

**INTEGRATED
REGULATORY
REVIEW SERVICE (IRRS)
MISSION
TO
THE REPUBLIC OF LATVIA**

Riga, Latvia

20-30 October 2019

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



Integrated
Regulatory
Review Service

IRRS



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INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
TO
REPUBLIC OF LATVIA**

Mission dates: *20 to 30 October 2019*
Regulatory body visited: *Radiation Safety Centre of State Environmental Service of Latvia*
Location: *Riga, Latvia*

Regulated facilities, activities and exposure situations in the mission scope:	<i>Radioactive waste management facilities, radiation sources in industrial and medical facilities, emergency preparedness and response, decommissioning, occupational radiation protection, patient protection, discharges and material clearance</i>
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Organized by:	<i>IAEA</i>
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The number of recommendations, suggestions and good practices is in no way a measure of the status of the national infrastructure for nuclear and radiation safety. Comparisons of such numbers between IRRS reports from different countries should not be attempted.

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EXECUTIVE SUMMARY

At the request of the Government of Latvia, an international team of senior nuclear and radiation safety experts met with representatives of the Radiation Safety Centre of State Environmental Service (RSC SES), from 21 to 30 October 2019, to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the IRRS mission was to perform a peer review of Latvia's national regulatory framework for nuclear, radiation, radioactive waste and transport safety. The review compared Latvia's 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 Latvia counterparts in areas covered by the IRRS mission.

The IRRS Team consisted of eight senior regulatory experts from eight IAEA Member States, two IAEA staff member, and one observer. The review covered the IRRS core modules 1 to 10, i.e. the responsibilities and functions of the government, the global safety regime, responsibilities and functions of the regulatory body, the management system of the regulatory body, the activities of the regulatory body including authorization, review and assessment, inspection and enforcement, regulations and guides, and emergency preparedness and response. Facilities, activities and exposure situations included radiation source applications, radioactive waste management facilities, decommissioning, transport, occupational exposure, medical exposure, and public exposure.

At the request of RSC SES, the IRRS mission included a discussion during which members of the IRRS Team and senior staff of RSC SES shared views and regulatory experiences regarding policy issue: Justification, Optimization and clinical audits in medical exposure

The review mission included a series of interviews and discussions with key personnel at the RSC SES. There was also an interview with a senior representative of the Ministry of Environmental Protection and Regional Development (MEPRD), which focussed mainly on responsibilities and functions of the government, national policies and the regulatory framework for safety, the establishment of RSC SES as an independent regulatory body, and the human resources of the Ministry. The IRRS Team also observed on-site inspections conducted by RSC SES at two different facilities, namely: Latvian Oncology Centre (radiotherapy and diagnostic nuclear medicine) of Riga East University Hospital, and the Radioactive Waste Repository (RADONS) of the State Limited Liability Company "Latvian Environment, Geology and Meteorology Centre" which also is conducting transport activities. The IRRS Team members reported very favourably on the professionalism of the RSC SES staff in the preparation and conduct of the inspections. During the site visits, open discussions took place with the authorized parties.

In preparation for the IRRS mission, RSC SES conducted a self-assessment and prepared a preliminary action plan. The results of the self-assessment and supporting documentation were provided to the IRRS Team as advance reference material for the mission. The IRRS Team was positively impressed by the extensive preparation, expertise and dedication of RSC SES. The IRRS Team was extended full cooperation in the regulatory, technical, and policy discussions with the management and staff of RSC SES, in a very open and transparent manner. Throughout the mission, the administrative and logistical support was outstanding.

The Law on Radiation Safety and Nuclear Safety establishes Radiation Safety Centre of State Environmental Service as the regulatory body for facilities and activities posing radiation risk. The State Environmental Service (SES) is a direct administration institution under the supervision of the MEPRD. RSC SES is funded from the state budget. In the last two years,

the Government provided RSC SES with additional financial resources in order to perform its functions effectively.

The IRRS Team found RSC SES staff and leadership to be highly competent and dedicated to improve the safety of facilities and activities in Latvia.

The IRRS Team also identified areas of good performance, as evidenced by the policies and the regulatory framework and activities implemented in Latvia. These included effective and efficient system for measuring and assessing the implementation of the different processes and activities of the regulatory body for senior management to evaluate and improve the management system.

The IRRS Team also identified challenges for the Government and RSC SES, specifically with regard to:

- Establishment of a national policy that includes a long-term commitment to radiation protection and nuclear safety.
- Development of human resources plan taking into the account competencies required to perform regulatory body functions.

The IRRS Team report includes a number of recommendations and suggestions to improve the Latvian regulatory system and the effectiveness of the regulatory functions in line with IAEA safety standards. The IRRS Team recognizes that many of its findings confirm the actions for further improvement that were identified in RSC SES's self-assessment. The IRRS Team concluded that the following issues are representative of those which, if addressed by the Government of Latvia and RSC SES, should further enhance the overall performance of the regulatory system.

The government should:

- Include all safety fundamentals in a national policy and strategy for safety that covers all facilities and activities that takes into account graded approach;
- Develop national policy to define long term goals for safe management of all classes of existing and future radioactive waste streams;
- Include provisions in the legislation for notification;
- Ensure that the establishment of diagnostic reference levels for medical exposures is based, as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstances;
- Revise the regulations for emergency preparedness and response in accordance with GSR Part 7 and for the transport of radioactive materials to be fully consistent with the international regulatory framework; and
- Include in the national legal framework provisions for safe planning and conduct of decommissioning activity.

The regulatory body, RSC SES, should:

- Prepare assessment of the necessary number of staff including competence and skills to perform its functions and to discharge its responsibilities, and based on this analysis to develop and implement a comprehensive human resources plan including, specific training programme, which is based on assessment of the necessary staff;

- Consider within its management system to establish procedures for analysing events, ensuring corrective actions, operating experience and disseminating the lessons learned within the country and internationally;
- Establish in its management system the arrangements for independent review to be made before decisions significant for safety are made, and to specify the requirements on the independent nature of the review and on the necessary competences of the reviewers;
- Consider applying the system for different types of authorization for all complex facilities, taking into account different stages in lifetime; and
- Systematically evaluate the operator`s on-site exercises to ensure that response functions can be implemented effectively during a nuclear or radiological emergency.

The IRRS Team believes that the recommendations and suggestions, if acted upon, will enhance nuclear and radiation safety in Latvia.

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

The IRRS Team findings are summarized in Appendix V.

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

I. INTRODUCTION

At the request of the Government of Latvia, an international team of senior safety experts met representatives from the Radiation Safety Centre of State Environmental Service of Latvia (RSC SES) from 21 to 30 October 2019 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review Latvia's regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Latvia in July 2017. A self-assessment workshop was conducted on 21 - 23 March 2017 at RSC SES Headquarters in Riga to introduce the IAEA Self-Assessment methodology and SARIS tool. A preparatory meeting was conducted 5 – 6 February 2019 at RSC SES Headquarters in Riga to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in Latvia and their related safety aspects and to agree the scope of the IRRS mission.

The IRRS Team consisted of eight senior regulatory experts from eight IAEA Member States, two IAEA staff member and one observer. The IRRS Team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response. The scope of regulatory activities reviewed during the mission covered radiation sources facilities and activities, occupational radiation protection, control of medical exposure, public and environmental exposure control, transport of radioactive material, radioactive waste management and decommissioning.

In addition, policy issues were discussed, including: Justification, Optimization and clinical audits in medical exposure.

