet to inform the public and interested stakeholders about general nuclear and radiation safety, 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 encourages its staff to communicate about these issues on social media as well. As a particular strength, STUK is proactive in educating and engaging the media in addition to providing information on regulatory activities. Specifically, STUK organizes and participates in topical meetings on nuclear and radiation safety matters, and invites the media to these meetings. In addition, STUK has offered tours of its facilities to members of the media to further engagement and understanding, is very responsive to media requests, and encourages direct interaction between its staff and the media at all levels of its organization. STUK's practices regarding education of the media were found to be remarkable for effective communication and consultation with interested parties.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: STUK educates and engages the media through inviting the media to various activities related to nuclear and radiation safety matters and setting expectations for STUK staff to be direct and responsive in their interactions.

(1)

BASIS: GSR Part 1 (Rev. 1) Requirement 36 para. 4.49 states that *“the regulatory body, in its public and informational activities and consultation, shall set up appropriate means of informing interested parties, the public, and the news media about the radiation risks associated with facilities and activities, the requirements for protection of people, and the environment, and the processes of the regulatory body. In particular, there shall be consultation by means of an open and inclusive*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<i>process with interested parties residing in the vicinity of the authorized facilities and activities, and other interested parties, as appropriate. Interested parties including the public shall have an opportunity to be consulted in the process for making significant regulatory decisions, subject to national legislation and international obligations. The results of these consultations shall be taken into consideration by the regulatory body in a transparent manner”.</i>
GP1	Good Practice: STUK’s practices regarding education and engagement of the media were found to be remarkable for effective communication and consultation with interested parties.

STUK requested a policy issue discussion on Strengthening Institutional Strength in Depth- Stakeholders, which relates closely to the topic of Communication and Consultation of Interested Parties during the mission. This discussion is documented in Annex I.

3.9. SUMMARY

STUK has a strong infrastructure and organization in place such that it effectively carries out its regulatory responsibilities. STUK has a detailed process in place for long term staffing and competence training and effectively communicates with the facilities it regulates, supported by its advisory bodies and technical support organizations. STUK’s decisions are independent and this independence is being strengthened through a legislative revision.

STUK operates and regulates the state-owned interim and low-level waste storage room at the Olkiluoto low- and intermediate disposal facility owned by TVO. The IRRS team identified this as insufficient organizational independence. A recommendation to the Government to address this issue has been raised.

The IRRS team also identified one area of potential improvement in the area of knowledge management and one good practice in the area of communication and consultation with interested parties.

4. MANAGEMENT OF THE REGULATORY BODY

4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

STUK's senior management is committed to demonstrate leadership for safety and they are also accountable for ensuring that the needed policies, structures, and resources are in place and that safety as a value and priority is demonstrated in daily operation.

Management uses a performance management system to ensure that STUK achieves the goals set for it using operational planning and an emphasis on risk management. Objectives, timelines and resource allocation for all goals and activities are also determined. A graded approach is implemented in the planning process and in developing and allocating 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.

Behavioural expectations of the management are defined and published in a guide. Management encourages the attitude that any identified problems and personal views are rigorously brought up. STUK employees are encouraged to bring forth all concerns they may have encountered in their work and to discuss these with other team members. The managers are expected to develop and foster a good and open work climate that supports the reporting of concerns by employees.

STUK has 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.

4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

STUK's mission is to protect people, society, the environment and future generations from the harmful effects of radiation. Ensuring fulfilment of the mission is the primary goal in strategic and annual planning processes. The time span for strategic planning has been five years. The strategy is based on analysis of the changes and drivers in the operating environment, expected developments in the regulated areas, and resource needs.

The first comprehensive Quality Management system was developed in 1997-98 covering all activities. The current Management System is an integrated system of management, including core and support processes, the organizational structure of STUK, rules of administration, guides and protocols, values and organizational culture, including safety culture, as well as procedures for assessment and continuous improvement with audit processes and management reviews.

The establishment, implementation and assessment of the management system supports the planned and systematic performance of regulatory activities. Senior management has assigned responsibilities within respective departments for development, application and maintenance of management system and quality issues. Manuals, guides and working instructions are updated regularly, and approved by management. By these actions the management system enhances the safety culture in the organization.

4.3. THE MANAGEMENT SYSTEM

STUK's 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.

STUK has an internal guide on the organizational change process and its evaluation. 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.

Openness and transparency are included in the basic principles for the regulatory control activities. All decisions are based on expert judgement including hearing all relevant parties, as appropriate. Identified problems and personal

views are rigorously brought up. Responsibilities for decisions are acknowledged, and errors are corrected. Each of the basic values also manifest the importance of safety. “Courage” is a STUK value which means that any problems and differing opinions are openly expressed. Cases of conflicting opinions are dealt with in discussions in which a consensus is sought.

According to the Finnish YEL Section 7 a “The safety requirements and measures for ensuring safety shall be graded and targeted so as to be commensurate with the risks in the use of nuclear energy”. This is seen in licensing requirements for different types of facilities and activities. Accordingly, this approach has been considered in regulatory activities.

Regulatory activities are recorded for traceability of the decision making. 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, 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.

4.4. MANAGEMENT OF RESOURCES

The departments take care of the development of professional competence in their own field of substance. The director of the department is responsible for ensuring that the department's competence and its development are managed in a planned manner and in accordance with the strategy. The management of the department (director, deputy director and heads of units) is responsible for the adequacy of material resources in their area of responsibility and, consequently, for arranging the conditions for the development of staff skills. The heads of the units are responsible for ensuring that the persons working in the unit are provided with the conditions to develop their own professional skills and that they receive the training necessary for the operation of the unit and the department.

The Management by Results System is in use in STUK. The focus in the planning of activities is not only in goals but also in the quality and effectiveness of the work. The follow-up of activities, the evaluation of achieved results are also covered by the Management by Results System. Within the system, objectives and timelines as well as resource allocation for all activities are determined.

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. The training and qualification programme is addressed in Chapter 7.1.

4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

A process chart of STUK 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.

The process chart of STUK mentions five core processes: Legislation Regulation, Regulatory Oversight, Preparedness, Communication and Expert Services.

The IAEA general safety guide GSG-13 suggests seven core processes including “Review and assessment of facilities and activities”, “Notification and Authorization” and “Enforcement” which also are supported by requirements of GSR Part 1 (Rev. 1). However, STUK demonstrated that the missing processes are included in the Regulatory Oversight process.

In addition, STUK committed to harmonize their regulatory oversight processes and to involve rules for processes and the roles of process owners in the management system, and accordingly to develop STUK's performance indicators further to be more visible to staff.

4.6. CULTURE FOR SAFETY

The safety culture has been adopted in STUK's Policy, which underlines the importance of safety in its daily operations and the commitment of senior management and all its employees to developing and maintaining a healthy safety culture and demonstrating safety as an overriding value through their actions.

A Safety Culture Program was developed in 2019 to support the development of a healthy safety culture in STUK. Senior management's role and their abilities to demonstrate leadership for safety are among the interest points observed and evaluated in the Safety Culture Program. The program compiles annual reports on the safety culture in STUK. The annual reports are presented to senior management and the key findings and/or outcomes of the safety culture work are discussed and turned into development actions if needed.

STUK ensures and enhances the safety culture by conducting a specific safety culture program that observes STUK's organization continuously, steers safety culture development activities and develops safety culture training. Furthermore, the management system has a fundamental role in fostering and sustaining a healthy safety culture. The management system steers and supports STUK to operate in a controlled manner that has a documented basis for decisions. Also, the management views and essential information on important decisions are communicated and discussed in the staff briefings and meetings taking place regularly.

In addition, the Safety Culture Programme provides an opportunity to report safety culture related concerns. The programme allows STUK employees to express their concerns even if they are not clearly defined. The concerns are handled with a high confidentiality. If possible or requested, the employee with the concern will receive updates about the direct actions taken based on the concern.

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
- internal surveys
- stakeholder feedback
- customer satisfaction surveys
- annual result discussions
- internal audits
- external audits

Once the opportunities for development have been identified, registered and analysed, corrective measures are taken and followed up to improve the quality of the regulatory work.

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.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: STUK is not consistently monitoring non-compliances related to the management system including implementation and closure of corrective actions in order to improve regulatory performance. This has been recognized in the ARM and is part of the action plan.

(1)

BASIS: GSR Part 2 Requirement 13 states that *“The causes of non-conformances of processes and the causes of safety related events that could give rise to radiation risks shall be evaluated and any consequences shall be managed and shall be mitigated. The corrective actions necessary for eliminating the causes of non-conformances, and for preventing the occurrence of, or mitigating the consequences of, similar safety related events, shall be determined, and corrective actions shall be*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>taken in a timely manner. The status and effectiveness of all corrective actions and preventive actions taken shall be monitored and shall be reported to the management at an appropriate level in the organization”.</i>
S4	Suggestion: STUK should consider enhancing the process for monitoring the implementation and closure of corrective actions related to STUK’s management system.

STUK has recently developed a process for managing regulatory experience from various sources. The process is designed for gathering and analysing experiences in a systematic way to support developing effective actions. See more information in Chapter 6.4.1. This process has been established as a pilot project in two departments but has not been completed. The future objective is to expand the pilot process to cover all regulatory departments, share the lessons learned with interested parties and integrate this process into STUK’s integrated management system.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: STUK’s systematic process for addressing regulatory experience does not yet cover all STUK’s regulatory departments and is not yet integrated in STUK’s management system. This has been recognized in the ARM and is part of the action plan.	
(1)	BASIS: GSR Part 2 Requirement 13 states that <i>“The management system shall include evaluation and timely use of the following: (a) Lessons from experience gained and from events that have occurred, both within the organization and outside the organization, and lessons from identifying the causes of events”.</i>
(2)	BASIS: GSR Part 1 (Rev. 1) requirement 15 states that <i>“The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities”.</i>
S5	Suggestion: STUK should consider fully developing the process for addressing regulatory experience and integrating this process into its integrated management system.

4.8. SUMMARY

STUK has a mature, integrated management system to ensure professional and systematic operations and commitment to achieve STUK’s strategic objectives. The Management System comprises all activities, ensures implementation of a strong safety culture, strategic plan, and that STUK fulfils its legal obligations.

STUK has implemented a policy document to demonstrate leadership for and commitment to safety by its senior management and a specific safety culture programme has been established. The Management System is comprehensively documented, regularly reviewed (internally and externally), adapted and continuously improved.

The IRRS team identified potential areas for improvement in STUK’s management system related to the implementation of corrective actions and the management of regulatory experiences.

5. AUTHORIZATION

The Finnish framework for authorization is defined primarily through two Acts, namely, the YEL for nuclear facilities and the SätL for radiation facilities and activities. YEL and SätL establish high level regulatory frameworks, define roles of involved organizations, formulate fundamental principles for safety, and set the licensing process.

The main nuclear facilities in Finland currently holding a licence are:

- Two nuclear power plants which include interim spent fuel storage facilities. The Loviisa NPP comprises two VVERs, while Olkiluoto NPP includes two BWRs and one PWR (EPR),
- Facilities for low- and intermediate-level waste (LILW) produced at the NPPs with separate operating licences at Olkiluoto. Fortum is currently applying for a separate operating license for Loviisa LILW repository at Loviisa,
- Research reactor FiR 1 (Triga Mark II) which has received a decommissioning licence in 2021. There are no plans to build new research reactors in Finland,
- A spent fuel encapsulation plant and a deep underground disposal facility, both under construction at Olkiluoto,
- A uranium extraction facility for which a licence has been granted to a mining company to produce U3O8 (yellow cake) in February 2020 (this activity has not yet begun),
- The storage of radioactive waste, originating from radiation facilities or activities, located in Olkiluoto, LILW-repository.

There are several types of radiation facilities or activities (including medical, industrial, research and transport) the authorization for which are to be granted by STUK, such as those resulting in:

- Occupational exposure,
- Medical exposure,
- Public exposure (for example, through discharges or emissions).

5.1. GENERIC ISSUES

There is an important distinction between licensing of radiation facilities and activities and that of nuclear facilities. STUK is enabled by the legislation to grant licences for the former. The licences for nuclear facilities are given by the Government (the Council of State) upon recommendation from the MEAE, which in turn requests statements from STUK and other stakeholders.

Having two Acts setting the legislative framework for nuclear facilities and radiation facilities and activities allowed development of more focussed, specialized regulatory frameworks, facilitating the graded approach on a generic level. However, this may have occasionally resulted in diverging practices when treating similar situations, for example in relation to radioactive waste arising from nuclear facilities compared to the waste originating from radiation practices.

The preparation for a renewal of the YEL and associated regulations is ongoing. It has been indicated to the IRRS team that the revision of the Act would consider refinement of the licensing process, among other things. At the same time, STUK plans to undertake revision of its regulations and guides for the regulated industry. Thus, the renewal of the legislation for nuclear facilities will provide an opportunity to refine the authorization process and promote the framework allowing greater use of the graded approach.

STUK requested a policy issue discussion on Regulatory Readiness for SMR Licensing and Deployment during the mission. This discussion is documented in Annex I.

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

The YEL requires any organization using nuclear energy to possess a licence, specifically for the stages of construction, operation and decommissioning of a nuclear facility.

The actual licensing authority for nuclear facilities is the Government of Finland. The process for evaluation of licence applications is led by the MEAE.

Before a prospective applicant can apply for a construction licence for a nuclear facility, such as an NPP, the government must issue a Decision-in-Principle (DiP).

Decision in Principle

For the Decision-in-Principle for an NPP, the environmental impacts must be evaluated and documented in the environmental impact assessment (EIA).

The MEAE requests statements related to an application for a DiP from multiple stakeholders. The host municipality also issues a statement and has veto power with regards to the DiP application. The MEAE also organizes a public hearing during this licensing phase. These elements of the licensing decision-making process help with public acceptance of nuclear facilities in their communities.

STUK's statement on safety is a crucial element in the evaluation of a DiP application and provides a regulatory evaluation of the preliminary safety assessment of the plant design and of the suitability of the plant site. The MEAE prepares an overall recommendation to the Government regarding an application for the DiP.

Once the Government issues the DiP, it will also require ratification by the Parliament, which cannot make any changes to the Decision but only approve or reject the DiP.

Construction, Operation and Decommissioning Licences

The application process for construction, operating and decommissioning licences is also prescribed by the YEL and administered by MEAE. In this process the MEAE request STUK's and other stakeholder statements; however, the municipality does not have a veto right to stop the process.

Just as during the DiP step, STUK provides its statement and addresses topics relevant to nuclear and radiation safety, nuclear security and safeguards, in accordance with the requirements set in the legislation (namely in the YEA, sections 35, 36 and 36a). A statement by the Nuclear Energy Advisory Committee is included as part of the STUK statement. This statement by the Committee could be considered a strength as it is adding an independent and international perspective on the overall safety. Effectively, STUK has the veto power in all licensing phases, should safety requirements, laid out in the YEL, not be met.

The authority issuing a licence also has the authority to revoke a licence. If the Council of State were to revoke or cancel a licence, STUK would be requested to issue a safety statement, provided the revocation is due to safety reasons.

In issuing the licence, the licensing authority (the Council of State) shall take into account the key considerations in the statements from stakeholders and reflect them in making the licensing decision.

Operating licences are granted for a term of limited duration which depends on the specific facility (not necessarily the type of a facility, so NPPs of the same vintage may have different licence durations). The exact factors determining the licence duration are not explicitly specified in the regulations or guides for nuclear facilities; this is an area where further clarity could be provided. If the licence is granted for more than ten years, the licensee is required to carry out a periodic safety review. The scope of the periodic safety review is essentially the same as the scope of an application for an operating licence renewal.

Other authorizations or approvals

STUK authorizes key personnel at nuclear facilities, prior to their appointment. The list of persons authorized by STUK include the facility responsible manager, and persons in charge of emergency response, security provisions and safeguards of nuclear material, and their deputies. Control room operators of a nuclear reactor also must be authorized. Appropriate guidance is provided in guide YVL A.4.

In accordance with YEL, STUK has the authority to approve manufacturers of nuclear equipment, inspection organizations and testing organizations. Guides YTV 2.d 1-3 provide sufficient requirements and guidance in this respect.

STUK also has the authority to impose many other approvals related to design and operation of NPPs, which are specified in numerous YVL-guides. For example, commissioning activities, which happen both under the construction and operation licences, include several hold points. Release of a hold point requires a STUK approval before the project is allowed to proceed, such as an approval for fuel loading. Design modifications which may have an impact on safety must be approved by STUK, as well as reactor restarts after outages. The underlying reasons and rules for requesting and substantiating requests for approvals may not always be clear to licensees. The terminology also appears to be mixed in the YVL and YTV guides (terms like permits, approvals, authorizations and even licences from STUK, are used). STUK should consider the graded approach in determining situation when an approval is required versus a notification. This should include, as may be justified, approvals for activities, design, limits and conditions, as well as plans, schedules, procedures and rules, such as training plans for authorized personnel or emergency response plans. On this basis the following suggestion is being made. STUK may also consider if sufficient clarity in the overall approach to regulatory approvals, using the graded approach, exists for facilities other than NPPs.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The rules and criteria to determine which arrangements require regulatory approval are not clearly defined by STUK.

(1)

BASIS: GSR Part 1 (Rev. 1) Requirement 22 Para 4.26 states that *“The regulatory process shall be a formal process that (...) The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by individual staff members of the regulatory body. The regulatory body shall be able to justify its decisions if they are challenged. In connection with its reviews and assessments and its inspections, the regulatory body shall inform applicants of the objectives, principles and associated criteria for safety on which its requirements, judgements and decisions are based”*.

S6

Suggestion: STUK should consider developing guidance with clear rules and criteria for when a licensee is to seek regulatory approvals, as pertains to safety of NPP, applying a graded approach.

5.3. AUTHORIZATION OF FUEL CYCLE FACILITIES

The category of fuel cycle facilities in Finland covers three types of facilities: the spent fuel interim storages, located at the nuclear power plants, the spent fuel encapsulation plant, and U3O8 production plants, also referred to as uranium extraction facilities.

The spent fuel interim storage facilities are operated as part of the respective nuclear power plants and are located at the same site. They are under the same regulatory framework as the NPPs, as such, the same authorization and licensing process are applied for both categories. The design and construction of spent fuel interim storage follow STUK regulation Y/1/2018 (Safety of Nuclear Power Plants).

The spent fuel encapsulation plant is being commissioned at Olkiluoto, next to the disposal facility. The authorization and licensing process follows the same requirements as for all nuclear facilities, with some additional requirements related to post-closure safety. YEL and YEA legislation, and STUK regulation Y/4/2018 are applicable for the encapsulation plant.

The construction licence was granted during 2015 for Posiva to construct the encapsulation plant and disposal facility. In December 2021, the operating licence application was submitted by Posiva to the Government along with supporting documentation to STUK. The licence application review should take 2 to 3 years. The encapsulation plant and final disposal facility operation will be covered by the same licence.

The licence for the mining company Terrafame Ltd. to extract uranium in their nickel mining and processing facility was granted by the government in February 2020 according to section 21 of YEA for ore enrichment operations. With slight modifications this decision was set in force by Supreme Administrative Court in June 2021. Before the uranium extraction activity can be started, the mining company will need a separate STUK authorization to start the operation (in accordance with YEL section 21 subsection 2). Licensing is performed according to YEL section 21, with one licensing phase rather than the three phases for nuclear facilities. After the granted licence the use of mining and milling operations aimed at producing uranium or thorium shall not be initiated before STUK's separate approval. The requirements concerning uranium extraction facilities are set in regulation STUK Y/5/2016, on the Safety of Mining and Milling Operations aimed at Producing Uranium or Thorium. Most of STUK's YVL guides are not applicable, except for YVL D.1 (safeguards), and YVL D.2 (transport).

The lack of specific guides for fuel cycle facilities, including mining and processing of uranium or thorium, identified by the IRRS team, is addressed in Chapter 9.3.

5.4. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

In Finland, radioactive waste is classified in two categories: nuclear waste, and radioactive waste that is not generated from the use of nuclear energy. Radioactive waste management for nuclear waste takes place at the NPP sites under their operating licence. Geological disposal facilities for low and intermediate level waste have been in operation at Olkiluoto and Loviisa since the 1990s. The Olkiluoto LILW disposal facility has its own operating licence, which was last updated in 2012. The Loviisa LILW disposal facility is currently operating under the NPP licence but is in the process of obtaining a separate operating licence for final disposal. A periodic safety review is required to be conducted every 15 years for disposal facilities.

Regarding the deep geological repository, the construction licence was granted during 2015 and the construction started in 2016 in Olkiluoto. In December 2021, the operating licence application was submitted by Posiva to the Government along with supporting documentation to STUK. The licence application review should take 2 to 3 years. It is noted that the encapsulation plant and final disposal facility operation will be covered by the same licence.

The YEL establishes nuclear waste generators' responsibilities for nuclear waste management and funding. The State has the secondary responsibility in case any producer of nuclear waste is incapable of fulfilling its obligations.

For state-owned radioactive waste not originated from the use of nuclear energy (generally disused sealed sources from industry), a storage room at Olkiluoto was leased by TVO to the State. The storage room does not have a separate licence and is under the overall licence for LILW facility held by TVO. The storage room is operated by STUK's Environmental Radiation Surveillance Department. The Radiation Waste and Safeguard Department of STUK regulates the storage room and inspects it using the same practices for inspecting the Olkiluoto LILW disposal facility. Recommendation R5 in Chapter 3.2 addresses this issue.

Currently, there is no final disposal pathway for the high activity disused sources (HADS). Options being considered are: disposal in the LILW facility with additional controls or disposal in the future DGR but there is no timetable for when a decision will be taken. The IRRS team considers that ageing mechanisms affecting waste package integrity containing HADS will need to be assessed before these sources are transported.

It was noted that there are currently neither detailed guidance nor requirements related to closure and institutional control of the repositories in operation or planned for the future, and that future work needs to be carried out for clarifying the licensing of the closure for disposal facilities. Finland's strategy is to ensure specific regulations and

guidance are in place prior to scheduled closure of a disposal facility, which are currently not planned until the end of the century. Further, the Nuclear Act is in the early stages of being updated and provisions regarding closure of final disposal facilities are under discussion. This issue is addressed in Chapter 1.2.

5.5. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

STUK has the authority under the SätL to issue safety licences following an application.

An applicant is required to perform a safety assessment of the radiation practice, provided it is subject to a safety licence (i.e., not otherwise exempt) and provide it to STUK as part of the application. In the safety assessment, the undertaking identifies the ways in which the practice can cause radiation exposure, considering any possible radiation safety deviations, and an assessment of the magnitude of the occupational, public and medical exposures arising from the practices, as well as the probability and magnitude of the potential exposure are assessed. The safety assessment must be reviewed regularly, at a frequency based on the established categories of radiation exposure, and as needed.

