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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

ESTONIA

Tallin, Estonia

4 to 14 September 2016

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

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REPORT OF THE
INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
TO
ESTONIA

Integrated Regulatory Review Service

IAEA IRRS

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Mission dates:	*4 to 14 September 2016*
Regulatory body visited:	*Environmental Board*
Location:	*Tallin, 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*

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IAEA-2016

The number of recommendations, suggestions and good practices is in no way a measure of the status of the national infrastructure for nuclear and radiation safety. Comparisons of such numbers between IRRS reports from different countries should not be attempted.

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EXECUTIVE SUMMARY

At the request of the Government of Estonia, an international team of senior safety experts visited the Ministry of Environment from 04 to 14 September 2016 to conduct an Integrated Regulatory Review Service (IRRS) Mission. The pupose of the IRRS mission was to perform a peer review of Estonia's regulatory framework for nuclear and radiation safety.

The IRRS mission covered all civilian facilities and activities in Estonia. The review compared the Estonian regulatory framework for safety against IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS team members and the Estonian counterparts in the areas covered by the IRRS.

The IRRS team consisted of ten senior regulatory experts from ten IAEA Member States, two IAEA staff members, one IAEA administrative assistant and two observers. The IRRS team conducted a review of the following areas: responsibilities and functions of the government; the global safety regime; responsibilities and functions of the regulatory body; management system of the regulatory body; the activities of the regulatory body including authorization, review and assessment, inspection, enforcement and development and content of regulations and guides; emergency preparedness and response; control of medical exposure, occupational radiation protection; control of radioactive discharges and materials for clearance; environmental monitoring; control of chronic exposures, and transport of radioactive materials. The IRRS mission included discussions on policy issues regarding: optimization of medical exposure, and enhancing regulatory effectiveness and competence.

The mission included observations of regulatory activities, interviews and discussions with staff of the Ministry of Environment, Environmental Board and Environmental Inspectorate as well as Ministry of Social Affairs. Activities included visits to A.L.A.R.A. Ltd, Scandinavian Clinics Estonia OU, the North Estonia Medical Center and East-Tallinn Central Hospital. The IRRS team members observed regulated activities and performance of inspection activities, including discussions with the licensee personnel and management.

In preparation for the IRRS mission, Estonia conducted a self-assessment and prepared a preliminary action plan to address weaknesses that were identified. The results of the self-assessment and supporting documentation were provided to the team as advance reference material for the mission. During the mission, the IRRS team performed a systematic review of all topics presented in the advance reference material. Throughout the mission, the IRRS review team was extended full cooperation in the regulatory, technical, and policy issues by all parties in a very open and transparent manner.

The Ministy of Environment was established by law to oversee nuclear and radiation safety of facilities and activities in Estonia. Over the years, the Ministry of Environment has developed safety standards and rules to carry out its regulatory responsibilities and for compliance with the IAEA safety standards and international best practices. The IRRS team recognized that the Ministy of Environment continues to update its regulatory requirements and encourages the Ministry of Environment to further enhance its regulatory framework. In this regard, the team identified a good practice that should be considered for implementation by other Member States, and identified recommendations and suggestions for improvement and for consistency of the Ministry of Environment regulatory functions with the IAEA safety standards.

The IRRS team found that Estonia has a dedicated regulatory body for the protection of people and the environment. As a result, the team identified the following good practice:

- Each year the senior executive management visits all the structural units of the Environmental Board and Environmental Inspectorate and discusses the goals and topical issues of the organization directly with the employees.

The IRRS team also identified issues warranting attention or in need of improvement and believes that consideration of these would enhance the overall performance of the regulatory system. These issues include:

- 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.
- The Environmental Board and Environmental Inspectorate should establish and implement, in each organization, an Integrated Management System.
- 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.
- The government should ensure that diagnostic reference levels and criteria and guidelines for the release of patients are established.
- 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.

I. INTRODUCTION

At the request of the Government of Estonia, an international team of senior safety experts met representatives of the Ministry of Enfvironment, Environmental Board and Environmental Inspectorate, as well as the Ministry of Social Affairs, from 5 to 14 September 2016 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the Estonian regulatory framework for radiation safety. The review mission was formally requested by the Government of Estonia in January 2012. A preparatory meeting was conducted on 25 February 2016 at the Environmental Board headquarters in Tallin 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 and to agree the scope of the IRRS mission.

The IRRS review team consisted of ten senior regulatory experts from ten IAEA Member States, two IAEA staff members and one IAEA administrative assistant, two observers from two Member States. The IRRS review team carried out the review in 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 the authorization, review and assessment, inspection and enforcement; and development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, control of medical exposure, public and environmental exposure control and transport of radioactive material.

In addition, policy issues relating to optimization of medical exposure, and enhancing regulatory effectiveness and competence were discussed.

In preparation of the mission, the Environmental Board coordinated and conducted a self-assessment together with Ministry of the Environemnt, the Environmental Inspectorate and Ministry of Soscial Affairs and prepared a preliminary action plan. The results of Estonia's self-assessment and supporting documentation were provided to the IRRS review team as advance reference material for the mission. During the mission the IRRS review team performed a systematic review of all topics within the agreed scope by reviewing the advance reference material, conducting interviews with management and staff from Environmental Board and Environmental Inspectorate direct observation of working practices during conduct of a regulatory inspection. Meetings with the Ministry of Environment, was also organized.

All through the mission the IRRS team received excellent support and cooperation from the Ministry of Environment.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review Estonia's radiation and nuclear safety regulatory framework and activities against the relevant IAEA safety standards to report on regulatory effectiveness and to exchange information and experience in the areas covered by the IRRS. The IRRS review scope included all facilities and activities regulated by the Ministry of the Environment. The review was carried out by comparison of existing arrangements against the IAEA safety standards.

It is expected this IRRS mission will facilitate regulatory improvements in Estonia and other Member State, utilizing the knowledge gained and experiences shared between the Ministry of Environment, Environmental Board and Environmental Inspectorate, and IRRS reviewers and the evaluation of the Estonia regulatory framework for radiation safety, including its good practices.

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

a) providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;

b) providing the host country (regulatory body and governmental authorities) with a review of its regulatory technical and policy issues;

c) providing the host country (regulatory body and governmental authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;

d) promoting the sharing of experience and exchange of lessons learned among senior regulators;

e) providing key staff in the host country with an opportunity to discuss regulatory practices with IRRS Review Team members who have experience of other regulatory practices in the same field;

f) providing the host country with recommendations and suggestions for improvement;

g) providing other states with information regarding good practices identified in the course of the review;

h) providing reviewers from Member States and IAEA staff with opportunities to observe different approaches to regulatory oversight and to broaden knowledge in their own field (mutual learning process);

i) contributing to the harmonization of regulatory approaches among states;

j) promoting the application of IAEA Safety Requirements; and

k) providing feedback on the use and application IAEA safety standards.

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) was conducted on 25 February 2016. The preparatory meeting was carried out by the appointed Team Leader Mr Manickam Selva Kumar, and the IRRS IAEA Team coordinator Mr Teodros Hailu.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of Environmental Board represented by Mr Ilmar Puskar, Head of the Radiation Safety Department of the Environmental Board, other senior management and staff. It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides

- Waste Management Facilities;
- Radiation sources facilities and activities;
- Transport of radioactive materials;
- Control of medical exposure;
- Occupational radiation protection;
- Public and Environmental exposure control;
- Existing exposure control;
- Selected policy issues

Mr Ilmar Puskar made presentations on the national context, the current status of the Environmental Board and the Environmental Inspectorate, and the progress of the self-assessment.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in Estonia in September 2016.

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

The Liaison Officer for the IRRS mission was confirmed as Mr Ilmar Puskar.

Estonia provided IAEA with the advance reference material (ARM) for the review by 4 July 2016. In preparation for the mission, the IAEA review team members reviewed the ARM and provided their initial impressions to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

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

C) CONDUCT OF THE REVIEW

The initial IRRS Review team meeting took place on Sunday, 4 September, 2016 in Tallin, directed by the IRRS Team Leader and the IRRS IAEA Team Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS programme. The understanding of the methodology for

review was reinforced. The agenda for the mission was presented to the team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

The host Liaison Officer was present at the initial IRRS Review team meeting, in accordance with the IRRS Guidelines, and presented logistical arrangements planned for the mission.

The IRRS entrance meeting was held on Monday, 5 September 2016, with the participation of Environmental Board's senior management and staff. Opening remarks were made by Mr Marko Pomerants, Minister of the Environment of the Republic of Estonia, Mr Manickam Selva Kumar IRRS Team Leader and Mr Teodros Hailu, IRRS Team Coordinator. Mr Ilmar Puskar gave an overview of Environmental Board activities.

During the IRRS mission, a review was conducted for all review areas within the agreed scope with the objective of providing Estonia with recommendations and suggestions for improvement and where appropriate, identifying good practice. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations regarding the national legal, governmental and regulatory framework for safety.

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

The IRRS exit meeting was held on Wednesday, 14 September, 2016. The opening remarks at the exit meeting were presented by Mr Meelis Munt, Deputy Secretary General of the Ministry of Environement and were followed by the presentation of the results of the mission by the IRRS Team Leader Mr Manickam Selva Kumar. Closing remarks were made by Mr Peter Johnston, IAEA, Director, Division of Radiation, Transport and Waste Safety

An IAEA press release was issued at the end of the exit meeting.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

The Government of Estonia has established a comprehensive national framework for radiation safety, through multiple legally binding instruments (acts, regulations and licences) to ensure adequate regulatory oversight of radiation practices to protect people and the environment. The national framework accounts for the main pillars of radiation safety regulation and makes adequate provision for the justification of practices, the limitation of risk and the optimization of protection for people and the environment. The Radiation Act is the main legally binding instrument that establishes radiation safety standards for the radiation practices conducted in Estonia and sets out the rights, obligations and liability of persons involved in these practices. More detailed requirements for implementing or clarifying the various provisions of the Radiation Act are contained in secondary legal instruments, for example in Regulations of the Government and Regulations of the Minister of the Environment.

National policy and strategy reflect the long-term commitment to safety and are established through the various legislation and the National Radiation Safety Development Plan (NRSDP) 2008-2017, which is a ten-year programme approved by the Government, guiding the development and enhancement of radiation safety in Estonia, hence ensuring constant and systematic radiation safety commitment by the Government. The objectives of the plan are to minimize radioactive waste, improve emergency preparedness, optimize the use of radiation in medicine and raise public awareness. The NRSDP is reviewed and amended or updated on a continuous basis, where relevant, in connection with changes in international instruments. All involved parties to the plan are kept abreast with developments through interaction and public information environments. The NRSDP is carried out according to its implementation plan. The NRSDP and its implementation plan are in force until the end of 2017. The next version of the NRSDP covering the period 2018-2027 is currently under development.

A national programme for radioactive waste management, which is aligned with the NRSDP, describes the institutions, technical and financial resources, and research and development activities for safe radioactive waste management until 2050. The programme is approved by the Minister of the Environment.

The national policy for safety and the NRSDP however do not contain all the requisite elements of a national policy and strategy for safety, such as the fundamental safety objective and safety principles in IAEA SF-1, and policy and strategy for human and financial resources.

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:* *(a) The fundamental safety objective and the fundamental safety principles established in the*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Fundamental Safety Principles [1]; *(b) Binding international legal instruments, such as conventions and other relevant international instruments;* *(c) The specification of the scope of the governmental, legal and regulatory framework for safety;* *(d) The need and provision for human and financial resources;* *(e) The provision and framework for research and development;* *(f) Adequate mechanisms for taking account of social and economic developments;* *(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.**

A graded approach, commensurate with risk, is taken into consideration towards the development of the radiation protection policy and relevant radiation safety legislation. For example, the legislation makes provision for regulatory requirements that reflect the degree of risk of exposure to ionizing radiation, the potential effects on the public health and environment in the event of a serious accident. The radiation practices are defined as being either low, moderate or high risk based on threshold levels of 1 mSv per year, to distinguish between low and moderate risk, and 6 mSv per year to distinguish between moderate and high risk practices. A risk informed approach is also used in inspections and enforcement. The amended Radiation Act, which will come into force in November 2016, will allow for the granting of licences without a fixed term for low-risk radiation practices, instead of the current five-year term.

There are also provisions in the Radiation Act for cost-recovery measures for services rendered by the regulatory bodies; and, requirements for persons responsible for radiation practices to establish sufficient financial resources to ensure the safe termination of regulated activities and long-term management of disused sources. The NRSDP provides information on human resources needs and expenses of the radiation safety domain, whose implementation plan covers actions to be performed to achieve the goals of the development plan and related financial means. Furthermore, the National Radioactive Waste Management Programme includes calculations regarding the funds needed to manage waste.

In the area of research and development (R&D), the activities, measures and financial means of the research and development are reflected in the NRSDP. The funding of R&D has remained modest in Estonia with respect to radiation safety.

Socio-economic aspects have been considered in the NRSDP which require people to be informed of the potential hazards of natural radiation and methods to reduce such hazards. The focus is therefore mainly on raising public awareness. The goals and activities of the management systems and improvement of the safety culture are also part of the NRSDP.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

Some of the fundamental radiation safety objectives and principles are established in the Radiation Act in respect of radiation facilities and activities. The Act and other national legislation establish the functions and responsibilities of organizations related to radiation facilities and activities.

Radiation practices are categorized in the Act as being of low, moderate or high risk, depending on their level of radiation hazard. In particular, a radiation practice is considered as high-risk if the radiation

practice concerns a high activity radiation source; or for operation, closure and decommissioning of any facilities in the nuclear fuel cycle; or for activities related to the management of radioactive waste. The level of hazard determined by the radiation safety assessment is taken into account upon processing and granting radiation practice licences because the requirements arising from the Radiation Act are applied based on the levels of hazard.

The Radiation Act makes provision for general safety requirements for the purpose of protecting human health and the environment from the damage caused by ionizing radiation. The Act assigns responsibility for safety on licence holders and sets out their rights, obligations and liability. The radiation practice licence holder is, therefore, responsible for complying with the requirements of the radiation practice licence, irrespective of where activities are carried out by several persons or by organizations successively.

The Radiation Act assigns regulatory oversight responsibility for radiation safety to the Ministry of the Environment. The areas of responsibility of the Ministry of the Environment, therefore, include radiation safety in addition to all other responsibilities for environmental protection, including environmental and nature protection, tasks related to land, the use, protection, re-production and accounting for natural resources, tasks related to climate change, environmental supervision, organizing meteorological observations, nature and marine research, and compiling strategic documents and draft legislation.

The Ministry of the Environment also develops radiation safety policies; cooperates with European Commission, IAEA, WHO and UN; and participates in EC working groups and advisory committees. The Environmental Board under the Ministry of Environment is responsible for preparing guidance materials in respect of radiation awareness, employment of good practices and adherence to basic obligations that are published on its Web site. The drafts of legally binding instruments are made public and all interested parties can provide their opinion or ask for a consultation.

The Radiation Act has provisions that refer to the Administrative Procedure Act, under which licensees can appeal to administrative decision of the Environmental Board and Environmental Inspectorate. The Radiation Act only assigns responsibility for safety on licence holders, whereas other persons or organizations responsible for activities and facilities are not specifically assigned legal responsibility for safety. The Environmental Board and Environmental Inspectorate may, under the Administrative Procedure Act, exercise discretion in carrying out their functions. However, the concept of the graded approach in radiation protection is not explicitly provided in the Radiation Act.

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:* *(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**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	approach to regulatory control of facilities and activities.

In order to obtain a radiation practice licence, the applicant must submit to the Environmental Board a written application that satisfies the requirements set out in the Radiation Act and in associated Regulation of the Minister of the Environment. The Environmental Board, taking into account the level of hazard involved in the radiation practice, assesses the information submitted in the application and conducts an on-site assessment, if necessary. Since licences are issued for up to five years, the application of the radiation practice licence with relevant documents needs to be resubmitted upon the end of the licence period for review by the Environmental Board. The scope and extent of the regulatory assessment take into consideration the risk level of the radiation safety practice.

When considering granting or changing a radiation practice licence, the Radiation Act provides for an open procedure whereby the applicant, the public and other stakeholders have the opportunity to provide their opinion on the proposed licence. Similarly, the Environmental Impact Assessment and Environmental Management System Act require that, in case the planned activity may involve a significant environmental impact, an environmental impact assessment must be initiated and an open procedure conducted. All draft legally binding instruments must be coordinated with relevant authorities and stakeholders, who are identified in the draft legislation and who will be subject to the proposed requirements.

The Radiation Act contains provisions for arrangements for emergency preparedness and response. The detailed national emergency plan is approved by the Ministry of Internal Affairs according to the Emergency Act, which defines the organization of intervention, tasks of the authorities and persons participating in intervention.

The Environmental Board maintains the national register of radiation sources, which is under restricted access.

Licence holders are required to have a financial guarantee in place for the elimination of radioactive substances, devices containing them, and radioactive waste that can only be used for that purpose. A detailed national radioactive waste management programme has been developed and defines the long-term goals for the management of radioactive waste.

Under the Radiation Act, a radiation practice licence is required from the Environmental Board before any transport, and export or import of radioactive material in to and from non-EU countries. Holders or receivers of sealed sources, who want to carry out a shipment of such sources, or arrange for such a shipment to be carried out, must provide the Environmental Board with information about consignees or senders of sources, the radionuclide, its quantity and activity as well as a copy of the contract with the (foreign) company importing, exporting or transiting the radioactive substance which should set out the end user, area of use and name of goods. Other legislation related to the transport of radioactive material includes the Road Transport Act, the Railways Act, the Maritime Safety Act, the Aviation Act and the Postal Act.

Other governmental authorities also have functions and responsibilities related to radiation safety. These are the Ministry of Interior related to emergencies and law enforcement; the Ministry of Economic Affairs and Communications which administrates a state-owned public radioactive waste management company; Ministry of Social Affairs which is responsible for protection of public health and healthcare arrangements, the Tax and Customs Board, under the Ministry of the Finances, which has responsibilities for verification of transport of goods and manages network of radiation monitors at entry points in State

border; the Ministry of Agriculture which has responsibilities for food safety; and the Ministry of Defence which has responsibilities to ensure safety during emergencies.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

Radiation safety is regulated by the Ministry of the Environment. The regulatory functions and responsibilities of the Ministry of the Environment for radiation safety are exercised by two authorities within the ministry: the Environmental Board and the Environmental Inspectorate. The Environmental Board is responsible for the assessment of applications and issuance of radiation practice licences as well as activity licences for qualified experts. It also advises persons exercising supervision, acts as a consultant body to provide regulatory advice, conducts radiation monitoring and manages the emergency notification and early warning system. The Environmental Inspectorate supervises fulfilment of conditions of radiation practice licences and obligations of radiation practice licence owner. It also has authority to impose sanctions and penalties, as set out in the Act, for violations of regulatory requirements. The Radiation Act makes provision regarding offences and penalties, in addition to provision as to when a licence shall be suspended in case of violation of regulatory requirements. The amounts of penalties are specified in the Act and depend on the seriousness of the offence.

The Minister of the Environment has the right to set up, reorganize and stop the operations of state institutions under the ministry, to approve their statutes and budgets and to determine their structure, members, procedures and organization of work, unless otherwise provided by the law or regulations of the Government of the Republic.

The Environmental Board and Environmental Inspectorate have authority to make decisions under their respective statutory obligations for the regulatory control of radiation facilities and activities. There is functional separation between the regulatory body and other entities having interests or responsibilities that could unduly influence regulatory decision making. The Environmental Board and Environmental Inspectorate have the legal authority to make independent regulatory judgements and decisions free from any influences that might compromise safety, such as pressures associated with changing political circumstances or economic conditions, or pressures from government departments or from other organizations. Furthermore, the Environmental Board is able to give independent advice to other bodies on matters relating to the safety of facilities and activities. The Environmental Board and the Environmental Inspectorate do not have responsibilities that might compromise or conflict with the conduct of their respective responsibilities for regulating the safety of facilities and activities. Both are governmental institutions that have separate budgets to fulfil their obligations.

