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**ORIGINAL: English**

# INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

## FOLLOW-UP MISSION

**TO**

# ESTONIA

*Tallinn, Estonia*

*04 to 09 March 2019*

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

Integrated
Regulatory
Review Service

IAEA | IRRS

# REPORT OF THE
# INTEGRATED REGULATORY REVIEW SERVICE (IRRS) FOLLOW-UP MISSION
# TO
# ESTONIA

Integrated Regulatory Review Service

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|---|---|
| **Mission dates:** | *04 to 09 March 2019* |
| **Regulatory body visited:** | *Environmental Board* |
| **Location:** | *Tallinn, Estonia* |
| **Regulated facilities and activities in the mission scope:** | *Radiation Sources in Industrial and Medical Facilities, Emergency Preparedness and Response, Waste Management and Decommissioning, Transport, Medical Exposure, Occupational Exposure, Public and Environmental Exposure* |
| **Organized by:** | *IAEA* |

| IRRS REVIEW TEAM | |
|---|---|
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| SIRC Igor | Reviewer (Slovenia) |
| MEDAKOVIC Sasa | Reviewer (Croatia) |
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| ALEXANDER Tom | IRRS Administrative Assistant (IAEA) |

IAEA-2019

**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.**

## CONTENTS

## EXECUTIVE SUMMARY

At the request of the Government of Estonia an international team of senior safety experts met with representatives of Estonia from 4 to 9 March 2019 to conduct an Integrated Regulatory Review Service (IRRS) follow-up mission. The purpose of the IRRS follow-up mission was to review Estonia's progress against the recommendations and suggestions identified in the initial IRRS mission, which was carried out 04 to 14 September 2016. The follow-up mission took place at the Environmental Board (EB) Headquarters in Tallinn, Estonia. The Ministry of Environment (MoE) is responsible for the implementation of the Radiation Act through the EB as the national radiation safety regulator responsible for regulating all aspects of radiation safety, and the Environmental Inspectorate (EI) which carries out inspection and enforcement functions. The scope of the IRRS follow-up mission was the same as the scope of the initial mission in 2016.

The IRRS review team consisted of six senior regulatory experts from six IAEA Member States, and two IAEA staff members.

The IRRS review team carried out a review of the progress made on each recommendation and suggestion that is documented in the 2016 IRRS mission report. These recommendations and suggestions cover the following areas: responsibilities and functions of the government; the global safety regime; 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, enforcement and the development and content of regulations and guides; emergency preparedness and response; transport of radioactive material; control of medical exposure; occupational radiation protection; control of radioactive discharges, materials for clearance and control of existing exposure situations and remediation; and environmental monitoring for public radiation protection.

To assess progress, the IRRS review team conducted a series of interviews and discussions with Ministry of Environment (MoE), EB and EI staff, and staff of the Ministry of Social Affairs (MoSA), and reviewed the advance reference material provided by EB.

Overall, the IRRS review team concluded that Estonia, through Ministry of Environment, Environmental Board, Environment Inspectorate and the Ministry of Social Affairs, has been responsive to each recommendation and suggestion made in 2016, and continues to place appropriate focus on implementing a framework that provides for effective radiation protection of health and safety. 28 out of 36 recommendations and 10 out of 14 suggestions identified in 2016 have been closed. During the follow-up mission, the IRRS review team developed 2 new recommendations and 4 new suggestions.

Since 2016, Estonia has taken positive steps to:

- Establish a policy and strategy for safety;
- Clearly delineate the responsibilities between the Health Board and EI regarding inspection of medical facilities;
- Develop guidance documents for review and assessment of applications for authorization, inspection and enforcement, including for verification of certificates of transport package designs;

- Establish a mechanism for information sharing between the EB and EI in carrying out their regulatory functions;
- Apply graded approach in the authorization process;
- Develop enforcement policy and criteria for enforcement actions;
- Update the regulatory framework for medical, occupational and public exposure for consistency with IAEA safety standards;

The IRRS review team identified areas including new findings warranting attention or need improvement that the team believes would enhance the legal and regulatory framework for radiation safety in Estonia.

Estonia needs to take further actions to:

- establish an integrated management system for the Environmental Inspectorate;
- consider to ensure that there is a sustainable provision of education and training in radiation safety;
- consider to include provisions on leadership for safety in the Integrated Management System in order to foster and sustain a strong safety culture;

The specific findings of the follow-up mission are summarized in Appendix V.

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

# I. INTRODUCTION

At the request of the Government of Estonia, an international team of senior safety experts met representatives of the Ministry of Enviornment (MoE), EB, EI and MoSA from 4 to 9 March 2019 to conduct an Integrated Regulatory Review Service (IRRS) follow-up mission.

The purpose of the follow-up mission is to review the implementation of the recommendations and suggestions given to the Government during the IRRS Mission in September 2016. The follow-up mission was formally requested by the Government of Estonia in July 2017. A preparatory meeting was conducted from 6 to 7 September 2018 at the headquarters of the Ministry of Enviornment (MoE) in Tallinn to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in Estonia and their related safety aspects.

The IRRS review team consisted of six senior regulatory experts from six IAEA Member States, and 2 IAEA staff members. The IRRS review team carried out the review in the areas covered by the main mission in 2016.

The follow-up self-assessment report and supporting documentation were provided to the IRRS review team as advance reference material (ARM) for the mission. During the mission, the IRRS review team performed a systematic review of all topics by reviewing the advance reference material, additional information, and by conducting interviews with management and staff of the MoE, EB, EI and MoSA.

All through the mission, the IRRS review team received excellent support and cooperation from MoE through the EB.

## II. OBJECTIVE AND SCOPE

The purpose of this IRRS follow-up mission was to conduct a review of the implementation of the recommendations and suggestions given to the Government of Estonia during the IRRS Mission in September 2016 and to exchange information and experience in the areas covered by the IRRS. The IRRS review scope included all facilities and activities regulated by MoE, through the EB and EI. The review was carried out by comparison of existing arrangements against the IAEA safety standards.

It is expected that the IRRS follow-up mission will facilitate regulatory improvements in Estonia and other Member States from the knowledge gained and experiences shared between MoE, EB and EI and IRRS reviewers and through the evaluation of the effectiveness of Estonia's regulatory framework for nuclear and radiation safety.

# III. BASIS FOR THE REVIEW

## A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Estonia, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) follow-up mission, and the Integrated Review Service for Radioactive Waste and Spent Fuel Management, Decommissioning and Remediation (ARTEMIS) mission, was conducted at the MoE Headquarters in Tallinn, on 6 and 7 September 2018. The preparatory meeting was carried out by the Team Leaders for IRRS and ARTEMIS missions and the IAEA Team coordinators, Mr. Teodros Hailu for IRRS mission and Mr Andrey Guskov for ARTEMIS mission, since Estonia was also preparing for an ARTEMIS mission planned for March 2019.

The IRRS Follow-up mission preparatory team had discussions regarding regulatory programmes with the senior management of MoE, the EB and EI represented by Mr Ilmar Puskar, Head of the Radiation Safety Department of the Environmental Board as the Liaison Officer. The discussions resulted in agreement that the regulatory functions covering the following facilities and activities were to be reviewed by the IRRS follow-up mission:

- Waste management facilities;
- Decommissioning;
- Radiation sources facilities and activities;
- Transport of radioactive material;
- Control of medical exposure;
- Occupational radiation protection;
- Public exposure control.

Mr Ilmar Puskar made presentations on the national context, the current status of MoE, EB and EI and the progress made since the initial mission of September 2016.

IAEA staff presented the process and methodology of conducting a follow-up IRRS mission. This was followed by a discussion on the tentative work plan for the implementation of the follow-up mission in Tallinn in March 2019.

The proposed IRRS review team composition (senior regulators from Member States to be involved in the review) was discussed and the size of the IRRS follow-up team was tentatively confirmed. Logistics including meeting and work space, counterparts and Liaison Officer, lodging and transport arrangements were also addressed.

The Liaison Officer for the preparatory meeting and the IRRS follow-up mission was Mr Ilmar Puskar.

The MoE provided the IAEA (and the review team) with the advance reference material for the review in March 2019 and additional materials. In preparation for the mission, the IRRS review team members conducted a review of the advance reference material and provided their initial review comments to the IRRS review team Coordinator and Team Leader prior to the follow-up 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. A list of IAEA publications used as the reference for this mission is given in Appendix VII.

## C) CONDUCT OF THE REVIEW

An initial IRRS review team meeting was conducted on Sunday 3 March 2019, in Tallin by the IRRS review team Leader and IAEA Team Coordinator to discuss the general overview, the focus areas and the specific issues of the mission; to clarify the basis for the review and the background and objectives of the IRRS; and to agree on the methodology for the review. The agenda for the mission was also presented.

The Liaison Officer, Mr Ilmar Puskar, was present at the initial IRRS review team meeting in accordance with the IRRS guidelines, and presented logistical arrangements planned for the mission.

The reviewers also reported their first impressions of the advance reference material. General approaches for mission conclusions drafting were agreed.

The IRRS entrance meeting was held on Monday 4 March 2019, with the participation of Deputy Secretary General of the MoE, senior management and staff of the EB and EI, and staff of the MoSA. Opening remarks were made by the Deputy Secretary General of the MoE, Mr Harry Liiv, and the Team Leader, Ms Stavroula Vogiatzi, gave a presentation on the expectations of the IRRS follow-up mission. Ms Reelika Runnel, representative of the MoE, gave an overview of the MoE, EB and EI activities and response to the 2016 mission findings.

During the mission, a review was conducted for all the mission scope areas with the objective of reviewing the Government and MoE's response to the recommendations and suggestions identified during the initial mission. The review was conducted through meetings, interviews and discussions regarding the national practices and activities.

The IRRS review team performed its activities based on the mission programme given in Appendix II.

The IRRS exit meeting was held on Saturday 9 March 2019 where the IRRS review team Leader Ms Stavroula Vogiatzi presented the results of the follow-up mission highlighting the main findings. This was followed by a statement by Ms Heidi Koger, Head of Ambient Air and Radiation Department of the MoE, in response to the Team Leader's presentation. Closing remarks were made by Mr. Teodros Hailu on behalf of the Director of the Division of Radiation, Transport and Waste Safety, Department of Nuclear Safety and Security.

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

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *The national policy and the National Radiation Safety Development Plan do not contain all the requisite elements of a national policy and strategy for safety.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 1, para. 2.3 states that** *"National policy and strategy for safety shall express a long term commitment to safety. The national policy shall be promulgated as a statement of the government's intent. The strategy shall set out the mechanisms for implementing the national policy. In the national policy and strategy, account shall be taken of the following:*<br>*(a) The fundamental safety objective and the fundamental safety principles established in the Fundamental Safety Principles [1];*<br>*(b) Binding international legal instruments, such as conventions and other relevant international instruments;*<br>*(c) The specification of the scope of the governmental, legal and regulatory framework for safety;*<br>*(d) The need and provision for human and financial resources;*<br>*(e) The provision and framework for research and development;*<br>*(f) Adequate mechanisms for taking account of social and economic developments;*<br>*(g) The promotion of leadership and management for safety, including safety culture.* |
| | |
| **R1** | **Recommendation: The Government should review the national policy and strategy for safety to be consistent with the elements listed in GSR Part 1, paragraph 2.3.** |

**Changes since the initial IRRS mission**

**Recommendation 1:** The draft National Radiation Safety Development Plan 2018-2027 (NRSDP), draft National Programme for Radioactive Waste Management (NPRWM), the draft National Radon Action Plan (NRAP), the Radiation Act, which was amended in 2018 and all related legislation compose an overall national policy and strategy for safety in Estonia. The draft NRSDP includes provisions on education and training, research and development and on human resources planning. The draft NRSDP elaborates the current situation and requirements regarding human resources and competencies of radiation workers, radiation safety specialists, radiation safety experts and public authorities' employees; and includes expectations and future plans to achieve sustainability of human resources and their competencies. Education through regular or E-learning programs, initial trainings and re-trainings, in-service trainings, "train the trainers" programs, web-based trainings, in-house trainings for regulators and IAEA organized trainings are some of the foreseen tools to achieve this goal. The draft NRSDP also

contains estimated costs of implementing the development plan for the next 3 years as well as estimation of costs for the next 10 years. The resources needed and sources of funding for the implementation plan were also predicted.

The draft NPRWM was revised paying attention to the provision for human and financial resources. The draft NRAP comprises coordinated actions to reduce activity concentrations of radon in existing buildings and in future buildings, including reference levels. The draft NRSDP, its implementation plan for the period of 2018-2021, draft NPRWM and draft NRAP are expected to be adopted by June 2019.

Fundamental safety objective and safety principles as defined in IAEA SF-1 are included in the amended Radiation Act. The first paragraph of the Act reflects the fundamental safety objective and some fundamental safety principles are included as the safety principles of the Act. Other elements of fundamental safety principles are provided for in other parts of the Radiation Act.

**Status of the finding in the initial mission**

**Recommendation 1 is closed on the basis of progress made and confidence in effective completion**, as a draft NRSDP and draft NPRWM and NRAP have been prepared that formulate the national policy and strategy for safety and are expected to be approved by the Government by June 2019.

### 1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *The legal framework does not explicitly assign primary responsibility for safety to the persons or organizations responsible for facilities and activities and does not explicitly provide for a graded approach to regulatory control of facilities and activities.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 2, para 2.5(6) states that** *"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:*<br>*(6) Provision for assigning legal responsibility for safety to the persons or organizations responsible for the facilities and activities."* |
| **R2** | **Recommendation: The Government should make provision in the Radiation Act to explicitly assigning primary responsibility for safety to the persons or organizations responsible for the facilities and activities and explicitly provide for a graded approach to regulatory control of facilities and activities.** |

**Changes since the initial IRRS mission**

**Recommendation 2:** The Radiation Act, amended in 2018, introduced a new safety principle on liability of licensees explicitly assigning primary responsibility for radiation safety to the licensees. Graded approach is also introduced in several paragraphs of the amended Act and was taken into account in determining the validity of radiation practice licenses. In the new amendment, the validity of a license for low risk radiation practices licence has no time limitation, while a license for moderate and high risk radiation practices licences could be valid for up to five years.

The Environmental Board (EB) is in process of developing internal guidelines (in three parts) for reviewing and assessing radiation practice license applications, which takes account of a graded approach, and the first part of the guidelines has been issued and implementation is foreseen starting April 2019. The second and third parts of these guidelines are planned to be finalized and implemented by the end of 2019. The EB has planned to develop guides for applicants and licensees for different type of practices after these internal guidelines are issued. The Environmental Inspectorate (EI) adopted in October 2016 a penalty matrix that categorizes non-compliances. The matrix is an annex to the internal guidelines for imposing penalties. These guidelines were amended in 2018 introducing additional elements of graded approach into the inspection and enforcement processes, and also to ensure consistency in enforcement actions for similar non-compliances with regulatory requirements.

**Status of the finding in the initial mission**

**Recommendation 2 is closed on the basis of progress and confidence in effective completion,** as the Radiation Act includes provisions for prime responsibility for safety and introduces a system of graded approach in authorization process, and internal guidelines are being developed.