STUK reviews and confirms the safety assessment that is submitted. STUK will grant a licence provided (1) the radiation practice complies with the principles of justification, optimization and limitation; (2) a safety assessment pursuant to section 26 of SätL has been drawn up for the radiation practice; (3) the practice can be carried out safely; (4) the undertaking has the right to engage in a trade in Finland.

The SätL specifies that the use of radiation requires a safety licence. There is currently no notification process or authorisation by registration. 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. STUK identified that the graded approach could be more fully implemented in some areas. The current regulatory framework for regulating sources, facilities, and activities does not provide sufficient means for processing licence applications based on assessed radiation risk. STUK is currently working on a project reviewing the arrangements for licensing. This project is expected to lead to proposals for updating the Management System documents and perhaps the SätL but is not expected to utilise notification or authorisation by registration.

STUK may exempt practices where exemption is the most appropriate outcome, and the applicant meets the specified criteria. Details of the exemption and clearance levels are provided in Regulation STUK SY/1/2018. STUK utilised the EU BSS to develop the list of nuclides and the associated exemption levels then added another 44 radionuclides that were in use in Finland at the time. However, the list does not cover all radionuclides provided by the Schedule 1 of GSR Part 3.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The list of radionuclides specified in the regulation covering exemption levels does not address all radionuclides given in Schedule I of GSR Part 3. This has been recognized in the ARM.

(1)

BASIS: GSR Part 3 Requirement 8 states that *“The government or the regulatory body shall determine which practices or sources within practices are to be exempted from some or all of the requirements of these Standards. The regulatory body shall approve which sources, including materials and objects, within notified practices or authorized practices may be cleared from regulatory control”.*

S7

Suggestion: STUK should consider reviewing and revising its regulation for exemption to cover all radionuclides specified in Schedule I of GSR Part 3.

5.6. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

The YEL (990/1987) was amended in 2018 to add provisions for decommissioning and now requires a licence for a nuclear facility to apply for a decommissioning licence from the Government.

According to YEL (990/1987), Section 7g (905/2017) provision shall be made for the decommissioning of the facility, since the design stage, including:

- attention shall be paid primarily to safety
- dismantling of the facility may not be postponed without due cause.
- at least at 6-year intervals, an updated plan for the decommissioning of the nuclear facility to be submitted for approval by the MEAE,
- during the decommissioning, the plan shall be kept up to date and submitted for approval by STUK.

The licensee is responsible for planning the decommissioning as well as for decommissioning costs.

The licensee is responsible for radiation waste management and spent fuel management with regards to closure of a waste facility. However, there are no provisions in the YEL regarding closure of a waste facility. As noted in Chapter 1.2, the YEL is in the early stages of being updated and provisions regarding closure of final disposal facilities are under discussion.

Additionally, the preliminary decommissioning plan shall declare the decommissioning strategy selected, the steps and time scheduled stages, waste management strategies and the planned end state of the facility site. Guide YVL D.4 requirement 404 establishes requirements related to expected content of the decommissioning plan during operation which is required to be updated every six years.

The licensee shall provide the final decommissioning plan for approval to STUK as part of the decommissioning license application. (YEL 990/1987 section 7 g, YEA 161/1988 sections 33 a, 34 a, and 36).

After STUK reviews aspects that can affect safety and all related safety requirements, the decommissioning stages are authorized to start. This review is done verifying compliance with law, regulations and STUK's YVL Guides.

During decommissioning of a nuclear facility, the licensee shall do the safety assessment according to licence conditions or at minimum after every 10 years (YVL D.4 609). In radiation practices, a safety assessment shall be done as part of a safety licence application or separately (Sätl section 26).

The FiR-1 Research Reactor was permanently shut down in 2015 and applied for a licence for decommissioning activities in 2017, which was granted in June 2021. The decommissioning waste is planned to be disposed at the Loviisa LILW disposal facility, but that authorization has not been granted and therefore decommissioning activities at FiR-1 have not begun.

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 the results of the survey demonstrating that the surface activity contamination levels specified in the legislation are not exceeded. STUK can perform confirmatory independent measurements, but it is not a requirement of the process. The basic radiation protection criteria for the clearance of the buildings and the site of a nuclear facility are that the typical annual dose constraint to the most exposed individual arising from the use of the cleared site and buildings is 0.01 mSv and in a case-specific clearance procedure an annual dose constraint of an individual 0.1 mSv may be permitted.

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

Given that the decommissioning of the research reactor will be the first decommissioning project for a nuclear facility, it will be important that STUK captures this experience, in particular the aspects related to the regulatory activities. This experience could then be used for refining the national regulation and guides related to decommissioning and sharing with international peers.

Decommissioning of FiR-1 will also likely be the first example when the site could be released from regulatory control (returned to "green" state) and used for other, non-nuclear application. Thus, it is important to put in place a regulatory process for "de-licensing" or releasing the site from regulatory control. A recommendation related to defining in legislation the stage of release of nuclear facilities from regulatory control, is provided in Chapter 1.2.

5.7. AUTHORIZATION OF TRANSPORT

The Act on the Transport of Dangerous Goods covers all categories of Dangerous Goods (Class 1 – 9), transported by all modes of transport. Radioactive material is dangerous goods Class 7. The SätL concerns safety licences and notification procedure for road and rail transports of High Activity Sealed Sources (HASS). The YEL concerns safety licences and notification procedure which relates to the transport of fresh fuel and nuclear waste, and future transports of spent fuel, the spent fuel is currently stored in the NPP facilities.

The department of Nuclear Waste Regulation and Safeguards, issue Package Design Validations and Transport Authorizations for the Type B Fissile packages used for the import of fresh nuclear reactor fuel, in accordance with the YEL and the ADR transport regulations, which are mandatory in the European Union; ADR which reflect SSR-6 (Rev. 1) in its entirety. There is one exception of compliance with SSR-6 (Rev. 1) with respect to the package design Validation process (Chapter 6.8, Recommendation 8), regarding the assessment of ageing mechanisms of package designs.

The department of Radiation Practices Regulation, issues Transport Authorizations for Type B packages containing High Active Sealed Sources (HASS) in accordance with the SätL and the ADR transport regulations. Whilst Type B(U) packages do not require package design validation, the IRRS team suggest that STUK verify that ageing mechanisms have been assessed and approved, for the packagings used in Finland, by contacting the Regulatory Bodies of the country of origins of the package designs and develop a way forward. This issue is addressed in Chapter 6.7.

5.8. AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE

The framework for the control of occupational exposure in planned, existing and emergency situations is set out in the SätL, Occupational Health and Safety Act 2002 and in a number of Government Decrees and STUK regulations. The YEL by reference incorporates requirements under the SätL for the protection of workers in nuclear facilities.

The Act has placed non-transferable obligations in relation to protection of workers on authorised parties and employers including for workers not directly employed by the authorised party. Commensurate obligations for compliance with the requirements have also been placed on the workers under the legal framework. The protection and safety of workers is underpinned by the principles of justification, optimisation and limitation. The dose limits for radiation workers, pregnant and breast-feeding women and for students and apprentices are consistent with International Safety Standards.

The application of dose constraints and reference levels is a critical tool in the optimization of protection and safety of workers. The SätL has established dose criteria to categorise workers, work areas and radiation practices (facilities and activities) for planned exposures which is applied by authorised parties in the optimisation of protection for workers. The dose constraints are set in a way by authorised parties that ensure that the anticipated exposures remain below the constraint due to the optimization of radiation protection.

Workers are classified as category A or B workers, on the basis of exposure during normal operations and potential exposure in un-anticipated events. If the effective dose can exceed 6 mSv/y then workers are classed as category A workers and required to undergo regular radiological and medical surveillance. Areas where the effective dose to workers exceeds 1mSv/year are classified as supervised areas and subject to special safety and protection measures. On the basis of actual and potential exposures, authorised parties are also required to categorise facilities and activities (radiation practices) into category 1, 2 or 3. The effective dose criteria of greater than 6mSv/y; less than or equal to 6mSv/y and less than or equal to 1 mSv/y has been established under the legislation. The legislated optimisation measures for occupational exposure provide a sound basis for the application of a graded approach in the application for protection measures for the workers. This is recognised as a good performance by the IRRS team. However, investigation levels have not been established under the regulation to monitor worker's exposures during normal operating conditions. To further enhance optimisation of protection and safety to workers, the IRRS team encourages the establishment of requirements on investigation levels. Recommendation R13 in Chapter 9.8. addresses this issue.

The radiation protection programme for protection of workers require adherence to a hierarchy of controls based on fail-safe engineered controls, followed by administrative procedures and personal protective equipment. STUK

maintains a national workers' dose register and as a part of its supervision role follows workers radiation exposure on the register. The register contains the identifying information of each worker and information on: their tasks; employers; the methods employed for determining individual radiation doses; factors impacting radiation exposure; and the results of individual monitoring. The retention periods of dose records are consistent with requirements of the international Safety Standards. STUK relies on industry established qualifications and competencies for workers to carry out activities requiring specialist skills.

The Act and the Decrees provide requirements for the protection of workers in existing exposure situations. According to the National Radon Action Plan 2021, Finland's indoor air radon concentration (mean concentration is 140 Bq/m³ from Gaskin et al. 2018) is among the highest in the world. Therefore, special consideration has been given to the regulatory control of exposure to radon in workplaces. The strategy for protection against radon and other natural radiation in workplaces includes the establishment of reference levels which are consistent with the international Safety Standards. Similarly, the reference level for the exposure for emergency workers and helpers has also been established under the Act.

The IRRS team was informed that one safety licence due to radon exposure has been issued for the protection of workers working in an underground tunnel. The IRRS team was also informed that exposure to radon is an issue in some nuclear and radiation facilities (e.g., bunkers) however, the time spent in areas with elevated radon levels is minimised.

5.9. AUTHORIZATION ISSUES FOR MEDICAL EXPOSURE

Licensing process and graded approach

Regarding a possible introduction of the registration approach in the authorisation process for medical exposure, for example in dentistry, the IRRS team was informed that STUK estimates that such a step would not be appropriate. With regards to the application of the graded approach to the licensing process, the IRRS team considers that it would be however appropriate to examine both the licensing process and also the procedures of control (remote survey, inspection).

Human resources for medical practices

The undertaking is responsible for ensuring that staff engaged in medical use of radiation with exposure of patients are in possession of the applicable qualifications, including patient radiation protection. In addition of provisions of the SätL, further provisions on the applicable qualifications and competence criteria for radiation protection are given by a decree of the MSAH.

A survey, conducted by STUK in 2019-2020, concerning the adequacy of radiology units' personnel resources, highlights that personnel resources were insufficient, especially for radiologists. The findings indicate that the inadequate resources did not impact radiation and patient safety. Overall, specifically for medical physicists, STUK estimates that the needs at the national level are covered.

As part of the authorisation process, STUK requires applicants of medical practices to provide information on human resources, including qualification, competence and skills. In addition, there are requirements on the objectives of the on-going (supplementary) training programmes on patient radiation protection. A comprehensive understanding of the on-going training programmes of all the categories of health care professionals, and their consistency with the above requirements, is not available at the national level. In addition, statistics on the number of professionals having benefited from such training, for each category, are not available at the national level. A survey of these trainings would be useful in order to take corrective actions if necessary.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: At the national level there is no comprehensive understanding of the on-going training programmes on radiation protection of patients for all categories of Health Care professionals is not available at national level.

(1)	BASIS: GSR Part 3 Requirement 35, para. 3.150 (b) states that <i>“The regulatory body shall ensure that the authorization for medical exposures to be performed at a particular medical radiation facility allows personnel (radiological medical practitioners, medical physicists, medical radiation technologists and any other health professionals with specific duties in relation to the radiation protection of patients ...b) Meet the respective requirements for education, training and competence in radiation protection, in accordance with para. 2.32”.</i>
S8	Suggestion: The Government should consider initiating an overall assessment of the on-going (supplementary) training programmes on radiation protection of patients for all categories of Health Care professionals.

Optimization and Diagnostic Reference Level (DRL)

The licensing process also allows STUK to control requirements for optimization of radiation protection in medical exposure. The value of a DRL determined by the undertaking itself, which may not exceed the values defined by STUK, is verified during the evaluation of the licensing application even if the deployment of DRL is mainly covered by inspections. Reference levels for a patient’s radiation exposure are defined by STUK on the basis of a specific survey and regularly updated (the last update was in 2019).

Justification

Requirements for justification of medical exposure are given in STUK regulation. General justification issues are considered during the authorization process but patient-specific justification issues are not specifically considered during the authorization process. STUK confirms the practice as justified either as part of granting the safety licence or separately. STUK website lists activities that are generally considered to meet the justification principle for the use of radiation as well as some activities that are never considered justified. This list is intended to be kept up to date. However, it does not cover justification of any medical uses, as STUK considers it is not needed.

Related to justification of new radiological procedures, there is a process in place: a statement from the National Institute for Health and Welfare for the evaluation of a health care method is requested by STUK, and in the case of medicinal products, medical equipment for diagnostic and treatment which causes a high level of medical exposure, a Health Technology Assessment (HTA) is used for justification assessments.

Management system, quality assurance programme and safety assessment

Documentation related to the management system, the quality assurance programme and the safety assessment is verified by STUK during the licensing process. The undertaking must have:

- a written management system for the radiation practice, in particular, sufficient information on the qualifications, training and induction of persons, the tasks which are significant in terms of radiation safety, the division of responsibilities and flow of information and the measures to maintain and develop a good safety culture;
- a quality assurance programme of the use of radiation in health care including actions to ensure, in particular, before commissioning a medical radiotherapy appliance, that adequate information on the risk assessment of the patients and the available clinical operation results of the appliance are available; the accuracy of the assessment radiation exposure caused to the patient and the verification of activity administered to the patient (the radiotherapy quality assurance programme shall include the risk assessment of exposure due to a radiation safety incident or unplanned exposure based on the safety assessment);
- a safety assessment carried out by the undertaking, in particular, assessing the magnitude of the occupational, public and medical exposure arising from the practices as well as the probability and magnitude of the potential exposure.

The IRRS team was informed that the content of the safety assessment and the articulation with the different concepts of management system, quality assurance and, in radiotherapy, risk analysis for patients need to be clarified by STUK. It was confirmed that SAMMIO does not allow, at this time, to provide all the clarifications needed of these different concepts. Useful information could be introduced in SAMMIO for the specific attention of inspectors and applicants.

Deviation and significant unplanned medical exposure

The SätL states that the undertaking shall immediately notify STUK of all significant unplanned medical exposure.

The licensee has to investigate the reasons why a radiation safety deviation happened and to make necessary corrective actions to prevent the same or similar type of events. A report from the investigation has to be submitted to STUK. An anonymized version of the event is stored in the electronic system, the most interesting ones are addressed at vocational training for radiation users and data are analysed for trends.

STUK has established general criteria for notification of significant radiation safety deviations. In addition, it has defined specific thresholds for notification of unplanned medical exposure.

The number of deviations which have been reported to STUK is around 20 per year (health care and veterinary medicine) in 2019, 2020 and 2021. Specifically, the numbers of reported unplanned medical exposure in radiotherapy were 2 (2019), 2 (2020) and 1 (2021). STUK considers that the current thresholds for immediate notification and reporting are adequate to allow STUK to focus on the most significant unplanned medical exposure cases.

The IRRS team considers that the number of reported unplanned medical exposure yearly, particularly in radiotherapy, challenges the robustness and the efficiency of the reporting system and national feedback experience. The IRRS team suggests that STUK reviews the reporting system, considering a benchmark with different regulatory bodies and the IAEA safety guide. Specific guidance (for instance in SAMMIO), could be developed, as well as instructions for inspectors to investigate the licensee's system of recording and analysing events. This would enhance efficient feedback and dissemination of lessons learned.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The small number of significant events reported to STUK does not allow for the organisation at the national level of an efficient feedback experience and the dissemination of the lesson learned to others radiotherapy units.

(1)	BASIS: SSG-46, para. 5.274. states that “... The regulatory body and/or the health authorities could disseminate information on significant events reported to them and on the corrective actions taken, so that other facilities might learn from these events (see also para. 5.275)”.
S9	Suggestion: STUK should consider enhancing the reporting system of significant events in radiotherapy to further enable the sharing and dissemination of operating experience to other licensees and interested parties.

5.10. AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE

SätL establishes the provisions that applicants for an authorization shall comply with to ensure adequate protection of the public. Requirements related to dose limitations and the establishment of appropriate dose constraints by authorized parties are included in the Act. Dose limits in compliance with the IAEA's GSR Part 3 are given in VnA 1034/2018. The Act also includes requirements for limiting the release of radioactive material to the environment. Annual dose constraints for nuclear facilities are given in Section 3 a in YEA. Authorized parties are required to comply with discharge limits established by STUK in the authorization if the discharges exceed the limit values for a minor discharge given in STUK regulation. However, in the case of radiation facilities no other possible operational limits and conditions are required to be included in the authorization issued by STUK. This issue has been identified by STUK during the analysis performed in preparation of the ARM report and is included in its action plan.

Nuclear facilities discharging radioactive material to the environment are required to implement a monitoring programme to demonstrate compliance with discharge limits. They are required as well to report periodically to STUK on the results of these programmes. STUK carries out an independent monitoring programme to verify the compliance with authorized discharge limits. The radiological monitoring of the environment is complemented with an environmental monitoring network with measuring stations distributed over the whole territory. Results of monitoring programmes are made available to the public through periodic reports and real time monitoring data from the national monitoring program is made available on the STUK web page.

In the case of radiation facilities, as a result of the analysis performed in preparation of the ARM report, STUK recognizes that authorized parties are not required to maintain records of the results of monitoring programmes and estimated doses to the public and make the results available to STUK. Similarly, they are not required to report promptly any significant deviations from the operational limits and conditions established in the authorization. An action related to this issue has been included in STUK's action plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Regulations for radiation facilities and activities do not have any provisions to maintain and report to STUK the records of the monitoring programmes and the estimated doses to the public. This has been recognized in the ARM and is part of the action plan.

(1)	BASIS: GSR Part 3 Requirement 32, para. 3.137 states that <i>“Registrants and licensees shall, as appropriate:</i> <i>(b) Maintain appropriate records of the results of the monitoring programmes and estimated doses to members of the public.</i> <i>(c) Report or make available to the regulatory body the results of the monitoring programme at approved intervals, including, as applicable, the levels and composition of discharges, dose rates at the site boundary and in premises open to members of the public, results of environmental monitoring and retrospective assessments of doses to the representative person.</i> <i>(d) Report promptly to the regulatory body any levels exceeding the operational limits and conditions relating to public exposure, including authorized limits on discharges, in accordance with reporting criteria established by the regulatory body.”</i>
R6	Recommendation: STUK should establish requirements for radiation facilities and activities to maintain and report to STUK the records of the monitoring programmes and the estimated doses to the public.

5.11. SUMMARY

Finland has a mature and robust legislative framework for the authorization of nuclear facilities and radiation facilities and activities. The legislative framework is generally well aligned with IAEA safety standards. However, the ongoing process of updating the YEL, and the associated regulations and guides allow a valuable opportunity to reflect the national experience and needs, the IAEA standards and the best international practices in the legislative provisions for authorization for nuclear facilities.

STUK has adequate resources to conduct assessments as required during the review of a licence application. STUK guidance establishes specific regulatory expectations related to various elements of regulatory approvals. Furthermore, STUK has implemented multiple digital tools, which promote a systematic approach in managing information, prioritization of activities and building required staff competencies.

Based on the review of advanced material, the self-assessment report, STUK regulations and guides, as well as interviews with counterparts, the IRRS team identified opportunities for further improvement of the authorization processes as described in this report. Further details on authorization can be found in the legislative provisions in Chapter 1 and on regulations and guides in Chapter 9.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

Nuclear facilities

Prior to any STUK regulatory decision, review and assessment is always conducted in order to determine compliance with legal and regulatory requirements. The purpose of the safety assessment is to ensure that a nuclear facility's design, construction, operation, decommissioning and closure is in accordance with YEL, the regulations issued under it, the decisions issued by STUK, and the obligations of international agreements. The submissions reviewed and assessed are mostly connected to licensing steps for the nuclear facilities and to modifications during the whole life cycle of the facilities.

Safety-related mandatory requirements for nuclear safety are found in YEL, YEA, STUK regulations, and partly in STUK YVL guides. YEL establishes the general requirements for the safe use of nuclear energy and nuclear facilities. A major legal principle 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. There are general requirements set for safety and for verification and assessment of safety where a nuclear facility shall assess the overall safety at least every 10 years and waste disposal facilities at least every 15 years. The YEA gives 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. The YVL guides specify compliance with regulations.

Management procedures in the form of multiple internal YTV guides in STUK's management system describe the review and assessment process. The review and assessment process of STUK also have several comprehensive support processes. These support processes include for example document management, decision-making and requirement management. These YTV guides cover most assessment areas for each discipline. There is an internal guide for reviewing a nuclear facility's process system design under preparation but currently it is not in place. STUK also does not have a guide for reviewing Environment Impact Assessments.

STUK's review and assessment is targeted to focus on matters with actual safety significance. YEL includes the provisions for a graded approach. STUK's regulations define the application of requirements for some facilities and STUK regulations require classification of systems, structure and components according to their safety significance. The safety class then directs the oversight measures. The internal guidance for review helps with applying the graded approach in practice.

STUK's process for handling applications from the licensees is described in detail in Guide YTV 8.a. In all review and assessment activities the goal is for STUK to evaluate whether the application fulfils all relevant requirements. A pre-review is conducted to establish if the application and related documents support STUK's review and assessment. The application is then either rejected, additional information is requested, or the application is considered sufficient.

The final step in the review process is STUK's decision which, in practice, is either approval, approval with conditions, rejection, or a clarification request. STUK's decisions must be in line with the legal basis and STUK shall be able to justify all its decisions. The decision-making process shall also be consistent.

A consultation of the licensee is done before the actual decision is made. The licensee is sent the content of the explanatory memorandum in order to be able to comment on the content and on the given deadlines of potential requirements. This consultation only gives the licensee a chance to correct factual mistakes or misunderstandings. The feedback from the consultation gets written in the explanatory memorandum.

STUK's document control is managed by SAHA in which all review and assessment documents are placed. SAHA also enables ongoing monitoring of the review and assessment process.

STUK applies as a basic principle that the applications should be processed without unnecessary delay, taking into account the urgency and safety significance of the application. STUK received in 2021 around 4600 applications (NPPs and waste facilities). Concerning prioritisation of various submissions, there is a meeting once a month to discuss resources and decisions about the priority are made in this meeting. Additionally, the prioritisation is

sometimes discussed in the department management meeting. This is the approach for “normal” applications. If there is an urgent application from the licensee, e.g., during an annual outage, it will usually be processed immediately.