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

The Radiation Act states that the licence holder is responsible for radiation safety and safety of radiation sources from the initial possession until disposal. The Act determines that the licensee must execute adequate control of the sources for the period that they are under the ownership of the licensee. A licence application must contain a plan for final disposal of the source and a bank warranty to ensure that there will be sufficient financial resources to do so. Where a licensee is unable to perform some of the authorized activities (for example the installation, maintenance of high activity sources) the licensee can retain the services of another licensee to perform the work. In this case, the contracted activity must be authorized prior to commencement of the work and must be part of the licence. The ultimate responsibility for safety still lies with the main licence holder.

The Environmental Board and the Environmental Inspectorate have statutory authority to require responsible persons or organizations to demonstrate compliance with regulatory requirements through the licensing process and inspections respectively. However, the Radiation Act only assigns responsibility for

safety on licence holders, whereas other persons or organizations responsible for activities and facilities are not specifically assigned legal responsibility for safety. Recommendation R2 in Section 1.2 addresses this issue.

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

The Radiation Act, Emergency Act and Statutes of the relevant institutions make provision for the coordination of various authorities. Overall coordination in Radiation Safety is conducted by the Ministry of Environment. The authority of the Environmental Inspectorate is established in the Radiation Act. The authority of the Health Board, under the Ministry of Social Affairs, with respect to the inspection of medical equipment is broadly defined in the Medical Devices Act. However, there is no clear delineation of authority between the Environmental Inspectorate and the Health Board to avoid overlap and conflicting roles and responsibilities regarding inspections of medical equipment. This has resulted in a lack of clarity in the respective roles of the Health Board and the Environmental Inspectorate in relation to the inspection of medical equipment. There is also lack of effective coordination related to the exchange and assessment of information related to transport of radioactive material (see section 6.4) and lack of effective coordination of the authorities having responsibilities for the protection and safety of patients (see section 11.1).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no clear delineation of authority between the Environmental Inspectorate 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.**

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.**

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

Estonia has established effective measures to reduce the risk of radiation in connection with unregulated sources and contamination due to past practices and events, as specified in the National Radiation Safety Development Plan and the Radiation Act with respect to intervention activities in an emergency exposure and permanent exposure situations. If the owner of a radioactive substance, the device containing it and radioactive waste is unknown or the person responsible cannot be identified, or if ownership thereof is illegal, or if there is reasonable suspicion that emergency exposure may occur, the government takes possession of the radioactive substance, the device containing it and radioactive waste. There is a dedicated budget under the Ministry of the Environment from which money can be drawn to cover the cost of safe management and storage of any radioactive material that is taken under control by the government.

1.7. PROVISIONS FOR THE MANAGEMENT OF RADIOACTIVE WASTE

The principles of radioactive waste management and obligations related to management are established in the Radiation Act. The government's policy objectives on radioactive waste are forecasted to 2050 in the National Programme for Radioactive Waste Management. The main goal of the policy is the reduction of waste volumes generated, which ensures that the amount of waste to be managed and stored would be as small as possible. The question of liability and the impact of future activity on national policy and the need to involve the public are also considered in the national programme. Estonia does not have a policy of spent fuel management, as there is no nuclear fuel in country. Matters related to radioactive waste management are to be organized in accordance with the programme and the aim of the plan is to offer decision-makers and waste handlers specific solutions for the systematic management of radioactive waste and to reduce their amounts in Estonia. The plan also provides information for the wider public about the radioactive waste generated and to be generated, as well as their management. More specific requirements for reducing the volumes of waste generated and for ensuring the safe management of radioactive waste are provided in regulations established under the Radiation Act and in the radiation practice licences issued by the Environmental Board to the waste generators and waste handlers.

The generator of radioactive waste is responsible to cover all costs incurred by the management of radioactive waste and must provide a financial guarantee sufficient for the elimination of the radioactive substance, the device containing it, and radioactive waste. A storage site for radioactive waste has been set up, owned by the State and governed by the Ministry of Economic Affairs and Communications (managed by the State-owned company AS A.L.A.R.A.) where radioactive waste generated in Estonia is stored. While the operation of the storage site is funded from the state budget and the private waste generators, the financial resources needed for the management of radioactive waste have been planned in the National Radiation Safety Development Plan and the National Radioactive Waste Management Programme. The national programme provides an overview of the radioactive waste currently existing and to be generated in Estonia in the future and ways of its management, and establishes a time schedule for the activities in line with national policy. Bodies authorized for the safe management of radioactive waste, existing technical and financial means, financing scheme and research and development activities are also described in the plan.

Research and development activities in the field of radiation safety are briefly described in the National Radiation Safety Development Plan. Given the small size of Estonia and the fact that Estonia does not have any nuclear installations and the waste stream generated in the future expected to be moderate, Estonia does not have a separate document on research and development in the field of radioactive waste management.

1.8. COMPETENCE FOR SAFETY

Radiation practice licence holders are responsible for training and instructing radiation workers. Using a risk-informed approach, the legislation makes provision for the frequency and content of necessary training and in-service training, as well as instruction and re-instruction. The Radiation Act and relevant regulation also provide for the procedure and bases of applying for a radiation expert licence. The Minister of Social Affairs regulation lays down the procedure of recognizing medical physicists. The training of the staff of Environmental Board and Environmental Inspectorate is conducted mainly by way of in-house training for freshly recruited staff and the existing staff will mainly use the training opportunities provided by the IAEA.

The Radiation Act requires that the licence holder prepares rules necessary to instruct radiation workers, provide radiation workers with training and radiation safety briefings allowing for the nature of their work and the conditions in their workplace. A radiation practice licence granted for high activity radiation source must also contain information about the radiation protection competences of the staff. The obligation and frequency of instructing and re-instructing radiation workers and participation in training courses and re-training courses depend on the risk level of the radiation practice.

As required under the Radiation Act, licensees must appoint a Radiation Protection Officer where the radiation practice involves more than ten radiation workers. Application for and granting of the relevant qualification occurs under the Professions Act through the Estonian Qualifications Authority. However, there are no requirements for the training of radiation safety specialists (i.e., Radiation Protection Officers, radiation safety training service providers, medical radiation technologists and radiopharmacists or radiochemists) and also for organizations providing the training. A new regulation has been prepared, which will enter into force together with the new Radiation Act and elaborate the requirements for the training of radiation workers, and provide requirements for the training of radiation safety specialists as well as the contents and duration of training courses.

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:* *—Technical training;*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	—Learning through academic institutions and other learning centres; *—Research and development work."*
(4)	**BASIS: GSR Part 1 Requirement 11, para 2.36 states that** *"The government:* *(a) Shall stipulate a necessary level of competence for persons with responsibilities in relation to the safety of facilities and activities;* *(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;* *(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 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.**

The requirements for the staff of competent authorities are established in the job descriptions approved on the basis of the Civil Service Act. The competences and development/in-service training needs of the staff are assessed annually during development interviews conducted on the basis of the Civil Service Act. As a result of interviews, a training plan for the next year will be drawn up to develop/maintain competences. There are no institutions dedicated for radiation safety training. Radiation safety training is offered by private companies, often in cooperation with the Environmental Board. Training opportunities provided by the IAEA are often used.

1.9. PROVISION OF TECHNICAL SERVICES

Estonia has established requirements for technical services related to safety, such as dosimetry, environment monitoring and calibration of equipment. The basic obligation of radiation practice licence holders is to ensure monitoring of the doses of radiation workers and submission of their data to the dose

register; the monitoring of personal doses must be performed only by approved dosimetry laboratories. The licensee has to ensure the regular verification and calibration of the measuring equipment used and assume responsibility for their suitability for use and for their competent use. The mandatory calibration interval of the measurement devices used by the licensee is determined in the radiation practice licence.

The existing technical services organizations provide only dosimetry services. With respect to personal dosimetry, Estonia has currently two accredited dosimetry laboratories for individual monitoring: the Radiation Safety Department of the Environmental Board (monitoring 1300 exposed workers) and the Laboratory of the North Estonia Medical Centre Foundation (monitoring their own approximately 300 workers). The Radiation Safety Department of the Environmental Board also has a laboratory which, in addition to the analyses performed within the framework of the national environmental radiation monitoring programme, also provides the option of the laboratory analyses of the radioactivity of substances as a paid service. In addition, the Radiation Safety Department of the Environmental Board also measures radon in indoor air and radiation levels, and prepares radiation safety assessments for low and moderate-risk radiation practice.

There is no separate provision in the legislation mandating the regulatory body to authorize specific technical services related to radiation practice. Where a technical service related to radiation safety can be treated as a radiation practice, a radiation practice licence needs to be issued for such services. For instance, the Environmental Board grants radiation practice licences for setting up and maintenance of X-ray devices. The requirements for the authorization of technical services are not clearly defined and the process for authorization is not described.

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 Environmental Board should consider to specify the technical services that need authorization and develop a process for granting an authorization.**

1.10. SUMMARY

The responsibilities and functions of the Estonian Government are for the most part are compliant with GSR Part 1. The IRRS team observed that there is lack of appropriate consideration and priority setting in the National Radiation Safety Development Plan with respect to certain requirements in GSR Part 1.

The IRRS team also observed that there are no training requirements for radiation safety specialists and radiation training service providers. Improvements are needed in these areas. In addition, there is no separate provision in the legislation mandating the regulatory body to authorize specific technical services related to radiation practice. It was also observed that there is lack of effective coordination among organizations with responsibilities for safety of facilities and activities. The requirements for the authorization of technical services are not clearly defined and the process for authorization is not described.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

The Government participates in relevant international arrangements for enhancement of safety globally, including international conventions, codes of conduct, safety standards, peer reviews and bilateral and multilateral cooperation agreements. The Government has identified all the obligations deriving from the international cooperation arrangements and has ensured the necessary means for fulfilling them. The Government promotes and contributes actively to international cooperation on safety. As Estonia is a member of European Union since 2004 the Government is following the requirements laid down in European Council (EURATOM) directives.

In 1994 Estonia joined:

- the Convention on the Physical Protection of Nuclear Material,
- Vienna Convention on Civil Liability for Nuclear Damage,
- Convention on Early Notification of a Nuclear Accident,
- Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency
- Joint Protocol to the Application of the Vienna Convention and Paris Convention.

Since 2005 Estonia is a member of:

- The Convention on Nuclear Safety,
- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.

In 2000 Estonia signed:

- an Agreement between the Government of the Republic of Estonia and the IAEA for the application of Safeguards in connection with the Treaty on the Non-proliferation of Nuclear Weapons
- Subsidiary Arrangements under the Safeguards Agreement under NPT between the Government of the Republic of Estonia and the IAEA,
- Additional Protocol to the IAEA Safeguards Agreement.

Estonia is a member of the Treaty on the Non-proliferation of Nuclear Weapons (NPT Treaty) since 1992 and ratified the Comprehensive Nuclear Test Ban Treaty (CTBT) in 1999. Estonia has made a political commitment to the Code of Conduct on the Safety and Security of Radioactive Sources. The Environmental Board is a member of various working groups, societies and networks, such as the Heads of European Radiological Protection Competent Authorities (HERCA), the Group of Experts under the Article 31 of the European Treaty, the Council of the Baltic Sea States (CBSS) Experts Group on Nuclear and Radiation Safety, participates in ENSREG as representative of the country etc.

Estonia has invited international Review Missions such as IAEA Radiation Safety and Security of Radioactive Sources Infrastructure Appraisal (RaSSIA) and Emergency Preparedness Review mission (EPREV). In being involved in multilateral and bilateral cooperation and assistance programmes, the Environmental Board promotes radiation awareness, use of good practice and conformity to main duties, and publishes guidelines and information materials on its website. The Environmental Board also communicates to licensees any relevant knowledge and experience from the international activities through various formal and informal meetings and correspondence.

When processing a licence application, the Environmental Board performs verification as to which relevant international guidelines and best practice will be followed for the radiation practice and, if necessary, appropriate standards and guidelines (IAEA, European Commission, ICRP etc.) are recommended. There are also a number of ISO standards that apply to certain activities. The IAEA safety standards as well as requirements of European Council Directives and other legal instruments are transposed and implemented in Estonian legislation. Reference is made to the appropriate standards used in the radiation practice license's requirements to the license holder and in the licence application review protocols.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

The national and international experience and information about events, incidents or accidents, in addition to experience (operating and regulatory) are shared with licensees and other relevant authorities by organizing various workshops, seminars and correspondence advising on problematic issues and possible solutions or good practice to adopt. The Environmental Board receives information on illicit trafficking of radioactive material that takes place globally. All the information on cases of illicit trafficking having occurred globally is forwarded to the authorized parties and other relevant institutions. Experience and good practices are taken into account and applied in practice also via the processing of radiation practice licence applications and the NRSDP.

The Environmental Board assesses and improves its processes, practices and requirements continuously, taking into account international experience and lessons learned, through various mechanisms such as self-assessments, internal audits and regular management review. Following participation in international events (training courses, workshops, technical meetings and etc.) staff upload the received materials to a shared folder and submit the summary of the meeting/training course, workshop to the special internet site. Based on the information gathered proposals can be made for improvement of Environmental Board's activities to ensure occupational, public and environmental radiation protection.

Regulatory experience from foreign countries is analysed and lessons learned from international regulatory experience is used to improve the radiation safety legislation and relevant activities as well as regulatory process. The information is received by participating in different meetings such as HERCA and ENSREG meetings, Baltic States Regulatory Authority meetings, and different IAEA workshops and meetings. All relevant information is published mainly on the website of the Environmental Board. If the new information will mean changes in the legislation or requirements, the information is then circulated to relevant stakeholders by emails or letters. Meetings with foreign experts (Finland, Baltic States) are organized for experience sharing purposes. Periodical domestic training courses are also organized both for the staff of the regulatory bodies (Environmental Board and Environmental Inspectorate), as well as for licence applicants and holders. Where legislation is improved based on lessons learned, regulatory inspections provide the means for verifying how authorized parties are implementing the new requirements.

2.3. SUMMARY

The Global Safety Regime of Estonia is in compliance with the requirements in GSR Part 1. The Government participates in all relevant international arrangements for enhancement of safety globally in fulfilling its international obligations. The regulatory body has made arrangements for implementing and using operational and regulatory experience feedback.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

The composition and structure of the Environmental Board are approved by the Ministry of the Environment. Within the Environmental Board, the Head of the Radiation Safety Department has the authority to change the structure of the unit, composition of positions or organization of work. The number of positions, the composition of positions and the classification of positions within the Environmental Board are approved by the General Director. However, any structural changes that require an increased number of positions must be approved by the Minister of the Environment, based on a proposal from the General Director. Structural changes and reorganization of work that do not require creation of additional jobs can be approved by the General Director. Currently, the Radiation Safety Department is made up of 17 employees and divided into the Radiation Protection Bureau (with 6 employees) and the Radiation Monitoring Bureau (with 8 employees). The main tasks of the Radiation Protection Bureau are the processing of applications of the radiation practice licences and preparation of radiation safety assessments, with the work organized by areas of activity (medical, research, industry, etc.). The degree of complexity of the licences being processed is also taken into account when dividing the workload. The main tasks of the Radiation Monitoring Bureau are the organization of the radiation monitoring of the environment, organization of early warning of radiation emergencies, laboratory analyses, and monitoring of the personal doses of radiation workers.

The structure, management and planning of the Radiation Safety Department, and the funds available for it are sufficient to ensure fulfilling the mandate of the department. The Environmental Board and the Environmental Inspectorate perform their obligations according to the risks of radiation practices. For instance, the licence applications of companies with low-risk radiation practice are not as detailed and lengthy and their inspection is not as detailed as in the case of high or moderate-risk radiation practice.

Radiation practice licence and radiation source registers are the bases for the planning of regulatory work. Based on the information retrieved from the registers, it is possible to precisely plan the work volume of the following year and hence to foresee any necessary reallocation of resources in order to perform the work adequately.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

Both, the Environmental Board and the Environmental Inspectorate have been and continue to be independent in fulfilling their duties. There have been no incidents of interfering with their activities in granting radiation practice licences and organizing supervision. The Environmental Board has exclusive competence to issue radiation practice licences, and can refuse to grant, modify and revoke a licence if necessary. The Environmental Inspectorate covers the state supervision of radiation safety, and has authority to impose monetary penalties if necessary and initiate misdemeanour procedures against a faulty licensee.

Based on the above, the fulfilment of the functions and obligations of both the Environmental Board and Environmental Inspectorate are clearly separated from those of radiation practice licence holders as well as from other organizations or associations that may have responsibilities or interests, which might affect decision-making. However, the Environmental Inspectorate faces challenges in recruiting a sufficient number of competent and qualified staff and therefore the licence holders of high and moderate risk radiation practice are inspected in cooperation with the Environmental Board. This has the potential to

impede the ability of the Environmental Board and the Environmental Inspectorate to discharge their functions in an effective and independent manner. Recommendation R6 in Section 3.3 addresses this issue

There is continuous close interaction (discussion, meetings, correspondence, etc.) between the Environmental Board and the Environmental Inspectorate to address any issues related to radiation safety that may emerge. Both the Environmental Board and the Environmental Inspectorate participate in the development of radiation legislation. Energy as such is within the scope of administration of the Ministry of Economic Affairs and Communications. Therefore, these functions do not interfere with those conducted by both the Environmental Board and the Environmental Inspectorate, which are under the scope of the Ministry of the Environment.

Each year the Radiation Monitoring Bureau of the Environmental Board draws up a monitoring plan which must be approved by the Head of the Radiation Safety Department, which forms the basis of the organization for dose and environmental monitoring. In addition, the Radiation Protection Bureau prepares, as a paid service, radiation safety assessments for licensees. The safety assessment report is in turn provided to the Radiation Protection Bureau during the authorization process. Under the Administrative Procedure Act, a person who is responsible for the licensing process must remove himself from any other function (e.g., provision of a service) that may conflict with the licensing process. Notwithstanding that provision, the fact that the licence application is processed by the Radiation Protection Bureau could potentially create a conflict of interest.

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.**

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

The NRSDP envisions the creation of a balanced training and education system whose first priority is to set up a training system for regulatory bodies, the inspectorate as well as the bodies intervening in emergencies and radiation workers. However, this goal has not been met as of today. The Environmental Board and the Environmental Inspectorate face challenges in recruiting and maintaining sufficient number of competent staff.

The Ministry of the Environment has initiated an amendment to the Radiation Act which, inter alia, includes the transposition of the EU BSS directive by February 2018. Hence, the amendments to the Radiation Act are expected to include provisions for training, fundamentals and capability requirements for all participants in a radiation practice (workers, regulatory bodies, experts, etc.). Furthermore, in October 2014, the Ministry of the Environment entered into a cooperation agreement with four universities to develop R&D in order to cover the needs of Estonia.

The structure of the Radiation Safety Department of the Environmental Board and the requirements applicable to different positions have been developed taking into account the number of radiation

practices in Estonia that need to be regulated and their complexity. If amendment of the legislation regulating the area incurs additional obligations, resources will be planned to recruit new staff to meet such obligations and also their necessary qualifications will be contemplated together with relevant amendments. If significant amendments are made regarding the radiation practices in Estonia (e.g., a substantial number of complex and sizeable radiation practices are added), the Environmental Board has the option to table a proposal to the Ministry of the Environment to create additional jobs within the structure of the Environmental Board and to allocate resources for their creation. However, there is no human resources plan in place to assure long-term sustainability of regulatory competence.

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."*
(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.**

Since there are not organizations that provide radiation safety training in Estonia, the staff recruited by the Environmental Board is trained in-house. The training course offered by the Radiation Safety Department of the Environmental Board addresses the basic principles, concepts and technologies related to the ionising radiation domain and radiation safety. In addition to the staff of the Environmental Board, employees of the Environmental Inspectorate and Rescue Board participate in the course. The remaining training that is needed is conducted under the supervision of experienced staff. The staff of the Environmental Board, Environmental Inspectorate, and Rescue Board are also trained under the IAEA technical cooperation programme to maintain and improve their competences.