## 1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

**There were no findings in this area in the initial IRRS mission.**

## 1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

**There were no findings in this area in the initial IRRS mission.**

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

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *There is no clear delineation of authority between the EI and the Health Board to avoid overlap and conflicting roles and responsibilities regarding inspections of medical radiological equipment.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 2, para 2.6 states that** *"Where several authorities are involved, the government shall specify clearly the responsibilities and functions of each authority within the governmental, legal and regulatory framework for safety."* |
| **R3** | **Recommendation: The Government should clearly delineate the authority of the Health Board and the Environmental Inspectorate with respect to inspection of medical radiological equipment.** |

**Changes since the initial IRRS mission**

**Recommendation 3:** In 2018 the Ministry of Social Affairs (MoSA) adopted Regulation no 71 "Radiation safety requirements for medical radiological procedures, clinical audit requirements for medical radiological procedures, and diagnostic reference levels and requirements for determination thereof", which explicitly clarifies responsibilities and refers to Health Services Organisation Act that

provides for inspection competencies of the Health Board (HB). In January 2019 a joint inspection of the EI and HB was conducted to identify any possible remaining overlaps in inspection of medical radiological equipment. The joint inspection found out that there are no overlaps and conflicting roles and responsibilities regarding inspections of medical radiological equipment. Some more joint inspections are planned in 2019 to strengthen common understanding of inspections strategy and purpose in medical facilities.

**Status of the finding in the initial mission**

**Recommendation 3 is closed,** as the Regulation of the MoSA provided for a clear specification of responsibilities regarding inspections of medical radiological equipment.

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *There is overlap of regulatory functions and lack of coordination and liaison between the Health Board and the Environmental Inspectorate in respect of inspection of medical equipment.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 7, para. 2.18 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties."* |
| **R4** | **Recommendation: The Government should make provision and arrangements for effective coordination of the national authorities having regulatory responsibilities for radiation safety of facilities and activities.** |

**Changes since the initial IRRS mission**

**Recommendation 4:** Although the responsibilities of the HB and EI were clarified, the mechanism for exchanging the information and notification between the EI and the HB has not been established yet. Both authorities recognize the need of such a mechanism and activities to sign Memorandum of Understanding have been initiated. The IRRS review team was informed that the MoU is expected to be signed by the end of 2019. Similar efforts for establishing coordination mechanisms with responsible authorities such as in the field of transport of radioactive material are also ongoing. EB plans to sign Memorandum of Understanding with the Road Administration for the transportation on roads, as well as with other Authorities (Ministry of Economic Affairs, Rescue Board, Health Board) in the areas where their competencies are shared.

**Status of the finding in the initial mission**

**Recommendation 4 is open** as the mechanism for coordination and exchanging the information and notification in the areas where several authorities have responsibilities for safety is not yet in place.

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

**There were no findings in this area in the initial IRRS mission.**

## 1.7. PROVISIONS FOR THE MANAGEMENT OF RADIOACTIVE WASTE

**There were no findings in this area in the initial IRRS mission.**

## 1.8. COMPETENCE FOR SAFETY

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *There are no regulatory requirements for the qualification and training of radiation safety specialists (i.e., Radiation Protection Officers, radiation safety training service providers, medical radiation technologists and radiopharmacists or radiochemists) and arrangements for training in order to ensure a reliable supply of trained radiation specialists.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 11 states that** *"The government shall make provision for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities.* |
| **(2)** | **BASIS: GSR Part 1 Requirement 11, para 2.34 states that** *"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."* |
| **(3)** | **BASIS: GSR Part 1 Requirement 11, para 2.35 states that** *"The building of competence shall be required for all parties with responsibilities for the safety of facilities and activities, including authorized parties, the regulatory body and organizations providing services or expert advice on matters relating to safety. Competence shall be built, in the context of the regulatory framework for safety, by such means as:*<br>*—Technical training;*<br>*—Learning through academic institutions and other learning centres;*<br>*—Research and development work."* |
| **(4)** | **BASIS: GSR Part 1 Requirement 11, para 2.36 states that** *"The government:*<br>*(a) Shall stipulate a necessary level of competence for persons with responsibilities in relation to the safety of facilities and activities;*<br>*(b) Shall make provision for adequate arrangements for the regulatory body and its support organizations to build and maintain expertise in the disciplines necessary for discharge of the regulatory body's responsibilities in relation to safety;*<br>*(c) Shall make provision for adequate arrangements for increasing, maintaining and regularly verifying the technical competence of persons working for authorized parties."* |
| **(5)** | **BASIS: GSR Part 1 Requirement 11, paragraph 2.37 states that** *"In cases where the training programmes available in the State are insufficient, arrangements for training shall be made with other States or with international organizations."* |
| **(6)** | **BASIS: GSR Part 3 Requirement 3, para. 2.32 states that** *"The regulatory body shall* |

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| | *ensure the application of the requirements for education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety."* |
| **(7)** | **BASIS: GSR Part 3 Requirement 35 states that** *"The regulatory body shall require that health professionals with responsibilities for medical exposure are specialized in the appropriate area and that they fulfil the requirements for education, training and competence in the relevant specialty."* |
| **R5** | **Recommendation: The Government should establish appropriate requirements for the qualification, and make sufficient arrangements for the training of radiation safety specialists (i.e., Radiation Protection Officers, medical radiation technologists, radiopharmacists and radiochemists) in order to ensure a reliable supply of trained radiation specialists.** |

**Changes since the initial IRRS mission**

**Recommendation 5:** The Radiation Act sets out requirements on technical competence for a person, designated as a radiation safety specialist (radiation protection officer). Regulation of the Minister of the Environment "Requirements for radiation safety training of radiation safety specialists and exposed workers" amended 2016 also established requirements for training and re-training of radiation safety specialists.

**Status of the finding in the initial mission**

**Recommendation 5: is closed,** as the Legal framework has established requirements for the qualification and for the training of radiation safety specialists.

**New observations from the follow-up mission**

The draft NRSDP recognizes that although the Estonian education system provided for a radiation safety training in the past, continuity of radiation safety training in some parts of the education system was interrupted. At present, teaching the principles of radiation protection is a part of curricula in the medical field but not in the other relevant fields (such as natural sciences). It was recognised in the draft NRSDP that without the support of educational institutions, the level of radiation protection and safety knowledge in Estonia would not be sustainable.

| FU MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *The Estonian education system does not ensure that constant radiation safety education and training is carried out Estonia faces a challenge for sustainable radiation safety knowledge without the support of educational institutions.* | |
| **(1)** | **BASIS: GSR Part 1 (Rev. 1) Requirement 11, para. 2.35 states that** *"The building of competence shall be required for all parties with responsibilities for the safety of facilities and activities, including authorized parties, the regulatory body and* |

| FU MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| | *organizations providing services or expert advice on matters relating to safety. Competence shall be built, in the context of the regulatory framework for safety, by such means as:*<br>*— Technical training;*<br>*— Learning through academic institutions and other learning centres;*<br>*— Research and development work."* |
| **SF 1** | **Suggestion: The Government should consider to ensure that there is a sustainable provision of radiation safety education and training.** |

### 1.9. PROVISION OF TECHNICAL SERVICES

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *The requirements for the authorization of technical services are not clearly defined and the process for authorization is not described.* | |
| **(1)** | **BASIS: GSR Part 1, Req.13 para.2.41 states that** *"Technical services do not necessarily have to be provided by the government. However, if no suitable commercial or non-governmental provider of the necessary technical services is available, the government may have to make provision for the availability of such services. The regulatory body shall authorize technical services that may have significance for safety, as appropriate".* |
| **S1** | **Suggestion: The EB should consider to specify the technical services that need authorization and develop a process for granting an authorization.** |

**Changes since the initial IRRS mission**

**Suggestion 1:** The Radiation Act provided for requirements on licensing of all technical services that are using radiation sources or are involved in installing, repairing or maintaining of sources. The IRRS review team noted that only services related to conducting measurements (such as individual dose monitoring, measurement of radon concentration, radiation level measurements) does not require a licence. Such services can be conducted without a special approval or authorization from the EB, and requirement that must be fulfilled is a valid accreditation in accordance with the Metrology Act. The EB considers the accreditation as approval for service provision. Any person with a valid accreditation can perform relevant measurements and can provide technical services to a licensee. The EB has developed an internal guideline for reviewers of applications for assessing submitted documents and making decisions on licensing.

**Status of the finding in the initial mission**

**Suggestion 1 is closed,** as the Radiation Act specified technical services that need licence and those, who do not need a licence are clarified, and the EB has issued an internal guidelines on the licensing process.

# 2. THE GLOBAL SAFETY REGIME

## 2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

**There were no findings in this area in the initial IRRS mission.**

## 2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

**There were no findings in this area in the initial IRRS mission.**

# 3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

**There were no findings in this area in the initial IRRS mission.**

## 3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *The services provided by the Radiation Protection Bureau include paid services to the licensees, such as safety assessments, which could potentially create a conflict of interest situation.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 17, para. 4.7 states that** *"The regulatory body shall prevent or duly resolve any conflicts of interests or, where this is not possible, shall seek a resolution of conflicts within the governmental and legal framework."* |
| **S2** | **Suggestion: The Environmental Board should consider to make arrangements to prevent any conflict of interest between its authorization and service provision functions.** |

**Changes since the initial IRRS mission**

**Suggestion 2:** The EB has established internal guidelines for reviewers of applications for assessing submitted documents and making decisions on licensing. This guideline includes provisions forbidding for the same staff reviewing an application for a license and at the same time providing any service to applicants or licensees. According to the internal guidance, the Head of Service has the obligation to prevent any potential conflict of interest between authorisation and service provision functions

**Status of the finding in the initial mission**

**Suggestion 2 is closed on the basis of progress and confidence in effective completion** as EB established internal guidelines to prevent potential conflict of interest on the level of its staff.

## 3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *There is no human resources plan for the radiation regulatory functions of the Environmental Board and Environmental Inspectorate.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 18, para. 4.11 states that** *"The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions."* |

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **(2)** | **BASIS: GSR Part 1 Requirement 18, para. 4.12 states that** *"The human resources plan for the regulatory body shall cover recruitment and, where relevant, rotation of staff in order to obtain staff with appropriate competence and skills, and shall include a strategy to compensate for the departure of qualified staff."* |
| **R6** | **Recommendation: The Environmental Board and Environmental Inspectorate should develop and implement a human resources plan to ensure the availability and competence of staff involved in regulatory functions.** |

**Changes since the initial IRRS mission**

**Recommendation 6:** The EB and EI as part of the general state administration are following Human Resources Management rules (planning of activities, following implementation of plans, determine need for professional development etc.). However, there is no human resources plan in place that states the number of staff necessary and the essential knowledge, skills and abilities for performing all the necessary regulatory functions, to assure long-term sustainability of the regulatory competence.

The draft NRSDP recognizes the need for availability and competence of staff involved in regulatory functions together with comprehensive human resources planning process.

**Status of the finding in the initial mission**

**Recommendation 6 remains open** as EB and EI have not developed a human resource plan.

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *Inspectors from the Environmental Inspectorate, who undertake radiation safety inspections, do not have sufficient radiation safety training. They only have generalist knowledge since radiation safety is a very small component of their work.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 18 state that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."* |
| **R7** | **Recommendation: The Environmental Inspectorate should ensure that adequate arrangements are made to build and maintain sufficient expertise in radiation safety.** |

**Changes since the initial IRRS mission**

**Recommendation 7:** There has not been sufficient progress in activities initiated by the EI to make changes in the existing situation with respect to ensuring adequate arrangements to build and maintain sufficient expertise in radiation safety. At present, there is no analysis made of the expertise needed and no plan to build and maintain expertise of technical staff of the EI.

In the draft NRSDP the need for availability and competence of staff involved in regulatory functions, together with the need for a comprehensive human resource planning process has been clearly recognised. However, there has not been any developments with regard to making sufficient arrangements to maintain adequate expertise in radiation safety within the EI to carry out its regulatory responsibilities adequately.

**Status of the finding in the initial mission**

**Recommendation 7 is remains open,** as not sufficient progress has been made in ensuring adequate arrangements are made to build and maintain the needed expertise in radiation safety.

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *The organization of the radiation regulatory function in Estonia involves a strict separation of the licensing and inspection functions. Radiation safety inspectors are drawn from a pool of inspectors in the Environmental Inspectorate, who are deployed in a wide variety of inspection roles, of which radiation safety forms only a small part.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 16, para. 4.5 states that** *"The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations effectively."* |
| **S3** | **Suggestion: The Ministry of Environment should consider to organize the radiation safety regulatory functions of authorization, inspection and enforcement in such a way that the functions are effectively performed by staff with sufficient expertise in radiation safety.** |

**Changes since the initial IRRS mission**

**Suggestion 3:** In order to organize the regulatory functions and responsibilities for effective implementation, the IRRS review team noted that a decision had been made by the Ministry of Environment in 2018 to merge the EB and EI by January 2019. This decision of the government was brought to the Parliament for endorsement and the process is not yet finalized. The IRRS review team was informed that there are plans to seek approval again from parliament, but this will not be implemented before April 2019 due to the national elections for March 2019. The draft NSRDP does not consider the merging process since, according to the plan, the regulatory functions are still divided between the EB and EI. For more effective regulatory control in radiation safety, the draft NSRDP considers increasing the competence of inspectors by appointing inspectors specialised in the field of radiation safety within the EI.

**Status of the finding in the initial mission**

**Suggestion 3 is remains open,** as sufficient progress has not been made in organizing the regulatory functions of authorization, inspection and enforcement for effective implementation.

## 3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

**There were no findings in this area in the initial IRRS mission.**

## 3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

**There were no findings in this area in the initial IRRS mission.**

## 3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *There is no internal guidance for reviewing and assessing submitted documents (including safety assessment) for authorization for facilities and activities. There are no specific internal guidance for inspection of facilities and activities. There is no established internal guidance related to taking enforcement actions.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 22, para. (4.26) states that** *"The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by the individual staff members of the regulatory."* |
| **R8** | **Recommendation: The Environmental Board and the Environmental Inspectorate should establish documented guidance for reviewing and assessing the information submitted with applications for authorization, and inspection and enforcement for facilities and activities.** |

**Changes since the initial IRRS mission**

**Recommendation 8:** EB has developed draft internal guidance document for reviewers of applications for license for assessing submitted documents and making decisions on the licensing process. These draft guidelines for reviewers of the applications has three main parts: 1) reviewing the documents and making a decision to start the administrative procedure 2) reviewing and assessing the documents presented with the application, taking in to account the graded approach 3) making the administrative decision on granting/not granting the licence and licence conditions. The EB has developed a number of internal guidelines that are currently in different stages of development and implementation. The Status is as follows:

- Guideline on making the safety assessment of the planned radiation activity. (implemented from 2018 December and in use);
- Guideline for the process of proceeding radiation practice licences which is being developed in three parts: part 1 is issued and planned to be implemented by April 2019, part 2 is in drafting stage and part 3 is not started yet. Parts two and three are planned to be finalized and implemented by the end of 2019);

- Guideline for the application for authorisation of radiation practice for the entry, exit and transit of radioactive substances (to be implemented by April 2019);

The EI also has developed guidelines and checklists for inspections of different radiation activities such as guidelines for radiation practice inspection; guidelines for transport of radioactive material - control instructions; and several checklists for inspection of different facilities and activities such as the radioactive waste facility, radiation devices, dental x-ray equipment, diagnostic x-ray equipment, fixed (installed) radiation source and industrial radiography.

**Status of the finding in the initial mission**

**Recommendation 8 is closed,** as EB and the EI developed and documented guidance for reviewing and assessing the information submitted with applications for authorization, and inspection and enforcement for facilities and activities.