RSC SES conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of the self-assessment and supporting documentation were provided to the IRRS Team as advance reference material for the mission. During the mission the IRRS Team performed a systematic review of all topics within the agreed scope through review of Latvia's advance reference material, conduct of interviews with management and staff from RSC SES and direct observation of regulatory activities at regulated facilities. A meeting with Alda Ozola, Deputy of State Secretary of the Ministry of Environmental Protection and Regional Development was also organized.

All through the mission the IRRS Team received excellent support and cooperation from RSC SES.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review the Latvian 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.

It is expected this IRRS mission will facilitate regulatory improvements in Latvia and other Member State, utilising the knowledge gained and experiences shared between Latvian counterparts and IRRS reviewers and the evaluation of the Latvian regulatory framework for nuclear and radiation safety, including its good practices.

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

- a) providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;
- b) providing the host country (regulatory body and governmental authorities) with a review of its regulatory technical and policy issues;
- c) providing the host country (regulatory body and governmental authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;
- d) promoting the sharing of experience and exchange of lessons learned among senior regulators;
- e) providing key staff in the host country with an opportunity to discuss regulatory practices with IRRS Team members who have experience of other regulatory practices in the same field;
- f) providing the host country with recommendations and suggestions for improvement;
- g) providing other states with information regarding good practices identified in the course of the review;
- h) providing reviewers from Member States and IAEA staff with opportunities to observe different approaches to regulatory oversight and to broaden knowledge in their own field (mutual learning process);
- i) contributing to the harmonization of regulatory approaches among states;
- j) promoting the application of IAEA Safety Requirements; 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 Latvia, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 5 to 6 February 2019. The preparatory meeting was carried out by the appointed Team Leader Ilmar Puskar, and the IAEA Coordinator Olga Makarovska and the RSC SES representatives.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of RSC SES represented by Dace Satrovskā, Marīte Čaikovska and Agnese Aizpuriete. It was agreed that the regulatory framework with respect to the following facilities and activities and exposure situations would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides:

- Radioactive Waste management facilities;
- Radiation sources facilities and activities;
- Decommissioning activities;
- Transport of radioactive materials;
- Control of medical exposure;
- Occupational radiation protection;
- Public and Environmental exposure control;
- Emergency preparedness and response; and
- Selected policy issues.

Dace Satrovskā made presentations on the national context, the current status of the national regulatory infrastructure and the self-assessment results to date.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in Latvia in October 2019.

The proposed composition of the IRRS 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 Agnese Aizpuriete.

Latvia provided IAEA with the advance reference material (ARM) for the review in August 2019. In preparation for the mission, the IRRS Team members reviewed the Latvian advance reference material and provided their initial impressions to the IRRS Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

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

C) CONDUCT OF THE REVIEW

The initial IRRS Team meeting took place on Sunday, 20 October, 2019 in Riga, directed by the IRRS Team Leader and the IAEA 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 country Liaison Officer was present at the initial IRRS Team meeting, in accordance with the IRRS Guidelines, and presented logistical arrangements planned for the mission.

The IRRS entrance meeting was held on Monday, 21 October, 2019, with the participation of the Deputy of State Secretary and staff members of the Ministry of Environmental Protection and Regional Development, General Director of State Environmental Service, senior management and staff of RSC SES. Opening remarks were made by Alda Ozola, Deputy of State Secretary of the Ministry of Environmental Protection and Regional Development, Elita Baklane-Ansberga, General Director of the State Environmental Service, and Ilmar Puskar, IRRS Team Leader. Dace Satrovskā, Director of RSC SES gave an overview of the Latvia context, activities and the action plan prepared as a result of the pre-mission self-assessment.

During the IRRS mission, a review was conducted for all review areas within the agreed scope with the objective of providing Latvia 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 Team performed its review according to the mission programme given in Appendix III.

The IRRS exit meeting was held on Wednesday, 30 October 2019. The opening remarks at the exit meeting were presented by Rudite Vesere, Director of Department of Environmental Protection of the Ministry of Environmental Protection and Regional Development and were followed by the presentation of the results of the mission by Mr Ilmar Puskar, IRRS Team Leader. Closing remarks were made by Mr Ibrahim Shadad on behalf Director, Division of Radiation, Transport and Waste Safety, Department of Nuclear Safety of the Security of IAEA.

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

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

The Ministry of Environmental Protection and Regional Development (MEPRD) is the policy maker in field of radiation protection and nuclear safety and its implementation is delegated to the Radiation Safety Centre of State administrative institution State Environmental Service (RSC SES) through the Law on Radiation Safety and Nuclear Safety in 2000 (Law) and other institutions. The purpose of the Law is to ensure the protection of people and the environment from the adverse effects of ionising radiation and to specify the duties and rights of institutions, natural persons and legal persons in the field of radiation safety and nuclear safety.

The MEPRD has adopted Environmental Policy Guidelines for 2014-2020 that includes radiation protection and nuclear safety. The goal of these Environmental Policy Guidelines is to ensure good environmental governance at all levels, as well as good environmental communication based on the most complete and balanced environmental information, and to promote wide public involvement in environmental issues.

In Latvia, long-term policy and strategies are in place only for certain key issues, such as carbon emissions, based on European Union (EU) directives. However, such long-term commitments are not provided for radiation protection and nuclear safety. A national policy and strategy for safety need to be updated to cover a long-term commitment to radiation protection and nuclear safety, more specifically with respect to radioactive waste management.

Most of the fundamental safety principles are generally addressed in the Law and its associated Regulations and Environmental Policy Guidelines including the principles of dose limitations and justification. However, the Law does not explicitly address some key fundamental safety principles, such as optimization.

Further, graded approach is not expressly stated in the Law, however the graded approach has been implemented to a certain degree in the regulations and internal procedures based on radiation risks associated with facilities and activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The fundamental safety objectives are generally addressed in the Law, Regulations and Environmental Policy Guidelines (2014-2020), including the principles of dose limitation and justification. However, the Law does not explicitly address some of the fundamental principles, such as optimization. Further, a long term commitment for radiation protection and nuclear safety has yet to be established.*

(1)	BASIS: GSR Part 1 (Rev 1) Requirement 1 , states that “The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals”.
(2)	Basis GSR Part 1 (Rev 1) para 2.3 states that “National policy and strategy for safety shall express a long term commitment to safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

R1	<p>Recommendation: The Government should include all safety fundamentals in a national policy and strategy for safety that covers all facilities and activities that takes into account graded approach. This policy and strategy should express a long term commitment to safety.</p>
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Latvia, being EU member state, is required to transpose and implement the requirements of the EU directives in its regulatory framework. Being also an IAEA member state, Latvia has adhered to international conventions such as Convention on Nuclear Safety and the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.

The State Administration Structure Law establishes the basic provisions regarding the operation of State administration, such as resources and competency. The Regulations issued by the Cabinet of Ministers establish the organization requirements of the MEPRD, SES and RSC SES. The SES is a governmental institution and its financial resources are determined in SES By-law. SES Order provides for the human resources need for RSC SES. The finances for RSC SES are granted annually by Parliament as a separate budget line for salaries under the budget of SES. Issues regarding the funding for RSC SES are further discussed in Section 3.1.

The IRRS Team was informed that MEPRD is responsible for preparing policy and legislation in radiation protection and nuclear safety. The capacity of its staff reflects the operational needs of the department. The IRRS Team reviewed RSC SES's structure and its resources being allocated for the organization to effectively carry out its activities. The findings and recommendations regarding RSC SES's resources are further discussed in Section 3.3.