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, which may lead to unsafe situations in radiation facilities and practices if inspectors fail to identify potential or actual radiation hazards or risks.

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*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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.**

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. This structure results in specialist radiation knowledge and experience residing only in the Radiation Safety Department of the Environmental Board. Consequently, there is little or no scope for inspectors to develop specialist radiation safety knowledge, leading to inspections of high and moderate risk radiation facilities and practices being undertaken in cooperation with the Environmental Board, which is an inefficient use of resources.

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.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

The legislation sets forth the requirements for experts and the procedure of their recognition that ensures for the decision-making regulatory body the availability of independent technical and non-technical advice in important issues related to radiation safety without the risk of a conflict of interests. The options to involve a qualified radiation expert are expected to be clarified both in the enforcement of the new Radiation Act and the regulation of the Minister of the Environment regarding the requirements to be met in order to submit a licence application.

Opinions of qualified radiation experts are submitted to the regulatory body in the process of applying for the radiation practice licence or changing the licence, and the need for such opinions arises directly out of the law.

An applicant for a radiation practice licence must submit to the Environmental Board a plan for the elimination of a radiation source after the use of the radiation source is discontinued and, in case of moderate and high-risk radiation practice, the plan has to be approved by a qualified radiation expert. The radiation practice licence holder is required to guarantee, in a high-risk radiation practice, that all design

documentation concerning facilities is reviewed by a qualified radiation expert, and that new radiation sources to be commissioned have been recognised beforehand. Where there is a possibility that radiation generated by the radiation practice could cause exposure to radiation in excess of the effective doses for members of the public or equivalent doses for occupational exposure by more than one tenth of such values per year, then the radiation practice licence holder shall consult with a qualified expert on the need to apply additional measures.

The requirements set forth in legislation, along with the practices conducted by the regulatory bodies treat qualified radiation experts as independent both with regards to the regulatory bodies as well as the radiation practice licence applicants. In order to ensure independence and objective decision-making of regulatory bodies, the Environmental Board does not accept the opinions or assistance of those qualified radiation experts who may have a conflict of interest as regards to the processing of a specific application and proposes to replace the opinion of such an expert.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

The Environmental Board and the Environmental Inspectorate have created both formal and informal mechanisms to communicate with the radiation practice licence applicants and holders as well as with the general public in issues related to the radiation safety, both through the licence and supervisory proceedings. Both independent regulatory bodies are transparent in their decision processes and their decisions are thoroughly substantiated and justified. Feedback from licence holders concerning the regulatory bodies' activities is received while processing new applications for licences; feedback is also obtained from the inspections carried out within the supervisory role of the Environmental Inspectorate depending on the risk levels of licences. The radiation practice licence proceeding itself is based not only on the Radiation Act, but also on the Administrative Procedure Act that places considerable emphasis on involving the person, regarding whom a decision will be made, in each stage of the process and, if necessary, they are given an opportunity to submit their opinion about the planned decision before it is taken.

The Radiation Act and the Environmental Impact Assessment Act foresee for certain types of radiation practice an obligation to conduct proceedings as an open procedure pursuant to the Administrative Procedure Act. The decisions, and the reasons for the decisions made by the regulatory bodies, are thoroughly explained both to the licence applicants and licence holders. For moderate and high-risk radiation practice, decisions are also based on the assessments and advice given by independent qualified radiation experts. Draft decisions that dismiss certain parts of the applications are first sent to the applicant for their opinion. Both regulatory bodies are prepared and competent to provide additional explanations and justifications of their decisions, if necessary.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

The Environmental Board and the Environmental Inspectorate closely follow the safety policies, basic principles, requirements and procedures set forth in legislation so as to ensure the consistency and stability of the proceedings conducted by regulatory bodies and avoid subjectivity in the decision process. All necessary policies, basic principles and conditions which the regulatory bodies should follow in their proceedings have been laid down in detail in the Radiation Act and other legislation.

In specific licence proceedings, the prior substantiation and justification of a relevant decision is guaranteed by the obligation to involve the applicant and ask for an opinion as well as the requirements applicable to the content of the decision as set forth in the Administrative Procedure Act. Information about specific licence proceedings, including rationale and justification, is disclosed to other interested parties only on the grounds set forth in the Radiation Act and the Environmental Impact Assessment Act.

The Radiation Act and associated regulations establish, for a majority of the radiation practice licence applications, formal procedural rules to implement the regulatory requirements, including licence proceedings, assessment, inspections, and imposing of sanctions.

The Ministry of the Environment either initiates the proceedings of relevant drafts or grants a regulation in case of a ministerial regulation. The Environmental Board and the Environmental Inspectorate do not have the legal right to issue legislation. However, they do participate in the development of legislation. It is in the jurisdiction of the Ministry of the Environment to decide on the need of involvement/consultation during such proceedings. The proceedings of legislative acts are public and, where ministerial and government regulations are concerned, all ministries and interested parties and the public have opportunities to present their opinions in the process. If additional requirements are prescribed by legislation or new requirements are included in the licence or supervisory proceedings, licence applicants and licensees are promptly notified through the website of the Environmental Board.

The Environmental Board conducts review and assessment of documents provided by applicants during the authorization process. However, internal guidance for conducting review and assessment of submitted documents are not currently in place. There are no specific internal guidance for inspection conducted by the Environmental Inspectorate of facilities and activities. There is also no internal guidance related to taking enforcement actions.

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.**

3.7. SAFETY RELATED RECORDS

The Environmental Board has set up registers of radiation sources and nuclear materials, the national radiation workers' dose register, and a radiation practice licences register.

The Environmental Board holds the following information on record:

- information required of applicants for radiation practice licences;

- information on the safety of radiation practice and the relevant sites (during processing licence applications submitted);

- information regarding the closure and decommissioning of radiation practice sites; and

- data about the inventories of radioactive waste.

The Environmental Board also collects and stores data about the radiation monitoring of the environment and about radon measurements in the air indoors.

Relevant requirements of the Radiation Act, along with the practices of the Environmental Board and Environmental Inspectorate, guarantee that the radiation practice licence holders collect, store and analyse safety-related information of their radiation practice licence holders and their facilities. All information, documents and data submitted by licence applicants and holders of a license are preserved for 75 years after discontinuation of specific radiation practice. All radiation practice licence holders are required to keep records of all radiation sources at their sites and deliveries that they are responsible for, take an annual inventory of the radiation sources, and submit the results of the inventory to the Environmental Board by 1st of March each year. Records must contain information about the radiation source that are required in the Radiation Act, unless set forth in the terms and conditions of the licence. The licence holder must also ensure that dose monitoring results for radiation workers are submitted to the dose register.

The Environmental Inspectorate uses the information obtained from the registers to prepare its supervision plans, taking into account the time limits and quality of meeting the obligations apparent from the registers. Likewise, specific supervisory actions are prepared on the basis of the information extracted from the registers. The Environmental Board uses the information obtained from the registers to assess radiation practice licences and verify the data submitted in them. 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. The effectiveness, efficiency and collaboration between the Environmental Board and the Environmental Inspectorate could be improved by providing appropriate access and combining their respective registers in order to have a single source of data for licensing and inspections.

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:* *—Registers of sealed radioactive sources and radiation generators;* *—Records of occupational doses;* *—Records relating to the safety of facilities and activities;* *—Records that might be necessary for the shutdown and decommissioning (or closure) of facilities;* *—Records of events, including non-routine releases of radioactive material to the environment;* *—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."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(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.**

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

The Environmental Board and the Environmental Inspectorate have created open communication mechanisms with radiation practice licence applicants in all issues related to safety both in the licence application proceedings and carrying out inspections. A majority of the relevant information is available on the website of the Environmental Board. The proceedings of the Environmental Board and Environmental Inspectorate need to be disclosed for certain radiation practices, including notification of the general public and consultations with interested parties.

In addition to the exchange of information with licence applicants during licence proceedings and inspections, the exchange of information and consultations related to radiation practices need to be disclosed to the public. In regard to the radiation practice licences that are subject to disclosure, under the Radiation Act, licence applicants are required to publicly display both the application and the draft licence at their location during the proceedings of the Environmental Board. Draft licences shall be made known two weeks before the commencement of the public display in the official publication *Ametlikud Teadaanded*, at least one nationally-distributed newspaper and on the Web site of the Ministry of the Environment. If any comments or objections are received on the draft licence, the body conducting the proceedings is to give relevant explanations in case they do not accept the comments/objections.

Where an environmental impact assessment plan is required to be prepared regarding the radiation practice, first public display and discussion must be organized. An environmental impact assessment report based on the plan needs to be prepared, and included in the public display and discussions process. Members of the general public may participate in the process and send in comments, supplements and amendments. During such proceedings, interested parties, media and the public are informed about the potential radiological risks related to the radiation practice and facilities, requirements for the protection of people and the environment and further proceedings. The Environmental Board grants the radiation practice licence taking into account the results of both the environmental impact assessment and the disclosure and discussion process. In the case where a proposed licensing decision by the Environmental Board is not fully in accordance with the application (some additional conditions in the licence, some activities not accepted, etc.), the draft decision is first forwarded to the licence applicant for review and opinions.

The Environmental Board is a member of the USIE, ECURIE, ITDB networks, and any incident must be recorded and informed through these networks in accordance with requirements. The incidents and abnormalities that can be evaluated as noncompliance with the licence requirements are communicated to the Environmental Inspectorate and to the licensee for further investigation. If the incident results in an emergency, the Environmental Board must inform the relevant governmental authorities and organizations according to the National Radiation Emergency Action Plan.

3.9. SUMMARY

The Responsibilities and Functions of the Environmental Board and Environmental Inspectorate are generally compliant with Requirements in GSR Part 1. The current NRSDP envisions the creation of a balanced training and education system whose first priority is to set up a training system for regulatory bodies, the inspectorate as well as the bodies intervening in emergencies and radiation workers. However, this goal has not been met as of today. The Environmental Board and the Environmental Inspectorate face challenges in recruiting and maintaining sufficient competent staff. This has the potential to impede on the ability of the Environmental Board and the Environmental Inspectorate to discharge their functions in an effective and independent manner. A reorganization of respective organizational structure could be envisaged in order to ensure a sufficient complement of qualified staff such as to preserve the independent decision-making ability of each organization. Also, there is no long-term human resource plan to ensure effective succession planning, training and knowledge management as a means to ensure sustainability of staff competence. The effectiveness, efficiency and collaboration of the Environmental Board and the Environmental Inspectorate could be improved by combining their respective registers in order to have a single source of data for licensing and inspections. Since radiation training services are not available in Estonia, the Environmental Inspectorate inspectors do not have sufficient radiation safety training, they have only generalist knowledge since radiation safety can be a very small component of their work.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. LEADERSHIP FOR SAFETY

The environmental policy of the Environmental Board has been developed and documented in the Manual of the Environmental Management System.

The environmental policy and vital environmental aspects are the basis for setting environmental goals in the environmental program and work plan of the Environmental Board and Environmental Inspectorate. The environmental policy and goals are described both in the Manual of the Eco-management Scheme as well as in the development plan of the Environmental Board. The Environmental Inspectorate has not established a manual for its management elements. The development plans of both organizations are strategic documents and contain the goals of the Environmental Board and Environmental Inspectorate for three years, and it is accessible to employees via the intranet. The development plan specifies the goals and achievement levels (benchmarks) of all areas. The development plan is reviewed every year, an overview of the fulfillment of the past year's development plan is prepared and the period of the development plan is extended by one year. The development plans of the Environmental Board for 2016-2019 and Environmental Inspectorate for 2015-2018 were approved by senior management.

The Environmental Board and Environmental Inspectorate prepare an annual activity report on their implementation of the development plan in their respective organizations and is submitted to the Ministry of the Environment. The activity report of the Ministry of the Environment is also forwarded to the Ministry of Finance, which coordinates the reporting of the development plans of all ministries.

The employees of Environmental Board and Environmental Inspectorate are involved in the preparation of the organizational mission, vision and development plan. The development plans of the Environmental Board and Environmental Inspectorate are published on the respective websites of the two organizations.

The Environmental Board has established a steering group composed of management, heads of functional units and the human resources manager. All important decisions (goals for the year, discussions about development needs, the development plan, annual work plans, etc.) are discussed in the steering group.

The Environmental Inspectorate has also established a group composed of management, similar to the steering group of the Environmental Board, and meetings are held at least twice in a year. Minutes of the meetings of the steering groups are stored in the document management system.

Although the Environmental Board and Environmental Inspectorate have defined the environmental goals, radiation safety goals are not clearly defined in their management systems. The safety policy of the Environmental Board and Environmental Inspectorate is also not identified in the management system.

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."

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(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:* *(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.**

The executive management of the Environmental Board and the Environmental Inspectorate conduct a tour across each organization annually and twice a year respectively. During the tour, the executive management of both organizations visit all the functional units of their respective organizations and discuss the organizational goals of the year and relevant issues directly with the employees.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The senior executive management of the Environmental Board and Environmental Inspectorate conduct annually and twice a year respectively a tour across each organization and visit all organizational units and discuss the organizational goals with the employees.	
(1)	**BASIS: GSR Part 2, Requirement 2 para 3.3. states that** *"Managers at all levels in the organization:* *(a) Shall encourage and support all individuals in achieving safety goals and performing their tasks safely."*
GP1	**Good Practice: Each year the senior executive management visits all the functional units of the Environmental Board and Environmental Inspectorate and discusses the goals and topical issues of the organization directly with the employees.**

4.2. MANAGEMENT FOR SAFETY

RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

The Environmental Board has adopted an Environmental Management System, the Eco-Management and Audit Scheme (EMAS), that was introduced in 2011. The Environmental Board obtained the first EMAS eco-management scheme certificate in 2013 which was renewed in January 2016. The environmental management system, which aims to minimize potential damages, complies with the key tasks of the organization. The scope of the environmental management system – mitigation of the negative environmental impact – is connected with the main activities of the Environmental Board: implementation of the State's use of the environment; implementation of nature conservation and radiation safety policies; participation in the development and improvement of environment-related legislation, programs and action plans.

The management system of the Environmental Board and Environmental Inspectorate has been established and implemented with environmental approach and the safety aspects are not clearly elaborated in their management systems. Recommendation R9 in Section 4.1 addresses this issue.

THE MANAGEMENT SYSTEM

The Environmental Board has elaborated a Quality Management System and is developing a quality manual. The management system for quality including the manual is however developed as a separate element of the management system and is not integrated into the already existing Environmental Management System. Many elements of the Management Systems are already in place and have documented processes but some processes are also being developed.

The Environmental Board and the Environmental Inspectorate have established their own Management Systems, and the elements of the managements systems in each organization, such as quality management and environmental management, have been established separately. The management systems developed in the Environmental Board and the Environmental Inspectorate are not integrated management systems that provide a single framework for the processes and arrangements in each organization.

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.**

The Environmental Board and Environmental Inspectorate employ in their activities a risk-based approach: decision-making competences are delegated to the officials at different levels based on the weight of the decision. Decision-making competences have been described in job descriptions and statutes of structural units, and also in process maps.

The "principle of proportionality" has been described in the internal document of the Environmental Board on "Good practices for environmental protection licenses", which is available to the staff in the Intranet of the Environmental Board. Three components – suitability, necessity and moderation – are taken as basis in the assessment of proportionality.

Within the organization, the principle of proportionality is applied by the following measures:

- The process maps of the Environmental Board take into account the results of the risk assessment (level of risk) and this is written into the process map.
- In case of more difficult process (e.g., processing of a complex license), more human resources (specialists of different levels) are involved in the proceedings.
- On-site visits (inspection of the site during the proceedings of the license) are risk-based and documented in the "Good practices for environmental license".

MANAGEMENT OF RESOURCES

The Environmental Board and Environmental Inspectorate have introduced a system for competence evaluation. The performance of employees and their competences are evaluated during annual performance reviews. As a result of the performance review training needs are identified which the Human Resources manager of the respective organization consolidates in the training plan of the Environmental Board and Environmental Inspectorate. Performance reviews are conducted and competences are evaluated by direct supervisors. The results of performance reviews (incl. competence evaluation) are integrated in the information system for work plans. The management approves the annual training plan and allocates funds for this from the budget. The documents describing the competence model and organization of training are accessible to all employees in the intranet, in the section of the human resources domain.

MANAGEMENT OF PROCESSES AND ACTIVITIES

Processes in the Environmental Board and Environmental Inspectorate have been described in both organizations' process maps (flowcharts), including defining the roles of personnel participating in the processes. In the case of the Environmental Board, main functions are documented in the process maps; 72 process maps were approved in 2015.

The Environmental Inspectorate has identified 6 main processes, such as inspection, administrative proceeding, misdemeanor proceeding, duty proceeding, criminal proceeding, registration of a notice and mandates of units.

The environmental and internal audit system ensures the control of process maps and service standards. The process owner also ensures that the process maps are updated and takes into account any new versions of legal acts. As a rule, the process owners are chief specialists who are the point of contact of the Ministry of the Environment in issues related to the amendment and development of legislation in their field.

Regular review of the process maps is conducted on an annual basis.

All critical documents and guidelines are approved by the Orders of the General Director and ease of availability for all employees is ensured through the online document management system KIRKE. KIRKE allows involvement of all necessary employees to the process of preparing documents and is the main means for notification of staff about the adoption and amendment of documents.

The entire decision-making process is documented in the document management system KIRKE. Employees have access to the documents necessary for their work. Document processing logs are traceable in KIRKE, both for outgoing and in-house documents. All the documents concerning one procedure are interrelated in the system.

Changes of documents are subject to the same level of approval as newly developed documents.

However, all processes of Environmental Board and Environmental Inspectorate are not identified and documented in the management system of both organizations, such as, assessing safety culture, managing organizational change, decision making for enforcement actions and for conducting inspections of specific areas such as radioactive waste management facilities and activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: Not all processes are identified and documented in the management systems of the Environmental Board and Environmental Inspectorate.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(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. "*
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.**

The Environmental Board has identified interested parties in the process maps. Communication with the interested parties takes place in several ways.

The Environmental Board has published its mission, vision and core values on its web site. A publication is available (in Estonian and English) for interested parties and the public, which explains the areas of activity of the Environmental Board. The Environmental Board annually provides information through the newspaper to inform the public on topics connected to the organizational functions.

The Environmental Board collects feedback randomly from customers and interested parties. If possible, feedback and suggestions are taken into account, provided that they are compatible with legislation and the goals of the Environmental Board. Feedback, suggestions and opinions are gathered with several methods. A customer feedback system in the form of an electronic survey has been introduced. Results are analyzed and reports are available to the entire organization in the Intranet. Regular meetings with different unions and associations, for instance with the Estonian Waste Management Association and the Estonian Council of Environmental NGOs, are organized to consolidate discussions and opinions,. The Environmental Board has set up an advisory council of customers comprised of representatives from different sectors who deal with the services of the Environmental Board on a day-to-day basis. The council discusses issues linked to services and shapes joint standpoints regarding the development of services. Information about the advisory council and its minutes are available on the Environmental Board's web site.

Although the Environmental Board annually develops a communication plan, there is no clearly established process for communication with the interested parties. Suggestion S5 in Section 4.2 addresses this issue.

4.3. CULTURE FOR SAFETY

Senior management and management at all levels in the regulatory body carry out self-assessment to evaluate the performance of work and the improvement of the safety culture. The Environmental Board and the Environmental Inspectorate conduct annually a performance review with all employees. The plan

of the performance reviews is annually approved by the Director General, and the results are discussed with the staff and approved by the supervisor of the respective staff.

During the performance review, the supervisors discuss with their respective staff the evaluation of competences to clarify staff development needs. The managers also evaluate to what level of acceptance the tasks have been fulfilled. Based on this evaluation, senior management and management at all levels set the goals for the next period that includes the tasks and training courses that are needed.