### 3.7. SAFETY RELATED RECORDS

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *The information about licences, review and assessment results and inspection results is stored in separate databases and is not always readily accessible for exchange of information between the Environmental Board and Environmental Inspectorate.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 35, para. 4.63 states that** *"The regulatory body shall make provision for establishing and maintaining the following main registers and inventories:*<br>*—Registers of sealed radioactive sources and radiation generators;*<br>*—Records of occupational doses;*<br>*—Records relating to the safety of facilities and activities;*<br>*—Records that might be necessary for the shutdown and decommissioning (or closure) of facilities;*<br>*—Records of events, including non-routine releases of radioactive material to the environment;*<br>*—Inventories of radioactive waste and of spent fuel."* |
| **(2)** | **BASIS: GSR Part 1 Requirement 16, para. 4.5 states that** *"The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations effectively."* |
| **(3)** | **BASIS: GSR Part 1 Requirement 29, para. (4.51) states that** *"Results of inspections shall be used as feedback information for the regulatory process (...)."* |
| **S4** | **Suggestion: The Environmental Board and Environmental Inspectorate should consider integrating their respective registers in order to have a single source of data and mutual easy access to the information of both regulatory bodies related to safety.** |

**Changes since the initial IRRS mission**

**Suggestion 4:** Since April 2018 a new online software, *Environmental Decisions Information System (KOTKAS)*, is used by the EB for applying, reviewing and granting radiation practise licenses and maintaining the register of sources of ionizing radiation. EI Inspectors are using their separate register for inspection – OKAS, but access has been granted both to EI inspectors to KOTKAS and to EB technical staff to OKAS. There are internal guidelines that require the use of OKAS in the authorization process and the use of KOTKAS in planning and conducting inspections. Currently some actions have been initiated to integrate the two registers, so that any final decision made by inspectors will be reflected in the KOTKAS register in the relevant authorization process.

**Status of the finding in the initial mission**

**Suggestion 4 is closed on the basis of progress and confidence in effective completion,** as mutual easy access to the registers of both EB and EI is implemented and full integration of the registers is planned.

## 3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

**There were no findings in this area in the initial IRRS mission.**

# 4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

## 4.1. LEADERSHIP FOR SAFETY

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| ***Observation:*** *The organizational **s**afety policy and safety goals of the Environmental Board and Environmental Inspectorate are not defined explicitly in the management system.* | |
| **(1)** | **BASIS: GSR Part 2, Requirement 3, para 4.2 states that** "Senior management shall be responsible for establishing safety policy." |
| **(2)** | **BASIS: GSR Part 2, Requirement 2, para 3.2. states that** *"Managers at all levels in the organization, taking into account their duties, shall ensure that their leadership includes:*<br>*(a) Setting goals for safety that are consistent with the organization's policy for safety, actively seeking information on safety performance within their area of responsibility and demonstrating commitment to improving safety performance."* |
| **R9** | **Recommendation: The Environmental Board and Environmental Inspectorate should define the safety policy and goals in the management system.** |

**Changes since the initial IRRS mission**

**Recommendation 9:** The Environmental Board and Environmental Inspectorate, under the Ministry of Environment, have developed a draft National Radiation Safety Development Plan (NRSDP) that is basic strategic document in the country in the area of radiation safety and contains safety policy and safety goals. Six strategic goals for radiation safety are defined in the NRSDP as: the functioning of radiation safety infrastructure is enhanced; radiation safety awareness and competence building are ensured; the risks associated with radioactive waste and its management have been reduced; preparedness to prevent emergencies and radiological emergencies is ensured; reduced risks from natural radiation sources; and reasonable use of medical exposure and radiation safety are guaranteed. These safety goals outline the organizational goals of the EB and EI and their regulatory activities.

**Status of the finding in the initial mission**

**Recommendation 9 is closed on the basis of progress and confidence in effective completion,** as the draft NSRDP contains safety policy and goals.

## 4.2. MANAGEMENT FOR SAFETY

### RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

**There were no findings in this area in the initial IRRS mission.**

## THE MANAGEMENT SYSTEM

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *The Environmental Board and Environmental Inspectorate have not established and implemented an Integrated Management System in each organization.* | |
| **(1)** | **BASIS*:* GSR Part 2, Requirement 6 states that** *"The management system shall integrate its elements, including safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements, so that safety is not compromised."* |
| **(2)** | **BASIS: GS-G-3.1., para. 2.1 states that** *"An integrated management system should provide a single framework for the arrangements and processes necessary to address all the goals of the organization. These goals include safety, health,* environmental*, security, quality and economic elements and other considerations such as social responsibility."* |
| **R10** | **Recommendation: The Environmental Board and Environmental Inspectorate should establish and implement, in each organization, an Integrated Management System.** |

### Changes since the initial IRRS mission

**Recommendation 10:** EB has a draft version of the integrated Management System (IMS) manual. The IRRS review team noted that there is a plan to finalize the draft IMS manual and implement it by the end of 2019. The manual covers areas related to management principles; description of the system of appointing the roles, obligations and the empowering; description of planning; description of the documentation administration system; description of the operational control system awareness insurance description; description of the management of services control of the non-compliances; description of the performance evaluation system; description of the system of the internal auditing; expectations of the clients and other interested parties; description of the supporting systems; description of the system on ensuring the competence of the specialists;

The core processes of EB have been identified and process diagram is a part of the draft IMS manual. Detailed processes for the different fields of the activity are included and described. For the radiation field the following processes have been identified and described: Authorization; Radiation workers dose measurements; Environmental monitoring; Laboratory analyses for the radionuclides; and Radiation emergencies (inland and transboundary).

### Status of the finding in the initial mission

**Recommendation 10: is closed on the basis of progress and confidence in effective completion,** as IMS manual is in place, processes have been identified and implementation of IMS is planned by the end of 2019 in the EB.

### New observation from Follow up Mission

There has not been significant progress with respect to the IMS of the EI. The EI has not established and implemented an IMS for its regulatory activities. Processes related to the regulatory responsibilities of the

EI have not been adequately identified and documented, and at present there is no identified connection with the processes of the EB in the existing process diagrams.

| FU MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *The Environmental Inspectorate have not established and implemented an Integrated Management System.* | |
| **(1)** | **BASIS: GSR Part 2, Requirement 6 states that** *"The management system shall integrate its elements, including safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements, so that safety is not compromised."* |
| **(2)** | **BASIS: GS-G-3.1., para. 2.1 states that** *"An integrated management system should provide a single framework for the arrangements and processes necessary to address all the goals of the organization. These goals include safety, health,* environmental, *security, quality and economic elements and other considerations such as social responsibility."* |
| **RF1** | **Recommendation: The Environmental Inspectorate should establish and implement an Integrated Management System.** |

**MANAGEMENT OF RESOURCES**

**There were no findings in this area in the initial IRRS mission.**

**MANAGEMENT OF PROCESSES AND ACTIVITIES**

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *Not all processes are identified and documented in the management systems of the Environmental Board and Environmental Inspectorate*. | |
| **(1)** | **BASIS: GSR Part 2, Requirement 8., para 4.16. states that** *"The documentation of the management system shall include as a minimum: policy statements of the organization on values and behavioural expectations; the fundamental safety objective; a description of the organization and its structure; a description of the responsibilities and accountabilities; the levels of authority, including all interactions of those managing, performing and assessing work and including all processes; a description of how the management system complies with regulatory requirements that apply to the organization; and a description of the interactions with external organizations and with interested parties."* |
| **(2)** | **BASIS: GSR Part 2, Requirement 10., para. 4.28 states that** *"Each process shall be developed and shall be managed to ensure that requirements are met without compromising safety. Processes shall be documented and the necessary supporting documentation shall be maintained. "* |

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **S5** | **Suggestion: The Environmental Board and Environmental Inspectorate should consider to develop, within their respective organizations, all processes relevant to safety and ensure that all processes are documented in the management system.** |

**Changes since the initial IRRS mission**

**Suggestion S5:** Since 2016, certain progress with respect to development and documentation of processes relevant to safety has been made by the Environmental Board (EB) but no significant progress has been made by the Environmental Inspectorate (EI). The Majority of core and supported processes of EB has been identified, described and made available on the website for use. However, not all relevant processes to safety have been identified, developed and documented within the management system.

**Status of the finding in the initial mission**

**Suggestion 5 is open,** as sufficient progress has not been made to establish and document all processes relevant to safety in the EB and EI.

### 4.3. CULTURE FOR SAFETY

**New observation from Follow up Mission**

There is a significant progress with respect to the establishment of Integrated Management System in EB. A draft Integrated Management System Manual has been developed, and core and supported processes has been identified and described and are made available for use. On the other hand, there is still not sufficient focus put on recognising and implementing leadership for safety in the management system. Safety culture has not been recognised or mentioned in the draft integrated management system manual nor in other documents. A common understanding of safety culture and awareness of radiation risks and hazards including a collective commitment to safety by teams and individuals is not ensured throughout the organization in a systematic manner.

| FU MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *Common understanding of safety culture and awareness of radiation risks and hazards relating to work and to the working environment including a collective commitment to safety by teams and individuals is not ensured thought organization on systematic manner.* | |
| **(1)** | **BASIS: GSR Part 2, Requirement 12 states that** *" Individuals in the organization, from senior managers downwards, shall foster a strong safety culture. The management system and leadership for safety shall be such as to foster and sustain a strong safety culture."* |
| **SF2** | **Suggestion: The Environmental Board should consider to include provisions on leadership for safety in Integrated Management System in order to foster and sustain a strong safety culture.** |

## 4.4. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *The EB and EI have not specified a process for measurement of the effectiveness of corrective actions, and for measurement, assessment and improvement of the level of the safety culture in the organizations.* | |
| **(1)** | **BASIS: GSR Part 2, Requirement 13, para 6.3 states that** *"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."* |
| **(2)** | **BASIS: GSR Part 2, Requirement 14., para 6.9. states that** *" Senior management shall ensure that self-assessment of leadership for safety and of safety culture includes assessment at all organizational levels and for all functions in the organization. Senior management shall ensure that such self-assessment makes use of recognized experts in the assessment of leadership and of safety culture."* |
| **R11** | **Recommendation: The Environmental Board and Environmental Inspectorate should develop and implement documented processes in their management systems for the measurement of effectiveness of corrective actions, and for assessment and improvement of the level of safety culture.** |

### Changes since the initial IRRS mission

**Recommendation R11:** The EB and EI have developed several internal guidelines within their management system for consistency in conducting regulatory activities. Although corrective actions are taken within the management system when necessary, however, there has not been any significant progress in the EB or the EI on developing and implementation of documented processes in their management systems for the measurement of effectiveness of corrective actions, and for assessment and improvement of the level of safety culture. This area recognised in initial mission as potential for improvement has not been addressed.

### Status of the finding in the initial mission

**Recommendation 11 is open** as the EB and EI have not developed and implemented documented processes for the assessment and improvement of the level of safety culture.

# 5. AUTHORIZATION

## 5.1. GENERIC ISSUES

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *Inspection findings, regulatory actions and the feedbacks from operational performance are not taken into account in making authorization decisions.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 24, para. 4.38 states that** *"The results of regulatory actions such as inspections, reviews and assessments, and feedback from operational performance (e.g. feedback on the exceeding of limits and conditions or on incidents), shall be taken into account in making decisions on the amendment, renewal, suspension or revocation of authorizations."* |
| **R12** | **Recommendation: The Environmental Board should where appropriate take into account inspection findings, regulatory actions and feedback from operational performance in making authorization decisions.** |

**Changes since the initial IRRS mission**

**Recommendation R12:** The Radiation Act establishes requirements to revoke radiation practice licence when the licensee has repeatedly failed to ensure compliance and when the licensee, its representatives or employees have purposefully and in bad faith prevented the EI from controlling the facilities and activities of the licensee. In practice, if non-compliance with regulatory requirements is discovered by the EI during inspection, it is communicated to the EB and a decision to amend or revoke the radiation practice licence could be made. This communication between EI and EB is facilitated through a common access to each organization's database OKAS and KOTKAS

EB is in the process of developing internal guidance for reviewers of applications for assessing submitted documents and making decisions on authorization. The internal guidance has three parts and the first part of guidance that lists the documents that have to be submitted with application for authorization was finalised and will be implemented in April 2019. Development of the second and third part is planned to be finalised and implemented by the end of 2019.

According to the outline and summary of the internal guidance provided by EB, the IRRS review team noted that the third part will describe the internal procedures for making licensing decisions by taking into account legal basis and different decisions made, including any enforcement decisions and previous inspection results, basis of reasoning of the decision and the licence conditions before an authorization to a facility or activity is issued, including issuance of any subsequent licences.

**Status of the finding in the initial mission**

**Recommendation R12 is closed on the basis of progress and confidence in effective completion,** as EB and EI communication mechanism is facilitated through mutual access to their registers and EB has developed internal guidance for authorization process that includes consideration of inspection results.

## 5.2. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *In the course of issuing an environmental license, the Environmental Board does not give due consideration to potential generation of radioactive waste. The management of specific types of waste is not defined in the national strategy.* | |
| **(1)** | **BASIS: GSR Part 5 Requirement 8, para. 4.6 states that** *"Measures to control the generation of radioactive waste .... have to be considered .... throughout the lifetime of the facility .... in the control of the materials and the selection of the processes, equipment and procedures used throughout its operation and decommissioning."* |
| **(2)** | **BASIS: GSR Part 1 Requirement 26, para. 4.45 states that** *"In the process of its review and assessment of the facility or activity, the regulatory body shall take into account such considerations and factors as: .....*<br>*(16) Feedback of operating experience nationally and internationally, and especially of relevant operating experience from similar facilities and activities."* |
| **(3)** | **BASIS: GSR Part 1 Requirement 7 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties."* |
| **(4)** | **BASIS: GSR Part 1 Requirement 7, para. 2.18 states that** *"The government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned in areas such as:*<br>*(1) Safety of workers and the public;*<br>*(2) Protection of the environment;*<br>*(4) Emergency preparedness and response;*<br>*(5) Management of radioactive waste"* |
| **R13** | **Recommendation: The Environmental Board should make provision for the effective coordination within its regulatory process for safety to ensure that due consideration is given to both radiation and non-radiation issues.** |
| **S6** | **Suggestion: The Ministry of Environment should consider, in the national strategy, the management of all types of radioactive waste, including NORM residues.** |

**Changes since the initial IRRS mission**

**Recommendation R13:** The Radiation Act includes provisions on naturally occurring radioactive material (NORM). The Radiation Act establishes the list of industrial sectors involving NORM, which may cause exposures to workers or members of the public in excess of the established effective dose limits. It also describes the requirements for the measures to protect workers and members of the public for activities in which natural radiation sources may cause exposures to workers or members of the public in excess of the dose limits of public exposure. Based on the Radiation Act, the EB can require a radiation safety assessment report from a licensee that has an environmental licence. So far only three enterprises involving NORM have been identified which may cause exposure to the workers and members of public exceeding dose limits of public exposure. The IRRS review team was informed that the EB has required a radiation safety assessment from one of these enterprises, based on the provisions in the Radiation Act.

The IRRS review team was informed that there is a draft regulation, *Specification for the environmental permit application and data compilation and the data set of the environmental permit, under the General Part of the Environmental Code*, which includes provisions to allow the EB to require a radiation safety assessment, in accordance with the Radiation Act, of planned activities when applying for an environmental licence. This draft regulation is currently in a proceeding and is expected to enter into force by 1 July 2019.

**Suggestion S6:** Since 2016, the NPRWM has been revised. Special attention has been paid to include the management of NORM waste and NORM residues.