In 2018, RSC SES adopted a Quality Management System Manual, which includes a section on safety culture. The IRRS Team was informed that RSC SES holds periodic meetings where safety issues are discussed. However, there is no systematic approach to promote safety and safety culture.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *A Quality Management System Manual was recently developed by RSC SES in 2018. The manual includes a section on safety culture that states that safety must be a top priority and safety culture is accordingly complied with by the RSC SES in the operations thereof, while fulfilling the functions and tasks thereof. However, a plan for the promotion of leadership and management for safety culture is not established.*

(1)	<p>BASIS: GSR Part 1 (Rev 1) Requirement 1 states that <i>“In the national policy and strategy, account shall be taken of the promotion of leadership and management for safety, including safety ^{[[]]} culture. ^{[[]]}</i></p>
(2)	<p>BASIS: GSR Part 2 Requirement 2 states that <i>“Managers shall demonstrate leadership for safety and commitment to safety”.</i></p>
(3)	<p>GSG-12 para 3.9: <i>The regulatory body should establish and maintain a programme to develop, foster and evaluate its safety culture. Such a programme should include safety culture self-assessments, workshops and seminars for defining improvement programmes, as well as training and support.</i></p>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

R2

Recommendation: RSC SES should develop a programme for the promotion of leadership and management for safety culture.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Law together with the Regulations issued by the Cabinet of Ministers establishes the regulatory framework for radiation protection and nuclear safety. MEPRD develops draft legal acts, regulations and policy planning documents in consultation with interested parties, including RSC SES. The Law is complemented by other applicable State laws (such as the State Administration Structure Law, Administrative Procedure Law) and Regulations. In addition to this legally binding framework, RSC SES has developed guides that provide for the implementation of the regulatory requirements.

The Law prescribes the safety requirements for sources of ionising radiation and related activities and provides for specific requirements for sources of ionising radiation of national significance. It also prescribes the roles and responsibilities of the different State authorities for radiation protection and nuclear safety.

In accordance with the Law, RSC SES performs regulatory oversight in the area of radiation protection and nuclear safety. The Law states the main functions of the RSC SES, which include:

- preparing proposals regarding policy for the supervision and control of radiation safety and nuclear safety in the State;
- performing the supervision and control of radiation safety and nuclear safety;
- performing supervision of inspection and use of ionising radiation measuring devices and personal dosimeters, as well as to ensure control;
- issuing licences for activities with sources of ionising radiation and register any activities with these sources;
- ensuring the registration of sources of ionising radiation, to create and update databases regarding radioactive substances;
- ensuring the 24-hour readiness for early notification of nuclear accidents and to perform the functions of a point of contact in accordance with the Convention on Early Notification of a Nuclear Accident.

RSC SES Rules of Procedure requires RSC SES to provide information to the public by distributing informative materials, cooperating with non-governmental organisations, providing information to mass media, as well as responding to requests for information in accordance with the procedure set out in the regulatory enactments.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

As described above, the Law has established RSC SES as the sole regulatory body in the field of radiation protection and nuclear safety in Latvia. The Law stipulates the main functions and rights of the RSC SES and makes provisions for RSC SES to perform its regulatory functions, more specifically for authorization, inspections and enforcement. RSC SES is effectively independent from influence of operators, political and economic, as well as from other public institutions and organizations.

The IRRS Team was informed that the RSC SES has an approved organizational structure by SES. RSC SES Rules of Procedure set out the roles and responsibilities, competence and work organisation of the RSC SES.

SES is a governmental institution and its financing is determined in SES By-law. The budget being allocated to SES, and in turn to the RSC SES, is approved annually by the Parliament.

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

The Law and Regulations defines the roles and responsibilities of operators. An operator is defined in the Law as a natural person or a legal person who has a license for activities with sources of ionising radiation or who has registered activities with sources of ionising radiation, and who is responsible for the activities, the radiation safety and nuclear safety in the zone controlled by it. In accordance with the Law, an operator shall be responsible for radiation safety and nuclear safety in the zone controlled by it.

The Law on Environmental Impact Assessment requires members of the public to be informed of request for license for the conduct of activities with sources of ionizing radiation of national significance, and procedures are in place for public engagement. Involvement of stakeholder, including the public, in authorization is also prescribed in Regulations 752 “Procedures for Licensing and Registering Activities with Sources of Ionizing Radiation”. The Environmental Policy Guidelines (2014-2020) promote the public participation in environmental-related issues, including radiation protection and nuclear safety.

The Law includes requirements of issuing licences for activities with sources of ionising radiation, and the activities that have to be registered are stated in the Regulations.

The Law prescribes that RSC SES has the right to prohibit activities involving sources of ionising radiation if the requirements of radiation protection and nuclear safety are being violated or if the activity being conducted poses any risks to human life and health. The Administrative Procedure Law and the Latvian Administrative Violations Code further prescribes specific actions for enforcement in cases of non-compliance with the Law.

Provisions for appeals against the decisions of the regulatory body are also provided for in the Law.

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

RSC SES cooperates with other Latvian authorities to reduce risks from exposure to ionising radiation. The roles of the different authorities having responsibilities for radiation protection and nuclear safety are provided in the Law and Regulations. For example, Section 9 of the Law states the collaborative responsibilities assigned to the Ministry of Health and its subordinate authorities, and RSC SES for control over the technical supervision of devices of ionising radiation used for medical purposes.

Another example in the Law for coordination between authorities responsible for safety is the shared responsibility within the Ministry of the Interior to inspect provision of physical

protection by the State Security Service and for emergency preparedness by the State Fire and Rescue Service.

RSC SES is required to notify other relevant State authorities such as the State Agency of Medicines, the Health Inspectorate and the National Health Service regarding its regulatory decision as may be necessary.

The State Administration Law also includes provisions for cooperation and interdepartmental agreements.

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

RSC SES is responsible for assessment of public exposures from existing exposure situations and, if necessary, provides consultation for risk assessment. Provisions of protection from radon and other NORM exposures are defined in Regulations No 149. The advance reference material describes the organizations responsible for radiation risks associated with such sources. For example, the Health Inspectorate and Food and Veterinary Service (packaged drinking water) is responsible for drinking water quality supervision and control according to Regulations No 671. In case of a non-compliance of parameters of radioactivity in drinking water, these institutions shall consult with RSC SES for appropriate actions. As well, according to an Order issued by MEPRD in 2015, a working group was established to coordinate activities with radon assessment and to establish a radon action plan according to EU BSS.

The IRRS Team was informed that the RSC SES does ensure the identification, research and evaluation of situation if it is suspected that any object contains an unknown radioactive substances or if it is suspected that an area is contaminated with radioactive material. Cabinet Instruction, various MEPRD and RSC SES Orders are issued to specify actions and ensure the cooperation between the responsible institutions for dealing with orphan sources. Accordingly, several institutions including RSC SES, State Police, State limited liability company “Latvian Environment, Geology and Meteorology Centre” and State Fire and Rescue Service are involved in such situations. The IRRS Team was informed that when an orphan source is found, its management is funded from the State budget.

RSC SES Quality Guidelines for Procedure No KV_Insp_Inc “Actions During Local Radiological Emergencies” determine the activities carried out by RSC SES in case of or detecting an increased level of ionizing radiation or discovering orphan sources.

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

The current national policy and strategy for radioactive waste management is established in the Law and Regulations, specifically Regulations No. 129 “Requirements for Operations with Radioactive Waste and Materials Related Thereto”. In addition, the Radioactive Waste Management Programme, at annex 5 of the Environmental Policy Guidelines, further describes the strategy for waste management in the country and defines long-term goals for management of low-level radioactive waste but does not define the same goals for intermediate level waste.