Based on the performance reviews, an individual work and training plan is compiled for each employee every year. The Environmental Board and the Environmental Inspectorate have prepared documents for this process such as a "Guide to conducting performance reviews" and "Principles of planning training needs and organizing training".

The management is also subjected to performance reviews (the General Director's development interview takes place at the Director General of the Ministry of the Environment, deputies of the General Director are interviewed by the General Director, etc.).

At the Environmental Board and the Environmental Inspectorate employee satisfaction surveys are conducted regularly, once in two years, with questions used in the self-assessment methodology. Satisfaction surveys give feedback about the motivation system of the Environmental Board, its remuneration scheme, the adequacy of communication and information stream and the results are communicated to employees via the Intranet.

The Environmental Board ensures the continuous development and improvement of the work processes by the audit system, including audits of the management system based on risk assessment and audits of the eco-management scheme in compliance with the requirements of the EMAS standard. The management includes an internal auditor who conducts annual risk assessment of the organization and based on the results organizes internal audits.

The Environmental Board has a system of auditing the eco-management scheme under which different structural units are annually audited. The consolidated results of audits are submitted annually to the management for review.

4.4. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

The Environmental Board and the Environmental Inspectorate conduct a performance review interviews annually covering all the employees of the regulatory body and during this interview the reviewers look at the competence model for the leaders as well. After the review they analyze the data and based on that training needs are identified.

The Environmental Board and Environmental Inspectorate have not specified any documented process or guide for assessment and improvement of the level of the organizational safety culture.

The Manual on Eco-management describes that heads of regions guarantee the management of non-conformances and measures for improvement in their regions. The direct supervisor decides on and organizes the remedy of non-conformances and reviews the actions taken and evaluates the effectiveness of measures.

After detection of a non-conformances in the management system e.g. after a reclamation has been filed, the measures to resolve it are clarified. In order to avoid a recurrence of the same failure, the Environmental Board and the Environmental Inspectorate develop a corrective action. In order to avoid the recurrence of non-conformances, preventive actions are applied. The information about non-conformances serves as an input of improvement actions. The management system of the Environmental

Board and Environmental Inspectorate mostly focuses on preventive actions, rather than on the remedy of consequences.

The monitoring and reporting of the status and effectiveness of all corrective and preventive actions are not defined in a documented process. After the implementation of corrective and preventive actions, the regulatory body takes improvements measure but does not conduct a re-assessment.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Environmental Board and Environmental Inspectorate 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.**

4.5. SUMMARY

The Environmental Board and Environmental Inspectorate have established and implemented similar management systems.

Senior executive management of the Environmental Board and the Environmental Inspectorate organize each year tours across their respective organizations. During the tours the management visits all the structural units of the Environmental Board and Environmental Inspectorate and discusses directly with employees.

The management systems of the Environmental Board and Environmental Inspectorate do not integrate all elements of the management systems to give a single framework for safety. Not all processes are also identified or documented.

5. AUTHORIZATION

5.1. GENERIC ISSUES

The legal framework related to authorization of radiation facilities and activities is laid out in the Radiation Act. According to the Radiation Act, the Ministry of Environment, within the limits of its competence, through the Environmental Board and Environmental Inspectorate regulates activities related to radiation safety.

Provisions to issue, amend or revoke a radiation practice license are established in the Radiation Act. The Environmental Board, when issuing, amending and revoking the radiation practice license bases its decisions on fundamental principles of radiation safety.

The Environmental Board and the Environmental Inspectorate may seek advice from a qualified expert in their authorization and inspection processes. The qualified expert may also provide services to the applicant for a radiation practice licence and the holder of a licence, as long as it is assured by the regulatory body that there is no conflict of interest.

The decisions of granting authorizations and licence amendments are published on the Environmental Board's website.

The Environmental Board applies similar levels of assessment during issuing new licenses for the first time and licenses that may be issued subsequently every five years. Subsequent licenses are therefore considered and treated as new licenses. The results of regulatory actions, such as inspections and feedback from operational performance, are not taken into account in making decisions on the subsequent authorization.

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.**

5.2. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

The management of radioactive waste, decommissioning of any nuclear facility and closure of radioactive waste disposal facility is subject to licensing and is considered high-risk practice. The Environmental Board issues a radiation practice license for the management of radioactive waste after the conformity of the facility with radiation safety requirements.

In the course of processing the license application followed by inspections, the Environmental Board and the Environmental Inspectorate control whether a radioactive waste generator or a waste manager comply with the regulatory requirements and license conditions.

During the authorization of a water treatment plant, the Environmental Board did not give due consideration to the control of the materials selected to process water, and the water cleaning filters, newly introduced in 2012, resulted in generation of Ra-226 bearing radioactive waste. Proper control of a material's potential to generate radioactive waste and the relevant existing operational experience (nationally and internationally) from similar facilities and activities were not inquired. Besides, the selection of the processes and procedures to prevent further generation of radioactive waste was not introduced. In 2014 the Environmental Board granted in addition a radiation practice license (for 2 years) to this facility for handling and storing radioactive wastes that are being generated.

For this reason, the generation of NORM waste is only allowed in exceptional situations, i.e. if the radiation safety assessment confirms that, considering economic, social and environmental aspects, the generation of waste is the best solution. The need for the establishment of national plan for management of NORM waste and residue is set in the national programme for radioactive waste management.

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: .....* *(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:* *(1) Safety of workers and the public;* *(2) Protection of the environment;* *(4) Emergency preparedness and response;* *(5) Management of radioactive waste"*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
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.**

5.3. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

According to the Radiation Act, the Environmental Board is empowered to authorize facilities and activities related to radioactive sources and radiation generators.

According to the Radiation Act, radiation practices are specified as the production, use, storage, import and export, disposal of radioactive substances; operation of any electrical equipment emitting ionizing radiation and containing components operating at a potential difference of more than 5 kilovolts; and the operation of nuclear installation. Radiation practices are divided into the following risk categories: low (annual effective dose for the worker - less than 1 mSv), moderate (annual effective dose for the worker – more than from 1 mSv, less than 6 mSv) and high risk (annual effective dose for the worker - higher than 6 mSv). The definition of *high activity radiation source* is also included in the Radiation Act.

However, categorization of radioactive sources in accordance with the IAEA safety standards is not applied and the Environmental Board has plans to incorporate categorization of sources into its regulatory system.

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 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.**

According to the Radiation Act, a radiation practice license can be valid for up to five years. Any decision for shorter license validity period needs to be justified. The time to issue, amend or revoke radiation practice licences, the license requirements and the license application format are specified in the Regulation No 41 of the Minister of Environment "Time limits of the procedure for the grant, amendment

and repeal of radiation practice licences, and specified requirements and forms for radiation practice licence applications and radiation practice licence forms".

The Radiation Act describes the contents of a licence application. An applicant should submit an application to the Environmental Board with the required information and supporting documents. The Environmental Board has not developed sufficient internal guidance for reviewing and assessing submitted documents (including safety assessment) for authorization of specific activities. Recommendation R8 in Section 3.6 addresses this issue.

A high risk practice requires additional provisions such as emergency action plan, qualified radiation expert, and provisions for the repatriation of disused sources. Financial guarantees are required for the long-term management of radioactive sources.

Import and export of radiation sources requires authorization when import and export takes place from and to non-EU Member States. Import and export of radiation sources from and to EU countries is regulated in accordance with the European Council Regulation (EURATOM).

The Environmental Board has developed guidance material for application of authorization for the most common radiation practices in Estonia.

The Radiation Act states, that a radiation practice licence gives a person the right to carry out the radiation practice. Estonia has only one type of authorization, which is granting a radiation practice licence. Other types of authorizations of radiation practices such as authorization by registration or by notification only are not established in Estonian legislation.

The Environmental Board may, under the Administrative Procedure Act, exercise discretion in carrying out its regulatory functions. The Environmental Board also has applied in some cases a graded approach to authorization. However, graded approach of regulatory control is not systematically applied consistently during authorization and review and assessment processes.

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:* *(3) The type of authorization that is required for the operation of facilities and for the conduct of activities, in accordance with a graded approach;* *(8) Provision for the review and assessment of facilities and activities, in accordance with a graded approach;* *(10) Provision for the inspection of facilities and activities, and for the enforcement of regulations, in accordance with a graded approach;"*
(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**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	approach to authorization and review and assessment of facilities and activities.

The Environmental Board reviews and assesses the provided information according to the relevant legislation and takes into account requirements of the Radiation Act. The Environmental Board also prepares a safety assessment report for some facilities or activities. The Environmental Board and the applicant both should agree on the contents of the safety report. Compliance with the requirements contained in the report is mandatory for the applicant. The applicant may propose a timeline for the goals set. The Environmental Board may incorporate these timelines into the radiation practice licence as conditions.

The application submitted for radiation practice licence is recorded in the document management system, KIRKE, in accordance with the Records Management Procedure. The bases for the records management procedures are regulated by the Government regulation "Uniform bases for the document management procedures".

According to the Radiation Act, the Environmental Board maintains the register of the radiation sources. Data entry onto the register is made either for possession of a radiation source, use of a radiation source, managing radioactive waste or importing the radiation source on the basis of the data contained in a radiation practice license application. A source and equipment datasheet (for unsealed and sealed sources, generators, accelerators) is provided by the applicant together with a license application. According to the Radiation Act, the license holder is required to update annually the information about the sources and generators. Radiation sources can be reused or recycled with the approval of Environmental Board.

Estonia has expressed support for the IAEA "Code of Conduct on the Safety and Security of Radioactive Sources", but not to the "Guidance on the Import and Export of radioactive sources".

5.4. AUTHORIZATION OF TRANSPORT

The carriage of radioactive substances or devices containing a radioactive substance is a radiation practice according to the Radiation Act and requires a radiation practice licence from the Environmental Board. Six companies are now licensed by the Environmental Board to carry radioactive substances or devices with radioactive substances.

The Radiation Act requires the owner of the radioactive substance or device that will be transported to meet certain requirements for road, railway, air and water transport. The consignor must ensure that the transport packages meet safety requirements, the mode of transport ensures safety and the carrier has been informed about the safety requirements for the transportation.

Transport of radioactive material between Estonia and other European Union countries is regulated with the Council Regulation (EURATOM) No 1493/93 of 8 June 1993 on shipments of radioactive substances between Member States and Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods. A holder of sealed sources or radioactive waste, who intends to carry out a shipment of such sources or waste, or to arrange for such a shipment to be carried out, is required to obtain a prior written declaration by the consignee of the radioactive substances. For import of radioactive substances to Estonia a recipient or its authorized representative is required to present a written declaration to the Environmental Board for verification and validation procedures.

The requirements and procedures for shipment of radioactive sources between Estonia and non-EU countries are provided in the Radiation Act and Regulation No 41 of the Minister of the Environment.

The Radiation Act also stipulates that transport over the state border should be in accordance with the international agreements that are in force in Estonia.

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.

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.	
(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.**

5.5. SUMMARY

The legal framework related to authorization of radiation facilities and activities is laid out in the Radiation Act. According to the Radiation Act, the Ministry of Environment, within the limits of its

competence, through the Environmental Board and Environmental Inspectorate organizes the activities related to radiation safety.

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 certain type of radioactive waste is not defined in the national strategy.

Inspection findings, regulatory actions and the feedbacks from operational performance are not taken into account in making authorization decisions.

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.

The Environmental Board does not take graded approach into consideration systematically in carrying out all its regulatory functions of authorization and review and assessment.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

The Environmental Board and the Environmental Inspectorate implement safety review and assessment related to activities and facilities. In accordance with the Radiation Act, an applicant for a radiation practice licence, whether a new applicant or an existing licence holder applying for a new licence, must submit to the Environmental Board an application that indicates the requirements of the Act are fulfilled, accompanied by required documents relevant to the radiation practice. The Environmental Board reviews the application and the submitted documents, and assesses the radiation safety of the practice against the regulatory requirements. The safety assessment can also be carried out by an external expert.

Where an application is in relation to an amendment to an existing licence, the Environmental Board conducts an assessment of the changes proposed to the radiation practice. During the assessment process, the Environmental Board may conduct a site visit at the applicant's facility, prior to issuing the licence and compliance information is taken into account. If the application is satisfactory, the Environmental Board will issue the radiation practice licence for a period of up to 5 years. The radiation practice licence will stipulate the requirements for radiation safety, including the requirements for radiation monitoring and submission of related data to the Environmental Board.

During the period of validity of the radiation practice licence, supervision over the authorized radiation practice is performed by the Environmental Inspectorate, by way of inspections during which the inspector assesses compliance against the terms and conditions of the radiation practice licence and against the relevant regulatory requirements. The Environmental Board continuously assesses performance of the licence holder over the licence period, including the required periodic reports. Where deficiencies are noted by the Environmental Board, it may notify the Environmental Inspectorate who has the right to use the enforcement actions.

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

Granting of radiation practice licences is in the exclusive mandate of the Environmental Board. State supervision of radiation safety is carried out by the Environmental Inspectorate. The organizational structure of the Environmental Board is approved by the Ministry of Environment. There are two bureaus in the Radiation Safety Department of the Environmental Board. The main tasks of the Radiation Protection Bureau are the processing of radiation practice licences and preparation of radiation safety assessments, with the work organized by areas of activity (medicine, science, industry, etc.). The degree of complexity of the licences being processed is also taken into account when distributing the workload. The main tasks of the Radiation Monitoring Bureau are the organization of the radiation monitoring of the environment, organization of early warning of radiation emergencies, laboratory analyses, monitoring of the personal doses of radiation workers. The qualification requirements are prescribed by the General Director of the Environmental Board in the job description of each specific position.

The Radiation Safety Department may seek advice and consultation or training from other departments of the Environmental Board. Staff of the Environmental Board are trained in-house as well as within the IAEA technical cooperation programme.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

The Radiation Act and relevant regulations specify the information and data that are required to be submitted in an application for each radiation practice licence; however it is not practice specific. In order to facilitate review and assessment, the Environmental Board has developed guidance material for application requirements for the most common radiation practices in Estonia. When authorizing radiation practice, the Environmental Board may seek additional information relevant to the applicant from other databases like the Commercial register, the National register of health care professionals, and the National register of activity licences for health services. Entries in the registries are public or accessed digitally through a secure access.

The application and submitted documents; decision of granting authorization, licence amendment, refusal of the granting of authorization or revoking of the licence; the radiation practice licence and other relevant documents like safety assessment reports; and monitoring data are entered and recorded in the document management system, KIRKE, of the Environmental Board, according to the internal guidance such as Records Management Procedure. The document management system of the Environmental Board keeps all documents issued and received by all departments and regions of the Environmental Board.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

The Environmental Board verifies the comprehensiveness and quality of the safety assessment against regulatory requirements and conditions of license. The Environmental Board and the Environmental Inspectorate perform their respective regulatory activities based on the risks of the radiation practices; licence applications pertaining to low-risk radiation practice, for instance, are not as detailed and lengthy and their inspection is not as detailed as in the case of high or moderate-risk radiation practice. The Environmental Board also takes into account internationally recognized good practices, standards and experience from other countries in its authorization and review and assessment activities.

Every planned radiation practice is required to be justified that it is the best option in terms of the economic, social or other benefits as regards to the potential health damage caused by radiation. If new or important evidence about the efficiency or consequences of an existing radiation practice is obtained, the justification will have to be reviewed. Upon the planned changing of the radiation practice, the radiation practice licence holder must submit to the Environmental Board documents justifying and describing the change in the radiation practice.

Subsection 11 (2) of the Environmental Impact Assessment and Environmental Management System Act indicate that environmental impact assessment needs to always be considered and the decision on the initiation/non-initiation of the environmental impact assessment must be made during the time of processing the licence being applied for. If required, the processing of the application for radiation practice is suspended by the period of the environmental impact assessment. An environmental impact assessment is however not needed for each application or amendment of the licence.

As part of the authorization process, the Environmental Board has the right to set the applicant a deadline for elimination of deficiencies in the application for the licence or for submission of more specific information concerning the materials included in the application. The processing time for the application is extended by the time needed to eliminate the deficiencies or to submit more specific information. In addition, the Environmental Board has the right to verify on-site compliance of information forming a safety assessment report with the actual situation. The safety assessment report sums up findings and concludes with proposals to improve safety. The Environmental Board may also refer to the international standards, when justifying the requirements in accordance with the relevant acts and regulations, to improve radiation safety.

6.2. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

Safety review and assessment is carried out in the licensing of radioactive waste management activities and facilities. During processing of the radiation practice license application, the Environmental Board verifies the presented data, and the situation on-site as necessary. As a precondition for granting a radiation practice license, the Radiation Act requires that the applicant present a confirmation on the safe management of any radioactive waste which may be generated.

Regulation No. 8 "The Classification of Radioactive Waste, the Requirements for Registration, Management and Delivery of Radioactive Waste and the Acceptance Criteria for Radioactive Waste" defines the requirements for safety assessment of radioactive waste handling, storage and landfill disposal facility. The following needs to be taken into account when assessing the radiation safety of a handling facility of radioactive waste: impact of the waste handling facility on radioactive contamination of the environment, taking into account the average level of natural radioactivity, expressed in the concentrations and scope of activity of radionuclides in the observed area; effective dose of the observed group of inhabitants; dose equivalent and effective dose of an exposed worker at the waste handling facility. A separate radiation safety assessment is required for closure of landfill disposal facility.

6.3. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The legislation defines a general list of documents to be submitted for authorization for a radiation practice. The safety assessment includes a systematic evaluation of the design of the radiation source, operating instructions, working procedures, safety systems, and compliance of organizational actions to the requirements of the radiation safety of workers and members of the public (for medical exposure, also patient radiation exposure) in normal working conditions and emergency situations.

For a new high-risk radiation practice, the applicant for the radiation practice licence is required to guarantee that all building design documentation concerning the facilities is reviewed, and that the new radiation sources to be used are approved beforehand by a qualified expert. In case equipment is commissioned, the applicant for the radiation practice licence attaches to the application all the relevant documents. The application needs, inter alia, to describe the methodology and equipment used, including safety evaluation.

6.4. REVIEW AND ASSESSMENT FOR TRANSPORT

According to the Radiation Act, every carrier of radioactive sources, with activity or special activity exceeding the exemption value, must have licence issued by the Environmental Board. A radioactive substance and a device containing radioactive substance, the activity or specific activity of which is greater than the exemption level, is transported by highway, railway, air and waterway according to the procedure established by legislation concerning hazardous loads. Transport across the state border takes place in accordance with international agreements in force in the Republic of Estonia and on the basis of Estonian legislation.

All radioactive sources used in medicine, research and industry are manufactured in other countries and are imported to Estonia. Estonia does not regulate the design of the package of radioactive material. The Environmental Board before granting approvals always checks the documentation according to regulatory requirements. There are no designers and manufactures of special form radioactive material, low dispersible radioactive material and packages in Estonia. There are not many international shipments and only few companies can perform shipment of radioactive sources in Estonia.

Conditions for radiation monitoring are imposed in the radiation practice licence on transport of a radioactive substance, which could be the monitoring of the exposed worker's workplace and/or exposed worker's personal doses. As a rule, an exposed worker is classified as category B, whose frequency of personal dose monitoring is defined in the licence conditions.

The various pieces of legislation on radiation safety contain the relevant content of the IAEA Regulations for the Safe Transport of Radioactive Material (SSR-6) and ensure the proper implementation of the international conventions and agreements that Estonia has agreed to. These international agreements are the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). Regulation concerning the International Carriage of Dangerous Goods by Rail (RID), the International Maritime Code for Dangerous Goods (IMDG Code) and International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air.

An established mechanism for the exchange and assessment of information related to transport of radioactive material is not however formally established. Recommendation R4 in Section 1.5 addresses this issue.

6.5. SUMMARY

The Environmental Board and Environmental Inspectorate have implemented a framework for safety review and assessment related to activities and facilities according to the Radiation Act.