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

In STUK there are about 230 technical staff. Some staff members perform both review and inspections. There are several specialist areas and competencies among the reviewer staff. STUK tries to circulate staff between sections, when possible, in order to widen and overlap competencies.

Nuclear Facilities

STUK regularly evaluates the competence and human resource needs taking into account upcoming departure of staff and expectations of forthcoming applications that will need review and assessment (see Chapter 3).

Concerning review and assessment STUK currently finds the number of resources adequate, especially because of the closure of the Fennovoima project. Retiring staff and job openings in the industry are factors that make STUK focused on how to remain an attractive employer.

When a new reviewer joins STUK, the new reviewer’s supervisor develops a qualification programme in line with STUK Guides. The training and development of new reviewers are mainly done through on-the-job-training, except the standard initial training. The Guide YTV 8.a is one key element in the training and included in the general exam for the staff since it goes through the review of documents and the preparation of decisions and all the related documents and roles. STUK considers on-the-job training in different forms as most effective for qualifying its staff.

Even though STUK has all needed competencies represented in-house, it benefits also from the availability of external independent resources for review and assessment. STUK uses external expert organizations to support review and assessment activities. STUK’s main TSO in Finland is VTT, STUK also uses other organisations both in Finland and abroad regularly and co-operates with other regulatory bodies. STUK is an intelligent customer since it has the competence needed to interpret and act on the material received from the TSO.

STUK can obtain experimental results through other sources available such as the national research programmes. Dedicated experiments can also be procured from other organisations for regulatory support in the review and assessment.

STUK has four advisory committees which are defined in the legislation (Section 56 YEL and in YEA). For review and assessment activities, the Advisory Committee on Nuclear Safety is the most relevant. The committee gives opinion statements about the review and assessment of STUK in connection with the main licensing steps and the statements of the Advisory Committee are included in the safety statement STUK provides to the ministry.

All steps of the review process are covered in SAHA. This includes the selection of a coordinator, recording and archiving of all submissions, task distribution, specification of intermediate actions, on-line monitoring of the review status, recording the STUK review and inspection reports and the justification of decisions made. Decisions, memorandums and protocols are electronically signed in the system.

STUK uses the Polarion management tool for several purposes that are related to review and assessment of the nuclear facilities. This involves annual planning of the main review and assessment tasks and other regulatory activities for the next year, follow-up of activities, management of regulations and regulatory guides, for managing international operating experience, and for the oversight of nuclear facilities. The latter includes collecting observations of licensees’ performance, information about inspections and operational events, minutes of weekly internal meetings and the overall safety assessment. The IRRS team considers that the way STUK uses Polarion in its activities is a good performance.

Radiation Practices

The VASARA system is used for the control of the documentation and assessment process for use of radiation.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

Nuclear facilities

For all facilities the basis in regulation and guidance for review and assessment are described under the corresponding Chapters of this report.

STUK has an internal Guide STUK 3.6 which describes the process of preparing regulation and guides. One of the requirements in this process is to align the requirements with the IAEA safety standards and with international good practices as much as possible.

STUK aims to be consistent in the regulatory requirements. However, both regulations and regulatory guides are revised when necessary. Concerning nuclear facilities and long projects, like new-builds, this can pose a problem. STUK is aware of this and addresses this in its reviews and assessments.

Radiation practices

Section 26 of SätL states that the applicant is required to submit an adequate demonstration of safety when applying for a safety licence. On the STUK website there are forms and guidance for carrying out the safety assessment (www.stuk.fi/lomakkeet).

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

Nuclear facilities

Concerning review and assessment, one important aspect of the process is the verification of the comprehensiveness and quality of the licensee's safety assessment. Verification of the comprehensiveness and quality is done by a pre-review and the actual review. Before the actual review, as mentioned in Chapter 6.1, a preliminary review is conducted. In the actual review, the compliance with requirements and the comprehensiveness and quality of material provided by the licensee are verified in detail. STUK's methods and the degree of the verification are driven by the type of application. The degree of verification is decided based on context, safety significance, type of topic, and technical areas. The methods of verification can be found in specific YTV guides. The YTV guides also give reference to the relevant STUK YVL guides and regulations.

The safety analysis report is one of the core documents which requires comprehensive review and assessment. The STUK reviewers have easy access to the current safety analysis report for all facilities through the shared STUK network where the licensees regularly upload up-to-date versions (in addition, official submissions of safety analysis report are available in SAHA).

The formal application documentation and related information going to and from the licensee is all managed in the SAHA system. Additionally, STUK's reviewers and licensee's experts can communicate and meet for clarification of issues and discussions about the application. These interactions can be more or less formal depending on the issues that need discussion. STUK emphasises the importance of independence as a regulator during these meetings, but also sees the great value in discussing issues less formally. However, no decisions related to the applications are taken during these interactions. All new employees at STUK get to learn the particularities of the work as public officials and the role of STUK in order to be able to work as an independent regulator.

STUK has some performance indicators related to review and assessment, mainly concerning the timeliness of applications and number of requirements in decisions. Employees can find the indicators shown in the STUK intranet. Management uses the indicators in the management review twice a year.

STUK's review and assessment performance is a fundamental part of the overall safety assessment process (YTV 1.b). This overall safety assessment of a licensee and the associated nuclear facility have six 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.

The goal of STUK is to have a systematic collection of oversight information from various sources such as resident inspectors, weekly reports, weekly meetings with licensees, results from inspections and reviews, plant changes meetings, events, etc., and process the information so that general conclusions can be drawn on the safety status of the nuclear facilities, the activities of the organisation responsible for the safety of the facility, and any trends. STUK

also aims to have a continuous overview of the issues which form the basis for safety assessments of the nuclear facilities performed in connection to licence applications or periodic safety reviews. All collected information is located in a specific area in the electronic system Polarion. The conclusion from each issue is given significance by a traffic light system and trends are evaluated.

Multi-disciplinary overall safety assessment meetings are held every fourth month for a summary safety assessment. Before these meetings specific further inputs are made such as the review of observations in the oversight observations tool HAKE for gathering e.g., organisational issues. This assessment gives STUK a recurring overview of the strengths and weaknesses of a licensee and the results are used for potential refocusing of and reallocation of resources for the regulatory activities.

The basis for the assessment of nuclear power plants is STUK Nuclear Power Plant Safety Regulation Y/1/2018. The segments of the assessments correspond to the sections in regulation. This means that the assessment corresponds to STUK's periodic safety assessment basis and also to the safety assessment conducted in connection to a licence application.

The overall safety assessment is also performed for the spent fuel encapsulation plant and disposal facility under construction, Posiva. The basis for the assessment is STUK Y/4/2018 regulation concerning the safety of nuclear waste disposal. The segments of the assessment correspond to the sections in this regulation, and consequently corresponds to the safety assessment basis connected to a licence application.

In addition, STUK Y/2/2018 on emergency arrangements for NPPs, STUK Y/3/2020 on security issues, and YEA for safeguards are used as bases.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: STUK's overall safety assessment for nuclear facilities is an ongoing systematic collection of oversight information and recurring multi-disciplinary meetings resulting in continuous overview of the strengths and weaknesses of these facilities and potential refocusing of and reallocation of resources for the regulatory activities.	
(1)	BASIS: GSR Part 1 Requirement 25 states that <i>"The regulatory body shall review and assess relevant information...to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization [...]".</i>
(2)	BASIS: GSR Part 1 Requirement 26, para. 4.46 states that <i>"For an integrated safety assessment, the regulatory body shall first organize the results obtained in a systematic manner. It shall then identify trends and conclusions drawn from inspections, from reviews and assessments for operating facilities, and from the conduct of activities where relevant. Feedback information shall be provided to the authorized party. This integrated safety assessment shall be repeated periodically, with account taken of the radiation risks associated with the facility or activity, in accordance with a graded approach".</i>
GP2	Good Practice: STUK has implemented a systematic model for continuous overall safety assessment of nuclear facilities which allows it to regularly monitor the licensees' overall safety and take adequate measures based on the results.

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

STUK's review and assessment process of nuclear power plants is based on the principles and requirements described under Chapter 6.1 during the entire life cycle (see also Chapter 5).

The different review stages for a nuclear facility in Finland are the licensing steps, possible plant modifications, periodic safety reviews and renewal of the operating licence and decommissioning. Changes to safety-related aspects of the NPP or activity requiring regulatory approval before implementation by the licensee are also reviewed such as for example plant modifications or power uprates as well as updates of documentation or technical specifications.

The licensee shall ensure that the documents submitted to STUK as provided in sections 35 and 36 of YEA are revised accordingly.

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.

When applying for an operating licence, the documents listed in section 36 of YEA, and other reports considered necessary by STUK shall be submitted to STUK for approval.

The renewal of the operating licence always involves a safety review of the facility. Documents required for the renewal of the operating licence and the periodic safety review are specified in section 36 YEA. It is stated that these shall be continuously updated, and the updated versions shall be regularly submitted to STUK. When applying for renewal of the operating licence, the licensee must only submit the documents which have been amended since the previous updates and which have not been submitted before. The licensee shall also submit its own periodic safety review, potential areas of development, and information on the maintenance of safety.

Regulation STUK/Y/1/2018 states that operating experience and safety research shall be taken 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 from the construction and operation of nuclear facilities, and there are YTV guides in place for the reviewing and assessing operational events in Finnish facilities and for foreign facilities.

The legislation states that STUK has an obligation to ensure that the operating organisation is adequate and serves its purpose, that personnel participating in the use of nuclear energy meet the qualification requirements, and that the organisation arranges for relevant training. Reviews of safety management, the management system, the competence and training of nuclear personnel and operational experience are performed by STUK as part of the periodic inspection programme and YTV guide provide guidance.

STUK has 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 procures external organisations specialised in performing safety analysis for performing independent calculations, e.g., computational analyses to gain confidence on the licensee's analysis results. STUK mostly uses VTT in this respect.

6.3. REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILITIES

STUK's review and assessment process for fuel cycle facilities is based on the principles and requirements described in Chapter 6.1 during the entire life cycle of a nuclear facility, including periodic safety reviews. These principles apply to the three types of facilities: the spent fuel interim storage facilities, located at the nuclear power plants (either on the same site in a separate building or in the same buildings as the nuclear power plants), the spent fuel encapsulation plant, and U3O8 production plants (or uranium extraction facilities).

In December 2021, Posiva submitted the license application for operation of the encapsulation plant and disposal facility (also referred as DGR) and the corresponding safety case. STUK is currently in the process of reviewing the operating license application.

The purpose of an encapsulation plant is to encapsulate spent nuclear fuel that has been stored in spent fuel interim storage facilities in disposal canisters to be disposed of in an underground disposal facility. Although several review and assessment requirements apply to an encapsulation plant as for any nuclear facility, some requirements are not applicable to encapsulation plants, and there are some additional requirements that must be considered, due to the specific features of an encapsulation plant. 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. The major difference compared to other types of nuclear facilities is that long-term safety shall be considered in the review and assessment of an encapsulation plant.

The operation lifetime of the spent fuel encapsulation facility is 100 years, and periodic safety reviews for operating and long term safety are required at least every 15 years. One point of concern is the knowledge management and the retention of technical expertise along the period between the PSRs for the encapsulation facility and during decades long breaks in encapsulation and disposal operations. Finland should consider dealing with long term knowledge management for the safety assessment of such unique facilities, considering their large lifetime, in an integrated manner and cooperating with other countries. In that sense, STUK should consider finding means to retain personnel and knowledge for reviewing and assessing this facility over its lifetime.

Regarding the uranium extraction facility, before the activity can be started, the mining company will need a separate STUK authorization to start the operation. In addition to the YEL, YEA is applicable to a uranium extraction facility. The requirements concerning review and assessment of uranium extraction facilities 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. For the review and assessment of the current uranium extraction facility, STUK used a draft regulatory guide. This draft guide is still to be finalized.

The lack of specific regulatory guides for review and assessment of fuel cycle facilities, including mining and processing of uranium or thorium, identified by the IRRS team, will be addressed in Chapter 9.4 of this report.

6.4. 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. Teollisuuden Voima Ltd operates the LILW disposal facility located at Olkiluoto which was originally licensed in 1992. Fortum Power and Heat Ltd operates the other LILW disposal facility located at Loviisa, since 1998.

In December 2021, Posiva submitted the license application for operation of the encapsulation plant and disposal facility (also referred as DGR) and the corresponding safety case. STUK is currently in the process of reviewing that safety case. STUK issued a series of Guidance YTV 3 related to the review and assessment process.

STUK performs continuous safety assessments for radioactive waste management facilities. A periodic safety review of large-scale disposal of nuclear waste is required every fifteen years and 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 waste management is carried out in connection with the periodic safety review of the NPPs every 10 years. The infrequent full safety case reviews could present a challenge with regards to knowledge management which is discussed in Chapter 3.3.

STUK states that personnel for inspection and assessment for radiation waste management and decommissioning in STUK is currently sufficient. STUK also has the ability to hire TSOs as necessary (domestic and international) to support their assessments.

6.5. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The SätL details the information required to be presented by an applicant. It includes details associated with identifying the applicant and understanding what it intends to do, the safety assessment, and the measures to maintain safety. STUK reviews the information in the application with the requirements established by the SätL, the Decrees and STUK Regulations. The process for the review and assessment of the information provided is described in management system documents (SKV 3.2 and its appendices).

When licensing is being sought, the applicant is required by the SätL to justify the practice which is considered by STUK. A list on the STUK website is updated as needed to provide details of those practices that are generally considered justified while those practices that are considered unjustified are listed in the SätL. In particular, the assessment of the justification of a practice includes the waste generated by the conduct of that activity and the future exposures stemming from the disposal of the waste.

STUK has published on its website an explanation about the justification of non-medical imaging. STUK requires that, in addition to apply for license that may be required for conducting medical imaging, the operator must also submit a request to specifically obtain a licence for the non-medical imaging. A small number of practices have been licenced for non-medical imaging and the SätL explicitly requires that the justification be reconsidered at least every five years.

As indicated above, all new safety license applications need to provide a written safety assessment as part of the application. The SätL requires the licensee to document in the safety assessment ways in which the practice can cause radiation exposure, considering any possible radiation safety deviations, and 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. Measures for preventing and preparing for identified radiation safety deviations need to be detailed. The safety assessment must be reviewed at specified frequencies based upon the level of risk associated to the practice, and as needed.

The concept of the optimization of protection is presented in the SätL and is one of the matters to be considered prior to granting a safety licence. STUK examines this information as part of the process of reviewing the safety assessment when initially granting a licence and as part of the ongoing work to keep the safety assessment up to date. Dose constraints are utilised as a tool in the process of optimisation. Another tool is a series of guides called “STUK Opastaa” that provide practical guidance in a variety of radiation practices which are often developed in collaboration with volunteering professionals and assist in embedding established measures that optimize protection and safety in that particular field.

6.6. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

The safety of a nuclear facility shall be assessed in relation to the updates of the decommissioning plan, when applying for a decommissioning licence (YEA) and as part of a PSR conducted during decommissioning activities. PSR during the decommissioning of a nuclear facility shall be done according to license conditions or at minimum every 10 years.

The objective of the safety assessment is to 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.

In 2019, the licence for decommissioning activities for Research Reactor FiR – 1 was issued by Government. During that licencing process, STUK performed the safety assessment.

6.7. REVIEW AND ASSESSMENT FOR TRANSPORT

As a member of the European Union, Finland has adopted the European Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods. In doing so, Finland has adopted the Agreement for the transport of dangerous goods by road (ADR) which sets out the requirements for the transport of radioactive material. ADR adopts the requirements set out in SSR-6 (Rev. 1) which includes the assessment of ageing mechanisms of the package design.

The approvals given by STUK are done by validating the certificates given by the competent authorities in the country of origin of the packages.

Fresh nuclear reactor fuel is imported into Finland in Type B(U)F packages, which require package design validation. As part of its authorisation process, STUK does not confirm that ageing mechanisms are included in the package design safety report upon which the package design approval of the country of origin of the design was based. For designs of sealed sources in Type B(U) packages, no validation of the package designs is required and therefore the existence of an analysis of ageing mechanisms remains unknown. The IRRS team therefore recommends that package assessment processes in STUK for both nuclear material and radioactive material, are revised to include the assessment of the ageing mechanisms of the package design.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: As part of its authorization process, STUK does not confirm that an assessment of the ageing mechanisms of a package design was included in the package design approval process of the country of origin of the package design.

(1)	BASIS: SSR-6 (Rev. 1) para 613A states that <i>“The design of the package shall take into account ageing mechanisms.”</i>
(2)	BASIS: SSG-26 (Rev. 1) states that <i>“613A.3. For packagings intended for repeated use, the effects of ageing mechanisms on the package should be evaluated during the design phase in the demonstration of compliance with the Transport Regulations. Based on this evaluation, an inspection and maintenance programme should be developed. ...demonstration of compliance of the package are confirmed to be valid through the lifetime of the packaging. ...”</i> <i>“613A.4. In the design of packages intended to be used for shipment after storage, consideration of ageing mechanisms is important due to the long period between loading and the end of shipment after storage, the conditions of storage (even though the Transport Regulations do not apply to the storage of the package), ...for the identification and assessment of ageing effects should be recognized”</i>
R7	Recommendation: STUK should ensure that ageing mechanisms are addressed as part of the authorisation process for package designs containing either nuclear or radioactive material.

STUK only inspects licensees for which they have issued a Transport Authorization, namely for High Active Sealed Sources (HASS) and Nuclear Material. STUK conducted a survey on the volumes of radioactive material transported by road in 2013 and recognise the need to repeat this process to update their records. On small number of occasions, STUK have investigated the transport of Type A packages in response to requests for support from the Finnish Customs. No inspections of Type A packages are included in the annual inspection programme for radioactive material transports in Finland. As a consequence, STUK does not have information of the Type A packages operating in Finland and therefore regulatory oversight of compliance with the transitional arrangements in SSR-6 (Rev.1) para. 819 is not possible.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: STUK only inspects licensees to which they issued a transport authorization, namely for High Active Sealed Sources (HASS) and Nuclear Material. STUK does not have information of the Type A packages operating in Finland.

(1)	BASIS: SSR-6 (Rev. 1) para. 104, states that <i>“The objective of these Regulations is to establish requirements that must be satisfied to ensure safety and to protect people, property, and the environment from harmful effects of ionizing radiation during the transport of radioactive material.”</i>
(2)	BASIS: GSR Part 1 Requirement 27, states <i>“The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization.”</i>
(3)	BASIS: SSR-6 (Rev. 1) para. 819 states <i>“Packages not requiring competent authority approval of design under the 1985, 1985 (As Amended 1990), 1996 Edition, 1996 Edition (Revised), 1996 (As Amended 2003), 2005, 2009 and 2012 Editions of these Regulations.</i> <i>819. Packages not requiring competent authority approval of design (excepted packages, Type IP-1, Type IP-2, Type IP-3 and Type A packages) shall meet this edition of these Regulations in full, except ...”</i>
(4)	BASIS: TS-G-1.5 para 4.117 states <i>“The inspection and enforcement programmes of the</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>competent authority should be applied to all activities that are important to safety (design, testing, manufacture and maintenance of packagings, preparation for and carrying out of transport, and use of the management system), irrespective of whether an approval certificate from the competent authority is required.”</i>
R8	Recommendation: STUK should include operators transporting IP and/or Type A packages in its regulatory oversight activities.

6.8. REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE

STUK’s management and organisation of technical resources provides for a comprehensive approach for review and assessment of occupational exposures in nuclear and radiation facilities and activities.

STUK’s website contains guidance on carrying out the safety assessment by applicants for radiation practices.

Internal guides are also available to guide the safety assessments by STUK officers. An essential part of the review and assessment is to verify the comprehensiveness and quality of the licensee’s safety assessment in relation to occupational exposures. Additionally, the verification of dose constraints includes consideration of technical specifications of facilities and activities to ensure that occupational exposures are kept as low as reasonably achievable. Measures assessed also include appropriate systems and programmes for monitoring of workers for occupational exposure in all operational states and in accident conditions. The application of safety requirements in the review and assessment of occupational exposure has implicitly applied the graded approach. STUK recognises the need for on-going improvement in the application of a graded approach within its processes. A project to this effect has already been launched.

The regulatory body has also established internal guidance for the review and assessment of occupational exposure to natural radiation such as radon.

Internal guidance is also available for the assessment of individual monitoring services. STUK has authorised a number of individual monitoring service providers for the provision of external dosimetry service. The IRRS team was informed that STUK has also used the criteria and procedure used for the approval of external dosimetry service for authorisation of the internal dosimetry service operated by STUK. The IAEA safety standards recognise that the government may need to provide technical services when a suitable non-government service provider is not available.

6.9. REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE

STUK's review and assessment is in principle based on a review of the information received from the licensee in the safety licence application, focusing on the safety assessment. All information related to the licensing application is stored in the VASARA system. Review and assessment of information relevant to safety concerning radiation practices are conducted during licensing and inspection processes described in internal Guides SKV 3.2 and 3.4.

In addition, for medical radiation practices, quality insurance program and clinical audits, in particular in radiotherapy units, are assessed and reviewed during the course of the activity, typically during inspections. Clinical audits shall be organized periodically during the operation and the periodicity of a clinical audit depends on the classification of medical exposure given in the safety assessment, which is confirmed during authorization or separately.

Review and assessment of justification of medical exposure (clinical audit particularly) has challenges in assessing because there are no national referral guidelines that would cover most of the diagnostic procedures in radiology and nuclear medicine (see Chapter 9.9.).

Patient doses

STUK is obligated to compile and publish nationwide assessments on exposures arising from medical use of radiation. STUK issued a report in 2021 on patient exposures level and collective dose to the population from radiological examinations in Finland. The main finding shows that the total collective effective dose from X-ray and nuclear medicine procedures has increased 59% between 2008 and 2018, mainly due to the increase of collective effective doses from computed tomography (CT) and interventional radiology. Nearly 70% of the collective effective dose from x-ray examinations was caused by CT in 2018, while the proportion of CT procedures was only 17%. STUK has engaged in discussion with professionals in order to better understand the causes of this increase and identify possible actions for reducing the rate of increase.

6.10. REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE

STUK performs the review and assessment of documentation submitted by applicants before a decision on granting an authorization is made. Regulations establish the requirements related to public protection that applicants should demonstrate compliance with, in particular the elements to be included as part of the safety assessment of the facilities or activities for which the authorization is requested. Safety assessment regarding public exposure is confirmed by STUK if the licensee can adequately demonstrate safety.

In the case of radiation facilities, the assessment of current regulations by STUK in preparation for the IRRS mission identified that practices that discharge radioactive materials to the environment are not explicitly required to characterize the material to be discharged and the possible points and method of discharge as part of their safety assessment.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Regulations for radiation facilities and activities discharging radioactive materials to the environment do not require explicitly that the registrants and licensees shall determine the characteristics of the material to be discharged and the possible points and methods of the discharge. This has been recognized in the ARM, and is part of the action plan.