Latvia has one centralized radioactive waste repository “Radons”, which is operated by State limited liability company “Latvian Environment, Geology and Meteorology Centre”

(LEGMC). The Law recognizes “Radons” repository as a facility of national significance and defines specific requirements for the facility.

Radioactive waste Storage Concept (approved by Cabinet of Ministers Order No.414) describes the approach to the setting up and operation of the radioactive waste storage system and disposal of radioactive waste without the intention to relocate the waste outside a radioactive waste repository.

The Radioactive Waste Management Programme identifies the possibility to store intermediate level waste, which cannot be placed into near surface disposal.

The Law and Regulations No. 129 stipulate that operator shall provide the necessary financial resources for management of radioactive waste and shall be responsible for covering the costs of management of radioactive waste. Section 27 of the Law states one of the principles of the radioactive waste management - the producer of the radioactive waste (operator) must cover expenses for waste management, respectively (the “polluter pays” principle).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>Radioactive Waste Management Programme defines the major actions for radioactive waste management that are to be taken within the defined period. The Environmental Policy Guidelines (2014-2020) define long term management goals for low level waste however, do not define long term goals for safe management for all classes of existing and future radioactive waste streams.</i>	
(1)	BASIS: GSR Part 1 (Rev.1) Requirement 1 states that <i>“The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities.”</i>
(2)	BASIS: GSR Part 5 Requirement 2 states that <i>“To ensure the effective management and control of radioactive waste, the government shall ensure that a national policy and a strategy for radioactive waste management are established. The policy and strategy shall be appropriate for the nature and the amount of the radioactive waste in the State shall indicate the regulatory control required, and shall consider relevant societal factors. The policy and strategy shall be compatible with the fundamental safety principles and with international instruments, conventions and codes that have been ratified by the State. The national policy and strategy shall form the basis for decision making with respect to the management of radioactive waste.”</i>
(3)	BASIS: SSR Part 5 Requirement 2 para 3.8 states that <i>“General standards for the protection of people and the environment are usually set out in national policy or in legislation...”</i>
(4)	BASIS: SF-1 para 3.29 states that <i>“Radioactive waste must be managed in such a way as to avoid imposing an undue burden on future generations; that is, the generations that produce the waste have to seek and apply safe, practicable and environmentally acceptable solutions for its long term management...”</i>
R3	Recommendation: The government should develop national policy to define long term goals for safe management of all classes of existing and future radioactive waste streams.

The current national policy and strategy for decommissioning is provided in the Law and Regulations (Regulation No. 129), and the Environmental Policy Guidelines (2014-2020).

The requirement for developing an initial decommissioning plan as a part of documents submitted to RSC SES for authorization is set by Regulation No. 752 “Procedures for Licensing and Registering Activities with Sources of Ionising Radiation”. However, the Regulation does not include a requirement to identify a decommissioning strategy, and for the periodical review and update of the decommissioning plan. Further, the requirements for the safe conduct of decommissioning are not fully developed. Also, the regulations do not contain requirements for operators to ensure financial provisions for decommissioning.

For decommissioning of Salaspils nuclear research reactor, a decommissioning concept was developed and approved by Order of Cabinet No.958. The authorization for decommissioning will be in accordance with Regulation No.661 “Construction Regulations in Respect of Structures Related to Radiation Safety”. However, the requirements of this Regulation are yet to be implemented. The financial provisions for the management of waste resulting from the decommissioning of Salaspils Research Reactor (legacy site) will be allocated from State budget.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>The requirement to develop initial decommissioning plan is established in regulations for selected licensees. There is no requirement for identifying decommissioning strategy, and the periodic review and update of the plan. This finding has been identified in the preliminary action plan. The regulations do not contain safety requirement for financial provision for decommissioning activity and safe conduct of decommissioning.</i>	
(1)	BASIS: GSR Part 1 (Rev 1) Requirement 10, para. 2.28 states that <i>“Decommissioning of facilities and the safe management and disposal of radioactive waste shall constitute essential elements of governmental policy and the corresponding strategy over the lifetime of facilities and the duration of activities”...</i>
(2)	GSR Part.1 (Rev 1) Req.10, para 2.33 states that <i>“Appropriate financial provision shall be made for: Decommissioning of facilities; ...”</i>
(3)	GSR Part.3 Req.2, para. 2,24 says that <i>“The government shall ensure that arrangements are in place for the safe decommissioning of facilities..”</i>
(4)	Basis: GSR Part 6 Req. 8 Selecting a decommissioning strategy <i>The licensee shall select a decommissioning strategy that will form the basis for the planning for decommissioning. The strategy shall be consistent with the national policy on the management of radioactive waste.</i> Para. 5.2 states that <i>“The selection of a decommissioning strategy shall be justified by the licensee.</i>
(5)	BASIS: GSR part. 6 Req. 10 para.7.3 states that <i>“For a new facility, planning for decommissioning shall begin early in the design stage and shall continue through to termination of the authorization for decommissioning.”</i>
(6)	BASIS: GSR part. 6 para. 7.5 states that <i>“The decommissioning plan shall be updated by the licensee and shall be reviewed by the regulatory body periodically...”</i>
R4	Recommendation: The Government should include in the national legal framework provisions for safe planning and conduct of decommissioning

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

activity. This includes requirements for identifying decommissioning strategy, periodical update of decommissioning plans, and providing financial support for decommissioning activity.

1.8 COMPETENCE FOR SAFETY

The Cabinet of Minister Regulations establishes the organization requirements of the MEPRD and SES, including RSC SES. In accordance with State Civil Service Law, government employees are hired by competition process based on specific requirements of education, training and skills.

Job descriptions have been established for state civil servants, including RSC SES staff. SES Human resources staff, with the support of RSC SES senior management, harmonize state civil servants job descriptions with the specific competency requirements, such as education in science or engineering, and asset qualifications, such as courses in radiation protection, for the safety responsibilities.

To maintain and build competency, RSC SES has developed a training plan “RSC SES Long term Training Plan for 2018-2022” with regard to necessary training of each employee which was approved by the Director of RSC SES. Annually, all staff are required to perform their self-assessment which include a review of their training needs. The RSC SES has also anticipated the development of a comprehensive human resource plan in 2020.

RSC SES staff take part in international training courses, workshops and fellowships. This primarily includes the events being organized under the IAEA technical cooperation programme. RSC SES staff are required to perform knowledge sharing exercise and store learning materials on the internal network (INTRA) hosted by SES.

1.9 PROVISION OF TECHNICAL SERVICES

Technical services, such as personal dosimetry and equipment calibration, are provided by institutions authorized by RSC SES which may also require an accreditation from the Latvian National Accreditation Bureau. The Law defines technical services for which an authorization is required e.g. technical maintenance, provision of services for verification of technical parameters, installation, repairing, dismantling and disposal of sources of ionizing radiation not containing radioactive substances.

Section 11 of the Law provides the basis for authorization of professional technical services providers by RSC SES. This includes the State limited liability company “Latvian Environment, Geology and Meteorology Centre” (LEGMC) who performs individual dosimetric measurements.

1.10 SUMMARY

Latvia has established a regulatory framework for radiation protection and nuclear safety. The Law and its Regulations issued thereunder, provide the basis for the protection of people and the environment with respect to radiation protection and nuclear safety. The Law identifies RSC SES as the sole regulatory body to perform the state supervision and control in the area

of radiation protection and nuclear safety and enables the coordination of responsibilities for safety with other State institutions.