Review and assessment of radiation safety is performed during the process of issuing/amending a licence by the Environmental Board and during the conduct of inspections by the Environmental Inspectorate.

7. INSPECTION

7.1. GENERIC ISSUES

The state supervision of radiation safety is carried out by the Environmental Inspectorate. In performing radiation supervision, the Environmental Inspectorate follows requirements laid down in the Radiation Act and regulations.

7.1.1. INSPECTION PROGRAMME

The Environmental Inspectorate performs different types of inspections including planned and reactive as well as announced and unannounced inspections.

The Environmental Inspectorate has an inspection programme based on the risk of facilities and activities as identified in the Radiation Act as low, moderate and high risk. The inspection programme of the Environmental Inspectorate establishes frequency of inspections; once in a year for high risk, once in 2-3 years for moderate risk and once in five years for low risk.

The Environmental Inspectorate inspects facilities and activities and could take measures as provided in the Law Enforcement Act, which also provides inspectors unlimited access to facilities and activities.

Announced inspections are planned and based on an annual plan, approved by the Director General of the Environmental Inspectorate, and unannounced inspections are performed if unauthorized radiation practice is suspected of non-compliance or if information is received from the Environmental Board that the conditions of the licence are not being complied with. Unannounced inspections are also conducted if there are indications of immediate hazard (for example, alarm signals or complaints from the public). If an illegal radiation practice is identified, the situation is recorded and misdemeanour or administrative proceedings are initiated, which will be followed by more thorough controls as necessary. When non-compliances are detected during inspection, the situation is recorded and administrative proceedings are initiated. If necessary, follow-up inspection is also performed.

7.1.2. INSPECTION PROCESS AND PRACTICE

During the period of validity of the radiation practice licence, the Environmental Inspectorate performs the inspection of a radiation facilities and activities. State supervision of the radiation safety is mostly carried out on the basis of an annual inspection plan which is prepared collaboratively with the Environmental Board as appropriate.

During the inspection, inspectors of the Environmental Inspectorate review the documentation related to the inspected radiation practice (including equipment, various monitoring data, calibration documents etc.). Adherence to conditions specified in the radiation practice licence is verified.

The Environmental Inspectorate does not perform any measurements during inspections. If it is necessary, a competent provider of measurement services or qualified radiation experts is used. Staff of the Environmental Board may accompany the inspectors during inspections of high risk facility as needed.

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:*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	• *Structures, systems and components and materials important to safety;* • *Management systems* • *Operational activities and procedures;* • *Records of operational activities and results of monitoring;* • *Liaison with contractors and other service providers;* • *Competence of staff;* • *Safety culture;* *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.**

After the inspection, an inspector prepares an inspection report with conclusions about compliance or detected non-compliances including records of irregularities found.

7.1.3. INSPECTORS

The Environmental Inspectorate is the only institution mandated to inspect radiation safety. The inspectorate also has other supervision responsibilities in various areas of environmental protection.

The Environmental Inspectorate currently has 16 inspectors, including the chief inspector who mostly deals with the responsibility of the coordination of supervision activates. One inspector mostly conducts inspection of high risk facilities and activities, but also includes inspections of moderate and low risk facilities. Most inspectors of the Environmental Inspectorate do not have the necessary training and expertise to carry out inspection of facilities and activities. Newly recruited personnel of the Environmental Inspectorate are trained though in-house mentoring, or through a basic five day training annually arranged by the Environmental Board. Environmental Inspectorate staff are also trained in courses and workshops organized by the IAEA. Recommendation R7 in Section 3.3 addresses this issue.

7.2. INSPECTION OF WASTE MANAGEMENT FACILITIES

The Environmental Inspectorate verifies the safety of radioactive waste management facilities and activities by periodic inspections, in accordance with the annual inspection plan. There are however no specific internal guidelines and procedures for inspection of waste management facilities or decommissioning activities. Recommendation R8 in Section 3.6 addresses this issue.

During the IRRS mission, team members visited a site to observe inspection at a waste management facility at the Paldiski site. Check lists were prepared and used during the inspection to verify:

- Labelling and warning systems;
- Transport of radioactive waste (transport register, vehicles, containers);
- Radioactive waste management (places and methods for handling and storage);
- Safety of workers;
- Environmental monitoring;
- Emergency preparedness;
- Information about radiation safety specialist and leadership;
- Data requested to send to the Environmental Board and condition in the license.

During the site visit, the IRRS team observed that the inspection findings were informally discussed with the licensee during the inspection; however it would be advisable that the inspector hold an exit meeting with the licensee to make sure that all the findings are summarized and well understood by the licensee. During the site visit, the IRRS team also observed that the inspectors of the Environmental Inspectorate did not have any measuring equipment for conducting independent tests and measurements. Recommendation R7 in Section 3.3 and R15 in Section 7.1 addresses this issue.

7.3. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The Environmental Inspectorate supervises all radiation practices such as use of radiation sources in medicine including veterinary medicine, industry, research and also management of radioactive waste.

Inspections are carried out based on annual plan which is developed from the inspection programme depending on risk of practices and feedback from operational performance (e.g. feedback on the exceeding of limits and conditions or on incidents). About 75 inspections are conducted on average annually the Environmental Inspectorate. The Environmental Inspectorate supervises high-risk radiation practice with a frequency of once a year; moderate-risk – every 2-3 year, low-risk radiation practice once in five years. However, the inspection programme based on the established frequency of inspection is not always realised.

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.**

Guidelines for inspectors, the "Guidelines for radiation practice controls (inspections)" that include checklists for common practices (dental X-ray, radiation device, X-ray diagnostics, stationary measuring instruments in industry and industrial radiography) are prepared. However, there are no internal guidelines that cover all facilities and activities inspected by the Environmental Inspectorate. Recommendation R8 in Section 3.6 addresses this issue.

7.4. INSPECTION OF TRANSPORT

The Environmental Board provides licences for transport activities in accordance with the Radiation Act. The Environmental Inspectorate is responsible for conducting supervision of all facilities and activities for compliance with regulatory requirements on radiation safety. Inspection conducted by the Environment Inspectors in a facility with a license also includes inspection for safety of transport of activities. However, although there are at present six companies licensed by the Environmental Board for carrying

out land transport activities of radioactive materials, the Environmental Inspectorate does not conduct inspection of transport activities to ensure compliance with regulatory requirements in such companies.

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.**

7.5. SUMMARY

According to the Radiation Act, state supervision of radiation safety is carried out by the Environmental Inspectorate.

In performing radiation supervision, the Environmental Inspectorate follows requirements laid down in the Radiation Act and relevant regulations.

For the purpose of developing an inspection programme, the inspection frequency in radiation practices is established based on facility risk levels. However, the established frequency of inspections in the inspection programme is not always achieved.

Inspectors are not sufficiently trained, or equipped to perform independent verification of safety and regulatory requirements, which would help them to evaluate regulatory compliance on-site, including instant detection of possible radiation hazards at the inspected facilities (e.g. metal-recycling facilities, waste storage, radiotherapy equipment shielding).

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

Inspectors of the Environmental Inspectorate, when they identify a non-compliance with safety requirements or with conditions specified in the authorization, can take enforcement actions ranging from verbal warnings to cessation of activities, in case of hazard to the population or the environment, in accordance with the provisions in the Law Enforcement Act, Administrative Procedure Act and the Code of Misdemeanour Procedure.

The inspectors of Environmental Inspectorate are independent in their activities and make decisions on the case-by-case basis based on their experience and individual judgement. However, although the Environmental Inspectorate has developed a generic guideline for imposing fines for non-compliance, it has not yet established an enforcement policy and criteria for taking enforcement actions and has not established any internal guidance and procedures.

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.**

The Environmental Inspectorate requests, if necessary, information needed to investigate misdemeanour or criminal proceedings from third parties (e.g., transportation service providers, maintenance service providers, etc.).

According to the Statute of Environmental Inspectorate, the Inspectorate:

1) performs state supervision and applies enforcement actions prescribed by the law;
2) is an extra-judicial body to conduct misdemeanour proceeding in cases provided in the law;
3) conducts pre-trial proceeding of crimes in cases provided by the law (has a status of an investigative body according to the Code of Criminal Procedure).

If the Environmental Inspectorate identifies during inspection an activity with radiation sources which involves or may involve a radiation hazard to human health, the Environmental Inspectorate has the right to temporarily stop activities or shut down a facility, while using other measures provided in the

Enforcement Act. The Code of Misdemeanour Procedure describes the process of imposing a penalty for non-compliance. Violations identified in the Radiation Act are:

1) a practice without a radiation practice licence;
2) violation of the obligations of the radiation practice licence;
3) a production of food, toys, and jewellery or cosmetics goods with radioactive substances;
4) the transport of a radiation source containing radioactive substances over the national border without permission;
5) delivery of radioactive substance without a licence.

When the Environmental Inspectorate identifies non-compliance with regulatory requirements or conditions of the license provided by the Environmental Board, the Environmental Inspectorate informs the Environmental Board and provide necessary documents. According to the Radiation Act, the Environmental Board based on this information, has a right to decide whether to amend or revoke the radiation practice licence.

Enforcement actions of the Environmental Inspectorate also include, imposing administrative fines, proposal of imposing criminal sanctions, and suggesting to the Environmental Board to amend or revoke a licence. When the holder of the radiation practice licence fails to comply with taking corrective actions specified by Inspectors of the Environmental Inspectorate for rectifying non-compliance, the Inspectorate has the right to propose to the Environmental Board to repeal the licence and process further actions to the Penal Code. Environmental Inspectorate conducts verification of its enforcement actions which incorporates through the process of receiving information, performing analysis and a follow-up over deadlines.

8.2. ENFORCEMENT IMPLEMENTATIONS

If, during inspection, a non-conformance is identified, the inspector prepares a report which includes information about detected non-compliance with correction deadlines. The inspector takes into account the risks associated with the facility or activity in making decisions about the appropriate action, including whether it is necessary to perform follow-up inspection. The licensee with more serious non-compliances or of a higher risk could be inspected more often. When the licensee informs about correction of non-compliance and provides necessary evidence, inspectors record all provided information in the database OKAS.

In case of serious non-compliances, inspector prepares a protocol recording the required enforcement action. If a detected violation can be a hazard to health or environment, the inspector has a right to stop activity with radiation source immediately to ensure elimination of the non-compliance. However, there is currently no guidance for inspectors on how to take an enforcement action for addressing non-compliance. Recommendation R8 in Section 3.6 addresses this issue.

All documents related to misdemeanour proceedings are signed and stored on paper in the misdemeanour file, and electronically within the misdemeanour portal.

The licensee has the right to appeal with regard to the enforcement action taken by the Environmental Inspectorate in accordance with the Administrative Procedure Act.

Training for new staff also includes topics on enforcement. The Environmental Inspectorate organizes training of inspectors and a mentoring system is in place for new recruits.

8.3. SUMMARY

The Environmental Inspectorate is empowered by Radiation Act and Law Enforcement Act to take enforcement actions, which include fines, penalties, suspension and revocation of licenses.

The Environmental Inspectorate conducts a follow-up inspection to ensure the corrective actions are properly implemented.

The Environmental Inspectorate has not yet developed formal criteria and procedures for taking enforcement actions commensurate with the gravity of non-compliance. The inspectors of Environmental Inspectorate are independent in conducting their activities. They make decisions on the case-by-case basis.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

Fifteen regulations have been issued under the Radiation Act. In developing radiation safety regulations the Ministry of Environment cooperates with other relevant Ministries and Government organizations.

The Environmental Board issues guides for licensees to ensure the fulfillment of the requirements of the Radiation Act by applying good practices, procedures and other measures. The Environmental Inspectorate participates in the preparation and coordination of new draft legislation and also analyses the effect of a legislation in its area of activity and makes proposals for its improvement if necessary.

The update of legislations and guides is also linked to the EU legislation updates or introduction of new legislative acts. The Ministry of the Environment organizes the transposition of EU laws and related legislative drafting, as well as reviews of and amendments to legislation, with national circumstances taken into account.

Radiation safety and protection requirements have been transposed to the Radiation Act from the Council directive 96/29/Euratom laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation.

By 6 February 2018, Estonia as a European Union member state has to transpose the directive 2013/59/Euratom that lays down basic safety standards for protection against hazards from ionizing radiation. Therefore, the requirements for radiation safety and radiation protection will be reviewed within the national legislation (additionally to the radiation safety development plan and audit).

A website information system on draft acts, the EIS, is used in the proceedings of draft acts and the system is available to interested parties for monitoring the processing of drafting acts, search for documents within the information system, participation in open consultations and comment on documents being approved.

Information directed to the public is also available on the websites of authorities involved in ensuring radiation safety. Besides, the Ministry of the Environment organizes an annual radiation information day and the development of any new legislation or guide is introduced at that time.

There are no guides on decommissioning and radioactive waste management activities that take into account the complexity of the operations and the magnitude of the hazards associated with the facility and operations. Although the Environmental Board has issued guides for most common radiation practices, there are no guides in place for specific activities with radiation sources (such as nuclear medicine, radiotherapy, use of unsealed sources in industry, sources in research) that are identified as moderate and high risk radiation practices.

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."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S10	**Suggestion: The Environmental Board should consider establishing and adopting regulatory guides that cover all facilities and activities.**

9.2. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

In accordance with legislation, requirements and associated safety criteria for radioactive waste management facilities and activities are further elaborated in regulations adopted by the Ministry of Environment.

The regulation "Classification of radioactive waste, requirements for the entry, handling, delivery and waste acceptance criteria" establishes requirements for management of radioactive waste and waste acceptance criteria for storage.

The regulation "Clearance levels of radioactive substances generated in radiation practice or items contaminated with radioactive substances, and the conditions for their release, recycling and recovery" establishes requirements for the clearance levels of materials containing any radioactive substances generated in the radiation practice or devices; facilities contaminated by radioactive substances, waste and emissions; and conditions for their recycling, recovery or discharge to the environment.

Current radioactive waste predisposal management includes processing and storage of solid radioactive waste and the waste acceptance criteria for storage are in place. However, there are no explicit provisions to ensure:

- the operator retains overall responsibility and control while delegating work associated with his responsibilities to other organizations;
- the responsibility of operator for establishing and implementing the overall strategy for the management of the waste that is generated;
- the waste and/or waste packages that do not meet process specifications and requirements for its and/or their safe handling, transport, storage and/or disposal are identified, assessed and dealt with;
- the results of the periodic safety review are reflected in the updated version of the safety case for the facility;
- the design of the storage facility depends on the type of radioactive waste, its characteristics and associated hazards, the radioactive inventory, and the anticipated period of storage;

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 requirements".*
R19	**Recommendation: The Ministry of Environment should amend the regulatory**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	framework on predisposal management of radioactive waste to establish explicit provisions related to the overall responsibilities of the operator.

Although there is waste acceptance criteria for the storage of radioactive waste, preliminary waste acceptance criteria for the disposal of radioactive waste has not been established. Sections 11 and 12 of the Regulation No. 8 "Classification of radioactive waste, requirements for the entry, handling, delivery and conformity indicators of radioactive waste" adopted by the Minister of Environment establish the requirements to radioactive waste packaging and the conformity indicators for radioactive waste packages. To ensure integrated consideration of effectiveness of radioactive waste predisposal management, due to interdependences among the various steps from the generation of radioactive waste up to its disposal, as well as the impact of the anticipated disposal option, it is important to consider the establishment of preliminary acceptance criteria for disposal of radioactive waste or the criteria that are anticipated for the most probable disposal option.

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.**

The Radiation Act defines the disposal of radioactive waste as radiation practice subject to authorization. The overall disposal concept is set in the national Radioactive Waste Management Programme and the decision for construction of radioactive waste disposal facility is expected to be taken by the Government by 2017. The radioactive waste disposal facility, according to the Radioactive Waste Management Programme and the Radioactive Waste Action Plan, is to be established by 2040. The preliminary studies for the decommissioning of the reactor compartments of the former Paldiski military nuclear site and for the establishment of a radioactive waste repository are launched.

The existing national regulatory framework for establishment of radioactive waste disposal facility is not consistent with the IAEA safety standard SSR-5. While activities have been initiated, the scope of characterization of and criteria for disposal site selection are yet to be established.

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.**

The prospective changes in and the amendment of regulatory framework is needed for further stages of the disposal facility lifetime (design, construction, commissioning, operation, shutdown and closure) to specify the principles, requirements and associated criteria for safety.

The existing national regulatory framework for decommissioning does not fully comply with the IAEA Safety Standard GSR Part 6.

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.**

9.3. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The Environmental Board has issued guides for most common radiation practices such as use of dental X-ray equipment, use of X-ray diagnostics equipment in veterinary medicine, use of sealed sources in industry, criteria for quality control for the dental X-ray equipment. However other specific activities with radiation sources (such as nuclear medicine, radiotherapy, use of unsealed sources in industry, source in research), usually identified such as moderate and high risk radiation practices, are not covered. When cases of new radiation practice occur, international recommendations are used. Suggestion S10 in Section 9.1 addresses this issue.

The existing regulations are not fully in line with the requirements of GSR Part 3 in such areas as notification and registration, and dose limits to the lens of the eyes. Estonia as a European Union member state has plans to transpose the directive 2013/59/Euratom that lays down basic safety standards for protection against hazards from ionizing radiation by 2018.

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 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."*
R22	**Recommendation: The Ministry of Environment should update the existing regulatory requirements for radiation safety in accordance with GSR Part 3.**

9.4. REGULATIONS AND GUIDES FOR TRANSPORT

The regulations that apply to the transport of radioactive material in Estonia are Regulation No. 118 of the Minister of Transport and Communications "*Rules for Carriage of Dangerous Goods by Road*" which regulates the transport of dangerous goods in the domestic and international road transport; and regulations No. 37 of the Minister of Economic Affairs and Communication "*Professional skills requirements, training rules and training course syllabus of a driver carrying hazardous loads*" which establish the skills and training requirements for drivers of a load of hazardous goods including radioactive materials.

For issuing licenses for transport activities the Environmental Board uses the IAEA safety guide SSG-26, Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material.

9.5. SUMMARY

The Environmental Board has established and implemented regulations covering the areas under their regulatory oversight. There were however exceptions in a few areas, leading to recommendations and suggestions.

An update of regulatory framework, taking into account the IAEA Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3 is planned.

The existing regulations for radioactive waste management are not in line fully with the appropriate IAEA safety requirements (GSR part 5 and SSR 5), and were partly identified in the self-assessment report.

It is observed that there is a need for the review and update of the existing national regulatory framework for decommissioning to comply with IAEA safety standard GSR part 6.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

10.1. GENERAL EPR REGULATORY REQUIREMENTS

Basic responsibilities

In Estonia the Emergency Act provides the legal basis for crisis management. The Emergency Act designates the Ministry of Interior (MoI) as a national coordination authority in case of crisis, as well as for preparedness and response to radiological emergencies. The Rescue Board (RB) under the MoI is the organization responsible for the coordination of any kind of emergency in the Estonian territory, which directs the response to an emergency and performs rescue work. The RB has the authority to activate and to involve different organizations in the response depending on the emergency type.

The functions of all other national authorities with responsibilities to respond in an emergency, as well as the Environmental Board, are described in the National Radiological Emergency Response Plan (NREP). This plan is approved by the Government.

The Emergency Act describes the functions of the Environmental Board in case of crisis and emergency. The Environmental Board provides high level expertise in case of radiological emergency and, upon request, may assist first responders on the scene.

Under the Radiation Act, the Environmental Board requires a licensee of a high risk radiation practice to submit an emergency preparedness and response plan. The plan, which must be based on the potential exposure assessment, is an obligatory document to obtain a license.

Additionally, the Radiation Act requires a licensee to inform the Environmental Board and the Emergency Response Centre (ERC) of the RB immediately about any emergency and to mitigate the consequences.

The NREP also takes account of possible emergencies arising out of transport accidents. In this respect radioactive substances are treated by the NREP as dangerous or hazardous goods depending on the activity levels.