(1)

BASIS: GSR Part 3 Requirement 31, para. 3.132 states that “Registrants and licensees, in cooperation with suppliers, in applying for an authorization for discharges, as appropriate:
(a) Shall determine the characteristics and activity of the material to be discharged, and the possible points and methods of discharge; ...”

R9

Recommendation: STUK should establish requirements, for radiation facilities and activities that discharge radioactive materials to the environment, to ensure that the characteristics of the material to be discharged and the possible points and methods of discharge are determined.

6.11. SUMMARY

The review and assessment processes of STUK are overall mature and well established. Methods and tools are in place to make sure the review and assessment activities can be performed systematically, and STUK has a sufficient number of reviewer staff and the competencies needed for the scope and volume of review and assessment activities.

However, the IRRS team has made recommendations to address gaps concerning oversight of ageing mechanisms of transport package designs and of transport of IP and/or Type A packages, and to establish requirements for radiation facilities and activities that discharge radioactive materials to the environment.

The IRRS team has also identified a good practice which is STUK’s systematic model for continuous overall safety assessment of nuclear facilities.

7. INSPECTION

7.1. GENERIC ISSUES

Broad inspection rights over facilities where nuclear energy is used are vested upon STUK by the YEL. Chapter 10 establishes rights and responsibilities related to the oversight of use of nuclear energy and the application of coercive measures when necessary, in order to secure the safe use of nuclear energy, to maintain appropriate security and emergency arrangements, and to fulfil Finland's international contractual obligations in the field. Section 63 clearly establishes STUK's right for inspection and control of facilities where nuclear energy is used and warrants unrestricted access for its inspectors to those facilities in order to achieve its purposes. STUK is also vested with the responsibility and rights for the regulatory oversight of the construction of nuclear facilities.

Similarly, STUK's rights and responsibilities for inspection of radiation facilities and activities are established in the SätL. Section 176 gives STUK the right to inspect any practice covered by the SätL, including the right to access the facility or practice where the use of radiation may result in harmful exposure.

STUK has established a systematic approach for conducting inspections that is in accordance with the requirements of IAEA safety standards. Inspection activities are organized around different inspection programs that cover STUK's different areas of oversight responsibility. Inspection plans are prepared based on the aforementioned programmes. Different STUK Guides (YTV, SKV) provide details on planning and execution of inspection activities. The inspection programs include announced, unannounced, and reactive inspections. Most commonly used methods to conduct its inspections are interviews with the licensee and review of documents. Several other inspection methods are also used, such as surveillance, walk downs, observation of activities, etc. The use of a graded approach is generally clearly defined in the corresponding guides for all areas of regulatory inspection.

STUK's training activities for inspectors include elements such as competence mapping at the different levels of the organization, applicable legislation, official duties, and responsibilities, familiarization with written internal instructions, mentoring in the induction of new inspectors, and observation of inspections followed by leading inspections accompanied by an experienced inspector.

STUK's process leading to inspector qualification could be strengthened in some areas by implementing a systematic approach. STUK inspectors are trained according to an introductory initial training plan, and knowledge and practical skill requirements are established on a case-by-case basis based on individual competency assessments and position task requirements. Requirements to become qualified include on-the-job training, formal training courses, and a qualification test. Following initial qualification, individual competency needs are assessed and developmental assignments and training activities are assigned. However, the degree of assessment of the needed basic proficiencies varies by unit or position. As such, even though there are some elements of a systematic and qualification program, the IRRS team found that there are still gaps that need to be filled for full implementation of a systematic program. In addition, existing STUK inspectors have no refresher training requirements established, and completed trainings are not recorded. Formal qualification and requalification procedures for inspectors in STUK's Nuclear Reactor Regulation (YTO) and Nuclear Waste Regulation and Safeguards (YMO) departments are established in Guide YTV 6.b. Nonetheless, the IRRS team was informed that the provisions of that guide present implementation problems, and hence, is currently not fully applied, as described above. STUK identified deficiencies in training during its self-assessment that were limited only to lead inspectors of periodic inspections of NPPs. In this regard, the IRRS team was presented with some of the planned future improvement measures to resolve these shortcomings.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: STUK's inspector training and qualification programmes do not follow a systematic approach. The implementation of training activities differs from unit to unit within STUK.

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| (1) | BASIS: GSR Part 1 (Rev. 1) Requirement 11, para. 2.34 states that <i>“As an essential element of the national policy and strategy for safety, the necessary professional training for maintaining the competence of a sufficient number of suitably qualified and experienced staff shall be made available”.</i> |
| (2) | BASIS: GSR Part 1 (Rev. 1) Requirement 18, para. 4.13 states that <i>“A process shall be established</i> |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills [...]”.</i>
R10	Recommendation: STUK should continue to develop inspector training and qualification programmes to ensure their systematic implementation.

The legal framework allows STUK to make use of external experts and of external authorized inspection and testing organizations for certain areas of regulatory inspection of lower safety significance. The scope, attributions and responsibilities of STUK and of the external organizations are generally well established and understood. Proper accreditation and auditing of external organizations is provided by FINAS, an independent accreditation body.

Currently, STUK conducts a limited number of joint inspections on NPPs with institutions regulating other subjects, such as local government agencies for emergency preparedness, and fire departments and rescue organizations for fire safety.

7.2. INSPECTION OF NUCLEAR POWER PLANTS

The Nuclear Reactor Regulation department of STUK is responsible for inspections of Nuclear Power Plants.

According to a graded approach, NPPs are subjected to the strongest regulatory effort for inspection during all stages of their life cycles. Facilities preparing for construction are covered by a specific inspection program (RKT); another program (RTO) focuses on construction activities of an NPP; while a different inspection program (KTO) focuses on operation. There is no current inspection program for the decommissioning stage, but it is expected that a program will be developed when the need becomes relevant. In addition to these inspections covered by the periodic inspection programs, the Nuclear Reactor Regulation department also performs out-of-program inspections required by YVL guides on aspects related to compliance with specific regulatory requirements.

Inspection programs are modified according to previous experience or regulatory needs and provide overarching guidance for establishing the areas covered by inspections. Detailed annual inspection plans for each NPP are developed according to the guidelines of the programs, setting the scope of inspection activities to be covered. Inspection plans for NPPs under construction are prepared every six months based on the phase of the construction project and the activities taking place. Licensees are informed in advance of the inspection activities planned for the following year.

In addition, one-day surveillance inspections are organized according to Guide YTV 4.b.1, Operational Oversight Inspections (KV). These inspections focus on simpler, scope-limited and documented verifications done over licensee's common activities. Currently there is not a planning process for KV inspections, but they are carried out whenever the possibility arises. The IRRS team was informed that it is STUK's objective to develop an integrated oversight program which will include periodic inspections and the KV inspections. The IRRS team encourages STUK to develop the described programme.

Most inspections are carried out by inspection teams from headquarters deployed on-site. The inspection teams are typically comprised of 3 to 5 inspectors, with a leading inspector in charge and for a typical duration of 2 or 3 days. Inspections are carried out according to detailed plans. Guidance is usually provided to the inspectors at a general level, allowing flexibility to the lead inspector to develop specific inspection details.

STUK has a permanent presence at nuclear sites with its resident inspectors. There are currently 5 resident inspectors at Olkiluoto site, and 2 resident inspectors at Loviisa site.

One of the main tasks of the resident inspectors is to publish weekly reports relaying the most important events of the past week at the plant units, limiting their involvement to gathering information of operation of the facilities, or when an event occurs. Resident inspector activities are not covered by any guide or procedure.

In addition, reactive inspections can also be carried out based on the occurrence of unexpected events, particular operative states of the facility, oversight results, deviations or non-compliances. In this case, clear, graded, written criteria for initiation of a reactive inspection are provided by STUK guides. Inspections can also be added to the plan, focusing on ongoing or upcoming activities at the plant or when changes are made to safety significant systems, structures or components.

The majority of inspections are carried out in an announced manner. A small number of inspections are unannounced. STUK has not identified the need to increase the number of unannounced inspections.

A formal process is followed for documenting and submitting inspection findings to the licensee within an established time frame.

Regarding training and qualification of lead inspectors for periodic inspections, the IRRS team was informed that there are no specific provisions for training and qualification of them. The IRRS team was also informed that there are no formal requirements or specific training in place for consideration of a lead inspector. Inclusion on the roster of lead inspectors is dependent on the decision of the managers with consideration of seniority and experience. STUK identified this situation during its self-assessment, and has included an action on its Preliminary Action Plan. Recommendation R10 in Chapter 7.1 addresses this issue.

The IRRS team was presented with examples of inspection activities for NPPs under construction carried out until 2021 for the now cancelled Hanhikivi NPP.

Site visit to Loviisa Nuclear Power Plant

The IRRS team visited the Loviisa NPP site and observed an on-site inspection of chemistry reporting and interfacing conducted by STUK's inspectors. The IRRS team was accompanied by STUK counterparts. STUK's inspection team was comprised of 2 inspectors. The inspection method consisted of an interview with the licensee's chemical processes staff, and the review of evidence of implementation of corrective measures. The inspectors were properly acquainted with the corresponding inspection plan and procedures. They presented the IRRS team with an approved inspection plan for the Loviisa 1 NPP 2022 outage, and also with the inspection plan for the observed activity. The inspection was previously announced to the licensee, in order to secure the presence of all necessary licensee's staff during the activity. Inspection results were documented and discussed with licensee staff. Inspectors were found to be well prepared and knowledgeable to conduct the inspection, and they maintained a professional and cordial attitude at all times, conducive to a productive interview. In their preparation, the inspectors specifically discussed the objectives of the inspection as well as specific items which had been previously identified. The IRRS team also met the Loviisa NPP Management staff, who identified that the work of STUK provides valuable feedback on the performance of the facility. STUK was commended for possessing the adequate competences to assess and inspect plant modifications, thus allowing the licensee to improve its operations accordingly. STUK's role and presence on site was identified as well understood, and a clear separation of roles and responsibilities was recognized.

7.3. INSPECTION OF FUEL CYCLE FACILITIES

STUK currently inspects the spent fuel interim storage facilities according to the same inspection programme of the nuclear power plants, since the spent fuel interim storages are operated by the same organizations and located at the same site of the respective nuclear power plants.

The spent fuel encapsulation plant at Olkiluoto is in the commissioning phase, thus they follow a regular Construction Inspection Programme (RTO). Once the operating licence is granted for this facility, the Operation Inspection Programme (KTO) will be applied.

The uranium extraction facility from Terrafame is not yet operating, therefore there is no regulatory oversight based on the YEL, yet the mining activities are subject to radiation protection inspections from STUK. STUK has the capability in place for inspecting the uranium extraction facility once it starts to operate. Due to the Supreme Administrative Court decision (see Chapter 5.4), the start of extraction facility operations will be expected latest by June 2024. Consequently, STUK will finalize its inspection and oversight program for the facility in 2023. There is

currently no uranium mining in Finland, and if any uranium deposit is mined, the regulatory body will need to build competence to inspect that.

7.4. INSPECTION OF WASTE MANAGEMENT FACILITIES

Inspections for predisposal waste management facilities and final disposal facilities closely follow inspection routines established for NPPs.

STUK has more than 10 inspectors dedicated to radioactive waste management facilities inspections and inspectors from other Departments can assist if needed.

During the mission, the IRRS team was informed that STUK performs approximately 15 planned inspections per year for waste management facilities and activities and that inspectors are generally qualified through on-the-job training activities.

7.5. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The inspections of radiation facilities and activities are based on STUK's management system Guide SKV 3.4. They can be announced or unannounced. Most of the inspections are planned but reactive inspections can also be carried out when necessary. The inspection programme includes the use of surveillance questionnaires and inquiries, as well as remote inspections.

The SätL states that STUK draws up an inspection programme concerning facilities and activities subject to a safety licence. During preparation of an inspection plan a graded approach is applied. Most inspections are thematic in nature and specifically examine certain topics. Each thematic inspection is managed as a project. The radiation risks are considered in conjunction with the possibility for improvement of inspected facilities and activities and effective regulation. The general outcomes of the thematic inspections are published on the STUK website, but not the individual inspection reports. Through the thematic inspections, STUK has the possibility to share findings and lessons learned to improve overall safety of all facilities and activities.

The content of each inspection is dependent on the nature and scope of the practices. Inspectors review relevant documentation, take radiation measurements, and conduct wipe tests of radioactive sources, to the extent that is possible and necessary. Checklists are used to provide for consistency amongst the inspectors. The inspection report contains all the relevant findings and measurement results related to radiation safety and the report is saved in STUK's register. Any deficiencies are, in addition to the report, separately saved in the VASARA register with the possible deadlines for corrective actions. During the interviews, two randomly chosen sample inspection reports were examined and it was concluded that they were both consistent with Guide SKV 3.4.

With the SätL revision, consideration was given to inspection of safety culture. Specifically, section 12 of the SätL specifies that the management of each applicant is responsible for ensuring that the organization's activities maintain and develop a good safety culture. In addition, the organization's management is required to ensure that the safety management system combines procedures, operating methods, and leadership for the management of safety.

STUK records observations of licensee safety culture in a database (VASARA) and has circulated a survey to some licensees to better understand their safety culture. However, the available information concerning observations is not systematically assessed in a manner that can be utilized in the conduct of inspections. The IRRS team considers that STUK has developed substantial expertise in the area of safety culture, and this expertise could be used to establish a systematic process to address the safety culture during inspection of radiation facilities and activities. In addition, the inspectors have not undertaken any formal training on this topic. This issue is addressed in Chapter 7.1.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: STUK does not have a systematic process in place to address safety culture during inspection of radiation facilities and activities.

(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 28/29 para 4.53 states that <i>“In conducting inspections, the regulatory body shall consider a number of aspects including: Safety culture /.../”</i> .
(2)	BASIS: GSG-13 Para 3.220 states that <i>“Regulatory inspection is performed to make an independent check on the authorized party and the state of the facility or activity, and to provide confidence that the authorized party is in compliance with the safety objectives prescribed or approved by the regulatory body. This should be achieved by confirming that: (b) The authorized party has in place an effective management system, a strong safety culture, and self-assessment systems for ensuring the safety of the facility or activity and the protection of people and the environment /.../”</i> .
S10	Suggestion: STUK should consider establishing a systematic process to address the safety culture during inspection of radiation facilities and activities, in accordance with a graded approach.

Site visit to Helsinki University Central Hospital (HUS), Comprehensive Cancer Centre

The Comprehensive Cancer Centre at HUS is in charge of all oncological cancer treatment, other than surgeries, throughout the entire Uusimaa region.

The scope of the inspection addressed the new premises housing the radioisotope unit of the cancer centre, in particular the laboratory dedicated to the preparation of radiopharmaceuticals used for molecular radiotherapy, the various locations for the gamma cameras, the sources, the waste and the dedicated rooms for receiving patients. The representative of the licensee was the Head of Radiotherapy Department, which is also Radiation Safety Officer for whole practice. One of the medical physicists working in the department was also present during the inspection. The radioisotope unit is not yet in operation (there are no patient, sources, equipment, staff or zoning). Consequently, this inspection was not representative of a usual inspection in a nuclear medicine unit.

During the visit the inspectors collected information on the flow of sources and wastes, the safety of the various rooms (the access and the light signalling particularly), and the measurement devices likely to be used by the operator in case of contamination event. STUK inspectors were also checking if the current state of the facility is in line with the safety assessment provided by HUS during the licensing process.

At the end of the inspection, the leading inspector presented orally the findings to the licensee representative. After the inspection, the IRRS team members met the hospital representative who underlined the useful interaction with the STUK inspectors and their technical expertise.

7.6. INSPECTION OF DECOMMISSIONING ACTIVITIES

STUK is empowered by YEL to inspect decommissioning of nuclear facilities to ensure that the activities are done in compliance with conditions established in the licence and according to existing safety requirements. The regulatory oversight covers the maintenance, repairs, inspections and tests of the systems, components, and structures of a nuclear facility.

Regarding decommissioning of research reactor FiR-1, STUK has developed an oversight plan for inspections of shutdown phase, and it is updating the inspection plan for the decommissioning phase including hold points. Decommissioning activities are expected to start when the waste disposal pathway to the Loviisa LILW facility is approved and are expected to last 1- 2 years in duration.

7.7. INSPECTION OF TRANSPORT

The departments of Nuclear Waste Regulation and Safeguards, and Radiation Practices Regulation, have essentially a common approach to training its inspectors which includes, additionally to those mentioned on 7.1, elements such as,

- Basic in-house training in transport control corresponds to ADR awareness training
- In the case of transport control, the inspector also has the possibility of training outside STUK in commercial courses, if this is considered to enhance the professional skills of the inspector

In the context of new staff members, the details of the training considered necessary are driven by the background of the new staff member and the STUK department they will work in. No formal external training courses have been documented as training requirements for transport inspectors, for example areas for consideration would include auditing (for management systems), radiation protection in a radiation area, personal safety of the inspector and others in the vicinity under routine transport and transport accident conditions.

The IRRS team recognizes that STUK has invested time and effort in documenting the elements of training inspectors, and that this is work in progress. There remains a level of discretion in the content of the training for individuals, which is not described in a documented training programme. Recommendation R10 in Chapter 7.1. addresses this issue.

Besides, extending the scope of the annual inspection plan prepared to include Type A packages. This would address the verification of compliance with SSR-6 (Rev. 1) para. 819, but also provide STUK confidence in the Type A package design and transport sector. This is addressed in Recommendation R7 in Chapter 6.7.

A report on the site visit to the industrial radiography facility – DEKRA can be found in Chapter 7.8.

7.8. INSPECTION OF OCCUPATIONAL EXPOSURE

STUK has internal guides for the inspection of occupational exposures for nuclear and radiation facilities and activities. Inspections are performed as onsite inspections (announced and unannounced), reactive inspection and, when needed, follow-up inspections to confirm rectification of non-compliances. One of the key objectives of the inspections is to ensure that the dose constraints specified for the workers are complied with. During the COVID-19 pandemic, STUK also commenced remote inspections using online platforms. In addition to onsite inspection, STUK is proposing to continue online inspections. The IRRS team notes that the use of online platforms for inspection will increase the oversight of facilities and activities.

If inspection deals with occupational exposure, then following issues are typically looked into: documentation of the licensee's radiation safety management system, processes and procedures for worker safety and protection are requested and reviewed by the inspector prior to the on-site inspection. The onsite inspection includes verification of the information provided in the documentation. This includes verification that special arrangements for pregnant workers, breastfeeding women, and underage persons have been appropriately provided for by the licensee. Confirmation that employers do not offer incentives as substitutes for safety measures are also verified by discussions during the inspection.

Compliance with requirements on existing exposure situations, such as occupational radon and NORM exposure, is described in Guide VALO 7. Measures are verified through document inspections, and additionally onsite inspections at NORM sites.

The IRRS team was informed that due to the high level of compliance by authorised parties, inspections are risk informed and performance based. The scheduling of inspections is strategic and takes into account compliance history of the authorised parties and does not rely solely on the perceived risk of facilities and activities. Therefore, facility or activity specific inspection check lists are not routinely used.

Inspectors are authorised to take enforcement actions commensurate to the level of non-compliance identified during inspections. This includes stopping or restricting a practice which is notified to the Head of Section as soon as possible.

Site visit to industrial radiography facility - DEKRA

The IRRS team was invited to observe an inspection carried out at a site operating industrial radiography generators and sources for non-destructive testing of materials. The visit by STUK was a planned inspection and undertaken by three STUK inspectors. The previous inspection of the facility was approximately three years ago. The inspection was conducted in a confident, professional, and systematic way and involved inspection of the licensee documentation and a visual inspection of the X-ray equipment, bunker, and storage facility. The inspection was conducted in Finnish with periodic English translation provided to the IRRS team. The inspectors reviewed the management system of the licensee which included verification of roles and responsibilities; procedures for use; transport; management of radiation safety deviations, training of workers, source inventory, personnel dose records etc. The safety assessment, previously submitted to STUK for approval in response to a request sent to all licensees, was also reviewed to confirm that it was still appropriate. In the inspection it was discussed when updated safety assessment should be sent to STUK for approval. All the 188 workers at the facility were categorised as Class category A workers. The inspection did not result in a finding of non-compliance, but found that it is important to pay attention to refresher training of workers. In particular, possible transport accidents as part of the training were discussed during the inspection.

A subsequent separate discussion between the licensee and the IRRS team revealed that the licensee was overall satisfied with STUK, however, they did comment that unannounced field inspections would further improve safety in the industry.

7.9. INSPECTION OF MEDICAL EXPOSURE

Information in Chapter 7.5. on the inspection program and types of inspection related to sources and facilities, covered by the guidance SKV 3.4. also apply to inspections on medical exposures conducted by STUK inspectors.

The training of inspectors includes a common module dedicated to the regulation, the licensing process, the inspector's job, and a technical module, tailored to each inspector according to his/her initial knowledge. A long period of assignment in the hospital is planned for the inspector by STUK to improve knowledge and understanding.

The graded approach is used to determine the frequencies of the inspections, with a high frequency for radiotherapy and nuclear medicine services. The oversight of the use of dental intraoral devices is specific: it is based on surveys and postal packages which contain a pair of TLD crystals and an X-ray film to be exposed to radiation. The package is to be returned to STUK for analysis. If deficiencies are detected or unusually high doses measured, corrective actions are required. If necessary, an inspection of the facility may be carried out.

7.10. INSPECTION OF PUBLIC EXPOSURE

Inspections of nuclear facilities include the verification of compliance with discharge limits and of the functioning of monitoring systems and equipment, as well as any possible modifications made. The results of discharge and environmental monitoring programmes are also verified.

Inspections of radiation facilities are conducted according to STUKS's inspections guidance and procedures that include the verification of equipment used for the monitoring of discharges, the status of records of radioactive materials in use and waste produced. During the inspections the provisions for the protection of the public established in the safety assessment approved by STUK are verified.

Regarding existing exposure situations, the inspection of remedial and protective actions is performed by STUK following internal guides, which are reviewed regularly for building materials and NORM scenarios and industries. Inspections related to radon in dwellings and public buildings, as well as radioactivity levels in consumption water, are conducted by local health protection authorities following local specific guidance.

7.11. SUMMARY

Inspections are planned and carried in a systematic manner; results are communicated to licensees and follow up of non-compliances occurs, providing feedback to the regulatory inspection process. The IRRS team conducted several observations of inspections at licensed facilities, and it was verified that inspectors have the right to unrestricted access, and that they exercise their responsibilities in a professional, open and knowledgeable manner. For transport, attention is drawn to Recommendation R8 in Chapter 6.7 which includes extending the scope of oversight activities of Radiation Practices Regulations Department, to include Type A packages.