In order to improve the national framework for radiation protection and nuclear safety, the IRRS Team recommended that Government and RSC SES to prepare:

- a national policy and strategy for safety that includes all the safety fundamentals and expresses a long-term commitment to safety; and
- develop a program for the promotion of leadership and management for fostering safety culture.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Latvia has ratified the international instruments related to nuclear safety and radiological protection: Convention on Nuclear Safety, Joint Convention on the Safety of Spent Fuel and Radioactive Waste Management, Convention on the Physical Protection of Nuclear Material and Amendment, Convention on Early Notification of a Nuclear Accident, Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, Vienna Convention on Civil Liability for Nuclear Damage and 1997 Protocol to Amend the Vienna Convention, Joint Protocol to the Application of the Vienna Convention and Paris Convention, International Labour Convention No 115 Convention concerning the Protection of Workers against Ionising Radiations.

Latvia fulfils its international obligations, prepares reports and participates in the relevant international meetings. In addition, Latvia has expressed political commitment to the IAEA Code of Conduct on the Safety and Security of Radioactive Sources and the supplementary Guidance on the Import and Export of Radioactive Sources. However, Latvia has not yet expressed political commitment to supplementary Guidance on the Management of Disused Radioactive Sources. This guidance was recently approved in the General Conference in September 2017.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Latvia has written a political commitment to endorse principles of the Code of Conduct on the Safety and Security of Radioactive Sources and Guidance on the Import and Export of Radioactive Sources. However, Latvia has not yet expressed political commitment to supplementary Guidance on the Management of Disused Radioactive Sources. This guidance was recently approved in the General Conference in September 2017.*

(1)

BASIS: GSR Part 1 (Rev1) Requirement 14, para. 3.2 (c) states that “*The features of the global safety regime include: (c) Internationally agreed IAEA safety standards that promote the development and application of internationally harmonized safety requirements, guides and practices.*”

S1

Suggestion: The Government should consider a commitment to implement the supplementary guidance under the Code of Conduct entitled “Guidance on the Management of Disused Radioactive Sources”.

Additionally, Latvia has concluded several bilateral and multilateral agreements with Lithuania, Belarus, Ukraine on Early Notification of Nuclear Accidents, Exchange of Information and Co-operation in the Field of Nuclear Safety and Radiation Protection and agreement on the Exchange of Radiation Monitoring Data (agreement between states in the Nordic and Baltic Sea Region).

With regards to the international obligations and arrangements for international cooperation, the Law defines the duties of RSC SES for submission of reports under the international conventions and agreements.

Latvia participates in Safety Standards Committees of IAEA and other international organizations e.g. ENSREG, HERCA, Council of the Baltic Sea States, Experts Group on Nuclear and Radiation Safety, Working Party on Atomic Questions of Council of the European Union and Decommissioning Funding Group (DFG) of European Commission.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

In accordance with the Law, licensees are required to report events to RSC SES. The criteria for reporting of events are established in both the Law and regulations. In addition, the RSC SES receives reports from the IAEA Incident and Emergency Centre (IEC). However, there is no systematic approach in place for analysis of the lessons learned, operating experience or for the dissemination of such information in the country or internationally. RSC SES provides safety related information in its national reports submitted under the Convention on Nuclear Safety and Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.

The IRRS Team was informed that the regulatory bodies from the three Baltic States (Latvia, Estonia, Lithuania) meet every year to share experiences. In addition, RSC SES shares experiences and information about significant events with representatives from other state institutions and operators. For example, RSC SES staff share operating experiences and lessons learned with operators during their inspections. RSC SES staff participate in the annual meeting of the Latvian Association of Dentists to share inspection results and lessons learned. The IRRS Team was also informed that information which is relevant for improving safety and safety culture is published on the SES website and is circulated to relevant stakeholders.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>Latvia has established criteria for reporting events, however, there is no systematic approach in place for analysis to identify lessons learned, operating experience or for dissemination of such information in the country or internationally.</i>	
(1)	BASIS: GSR Part 1 (Rev.1), Requirement 15 states that <i>“The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities”</i>
(2)	BASIS: GSR Part 1. Req. 1 (Rev.1) para 3.4. <i>The regulatory body shall establish and maintain a means for receiving information from other States, regulatory bodies of other States, international organizations and authorized parties, as well as a means for making available to others lessons learned from operating experience and regulatory experience. The regulatory body shall require appropriate corrective actions to be carried out to prevent the recurrence of safety significant events. This process involves acquisition of the necessary information and its analysis to facilitate the effective utilization of international networks for learning from operating experience and regulatory experience</i>
S2	Suggestion: RSC SES should consider within its management system to establish procedures for analysing events, ensuring corrective actions,

	operating experience and disseminating the lessons learned within the country and internationally.
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2.3. SUMMARY

On behalf of Latvia, RSC SES is involved in international agreements, working groups and committees related to radiation protection and nuclear safety. The IRRS Team concluded that Latvia and RSC SES fulfils their international obligations, participates in the relevant international arrangements, including international peer reviews, and promotes international cooperation.

Provisions are made in the legal framework for reporting events. The IRRS Team made suggestion to improve the sharing of operating and regulatory experience.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

The Law establishes RSC SES as the regulatory body for facilities and activities relating to radiation protection and nuclear safety. The RSC SES operates as effectively independent unit under the SES. SES is a direct administration institution under the supervision of MEPRD. The organizational structure of SES is approved by the Cabinet of Ministers with Regulations No. 962 (By-law of the State Environmental Service).

According to the State Administration Structure Law, the Rules of Procedure establishes the structure, competence and organization of work within SES.

The Director of RSC SES and Deputy Director of RSC SES are appointed by the Director General of SES (Article 9 of Cabinet Regulations No. 962). Director of RSC SES, Deputy Director and Head of Inspection Division, and Senior Inspectors hold the status of the State's Environmental Inspectors. The Director General of SES also appoints and dismisses the employees of the Radiation Safety Centre (Article 22.9 and 22.10 of Rules of Procedure of SES No.1)

To fulfil tasks and functions of RSC SES, the Director has the right to issue internal procedures for effective work of RSC SES (Article 24 and 25 of Rules of Procedure of SES No.1)

The organizational structure of RSC SES and the main tasks of each divisions are defined in Rules of Procedure of RSC SES which is approved by director of RSC SES. RSC SES is divided into two divisions, the Inspection Division, which includes Early Warning Group, and Licencing and the Registry Division.

Currently, RSC SES employs 16 staff, including the Director of RSC SES. The total number of posts within RSC SES staff is 17, as defined in the Order of Director – general of SES titled “Human resource order about RSC structure and position” issued 30th June 2009.

The IRRS Team was informed that an assessment of the staff requirement is needed as a component of the human resource plan. **See Recommendations R5 under Section 3.3.**

RSC SES is funded from the State budget. It develops a budget plan for the three years after evaluating the implementations from previous year's plans and current needs. The finances for RSC SES are granted annually by the Parliament as a separate budget line for salaries under the budget allocated to the SES. Additional funding for equipment procurement (e.g. for medical exposure equipment) is also received from EU and IAEA technical cooperation projects. Separate budget line is assured for salaries and for maintaining their early warning radiation system. Other costs are covered through the budget of SES. In the last two years, the Government provided RSC SES with additional financial resources. The IRRS Team was informed that financial resources provided to the RSC SES are adequate to carry out its activities.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

The Law and the Regulation No. 962 establishes the RSC SES as an effectively independent regulatory body operating under the SES. Provisions are established in the Law and Regulations to ensure clear separation between the RSC SES and promoters and users of radiation or nuclear related technologies.