Hazard assessment

The Government of Estonia, under the Emergency Act, must establish a list of emergencies that require hazard assessment and nominate the responsible state authority in charge with the preparation of the respective assessments. The responsible state authorities are required at least once in two years to conduct a review of the hazard assessment, in order to take into account any changes to the hazards and make amendments as necessary. The Environmental Board is responsible for performing the hazard assessment on radiological accidents with domestic and cross-border consequences.

The MoI has published guidelines for preparing hazard assessments in accordance with requirements in the Emergency Act. Two hazard assessments have been developed by the Environmental Board based on these guidelines and have been approved and submitted to the MoI, which is responsible for providing country hazard analyses. These hazard assessments are:

- hazard assessment of radiological emergencies from the trans-boundary effects (a significant release of radioactive material from NPP of neighboring counties, re-entry of a satellite with radioactive material) and
- hazard assessment on domestic emergency with radioactive sources (lost, orphan or accidental sources, transport accidents, dirty bomb).

The Emergency Act requires that every two years, or in case new information becomes available, the hazard assessment must be reviewed. As the NREP and the Communication Plan for Notification of the Public have been developed on the basis of the hazard assessment, those Plans will be updated if the hazard assessments are revised as part of the two-year review. Operational feedback is taken into account in the current NREP and the Communication Plan.

There are no sufficient requirements in legislation for the licensee to develop a hazard assessment which is the basis of on-site EPR planning.

Estonian legislation does not specify emergency preparedness categories such as described in GSR Part 7, which is the basis for implementation of the graded approach for EPR. For example GSR Part 7 requirements such as establishing requirements for classifying emergency; arrangements for initial assessment of the situation and for mitigatory actions; and transition from an Emergency Exposure Situation to an Existing Exposure Situation are not addressed.

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**

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	licensees to develop and update hazard assessments relevant to their facilities and activities.

10.2. FUNCTIONAL REGULATORY REQUIREMENTS

Establishing emergency management system and operations

Emergency response to any emergency is organized under the Emergency Act. The Act establishes response conditions on the basis of an all-hazard concept. The available infrastructure is used for any type of emergency, as well as for radiological emergencies.

Coordination of emergency response is performed by the crisis management committees established at State level (Crisis Management Committee of the Government of the Republic of Estonia), regional level (regional crisis management committees) and local Governmental level (crisis management committees of the local Government). A rescue institution forms a management structure for the organization of directing the response to an emergency depending on the emergency. The crisis management committees, if necessary, assist the rescue institution in their area of activity in responding to an emergency.

The Environmental Board has full authority for the regulation of licensees with respect to EPR. The Environmental Board grants the radiation practice licence only if the prescribed conditions are met. The Environmental Inspectorate verifies compliance with licensee during inspections.

The Radiation Act specifies the details that must be described in the emergency plan for high-risk radiation practice.

Identifying, notifying and activating

Regulatory requirements have not been developed for classifying the emergency. However, the licencee's emergency response plan specifies the dose rate limit above which emergency is declared and contains a list of events over which the event becomes an emergency. Recommendation R23 in Section 10.1 addresses this issue.

In case of loss, theft or unauthorized use of a radiation source and an incidence or accident related to radiation practices, the licensee is required to immediately notify the Environmental Board and the Alarm Centre (MoI).

The Emergency Act includes specific requirements in relation to the emergency notification. An Emergency phone 112 is established under the Rescue Board in MoI (continuously available 24/7) and is dedicated for receiving notifications of any type of emergency, including radiological one.

The dispatcher of the Emergency phone 112 uses questionnaires to establish the priority of the emergency, and accesses the resource database to identify the most appropriate Rescue Unit for responding to the notified event. The Rescue Unit which is the closest to the location of the event is contacted immediately after receiving the notification. When an accidental event involves a radiological hazard, the CBRN Unit of the Rescue Board is also notified and activated immediately in order to support the local Rescue Unit in the field. In case of radiological emergency, based on the "Procedure of forwarding operational information of the ERC" the Environmental Board is immediately simultaneously notified.

The Estonian Early Warning System (EWS) is operated by the Environmental Board. When the pre-established alarm level (200nSv/h) is exceeded, a warning message is sent to the Environmental Board duty officer, who verifies and notifies the other relevant agencies according to the "Procedure for

notification of MoI of emergency impending risk of occurrence of emergency" (2010). The group of duty officers (4 persons designated to this task) within the Environmental Board receive messages if any information is received in the emergency mail.

In Estonia there are two major scrap metal facilities and no melting facilities. The major facilities are equipped with portal monitors. The smaller collection points are using portable radiation detection equipment for checking the level of radioactivity of the scrap.

At the borders, the Estonian Tax and Customs Board is responsible for the control of goods which are imported, exported or in transit. The borders are equipped with portal monitors and hand-held equipment.

Estonia is a Party to the IAEA Conventions on Early Notification and Assistance. Bilateral agreements with Latvia and Sweden are in place.

Taking migratory actions

There are no first responders defined as required by IAEA GSR Part 7. It is the obligation of the licensee to first respond to an emergency and to take measures to mitigate the consequences. In the event of a more complex emergency, the initial mitigatory actions can be taken within the existing national emergency response system, and the IAEA Convention on Assistance may be invoked. However, the NREP does not address arrangements for initial assessment of the situation and for mitigatory actions to prevent any unnecessary risk to the emergency workers and the population. Recommendation R23 in Section 10.1 addresses this issue.

Taking urgent protective action

National intervention levels are established in the current legislation, in compliance with GSR Part 7 and are consistent with recommended values. Regulation No.93/2004 "Intervention and action levels and emergency exposure limits in a radiological emergency" specifies Generic Intervention Levels (GILs) for urgent (sheltering, evacuation, thyroid blocking) and late (temporary relocation, returning, permanent resettlement) protective actions, and prescribes action levels for foodstuffs.

Estonia does not have emergency preparedness category I and II and no emergency planning zones have been outlined in law; however, based on the hazard assessment of transboundary emergency, Estonia is considered as falling in emergency preparedness category V. NREP does not contain "planning distances". The Environmental Board is a body to be involved in such planning activities.

Where a nuclear accident with cross-border effects occurs in a neighboring country, action levels for restriction of the consumption of drinking water and food exists, but there are no guides for their practical implementation. Suggestion S10 in Section 9.1 addresses this issue.

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*

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	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.**

Providing information and issuing instructions

In Estonia, it is the obligation of the Environmental Board and RB to issue warnings and instructions to the public upon receiving notification from the licensee of emergency on the site.

The instruction of the general public is regulated by the regulation No 92 of the Government of the Republic "Procedure for the notification of the general public about the imminent danger of an emergency and resolution of the emergency, and requirements for the information forwarded". The licensee of high-risk radiation practice must notify the general public of any accidents during performance of their tasks or in their area of activity if this endangers the life or health of many (several tens of) people or may cause significant material or environmental damages or serious and extensive interruptions in the sustainability of vital services. The Environmental Board inspects the organization of notification in the licensing process.

Protecting emergency workers

In the existing legislation, there are no criteria to designate workers as "emergency workers" in advance of a radiological emergency. There is no clear description of how the individual dosimetry and dose management is performed for emergency workers, although a regulation to address this issue is under preparation. Nevertheless, a legal basis for the protection of emergency workers is outlined in Regulation No.93/2004: "Intervention and action levels and emergency exposure limits in a radiological emergency" that includes provisions related to the dose limits, which have to be applied for the exposed workers. For life saving actions, the dose limit might be exceeded, but only on a voluntary basis.

In the NREP the dose limits for intervention personnel are much more detailed, according to the specific tasks (lifesaving actions, mitigatory actions, recovery actions, etc.).

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.**

Assessing the initial phase

There is a guidance document by the Health Board entitled "Recommendations of the Health Board for medical treatment of patients exposed during radiological emergency". Operational Intervention Levels (OILs) are only adopted in the new approved NREP in order to provide guidelines for the approximate radius of the inner cordoned area in radiological emergencies. These OILs are expressed as gamma dose rates (microSv/h), alpha surface contamination (Bq/cm^2) and beta surface contamination (Bq/cm^2).

Managing the medical response

As a practical rule, any treatment needed as a result of emergencies will be provided in regional hospitals, which have departments of hematology.

According to the NREP, the authority responsible for the provision of healthcare services in a radiological emergency is the Health Board (HB). The guidance document "Recommendations of the Health Board for medical treatment of patients exposed during radiological emergency" developed by the Health Board is directed mainly to the medical personnel of emergency departments of the hospitals and ambulance units. It describes the types of injuries caused by ionizing radiation (symptoms), dealing with external contamination, triage of patients, medical examination, laboratory analyses, initial and follow-up treatment and estimation of doses. Additionally the Environmental Board provides the HB with technical expertise. The decontamination of persons (injured or not) is the responsibility of the Rescue Units and the medical staff is assisting the rescuers in the decontamination of injured persons.

Other activities in emergency preparedness

The RB has a role in defining the criteria for agricultural countermeasures, ingestion and longer-term protective actions. Pursuant to the radiological emergency response plan, the Veterinary and Food Board in conjunction with the Health Board and the Environmental Board develops guidelines regarding the restriction of the consumption of food by the members of the public. The values are described in the Minister of the Environment Regulation No.93. However, there is no documented procedure to guide the coordination of these activities, although some consultation to address this issue has been initiated. Suggestion 10 in Section 9.1 addresses this issue

The transition from an Emergency Exposure Situation to an Existing Exposure Situation is currently not defined in the Estonian legislation or in regulatory requirements. Recommendation R23 in Section 10.1 addresses this issue.

10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE

Authority

During the licensing process, the Environmental Board assesses the submitted emergency plan based on the nature of the radiation practice. By granting the license, the Environmental Board also approves the licensee's emergency response plan.

Decree of the Minister of the Environment "Summoning and working procedure of the crisis management team of the Ministry of the Environment" (2009) states the activities for summoning the team, the members of the team (and substitute members) to cover all the tasks of the team. The decree contains detailed description of information exchange between involved parties.

In case of a radiological emergency, the coordination of the response of the authorities is governed by the NERP, which provides the tasks of all authorities participating in the resolution of a radiological emergency.

Organization

According to the Regulation of the Minister of the Environment No.41 the licensee should indicate the name and contact details of the staff member responsible for the actions in case of the emergency. The Radiation Act contains requirements for high risk radiation practices, the emergency plan contains also data on radiation protection competences, notification and training of the staff.

Coordination of emergency response

The coordination of emergency response is regulated by the regulation of the Government of the Republic "Organization of exchange of information between institutions and persons responding to emergency" and in the Regulation of the Government No 44 of 23.01.2002 "Order of cooperation of rescue services, police and emergency medical response services".

Different facilities in Estonia have different arrangements for coordination; for example, an emergency plan of the irradiator facility is fully coordinated with the local rescue and ambulance services and is a part of the plan of the local Government, while the AS ALARA waste storage facility is not required to coordinate its emergency response documents with off-site organizations. Recommendation R25 in Section 10.1 addresses this issue.

Procedure on response in case of lost-found sources (orphan source) have been developed by the national radioactive waste management facility (AS ALARA), which is responsible according to the NREP for covering management, transport and storage of radioactive waste and participation in arrangements for decontamination of the contaminated areas.

Plans and procedures

There are regulatory requirements regarding plans and procedures for licensees. Pursuant to the Radiation Act, one of the main obligations of the radiation practice licensee is to prepare an emergency plan and to test it in accordance with the requirements and frequency established by legislation. The emergency plans are reviewed by the Environmental Board in the licensing process. By granting the radiation practice license the Environmental Board also approves the emergency exposure response plan.

Logistical support and facilities

Regulation No.41 contains the requirements for the necessary means and resources which should be available for emergency preparedness and response. During the inspections Environmental Inspectorate checks/evaluates the licensee emergency plan and the adequacy of tools, personal protective equipment, available dose control devices, and documentation.

Training, drills and exercises

The Environmental Board has regulatory requirements for training, drills and exercises in EPR by licensees. Pursuant to the Radiation Act the licensee emergency plan is tested once a year. The test result is the basis for updating the emergency plan, which is evaluated during the inspections.

The Regulation No. 86 "Requirements for radiation safety training for radiation workers" prescribes that all radiation workers must participate in training courses for moderate or high-risk radiation practice. The licensee ensures the attendance at training events of persons at least once in five years. There are requirements that the radiation safety training should include at least 4-hour lecture covering actions in case of emergency.

The MoI has developed "Requirements on conducting trainings on national and regional level and documented the results". The requirements request preparation of training plan, evaluation report and action plan for implementation of lesson learnt.

The training programme, trainings and exercises are evaluated by the Environmental Board during the pre-authorization inspection based on the documentation provided by the licensee. The Environmental Board is notified following the on-site emergency plan during the exercises. The Environmental Board is involved in the on-site emergency plan testing, but such involvement is voluntary and the feedback given to the licensee is informal. The Environmental Board does not have the practice of observing exercises and the arrangements are informal. Recommendation R23 in Section 10.1 addresses this issue.

Quality management programme

Under section 32 of the Radiation Act, the licensee should put in place a quality assurance programme. However, there is no well-developed quality management system for EPR. Recommendation R10 in Section 4.2 addresses this issue.

10.4. ROLE OF REGULATORY BODY DURING RESPONSE

Pursuant to the Radiation Act the Environmental Board participates in the development of the NREP and its testing. According to the NREP, the role of the Environmental Board is as follows:

1) organizes the monitoring of the radioactivity of the air and soil and prepares radiation analyses for rescue authorities.
2) organizes the temporal and spatial dispersion of the potential radioactive substance and assessment of doses and advises the rescue authority, other authorities and persons participating in the emergency;
3) ensures that radioactively contaminated area(s) is (are) identified and advises the rescue authority as regards the determination and limitation of the danger zone and the protection zone;
4) runs a rescue service agency for the necessary recommendations for the implementation of emergency measures on radioactive pollution;
5) advises the rescue authority radioactive waste treatment;
6) organizes the assessment and documentation of radiation doses of persons who may be exposed and in collaboration with the Health Board supervise the medical assessment carried out by the medical officer;
8) records the doses received in emergency in the national exposure register.

Pursuant to Regulation No.92 of the Government of the Republic "Procedure for the notification of the general public about the imminent danger of an emergency, emergency response and requirements for the information forwarded" the role of the Environmental Board is to inform the Minister of the Environment of the imminent danger of exceeding the intervention levels set for the case of a cross-border nuclear accident or a radiation accident of domestic origin.

The exchange of information between the authorities and persons participating in the emergency is coordinated by the Rescue Board or a Rescue Centre.

If the Environmental Board is the first to know about the accident, it is required to immediately notify the Ministry of Internal Affairs. Notification is regulated by the Government of the Republic Regulation No.57 "Procedure for the notification of the Ministry of Internal Affairs about an emergency or the imminent danger of an emergency".

The Environmental Board, as an international liaison point, exchanges information with the EC (ECURIE system) and the IAEA (USIE system).

Although that the Environmental Board plays an important role in case of emergency, its own emergency response system should be fully comprehensive to fulfil all its responsibilities during an emergency. Recommendation R10 in Section 4.2 addresses this issue.

10.5. SUMMARY

Estonia has established an operational emergency preparedness and response capability based on an integrated all hazard approach including radiological emergencies.

According to the IAEA emergency response categorization of radiation related hazards Estonia is a country with facilities and activities belonging to EPC III, IV and V. Estonian legislation does not specify emergency preparedness categories such as described in GSR Part 7 which is the basis for implementation the graded approach on EPR, although the existing legislation and hazard assessments provide a good basis for implementing the IAEA requirements in order to achieve a harmonized graded approach for establishing arrangements for preparedness and response to radiological emergencies.

The Environmental Board has a range of roles and responsibilities in response to radiological emergency. These roles vary from acting as adviser to the Government and response organizations in an emergency and acting as a national competent authority under Early Notification and Assistance Conventions to provider of public information to taking active role in the emergency response on-site and off-site as a response organization. The Environmental Board has not fully established its own emergency plan and procedures to ensure it will respond effectively in an emergency. The Environmental Board needs to further develop comprehensive emergency arrangements (plans, procedures, emergency management organization, staffing plan, training and exercise programmes, quality assurance programme etc.) to comply with IAEA Safety Standards in EPR.

11. ADDITIONAL AREAS

11.1. CONTROL OF MEDICAL EXPOSURES

- **Regulatory framework and responsibilities**

The Radiation Act provides the Minister of Social Affairs the power to regulate medical radiological procedures. The Minister regulates this area through Regulation No. 29, which covers referrals, use of medical radiological equipment, licensees' radiation safety quality manuals and clinical audits. The Radiation Act also requires that activities related to radiation protection be organized by the Ministry of Environment within the limits of its competence i.e. Environmental Inspectorate and Environmental Board. Therefore, medical uses of ionizing radiation fall within the authorization scheme of the Environmental Board. In addition, an activity licence is required for the provision of specialised medical care which is issued by the Health Board under the Health Services Organization Act. The radiation practice licence registry is maintained by the Environmental Board and the national activity licence registry of specialized medical care is maintained by the Health Board. The Medicines Department of the Ministry of the Social Affairs is responsible for developing policies and preparing legislation regarding medical devices and medical exposure. There is lack of effective coordination of the authorities having responsibilities for the protection and safety of patients. Recommendation R4 in Section 1.5 addresses this issue.

The Health Service Organization Act requires health professionals to submit to the Health Board, documentation certifying their qualifications in terms of their registration with the National Health Professional Registry. Requirements for the continuous training of health professionals are set out in Regulation no. 128 of the Minister of Social Affairs. Similar requirements on qualifications and continuous training are however not in place for medical radiation technologists and radiopharmacists or radiochemists. It is noted that medical radiation technologists may apply, on a voluntary basis, for qualification Level 6 or 7 as established by the Estonian Qualification Authority.

Due to the lack of the afore-mentioned qualification and continuous training requirements, the Environmental Board does not have a legal basis for assessing the training, qualification and competence of medical radiation technologists and radiopharmacists or radiochemists. The health care providers assess the appropriateness of qualification and competence of medical radiation technologists in a non-harmonized way.

Requirement for the employment of medical radiation technologists in diagnostic and interventional radiology, radiotherapy and nuclear medicine are set out in Regulation No. 103 of the Minister of Social Affairs. Similar provisions for radiopharmacists or radiochemists are not in place. All professionals with specific duties in relation to the radiation protection of patients are not specialized in the appropriate area and do not fulfil requirements for training, qualification and competence in the relevant specialty. Recommendation R5 in Section 1.8 addresses this issue.

- **Justification of medical exposure**

Regulatory provisions related to justification of medical exposure do not fully comply with IAEA safety standard GSR Part 3. With regard to individual medical exposures, the Radiation Act states that health care professionals are required to conduct medical radiological procedures in compliance with the principles of justification and optimization. The majority of medical radiological procedures are registered in the Health Service List (HSL) of the Estonian Health Insurance Fund; the criteria for updating this reimbursement related registry and assessing the health services are set in Regulation no. 301 of the

Minister of Social Affairs. Not all medical radiological procedures conducted in Estonia are registered in the HSL. For example, CBCT and dental X-ray procedures performed to adult patients are not included in the HSL. In the case of mammography screening, several entities participated in the program's plan and reimbursement, namely the Estonian Health Insurance Fund, the National Institute of Health Development and the Ministry of Social Affairs. The programme was also assessed against the policies set out in the Development Plan of the Radiology Society.

There are no standardized procedures or regulatory requirements for the generic justification of medical radiological procedures, including new techniques and technologies, for the justification of health screening programmes or for asymptomatic individuals undergoing medical radiological procedures.

With regard to the medical exposure of volunteers as part of a biomedical research programme, approval is sought from the ethics committee; however, the requirement is not explicitly mentioned in the regulation. Biomedical research programmes are however extremely rare in Estonia.