The IRRS team recommends STUK to implement a systematic inspector qualification program in order to ensure that its staff has the competencies necessary to perform their duties and that a sufficient number of qualified staff is available to carry out inspections.

The IRRS team concludes that STUK has in place a comprehensive, robust, inspection programme to verify compliance with regulatory requirements and license conditions established for nuclear facilities, radiation sources facilities and activities, transport, and the protection of exposed workers, the public and the environment. This programme is adequately implemented and covers all the areas of regulatory responsibility, although a gap was identified related to assessment of safety culture issues during inspections of radiation facilities and activities.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

Legislation provides STUK with the mandate and the authority to implement the enforcement of regulatory requirements on nuclear and radiation facilities and activities. These enforcement rights are provided to STUK in the YEL and in the SätL. The Acts give well defined powers and enable STUK to ask for executive assistance from other authorities to fulfil its duties.

In line with these powers and responsibilities, STUK has established an enforcement policy covering the coercive measures that can be implemented according to a graded approach, including conditional fines, threat that the activity is interrupted or limited and the threat that the necessary work is done at the cost of the neglectful organization. For safety licenses issued under SätL, the enforcement policy includes also the cancellation of a license. According to the YEL, the power to cancel or revoke a license lies with the authority that first granted the license. For nuclear facilities, the licence is granted by the Finnish government through the preparation process by the Minister of Economic Affairs and Employment (MEAE). For other uses of nuclear energy (under YEL), the licence is granted by STUK and therefore the power of license cancellation lies with STUK. The cancellation of a license is an enforcement tool described in the legal framework, but not included in STUK's enforcement policy for nuclear facilities. This lessens the comprehensiveness of the enforcement policy for nuclear facilities since it lacks description of an existing enforcement measure. The IRRS team encourages STUK to include the cancellation of a license within its enforcement policy. It remains clear nonetheless, that STUK has the authority to suspend any activity or command the shutting down of any facility under its regulatory control and to take any necessary action to preserve safety.

For circumstances where a non-compliance 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 is not the responsibility of STUK, but the prosecution is the responsibility of the public prosecutor. However, STUK is involved in the preparation of an initial assessment of the case and, on that basis, to address a request for investigation. STUK shall be requested by the prosecutor to make a statement before bringing a prosecution for an offence under SätL.

8.2. ENFORCEMENT IMPLEMENTATIONS

According to STUK's experience, the enforcement tool that is most commonly used is the "STUK decision" (notice to take action). This is a binding decision issued by STUK, primarily used to oblige licensees to implement necessary measures for correcting non-compliances; or to oblige licensees to implement necessary changes when needed.

The decision-making process for enforcement tool is well established, and the nature of the deficiency to be solved is clearly indicated, as well as a time limit for the implementation of the corrective actions. Openness regarding this enforcement measure is secured by the right of the licensee's views about the matter to be heard before the decision is made, and thereafter to appeal.

For non-compliances below the threshold of that requiring a written regulatory requirement, other enforcement tools are used, such as oral notices, or requests for action stated within an inspection protocol made by an inspector.

Guide YTV 5.a provides clear written criteria for the application of enforcement actions on the use of nuclear energy (i.e., related to the YEL). A graded approach is described in the guide by means of case-studies for the application of each action. Actions of lesser significance, applied by virtue of inspectors are oral reprimands and written notices to take action. These measures are described by STUK as containing no enforceable obligation, but rather regulatory steering measures. In case of non-compliances of greater significance, or recurrence on minor non-compliances, measures taken by virtue of STUK's decision are applied. These actions are described by STUK as "actual implementation procedures", and are comprised of written notices to take action, encompassing a higher degree of formality. Enforcement actions taken by STUK can be reinforced by means of coercive administrative measures such as conditional fines, threat to limit and interrupt activities, and threat that STUK will have the neglected measure carried out at the relevant licensee's expense.

According to STUK's experience, the threat to suspend the operation of a facility has always been incentive enough for the licensee to comply, whereas conditional fines have never been implemented.

Guide SKV 3.7 provides similar clear criteria for the application of enforcement actions on uses of radiation (i.e., related to the SätL). The graded approach on the selection of the appropriate action is also described. There is a comprehensive set of mechanisms for enforcement and the documents in the STUK management system define clear policies and procedures for their systematic, consistent and risk-based implementation. It is the inspector's duty to follow through any binding enforcement action. These duties are described in internal guidance, STUK 3.1 and SKV 3.7. Enforcement actions are recorded in STUK's document management systems including dates for reporting remedial actions.

STUK's inspectors have the power, granted by law to take precautionary measures in the scope of their competence, with the urgency each situation requires, in order to ensure nuclear safety or protect people against the harmful effects of ionizing radiations or to mitigate such effects, which may include the discontinuation or restriction of an activity, practice or the shutting down or limitation of operation of a facility.

The IRRS team was presented with three examples of enforcement measures. The first example consisted of an oral notice given by a STUK inspector during an inspection, for identified violations to the licensee's own procedures for corona virus-prevention measures. The finding was properly recorded on STUK's HAKE database.

A second example consisted of a written notice given by STUK inspectors when deficiencies were observed in the submission of annual evaluation reports of testing institutes required in Guide YVL E.12.

The last example consisted of the suspension of the performance of an individual function of the refuelling machine of Loviisa 2 NPP after a fuel handling incident. STUK required (clarification request 1/B43713/2017) the licensee not to proceed with fuel transfers until permission from STUK was granted.

Even though STUK inspectors receive an initial training for the use of enforcement actions during their basic training, the IRRS team found that, since inspectors rarely limit operations or suspend a nuclear facility, confidence in the application of these measures might not be guaranteed. In this line, training of STUK inspectors on the enforcement procedures should be included within a systematic training, retraining and qualification program. Recommendation R10 in Chapter 7.1 addresses this issue.

8.3. SUMMARY

The existing legal framework provides adequate enforcement powers to STUK. STUK has developed and implemented a robust and open enforcement policy which includes and describes graded actions for coping with non-compliances ranging from those of minor safety significance to those requiring strong enforcement measures.

STUK's inspectors have adequate enforcement powers in order to restore safety when a detriment is identified. However, the practical implementation of those powers could be strengthened by periodically retraining the inspectors. In that line, STUK's enforcement could benefit from a systematic refresher training for inspectors on the application of most severe enforcement procedures.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

The principles, requirements and associated criteria for safety upon which regulatory judgements, decisions and actions are based on are laid down in legislation which includes acts, decrees and STUK regulations. These are legally binding instruments.

STUK has authority to issue guidance in the field of its statutory tasks without a special legal authorization by means of legislation. The guides are not legally binding.

STUK has issued an internal Guide STUK 3.6 which sets out the drafting process of STUK regulations and YVL guides. Same principles and proceedings are followed in principle also when giving guidance concerning the SätL and legal rules subject to it. 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 STUK's regulations and guides shall be checked at least every five years and if needed the updating process should be started.

The update plans of regulations and guides are included in STUK's oversight departments' annual planning process. 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 or guide are presented in the work plan including changes in national legislation or international safety standards such as of IAEA, ICRP, WENRA. Regulatory experience and expert opinions from different stakeholders are taken into account.

The preparation process of regulations and YVL guides includes internal commenting and external commenting by stakeholders. Public participation is made possible via a specific web page, lausuntopalvelu.fi (maintained by the Ministry of Justice), where the drafts for external commenting are available. Anyone can comment on the regulations and read the comments made by others. Further, stakeholders have had the possibility to send comments through STUK's website.

Prior to issuing the regulations within the scope of YEL, STUK collects 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. Transitional provisions for implementation of new regulations are well addressed in all regulations issued by STUK.

During the interviews, it was revealed that the YVL guides are of dual nature and these guides are prepared to fulfil the requirements of section 7r of YEL which states that "The safety requirements of the Radiation and Nuclear Safety Authority are binding on the licence holder, while preserving the licence holder's right to propose an alternative procedure or solution to that provided for in the regulations. If the licence holder can convincingly demonstrate that the proposed procedure or solution will implement safety standards in accordance with this Act, the Radiation and Nuclear Safety Authority may approve the procedure or solution". The IRRS team noted that the dual functionality of the YVL guides in some cases has impacted the application of regulatory requirements. For example, most of the IAEA requirements of SSR-1, SSR-2/1, SSR-2/2 and SSR-3 etc. are addressed as guides. Thus, licensee has the option to choose alternate solutions to these requirements. STUK explained that renewal of STUK regulations and YVL guides and for MEAE's renewal of the YEL and Decree are planned.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The YVL guides include both requirements and guidance. This has been recognized in the ARM and is also part of the action plan.

(1)

BASIS: GSR Part 1 (Rev. 1) Requirement 32, states that *"The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."*

(2)

BASIS: GSG 13, para. 3.9 states that *"Guides are advisory in nature; they should allow the authorized party flexibility in applying new technologies and developing new procedures to enhance safety. ..."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(3)	BASIS: GSG 13, para. 3.23 states that <i>“In determining whether a particular topic should be made mandatory and thus be addressed in a regulation rather than a guide, consideration should be given to the regulatory requirements and the extent to which the topic in question can be considered as essential for implementing these requirements.”</i>
S11	Suggestion: STUK should consider, while renewing its regulations and guides under YEL, to better distinguish requirements and guidance.

STUK historically published the series of ST guides based on the old SätL (592/1991) that was repealed in 2018. The ST guides are still available on the STUK website and can be used to the extent that they do not contradict the new SätL and subsequent legislation. STUK Team explained that the ST guides are part of the transition to the new guides following the commencement of new SätL and it is acknowledged that the STUK website does indicate that the ST Guides are recommendatory in nature.

The IRRS team noted that, all regulations are published on STUK’s website and on the Finlex database. STUK has developed and published a web-based tool, SAMMIO which provides licensees and others, including the general public, with information about the requirements under the SätL. SAMMIO allows users to search by type of radiation practice, topic areas and free search words and to save the results of individual searches. The search result includes the specific requirement, its rationale and further guidance including STUK’s expectations on its practical application. The guidance is regularly updated to ensure it is current and accurate. Users of SAMMIO can send feedback to STUK. The IRRS team was given a presentation on SAMMIO, and the IRRS team considers that this information system for legislation, regulations and guides to support licensees in clarifying and implementing the requirements as a good practice. SAMMIO enables the provision of timely, accurate and current information to licensees or applicants without the need for further engagement with STUK, thus improving the efficiency and effectiveness of the regulatory body. STUK has advised that a similar system will be developed in the application of the YEL.

In Finland there are several Acts and Regulations, and Authorities, that give requirements relating to the transport of nuclear material, radioactive material, and NORM. The IRRS team noted that consideration is given to develop a process and to clarify such regulatory requirements in the regulatory framework, with guidance on the required authorization processes for nuclear, radioactive and NORM material, possibly using SAMMIO as a platform for operators.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: STUK has developed and published a web-based searchable tool, SAMMIO which provides licensees and the general public with information about the requirements under the Radiation Act. Any search result includes the specific requirement, its justification and further guidance including STUK’s expectations on its practical application.

(1)	BASIS: GSR Part 1 Requirement 34, states that <i>“The regulatory body shall notify interested parties and the public of the principles and associated criteria for safety established in its regulations and guides, and shall make its regulations and guides available.”</i>
GP3	Good Practice: STUK has developed a web-based searchable tool “SAMMIO” which provides access to timely information regarding the radiation legislation, regulations and guides for licensees and licence applicants including STUK’s expectations on its practical application.

Administrative Procedure Act (434/2003) section 6 requires that the acts of an authority shall be proportionate to the objectives sought. This concept of graded approach applies to all activities of an authority e.g., regulatory oversight, administrative decisions, drafting legislation and issuing guidance.

The 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.” Further, the concept of graded approach is also addressed in SätL such as the obligation to classify radiation activities in respect of radiation exposure level and the types of radiation sources, the classification of radiation workers. STUK has implemented the graded approach in STUK legislation and is reaching accordingly to lower-level in regulations and guides.

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

Safety requirements for NPPs are written in Nuclear Act, Decree and in regulations. STUK has also issued the detailed safety requirements concerning the implementation of safety level in YVL guides.

STUK has published several regulations for nuclear power plants related to safety, emergency arrangements, security, safety of disposal of waste.

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.

The IRRS team noted that STUK does not have specific safety requirements for planning and preparation of decommissioning of NPPs including the transition from operation to decommissioning.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: STUK does not have specific safety requirements for planning and preparation of decommissioning of NPPs including transition from operation to decommissioning. This has been recognized in the ARM and is also part of the action plan.	
(1)	BASIS: SSR-2/2 Requirement 33 para 9.3 states that: <i>“In the preparatory period for decommissioning, a high level of operational safety shall be maintained until the nuclear fuel has been removed from the plant”.</i>
(2)	BASIS: SSR-2/2 Requirement 33 para 9.6 states that: <i>“The implications for safety of the activities in the transitional phase prior to the commencement of decommissioning shall be assessed and shall be managed so as to avoid undue hazards and to ensure safety”.</i>
R11	Recommendation: STUK should establish requirements for planning and preparation of decommissioning of NPPs including transition from operation to decommissioning while renewing its regulations and guides under YEL.

9.3. REGULATIONS AND GUIDES FOR FUEL CYCLE FACILITIES

The requirements concerning the handling, packing and storing of spent nuclear fuel and facilities performing these functions are established in 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).

Specific guidance on spent fuel storage facilities is given in YVL Guide D.3, which contains references to various YVL guides that concern nuclear power plants. These YVL guides are valid for fuel cycle facilities applying the graded approach principle. YVL Guide D.3 defines the primary requirements to meet the safety objectives for

handling and storage of nuclear fuel, with the safety objectives of prevention of criticality and damage to the fuel; adequate cooling; and the safety of operations and prevention of load drops and damage to safety related systems.

STUK developed YVL Guides B.1, B.2 and D.3 for safety design and classification criteria of systems, components and structures that are specific to nuclear power plants which form the basis for review and assessment of fuel cycle facilities. STUK waives some of the requirements of these guides that are not applicable to fuel cycle facilities, considering a graded approach. Conduct of operations of fuel cycle facilities is assessed based on YVL guide A.6, which is also for NPPs. These practices are confusing for applicants and regulator. The existing guides do not cover with sufficient detail all the safety requirements that are applicable to fuel cycle facilities. The lack of specific guides for review and assessment of fuel cycle facilities and the usage of guides that have been specifically developed for Nuclear Power Plants has been identified by the IRRS team. So, STUK should consider developing specific guides for fuel cycle facilities.

The requirements for the uranium extraction facility are established in the regulation on the Safety of Mining and Milling Operations Aimed at Producing Uranium or Thorium (STUK Y/5/2016). The licensing of a uranium extraction facility is performed according to YEL section 21 (Other use of nuclear energy). Only two guides are applied to these facilities: YVL guide D.1 (safeguards) and YVL guide D.2 (transport). A YVL guide on uranium extraction has been drafted but has not been published yet.

The lack of specific guides for fuel cycle facilities including mining and processing of uranium or thorium, has been identified by the IRRS team.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no specific guides for fuel cycle facilities or for the mining and processing of uranium.	
(1)	BASIS: GSR Part 1 Req. 24, para. 4.34 states that <i>“The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization...”</i>
(2)	BASIS: GSG-13, para. 3.43, states that <i>“In order to fulfil these requirements, the regulatory body should issue regulations and guides that describe the safety assessments to be performed by the authorized party for the facility or activity, and how these should be submitted for review by the regulatory body prior to the granting of the authorization at each lifetime stage.”</i>
S12	Suggestion: STUK should consider developing specific guides for fuel cycle facilities and for the mining and processing of uranium while renewing its regulations and guides.

9.4. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

Provisions for handling and storing nuclear waste and spent fuel are established in the Radiation and Nuclear Safety Authority’s Regulation on the Safety of a Nuclear Power Plant.

The STUK Regulation on the Safety of Disposal of Nuclear Waste applies to:

- disposal of spent nuclear fuel and other nuclear waste at nuclear facilities to be constructed in bedrock and facilities constructed into the ground;
- to nuclear facilities intended for the handling and storage of spent nuclear fuel;
- 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;
- radioactive waste if it is handled or stored at a nuclear facility or disposed of in a disposal facility for nuclear waste.

Provisions for radioactive waste management are established in the Radiation and Nuclear Safety Authority Regulation on Radioactive Waste and Discharges of Radioactive Substances in the Use of Unsealed Sources STUK S/2/2019.

Environmental Protection Act (527/2014) or Waste Act (646/2011) could be applied when the waste contains so little radioactive material that it is not radioactive waste within the meaning of SätL.

As discussed in Chapter 1.2, the IRRS team noted that there are currently neither requirements nor guidance related to closure of waste final disposal facilities.

9.5. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

In Finland, the SätL is extensive and detailed and is supplemented by the decrees and by STUK 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 Good Practice GP3 in Chapter 9.1. recognises this.

STUK communicates relevant matters such as requirements changed by the reform of radiation legislation by sending information or notifications directly for those concerned and by publishing e-newsletters.

Finland has access to an extensive range of medical uses of radiation including radiopharmaceuticals for diagnostic and therapy purposes. There is the potential that a patient may perish after treatment prior to excreting the radioactivity. On a different note, it is also possible that, a person containing sealed or unsealed radioactive sources may perish. In Finland, there are no formal provisions for ensuring protection and safety in the handling of deceased persons or human remains that are known to contain sealed or unsealed radioactive sources.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: In the Finnish legislation, there are no provisions for ensuring the protection and safety in the handling of deceased persons or human remains that are known to contain sealed or unsealed radioactive sources. This has been recognized in the ARM and is part of the action plan.

(1)

BASIS: GSR Part 3 Requirement 3, para. 2.37. states that: *“The regulatory body, in consultation with the health authority, shall ensure that provisions are in place for ensuring protection and safety in the handling of deceased persons or human remains that are known to contain sealed or unsealed radioactive sources, either as a result of radiological procedures for medical treatment of patients or as a consequence of an emergency.”*

R12

Recommendation: STUK, in consultation with the relevant authorities and professional bodies, should develop and implement provisions for ensuring the protection and safety in the handling of deceased persons or human remains that are known to contain sealed or unsealed radioactive sources.

9.6. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

The STUK Regulation on the Safety of a Nuclear Power Plant is applied to decommissioning.

STUK has identified that there is a need to clarify requirements for the transition from operation to decommissioning for NPPs. This is planned to be addressed in the context of the renewal of the YEL. Recommendation R11 in Chapter 9.2. addresses this issue.

YVL Guide D.4, Predisposal management of low and intermediate level nuclear waste and decommissioning of a nuclear facility addresses 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. This guide also addresses the clearance of nuclear waste, including recyclable material, arising from the operation and decommissioning of a nuclear facility. This guide further, discusses the clearance procedures and the activity determination and record-keeping of the materials to be cleared.

9.7. REGULATIONS AND GUIDES FOR TRANSPORT

There are several Acts and Regulations, and Authorities, that have requirements relating to the transport of nuclear material, radioactive material, and NORM.

STUK is in discussion with the Ministry preparing the draft YEL to recommend the transport requirements cited in the SätL are not duplicated and replaced by a cross reference to the SätL. This process will remove duplication of requirements and, to an extent, simplify the regulatory framework.

However, with these changes in place, the regulatory framework remains complex and does not facilitate regulatory compliance. STUK should give consideration to developing a process to clarify the regulatory requirements in the regulatory framework, with guidance on the required authorization processes for nuclear, radioactive, and NORM material.

During the transport inspection at DEKRA, observed by two members of the IRRS team, the licensee reported that one of their vehicles was stopped by the Police for an ADR roadside check. It is suggested that STUK considers seeking agreement with the Police that they inform STUK of the findings of roadside checks, as this would be a helpful indicator of the level of compliance, particularly as the inspection of the transport of Type A packages does not take place at this time. Recommendation R8 in Chapter 6.7. addresses this issue.

9.8. REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE

The regulations and guides to support the implementation of protection and safety measures for occupational exposures in planned, existing, emergency exposures have been addressed in STUK regulations and guides.

While the YEL refers to the SätL and regulations for the protection of workers in nuclear facilities, separate regulatory and internal guides have been prepared for such workers. The ARM has provided detailed information on the legislated requirements for occupational exposures which have been incorporated in STUK regulations and guides. These are set out under the YVL guides for protection and safety of workers in nuclear facilities and in SAMMIO for radiation source facilities and activities. The IRRS team was advised that the YVL guide (YVL C.2) includes both requirements and guidance for the monitoring of nuclear facility workers. This has the potential to confuse licensees. A suggestion regarding this has been made under Chapter 9.1. There are also internal guides for STUK to ensure consistent application of regulatory measures.

The legal framework has largely addressed requirements of the IAEA Safety Standards with some minor gaps which have been identified in the ARM. There are dose constraints for the protection of workers. However, investigation levels for the optimization of protection of workers and the public during normal working conditions or for authorised parties to conduct investigation when an operating parameter exceeds the investigation level, have not been provided under the regulation. The IAEA Safety Standards require that the regulatory body establish appropriate investigation levels for implementation by authorised parties under their safety procedures to ensure timely actions for the investigation and management of excursions of the investigation levels. This will further enhance optimisation of protection and safety to workers. The need for establishment of investigation levels have been raised in the ARM and confirmed during discussion with the IRRS team.

The IRRS team commends STUK on the number of guides to support consistent application of safety and protection measures for workers. However, it may be appropriate to undertake a gap analysis to verify the full adequacy of guidance of occupational exposures, specifically for nuclear facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: While there are provisions for dose constraints for the optimisation of protection for workers, there are no requirements to set investigation levels and to conduct investigation when a quantity or operating parameter related to protection and safety exceeds investigation levels.

(1)	BASIS: GSR Part 3 Requirement 16, states that <i>“Registrants and licensees shall conduct formal investigations of abnormal conditions arising in the operation of facilities or the conduct of activities, and shall disseminate information that is significant for protection and safety”.</i>
(2)	BASIS: GSR Part 3 Requirement 16, para. 3.46. (a) <i>“Registrants and licensees shall conduct an investigation as specified by the regulatory body in the event that: (a) A quantity or operating parameter relating to protection and safety exceeds an investigation level or is outside the stipulated range of operating conditions;...”</i>
R13	Recommendation: STUK should establish requirements for investigation levels and for investigations to be conducted if investigation levels are exceeded.

9.9. REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE

STUK has developed regulations and guides particularly on the justification and optimisation of medical exposure.

National referral guidelines

Although provided for in the current legislation, there are no national referral guidelines for the justification of the medical exposure of individual patients. MSAH has initiated a preliminary evaluation in 2020 to determine the situation in Finland and to develop a possible way forward. The results of surveys sent to physicians and dentists indicate that Finland needs a referral guideline that should be integrated in health care IT systems and electronic referral systems and should also provide support for decision-making.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: There are no national referral guidelines for the justification of the medical exposure of individual patients. This has been recognized in the ARM and is part of the action plan.