Administrative and regulatory measures for prevention and resolution of potential conflicts of interest in the decision-making process are covered in the Law on Prevention of Conflict of Interest in Activities of Public Officials. The SES has also developed an Anti-Corruption Action Plan (approved on 18.12.2017 by order No.10), which contains several measures aimed at preventing situations of conflict e.g. inspectors can only inspect the same licensee two times in a row.

The Law on Conflict of Interest prescribes employment restrictions with regards to recruitment of new staff from authorized parties. In addition, the RSC SES employees follow the Guidelines of the Cabinet of Ministers No. 1 “Values of Public Administration and Ethical Basic Principles” from 21st November 2018 and the Ethical Code of State Environmental Service (adopted on 31st October 2006). In case a significant risk regarding integrity of staff in the regulatory body is identified, they must report to the Corruption Prevention and Combating Bureau of Latvia. In accordance to the Law (Section 6), contesting or appeal of decisions made by officials of the RSC SES shall not suspend the execution thereof.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

RSC SES currently employs 16 persons of which 5 are of the Inspection Division, 5 employees of the Early Warning Group, 5 employees in Licensing and Registry Division and director of RSC SES. In 2019, one additional employee is expected to join the organization.

A job description is provided for each position at the RSC SES which set out the education (e.g. high-level of education in science and engineering), basic knowledge, skills and abilities required for the position. RSC SES employees are recruited through the public tender from applicants with appropriate education and skills in accordance with job descriptions.

All RSC SES staff are required to perform a self-assessment of their performance, which are reviewed by their respective supervisor through the state system called “NEVIS” which is developed for all state employees. This system is described in Chapter 7.4 of the Quality Management System Manual. Based on this system an annual training programme, for each RSC SES staff has been developed and implemented. A training plan (2018-2022), for staff training was developed and approved by the director of RSC SES however, a comprehensive human resources plan has not been established. In areas where there is limited expertise in Latvia, RSC SES participates in training from experts from other countries.

In addition, the IRRS Team was informed that RSC SES has a lot of measures to compensate for the departure of qualified staff. For knowledge sharing, RSC SES staff are required to share training materials. These learning materials are collected and stored on internal network which is accessible to all RSC SES staff.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *RSC SES has prepared a training plan (2018-2022) for each employee, however, a comprehensive human resources plan has not been established. This issue has been also recognised in the self-assessment.*

(1)	BASIS: GSR Part 1 (Rev.1) Requirement 18, para. 4.11 states that “The regulatory body has to have appropriately qualified and competent. 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 (Rev.1) Requirement 18, para. 4.13 states that “A process shall be established to develop and maintain the necessary competence and skill of staff of the regulatory body as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills.”
R5	Recommendation: RSC SES should prepare assessment of the necessary number of staff including competence and skills to perform its functions and to discharge its responsibilities, and based on this analysis to develop and implement a comprehensive human resources plan including, specific training programme, which is based on assessment of the necessary staff.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

The Law establishes the Radiation Safety Council (Council) as the consultative institution (advisory body) on matters related to radiation protection and nuclear safety. The composition of the Council is approved by the Cabinet. It comprises representatives of Ministry of Interior, Ministry of Defense, Ministry of Economy, Ministry of Welfare, Ministry of Transport, Ministry of Health, RSC SES, Latvian University/Riga Technical University and Radiological Association of Latvia.

The MEPRD organizes the activities of the Council. According to the Law (Section 8), the role of the Council is to consult state and local government institutions and authorities, as well as other institutions and authorities regarding matters that are connected with radiation protection and nuclear safety, and to promote the cooperation of different institutions for strengthening of radiation safety.

Regulation for Protection against Ionising Radiation No. 149 has provided the legal basis of recognition of a “radiation safety expert”, a “nuclear safety expert” and a “medical physics expert”. For recognition of a “radiation safety expert” and a “nuclear safety expert” the Radiation Safety and Nuclear Safety Expert Attestation Commission is established and consist of at least nine members who represent professional associations, the MEPRD, the RSC SES staff, the Council and educational institutions which ensure vocational further education. The Minister of MEPRD approves the composition of the commission. According to the Article 9 of Regulation No. 149, the Commission issues a certificate of recognition of a “radiation safety expert” or “nuclear safety expert”.

Currently, RSC SES has a number of dedicated TSO and “radiation safety experts” or other expert professionals, who advise or service in support of its regulatory functions and include obtaining technical advice in review and assessment process of authorization applications or while carrying out inspections.

TSO covers different areas such as consumer product control, investigation of orphan sources, transport of orphan sources, construction issues, radiation safety, nuclear safety, environmental monitoring, calibration of radiation measuring equipment, medical areas, etc. In addition, RSC SES has a possibility to consult with Medical Ethics Committee regarding the justification of exposure applied to the individuals participating in medical and biomedical research projects. When expert opinion is required, the RSC SES identifies the appropriate institution that can provide it, taking into account potential conflicts of interest. RSC SES obtain technical or other expert professional advice or services as necessary in support of its regulatory functions, but this does not relieve the regulatory body of its assigned responsibilities.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

The RSC SES has established formal and informal mechanisms of communication with authorized parties. Explanatory information about the regulatory process conditions and documentation required for authorization and different guidelines are available on the SES website. The Laws and Regulations are made available on the SES website. Information on issued authorizations is also available on the website of SES, which includes information on the type of source or practice and allowed activities.

A formal mechanism of communication between RSC SES and licensees on safety related issues is established in accordance with the procedures prescribed in the Administrative Procedure Law. RSC SES staff communicate with applicants in the event of missing or insufficient information. Following a review of applications, the RSC SES may, as appropriate, perform visits to the site (pre-authorization inspection) to confirm documents and conditions of facilities, and perform indicative radiological measurements.

The RSC SES have also established working groups for specific areas (e.g. in medical fields) to discuss safety related issues such as assessment of patients' dose and diagnostic reference levels. The working groups consist of experts, professional associations, technical staff and RSC SES staff.

RSC SES regularly organises meetings with representatives of operators or radiation safety experts on different aspect of radiation protection, for example, patient dose registration, performing internal audits of medical facilities, verifying technical parameters of medical X-ray devices, carrying out workplace monitoring, preparing safety assessment, preparing radiation protection programme.

According to the Law (Section 5), RSC SES is also responsible for organising and co-ordinating training on radiation safety to enhance the level of radiation safety in the State. The IRRS Team was informed that RSC SES periodically organizes informative seminars for licensees.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

General formal procedures for the implementation of RSC SES core processes are defined in the Law and regulations, and are adopted on the basis of Administrative Procedure Law and State Civil Service Law. In addition, a detailed description of the authorization processes is included in various RSC SES guidelines which are published on the SES website. Guidelines set out regulatory expectations and are made available to all authorized parties.

Stability and consistency of regulatory control is ensured by application of RSC SES quality management system and RSC SES internal procedures for authorization, inspection and other regulatory functions. There are RSC SES internal procedures about how to evaluate licence and registration applications and supporting documents (e.g. KV_lic_1, Procedure for Licensing and Registration of Activities with Sources of Ionising Radiation, KV_lic_4, Procedure for Review of Operators Radiation Protection Programmes). Internal documents define procedures for making decisions, reviewing documents, and also performing inspections. The implementation of internal procedures has ensured that the RSC SES has a unified approach. This ensures the stability and consistency of regulatory control and prevents subjectivity in decision making by individual staff members of the regulatory body.

The process for developing and modifying regulatory requirements is discussed further in Chapter 9, including consultation with interested parties.