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.**

- **Optimization of medical exposure**

Regulatory provisions related to optimization of medical exposure are in place. Regulation no. 29 of the Minister of Social Affairs requires the licensee to establish dose constraints for carers and comforters as well as for volunteers participating in biomedical research programs, and document them in the quality manual. In addition to that, the licensee is required to seek for approval from the Health Board, if the proposed dose constraints for carers and comforters and the ones for volunteers participating in biomedical research programs exceed 5mSv and 10mSv accordingly.

National diagnostic reference levels (DRLs) have not been established, although relevant elements do exist in the Regulation No. 29 of the Minister of Social Affairs and in the Radiation Act as follows:

a) the licensee is required to collect and document in the quality manual, the average patient doses for the standard size patient undergoing the medical radiological procedures listed in Annex 2 of the regulation, for the most commonly used medical radiological equipment;

b) in case that doses exceed the established DRLs, the licensee is required to suspend the medical radiological practice until investigation is made and any necessary corrective actions are taken.

It is noted that the afore-mentioned list of radiological procedures does not include nuclear medicine procedures. Furthermore, it is not explicitly mentioned which relevant parties are authorized to establish the national DRLs.

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.

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.**

Regulation no. 29 of the Minister of Social Affairs specifies that a medical physics specialist is required to have a professional certificate of a biomedical engineer. According to the new Radiation Act, issued in June 2016 but not in force till November 2016, a medical physics expert should hold a professional certificate of a biomedical engineer or equal in the speciality of diagnostic radiology, nuclear medicine or radiation therapy. The professional certificate of biomedical engineering is issued pursuant to the procedure provided for in the Professions Act. The competencies of the medical physics expert include patient dosimetry, optimization of medical exposure and quality assurance of medical services.

The requirements for the use of medical radiation devices set out in Regulation no. 29 of Minister of Social Affairs states that the approval and operating tests may be performed by a medical physics specialist, or a person authorized by the manufacturer or a laboratory accredited in the relevant measurement area. Moreover, a medical physics specialist should be involved in the planning and performance of nuclear medicine procedures and should be available for other medical radiology procedures to optimize medical exposure, to ensure quality and to advice on radiation safety, if necessary.

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:* *(a) Measurements of the physical parameters of medical radiological equipment made by, or under the supervision of, a medical physicist:* *(i) At the time of acceptance and commissioning of the equipment prior to its clinical use on patients;* *(ii) Periodically thereafter;* *(iii) After any major maintenance procedure that could affect protection and safety of patients;* *(iv) After any installation of new software or modification of existing software that could*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	affect protection and safety of patients. *(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:* *(a) All sources giving rise to medical exposure are calibrated in terms of appropriate quantities using internationally accepted or nationally accepted protocols;* *(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;* *(c) Calibrations of radiation therapy units are subject to independent verification prior to clinical use;* *(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 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.**

- **Pregnant women and breast feeding women**

Health care professionals conducting medical radiological procedures are required to provide information to patients concerning the risk of ionizing radiation, although pregnant or breast-feeding female patients are not explicitly mentioned. Regulation no. 29 of the Minister of Social Affairs states that female patients of reproductive capacity should be interviewed about the possibility and the status of pregnancy, when planning a medical radiological procedure. During the site visit to observe the inspection in the East Tallin Central Hospital, the IRRS team observed that appropriate signs also exist.

- **Release of patients after radionuclide therapy**

During the site visit to observe the inspection in the East Tallin Central Hospital, the IRRS team was informed that the dose rate of 15μSv/h measured at 1m distance from the patient, who has undergone therapeutic radiological procedures in which γ-emitter radiopharmaceuticals are administered, is used as patient release criterion. This dose rate value has been agreed between the Environmental Board and the three nuclear medicine departments operating in Estonia.

- **Unintended and accidental medical exposures**

The licensees are required to apply measures for the prevention of accidental medical exposures and document them in the quality manual. Although there are requirements in place regarding notification to:

a) state health protection supervisory agencies and local Governments in case of accidents and situations which may harm human health of the physical and social environment (Public health Act),

b) the Environmental Board and the Alarm Centre in the case of loss, theft or unauthorized use of radiation sources and of incident or accident that has taken place in the course of a radiation practice, as a result of which an employee or inhabitant has unintentionally been exposed to radiation,

unintended and accidental medical exposures are not explicitly mentioned either in terms of timely notification or in terms of investigation and implementation of corrective actions.

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.**

- **Reviews and records**

Licensees are required to implement a quality management system for radiation safety and document in a quality manual. Regulation No. 29 of the Minister of Social Affairs stipulates the retention period for quality manual documents and data as 10 years and describes the data and documents required to be included in the quality manual.

Additional requirements for data and digital imaging and communications in medicine (DICOM) images registration to the National Health Information System are in place. However, delegation of responsibilities as in the case of calibration, dosimetry and quality assurance undertaken under the oversight of or with the documented advice of a medical physicist are not required to be documented.

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:* *(a) Records of any delegation of responsibilities by a principal party (as required in para. 3.154(f));* *(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.**

11.2. OCCUPATIONAL RADIATION PROTECTION

11.2.1. LEGAL AND REGULATORY FRAMEWORK

The protection of workers from the risks of ionizing radiation is regulated by the Ministry of Environment (MoE) through the Environmental Inspectorate and the Environmental Board.

There are about 1600 registered occupationally exposed workers of which 72% are in the medical area.

The Radiation Act provides the requirements for the protection of persons and the environment against the dangers arising from ionizing radiation and the rights, obligations and liability of persons using ionizing radiations. The requirements include the radiation protection principles of justification, optimization and limitation, the procedure for getting an authorization, the responsibilities of the holder of an authorization, and the definition of the categories of workers.

Other relevant legislation are the Occupational Health and Safety Act (OHSA), which deals with all types of workplace risks. The OHSA stipulates the responsibilities of employers and licensees for the protection of workers, and the rights and duties of workers.

Regulations provide for the dose limits for workers and for the population.

The concept of "constraints" (or "dose restriction") is used in the medical area. The Radiation Act specifies the optimization principle and requires licensees to optimize protection of occupationally exposed workers. However, there are no explicitly established requirements for licensees to specify dose constraints although dose constraints are considered during the licensing process. The Radiation Act also 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.

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:* *(a)* *(b) Shall establish and use, as appropriate, constraints as part of optimization of protection and safety."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(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:* *(a) Shall establish and enforce requirements for the optimization of protection and safety;* *(b) Shall require documentation addressing the optimization of protection and safety;* *(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."*
(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.**

11.2.2. GENERAL RESPONSIBILITIES OF LICENSEES AND EMPLOYERS

The OHSA describes the general responsibilities, the obligations and the rights of the registrants, licensees and employers. Employers are required to ensure conformity with occupational health and safety requirements in every work-related situation for both permanent and temporary worker. When workers of two employers are present on a same workplace, compliance with these obligations have to be clearly defined between the two employers.

The Radiation Act states that the holder of a radiation practice license may appoint a radiation safety specialist that organizes compliance with the radiation safety requirements. If more than ten exposed workers are employed, it is mandatory to appoint such specialist.

The document "Statutes of the national radiation workers dose register" requires that the register should include, in the event of occupational exposure limits being exceeded, a report by the holder of a radiation practice license about the measure taken in case of accidental or emergency exposure. However, such a requirement is not stipulated in the Radiation Act.

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.**

11.2.3. GENERAL RESPONSIBILITIES OF WORKERS

Workers are classified in two classes:

- class A : workers who may receive, per year, an effective dose greater that 6 mSv or more than three tenths of the limit for the lens of the eye:
- class B : workers who are not classified as category A workers and whose effective dose lies between 1 and 6 mSv per year.

The definition of these two classes is close to the definition of the three levels of risk in the Radiation Act. (see 11.2.1 above)

There is no definition of emergency workers and the Environmental Board has plans to develop requirements for workers involved in existing exposure situations in its Action Plan for Occupational Radiation Protection.

The dose limits for workers are clearly defined and are compliant with related IAEA's safety standards, except for the lens of the eye which still have to be updated in accordance with the requirements of GSR Part 3.

There is no mention of the responsibilities of the workers in the Radiation Act but the Occupational Health and Safety Act describes the obligations and the rights of workers on their health and safety in workplaces.

Under the Radiation Act, art.41 a person under the age of 18 years shall not be permitted to perform any radiation practices. During the training, the permitted level of effective dose of a student or a trainee is 6 mSv per year.

11.2.4. REQUIREMENTS FOR RADIATION PROTECTION PROGRAMMES

The Radiation Act describes the information to be provided by the applicant in order to get a license. This information should include the full description of the planned activity and all the information concerning the setup of a Radiation Protection Programme.

Regulation No. 86 of the Minister of Environment makes provisions for female workers who notify their pregnancy or their breastfeeding situation. During the information or training sessions for new workers, female workers are advised to inform their employer as soon as possible about pregnancy and

breastfeeding, and the employers need to take appropriate measures in order to ensure the protection of the fetus.

Although the responsibilities of licensees are clearly defined in the Radiation Act, there is no requirement which prohibits offering compensation to workers faced with the risks from ionizing radiation as a substitute for measures for protection and safety.

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.**

11.2.5. MONITORING PROGRAMMES AND TECHNICAL SERVICES

The Radiation Act provides requirements for the monitoring of occupational exposure and for the recording of doses. According to the Radiation Act, individual monitoring of exposed workers should be carried out by an approved dosimetry service, such service being also responsible for the calibration of the devices used.

The document "Statutes of the national radiation workers dose register" provides information on the management of the dose register. The radiation practice license holder and the recognized dosimetry laboratories organize the submission of the data from the personal monitoring of doses to the register at least twice a year. The frequency of the monitoring is 1 month for the category A workers, and 3 to 6 months for the B category workers.

There are three nuclear medicine services in the country. The IRRS team visited one located at the East-Tallinn Central Hospital. This installation is performing around 10 nuclear medicine procedures per day. There have been very few incidents, and daily measurements of the working surfaces and of the floor are done in order to detect any potential contamination. However, there is no mechanism available (laboratory for bioassays, whole body counter) in the country to assess the committed dose resulting from an internal contamination.

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."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R34	**Recommendation: The Environmental Board should ensure that measures are taken by the employers or licensees to ensure appropriate monitoring of internal exposure.**

11.2.6. QUALIFIED EXPERTS AND RADIATION PROTECTION OFFICERS

The Radiation Act defines the "qualified radiation expert" as a person that has the knowledge and training for assessing dose and advising people, to ensure their effective protection and the appropriate operation of protective devices and recognized according to the established procedure. The Act also provides that the holder of a radiation practice is obliged to ensure that in the case of high risk radiation practice a radiation expert qualified in radiation safety matters would have reviewed the installation project in advance and recognized the new radiation source into use, and also that if more than 10 exposed workers are employed, specifying a radiation safety specialist is mandatory for the holder of a radiation practice holder.

However, the regulations do not describe the requirements for the recognition of Radiation Protection Officers. Recommendation R5 in Section 1.8 addresses this issue.

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

Exemption levels are established in Regulation No 163 of the Minister of Environment and clearance levels are established in Regulation No 10 of the Minister of Environment. The Environmental Board approves clearance from regulatory control for discharges of radioactive substances from facilities to the environment. To obtain a licence for releasing radioactive materials into the environment, the applicant should include information on data about the radioactive waste or emissions generated in the course of the activity. The licence then includes the limits of discharges of radioactive substances to the environment.

According to Regulation No 193 of the Government the dose limit to a member of the public is 1 mSv per year and the sum of doses from all relevant activities should not exceed this dose limit. The Environmental Board enforces compliance with the dose limits. The Radiation Act specifies the optimization principle and requires licensees to optimize protection of occupationally exposed workers. However, there are no explicitly established requirements for licensees to specify dose constraints 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 fully cover the requirements of GSR Part 3 regarding dose constraints and optimization. Suggestion S12 in Section 11.2.1 addresses this issue.

Environmental monitoring for public radiation protection

Provisions on various aspects of environmental monitoring can be found in the Radiation Act and in Regulations No 41 and 45 of the Minister of Environment. The Radiation Act states that the Environmental Board should ensure the dose assessment of the members of the public. In the application process for a license, the applicant is required to provide a radiation monitoring programme including information about measuring devices. The Environmental Board reviews and approves the monitoring programme. Only a few facilities are required to monitor and report. The facilities maintain records of the monitoring results and estimated doses to the public and store them throughout the entire activity; they report immediately to the Environmental Board should records exceed limits and conditions relating to public exposure; and they have an emergency plan in case of unexpected increases in radiation levels in

the environment. The Environmental Board reviews periodic reports on public exposure, which the licensees are required to submit once a year. The Environmental Board compiles yearly reports of environmental monitoring, which are accessible to the public on the website.

In addition to the overall environmental radiation monitoring, based on the National Radiation Monitoring Programme, the Environmental Board also carries out independent environmental monitoring. Although the Environmental Board carries out independent monitoring programme, it does so without an explicit requirement in the legislation.

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:* *(c) Making provision for an independent monitoring programme.* *(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.**

There is no production or import of consumer products with radioactive material in Estonia. The Radiation Act prohibits the deliberate addition of radioactive substances in the production of foodstuffs, toys, personal ornaments and cosmetics, and the import or export of such consumer products.

Existing exposure situations

The Environmental Board is responsible for identifying existing exposure situations. Radon indoors and exposure caused by radium in drinking water have been identified as existing exposure situations of concern from a radiation protection point of view. The Ministry of Economic Affairs and Communication regulates the design and construction of buildings. The Ministry of Social Affairs through the Health Board monitors the quality of drinking water. The Environmental Board carries out radon surveys and the Estonian Geological Survey, a state-owned company, studies radon in soil air. Systematic Radon studies started in 1989. The Environmental Board's aim is to carry out radon surveys on a regular basis, and the latest survey was in 2012. The Environmental Board registers the measurements from dwellings, workplaces and public buildings in a database. The Estonian Radon Map, based mainly on geological studies and radon measurements in soil air, was published in 2004. The map will be updated shortly, which gives the opportunity to develop it into a more detailed map over areas with higher radon concentrations. The Ministry of Environment in cooperation with the Environmental Board and Health Board prepares information materials concerning the health risk from radon and associated health risks from smoking. The information is available on their websites. In addition, the Ministry and the Board organize information days for the public, local governments, health protection officials, media and other stakeholders.

The National Radiation Safety Development Plan addresses radon, but not in full compliance with the requirement in GSR Part 3. This is one of the actions identified in the Estonian Action plan. On the

initiative by the Ministry of Environment, a working group has started to map what changes in legislation are necessary, as a first step, with the aim to have an Estonian radon action plan in place in February 2018.

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.**

Reference levels are used for optimization of protection and safety in existing exposure situations. Reference levels for radon indoors in kindergartens and schools are established in Regulations No 131 and 84 of the Government. According to the regulations, the annual average radon content of indoor air must be less than 200 Bq/m³. For dwellings, workplaces and public buildings other than schools, radon reference levels have not been established in the legislation. Reference levels for commodities have been established: for drinking water, construction material and food in the Regulation No 82 of the Minister of Social Affairs, and in Regulations No. 45 and 93 of the Minister of Environment. The Ministry of Economic Affairs and Communications is in the process of finalizing new regulations on indoor climate which will concern all buildings. These regulations are expected to include requirements on reference levels and gamma dose rate.

The Ministry of Environment is also currently drafting an amendment to the Regulation No 93 so that it fully complies with GSR Part 3. A protection strategy for radon indoors is expected to be developed in connection to the national radon action plan. Should new existing exposure situations be identified, protection strategies are expected to be established for those as well. The establishment of the strategies is to ensure the appropriate management of existing exposure situations in proportion to the risks.

There are only three known sites where radioactive material has been produced or stored: Sillamäe which is the only site that has been remediated (the tailing pond), and the two ALARA facilities at Tammiku and Paldiski. A post-remediation national monitoring programme is being carried out around the Sillamäe radioactive tailing pond. Because these sites are few and under regulatory control, the Environmental Board has not felt the need to establish a national strategy for identifying, prioritizing or managing remediation situations. Remediation requires a licence from the Environmental Board and conditions are indicated in the licence. The licensee is responsible for securing the remaining sites and for the management of the waste.

The Radiation Act lists workplaces in which natural radiation sources may cause a significant increase of exposure for workers: mineral water springs, caves, mines, underground construction works, work with materials that contain natural radioactive substances and aircrews in high-altitude flights. There are two mines in Estonia, where oil shale is mined. A preliminary radon survey has been carried out, indicating low levels of radon in both mines. This will be verified as a more detailed survey is planned in the near future. A radon survey that was carried out some years ago, which included spas and water treatment plants, showed no deviations in radon levels.

The Radiation Act requires exposure of aircrews to cosmic radiation to be assessed to protect air crew who might be subject to exposure in excess of annual effective dose limit for the public. The Act requires the employer to organize assessment of doses from the exposure, take into account the assessed exposure when organizing work schedules, inform the workers concerned of the health risks, and apply special measures for protection of the health of female workers during pregnancy and breastfeeding.

As a first step, the Environmental Board has contacted the Civil Aviation Administration to help with determining whether assessment of the exposure of aircrew due to cosmic radiation is warranted or not.

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.**

11.4. SUMMARY

The Estonian legal and regulatory framework addresses medical exposure control, in a manner that it is in line with GSR Part 3. Generic justification of medical radiological procedures, diagnostic reference levels, qualifications and training for medical radiation technologists and radiopharmacist/radiochemist, prompt investigation of unintended/accidental medical exposures, are some of the areas where improvements should still be done.

Existing requirements on occupational exposure in the Estonian regulations are complying with the IAEA safety standards. Additional requirements on the implementation of the optimization principle and on the conditions of services for exposed workers need to be addressed. Actions for the improvements for the recognition of the qualified experts and Radiation Protection Officers are already integrated in the Estonian Action Plan for Radiation Protection.

The legislation contains provisions for control of radioactive discharges, materials for clearance, existing exposure situations and environmental monitoring for public radiation protection. The principle of optimization is provided for in the Radiation Act, but the existing requirements on dose constraints for the public are not fully consistent with GSR Part 3. 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. Radon indoors has been identified as a concern for public health. However, a national action plan for radon is not yet in place. 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.

APPENDIX 1 POLICY ISSUES

The policy discussions were on two topics, namely, "enhancing regulatory effectiveness and competence" and "optimization of medical exposure": The discussions were chaired by IRRS Team Leader and attended by the IRRS Team and representatives from the Environmental Board and the Ministry of Social Affairs.

Enhancing regulatory effectiveness and competence

There were two sub issues under this topic, namely (1) the competence of the Environmental Inspectorate and (2) the overlap and lack of clarity in supervisory functions of the Environmental Inspectorate and the Health Board. The Liaison Officer made a presentation on the key issues. This was followed by a discussion.

The competence of the Environmental Inspectorate

The presentation covered the structure, composition and inspection program of the Environmental Inspectorate concluding that it leads to a situation where inspectors are unable to acquire and retain sufficient expertise in radiation safety. The IRRS team agreed that while there are examples of regulatory bodies with structures similar to Estonia's, many IAEA member states' regulatory bodies adopt a structure in which licensing and inspection functions are within the same organization and exercise functions that are fully dedicated to radiation safety. Examples of such structures were drawn from Ethiopia, Australia and Greece.

The overlap and lack of clarity in supervisory functions of the Environmental Inspectorate and the Health Board

On this issue, the Liaison Officer explained the circumstances that has led to both the Environmental Inspectorate and Health Board undertaking inspection of medical radiological facilities and devices, which is causing confusion and inconvenience to licence holders. The discussion that followed showed that a good approach to address the issue is to amend the Radiation Act or other relevant legislation to specifically provide for the scope the Health Board responsibility for the inspection of medical radiological facilities and devices. The IRRS team members also urged the Environmental Board and the Ministry of Social Affairs to consider the use of formal memoranda of understanding to improve cooperation and minimise duplication of roles and responsibilities.