(1)	BASIS: GSR Part 3, Requirement 37, 3- 158 states that <i>“Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure”.</i>
R14	Recommendation: The Ministry of Social Affairs and Health (MSAH) and medical societies, should establish relevant national referral guidelines for the justification of the medical exposure of individual patients.

Justification of the radiological procedure on an asymptomatic individual

Justification of the radiological procedure on an asymptomatic individual is subject to the preparation of special written grounds concerning the individual in question. The preparation of the grounds must comply with special criteria. Based on the requirement in SätL, the Council for Choices in Health Care in Finland, working in conjunction with the MSAH, has started to prepare criteria for the justification of imaging on an asymptomatic individual. Four criteria have been issued between 2021-2022. However, there is no assurance of funding to fulfil this requirement in future. The IRRS team encourages the MSAH to secure appropriate resources enabling the Council for Choices in Health Care to continue to publish criteria for the justification of the radiological procedure of asymptomatic persons.

9.10. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE

Regulatory requirements for limiting and assessing public exposure include the establishment of basic radiation protection principles, provisions for the control of radioactive releases to the environment, criteria for authorizing the use of commodities and products containing radioactive material and for the use of consumer products, the establishment of clearance levels and the establishment of reference levels for the protection of the public in existing exposure situations. Requirements for limiting external exposure and contamination in areas accessible to members of the public and for limiting the exposure of visitors to controlled and supervised areas are also in place.

In regards of remedial actions associated with the protection of the public in existing exposure scenarios, STUK has recognised in its ARM that persons or organizations responsible for implementing these actions are not required to maintain records of the remedial actions taken. An action related to this issue has been included in STUK's action plan.

9.11. SUMMARY

The Finnish legal and regulatory framework for nuclear and radiation safety consist of Acts, Decrees, STUK Regulations and guides. Regulations needed for the use of nuclear energy and radiation safety are in place. STUK has developed and published a web-based tool, SAMMIO which provides licensees and the general public with information about the legal requirements under the SätL. The IRRS team identified this as a good practice. STUK prepared guides which are not legally binding.

The IRRS team identified a number of gaps and further improvements in STUK Regulations and Guides.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

10.1. AUTHORITY AND RESPONSIBILITIES FOR REGULATING ON-SITE EPR OF OPERATING ORGANIZATIONS

Responsibility for on-site emergency arrangements

The YEL lays out basic requirements for the emergency arrangements of operating organizations of nuclear facilities and obliges the operator to carry out those emergency arrangements.

The SätL requires the operator of any practice subject to a license to prepare for radiation safety emergencies. As part of the licensing process the operator shall carry out a safety assessment that among other things presents measures to prevent and prepare for identified radiation safety emergencies. This chapter of the IRRS report only refers to radiation safety deviations that may lead to emergency situations.

Authorities and responsibilities for regulating the on-site emergency arrangements of operating organizations

According to the YEL, STUK has the authority to regulate the Emergency Preparedness and Response (EPR) arrangements of operating organizations of nuclear facilities and shall issue regulations on the planning and the arrangements for preparedness and response to emergency situations.

According to the SätL, STUK shall issue detailed regulations on the content and preparation of the safety assessment for practices subject to a safety licence. This includes the identification of possible radiation safety emergencies and mitigating measures. STUK issues regulations on the required plan for radiation safety deviations.

Coordination of organizations with responsibilities in regulating EPR of operating organizations

STUK has the sole responsibility for regulating on-site EPR of operating organizations. However, in the licensing phase and during periodic safety reviews of nuclear facilities, STUK must seek the opinion of the Ministry of Interior (MI) on the operator's emergency plans.

10.2. REGULATIONS AND GUIDES ON ON-SITE EPR OF OPERATING ORGANIZATIONS

Requirements for operator's on-site emergency arrangements and emergency planning for nuclear facilities and transports of nuclear materials

The YEL requires on-site emergency arrangements to be based on the outcome of a hazard and consequence assessment. Further requirements are specified in STUK regulations and guides for operating nuclear power plants. However, these STUK regulations and guides also apply to other nuclear facilities or transport activities as appropriate according to individual hazard assessments. Further specifications for transport of nuclear materials are given in the guide YVL D.2.

According to STUK regulations and guides, the operator's emergency arrangements shall ensure that emergency situations are quickly brought under control, the safety of the individuals in the site area is assured, and timely action is taken to prevent or limit radiation exposure to the public in the emergency planning zone. In order to achieve this, the operator shall establish and maintain an emergency response organisation, an emergency response centre and a redundant emergency centre located off site. The infrastructure for communication shall include automatic data transmission systems.

The operator is obliged to prepare an emergency plan describing all technical and organizational arrangements, procedures, roles and responsibilities within the emergency response organisation.

The operator's emergency plan shall be coordinated with the emergency plans of authorities that may be involved in the on-site or off-site emergency response.

The guide YVL D.2 further specifies the requirements for emergency plans for transport of nuclear materials in addition to the applicable requirements formulated in ADR and RID.

Emergency arrangements and emergency planning for practices licensed under the Radiation Act

The SätL requires an action plan for possible safety deviations for any practice subject to a license. This action plan shall be based on a safety assessment including the identification of possible radiation safety emergencies and preparedness for such emergencies. These basic requirements are further specified in STUK regulations. The action plan shall include operating instructions for immediate actions to be taken in order to limit radiation exposure in the event of a radiation safety deviation and actions needed to return the practice to a safe status. The scope of these instructions depends on the radiation exposure category as well as on the specific type of the activity. There are some requirements specific to medical exposure and high-activity sealed sources, but there are no requirements specific to transport activities other than those given in ADR and RID. There are also requirements for reporting radiation safety emergencies as well as identifying the cause and possible lessons learnt.

The safety assessments have to be performed as part of the licensing process and shall be repeated on a regular basis (depending on the radiation exposure category) and in case of changes to the practice or after a safety deviation has occurred.

Protection of emergency workers responding on the site

Any person acting on the site of a nuclear facility or other radiation activities during an emergency is classified as emergency worker or emergency helper according to the SätL. Therefore, the general regulations of the SätL and the Government Decree on Ionizing Radiation apply. Any personnel foreseen to act as emergency worker shall be nominated in advance. The exposure of emergency workers and helpers must be kept lower than the dose limits for occupational exposure in planned exposure situation to the extent possible. If this is not possible reference values of 100 mSv/a or in case of life-saving actions 500 mSv/a apply. In line with the European Council Directive 2013/59/Euratom the participation in emergency response actions shall be voluntarily when a doses of more than 100 mSv/a could be received. It is noted that according to GSR-7 para. 5.57 this threshold should be 50 mSv/a.

With respect to nuclear facilities STUK regulations and guides stipulate various requirements with respect to the operator's preparedness to protect any personnel acting on the site during emergency situations. During an emergency the emergency manager of the nuclear facility is responsible for the protection of the personnel at the site.

The safety assessment of practices licensed under the SätL must include an analysis of potential exposures of workers in case of safety deviations and operational arrangements by which radiation exposure is limited.

Training and exercises

For nuclear facilities, regulations and guides require the operator to arrange emergency training for all personnel and other permanent or temporary employees working on-site. The training shall address alarms, emergency procedures, places of assembly at the site area and exit from the site area as well as an overview of the operator's emergency response organisation and its tasks and operation during emergency situations. Personnel that is part of the emergency response organisation shall receive task related training prior to appointment to the task and shall further be provided with annual refresher training and advanced training. This training shall be based on a minimum three-year training plan to ensure that training is given on all aspects of preparedness to act at regular intervals. The training plan together with a report on its implementation shall be reported annually to STUK. The operator shall also provide training possibilities for personnel of organisations that might have to participate in rescue operations on site during in an emergency.

STUK regulations and guides require operators of nuclear facilities to arrange emergency exercises on an annual basis. The annual emergency exercises shall cover significant parts of the activities foreseen in the emergency plan and the licensee shall ensure that all sectors of the emergency plan are exercised over longer time spans. Exercises shall account for simultaneous emergency situations of several nuclear facilities located at the same site as well as threats due to unlawful actions. Exercises shall be based on an exercise plan prepared in advance. Assessment reports shall indicate any deficiencies or areas of improvement identified during the exercise as well as actions to address these. The requirements for exercising transport activities licenced under the YEL are specified in STUK guide YVL D.2. The Rescue Act and the Decree on External Rescue Plans of the Ministry of Interior require joint emergency exercises to be arranged in co-operation with the authorities responsible for the off-site response and for supporting the operator's on-site response at least once every three years. Before commissioning of a new plant unit or new transport activities an exercise must be held.

The plan for radiation safety emergencies in practices licensed under the SätL shall include provisions for training and exercises. However, there is currently no requirement for the operator to conduct exercises on a regular basis and according to the hazard. STUK is proposing an amendment of the SätL that will include this obligation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no requirements for radiation facilities and activities to conduct emergency exercises on a regular basis.	
(1)	BASIS: GSR Part 1 Requirement 8 states that <i>“The government shall make provision for emergency preparedness to enable a timely and effective response in a nuclear or radiological emergency.”</i> Para. 2.24A states that <i>“The government shall ensure that adequate training, drills and exercises, involving authorized parties and response organizations, including decision makers, are carried out regularly to contribute to an effective emergency response [...]”.</i>
(2)	BASIS: GSR Part 7 para. 6.30. states that <i>“Exercise programmes shall be developed and implemented to ensure that all specified functions required to be performed for emergency response, all organizational interfaces for facilities in category I, II or III, and the national level programmes for category IV or V are tested at suitable intervals [...]”.</i>
S13	Suggestion: STUK should consider expanding and harmonizing emergency exercise requirements beyond nuclear facilities, to cover other regulated facilities and activities, including transport, using a graded approach.

10.3. VERIFYING THE ADEQUACY OF ON-SITE EPR OF OPERATING ORGANIZATIONS

The YEA requires operating organizations to submit their emergency plans to STUK for approval when applying for either a construction, operating or decommissioning license. The operator’s emergency plan must address adequately the criteria defined in the applicable STUK regulations and guides. These criteria include the emergency response organization as well as its tasks and responsibilities, the measures and activities foreseen during an emergency as well as relevant facilities, equipment and devices. It must also contain a report on how emergency preparedness is maintained. According to the YEL the operation, decommissioning or any other use of a nuclear facility under a license shall not be started until STUK has ascertained that the emergency arrangements are sufficient.

During normal operation STUK performs inspections of the on-site EPR arrangements of nuclear facilities as part of the KTO inspection programme once every year. The depth of inspection can vary depending on the facilities hazard potential and experience from past. If needed there STUK will conduct additional inspections. STUK’s procedures for the supervision and inspection of the emergency arrangements as well as internal responsibilities are described in the Guide YTV 3.c.6. In addition to the formal inspections, STUK collects and verifies information through visits, meetings and informal discussions with operating organizations. STUK reviews the operator’s emergency training plans and their implementation, including the task-specific training provided to the emergency response organization as well as the training provided to other personnel, emergency workers and helpers. STUK takes part in training events on a selective basis.

According to the SätL, STUK shall verify the safety assessment conducted by operating organizations of practices subject to a license either as part of granting the license or separately. This verification includes the preparedness for radiation safety deviations. STUK also verifies these arrangements within regular inspections taking place at varying frequencies. Most inspections, however, are conducted as topical inspections, which do not always include preparedness for radiation safety deviations. The principles and methods for these inspections are described in the Guide SKV 3.4.

STUK’s inspection programmes and supervisory activity is documented in protocols, assessment and inspection reports, decision letters as well as through entries in dedicated electronic databases.

Exercises

According to the Rescue Act, the regional state administrative agency is in charge of supervising emergency exercises jointly prepared and conducted by the rescue services and the operating organizations of nuclear facilities every three years. According to a STUK guide, STUK takes part in the planning and evaluation of these joint emergency exercises as well as in the operator's annual exercises.

STUK participates in exercises of nuclear power plants and their evaluation. This includes annual exercises as well as joint exercises organized under the lead of the regional state administrative agency every three years. So far, STUK does not take part in annual exercises of other nuclear facilities or other radiation practices.

10.4. ROLES OF THE RB IN A NUCLEAR OR RADIOLOGICAL EMERGENCY

STUK's role in an emergency

As laid out in the Rescue Act STUK's role in the early phase of an emergency is integrated in an all-hazard emergency management system under direction of the rescue services. STUK provides recommendations regarding adequate urgent protective measures that should be taken to protect the population off the site. Decision making and implementation of such measures lies within the responsibility of the rescue services. STUK also provides recommendations on other protective measures that lie within the responsibility of various authorities. In case of security events, STUK also liaises with the police. If needed, STUK can send contact persons to the command posts of the rescue services, the police or the operator.

STUK's technical and personnel resources

STUK maintains a well-equipped emergency centre within its premises. In the preparedness phase the emergency centre is run by a core team of four radiation protection and crisis response experts. In addition, there is a task force consisting of 14 experts from every department of STUK. In order to ensure 24/7 readiness, there is always one of 15 trained duty officers in charge. In case of full scale activation, the emergency centre would be operated by approximately 50 to 60 staff members at a time. In addition, there may be up to approximately 20 staff members outside of the emergency centre supporting STUK's and other authorities' response activities. There are typically between 3 to 5 people named and trained per role. Roles and procedures for notification, activation and operation are documented in internal procedures and handbooks.

During an emergency, STUK performs dispersion modelling in cooperation with the Meteorological Institute based on JRODOS and other in-house developed tools.

STUK uses the all-hazard electronic situation awareness system KRIVAT to provide its recommendations and advise to other authorities or to exchange other information. However, KRIVAT is not used by all authorities that may depend on data exchange with STUK in emergency.

Information of the public

According to STUK, the National Strategy for Crisis Communication foresees that every authority communicates to the public regarding its field of responsibility. According to STUK, there are no specific arrangements for coordinated crisis communication for nuclear and radiological emergencies.

International information exchange and coordination

STUK is responsible for the international information exchange via ECURIE, USIE and according to bilateral agreements with neighbouring and other countries. STUK is also a contact point within the IAEA's Response and Assistance Network (RANET). However, the responsible ministries decide on providing or accepting support through RANET.

Emergency Planning

STUK has carried out hazard assessments covering various emergency scenarios including security events. STUK has also issued the VAL guides that provide a basic protection strategy covering all emergency phases and all sectors that are likely to be affected by an emergency. The VAL guides, among other things, provide dose criteria and

operational intervention levels that can be used/applied as criteria for various sector-specific protective measures upon decision by the ministry responsible for the sector at hand.

STUK has internal procedures in place describing internal processes, responsibilities and tasks during a nuclear or radiological emergency.

In addition to participating in emergency exercises, STUK has established co-operation and coordination meetings with other relevant response organizations in order to facilitate a smooth cooperation in the urgent phase of any emergency.

Especially in the transition phase of a severe emergency causing long lasting and cross cutting consequences, the emergency response will involve multiple authorities from different sectors. There is no clearly assigned responsibility for a coordinated planning for this cross-cutting response nor there are sufficiently coordinated emergency plans that would support an efficient and timely cross-cutting emergency response. Also, there is no sufficient mechanism in place to coordinate this cross-cutting response in the later phases of an emergency when the rescue services are no longer in charge.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Emergency arrangements are not fully coordinated; they include neither mechanisms for the coordination of the overall emergency response beyond the early phases nor coordinated crisis communication.	
(1)	BASIS: GSR Part 1 Requirement 8 states that “The government shall make provision for emergency preparedness to enable a timely and effective response in a nuclear or radiological emergency.”
(2)	BASIS: GSR Part 7 Requirement 22 states that “ <i>The government shall ensure that arrangements are in place for the coordination of preparedness and response for a nuclear or radiological emergency between the operating organization and authorities at the local, regional and national levels, and, where appropriate, at the international level.</i> ”
(3)	BASIS: GSR Part 7 requirement 20 states that: “<i>The government shall ensure that authorities for preparedness and response for a nuclear or radiological emergency are clearly established.</i>” Para. 6.5: “<i>The emergency arrangements shall include clear assignment of responsibilities and authorities, and shall provide for coordination and for communication in all phases of the response. These arrangements shall include [...] clearly assigning the authority and responsibility for the direction and coordination of the entire response (see para. 5.7) and for the prevention and resolution of conflicts between response organizations [...]</i>” Para. 6.4. states that “<i>The authority and responsibility for making decisions on response actions to be taken on the site and off the site (see para. 5.7) and the authority and responsibility for communication with the public shall be clearly assigned for each phase of the response.</i>”
R15	Recommendation: The Government should strengthen coordinated emergency arrangements between all involved organizations. These arrangements should address mechanisms for coordination during the emergency (also beyond the early phase), including crisis communication.

Measurements and situation assessment

STUK is responsible for monitoring the radioactivity in the environment in normal operation and in emergency situations. For this purpose, STUK operates a network of almost 300 stationary probing stations distributed all over Finland to measure ambient dose rate. Some of the probes are spectroscopic. STUK has also access to the data of probes from domestic NPP operators as well as to some probes in the vicinity of the Russian NPP Leningrad. In addition, STUK has some mobile measurement equipment and field teams as well as laboratory capacities to measure activity levels. Further mobile measurements can be taken by the defence forces and the rescue services. The responsibilities for monitoring the radioactivity in forest products, milk, drinking water supplies, animal feed and commodities lie with different ministries.

In June 2022, the Ministry of Interior published a national strategy for measurements in nuclear or radiological emergencies. This strategy will be implemented through a national action plan that is currently pending approval by the Ministry. STUK has developed its own plan to implement the national strategy. However, until the action plan is approved, and appropriate resources are allocated by the Government, STUK and other involved authorities will not be able to implement it. STUK and other involved authorities will not have the capabilities and the capacities to answer to the demands of the society.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: STUK and other involved authorities are not in position to carry out their functions under the national measurement strategy for radiological emergencies pending the approval of the related national action plan and the allocation of the associated resources.

(1)

BASIS: GSR Part 1 (Rev. 1) Requirement 8 states that *“The government shall make provision for emergency preparedness to enable a timely and effective response in a nuclear or radiological emergency”*

para 2.24: *“In preparing an emergency plan and in the event of an emergency the regulatory body shall advise the government and response organizations, and shall provide expert services (e.g., services for radiation monitoring and risk assessment for actual and expected future radiation risks) in accordance with the responsibilities assigned to it”.*

(2)

BASIS: GSR Part 7 Requirement 14 states that *“The government shall ensure that arrangements are in place to take early protective actions and other response actions effectively in a nuclear or radiological emergency.*

Para. 5.76: *Within the extended planning distance [...] These arrangements shall include: [...] (b) Prompt monitoring and assessment; [...] (e) Provisions to extend monitoring and assessment and actions beyond the extended planning distance if necessary.*

Para. 5.77: *For areas within the ingestion and commodities planning distance [...], arrangements shall be made for prompt protection in relation to, and for restriction of, non-essential local produce, forest products (e.g., wild berries, wild mushrooms), milk from grazing animals, drinking water supplies, animal feed and commodities with contamination or possibly with contamination following a significant radioactive release, in accordance with the protection strategy [...]. These arrangements shall include: [...] (b) Prompt monitoring, sampling and analysis. [...] (e) Provisions to expand monitoring and assessment and actions beyond this distance if necessary.*

Para. 5.78: *Within the emergency planning zones and the inner cordoned off area, arrangements shall be made for monitoring the levels of contamination of people, vehicles and goods moving out of areas with contamination, in order to control the spread of contamination and, as applicable, for the purposes of decontamination in accordance with the protection strategy [...].”.*

R16

Recommendation: The Government should take steps to implement the national measurement strategy for nuclear or radiological emergencies to ensure the prompt and coordinated monitoring, sampling, and analysis by all responsible organisations in all relevant sectors.

10.5. SUMMARY

STUK has established mature arrangements for regulating the on-site arrangements for preparedness and response of operators of nuclear facilities and other radiation activities. A graded approach in the regulation is implemented by means of the different licensing regimes under the YEL and the SätL, but also within these regimes through graded requirements according to the hazard potential of a facility or activities. This, however, is not well documented in the existing guidance for all facilities and activities.

STUK plays a key role in the off-site emergency management system. And while STUK's emergency centre has effective technical and organizational arrangements to facilitate its key functions, there seems to be a lack of national preparedness for a cross-cutting emergency response involving various authorities from different sectors. Neither are there sufficient national mechanisms for coordinating this response after the urgent phase of an emergency and for coordinating the crisis coordination of the responsible authorities. Steps should be taken to ensure that all authorities in charge have the resources and capabilities to fulfil their tasks according to the National Measurements Strategy for Radiological Emergencies. Also, STUK should consider broadening its exercise activities beyond NPP related scenarios according to a graded approach.

11. INTERFACE WITH NUCLEAR SECURITY

11.1. LEGAL BASIS

Finland has a comprehensive legislation that covers radiation and nuclear safety, nuclear security, safeguards and interfaces between them. STUK as a "3S or one house authority" supervises the operator of any facility or activity using radiation source who must comply with the Legislation that the operator of any facility or activity using radiation source must comply with. Legislation is revised on a regular basis to incorporate the changes in the operating environment.

Security arrangements are coordinated together with nuclear safety, emergency arrangements and safeguards. The Legislation requires that the safety-security interface be considered during the design, construction, operation and decommissioning of the nuclear facilities as the legislation stipulates

Finland has hosted several IPPAS mission. The last one was conducted in June 2022.

11.2. REGULATORY OVERSIGHT ACTIVITIES

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. The oversight function also includes a comprehensive inspection programme applicable to the construction phase, preparation for operations and the operations phase.

STUK' field inspections to nuclear and radiation facilities and activities may include elements to assess the interfaces security and safety.

Resident inspectors who work at the nuclear power plant site are an important channel for gathering information about daily activities which may impact security and safety interface. To that effect, the resident inspectors are also trained for nuclear security-related topics with access to some restricted information, further improving the safety-security interface

STUK supervises compliance with SätL including security requirements for licensing process, oversight, and enforcement. According to SätL security arrangements must be adequate in terms of risk related to the practice and the radiation sources and they must be compatible with measures concerning radiation safety. STUK has published the Regulation STUK S/9/2021 concerning security of radiation sources. Accordingly, STUK supervises the use of nuclear energy in compliance with YEL and the Regulation STUK Y/3/2020 covers the security in the use of nuclear energy.

11.3. INTERFACE AMONG AUTHORITIES

STUK's Advisory Committee on nuclear security was established in March 2008. The Advisory Committee supports STUK to develop its functions as a regulatory, and expert organization. The Advisory Committee can make assessments of the STUK's actions and give recommendations to STUK. The Advisory Committee is nominated by Government.

STUK is responsible for overseeing nuclear security and safety. Other different authorities provide assistance to the regulatory body. Some of these responsibilities are stipulated in the legislation.

11.4. SUMMARY

STUK has made significant efforts to ensure that safety, security, and safeguards arrangements are harmonized.