3.7. SAFETY RELATED RECORDS

The Law (Section 6, Articles 13, 14 and 15) stipulates the duties and responsibilities of RSC SES to keep records regarding exposure of workers and members of the public, registration of sources of ionising radiation, creation and updates of databases regarding radioactive substances, nuclear materials, radioactive waste and other sources of ionizing radiation. In addition, RSC SES uses the Regulatory Authority Information System (RAIS) for maintaining records of the regulatory activities, including the registry of ionising radiation sources and radioactive materials and occupational exposure.

Records of events, including non-routine releases of radioactive material into the environment, and records relating to the safety of facilities and activities are managed by RSC SES as 'operators file' in the documentation system.

The Law also establishes requirements for licensees to maintain records and report them to the RSC SES. Requirements for reporting safety related events are in place in the Law (Section 14).

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

RSC SES does communicate and consult with its interested parties, however the mechanism for communication and consultation is not formalized and documented. **See suggestion 3 under section 4.3.** RSC SES maintains a website that provides general information on its activities and inform the public regarding facilities of national significance. The Law (Section 12) requires RSC SES to inform the public if a facility of national significance has submitted an authorization application to receive, modify or renew an authorization. According to the Law and Regulations No 149, these facilities must also report to local authorities including results of the environmental monitoring.

Annual reports on the work of the RSC SES are also published on the SES website along with the information on the implementation of RSC SES inspection plan. RSC SES occasionally organizes press conferences and through other media reports on their activities and informs public on important topics, for example, radon gas control.

Online data on radiation monitoring stations results are available on the SES website. Other information is published on SES website, in accordance with the Law.

Information about emergency preparedness and actions to be taken in the event of an emergency are published on SES webpage.

3.9. SUMMARY

Latvia has established RSC SES within SES as an independent state regulatory body for state supervision and control in the field of radiation safety and nuclear safety. RSC SES has the necessary level of independence to perform its functions and to discharge its responsibilities provided by legislation.

RSC SES established quality guidelines for procedures (internal procedures) to ensure consistency in its regulatory decision processes. RSC SES is using RAIS system for maintaining all regulatory records. The RSC SES do have consultations with stakeholders however, there is no formal mechanism in place for the consultation processes. The IRRS Team made some recommendations for the RSC SES to improve on performance of its activities.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

The RSC SES operates as an independent structural unit under SES. In accordance with the State Environmental Service Rules of Procedure, the Director of RSC SES has been assigned the responsibility to plan, manage and organize the work of the RSC SES.

According to the SES Rules of Procedure and the Rules of Procedure for the Operation of the RSC SES, the senior managers of the RSC SES ensure the supervision of activities and all processes developed and implemented. The safety-related roles and responsibilities of the different staff of the senior management team of the organisation are defined in the management system to ensure that the fundamental safety objective of protecting people and the environment from harmful effects of ionizing radiation is achieved.

The Quality Guidelines for Procedure No KV_Vis_Rokasgramata “Quality Management System Manual” developed by the RSC SES clearly define the mission, vision, and the organisation’s goals and primary safety objectives.

The implementation of the RSC SES management system is ensured by a series of internally approved documents, which define the functions and tasks of the RSC SES, its responsibilities, and the conditions for system improvement through planning, control and supervision.

4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

The Director of the RSC SES has established and implemented a management system that is aligned with its safety goals and contributes to their achievement, with measurable goals and plans set for the regulatory body to effectively carry out all its activities. The staff of the RSC SES is committed at all levels to the implementation, assessment and continual improvement of the management system.

The responsibility and accountability of the Director of the RSC SES is established in the management system and the safety policy of the organisation.

4.3. THE MANAGEMENT SYSTEM

The management system is documented in a variety of documents which are approved at different levels. The Quality Guidelines for Procedures known as the ‘Quality Management System Manual’ has been developed and adopted by the RSC SES in 2018, bringing together in a coherent and integrated manner various elements for the organisation to attain its goals.

The RSC SES has further developed a series of Quality Guidelines for Procedures for the organisation to effectively and efficiently carry out its activities. These Quality Guidelines for Procedures are developed by the Heads of Divisions and approved by the Director RSC SES for implementation.

The Director RSC SES is responsible for the implementation the management system and its further development, and for the review of all processes and procedures in a timely and consistent manner to ensure their adequacy and effectiveness.

The RSC SES has adopted the graded approach for the development of its management system. Provisions are also made in the management system for the RSC SES to adopt the graded approach in its implementation with due consideration to the hazards and the magnitude of the potential risks associated with the facilities and activities being regulated.

The management system established by the RSC SES is comprehensive and rather well documented. There is also arrangement in place for the documents to be controlled, reviewed and recorded.

The management system does elaborate on the decision-making process of the RSC SES, however there is no information regarding the arrangements for independent review to be made before decisions significant for safety are made, and also on the requirements on the independent nature of the review and on the necessary competences of the reviewers.

Chapter 4.6 of the Quality Management System Manual do provide the overarching arrangements for the cooperation of the RSC SES with its stakeholders. However, there is no detailed information provided in the management system regarding the interaction of the RSC SES with interested parties, though in practice such activities are carried out by the RSC SES.

The IRRS Team was informed that the RSC SES do ensure the review of the management system at planned intervals to confirm its suitability and effectiveness, and its ability to enable the objectives of the organization to be accomplished, with account taken of new requirements and changes in the organization. However, there is no information provided in the management system for the RSC SES to identify any changes, including organisational changes, that could have significant implications for safety and to ensure that they are appropriately analysed.

The management system which has been developed and implemented by the RSC SES includes various elements to demonstrate how the organisation achieves its goals without compromising safety. However, no information is provided therein on the interface between safety and security, more specifically on the arrangements for the resolution of any conflict that may arise in decision making processes, related to potential impacts of security measures on safety and potential impacts of safety measures on security, which is to be identified and resolved without compromising safety or security.

Most of the processes established by the RSC SES are well documented. The RSC SES is pursuing its efforts to further consolidate its management system with the documentation of some new processes and procedures, and to review and update existing procedures to provide further details to improve clarity and transparency. It was noted that a few key processes have not yet been documented, which include the development and review of guides and the interactions with interested parties.

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Observation: *The RSC SES does interact with its interested parties. However, there is no clear information in its management system on the strategy and means adopted by the RSC SES for interaction with interested parties, including the public and other external organisations.*

(1)	<p>BASIS: GSR Part 1 (Rev. 1) Requirement 36 states that <i>the regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body.</i></p>
(2)	<p>BASIS: GSR Part 2 Requirement 5 states that <i>"Senior management shall ensure that appropriate interaction with interested parties takes place."</i></p> <p>Para 4.6. <i>Senior management shall identify interested parties for their organization and shall define an appropriate strategy for interaction with them.</i></p> <p>Para 4.7. <i>Senior management shall ensure that the processes and plans resulting from the strategy for interaction with interested parties include:</i></p> <ul style="list-style-type: none"> <i>(a) Appropriate means of communicating routinely and effectively with and informing interested parties with regard to radiation risks associated with the operation of facilities and the conduct of activities;</i> <i>(b) Appropriate means of timely and effective communication with interested parties in circumstances that have changed or that were unanticipated;</i> <i>(c) Appropriate means of dissemination to interested parties of necessary information relevant to safety;</i> <i>(d) Appropriate means of considering in decision making processes</i>
S3	<p>Suggestion: The RSC SES should consider to document, in its management system, the strategy and means for interaction with interested parties.</p>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The management system which has been developed and implemented by the RSC SES includes various elements to demonstrate how the organisation achieves its goals without compromising safety. However, no information is provided therein on the interface between safety and security, more specifically on the arrangements for the resolution of any conflict that may arise in decision making processes.*

(1)	<p>BASIS: GSR Part 2, Requirement 6 Para 4.10 states that <i>"Arrangements shall be made in the management system for the resolution of conflicts arising in decision making processes. Potential impacts of security measures on safety and potential impacts of safety measures on security shall be identified and shall be resolved without compromising safety or security."</i></p>
R6	<p>Recommendation: The RSC SES should include in its management system details on the arrangements for the resolution of conflicts arising in decision making processes, most specifically those related to potential impacts of security measures on safety and potential impacts of safety measures on security.</p>

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Observation: *There is no information provided in the management system for the RSC SES*

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to identify any changes, including organisational changes, that could have significant implications for safety and to ensure that they are appropriately analysed.