Optimization of medical exposure

The second policy issue discussion was on actions taken in Estonia to establish national Diagnostic Reference Levels (DRLs). The representative from the Ministry of Social Affairs made a detailed presentation on the steps being taken to establish national DRLs. These include regulatory requirements and guidance on the collection and evaluation of average patient doses for the standard size patient undergoing medical radiological procedures for the most commonly used medical radiological equipment. The Ministry of Social Affairs has collected data from 40% of hospitals in Estonia. The next step will be to review and assess the data, estimate national DRLs for adult patients, organize workshops to disseminate the results and finally establish national DRLs via a new regulation.

The IRRS team members acknowledged that the procedure for establishing national DRLs in Estonia is well advanced and provided comprehensive information regarding relevant literature, recommended approaches for identifying the most common medical radiological procedures, collecting frequency data, defining dosimetric indicators to be measured for each diagnostic and interventional radiology modality and administered radiopharmaceuticals activity for nuclear medicine procedures, as well as weight and age ranges recommended for the collection of data regarding pediatric patients.

The IRRS team members shared their experiences regarding several issues, including the clear definition of medical radiological procedures and the fact that the 3rd quartile is not the recommended approach for estimating DRLs in nuclear medicine. IRRS team members also suggested that Estonia may consider getting direct feedback from member states, including those represented at the IRRS mission.

APPENDIX II LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS			
1.	SELVA KUMAR Manickam	Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Australia	Selva.Kumar@arpansa.gov.au
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10.	ZOLTÁNNÉ BÓDIS Elizabeth	Hungarian Atomic Energy Authority (HAEA) Hungary	Bodis@haea.gov.hu
11.	DEMETRIADES Panicos (Observer)	Radiation Inspection and Control Service	pdemetriades@dli.mlsi.gov.cy
12.	DRAVNIECE Agnese (Observer)	Radiation Safety Centre of State Environmental Service of Latvia	agnese.dravniece@rdc.vvd.gov.lv

IAEA STAFF MEMBERS			
1.	HAILU Teodros	Division of Radiation Transport and Waste Safety	T.Hailu@iaea.org
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3.	SWOBODA Zumi	Division of Radiation Transport and Waste Safety	Z.Swoboda@iaea.org
LIAISON OFFICERS			
1.	PUSKAR Ilmar	Environmental Board Radiation Safety Department	ilmar.puskar@keskkonnaamet.ee

APPENDIX III MISSION PROGRAMME

IRRS MISSION PROGRAMME		
Sunday, 4 September 2016		
IRRS Initial IRRS Review Team Meeting		
Team Lunch 13:30 - 17:30	12:00 – 13:00 Opening remarks by the IRRS Team Leader (Mr Selva Kumar) Introduction by IAEA Self-introduction of all attendees IRRS Process (IAEA) Report writing (IAEA) Schedule (TL, IAEA, LO) First impression from experts arising from the Advanced Reference Material (ARM) (All Experts) Administrative arrangements (EB IRRS Liaison Officer, IAEA): Detailed Mission Programme	Venue: Hotel Participants: the IRRS Team + the LO
Monday, 5 September 2016		
IRRS Entrance Meeting		
09:00 – 12.00	09:00 Arrival, registration, 09:30 Welcoming Address by Mr Marko Pomerants, Minister of the Envionment 09:45 IRRS Coordinator – The IRRS programme 10:00 IRRS Team Leader – Expectations for the Mission and introduction of the IRRS Team Introduction of the Main Estonian Counterparts Group photo of the meeting participants 10:30 Coffee 11:00 EB Presentation – Regulatory Overview, SARIS results (strength, challenges, action plan)	Venue: *Ministry of Environment* Participants: High Level Government Official, EB/LO Management and staff, Official from relevant organizations, the IRRS Team + the LO
12:00 – 13:00	*Lunch*	
13:30 – 17:00	Interviews and Discussions with Counterparts (parallel discussions)	IRRS Reviews and Counterparts Venue: *EB Premises counterparts offices*
17:00 – 18:00	Daily IRRS Review Team meeting	Venue: *EB Premises* Participants: the IRRS team + LO.
18:00 –	Writing draft report	IRRS Team (each reviewer in his/her specific area)
Tuesday, 6 September 2016		
Daily Discussions / Interviews		
09:00 – 17:00	Interviews and discussions with counterparts (parallel discussions)	IRRS Reviews and Counterparts Venue: *EB Premises counterparts offices*

IRRS MISSION PROGRAMME		
12:00 – 13:00	*Lunch*	
TBD	Visit Government /Ministry(ies)	Participants: IRRS TL, TC , Reviewer Modules 1,2, and 3
17:00 – 18:00	Daily IRRS Review Team meeting	Venue: *EB Premises* Participants: the IRRS team + LO.
18:00	Writing draft report	IRRS Team (each reviewer in his/her specific area)
Wednesday, 7 September 2016		
Daily Discussions / Interviews		
09:00 – 17:00	Follow-up interviews and discussions with counterparts for all modules	IRRS Reviews and Counterparts Venue: *EB Premises counterparts offices*
08:30 – 14:00	Site Visit (ALARA waste facility and Irradiation Plant)	IRRS Experts and EB/EI Inspectors
12:00 – 13:00	*Lunch*	
13:30 – 17:00	Writing first draft of preliminary findings (Rs, Ss and GPs)	The IRRS team
17:00 – 18:00	Daily IRRS Review Team meeting	Venue: *EB Premises* Participants: the IRRS team + LO.
18:00 –	Writing draft report	IRRS Team (each reviewer in his/her specific area)
Thursday, 8 September 2016		
Daily Discussions / Interviews		
09:00 – 09:15	Quick briefing on site visits	IRRS Team
09:15 – 16:00	Follow-up Interviews and discussions with counterparts (parallel discussions)	IRRS Reviews and Counterparts Venue: *EB Premises counterparts offices*
12:00 – 13:00	*Lunch*	
08:30 – 12:00	Site Visit (East-Tallin Central Hospital)	IRRS Experts and EB/EI Inspectors (from Hotel)
13.00-16.00	Site Visit (North Estonia Medical Centre)	IRRS Experts and EB/EI Inspectors (from EB Premises)
16:30-17:00	Quick briefing on site visits	IRRS Team
17:00 – 20:00	Daily IRRS Review Team Meeting: recommendation, suggestions and good practices	Venue: *EB Premises* Participants: the IRRS team + LO.
20:00 –	Writing draft report	IRRS Team (each reviewer in his/her specific area)
Friday, 9 September 2016		
Daily Discussions / Interviews		
09:00 – 16:00	Team members write draft report Finalize Observations, Recommendations, Suggestions and Good Practices	IRRS Team Venue: *EB Premises*
13:30 – 16:00	Policy issue discussion:	Reviewers and Counterparts

IRRS MISSION PROGRAMME		
	Parallel discussion sessions if needed	Venue : *EB Premises*
16:00 – 18:00	Daily Team Meeting: Team finalizes recommendation, suggestions and good practices	Venue: *EB Premises* Participants: the IRRS team + LO.
Saturday, 10 September 2016		
Daily Discussions/ Interviews (if needed)		
09:00 –22:00	Team finalize the draft report together	IRRS Team + LO Venue: *EB Premises*
Sunday, 11 September 2016		
08:00–10:00	TL and TC review draft report Draft report submitted to EB for comments	TL and TC Venue: *Hotel*
10:00-	IRRS Team rest day and Social Event	
Monday, 12 September 2016		
Daily Discussions		
9:00 – 16:00	EB review draft report	
16:00 –	EB submits comments to IRRS team	
Tuesday, 13 September 2016		
Daily Discussions		
09:00 – 11:00 11:00 – 13:00	IRRS Team review EB comments Finalize the draft report with EB	Venue: *EB Premises* IRRS Team and EB
13:00 -	Draft report handed over to EB	IRRS Team
Wednesday, 14 September 2016		
09:00 – 11:00	Main findings of the IRRS mission (Team Leader) Remarks by EB in response to the mission findings	Venue: *Ministry of Environment* Participants: Government Officials, EB Management and staff, Officials from relevant organizations, the IRRS Team + the LO(s)
	Closing Remarks by IAEA Official (NSRW Director) Publication of the IAEA Press Release	

APPENDIX IV SITE VISITS

1. A.L.A.R.A. Ltd,
   field: radioactive waste management

2. Scandinavian Clinics Estonia OÜ,
   field: industrial irradiation plant (sterilization),

3. East-Tallinn Central Hospital
   field: diagnostic radiology, nuclear medicine

4. The North Estonia Medical Centre
   field: diagnostic radiology, nuclear medicine. radiotheraphy

APPENDIX V LIST OF COUNTERPARTS

RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	
Manickam Selva Kumar Andre Regimbald	Ilmar Puskar (EB) Karin Muru (EB) Marily Jaska (EI) Pavel Ojava (EI) Reelika Runnel (MoE)
GLOBAL SAFETY REGIME	
Manickam Selva Kumar Andre Regimbald	Ilmar Puskar (EB) Karin Muru (EB) Marily Jaska (EI) Pavel Ojava (EI) Reelika Runnel (MoE)
RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	
Manickam Selva Kumar Andre Regimbald	Ilmar Puskar (EB) Karin Muru (EB) Marily Jaska (EI) Pavel Ojava (EI) Reelika Runnel (MoE)
MANAGEMENT SYSTEM	
Elizabeth Zoltánné Bódis	Siiri Suursoo (EB) Rainis Uiga (EB) Ilmar Puskar (EB)
AUTHORIZATION	
Dovile Serenaite Darius Mroz Nelli Aghajanyan Friedrich Kirchnawy	Karin Muru (EB) Jelena Šubina (EB) Marily Jaska (EI) Siiri Koidla (EB) Krista Saarik (MoE) Alar Polt (EB) Karin Muru (EB) Margit Kuulmann (EB)

REVIEW AND ASSESSMENT	
Dovile Serenaite Darius Mroz Nelli Aghajanyan Friedrich Kirchnawy	Karin Muru (EB) Jelena Šubina (EB) Marily Jaska (EI) Siiri Koidla (EB) Krista Saarik (MoE) Alar Polt (EB) Karin Muru (EB) Margit Kuulmann (EB)
INSPECTION	
Dovile Serenaite Darius Mroz Nelli Aghajanyan Friedrich Kirchnawy	Karin Muru (EB) Jelena Šubina (EB) Marily Jaska (EI) Siiri Koidla (EB) Krista Saarik (MoE) Alar Polt (EB) Karin Muru (EB) Margit Kuulmann (EB)
ENFORCEMENT	
Dovile Serenaite Darius Mroz Nelli Aghajanyan Friedrich Kirchnawy	Karin Muru (EB) Jelena Šubina (EB) Marily Jaska (EI) Siiri Koidla (EB) Krista Saarik (MoE) Alar Polt (EB) Karin Muru (EB) Margit Kuulmann (EB)
REGULATIONS AND GUIDES	
Dovile Serenaite Darius Mroz Nelli Aghajanyan Friedrich Kirchnawy	Karin Muru (EB) Jelena Šubina (EB) Marily Jaska (EI) Siiri Koidla (EB) Krista Saarik (MoE) Alar Polt (EB) Karin Muru (EB) Margit Kuulmann (EB)

EMERGENCY PREPAREDESS AND RESPONSE	
Marina Nizamska	Uko Rand (EB) Alar Polt (EB)
ADDITIONAL AREAS - Medical Exposure	
Stavroula Vogiatzi	Jelena Šubina (EB) Marina Lacis (EB) Tiina Drell (MoS)
ADDITIONAL AREAS - Occupational Exposure	
Pascal Deboodt	Monika Lepasson (EB) Kristel Kilk (EB) Marina Lacis (EB)
ADDITIONAL AREAS **Environmental monitoring associated with authorized practices for public radiation protection purposes, Control of chronic exposure remediation**	
Erica Brewitz	Monika Lepasson (EB) Alar Polt (EB)

APPENDIX VI RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1.	RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	R1	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.
		R2	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.
		R3	The Government should clearly delineate the authority of the Health Board and the Environmental Inspectorate with respect to inspection of medical radiological equipment.
		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.
		R5	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, radio pharmacists and radiochemists) in order to ensure a reliable supply of trained radiation specialists.
		S1	The Environmental Board should consider to specify the technical services that need authorization and develop a process for granting an authorization.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
2.	**GLOBAL SAFETY REGIME**		None
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**	S2	The Environmental Board should consider to make arrangements to prevent any conflict of interest between its authorization and service provision functions.
		R6	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.
		R7	The Environmental Inspectorate should ensure that adequate arrangements are made to build and maintain sufficient expertise in radiation safety.
		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.
		R8	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.
		S4	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.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**	R9	The Environmental Board and Environmental Inspectorate should define the safety policy and goals in the management system
		GP1	Each year the senior executive management visits all the structural units of the Environmental Board and Environmental Inspectorate and discusses the goals and topical issues of the organization directly with the employees.
		R10	The Environmental Board and Environmental Inspectorate should establish and implement, in each organization, an Integrated Management System.
		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.
		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
5.	**AUTHORIZATION**	R12	The Environmental Board should where appropriate take into account inspection findings, regulatory actions and feedback from operational performance in making authorization decisions.
		R13	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.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		S6	The Ministry of Environment should consider in the national strategy the management of all types of radioactive waste, including NORM residues.
		S7	The Environmental Board should consider to adopt the IAEA system of categorization of radioactive sources to ensure that the degree of regulatory control is commensurate with the potential risk.
		S8	The Environmental Board should consider to consistently apply graded approach to authorization and review and assessment of facilities and activities.
		R14	The Environmental Board should approve transport packages or validate the approval certificates of transport packages in accordance with IAEA SSR-6.
		S9	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.
6.	**REVIEW AND ASSESSMENT**		None
7.	**INSPECTION**	R15	Inspectors should conduct tests and measurements as appropriate for independent verification of safety of facilities and activities.
		R16	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.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R17	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.
8.	**ENFORCEMENT**	R18	The Environmental Inspectorate should establish an enforcement policy and documented criteria for taking corresponding corrective actions commensurate with the gravity of the non-compliance.
9.	**REGULATION AND GUIDES**	S10	The Environmental Board should consider establishing and adopting regulatory guides that cover all facilities and activities.
		S19	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.
		S11	The Environmental Board should consider ensuring the development by the operator of appropriate waste acceptance criteria for the disposal of radioactive waste.
		R20	The Ministry of Environment should establish requirements for site selection for radioactive waste disposal facility in line with SSR-5.
		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.
		R22	The Ministry of Environment should update the existing regulatory requirements for radiation safety in accordance with GSR Part 3.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**	R23	The Government should ensure that appropriate regulations or guidance documents are developed and implemented for the application of GSR Part 7 in Estonia.
		R24	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.
		R25	The Ministry of Environment should establish requirements for licensees to develop and update hazard assessments relevant to their facilities and activities..
		R26	The Government should establish and ensure the implementation of emergency planning distances for emergency response category V.
		R27	The Government should establish criteria for designating in advance emergency workers, including making arrangements for their protection.
11.1	**CONTROL OF MEDICAL EXPOSURES**	R28	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.
		R29	The Government should ensure that diagnostic reference levels and criteria and guidelines for the release of patients are established.
		R30	The Ministry of Social Affairs should establish requirements that the calibration, dosimetry and quality assurance, including the

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			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.
		R31	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.
		R32	The Ministry of Social Affairs should establish requirements for the documentation of any delegation of responsibilities by a principal party.
11.2	**OCCUPTIONAL RADIATION PROTECTION**	S12	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.
		S13	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.
		R33	The Government should establish requirements in legislation to prohibit the offering of benefits as substitute for measures for protection and safety.
		R34	The Environmental Board should ensure that measures are taken by the employers or licensees to ensure appropriate monitoring of internal exposure.
11.3	**CONTROL OF RADIOACTIVE**	S14	The Government should consider establishing provisions in

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	DISCHARGES, MATERIAL FOR CLEARANCE, AND EXISTING EXPOSURES SITUATIONS; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION		legislation for the regulatory body to perform an independent monitoring programme to ensure the continued independent verification on the operation of the facilities.
		R35	The Government should ensure that a national radon action plan is established.
		R36	The Environmental Board or other relevant authority should determine whether assessment of the exposure of aircrew due to cosmic radiation is warranted.

APPENDIX VII 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

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

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 VIII 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 General Safety Requirement Part 1(Rev 1) (Vienna2016)
3. INTERNATIONAL ATOMIC ENERGY AGENCY – Leadership and Management for Safety General Safety Requirement Part 2 (Vienna2016)
4. INTERNATIONAL ATOMIC ENERGY AGENCY – Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, (2014)
5. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety assessment for facilities and activities, General Safety Requirements Part 4, No. GSR Part 4 (Rev 1), IAEA, Vienna (2016)
6. INTERNATIONAL ATOMIC ENERGY AGENCY – Predisposal Management of Radioactive Waste General Safety Requirement Part 5, No. GSR Part 5, IAEA, Vienna (2009)
7. INTERNATIONAL ATOMIC ENERGY AGENCY – Decommissioning of Facilities General Safety Requirement Part 6, No. GSR Part 6, IAEA, Vienna (2014)
8. INTERNATIONAL ATOMIC ENERGY AGENCY – Preparedness and Response for a Nuclear or Radiological Emergency General Safety Requirement Part 7, No. GSR Part 7, IAEA, Vienna (2015)
9. INTERNATIONAL ATOMIC ENERGY AGENCY - Regulations for the Safe Transport of Radioactive Material Specific Safety Requirements 6, No. SSR 6, IAEA, Vienna (2012)8.
10. INTERNATIONAL ATOMIC ENERGY AGENCY - Organization and Staffing of the Regulatory Body for Nuclear Facilities, Safety Guide Series No. GS-G-1.1, IAEA, Vienna (2002)
11. INTERNATIONAL ATOMIC ENERGY AGENCY - Review and Assessment of Nuclear Facilities by the Regulatory Body, Safety Guide Series No. GS-G-1.2, IAEA, Vienna (2002)
12. INTERNATIONAL ATOMIC ENERGY AGENCY - Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, Safety Guide Series No. GS-G-1.3, IAEA, Vienna (2002)
13. INTERNATIONAL ATOMIC ENERGY AGENCY - Documentation for Use in Regulatory Nuclear Facilities, Safety Guide Series No. GS-G-1.4, IAEA, Vienna (2002)
14. INTERNATIONAL ATOMIC ENERGY AGENCY- - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)
15. INTERNATIONAL ATOMIC ENERGY AGENCY – Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna (2011)
16. INTERNATIONAL ATOMIC ENERGY AGENCY– Assessment of Occupational Exposure Due to Intake of Radionuclides Safety Guide Series No. RS-G-1.2, IAEA, Vienna (1999)
17. INTERNATIONAL ATOMIC ENERGY AGENCY - Assessment of Occupational Exposure Due to External Sources of Radiation Safety Guide Series No. RS-G-1.3, IAEA, Vienna (1999)
18. INTERNATIONAL ATOMIC ENERGY AGENCY - Building Competence in Radiation Protection and the Safe Use of Radiation Sources, Safety Guide Series No. RS-G-1.4, IAEA, Vienna (2001)

19. INTERNATIONAL ATOMIC ENERGY AGENCY – Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)

20. INTERNATIONAL ATOMIC ENERGY AGENCY – Regulatory Control of Radioactive Discharge to the Environment, Safety Guide Series No. WS-G-2.3, IAEA, Vienna (2000)

21. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No. WS-G.5.2, IAEA, Vienna (2009)

22. INTERNATIONAL ATOMIC ENERGY AGENCY – Establishing the Safety Infrastructure for a Nuclear Power Programme Specific Safety Guide No SSG-16, IAEA, Vienna (2011)

23. INTERNATIONAL ATOMIC ENERGY AGENCY - Disposal of Radioactive Waste Specific Safety Requirements 5, No. SSR 5, IAEA, Vienna (2011)

APPENDIX IX ORGANIZATIONAL CHART