The nuclear regime assesses the interfaces of safety, security, and safeguards to ensure that potential conflicts are precluded. Training of safety staff and safeguards inspectors on nuclear security carried out at same that joint inspections are conducted.

ANNEX 1 – POLICY DISCUSSIONSⁱ

Institutional Strength in Depth (role of stakeholders challenging the accountability of regulators and licensees).

INSAG emphasizes that the primary responsibility for safety lies with the operating organization, the primary responsibility for independent safety oversight lies with the regulator, and that the primary stakeholders for safety are those who may be directly affected by nuclear facilities, both during normal operation and accidents are workers and the general public. INSAG-27 defines these three pillars as sub-systems of the national nuclear safety systems and states that the national system relies on the interaction among them, and most specially the interaction with the public which stimulates a sense of responsibility and accountability, and helps to ensure high levels of attention to nuclear safety in both the operational and regulatory organizations.

In Finland, there is a general perception that they have a strong industry and regulator. There is a high level of trust in government institutions including in STUK as a regulatory body. The interest in nuclear safety or regulatory issues is limited among stakeholders. STUK is seeking to have a more engaged public to improve the level of accountability. The question in Finland is how to strengthen the third sub-system. For instance, how to encourage stakeholders to be actively engaged and challenging both the regulator and the industry. STUK is keen to understand what are the practical and effective means to demonstrate accountability to the stakeholders?

In France, trust in institutions is not as strong as in Finland. ASN has a programme for public outreach and communicates information on radiation risks to the members of public. This programme is effective on waste management as the policy is revised every five years. In the frame of the fourth periodic safety review, several steps were taken to involve the public. These steps aimed to inform the public, facilitate understanding of the safety issues, explain the ASN requirements and find out the expectations, queries, questions of the public. Besides, every year, ASN must report to Parliament in a public hearing. Routine surveys are done about safety. Furthermore, one issue is to ensure that people know what to do in case of nuclear emergency. Additional work has been done through an external group to help the members of public understand and prepare for emergencies. These groups include NGO which increases the credibility with the members of public, who usually mistrust the public institutions. Now a national day (risk day) is defined to explain risks from all type of hazards to the public are being organized and ASN is also involved.

In the US, there is also a lack of trust in public institutions. Engagement is conducted at the local level with representatives from the regulator to gain trust from the public. The meetings are on specific topics. It is important to listen first (people don't want to be talked to) and address their concerns. In the last few years, the NRC has consistently increased the use of social media. In terms of accountability, the regulator takes public comments on regulations and accepts anonymous public complaints. Public hearings are held in front of the Commission. Public briefings to Congress are conducted which include public questions from Congressional representatives. Comments from NGOs and other stakeholders need to be addressed. Feedback from the public is received through public meetings across the country. In the vicinity of the NPP, there is an annual meeting to discuss the facility performance with the public. In the area of decommissioning, citizens advisory boards which provide an opportunity for public engagement are conducted for most licensees but these forums are not required. For development of technology neutral regulation, the NRC got more public engagement by requesting information on partial contents of the regulation. This has made stakeholders feel more part of the process.

In Spain, the CSN hires expert companies to help them to gauge public trust and increase their level of engagement through surveys, the last of which was 2 years ago. There is a lack of knowledge of the activities of the regulator. For radiation facilities CSN created a working group which included professional associations with specific expertise and covering the whole country. A lot of work to involve those stakeholders has been done during the EU directive transpositions. CSN increased communications with the media through seminars. CSN presents an annual report to explain the regulator's activities in a public setting. Parliament can invite other people. These appearances have more media coverage.

In Australia, the former head of ARPANSA requested that all inspection reports be made public allowing for them to be scrutinized. In one instance, an inspection report led to substantial stakeholder interest, and consequently, the

ⁱ Disclaimer: the text reflects the opinion of the reviewers and not necessarily the position of their countries' Government.

operator received more resources. Despite this, publishing inspection reports has been an overwhelmingly positive experience. On another subject, ARPANSA has been proactive in preparing to receive an application for a national repository. This has included visiting the area to be more visible as an independent regulatory body. In Queensland, major policies and legislation are scrutinized by the parliament, this includes consultation with stakeholder groups and members of public. Efforts are made to simplify complex terminology to assist the understanding of the members of the public. The objective is to build community confidence and trust through open and transparent discussions. Community representatives are also included in high level committees to represent the interest of the general public.

It was stated that it is positive that while STUK has public trust they still remain vigilant about the challenges related to stakeholders involvement. This attitude shows commitment to improvement. A recently published IAEA safety guide on communication with interested parties was mentioned. A few key attitude attributes were highlighted: adjust your communication to the needs and wishes of your audience, listen before educating, accepting and explaining when information might be missing for decision making to demonstrate independence from operators and from the government.

STUK: used to reach out regularly to local communities. These meetings did not gain public interest and were not useful in providing information or place for discussion among public. Pyhäjoki municipality at the onset of the Fennovoima project had many members of the public participating in public meetings at the beginning, but engagement dropped very rapidly. Need new ways to engage the stakeholders. One possibility could be to involve NGOs and groups of interest. Proactive engagement with parliament and politicians has been initiated. STUK is committed to be transparent and is openly providing information, but more could be done in proactive manner.

In Canada the CNSC has set public trust as one of the key priorities. Furthermore, engagement with Indigenous communities is an important element of the public trust strategy. CNSC maintains an extensive public information programme which involves CNSC staff participation in outreach activities in host communities. There is also an expectation that the larger licensees implement their own public outreach programme. Public Hearings of the Commission for licensing decisions include provisions for public input and interventions. Public interventions (oral or written) typically include challenging positions from NGOs and individual members of the public. The Commission requires that staff address challenges made by intervenors which increases the sense of responsibility and accountability of staff and the Commission.

After the debate session, the expert from Sweden added that in Sweden the trust in public institutions has decreased over the years. However, in connection with some events and e.g., the regulators handling of the Ukraine/Zaporizhzhia there seems to be trust in place. Generally, the public does not know what is the mission of SSM. SSM lately focus more on the use of social media, enhancing media communication, and taking part in events where the regulator can inform about its mission and its activities. The public can attend the local safety committee meetings for information in the NPP regions.

Regulatory Readiness for SMR Licensing and Deployment

Interest for deploying SMRs has been increasing during the recent years everywhere in the world. In Finland, there is interest especially for district heating and combined heat and power (electricity) applications to replace fossil fuels. STUK is building its competence on SMRs and updating its regulations and regulatory guides to be prepared for potential SMR license applications.

STUK made a brief presentation of the main challenges identified by STUK and what questions they would like to address on SMRs during the debate. Namely,

- What are major challenges (either in the licensing process or in safety) in licensing SMRs compared to traditional reactors or what other new aspects may exist in licensing SMRs?
- What kind of licensing process would ensure timely regulatory intervention and at the same time enable feasible licensing from the point of view of the license applicant? Should the licensing process include a pre-review step, and what kind of pre-review process would be optimal?
- What would be a recommended approach for regulatory body's competence building for SMRs?
- What would be a good way to define the EPZ size?

In Pakistan they are thinking of a licensing process for SMR. As a first step they need to develop technology neutral requirements to account for special features of these novel designs, such as passive systems. Internal WGs determined that the present set of regulations are OK. On competencies, they plan to increase competencies through their regular training programme but for now they only have training courses on water cooled reactors. Have not worked on other trainings because the country has not yet decided what design they will adopt. They are thinking on improving legislation to make it goal oriented. The revision of regulation process usually takes 2-3 years but they are still assessing what to change and how.

Argentina is building an SMR now. The builder of the SMR is their own national R&D organization. Competence building by the regulator has been done through work on the regulatory assessment and interaction with the designer. For the licensing process, they are applying the existing process which uses a performance-based approach. May be in the future they will need to develop requirements and processes for special cases. Siting of the SMR was not problematic as it is on a nuclear site, which features 2 NPP already. The process used was the process used for class I facility, but some flexibility has been introduced considering that the reactor is a prototype. The licensing chronogram is also flexible to accommodate for the R&D needs of the prototype.

In US, competence building in the US is being developed with a flexible approach. Competence building was not in general challenging, and there is a quite a bit of interaction with all designers to help build capacity. The US has found early interactions with applicants to be especially important for new designers that may not be familiar with the regulatory process. These interactions have also been important to build the competencies of the regulatory staff, and may result in the identification of issues that may require additional research. The USNRC is currently developing a technology neutral risk informed framework to be ready by 2027. This new framework relies heavily on PRA; some stakeholders have indicated their preference for more deterministic requirements. Guidance is similarly being updated to be more risk-informed and performance based. With regard to EPZs, the USNRC has developed a new regulation that is in final stages of approval and would apply a graded approach to allow a reduced size EPZ. Additionally, topical reports may be used to seek approval of different methodologies and more risk informed approaches to support alternate EPZs on a design-specific basis.

In Canada, the CNSC implemented an optional Vendor Design Review process (VDR) that attracted the attention of multiple design vendors at different level of design maturity. The process proved to be useful for the CNSC as it helped staff to familiarize with the various technologies. It is clear from this process that the water-cooled reactor technologies are in a better state of readiness. The other technologies are not at the same level of readiness. In addition, the water-cooled designs are often presented by very well-known designers. For other technologies, such as molten salt designs, it is a challenge for the regulator to get the adequate expertise. The best training providers for competency building may be the designers. Cooperation among regulators familiar with the same technology may be another option. On EPZ, the 2 currently proposed SMRs are sited on nuclear sites which is expected to facilitate concerns related to the EPZ. It is expected that the EPZ for the SMRs may be greatly reduced. For SMR, especially located in remote locations, the security provisions may be a significant challenge. Another challenge is the application of DID principle and the application of graded approach. The CNSC has benefitted from the Government support for innovation initiative which gave an opportunity to increase funding and resources, but it has been difficult to find qualified candidates. Circa 2008-2012 the CNSC started working on technology neutral requirements in preparation to the nuclear renaissance (a departure from existing requirements which were CANDU focused). In Canada, each province has their own energy policy, however, collaboration between provinces is expected to reduce the initial cost given the increased number of provinces interested in SMRs. In addition, Canadian utilities are collaborating with US utilities as well.

In France, competence building was based on technologies and national experts experience. There are new challenges such as remote operation and security aspects. It was emphasized that SMR deployment in embarking countries means mobilisation during more than one century to deal with decommissioning and waste. In the frame of the EU pre-partnership, a report is in progress to document the needs to launch new R&D project on these needs.

SMR are very attractive to newcomers. They are more affordable and have a shorter timetable. That presents a challenge as many of those countries do not have a competent regulator to make independent informed regulatory decisions. The needs of waste management and decommissioning needs to be emphasized from the beginning and before the political decision is made.

One of the Australian representatives stressed the importance of encouraging the collaborative approach to safety; whether this be bilateral, Nordic, European, International, or among countries considering similar technologies, it doesn't need to be done in isolation, common safety standards should be used.

For SMR in Finland, deployment by a known operators will be much easier than considering deployment by a new player. Existing operators have developed the necessary provisions for the management of waste, which will be a challenge for new players.

Brazil has started looking into the safety and licensing of SMRs and is participating in international regulators' working groups. SMR are considered for remote areas that are disconnected from the national electricity grid. Especially in the Amazon region, they might provide a sustainable development solution that will help decarbonization and help reduce dependency of the local economy on primary products by providing more affordable sustainable energy sources that would permit the implementation of technological value chains in the region. In order to avoid deforestation, SMRs will need to be deployable through rivers or air, not roads or railways, and preferably be operated remotely. SMRs can also be considered for water desalinization in the semi-arid north-eastern interior of the country.

The IAEA activities on SMRs regulation are varied. Notably, the role of the SMR Regulators' Forum was highlighted as a regulator-to-regulator group of experienced regulators working on the challenges of regulating SMRs. The Forum documents the common positions of its members on various technical and regulatory matters selected by the members. The common position documents are displayed on the Forum website (Small Modular Reactor (SMR) Regulators' Forum | IAEA) hosted by the IAEA.

The IAEA has recently published TECDOC-2003 "Lessons Learned in Regulating Small Modular Reactors, Challenges, Resolutions and Insights" that documents the responses from 10 member state's regulators to a questionnaire on main challenges they have experienced in regulating or preparing for the regulation of SMRs and how they resolved them.

The IAEA also highlighted the Nuclear Harmonization and Standardization Initiative (NHSI) recently launched by the Director General. It is expected that this initiative will enhance harmonization of regulatory activities and the standardization of industrial approaches to facilitate the safe and secure deployment of SMRs as a way to contribute to reach net zero carbon emissions by 2050. The activities of the working groups created to support the objectives of this initiative have already begun their tasks.

After the debate session, the expert from Sweden added that there are a lot of discussions about SMRs. One of the large owners have expressed a sincere interest in SMRs at a current NPP site and have started a project to investigate further. SSM would have to do a lot of work to get prepared for SMRs and have to build capacity in many areas.

APPENDIX I – LIST OF PARTICIPANTS

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GROUP PHOTO



APPENDIX II – MISSION PROGRAMME

Initial Mission First Week

Time	SAT 01 Oct	SUN 02 Oct	MON 03 Oct	TUE 04 Oct	WED 05 Oct		THU 06 Oct		FRI 07 Oct	SAT 08 Oct	SUN 09 Oct	
8:00 – 9:00				Team meeting Discussion w/Counterpart	Team meeting Discussion w/Counterpart		Team meeting Discussion w/Counterpart		Team meeting Discussion w/Counterpart	Team meeting Discussion w/Counterpart		
9:00-12:00	Arrival of Team Members		Entrance Meeting	Interviews and Visits	Interviews	TL, Meets DGs	Interviews and Visits	DTC writes introductory parts	TM write Report TL and DTL review introductory part Draft text to TL	- Discussing and improving Draft Report - Cross-Reading - TL, DTL, TC and DTC read everything	Free day, Social Tour	
12:00-13:00			Lunch with Host	Standing lunch								
13:00-14:00				Interviews and Visits	Interviews	Follow-up Interviews	DTC writes introductory parts	Policy Discussions		Finalisation of the Draft Report	Reading, cross-reading of the draft report if needed	
14:00-15:00		Interviews (individual or in groups)	Secretariat edits the report Preliminary Draft Report Ready					Cross-reading by TM				
15:00-16:00					IRRS Initial Team Meeting - Welcome 5 minutes/TM self-intro - Refresher training - Meet host liaison officer - Mission logistics - Discussion of first impressions Closing	Written preliminary findings delivered						
16:00-17:00		Daily Team Meeting	Daily Team Meeting			Daily Team Meeting: Discussion of findings		Daily Team Meeting				
17:00-18:00			Daily Team Meeting		Daily Team Meeting		Daily Team Meeting					
18:00-20:00		Team Dinner	Dinner	Dinner	Dinner	Dinner	Dinner	Dinner	Dinner			
20:00-24:00			Writing of the report	Writing of the report	Daily Team Meeting: Discussion of findings	Writing of the report		TM Read Draft		Secretariat edits the report		

Initial Mission Second Week



	MON 10 Oct	TUE 11 Oct	WED 12 Oct	THU 13 Oct	FRI 14 Oct
8:00 – 9:00	Team meeting Discussion w/Counterpart	Team meeting Discussion w/Counterpart	Team meeting Discussion w/Counterpart	Team meeting Discussion w/Counterpart	Submission of the Preliminary Report
9:00-10:00	Discussion of Recommendations, Suggestions and Good Practises with counterparts by module	Cross-Reading of the Report TL, DTL, TC and DTC read everything Finalisation	Common read through and finalisation of the Report by the Team	Host reads Draft Report	Exit Meeting Press Conference Publication of Press Release
10:00-12:00			Submission of the Draft to the Host	Team discusses the Mission and provides IAEA with feedback	
12:00-13:00	Standing lunch	Standing lunch	Lunch	Standing Lunch	Lunch
13:00-15:00	Individual discussions of Recommendations, Suggestions and Good Practises with counterparts	Discussion of the Report by the Team	Host reads Draft Report	Written comments provided by the Host	Departure of the IRRS Team
15:00-17:00				Team meeting to discuss and resolve Host comments	
17:00-18:00	Daily Team Meeting		TL finalises Executive Summary and Exit Presentation	Plenary (Team + Host) to discuss Host comments and finalize the report	
18:00-20:00	Dinner	Dinner	TC Drafts the Press Release	Briefing of the Senior IAEA Manager. Finalisation of the press release and of the Preliminary Report	
20:00-21:00	Secretariat updates Report	Secretariat finalises Report	Discussion of Executive Summary and delivery to the Host	Farewell Dinner	
21:00-24:00				Free	

APPENDIX III – SITE VISITS

DEKRA (industrial radiography)

Helsinki University Hospital (radioisotope unit, comprehensive cancer centre)

Loviisa Nuclear Power Plant.

APPENDIX IV – LIST OF COUNTERPARTS

	IRRS EXPERTS	Lead Counterpart	Support Staff
1.	LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES		
	VILLANUEVA DELGADO Isabel	TIIPPANA Petteri	MARKKANEN Mika, HEINONEN Jussi
2.	GLOBAL NUCLEAR SAFETY REGIME		
	VILLANUEVA DELGADO Isabel	MARTIKKA Elina	LÅNG Ossi, TIIPPANA Petteri, KAIJANEN Mika, TOIVONEN Tommi, ANDERSEN Milka
3.	RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY		
	KOCK Andrea	HEINONEN Jussi	PASTILA Riikka, TOIVONEN Tommi, SIISKONEN Teemu, TIIPPANA Petteri, MERIKARI Mikko
4.	MANAGEMENT SYSTEM OF THE REGULATORY BODY		
	JUHASZ Laszlo	VASTAMÄKI Pirjo	KOSKINEN Kaisa, MERIKARI Mikko VAARAMAA Kaisa, ANDERSEN Milka, RIIPINEN Pilvikki, VENELAMPI Eija, HEINONEN Jussi, KIVIOJA Markku
	SOARE Gabriel		
5.	AUTHORIZATION		
	VIKTOROV Alexandre FIGUEIRA DA SILVA Eduardo McCORMICK Andrew KAWA Szymon MEDICI Marcela TAPPERT John WHITTINGHAM Stephen RAMASAMY Uma GODET Jean-Luc TOMAS ZERQUERA Juan SOARE Gabriel	NEVALAINEN Janne AALLOS-STÅHL Siiri-Maria	MONONEN Niko, KOSKINIEMI Tomi, CEDERBERG Mark. OEDEWALD Pia, VIROLAINEN Tapani, AURELA Jorma MARKKANEN Mika, TENKANEN- RAUTAKOSKI Petra , KUHMENEN Venla, TAKKINEN Antti, KAIJALUOTO Sampsa, LEHTINEN Maaret, KURTTIO Päivi, HENTTINEN Jukka, KALLIO Antti, KOJO Katja, BLY Ritva, LIUKKONEN Jukka, MATTILA Aleks, TURTIAINEN Tuukka, RENVALL Tommi

	IRRS EXPERTS	Lead Counterpart	Support Staff
6.	REVIEW AND ASSESSMENT		
	AXELSSON Lars FIGUEIRA DA SILVA Eduardo McCORMICK Andrew KAWA Szymon MEDICI Marcela TAPPERT John WHITTINGHAM Stephen RAMASAMY Uma GODET Jean-Luc TOMAS ZERQUERA Juan SOARE Gabriel	TUOMAINEN Minna AALLOS-STÅHL Siiri-Maria	MÄENALANEN Päivi, KOSKINIEMI Tomi, TENKANEN-RAUTAKOSKI Petra, MARKKANEN Mika, KUHMENEN Venla, TAKKINEN Antti, KAIJALUOTO Sampsa, LEHTINEN Maaret, KURTTIO Päivi, HENTTINEN Jukka, KALLIO Antti, KOJO Katja, BLY Ritva, LIUKKONEN Jukka, MATTILA Aleks, KYLLÖNEN Jarkko, TYNKKYNNEN Antti, TURTIAINEN Tuukka, RENVALL Tommi
7.	INSPECTION		
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8.	ENFORCEMENT		
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	IRRS EXPERTS	Lead Counterpart	Support Staff
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9.	REGULATIONS AND GUIDES		
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10.	EMERGENCY PREPAREDNESS AND RESPONSE		
	SCHLUMMER Tobias	PELTONEN Karim	HEINONEN Jyrki, SOVIJÄRVI Jukka/RENVALL Tommi, KUPILA Jukka/KUUSI Antero
11.	INTERFACE WITH NUCLEAR SECURITY		
	VILLANUEVA DELGADO Isabel	OLANDER Ronnie	SIRU Tuomas, KARHU Paula
	SOARE Gabriel		

APPENDIX V – RECOMMENDATIONS (R), SUGGESTIONS (S) AND GOOD PRACTICES (GP)