The draft NPRWM was finalized in October 2018. However, the NRPWM is an Annex to the draft NRSDP and has to be officially approved as part of the NRSDP. The draft NSRDP is planned to be adopted by June 2019.

**Status of the finding in the initial mission**

**Recommendation R13: is closed,** as the Radiation Act includes provisions that the EB can require a radiation safety assessment from a licensee that applies for or already has an environmental licence.

**Suggestion S6: is closed on the basis of progress and confidence in effective completion,** as the management of NORM waste and NORM residues have been included in the draft NPRWM.

## 5.3. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *Radiation practices are classified by risk categories, depending on the risk presented by a radiation practice or radiation source as low, moderate or high risk. However, categorization of radioactive sources in accordance with international instruments is not used.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 24, paras. 4.33 states that** *"The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."* |
| **(2)** | **BASIS: Code of Conduct, para. 23 states that** *"Every State involved in the import or* |

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| | *export of radioactive sources should take appropriate steps to ensure that transfers are undertaken in a manner consistent with the provisions of the Code and that transfers of radioactive sources in Categories 1 and 2."* |
| **S7** | **Suggestion: The Environmental Board should consider adopting the IAEA system of categorization of radioactive sources to ensure that the degree of regulatory control is commensurate with the potential risk.** |

### Changes since the initial IRRS mission

**Suggestion S7:** The Radiation Act provides a new definition of radiation source category that takes into account not only the assessment of the potential exposure, but also, where appropriate, the physical and chemical properties of the radioactive substance and the activity of the radionuclides contained in it. The Radiation Act also includes provisions stating that the difference between low risks, moderate risks and high risk practices is made depending on the category of radioactive sources or extent of risks connected with radiation practices.

According to the Radiation Act, categories of radioactive sources and requirements for physical protection of radiation sources depending on the category of radiation source are established. Regulations No 52 "Requirements for premises where radiation sources are located, for marking the premises and radiation sources, and radionuclide activity levels "(adopted 16.11.2016.) categorize sources according to the physical protection requirements into A, B and C categories where category A corresponds to Category 1 in IAEA categorization system, B to Category 2 and C to Categories 3-5.

The IRRS review team noted that EB plans to conduct analysis of the current situation in Estonia and of the international best practices to assess the changes that need to be made in order to implement the categorization of radioactive sources in accordance with the IAEA safety guides, and this plan is included in the EB development plan for 2019 - 2022, which was approved in June 2018.

### Status of the finding in the initial mission

**Suggestion S7 is closed on the basis of progress and confidence in effective completion,** as a new definition of radioactive source category has been introduced, level of risks is also determined on category of sources and EB has planned to review best approach to include categorization of radioactive sources.

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *The Environmental Board does not apply graded approach systematically during authorization and review and assessment of facilities and activities.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 2, paras. 2.5 (3), (8) and (10) states that** *"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:*<br>*(3) The type of authorization that is required for the operation of facilities and for the* |

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| | *conduct of activities, in accordance with a graded approach;*<br>*(8) Provision for the review and assessment of facilities and activities, in accordance with a graded approach;*<br>*(10) Provision for the inspection of facilities and activities, and for the enforcement of regulations, in accordance with a graded approach;"* |
| **(2)** | **BASIS: GSR Part 1 Requirement 15, paras. 4.3 states that** *"The performance of regulatory functions shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."* |
| **S8** | **Suggestion: The Environmental Board should consider to consistently apply graded approach to authorization and review and assessment of facilities and activities.** |

**Changes since the initial IRRS mission**

**Suggestion S8:** Radiation Act provides that the radiation practice license for practices of small risk is issued for an unspecified term instead of term of 5 years as it is for moderate and high-risk radiation practices. In order to facilitate the application process, an online authorization system is in use since April 2018 for applying, processing and issuing licences.

Graded approach in review and assessment is demonstrated in the first part of the guidance where the documents that have to be submitted with application are listed for different practices in accordance with the risks associated with the practice. Further application of graded approach is also planned to be included in the second part of the guidance where the content of documents and the scope of review and assessment will be prescribed.

The IRRS review team was informed that the second part of internal guidance that EB is developing, for reviewers of applications for assessing documents submitted by an applicant and making decisions on licensing, will describe the requirements and guidelines for the review and assessment of application and supporting documents with account taken of the type of practice and radiation source.

**Status of the finding in the initial mission**

**Suggestion S8 is closed on the basis of progress and confidence in effective completion,** as different validity terms of authorization have been introduced and EB has developed internal guidance for ensuring consistent review and assessment process that takes into account a graded approach.

## 5.4. AUTHORIZATION OF TRANSPORT

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES |
|---|
| **Observation:** *The Environmental Board does not approve transport packages or validate the approval certificates of transport packages. There is no guidance to help consignors and consignees understand the system of approvals in Estonia for the transport of radioactive materials that may involve more than one mode of transport, including information on the name and contact details of each competent authority.* |

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **(1)** | **BASIS: GSR Part 1 Req. 23 states that** *"Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process."* |
| **(2)** | **BASIS: SSR-6, para 501 states that** *"Before a packaging is first used to transport radioactive material, it shall be confirmed that it has been manufactured in conformity with the design specifications to ensure compliance with the relevant provisions of these Regulations and any applicable certificate of approval."* |
| **(3)** | **BASIS: SSR-6, para 840 states that** *"Multilateral approval may be by validation of the original certificate issued by the competent authority of the country of origin of the design or shipment. Such validation may take the form of an endorsement on the original certificate or the issuance of a separate endorsement, annex, supplement, etc., by the competent authority of the country through or into which the shipment is made."* |
| **(4)** | **BASIS: GSR Part 1 Requirement 32states 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."* |
| **R14** | **Recommendation: The Environmental Board should approve transport packages or validate the approval certificates of transport packages in accordance with IAEA SSR-6.** |
| **S9** | **Suggestion: The Environmental Board should consider developing national guidance to explain the system of approvals in Estonia for the transport of radioactive materials that may involve more than one mode of transport, including information on the name and contact details of each competent authority.** |

**Changes since the initial IRRS mission**

**Recommendation R14:** The EB has developed, a guideline, *Guidance for the application for authorisation of radiation practice for the entry, exit and transit of radioactive substances (*planned to be implemented in April 2019) that includes sections relating to certificates of approval of package designs for the transport of radioactive material. The guidelines establish the documents that need to be submitted to the EB as part of the application for authorization related to transport activities. These include copies of certificates of approval of package designs, by the competent authority of the country of origin, for types of packages requiring such an approval as provided for in the IAEA SSR-6 (Rev.1). The guideline also provides, in its annex, further details on the contents of the package certificates that should be submitted to EB.

**Suggestion S9:** The document *Guidance for the application for authorisation of radiation practice for the entry, exit and transit of radioactive substances* clarifies the content of the documents required to be submitted to EB for authorization of a radiation practice under the Radiation Act and legislation governing the transport of radioactive material. The guidance is to be used in parallel with the manual "Manual – 008-1-AVE User Guide", which provides an overview of the EB's Environmental Decision

Information System in KOTKAS. The guideline requires that the application should be submitted through the online system KOTKAS and based on the information provided by the applicant, the online system will select the mandatory data forms to be filled for application.

The IRRS review team was informed that a presentation was made in a national seminar in relation to the requirements for transport of radioactive material for different stakeholders. The IRRS review team noted that the EB is planning to develop a guide on radiation safety requirements for carriers, and plans to include information related to the competent authorities in Estonia responsible for specific transport modes.

**Status of the finding in the initial mission**

**Recommendation R14 is closed,** as EB has included in its authorization system verification of certificates for design of packages and has issued a guideline clarifying this.

**Suggestion (S9): is closed on the basis of progress and confidence in effective completion,** as EB has developed a guidance that clarifies the requirements for obtaining an authorization from EB for transport activities and plans to develop additional guidance for carriers.

# 6. REVIEW AND ASSESSMENT

## 6.1. GENERIC ISSUES

### 6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

**There were no findings in this area in the initial IRRS mission.**

### 6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

**There were no findings in this area in the initial IRRS mission.**

### 6.1.3. BASES FOR REVIEW AND ASSESSMENT

**There were no findings in this area in the initial IRRS mission.**

### 6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

**There were no findings in this area in the initial IRRS mission.**

## 6.2. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

**There were no findings in this area in the initial IRRS mission.**

## 6.3. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

**There were no findings in this area in the initial IRRS mission.**

## 6.4. REVIEW AND ASSESSMENT FOR TRANSPORT

**There were no findings in this area in the initial IRRS mission.**

# 7. INSPECTION

## 7.1. GENERIC ISSUES

**There were no findings in this area in the initial IRRS mission.**

### 7.1.1. INSPECTION PROGRAMME

**There were no findings in this area in the initial IRRS mission.**

### 7.1.2. INSPECTION PROCESS AND PRACTICE

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *Inspectors do not make independent tests and measurements during the inspections to verify compliance with the regulatory requirements and conditions of authorization.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 29 para. 4.53 states that** "*In conducting inspections, the regulatory body shall consider a number of aspects, including:*<br>• *Structures, systems and components and materials important to safety;*<br>• *Management systems*<br>• *Operational activities and procedures;*<br>• *Records of operational activities and results of monitoring;*<br>• *Liaison with contractors and other service providers;*<br>• *Competence of staff;*<br>• *Safety culture;*<br>*Liaison with the relevant organization for joint inspections, where necessary*." |
| **R15** | **Recommendation: Inspectors should conduct tests and measurements as appropriate for independent verification of safety of facilities and activities.** |

**Changes since the initial IRRS mission**

**Recommendation R15:** Due to the lack of sufficient equipment within the EI, the previous practice of EB accompanying EI in order to make measurements during inspections is continued basically for independent verification during inspection of most of the high-risk facilities and activities in order to make the necessary measurements. The IRRS review team noted that measurements taken are also described in the inspection report. A possibility for signing agreement between EB and EI regarding use of EB`s equipment has also been considered. The IRRS review team was informed that EI staff involvement in refreshment trainings organized by EB has been increased over the years.

The IRRS review team noted that a decision has been taken by the Ministry of Environment to merge the EB and EI, which is yet to be endorsed by parliament, as discussed in S3 section 3.3. Following such a merge, optimization of resources is envisaged by the EB and EI to ensure that EI staff will be able to use the inspection equipment already available in the EB.

A strategy plan of inspection has been developed which indicates obtaining inspection equipment and continuous training of inspectors as main priorities. The draft NRSDP includes, in its financial requirements, an allocation of resources for purchasing equipment for the EI by 2020. The NRSDP also foresees allocation of dedicated inspectors in the EI for radiation safety.

**Status of the finding in the initial mission**

**Recommendation R15 is closed on the basis of progress and confidence in effective completion,** as strategy plan of inspection has been developed to ensure availability of adequate equipment to EI and draft NRSDP foresees allocation of financial resources to the EI for purchasing equipment.

### 7.1.3. INSPECTORS

**There were no findings in this area in the initial IRRS mission.**

## 7.2. INSPECTION OF WASTE MANAGEMENT FACILITIES

**There were no findings in this area in the initial IRRS mission.**

## 7.3. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** For the purpose of the inspection planning, the inspection frequency is established based on facility risk levels (high risk – annually, moderate risk – every 2-3 years, low risk – every 5 years); past performance of the licensees, and completeness of information received. However, the established frequency of inspections in the inspection programme is not always achieved. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 29 states 4.50 that** *"The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach."* |
| **R16** | **Recommendation: The Environmental Inspectorate should ensure that inspection is conducted in all facilities and activities in accordance with the established frequency of inspection in its inspection programme.** |

**Changes since the initial IRRS mission**

**Recommendation R16:** The EI Strategy plan of inspection has provisions to create a Radiation Safety Working Group of 4 inspectors and a chief inspector to focus on inspections of high and moderate risk facilities in 2019, and on small risk facilities in 2020. The IRRS review team noted that timelines of the strategy plan of inspection will be adjusted due to the postponed merging of EB and EI as discussed in S3 in section 3.3. The strategy plan also stipulates that the frequency of planned inspections has to be in accordance with international recommendations.

The strategy plan of inspection analyses the reasons why established frequency of inspection in EI's inspection programme was not being implemented and provides strategic solution. For example, to ensure the optimal use of EI human resources and to ensure the implementation of inspections, it is necessary to ensure specialization of dedicated EI inspectors to radiation safety area. The strategy plan will be reviewed by 2020 and required changes will be incorporated as necessary. For more effective regulatory control in radiation safety, the draft NSRDP also considers to increase the competence of inspectors by appointing inspectors specialised in the field of radiation within the EI.

The IRRS review team was informed that in practice, EI carries out inspection of high risk and moderate risk practices within the determined frequency, however, EI still faces challenge for inspecting all the small risk practices with the set frequency of once every 5 years.

**Status of the finding in the initial mission**

**Recommendation R16 is closed on the basis of progress and confidence in effective completion,** as strategy plan has been established by EI and it foresees the priorities, the actions and the performance indicators for the improvement of inspection to ensure that the inspection programme is implemented.

## 7.4. INSPECTION OF TRANSPORT

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *The Environmental Inspectorate does not conduct inspection of transport activities.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 27 states that** "*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."* |
| **(2)** | **BASIS: SSR-6, para 307 states that** *"The competent authority shall assure compliance with these Regulations."* |
| **R17** | **Recommendation: The Environmental Inspectorate should include in the inspection programme and conduct inspection of carriers who are authorized by the Environmental Board to carry out transport activities.** |

**Changes since the initial IRRS mission**

**Recommendation R17:** Inspection of transport activities has been included since 2017 in the annual inspection plan of the EI. The EI also provided the IRRS review team with examples of inspections that has been conducted in relation to transport activities. An internal procedure, *Control guidelines for transport of radioactive material*, has been developed which describes the overall control of transport activities. The guideline includes details of the issues and areas that need to be verified during inspection of transport activities and requires that any non-compliances with regulatory requirements be reported to the EB.

**Status of the finding in the initial mission**

**Recommendation R17 is closed,** as the EI has included in its inspection program and is conducting inspection of transport activities.

# 8. ENFORCEMENT

## 8.1. ENFORCEMENT POLICY AND PROCESS

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *The Environmental Inspectorate has generic guidelines for imposing fines but does not have an enforcement policy and documented criteria for taking corrective actions in response to non-compliance with regulatory requirements.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 30, states that** *"The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization."* |
| **(2)** | **BASIS: GSR Part 1 Requirement 30, para. 4.58 states that** *"The regulatory body shall establish criteria for corrective actions, including enforcing the cessation of activities or the shutting down of a facility where necessary."* |
| **R18** | **Recommendation: The Environmental Inspectorate should establish an enforcement policy and documented criteria for taking corresponding corrective actions commensurate with the gravity of the non-compliance.** |

**Changes since the initial IRRS mission**

**Recommendation R18:** The EI has developed penalty matrix, adopted in October 2016, to cover all relevant circumstances that have to be taken into account, such as, for example, repeatability of the offence and impact on the environment, when making decision on an enforcement action.

A set of internal guidelines for imposing penalties was established by the EI in 2018 in order to ensure consistency in enforcement actions across similar non-compliances with regulatory requirements and to ensure traceability of the enforcement action. These guidelines are applicable to all the areas supervised by the EI, including radiation safety.

Quality control of an inspector`s decisions is carried out by the chief inspector annually, including assessment of inspection protocols and discussion of necessary improvements, and results are discussed directly with inspectors. In addition, enforcement decisions are reviewed by the legal department of EI.

**Status of the finding in the initial mission**

**Recommendation R18 is closed,** as the EI has developed an enforcement policy including a set of internal guidelines for imposing penalties and a sanction matrix.

**New observation from the follow-up mission**

Although EI has developed general set of internal guidelines for imposing penalties and penalty matrixes that cover different ranges of fines and cessation of activities, there is no criteria for determining conditions and deadlines for taking corrective actions in response to a non-compliance discovered during inspection. The non-compliances are described in an inspection report and deadline for corrective action

is assigned by the inspector on a case by case basis, which could potentially lead to inconsistent application of enforcement actions.

| FU MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *The internal guidelines of the Environmental Inspectorate for imposing penalties do not contain criteria for determining conditions and deadlines for taking corrective actions in response to non-compliance.* | |
| **(1)** | **BASIS: GSR Part 1 (Rev. 1) Requirement 30, para. 4.58 states that** *"The regulatory body shall establish criteria for corrective actions, including enforcing the cessation of activities or the shutting down of a facility where necessary."* |
| **SF3** | **Suggestion: The Environmental Inspectorate should consider establishing documented criteria for taking corrective actions in response to non-compliance.** |

## 8.2. ENFORCEMENT IMPLEMENTATIONS

**There were no findings in this area in the initial IRRS mission.**

# 9. REGULATIONS AND GUIDES

## 9.1. GENERIC ISSUES

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *The existing guides do not cover specific activities involving radiation sources such as nuclear medicine, radiotherapy, the use of unsealed sources, and source in research. There are no guides are issued by the Environmental Board to facilitate compliance with regulatory requirements for decommissioning and waste management facilities and activities.* | |
| **(1)** | **BASIS: GSR Part 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."* |
| **S10** | **Suggestion: The Environmental Board should consider establishing and adopting regulatory guides that cover all facilities and activities.** |

**Changes since the initial IRRS mission**

**Suggestion S10:** EB has developed guides for dentists for assessing doses for the workers and the public (issued in 2018) and has drafted Guides for x-ray measurements (expected to be issued by June 2019). The IRRS review team was informed that EB plans to establish guidance for applicants applying for a license for practices such as conventional radiology, nuclear medicine, veterinary and sources in research.

The EB has produced a guidance material for the radioactive waste management facility on decommissioning. The IRRS review team was informed that this guide was developed in 2012 specifically for the decommissioning of the Tammiku radioactive waste facility.

The IRRS review team noted that at the moment EB has prioritized on the development of internal guidelines for review and assessment of applications, and guides for applicants and licensees are planned to be developed afterwards. Nevertheless, this plan was not included in the development plan of the EB.

**Status of the finding in the initial mission**

**Suggestion S10 is open,** as regulatory guides that cover all facilities and activities are not yet established.

## 9.2. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *There is lack of explicit provisions related to the overall responsibilities of the operator for consistency with GSR Part 5.* | |
| **(1)** | **BASIS: GSR Part 5 Requirement 4 states that** *"Operators shall be responsible for the safety of predisposal radioactive waste management facilities or activities. The operator shall carry out safety assessments and shall develop a safety case, and shall ensure that the necessary activities for siting, design, construction, commissioning, operation, shutdown and decommissioning are carried out in compliance with legal and regulatory* |

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| | *requirements".* |
| **R19** | **Recommendation: The Ministry of Environment should amend the regulatory framework on predisposal management of radioactive waste to establish explicit provisions related to the overall responsibilities of the operator.** |

**Changes since the initial IRRS mission**

**Recommendation R19:** The overall responsibilities of the operator are included in the Radiation Act, which assigns liability for safety to holders of radiation practice licenses, including radioactive waste management facilities.

The IRRS review team was provided with examples of licenses issued to the radioactive waste management facility for radioactive waste management and for decommissioning. The Radiation Act, and the license for radioactive waste management provided under this Act, assign the overall responsibilities of the operator for radioactive waste management.

**Status of the finding in the initial mission**

**Recommendation R19 is closed,** as the Radiation Act has been amended and includes provisions for the overall responsibilities of the operator of radioactive waste management.

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *Waste acceptance criteria for disposal of radioactive waste are not established.* | |
| **(1)** | **BASIS: GSR Part 5 Requirement 6 states that** *"Interdependences among all steps in the predisposal management of radioactive waste, as well as the impact of the anticipated disposal option, shall be appropriately taken into account."* |
| **(2)** | **BASIS: GSR Part 5 Requirement 6, para. 3.21 states that** *"Owing to the interdependences among the various steps in the predisposal management of radioactive waste, all activities from the generation of radioactive waste up to its disposal, including its processing, are to be seen as parts of a larger entity, and the management elements of each step have to be selected so as to be compatible with those of the other steps. This has to be achieved principally through governmental and regulatory requirements and approaches. It is particularly important to consider the established acceptance criteria for disposal of the waste or the criteria that are anticipated for the most probable disposal option."* |
| **S11** | **Suggestion: The Environmental Board should consider ensuring the development by the operator of appropriate waste acceptance criteria for the disposal of radioactive waste.** |

**Changes since the initial IRRS mission**

**Suggestion S11:** The EB recognizes the need for establishing waste acceptance criteria for the disposal facility and, according to the draft NPRWM, waste acceptance criteria will be developed during the construction process of the radioactive waste disposal facility, which is envisaged by 2025.
Based on the decision in 2016 to build a final disposal facility for radioactive waste by 2040, the draft NRSDP identifies the need for reviewing and updating the legislation regarding radioactive waste management, decommissioning and associated activities. The IRRS review team was informed that legislative changes on radioactive waste management and decommissioning should be in place by 2025 according to the draft NRSDP.

**Status of the finding in the initial mission**

**Suggestion S11 is open,** as waste acceptance criteria for the disposal of radioactive waste are not established yet**.**

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *Site selection activities for disposal facility have been started. However, there are gaps in the regulatory framework in respect of site selection for radioactive waste disposal facility.* | |
| **(1)** | **BASIS: SSR-5 Requirement 3 states that** *"The operator of a disposal facility for radioactive waste shall be responsible for its safety. The operator shall carry out safety assessment and develop and maintain a safety case, and shall carry out all the necessary activities for site selection and evaluation, design, construction, operation, closure and, if necessary, surveillance after closure, in accordance with national strategy, in compliance with the regulatory requirements and within the legal and regulatory infrastructure".* |
| **R20** | **Recommendation: The Ministry of Environment should establish requirements for site selection for radioactive waste disposal facility in line with SSR-5.** |

**Changes since the initial IRRS mission**

**Recommendation R20:** Requirements for site selection for the radioactive waste disposal facility have not yet been established. However, the Ministry of Environment recognizes the need of having the requirements in place and based on the decision to build a final disposal facility for radioactive waste by 2040, the draft NRSDP identifies the need for reviewing and updating the legislation regarding radioactive waste management, decommissioning and associated activities. For site selection, the IRRS review team was informed that it may also be necessary to amend other legislation like the Environmental Impact Assessment and Environmental Management System Act, and the Building Code.

According to the draft NPRWM, the studies for site location are expected to be completed by 2023. The results of the studies are expected to be used for establishing requirements for site selection.

The IRRS review team was informed that legislative changes on radioactive waste management and decommissioning should be in place by 2025 according to the draft NRSDP.

**Status of the finding in the initial mission**

**Recommendation R20 is open,** the MoE has not yet established requirements for site selection of the radioactive waste disposal facility.

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *The existing regulatory requirements with regard to decommissioning are not fully compliant with the IAEA GSR Part 6.* | |
| **(1)** | **BASIS: GSR Part 6 Requirement 5 states that** *"The regulatory body shall regulate all aspects of decommissioning throughout all stages of the facility's lifetime, from initial planning for decommissioning during the siting and design of the facility, to the completion of decommissioning actions and the termination of authorization for decommissioning. The regulatory body shall establish the safety requirements for decommissioning, including requirements for management of the resulting radioactive waste, and shall adopt associated regulations and guides. The regulatory body shall also take actions to ensure that the regulatory requirements are met."* |
| **R21** | **Recommendation: The Ministry of Environment should review and update the regulatory framework on decommissioning of facilities to ensure its compliance with the GSR Part 6.** |

**Changes since the initial IRRS mission**

**Recommendation R21:** The regulatory framework on decommissioning of facilities has not yet been updated. Both the MoE and the EB recognize the need of having a fully updated regulatory framework in place, and the analysis of requirements needed for decommissioning (including decommissioning plan) of radiation facilities, is one of the planned activities described in the draft NRSDP. The IRRS review team was informed that in order to establish radiation safety requirements for decommissioning and, if necessary, to introduce additional definitions in to the Radiation Act, analysis needs to be carried out on the basis of international guidelines and best practice. The analysis is planned to be carried out during the first implementation period of the draft NRSDP (2018-2021).

The decommissioning activities of the reactor compartments at the former Paldiski nuclear site are planned to start after 2040 according to the NPRWM.

**Status of the finding in the initial mission**

**Recommendation R21 is open,** since the MoE has not yet updated the regulatory framework on decommissioning of facilities.

### 9.3. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *The current regulations for radiation safety do not fully address the requirements of GSR Part 3.* | |
| **(1)** | **BASIS: GSR Part 1 Rev 1 Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained."* |

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **R22** | **Recommendation: The Ministry of Environment should update the existing regulatory requirements for radiation safety in accordance with GSR Part 3.** |

**Changes since the initial IRRS mission**

**Recommendation R22:** The regulations *"Limits for effective doses of exposed workers and members of the public, and limits for equivalent doses of the lens of the eye, the skin and extremities"* issued in November 2016 establish dose limits to the lens of the eyes for an exposed worker, apprentices and students in accordance with GSR Part 3. The IRRS review team was informed that the variation in the validity period of the licenses as provided in the Radiation Act which, along with the internal guidelins and the KOTKAS system discussed in R2, introduced graded approach in the authorization process.

The legislative framework does not explicitly provide for a requirement on notification to the regulatory body from person or organization intending to operate a facility or to conduct an activity. However, in practice, all radiation practices, which are not exempted from authorization, including the low risk practices that are provided an authorization without validity limit, should get a radiation practice license to operate a facility or conduct an activity. Therefore, receiving application for a practice license is considered as a notification to EB.

**Status of the finding in the initial mission**

**Recommendation R22 is closed on the basis of progress and confidence in effective completion,** as the the requirements for graded approach in authorization have been introduced and the requirements for dose limits to the lens of the eye have been updated to be in line with GSR Part 3. Guidelines for the authorization process are also being developed.

## 9.4. REGULATIONS AND GUIDES FOR TRANSPORT

**. There were no findings in this area in the initial IRRS mission.**

## 10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

### 10.1. GENERAL EPR REGULATORY REQUIREMENTS

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *The existing requirements for EPR are not fully consistent with the requirement of GSR Part 7. Legislation does not define emergency preparedness categories, which is the basis for implementation of the graded approach for EPR. There are no sufficient regulatory requirements for the licensee to develop a hazard assessment to be the basis of its EPR planning.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained."* |
| **R23** | **Recommendation: The Government should ensure that appropriate regulations or guidance documents are developed and implemented for the application of GSR Part 7 in Estonia.** |
| **(2)** | **BASIS: GSR Part 7 Requirement 4, para 4.19 states that** *"For the purposes of these safety requirements, assessed hazards are grouped in accordance with the emergency preparedness categories shown in Table 1. The five emergency preparedness categories (hereinafter referred to as 'categories') in Table 1 establish the basis for a graded approach to the application of these requirements and for developing generically justified and optimized arrangements for preparedness and response for a nuclear or radiological emergency."* |
| **R24** | **Recommendation: The Government should specify the five emergency preparedness categories in order to achieve a harmonized graded approach and for developing generically justified and optimized arrangements for preparedness and response to radiological emergencies.** |
| **(3)** | **BASIS: GSR Part 7 Requirement 4, para 4.18 states that** *"Hazards shall be identified and potential consequences of an emergency shall be assessed to provide a basis for establishing arrangements for preparedness and response for a nuclear or radiological emergency. These arrangements shall be commensurate with the hazards identified and the potential consequences of an emergency."* |
| **R25** | **Recommendation: The Ministry of Environment should establish requirements for licensees to develop and update hazard assessments relevant to their facilities and activities.** |

**Changes since the initial IRRS mission**

**Recommandation R23 :** One of the strategic objectives of the NRSDP is to improve emergency preparedness and response. To enhance emergency preparedness, the NRSDP also includes estimated

costs for the implementation of trainings; acquiring and maintaining equipment; and the establishment of the new Emergency Response Plans (HOLP) in the period 2018-2021.

The Regulation of the Ministry of Environment on "Detailed requirements for applications for radiation practice licences, lists of data of applications and radiation practice licences, and lists of data characterising radiation sources used to keep lists of nuclear materials No. 60" (last amended on 09-02-2019) describes in detail the requirements for the composition of the emergency response plan of high risk radiation practices. However, requirements for high risk radiation practices to classify emergencies are not in place.

Some provisions in the Radiation Act related to "Intervention and Implementation of Protective Measures" are not in compliance with GSR Part 7, and generic intervention levels, based on the avertable equivalent or effective dose are still in use. Generic criteria for taking protective actions and other response actions, expressed in terms of projected dose or of dose that has been received, are not developed in line with generic criteria in GSR Part 7. Protective actions described in the document *National Emergency Risk Assessment for Radiological and Nuclear Emergencies (2018)* are applied on the basis of Generic intervention levels and are not in line with IAEA Safety Standards' recommendation to use Generic criteria, which are based on projected or received dose. Operational intervention levels (OIL-s) for initiating the emergency response and taking protective and other response actions need renewal, as OIL-s described in the national radiological emergency response plan are not sufficient.

Generic criteria for enabling a transition from the emergency exposure situation to an existing exposure situation are not established explicitly in the Radiation Act. Arrangements for the transition phase are also not described explicitly in the regulations.

**Recommandation R24:** The government has developed and issued a document on the *National Emergency Risk Assessment for Radiological and Nuclear Emergencies*. Five emergency preparedness categories (EPC) are defined in this document in line with GSR Part 7.

**Recommendation R25:** According to the "Regulation on detailed requirements for applications for radiation practice licences, lists of data of applications and radiation practice licences, and lists of data characterising radiation sources used to keep lists of nuclear materials N. 60", radiation safety assessment includes the following important topics for hazard assessments of the relevant facilities and activities:

1) analysis of safe use of the radiation source in all stages of the planned radiation practice, starting from the installation of the source to the termination of use thereof;
2) projected dose to exposed workers and members of the public both under normal working conditions and in case of accidental and existing exposure situations;
3) analysis of accidental and existing exposure situations related to the use of a radiation source;
4) information on actions to be taken to ensure radiation safety both under normal operating conditions and in case of emergency exposure situation and in existing exposure situations.

However, the requirements for the licensee of a high-risk practices to develop hazard assessment, which is the basis of on-site EPR planning, are not sufficiently addressed. The IRRS review team noted that EB has planned to further develop the requirements on hazard assessment for the on-site EPR planning.

**Status of the finding in the initial mission**

**Recommendation R23 is open,** as the basic requirements of GSR Part 7, essential for appropriate emergency preparedness planning and response, are not fully addressed in the legal framework.

**Recommendation R24 is closed,** as the five emergency categories have been defined.

**Recommendation R25 is closed on the basis of progress and confidence in effective completion,** as radiation safety assessment includes the important topics for hazard assessments of the relevant facilities and activities, and EB has planned to further develop the requirements.