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES	R1	Recommendation: The Government should incorporate a licensing phase for release of nuclear facilities from regulatory control upon completion of decommissioning.
	S1	Suggestion: The Government should consider incorporation of the stage of site evaluation, in the Finnish legislation for nuclear facilities.
	R2	Recommendation: The Government should expand the legislative framework to encompass adequate provisions for closure of radioactive waste repositories.
	R3	Recommendation: The Government should evaluate competencies and infrastructure needs on radiation protection and make provisions to cover current and future demands.
	R4	Recommendation: The Government should make the necessary arrangements to ensure the professional training of a sufficient number of qualified and experienced RPEs.
2. THE GLOBAL SAFETY REGIME	S2	Suggestion: STUK should consider establishing a systematic process to identify lessons from operating experience at the domestic and international level for radiation facilities and activities and promote their use by authorized parties.
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	R5	Recommendation: The Government should separate responsibilities for operation and oversight of state-owned radioactive waste at the storage room leased to the state by TVO so that STUK no longer has responsibility for operating the storage room.
	S3	Suggestion: STUK should consider developing a systematic and centralized process for knowledge management and for sharing knowledge across STUK.
	GP1	Good Practice: STUK's practices regarding education and engagement of the media were found to be remarkable for effective communication and consultation with interested parties.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	S4	Suggestion: STUK should consider enhancing the process for monitoring the implementation and closure of corrective actions related to STUK's management system.
	S5	Suggestion: STUK should consider fully developing the process for addressing regulatory experience and integrating this process into its integrated management system.
5. AUTHORIZATION	S6	Suggestion: STUK should consider developing guidance with clear rules and criteria for when a licensee is to seek regulatory approvals, as pertains to safety of NPP, applying a graded approach.
	S7	Suggestion: STUK should consider reviewing and revising its regulation for exemption to cover all radionuclides specified in Schedule I of GSR Part 3.
	S8	Suggestion: In collaboration with the relevant authorities and universities, the Government should consider initiating an overall assessment of the on-going training programmes on radiation protection of patients for all categories of Health Care professionals.
	S9	Suggestion: STUK should consider enhancing the reporting system of significant events in radiotherapy to further enable the sharing and dissemination of operating experience to other licensees and interested parties.
	R6	Recommendation: STUK should establish requirements for radiation facilities and activities to maintain and report to STUK the records of the monitoring programmes and the estimated doses to the public.
6. REVIEW AND ASSESSMENT	GP2	Good Practice: STUK has implemented a systematic model for continuous overall safety assessment of nuclear facilities which allows it to regularly monitor the licensees' overall safety and take adequate measures based on the results.
	R7	Recommendation: STUK should ensure that ageing mechanisms are addressed as part of the authorisation process for package designs containing either nuclear or radioactive material.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R8	Recommendation: STUK should include operators transporting IP and/or Type A packages in its regulatory oversight activities.
	R9	Recommendation: STUK should establish requirements, for radiation facilities and activities that discharge radioactive materials to the environment, to ensure that the characteristics of the material to be discharged and the possible points and methods of discharge are determined.
7. INSPECTION	R10	Recommendation: STUK should continue to develop inspector training and qualification programmes to ensure their systematic implementation.
	S10	Suggestion: STUK should consider establishing a systematic process to address the safety culture during inspection of radiation facilities and activities, in accordance with a graded approach.
8. ENFORCEMENT	n/a	n/a
9. REGULATIONS AND GUIDES	S11	Suggestion: STUK should consider, while renewing its regulations and guides under YEL, to better distinguish requirements and guidance.
	GP3	Good Practice: STUK has developed a web-based searchable tool “SAMMIO” which provides access to timely information regarding the radiation legislation, regulations and guides for licensees and licence applicants including STUK’s expectations on its practical application.
	R11	decommissioning of NPPs including transition from operation to decommissioning while renewing its regulations and guides under YEL.
	S12	Suggestion: STUK should consider developing specific guides for fuel cycle facilities and for the mining and processing of uranium while renewing its regulations and guides.
	R12	Recommendation: STUK, in consultation with the relevant authorities and professional bodies, should develop and implement provisions for ensuring the protection and safety in the handling of deceased persons or human remains that are known to contain sealed or unsealed radioactive sources.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R13	Recommendation: STUK should establish requirements for investigation levels and for investigations to be conducted if investigation levels are exceeded.
	R14	Recommendation: The Ministry of Social Affairs and Health (MSAH) and medical societies, should establish relevant national referral guidelines for the justification of the medical exposure of individual patients.
10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS	S13	Suggestion: STUK should consider expanding and harmonizing emergency exercise requirements beyond nuclear facilities, to cover other regulated facilities and activities, including transport, using a graded approach.
	R15	Recommendation: The Government should strengthen coordinated emergency arrangements between all involved organizations. These arrangements should address mechanisms for coordination during the emergency (also beyond the early phase), including crisis communication.
	R16	Recommendation: The Government should take steps to implement the national measurement strategy for nuclear or radiological emergencies to ensure the prompt and coordinated monitoring, sampling, and analysis by all responsible organisations in all relevant sectors.
11. INTERFACE WITH NUCLEAR SECURITY	n/a	n/a

APPENDIX VI –GOOD PERFORMANCES

AREA	Good Performance
3.RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	3.3. STUK has identified that when people have expertise in more than one area, this might not be addressed when allocating review and assessment tasks since the tasks are divided based on the department's identified competencies. STUK is continuing to refine the process to address issues such as this. Given the thorough nature of the process and the frequency of the evaluation, STUK's competency planning process is an area of good performance.
	3.4. The Finnish Advisory Committee on nuclear safety is an independent body giving recommendations to STUK and the Government concerning important topical safety issues and delivering statements on license applications and regulations. The Committee has two Subcommittees related to nuclear power plants and radioactive waste with non-Finnish experts with the exception of the Chair. These subcommittees provide an independent opinion based on knowledge and experience from foreign countries on the topics put in front of them to enrich the technical assessment delivered by the Advisory Committee to STUK or the Government. This also promotes international cooperation concerning the safe use of nuclear energy and further ensures independence of the committees given the limited independent expertise available and the strong culture of trust of the government within Finland. This demonstrates the importance and visibility given by Finland to external independent assessments. As such, this is an area of good performance.
5.AUTHORIZATION	5.8. The legislated optimisation measures for occupational exposure provide a sound basis for the application of a graded approach in the application for protection measures for the workers. This is recognised as a good performance by the IRRS team.
6.REVIEW AND ASSESSMENT	6.1.2. STUK uses the Polarion management tool for several purposes that are related to review and assessment of the nuclear facilities. This involves annual planning of the main review and assessment tasks and other regulatory activities for the next year, follow-up of activities, management of regulations and regulatory guides, for managing international operating experience, and for the oversight of nuclear facilities. The latter includes collecting observations of licensees' performance, information about inspections and operational events, minutes of weekly internal meetings and the overall safety assessment. The IRRS team considers that the way STUK uses Polarion in its activities is a good performance.

APPENDIX VII – COUNTERPART’S REFERENCE MATERIAL USED FOR THE REVIEW

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	MSAH 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), <i>in Finnish only</i> 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

STUK's YVL Guides

<https://www.stuk.fi/web/en/regulations/stuk-s-regulatory-guides/regulatory-guides-on-nuclear-safety-yvl->

YVL A.1	Regulatory oversight of safety in the use of nuclear energy, 17.3.2020
YVL A.2	Site for a nuclear facility, 15.2.2019
YVL A.3	Leadership and management for safety, 15.3.2019
YVL A.4	Organisation and personnel of a nuclear facility, 15.12.2019
YVL A.5	Construction and commissioning of a nuclear facility, 15.3.2019
YVL A.6	Conduct of operations at a nuclear power plant, 15.6.2019
YVL A.7	Probabilistic risk assessment and risk management of a nuclear power plant, 15.2.2019
YVL A.8	Ageing management of a nuclear facility, 15.2.2019
YVL A.9	Regular reporting on the operation of a nuclear facility, 15.2.2019
YVL A.10	Operating experience feedback of a nuclear facility, 15.2.2019
YVL A.11	Security of a nuclear facility, 12.2.2021
YVL A.12	Information security management of a nuclear facility, 12.2.2021
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
YVL E.13	Ventilation and air conditioning equipment of a nuclear facility, 23.10.2020

Other documents

Building Information Ltd. Guidelines for radon prevention in new construction (Rt 103123, 2019), *in Finnish only*
Country Specific Safety Culture Forum Finland, OECD 2019, NEA No 7488

Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management, STUK-B 259 / October 2020

JYSE 2014 Services, General Terms of Public Procurement in Service Contracts, Ministry of Finance, April 2017/Updated version

Management of spent nuclear fuel and radioactive waste in Finland, 2022 (Publications of the Ministry of Economic Affairs and Employment Energy • 2022:20 Management of spent nuclear fuel and radioactive waste in Finland Second national programme under Article 12 of Directive 2011/70/EURATOM of the Council of the European Union)

Member State Report of Finland as required under Article 14.1 of Council Directive 2011/70/EURATOM, STUK 20.8.2021

National Programme for Radiation Safety Research 2018-2022, STUK-A262/-December 2018

Overall Safety and Organisations: Institutional Strength-in-Depth and National Actors, VTT Research Report, SAFIR 32/2017 8.3.2017, VTT-R--V-113017-16

Overall Safety Conceptual Framework - ORSAC, Lappeenranta University of Technology, December 2016

Protective measures in a nuclear or radiological emergency, Guide VAL 1/1 September 2020

Radiation practices: Annual Report 2021, STUK-B 282, *in Finnish only*

Regulatory oversight of nuclear safety in Finland, Annual Report 2020, STUK-B 267, May 2021

Regulatory oversight of nuclear safety in Finland, Annual Report 2021, STUK-B 283, May 2022

Report of the Committee for Nuclear Energy Competence in Finland, the Ministry of Employment and the Economy, Energy and the Climate, 14/2012

Safety case methodology for nuclear waste disposal – possible update considerations for Finnish usage, VTT Technology 364, 2019

SAFIR2018 – The Finnish Research Programme on Nuclear Power Plant Safety 2015-2018, Final Report, VTT Technology 349

Security arrangements in the transport of radioactive substances, STUK / June 2015

STUK-B 273 Preliminary study for the development of transmission recommendations under the SätL, 02/2021, *in Finnish only*

The National Building Code of Finland (Ministry of the Environment 2018), *in Finnish only*

Transport of Radioactive Material (based on ADR 2012, 2020), *in Finnish only*

STUK's Management System Guides

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 SätL
 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
 Guide YTV 1.c Appendix 1 Preparation of Finnish National Report on Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management
 Guide YTV 2.a Licences and approvals for nuclear facilities
 Guide YTV 2.b Processing of licence applications related to nuclear materials and nuclear waste and mining an ore enrichment activity
 Guide YTV 2.b Appendix 1 Licence application handling process in a diagram
 Guide YTV 2.b Appendix 2 Particular safeguards obligations as a result of bilateral agreements
 Guide YTV 2.b Appendix 3 Government-to-Government Assurances required by the NSG
 Guide YTV 2.c Personnel approvals
 Guide YTV 2.d.1 Manufacturers of nuclear mechanical equipment and structure
 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
 Guide YTV 3.a.2 Appendix 7 Pre-review of the initial suitability assessment

Guide YTV 3.b.1 Deterministic safety analyses
 Guide YTV 3.b.2 Probabilistic risk assessment (PRA)
 Guide YTV 3.b.4 Long-term safety oversight
 Guide YTV 3.c.1 Oversight of technical specifications
 Guide YTV 3.c.4 Radiation safety
 Guide YTV 3.c.5 Security arrangements
 Guide YTV 3.c.6 Emergency arrangements
 Guide YTV 3.c.10 Regulatory oversight of nuclear waste management
 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
 Guide YTV 3.d Oversight of organisations - safety culture: management systems and human resources
 Guide YTV 3.d.1 Oversight of safety culture
 Guide YTV 3.d.2 Management system oversight
 Guide YTV 3.d.2 Appendix 1 Oversight of licensee auditing activities
 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
 Guide YTV 3.g.1 Oversight of transport of nuclear material and nuclear waste
 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
 Guide YTV 4.a.1 Appendix 3 Oversight of organisations at KTO inspection
 Guide YTV 4.a.3 Oversight of authorized inspection organisations, inspection programme for inspection organizations (TTO)
 Guide YTV 4.b.1 Operational oversight inspections
 Guide YTV 4.b.2 Inspection of mechanical components and structure
 Guide YTV 4.b.2 Appendix 1 Review of modification and repair plan
 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
 Guide YTV 4.b.2 Appendix 4 Processing class in oversight of conformity of mechanical components
 Guide YTV 4.c.1 Nuclear use item verifications and verification visits
 Guide YTV 4.c.1 Appendix 1 Approval of international inspections
 Guide YTV 4.c.1 Appendix 2 Nuclear safeguards verification procedures during field inspections
 Guide YTV 4.c.1 Appendix 3 Forms for safeguards verifications
 Guide YTV 4.c.1 Appendix 4 STUK's activity at IAEA's short notice inspections
 Guide YTV 5.a Implementation procedures in regulatory control of use of nuclear energy
 Guide YTV 5.b Implementation of YVL Guides
 Guide YTV 6.a Planning and monitoring of YTO and YMO operations
 Guide YTV 6.b Competence development at YTO and YMO
 Guide YTV 6.c Application of Graded Approach in regulatory oversight of nuclear facilities
 Guide YTV 6.c Appendix 1 Graded Approach assessment form
 Guide YTV 6.c Appendix 2 Graded Approach assessment model
 Guide YTV 6.e Internal indicators for YTO's activities

Guide YTV 6.f National safety research programmes for nuclear power plants and nuclear waste management
 Guide YTV 6.g Assessment and development of YTO and YMO operations
 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); organisation 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
 Guide YTV 8.a Processing of documents
 Guide YTV 8.c Regulatory oversight of modifications to nuclear facilities

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

APPENDIX VIII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1.	INTERNATIONAL ATOMIC ENERGY AGENCY - Fundamental Safety Principles, No SF-1, IAEA, Vienna (2006)
2.	INTERNATIONAL ATOMIC ENERGY AGENCY - Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements Part 1, No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016)
3.	INTERNATIONAL ATOMIC ENERGY AGENCY – Leadership and Management for Safety, General Safety Requirements Part 2, No. GSR Part 2, IAEA, Vienna (2016)
4.	INTERNATIONAL ATOMIC ENERGY AGENCY - Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, No. GSR Part 3, IAEA, Vienna (2014).
5.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety assessment for facilities and activities, General Safety Requirements Part 4, No. GSR Part 4 (Rev. 1), IAEA, Vienna (2016)
6.	INTERNATIONAL ATOMIC ENERGY AGENCY - Predisposal Management of Radioactive Waste, General Safety Requirement Series Part 5, No. GSR Part 5, IAEA, Vienna (2009)
7.	INTERNATIONAL ATOMIC ENERGY AGENCY - Decommissioning of Facilities, General Safety Requirement Series No. GSR Part 6, IAEA, Vienna (2014)
8.	INTERNATIONAL ATOMIC ENERGY AGENCY - Preparedness and Response for Nuclear or Radiological Emergency, General Safety Requirement Series No. GSR Part 7, IAEA, Vienna (2015)
9.	INTERNATIONAL ATOMIC ENERGY AGENCY - Site Evaluation for Nuclear Installations, Specific Safety Requirement Series No. SSR-1, IAEA, Vienna (2003)
10.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Nuclear Power Plants: Design, Specific Safety Requirements Series No. SSR-2/1 (Rev. 1), IAEA, Vienna (2016)
11.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Nuclear Power Plants: Commissioning and Operation, Specific Safety Requirements Series No. SSR-2/2 (Rev. 1), IAEA, Vienna (2016)
12.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Research Reactors, Specific Safety Requirements Series No. SSR-3, IAEA, Vienna (2016)
13.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Nuclear Fuel Cycle Facilities, Specific Safety Requirements Series No. SSR-4, IAEA, Vienna (2017)
14.	INTERNATIONAL ATOMIC ENERGY AGENCY - Disposal of Radioactive Waste, Specific Safety Requirements Series No. SSR-5, IAEA, Vienna (2011)
15.	INTERNATIONAL ATOMIC ENERGY AGENCY – Regulations for the Safe Transport of Radioactive Material, Specific Safety Requirements Series No. SSR-6, IAEA, Vienna (2012)
16.	INTERNATIONAL ATOMIC ENERGY AGENCY - Regulations for the Safe Transport of Radioactive Material, 2018 Edition, Specific Safety Requirements Series No. SSR-6 (Rev. 1), IAEA, Vienna (2018)
17.	INTERNATIONAL ATOMIC ENERGY AGENCY - Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)
18.	INTERNATIONAL ATOMIC ENERGY AGENCY - Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency, Safety Guide Series No GSG-2, IAEA, Vienna (2012)
19.	INTERNATIONAL ATOMIC ENERGY AGENCY - Communication and Consultation with Interested Parties by the Regulatory Body, General Safety Guide Series No. GSG-6, IAEA, Vienna (2017).
20.	INTERNATIONAL ATOMIC ENERGY AGENCY - Occupational Radiation Protection, Safety Guide Series No. GSG-7, IAEA, Vienna (2018)
21.	INTERNATIONAL ATOMIC ENERGY AGENCY - Regulatory Control of Radioactive Discharges to the Environment, Safety Guide Series No GSG-9, IAEA, Vienna (2018)

22.	INTERNATIONAL ATOMIC ENERGY AGENCY - Organization, Management and Staffing of the Regulatory Body for Safety, General Safety Guide Series No. GSG-12, IAEA, Vienna (2018).
23.	INTERNATIONAL ATOMIC ENERGY AGENCY - Functions and Processes of the Regulatory Body for Safety, General Safety Guide Series No. GSG-13, IAEA, Vienna (2018).
24.	INTERNATIONAL ATOMIC ENERGY AGENCY - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)
25.	INTERNATIONAL ATOMIC ENERGY AGENCY - The Management System for the Disposal of Radioactive Waste, Safety Guide Series No GS-G-3.4, IAEA, Vienna (2008)
26.	INTERNATIONAL ATOMIC ENERGY AGENCY - Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna (2011)
27.	INTERNATIONAL ATOMIC ENERGY AGENCY - A System for the Feedback of Experience from Events in Nuclear Installations, Safety Guide Series No. NS-G-2.11, IAEA, Vienna (2006)
28.	INTERNATIONAL ATOMIC ENERGY AGENCY - Modifications to Nuclear Power Plants, Safety Guide Series No NS-G-2.3, IAEA, Vienna (2001)
29.	INTERNATIONAL ATOMIC ENERGY AGENCY - Recruitment, Qualification and Training of Personnel for Nuclear Power Plants, Safety Guide Series No NS-G-2.8, IAEA, Vienna (2002)
30.	INTERNATIONAL ATOMIC ENERGY AGENCY - Environmental and Source Monitoring for Purposes of Radiation Protection, Safety Guide Series No. RS-G-1.8, IAEA, Vienna (2005)
31.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Radiation Generators and Sealed Radioactive Sources, Safety Guide Series No. RS-G-1.10, IAEA, Vienna (2008)
32.	INTERNATIONAL ATOMIC ENERGY AGENCY - Borehole Disposal Facilities for Radioactive Waste, Safety Guide Series No SSG-1, IAEA, Vienna (2009)
33.	INTERNATIONAL ATOMIC ENERGY AGENCY - Deterministic Safety Analysis for Nuclear Power Plants, Specific Safety Guides Series No. SSG-2, IAEA, Vienna (2010)
34.	INTERNATIONAL ATOMIC ENERGY AGENCY - Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-3, IAEA, Vienna (2010)
35.	INTERNATIONAL ATOMIC ENERGY AGENCY - Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-4, IAEA, Vienna (2010)
36.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Conversion Facilities and Uranium Enrichment Facilities, Specific Safety Guide Series No. SSG-5, IAEA, Vienna (2010)
37.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Uranium Fuel Fabrication Facilities Specific Safety Guide Series No. SSG-6, IAEA, Vienna (2010)
38.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Uranium and Plutonium Mixed Oxide Fuel Fabrication Facilities, Specific Safety Guide Series No. SSG-7, IAEA, Vienna (2010)
39.	INTERNATIONAL ATOMIC ENERGY AGENCY - Licensing Process for Nuclear Installations, Specific Safety Guide Series No. SSG-12, IAEA, Vienna (2010)
40.	INTERNATIONAL ATOMIC ENERGY AGENCY - Geological Disposal Facilities for Radioactive Waste Specific Safety Guide Series No. SSG-14, IAEA, Vienna (2011)
41.	INTERNATIONAL ATOMIC ENERGY AGENCY - Storage of Spent Nuclear Fuel, Safety Guide Series No SSG-15 (Rev. 1), IAEA, Vienna (2020)
42.	INTERNATIONAL ATOMIC ENERGY AGENCY - Periodic Safety Review for Nuclear Power Plants, Safety Guide Series No SSG-25, IAEA, Vienna (2013)
43.	INTERNATIONAL ATOMIC ENERGY AGENCY - Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material, Specific Safety Guide No SSG-26, IAEA, Vienna, (2014)
44.	INTERNATIONAL ATOMIC ENERGY AGENCY - Commissioning for Nuclear Power Plants, Safety Guide Series No. SSG-28, IAEA, Vienna (2014)

45.	INTERNATIONAL ATOMIC ENERGY AGENCY - Predisposal Management of Radioactive Waste from Nuclear Power Plants and Research Reactors, Safety Guide Series No SSG-40, IAEA, Vienna (2016)
46.	INTERNATIONAL ATOMIC ENERGY AGENCY - Predisposal Management of Radioactive Waste from Nuclear Fuel Cycle Facilities, Safety Guide Series No SSG-41, IAEA, Vienna (2016)
47.	INTERNATIONAL ATOMIC ENERGY AGENCY - Management of Waste from the Use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education, Safety Guide Series No SSG-45, IAEA, Vienna (2019)
48.	INTERNATIONAL ATOMIC ENERGY AGENCY - Radiation Protection and Safety in Medical Uses of Ionizing Radiation, Safety Guide Series No SSG-46, IAEA, Vienna (2018)
49.	INTERNATIONAL ATOMIC ENERGY AGENCY - Decommissioning of Nuclear Power Plants, Research Reactors and Other Nuclear Fuel Cycle Facilities, Safety Guide Series No SSG-47, IAEA, Vienna (2018)
50.	INTERNATIONAL ATOMIC ENERGY AGENCY – Ageing Management and Development of a Programme for Long Term Operation of Nuclear Power Plants, Safety Guide Series No SSG-48, IAEA, Vienna (2018)
51.	INTERNATIONAL ATOMIC ENERGY AGENCY –Decommissioning of Medical, Industrial and Research Facilities, Safety Guide Series No SSG-49, IAEA, Vienna (2019)
52.	INTERNATIONAL ATOMIC ENERGY AGENCY – Operating Experience Feedback for Nuclear Installations, Safety Guide Series No SSG-50, IAEA, Vienna (2019)
53.	INTERNATIONAL ATOMIC ENERGY AGENCY - Accident Management Programmes for Nuclear Power Plants, Safety Guide Series No SSG-54, IAEA, Vienna (2019)
54.	INTERNATIONAL ATOMIC ENERGY AGENCY - Planning and Preparing for Emergency Response to Transport Accidents Involving Radioactive Material, Safety Guide No TS-G-1.2 (2002)
55.	INTERNATIONAL ATOMIC ENERGY AGENCY - Radiation Protection Programmes for the Transport of Radioactive Material, Safety Guide No TS-G-1.3, IAEA, Vienna, (2007)
56.	INTERNATIONAL ATOMIC ENERGY AGENCY - The Management System for the Safe Transport of Radioactive Material Safety Guide No TS-G-1.4, IAEA, Vienna, (2008)
57.	INTERNATIONAL ATOMIC ENERGY AGENCY - Compliance Assurance for the Safe Transport of Radioactive Material, Safety Guide No TS-G-1.5, IAEA, Vienna, (2009)
58.	INTERNATIONAL ATOMIC ENERGY AGENCY - Schedules of Provisions of the IAEA Regulations for the Safe Transport of Radioactive Material (2009 Edition), Safety Guide No TS-G-1.6 (Rev.1), IAEA, Vienna, (2014)
59.	INTERNATIONAL ATOMIC ENERGY AGENCY - Storage of Radioactive Waste, Safety Guide Series No WS-G-6.1, IAEA, Vienna (2006)
60.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No.WS-G-5.2, IAEA, Vienna (2009)
61.	INTERNATIONAL ATOMIC ENERGY AGENCY - Storage of Radioactive Waste, Safety Guide Series No. WS-G-6.1, IAEA, Vienna (2006)

APPENDIX IX – STUK’s ORGANIZATIONAL CHART, DECEMBER 2021