## 10.2. FUNCTIONAL REGULATORY REQUIREMENTS

### Establishing emergency management system and operations

**There were no findings in this area in the initial IRRS mission.**

### Identifying, notifying and activating

**There were no findings in this area in the initial IRRS mission.**

### Taking migratory actions

**There were no findings in this area in the initial IRRS mission.**

### Taking urgent protective action

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *Based of the hazard assessment of transboundary emergency Estonia is considered as falling in emergency preparedness category V. For coordinating the response, taking protection actions and other response actions and for providing mutual support, emergency planning distances need to be established.* | |
| **(1)** | **BASIS: GSR Part 7 Requirement 6, para 5.39 states that** *"Within the emergency planning zones and emergency planning distances, arrangements shall be made for taking appropriate protective actions and other response actions effectively, as necessary, promptly upon the notification of a nuclear or radiological emergency. …The arrangements shall be coordinated with all jurisdictions (including, to the extent practicable, jurisdictions beyond national borders, where relevant) within any emergency planning zone or distance."* |
| **R26** | **Recommendation: The Government should establish and ensure the implementation of emergency planning distances for emergency response category V.** |

**Changes since the initial IRRS mission**

The emergency planning distances for the emergency preparedness category V have been established in the document *National Emergency Risk Assessment for Radiological and Nuclear Emergencies* and are being implemented.

**Status of the finding in the initial mission**

**Recommendation R26 is closed,** as Emergency planning distances for emergency preparedness category V have been established and implemented.

**Providing information and issuing instructions**

**There were no findings in this area in the initial IRRS mission.**

**Protecting emergency workers**

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *The criteria to designate workers as emergency workers are not established in legislation and arrangements to protect emergency workers are not in place.* | |
| **(1)** | **BASIS: GSR Part 7 Requirement 5.49 states that** *"Arrangements shall be made to ensure that emergency workers are, to the extent practicable, designated in advance and are fit for the intended duty. These arrangements shall include health surveillance for emergency workers for the purpose of assessing their initial fitness and continuing fitness for their intended duties."* |
| **(2)** | **BASIS: GSR Part 3 Requirement 4.5 states that** *"The emergency management system shall provide for essential elements at the scene, and at the local, national and international level, as appropriate, including the following:… (g) Arrangements for the protection of emergency workers."* |
| **R27** | **Recommendation: The Government should establish criteria for designating in advance emergency workers, including making arrangements for their protection.** |

**Changes since the initial IRRS mission**

**Recommendation R27:** Training of radiation workers is organized on the basis of the regulations "Requirements for radiation safety training for exposed workers and radiation safety officers No. 57", adopted by the Ministry of Environment (amended in 2018). Basic training program for exposed workers includes topics about emergency preparedness and response, including designating in advance emergency workers. The training of the emergency workers at the operating facilities, is based on the same training program. Emergency workers, designated in advance, at the operating facilities have appropriate specialized protective equipment and monitoring equipment.

Implementation of managing, controlling and recording doses received by on site emergency workers during emergency situations are not currently separated in the national dose register. However, initiatives and arrangements to achieve that are currently in progress.

The longer-term medical actions and psychological counselling of emergency workers are not yet arranged. However, the National Emergency Risk Assessment for Radiological and Nuclear Emergencies (2018) includes provisions on the necessity to develop psychological counselling service to emergency workers, which is the responsibility of MoSA.

**Status of the finding in the initial mission**

**Recommendation R27 is closed on the basis of progress and confidence in effective completion,** as the steps to solve the implementation of managing, controlling and recording doses received by onsite emergency workers during emergency situations are taken. MoSA was appointed to be responsible for the area of longer-term medical actions and psychological counselling of emergency workers but arrangements are not in place yet.

**Assessing the initial phase**

**There were no findings in this area in the initial IRRS mission.**

**Managing the medical response**

**There were no findings in this area in the initial IRRS mission.**

**Other activities in emergency preparedness**

**There were no findings in this area in the initial IRRS mission.**

## 10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE

**There were no findings in this area in the initial IRRS mission.**

**Organization**

**There were no findings in this area in the initial IRRS mission.**

**Coordination of emergency response**

**There were no findings in this area in the initial IRRS mission.**

**Plans and procedures**

**There were no findings in this area in the initial IRRS mission.**

**Logistical support and facilities**

**There were no findings in this area in the initial IRRS mission.**

### Training, drills and exercises

**There were no findings in this area in the initial IRRS mission.**

### Quality management programme

**There were no findings in this area in the initial IRRS mission.**

## 10.4. ROLE OF REGULATORY BODY DURING RESPONSE

**There were no findings in this area in the initial IRRS mission.**

# 11. ADDITIONAL AREAS

## 11.1. CONTROL OF MEDICAL EXPOSURES

- **Regulatory framework and responsibilities**

**There were no findings in this area in the initial IRRS mission.**

- **Justification of medical exposure**

**There were no findings in this area in the initial IRRS mission**

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *Standardized procedure for the generic justification of medical radiological procedures and new techniques and technologies as well as provisions for the justification of health screening programs and for asymptomatic individuals undergoing medical radiological procedures are not in place. Ethics committee approval for medical exposure of volunteers as part of a programme of biomedical research is not explicitly required.* | |
| **(1)** | **BASIS: GSR Part 3 Requirement 37, Justification of medical exposures states that** *"Relevant parties shall ensure that medical exposures are justified."* |
| **R28** | **Recommendation: The Government should ensure that generic justification of medical radiological procedures including for new techniques and technologies is carried out, and health screening and biomedical research programmes as well as medical radiological procedures conducted to asymptomatic individuals are justified.** |

**Changes since the initial IRRS mission**

**Recommendation R28:** The Radiation Act, amended in 2018, introduced requirements for the justification of radiation practices. Moreover, the regulations "*Radiation safety requirements for medical radiological procedures, clinical audit requirements for medical radiological procedures, and diagnostic reference levels and requirements for determination thereof"* (Regulation No. 71) issued by MoSA provides for the justification of medical radiological procedures for an individual patient, for health screening programs and biomedical research programmes; as well as of medical radiological procedures conducted to asymptomatic individuals, in line with GSR Part 3.

**Status of the finding in the initial mission**

**Recommendation R28: is closed,** as requirements for the justification of medical exposure for an individual patient and for the justification of health screening and biomedical research programmes as well as medical radiological procedures conducted to asymptomatic individuals are established.

**New observations from the follow-up mission**

Regulatory requirements or standardised procedures for the generic justification of medical radiological procedures, including new technologies and techniques, are not established. Requirements for health

technologies assessment are established by the Health Service Organization Act, but mainly relate to reimbursement purposes.

| FU MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *Generic justification of a radiological procedure, including new technologies and techniques is carried out only when related to compensation purposes.* | |
| **(1)** | **BASIS: GSR Part 3 Requirement 37, para. 3.156 states that** *"Generic justification of a radiological procedure shall be carried out by the health authority in conjunction with appropriate professional bodies, and shall be reviewed from time to time, with account taken of advances in knowledge and technological developments."* |
| **(2)** | **BASIS: GSR Part 3 para. 1.14 states that** *"The application of the justification principle to medical exposures requires a special approach. As an overarching justification of medical exposures, it is accepted that the use of radiation in medicine does more good than harm. However, at the next level, there is a need for generic justification, to be carried out by the health authority in conjunction with appropriate professional bodies, of a given radiological procedure. This applies to the justification of new technologies and techniques as they evolve…"* |
| **RF2** | **Recommendation: The Ministry of Social Affairs should ensure that generic justification of a radiological procedure, including for new techniques and technologies is carried out and is reviewed whenever deemed necessary.** |

- **Optimization of medical exposure**

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *Diagnostic reference levels for medical imaging, including image guided interventional procedures and criteria and guidelines for the release of patients who have undergone therapeutic radiological procedures using unsealed sources or patients who still retain implanted sealed sources have not been established.* | |
| **(1)** | **BASIS: GSR Part 3 Requirement 34 states that** *"The government shall ensure that relevant parties are authorized to assume their roles and responsibilities, and that diagnostic reference levels, dose constraints, and criteria and guidelines for the release of patients are established."* |
| **R29** | **Recommendation: The Government should ensure that diagnostic reference levels and criteria and guidelines for the release of patients are established.** |

**Changes since the initial IRRS mission**

**Recommendation R29:** The Radiation Act delegates the responsibility for the establishment of Diagnostic Reference Levels (DRLs) to the HB and the Regulation 71 of MoSA sets the frequency for

their review on a 5-year basis. DRLs for three medical radiological procedures have been established and are published in Annex 1 of Regulation No. 71.

Moreover, Regulation No. 71 requires the licensee to establish criteria and guidelines for the release of patients and that these are documented in the facility's operating manual which is made available to the inspectors upon request. The IRRS review team noted that EB plans to exercise its regulatory oversight, by including to its internal guidelines for review and assessment elements relating to the proper use of the established DRLs as an optimization tool for medical exposures and to the actual implementation of the established criteria and guidelines for the release of patients.

**Status of the finding in the initial mission**

**Recommendation R29: is closed**, as the regulatory framework explicitly delegates to specific entities the responsibility for the establishment of diagnostic reference levels, criteria and guidelines for the release of patients, and their establishment has been commenced.

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *A person authorized by the manufacturer of medical radiological equipment may perform acceptance and quality control measurements on behalf of the licensee, while not under the supervision of or without the documented advice a medical physicist.* | |
| **(1)** | **BASIS: GSR Part 3 Requirement 38, para. 3.171 states that** *"Registrants and licensees shall ensure that programmes of quality assurance for medical exposure include, as appropriate to the medical radiation facility:*<br>*(a) Measurements of the physical parameters of medical radiological equipment made by, or under the supervision of, a medical physicist:*<br>*(i) At the time of acceptance and commissioning of the equipment prior to its clinical use on patients;*<br>*(ii) Periodically thereafter;*<br>*(iii) After any major maintenance procedure that could affect protection and safety of patients;*<br>*(iv) After any installation of new software or modification of existing software that could affect protection and safety of patients.*<br>*(b) ... (c)... (d)...* |
| **(2)** | **BASIS: GSR Part 3 Requirement 38, para. 3.167 states that** "*In accordance with para. 3.154 (d) and (e), the medical physicist shall ensure that:*<br>*(a) All sources giving rise to medical exposure are calibrated in terms of appropriate quantities using internationally accepted or nationally accepted protocols;*<br>*(b) Calibrations are carried out at the time of commissioning a unit prior to clinical use, after any maintenance procedure that could affect the dosimetry and at intervals approved by the regulatory body;*<br>*(c) Calibrations of radiation therapy units are subject to independent verification prior to clinical use;*<br>*(d) Calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standards dosimetry laboratory."* |
| **R30** | **Recommendation: The Ministry of Social Affairs should establish requirements that** |

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| | **the calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, are undertaken by medical physicists or under the oversight of or with the documented advice of a medical physicist.** |

**Changes since the initial IRRS mission**

**Recommendation R30:** In the amendment of the Radiation Act, requirements for the medical physics expert (MPE) have been established in line with GSR Part 3, which include requirements for the calibration, dosimetry and quality assurance of medical radiological equipment, to be undertaken by medical physicists or under their oversight. Moreover, Regulation No. 71 sets out the requirements for the involvement of a Medical Physics Expert (MPE) in medical radiological procedures and, inter alia, provides that the acceptance and commissioning of medical radiological equipment should be performed by a MPE.

**Status of the finding in the initial mission**

**Recommendation R30 is closed**, as requirements for the calibration, dosimetry and quality assurance of medical radiological equipment, to be undertaken by medical physicists or under their oversight are established.

- **Pregnant women and breast feeding women**

**There were no findings in this area in the initial IRRS mission.**

- **Release of patients after radionuclide therapy**

**There were no findings in this area in the initial IRRS mission.**

- **Unintended and accidental medical exposures**

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *Provisions for the prompt investigation of unintended or accidental medical exposures and the implementation of any appropriate corrective actions are not in place.* | |
| **(1)** | **BASIS: GSR Part 3 Requirement 41 states that** *"Registrants and licensees shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures. Registrants and licensees shall promptly investigate unintended or accidental medical exposures and, if appropriate, shall implement corrective actions.* |
| **R31** | **Recommendation: The Ministry of Social Affairs should establish requirements for the prompt investigation and implementation of appropriate corrective actions, and reporting for significant unintended or accidental medical exposures or as otherwise required.** |

**Changes since the initial IRRS mission**

**Recommendation R31:** Regulation No. 71 sets out the requirements for the documentation, prompt investigation and implementation of appropriate corrective actions for unintended and accidental exposures, and also requires that concerned persons be informed by the holder of the radiation practice license. Nevertheless, there is no guidance available to clarify whether competent authorities are included in the concerned persons or guidance on the reporting procedure for significant unintended and accidental exposures. The IRRS review team was informed that Estonia is participating in a regional IAEA technical cooperation project on "Enhancing Member States' Capabilities for Ensuring Radiation Protection of Individuals Undergoing Medical Exposure" and reporting procedures will be developed and implemented based on the 'Task 3' outcomes of the project.

**Status of the finding in the initial mission**

**Recommendation R31 is closed on the basis of progress and confidence in effective completion**, as requirements for the prompt investigation and for the implementation of appropriate corrective actions for unintended and accidental exposures are established and plans are made for finalisation of guidelines for reporting significant unintended or accidental medical exposures.

- **Reviews and records**

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *Licensees are not required to maintain records of any delegation of responsibilities by a principal party.* | |
| **(1)** | **BASIS: GSR Part 3 Requirement 42, para. 3.183 states that** *"Registrants and licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following personnel records:*<br>*(a) Records of any delegation of responsibilities by a principal party (as required in para. 3.154(f));*<br>*(b) Records of training of personnel in radiation protection (as required in para. 3.150(b))".* |
| **R32** | **Recommendation: The Ministry of Social Affairs should establish requirements for the documentation of any delegation of responsibilities by a principal party.** |

**Changes since the initial IRRS mission**

**Recommendation R32:** Annex 2 of Regulation No. 71 includes information on the structure and contents of the licensees operating manuals. In accordance with these regulations, licensees are required to document in the operating manuals, inter alia, description of the work processes, including details of full or partial delegation of responsibility along with the scope of the delegation.

**Status of the finding in the initial mission**

**Recommendation R32 is closed,** as requirements for the documentation of any delegation of responsibilities by a principal party are established.

## 11.2. OCCUPATIONAL RADIATION PROTECTION

### 11.2.1. LEGAL AND REGULATORY FRAMEWORK

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *There are no explicitly established requirements for licensees to specify dose constraints for occupationally exposed workers, although dose constraints are considered during the licensing process. The Radiation Act contains some provisions on dose constraints for the public. However, it does not cover fully the requirements of GSR Part 3 regarding dose constraints and optimization.* | |
| **(1)** | **BASIS: GSR Part 3 Requirement 11 states that** *"The government or the regulatory body shall establish and enforce requirements for the optimization of protection and safety, and registrants and licensees shall ensure that protection and safety is optimized."* |
| **(2)** | **BASIS: GSR Part 3 Requirement 11, para. 3.122 states that** *"Before authorization of a new or modified practice, the regulatory body shall require the submission of, and shall review, the safety assessments and other design related documents from the responsible parties that address the optimization of protection and safety, the design criteria and the design features relating to the assessment of exposure and potential exposure of members of the public."* |
| **(3)** | **BASIS: GSR Part 3 Requirement 21, para.3.77 states that** *"Employers, registrants and licensees:*<br>*(a)*<br>*(b) Shall establish and use, as appropriate, constraints as part of optimization of protection and safety."* |
| **(4)** | **BASIS: GSR Part 3 Requirement 29, para. 3.120 states that** *"The government or the regulatory body shall establish or approve constraints on dose and constraints on risk to be used in the optimization of protection and safety for members of the public.* |
| **(5)** | **BASIS: GSR Part 3 Requirement 29, para. 3.22 states that** *"The government or the regulatory body:*<br>*(a) Shall establish and enforce requirements for the optimization of protection and safety;*<br>*(b) Shall require documentation addressing the optimization of protection and safety;*<br>*(c)Shall establish or approve constraints on dose and on risk, as appropriate, or shall establish or approve a process for establishing such constraints, to be used in the optimization of protection and safety."* |
| **(6)** | **BASIS: GSR Part 5 para. 2.6 states that** "*Requirements for radiation protection have to be established at the national level, .... radiation protection to be optimized for any persons who are exposed as a result of activities in the predisposal management of radioactive waste, with due regard to dose constraints, and require the exposures of individuals to be kept within specified dose limits."* |

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **(7)** | **BASIS: GSR Part 6 Requirement 1, para.2.1. states that** *"Radiation protection of persons who are exposed as a result of decommissioning actions shall be optimized with due regard to the relevant dose constraints."* |
| **S12** | **Suggestion: The Environmental Board should consider to require the licensee to specify appropriate dose constraints for occupationally exposed workers. The Ministry of Environment should consider to update the requirements for dose constraints to the public for consistency with GSR Part 3.** |

**Changes since the initial IRRS mission**

**Suggestion S12:** The Radiation Act sets out the requirements for the establishment of dose constraints for occupationally exposed workers and for the members of the public in the case of moderate and high risk radiation practices. Moreover, the amendment to the Regulation of the Minister of Environment "Specified requirements for application for radiation practice license, application and radiation practice forms and forms for characterizing radiation sources used for nuclear material accountancy" that entered into force in January 2019 also requires licensees to establish dose constraints for workers and members of the public.

**Status of the finding in the initial mission**

**Suggestion S12 is closed**, as the requirements to specify appropriate dose constraints for occupationally exposed workers are established and requirements for dose constraints to the public have been updated in line with GSR Part 3.

### 11.2.2. GENERAL RESPONSIBILITIES OF LICENSEES AND EMPLOYERS

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *In case where workers are exposed and receive doses above the legal limits, there is a requirement for the licensee to make an assessment of the dose. However, this requirement is not enacted in legislation.* | |
| **(1)** | **BASIS: GSR Part 3, Requirement 24, para. 3.102. states that** *"Employers shall ensure that workers who could be subject to exposure due to contamination are identified, including workers who use respiratory protective equipment. Employers shall arrange for appropriate monitoring to the extent necessary to demonstrate the effectiveness of the measures for protection and safety and to assess intakes of radionuclides and the committed effective doses."* |
| **S13** | **Suggestion: The Ministry of Environment should consider adding the requirement on the need for analyzing each situation leading to a dose above the legal limit in the Radiation Act.** |

**Changes since the initial IRRS mission**

**Suggestion S13:** Occupational Health and Safety Act sets out provisions relating to accidents and risks of accidents at workplaces. A situation leading to a dose above the legal limit defined in the Radiation Act, does not seem to fall within the scope of the Occupational Health and Safety Act, considering that accident is defined as "fire, explosion or another incident at a workplace which may endanger the life and health of employees and those of other persons". The IRRS review team noted that the MoE plans to include a requirement to the amendment of the Radiation Act in 2019, paragraph 32(1), concerning the need for analysis and the implementation of corrective actions whenever the legal limit is exceeded.

**Status of the finding in the initial mission**

**Suggestion S13 is closed on the basis of progress and confidence in effective completion,** as the Ministry of Environment plans to include this requirement in paragraph 32(1) of the amendment of the Radiation Act foreseen to enter into force in 2019.

### 11.2.3. GENERAL RESPONSIBILITIES OF WORKERS

**There were no findings in this area in the initial IRRS mission.**

### 11.2.4. REQUIREMENTS FOR RADIATION PROTECTION PROGRAMMES

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** There is no requirement in legislation that prohibits offering compensation for workers as substitute for measures for protection and safety. | |
| **(1)** | **BASIS: GSR Part 3, Requirement 27, states that** *"The employers, registrants and licensees shall not offer benefits as substitutes for measures for protection and safety."* |
| **R33** | **Recommendation: The Government should establish requirements in legislation to prohibit the offering of benefits as substitute for measures for protection and safety.** |

**Changes since the initial IRRS mission**

**Recommendation R33:** The IRRS review noted that the MoE plans to include, during the amendment of the Radiation Act in 2019, in paragraph 24, new provisions entitled "prohibition of proprietary or other advantage" that will address the offering of benefits as substitutes for measures for protection and safety. The team was provided with a draft text to be included in the amendment of the Radiation Act which states "the holder of a radiation practice license may not offer the employee any proprietary or other benefit in the event of non-use of radiation protection equipment or failure to comply with radiation safety requirements".

**Status of the finding in the initial mission**

**Recommendation R33 is closed on the basis of progress and confidence in effective completion,** as the MoE to add the given prohibition to the amendment of the Radiation Act foreseen to enter into force in 2019.

### 11.2.5. MONITORING PROGRAMMES AND TECHNICAL SERVICES

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *No individual monitoring is done for internal contamination of workers for activities in nuclear medicine.* | |
| **(1)** | **BASIS: GSR Part 3, Requirement 25, paragraph 3.102 states that** *"Employers shall ensure that workers who could be subject to exposure due to contamination are identified, including workers who use respiratory protective equipment. Employers shall arrange for appropriate monitoring to the extent necessary to demonstrate the effectiveness of the measures for protection and safety and to assess intakes of radionuclides and the committed effective doses."* |
| **R34** | **Recommendation: The Environmental Board should ensure that measures are taken by the employers or licensees to ensure appropriate monitoring of internal exposure.** |

**Changes since the initial IRRS mission**

**Recommendation R34:** The Radiation Act provides for the monitoring of individual doses, organised by the holder of a radiation practice licence, that must enable to assess or measure the individual doses incurred by intake of radionuclides for exposed workers who may incur significant exposure due to intake of radionuclides. Nevertheless, as also recognized in the NRSDP, the capacity to measure or to perform biological analysis for assessing radioactivity in the human body is not available in Estonia.

**Status of the finding in the initial mission**

**Recommendation R34 is open,** as measures have not been taken to ensure appropriate monitoring of internal exposure.

### 11.2.6. QUALIFIED EXPERTS AND RADIATION PROTECTION OFFICERS

**There were no findings in this area in the initial IRRS mission.**

## 11.3. CONTROL OF RADIOACTIVE DISCHARGES, MATERIALS FOR CLEARANCE, AND EXISTING EXPOSURES SITUATIONS; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION

**Control of radioactive discharges and materials for clearance**

**There were no findings in this area in the initial IRRS mission.**

**Environmental monitoring for public radiation protection**

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *The legal framework does not require that the regulatory body makes provisions for an independent monitoring programme. In practice however, the Environmental Board carries out monitoring independent of the licensees.* | |
| **(1)** | **BASIS: GSR Part 3 Requirement 32, para. 3.135 states that** *"The regulatory body shall be responsible, as appropriate, for:*<br>*(c) Making provision for an independent monitoring programme.*<br>*(d) Assessment of the total public exposure due to authorized sources and practices in the State on the basis of monitoring data provided by registrants and licensees and with the use of data from independent monitoring and assessments."* |
| **S14** | **Suggestion: The Government should consider establishing provisions in legislation for the regulatory body to perform an independent monitoring programme to ensure the continued independent verification on the operation of the facilities.** |

**Changes since the initial IRRS mission**

**Suggestion S14:** Although considerations for establishing provisions in the Radiation Act were made during the amendment of the Act, it was concluded that special provisions in the Act are not warranted since there are only two licensed practices that might pose a risk to the environment.

The EB's independent monitoring programme is included in the National Environmental Monitoring Programme, established by the amended Environmental Monitoring Act, which entered into force in January 2017. The National Environmental Monitoring Programme is adopted by the Minister of Environment. According to the Act, for monitoring points on private premises, there has to be an agreement with the party to do the monitoring. In case the party refuses an agreement, the State can establish enforced possession of an area needed for monitoring

There is an agreement between the EB and the facilities that the EB can perform independent monitoring on their premises. Should the agreement fail for some reason, there are sufficient provisions in the Radiation Act that would allow the EB or the EI to continue performing independent monitoring.

Currently, the EB's independent monitoring programme, which runs on a yearly basis, includes one facility.

**Status of the finding in the initial mission**

**Suggestion S14 is closed,** as provisions for independent monitoring programme are addressed in both the Radiation Act and in the Environmental Monitoring Act.

**Existing exposure situations**

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES |
|---|

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *Radon indoors has been identified as a concern for public health. However, a national action plan for radon is not yet in place.* | |
| **(1)** | **BASIS: GSR Part 3 Requirement 50, para. 5.20 states that** *"Where activity concentrations of radon that are of concern for public health are identified on the basis of the information gathered as required in para. 5.19(a), the government shall ensure that an action plan is established comprising coordinated actions to reduce activity concentrations of radon in existing buildings and in future buildings."* |
| **R35** | **Recommendation: The Government should ensure that a national radon action plan is established.** |

**Recommendation R35:** The Ministry of the Environment has prepared the draft National Radon Action Plan (NRAP) in cooperation with the EB. The plan comprises coordinated actions to reduce activity concentrations of radon in existing buildings and in future buildings, including reference levels. The plan also includes a list of radon related activities to be implemented. These activities include further research, information to the public and training of EI inspectors. The NRAP also includes other potential radon sources, such as drinking water.

The draft NRAP was finalized in January 2019. However, the NRAP is an Annex to the NRSDP and has to be officially approved at the same time as the NRSDP currently envisaged for June 2019.

**Changes since the initial IRRS mission**

**Recommendation R35 is closed on the basis of progress and confidence in effective completion,** as a draft NRAP has been developed and is expected to be promulgated by June 2019.

| 2016 RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *Exposure of aircrew due to cosmic radiation has been identified as receiving doses from occupational exposure to cosmic radiation but they have not yet been assessed.* | |
| **(1)** | **BASIS: GSR Part 3 Requirement 52, para. 5.30 states that** *"The regulatory body or other relevant authority shall determine whether assessment of the exposure of aircrew due to cosmic radiation is warranted."* |
| **R36** | **Recommendation: The Environmental Board or other relevant authority should determine whether assessment of the exposure of aircrew due to cosmic radiation is warranted.** |

**Recommendation R36:** According to the Radiation Act, amended in 2018, the EB is responsible to ensure the identification of all activities where natural radiation sources may cause exposers to workers or members of the public in excess of the effective dose limits established for members of the public. The Act includes requirements on measures for protection of air crew and spacecraft crew.

In 2018 the EB in cooperation with the regulatory body in the field of aviation, the Ministry of Economic Affairs and Communication, identified four Estonian aviation companies that have the longest high-altitude flights and contact has been established. One of the companies has declared that dose assessments are implemented by using special software and that doses are below 1 mSv per year for crew. The average duration of the flight segment is 1 h 40 min and the altitude range is mostly 11,900–12,500 m.

The IRRS review team was informed that another two of the identified companies have been further investigated by the EB and that the companies have similar flights for their air crew as the company that has performed dose assessments. The EB has decided to confirm the dose assessments and has included this activity in its workplan for 2019.

The EB also plans to continue the cooperation with the Ministry of Economic Affairs and Communication in order to identify new aviation companies where assessment of the exposure of aircrew due to cosmic radiation might be warranted. Also, the EB plans to keep contact with aviation companies on a regular basis to ask feedback about changes in their activities and dose assessment procedures to ensure that their activities are in compliance with the requirements of the Radiation Act.

**Status of the finding in the initial mission**

**Recommendation R36 is closed,** as the EB has implemented activities to identify those companies that should implement dose assessments.

# APPENDIX I LIST OF PARTICIPANTS

| | | | |
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# APPENDIX II MISSION PROGRAMME

## Follow-up IRRS Mission Estonia 3-9 March 2019

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<tr><th>Time</th><th>SUN – 3 March</th><th>MON – 4 March</th><th>TUE – 5 March</th><th>WED – 6 March</th><th>THU – 7 March</th><th>FRI – 8 March</th><th>SAT – 9 March</th></tr>
<tr><td>9:00-10:00</td><td rowspan="3"></td><td rowspan="2">Entrance Meeting</td><td rowspan="3">Interviews</td><td rowspan="2">TM write Report<br>TL and TC review introductory part</td><td>Discussion Counterpart/Expert</td><td>Written comments by the Host</td><td rowspan="2">Exit Meeting<br><br>Press release<br>Farewell</td></tr>
<tr><td>10:00-11:00</td><td rowspan="2">Finalisation of the Report</td><td rowspan="2">Finalisation of the Report</td></tr>
<tr><td>11:00-12:30</td><td>Interviews</td><td>Draft text to TL and Secretariat</td><td rowspan="11">Departure of Team Members</td></tr>
<tr><td>12:30-13:30</td><td></td><td>Lunch</td><td>Lunch</td><td colspan="2">Lunch</td><td>Lunch</td><td>Lunch</td></tr>
<tr><td rowspan="2">14:00-16:00</td><td></td><td rowspan="4">Interviews</td><td rowspan="2">Interviews</td><td rowspan="2">Secretariat edits the report</td><td rowspan="2">Cross-reading</td><td colspan="3">Submission of the Draft to the Host</td><td rowspan="2">Finalisation of the Report</td></tr>
<tr><td rowspan="2">Initial Team Meeting (Attended by the LO):<br>• IRRS process<br>• Main objectives<br>• Report writing<br>• Schedule<br>• First observations</td><td>Host reads Draft and prepares written comments</td><td>TL finalises the presentation</td><td>TC drafts the Press Release</td></tr>
<tr><td>16:00-17:00</td><td>Team deliver written preliminary findings</td><td colspan="2">Preliminary Draft Report Ready</td><td colspan="3" rowspan="2">TL and TC draft Executive Summary</td><td rowspan="2">Submitting the final Draft of the Report to the Host</td></tr>
<tr><td>17:00-18:00</td><td></td><td>Daily Team Meeting</td><td>Daily Team Meeting: Discussion of findings</td><td colspan="2" rowspan="3">Team Review Preliminary Draft Report</td></tr>
<tr><td>18:00-19:00</td><td></td><td rowspan="2">Dinner</td><td rowspan="2">Dinner</td><td colspan="3" rowspan="3">Dinner</td></tr>
<tr><td>19:00-20:00</td><td rowspan="2">Team Dinner</td><td rowspan="2">Dinner</td></tr>
<tr><td>20:00-</td><td>Writing of the report</td><td>Secretariat edits Report<br>TM write Report</td></tr>
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## APPENDIX III MISSION COUNTERPARTS

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|---|---|
| **RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT** | |
| Igor Sirc | Ilmar Puskar (EB)<br>Pavel Ojava (EI)<br>Reelika Runnel (MoE) |
| **GLOBAL SAFETY REGIME** | |
| Igor Sirc | Ilmar Puskar (EB)<br>Pavel Ojava (EI)<br>Reelika Runnel (MoE) |
| **RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY** | |
| Sasa Medakovic | Ilmar Puskar (EB)<br>Pavel Ojava (EI)<br>Reelika Runnel (MoE) |
| **MANAGEMENT SYSTEM** | |
| Sasa Medakovic | Ilmar Puskar (EB)<br>Pavel Ojava (EI)<br>Reelika Runnel (MoE)<br>Rainis Uiga (EB) |
| **AUTHORIZATION** | |
| Agnese Aizpuriete<br>Erica Brewitz<br>Teodros Hailu | Marily Jaska (EI)<br>Krista Saarik (MoE)<br>Karin Muru (EB)<br>Margit Kuulmann (EB) |
| EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS | |
| Danute Sidiskiene | Uko Rand (EB)<br>Teet Koitjärv (EB) |
| **CONTROL OF MEDICAL EXPOSURES** | |
| Da Stavroula Vogiatzi | Jelena Šubina (EB)<br>Madis Tõns (MSA)<br>Marina Lacis (EB) |
| **OCCUPATIONAL RADIATION PROTECTION** | |
| Da Stavroula Vogiatzi | Jelena Šubina (EB)<br>Madis Tõns (MSA)<br>Marina Lacis (EB) |

| CONTROL OF RADIOACTIVE DISCHARGES, MATERIALS FOR CLEARANCE, AND EXISTING EXPOSURES SITUATIONS; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION | |
|---|---|
| Erica Brewitz | Alar Polt (EB)<br>Monika Lepasson (EB) |

## APPENDIX IV RECOMMENDATIONS (R) AND SUGGESTIONS (S) FROM THE IRRS MISSION THAT REMAIN OPEN

| Section | Module | R/S | Recommendations/Suggestions |
|---|---|---|---|
| 1.5 | Module 1 | R4 | The Government should make provision and arrangements for effective coordination of the national authorities having regulatory responsibilities for radiation safety of facilities and activities. |
| 3.3. | Module 3 | R6 | The Environmental Board and Environmental Inspectorate should develop and implement a human resource plan to ensure the availability and competence of staff involved in regulatory functions. |
| 3.3. | Module 3 | R7 | The Environmental Inspectorate should ensure that adequate arrangements are made to build and maintain sufficient expertise in radiation safety. |
| 3.3. | Module 3 | S3 | The Ministry of Environment should consider to organize the radiation safety regulatory functions of authorization, inspection and enforcement in such a way that the functions are effectively performed by staff with sufficient expertise in radiation safety. |
| 4.2 | Module 4 | S5 | The Environmental Board and Environmental Inspectorate should consider to develop, within their respective organizations, all processes relevant to safety and ensure that all processes are documented in the management system. |
| 4.4 | Module 4 | R11 | The Environmental Board and Environmental Inspectorate should develop and implement documented processes in their management systems for the measurement of effectiveness of corrective actions, and for assessment and improvement of the level of safety culture. |
| 9.1 | Module 9 | S10 | The Environmental Board should consider establishing and adopting regulatory guides that cover all facilities and activities. |
| 9.2 | Module 9 | S11 | The Environmental Board should consider ensuring the development by the operator of appropriate waste acceptance criteria for the disposal of radioactive waste. |
| 9.2 | Module 9 | R20 | The Ministry of Environment should establish requirements for site selection for radioactive waste |

| Section | Module | R/S | Recommendations/Suggestions |
|---|---|---|---|
| | | | disposal facility in line with SSR-5. |
| 9.2 | Module 9 | R21 | The Ministry of Environment should review and update the regulatory framework on decommissioning of facilities to ensure its compliance with the GSR Part 6. |
| 10.1 | Module 10 | R23 | The Government should ensure that appropriate regulations or guidance documents are developed and implemented for the application of GSR Part 7 in Estonia. |
| 11.2.5 | Module 11 | R34 | The Environmental Board should ensure that measures are taken by the employers or licensees to ensure appropriate monitoring of internal exposure. |

## APPENDIX V RECOMMENDATIONS (RF), SUGGESTIONS (SF) AND GOOD PRACTICES (GPF) FROM THE 2019 IRRS FOLLOW-UP MISSION

| Section | Module | R/S | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| 1.8 | Module 1 | SF1 | The Government should consider to ensure that there is a sustainable provision of radiation safety education and training. |
| 4.2 | Module 4 | RF1 | The Environmental Inspectorate should establish and implement an Integrated Management System. |
| 4.3 | Module 4 | SF2 | The Environmental Board should consider to include provisions on leadership for safety in Integrated Management System in order to foster and sustain a strong safety culture. |
| 8.1 | Module 8 | SF3 | The Environmental Inspectorate should consider establishing documented criteria for taking corrective actions in response to non-compliance. |
| 11.1 | Module 11 | RF2 | The Ministry of Social Affairs should ensure that generic justification of a radiological procedure, including for new techniques and technologies is carried out and is reviewed whenever deemed necessary. |

# APPENDIX VI REFERENCE MATERIAL USED FOR THE REVIEW

| | |
|---|---|
| 1. | 2009_RP_159_Clinical_Audit_Guideline.pdf |
| 2. | 2012_RP_162_Criteria_for acceptability of medical_radiological_equipment.pdf |
| 3. | Activity levels of radionuclides,.docx |
| 4. | Administrative Procedure Act.pdf |
| 5. | Bases for the derivation of exemption levels.docx |
| 6. | Building Code.pdf |
| 7. | Civil Service Act.pdf |
| 8. | Classification of radioactive waste, requirements.docx |
| 9. | CoC National Points of Contact for ImportExport.pdf |
| 10. | CoC Status list 17 05 2016.pdf |
| 11. | Code of Misdemeanour Procedure.pdf |
| 12. | concil regulation Euratom no 1493_93.pdf |
| 13. | Consumer Protection Act.pdf |
| 14. | Control of Medical Exposure Regulator_en ED.doc |
| 15. | Core Questions Core IRRS Modules_en ED.doc |
| 16. | Digital Signatures Act.pdf |
| 17. | EMAS users guide_2013_131_EU.pdf |
| 18. | Emergency Act.pdf |
| 19. | Employment Contracts Act.pdf |
| 20. | Environmental Impact Assessment and Environmental Management System Act.pdf |
| 21. | Environmental Monitoring Act.pdf |
| 22. | Environmental Supervison Act.pdf |
| 23. | Estonia IRRS ARM summary report.DOCX |
| 24. | Explanatory to the new Radiation Act.docx |
| 25. | Food Act.pdf |
| 26. | General Part of the Environmental Code Act.pdf |
| 27. | Health Insurance Act.pdf |

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| 28. | Health Services Organization Act.pdf |
| 29. | IAEA_TRAM_competent authorities list.pdf |
| 30. | Intervention and activity levels and the.docx |
| 31. | Law Enforcement Act.pdf |
| 32. | Medical Devices Act.pdf |
| 33. | Medicinal Products Act.pdf |
| 34. | Metrology Act.pdf |
| 35. | National Radiation Safety Development Plan 2008-20017.pdf |
| 36. | National_programme_radioactive_waste.docx |
| 37. | Notifification of Ministry  Interior_EN.doc |
| 38. | Occupational Health and Safety Act.pdf |
| 39. | Occupational Radiation Protection.doc |
| 40. | Penal Code.pdf |
| 41. | Permitted levels of the effective dose of an exposed worker and resident,.docx |
| 42. | Procedure for granting, extending, suspending and.docx |
| 43. | Procedure for monitoring and evaluation of effective dose.docx |
| 44. | Procedure for monitoring and evaluation of.docx |
| 45. | Product Confirmity Act.pdf |
| 46. | Public and Environmental Exposure Control Waste Management and Decommissioning EN.docx |
| 47. | Public Health Act.pdf |
| 48. | Public Information Act.pdf |
| 49. | Rad emergency plan approved 2011_EN.doc |
| 50. | Rad emergency plan attachment1_EN.doc |
| 51. | Radiation Act V2.docx |
| 52. | Radiation Act.docx |
| 53. | Radiation Safety requirements for medical radiology procedures.pdf |
| 54. | Referral Guidelines for Imaging RP 118.pdf |
| 55. | Release levels  of radioactive substances generated in.docx |
| 56. | Requirements for providing radiation safety training to exposed workers.docx |

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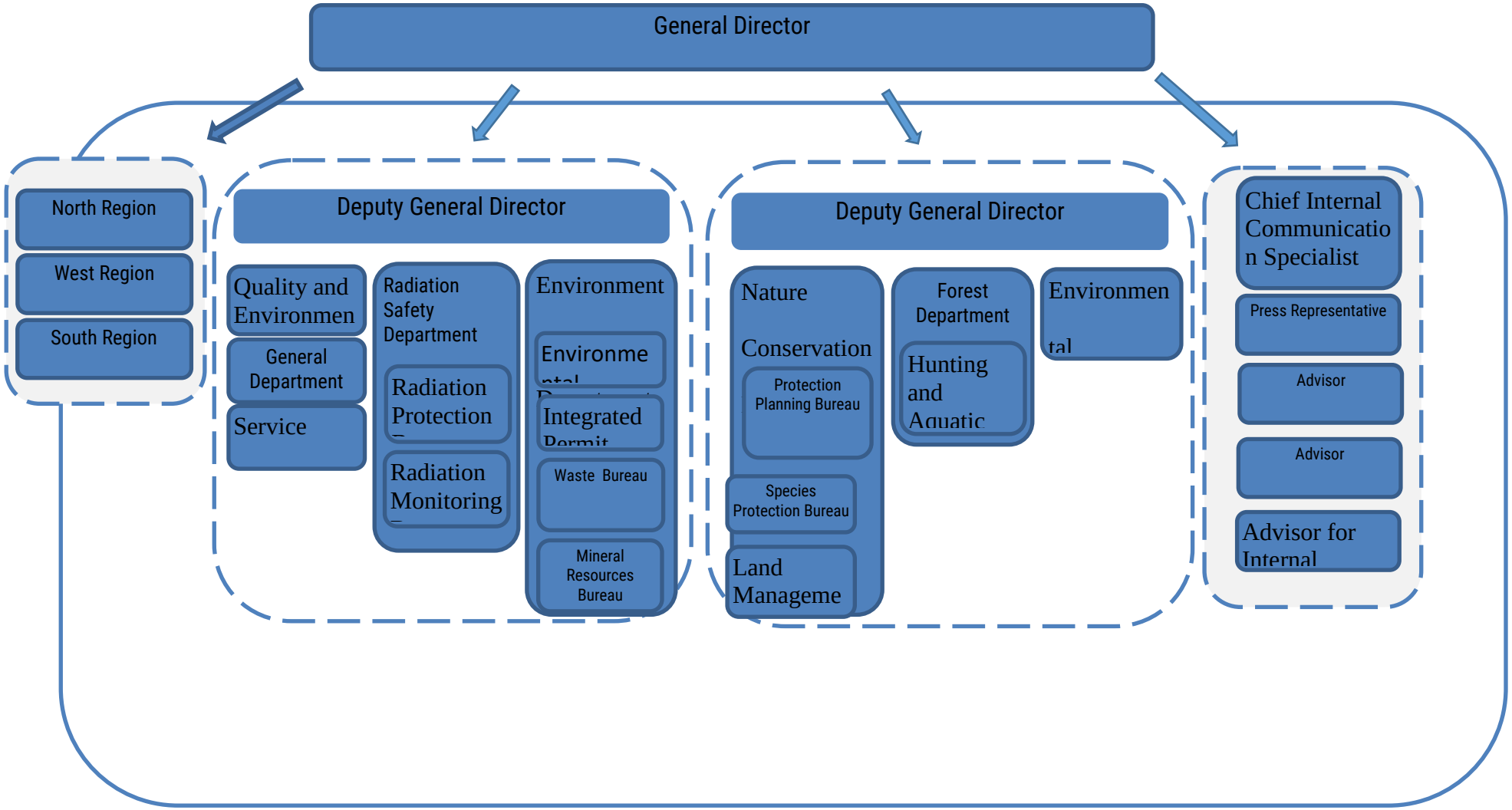
| 57. | Requirements for Qualifications of Competent Persons and List of Evidence of Formal Qualification.pdf |
| 58. | Rescue Act.pdf |
| 59. | Road Transport Act.pdf |
| 60. | Safe Transport of Radioactive Material EN.docx |
| 61. | Safety of Radioactive Sources in accordance with the CoC_en ED.doc |
| 62. | SARIS Action Plan.docx |
| 63. | State Budget Act.pdf |
| 64. | Statutes of the Environmental Board.docx |
| 65. | Statutes of the Environmental Inspectorate.docx |
| 66. | Statutes of the Ministry of the Environment.docx |
| 67. | Statutes of the national radiation workers dose register.docx |
| 68. | Statutes of the Radiation Safety Department.docx |
| 69. | Substitutive Enforcement and Penalty Payment Act.pdf |
| 70. | Terms for granting, amending and procedure for repealing the radiation practice licence.doc |
| 71. | The Constitution of the Republic of Estonia.pdf |

## APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW


1. No. SF-1 - Fundamental Safety Principles
2. INTERNATIONAL ATOMIC ENERGY AGENCY– Governmental, Legal and Regulatory Framework for Safety, Safety Standards Series No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016)
3. INTERNATIONAL ATOMIC ENERGY AGENCY– Leadership and Management for Safety, Safety Standards Series No. GSR Part 2, IAEA, Vienna (2016)
4. INTERNATIONAL ATOMIC ENERGY AGENCY– Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014)
5. INTERNATIONAL ATOMIC ENERGY AGENCY– Safety Assessment for Facilities and Activities, Safety Standards Series No. GSR Part 4 (Rev 1), IAEA, Vienna (2016)
6. INTERNATIONAL ATOMIC ENERGY AGENCY – Predisposal Management of Radioactive Waste, Safety Standards Series No. GSR Part 5, IAEA, Vienna (2009)
7. INTERNATIONAL ATOMIC ENERGY AGENCY – Decommissioning of Facilities, Safety Standards Series No. GSR Part 6, IAEA, Vienna (2014)
8. INTERNATIONAL ATOMIC ENERGY AGENCY – Preparedness and Response for a Nuclear or Radiological Emergency, Safety Standards Series No. GSR Part 7, IAEA, Vienna (2015)
9. INTERNATIONAL ATOMIC ENERGY AGENCY - Regulations for the Safe Transport of Radioactive Material, Safety Standards Series No. SSR 6 (Rev. 1), IAEA, Vienna (2018).
10. INTERNATIONAL ATOMIC ENERGY AGENCY- - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Standards Series No. GS-G-2.1, IAEA, Vienna (2007)
11. INTERNATIONAL ATOMIC ENERGY AGENCY – Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, Safety Standards Series No. GSG-2, IAEA, Vienna (2011)
12. INTERNATIONAL ATOMIC ENERGY AGENCY – Classification of Radioactive Waste, Safety Standards Series No. GSG-1, IAEA, Vienna (2009)
13. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Standards Series No. WS-G.5.2, IAEA, Vienna (2009)
14. INTERNATIONAL ATOMIC ENERGY AGENCY – Establishing the Safety Infrastructure for a Nuclear Power Programme, Safety Standards Series No SSG-16, IAEA, Vienna (2011)
15. INTERNATIONAL ATOMIC ENERGY AGENCY - Disposal of Radioactive Waste, Specific Safety Standards Series No. SSR 5, IAEA, Vienna (2011)

## APPENDIX VIII ORGANIZATIONAL CHART

ENVIRONMENTAL BOARD



STRUCTURE (EI)