(1)	BASIS: GSR Part 2, Requirement 6 Para 4.13 states that <i>“Provision shall be made in the management system to identify any changes (including organizational changes and the cumulative effects of minor changes) that could have significant implications for safety and to ensure that they are appropriately analysed.”</i>
R7	Recommendation: The RSC SES should identify in its management system any changes, including organizational changes, that could have significant implications for safety and to ensure that they are appropriately analysed.

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Observation: *There is no arrangement established in the management system for the RSC SES to carry out an independent review before decisions significant for safety are made.*

(1)	BASIS: GSR Part 2, Requirement 6 Para 4.14 states that <i>“Arrangements shall be established in the management system for an independent review to be made before decisions significant for safety are made. The requirements on the independent nature of the review and on the necessary competences of the reviewers shall be specified in the management system.”</i>
R8	Recommendation: The RSC SES should establish in its management system the arrangements for independent review to be made before decisions significant for safety are made, and to specify the requirements on the independent nature of the review and on the necessary competences of the reviewers.

4.4. MANAGEMENT OF RESOURCES

RSC SES is comprised by its Director and 15 staff. The IRRS Team was informed that no assessment of the necessary number of staff to discharge its responsibilities was carried out, however RSC SES do consider that they have an adequate number of staff to effectively carry out all their activities, and to effectively implement all its processes of its management system. The administrative support to the RSC, such as financial management, human resources management, procurement etc are ensured by the SES. **See Recommendations 5 in Section 3.3.**

The RSC SES has assessed the competences of all its staff, based on which a training plan has been developed to ensure that the regulatory body has adequate capacity necessary to conduct its activities. The RSC SES does have a system in place for monitoring the performance of its staff to perform their assigned tasks.

The Director of RSC SES does monitor the availability of the resources for the organisation to effectively carry out all its activities. Any need for any additional resources is submitted to the SES for consideration.

4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

The RSC SES has identified, developed and documented most of its processes and procedures established by the organisation to effectively carry out its activities. As highlighted in section 4.3 above, not all the processes have been documented in the management system. There are a few processes which have been established but not yet documented, such as the development of guides and interactions with interested parties.

The different processes in the management system are approved by the Director of RSC SES with the necessary documentation maintained. The Director and the Heads of Divisions of the RSC SES are the process owners for the different processes established by the RSC SES. The process owners are responsible for the effective implementation of management system and for ensuring that the processes are being managed to meet all the requirements without compromising safety. They are also responsible for the periodic review of their respective processes.

All the documented processes and procedures are posted on the secured intranet system INTRA hosted by SES. This system facilitates the dissemination of the management system to all the staff of the RSC SES for them to readily have access to the latest versions of the management system.

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Observation: <i>Most of the processes established by the RSC SES to achieve its goals have been documented in its management system. It has been identified that few processes have not yet been developed and documented.</i>	
(1)	BASIS: GSR Part 2 Requirement 8 states that <i>“The management system shall be documented. The documentation of the management system shall be controlled, usable, readable, clearly identified and readily available at the point of use.”</i>
(2)	BASIS: GSR Part 2 Requirement 10 Para 4.28 states that <i>“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. It shall be ensured that process documentation is consistent with any existing documents of the organization. Records to demonstrate that the results of the respective process have been achieved shall be specified in the process documentation.”</i>
S4	Suggestion: The RSC SES should consider to identify, develop and document all its processes.

4.6. CULTURE FOR SAFETY

The IRRS Team was informed that the RSC SES promotes a safety culture throughout the organisation. However, there is no detailed information in the management system on the methods being adopted by the regulatory body for fostering a strong safety culture and to ensure a common understanding of safety and safety culture. **See Recommendation 2 in Section 1.1.**

The principle “Consult First” has been implemented in public administration in Latvia to achieve mutual understanding between operators and regulators by promoting compliance with established requirements rather than imposing penalties. This initiative encourages customer-oriented action that focuses on openness, accessibility and clarity, as well as, more effective supervision aimed at proportionality, consistency and oriented on the goal. RSC SES has

applied the “Consult First” principle in development of its guidelines for operators and internal procedures for RSC SES staff. Both operators and RSC SES staff have been surveyed in 2018 and 2019 regarding their understanding of the principle and satisfaction of the level of implementation. Feedback from surveys is being used for adjusting implementation and planning further actions such as additional guidelines or more user friendly tools such as online authorization. Through the implementation of this principle, the RSC SES has made a step ahead in promoting a common understanding of safety and safety culture.

4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

RSC SES have a system in place for senior management to evaluate and improve the management system. It has adopted the LEAN thinking and ASAICHI Meetings as an effective and efficient system for measuring and assessing the implementation of the different processes and activities of the regulatory body and to evaluate their effectiveness.

RSC SES is applying these management methods to continuously monitor key indicators, immediately escalate problems and assign people responsible for the identification and solution of them. RSC SES Inspection Division and Licensing and Registry Division have developed indicators to monitor compliance with and effectiveness of internal procedures. Leadership and involvement of senior managers is ensured through ASAICHI meeting at the level of heads of divisions and RSC SES Director every two weeks. This is considered by the IRRS Team as a good performance.

Beside the regular internal audit being carried out by the RSC SES, the processes of the regulatory body are also being periodically monitored by the Supervision Department of the SES to ensure that the organisation does effectively carry out all its functions and activities. The results of the assessment on the evaluation of the processes are communicated to the relevant staff for appropriate action.

4.8. SUMMARY

RSC SES has established and implemented an Integrated Management System which is continually being measured and assessed. Though the management system is comprehensive, it is not fully documented.

5. AUTHORIZATION

5.1. GENERIC ISSUES

The main tasks of the Licensing and Registry Division is to handle applications for licenses and registrations, perform review and assessment of applications as well as handling amendments to licences, reviewing of annually reports and maintaining the national dose register. Training and education of the staff at the Division is according to the training scheme in Quality Guidelines for Procedure “RSC SES Training Module”.

RSC SES may involve advisory bodies or technical support organizations in the authorization process. This includes the possibility to ask for opinion of certified radiation safety experts or educational institutions like universities.

Activities that have to be licensed are stated in the Law, while activities that have to be registered as well as criteria and requirements necessary for safety that have to be fulfilled when applying for authorization, are stated in Regulations No. 752 “Procedures for Licensing and Registering Activities with Sources of Ionising Radiation”.

Graded approach is implemented by applying licensing, registration and exemption and there are special requirements for facilities of national significance. There are three facilities of a national significance in Latvia, these are: shutdown research reactor in Salaspils; the radioactive waste repository «Radons» in Baldone; and State Blood Donor Centre which carries out activities with high activity sealed source.

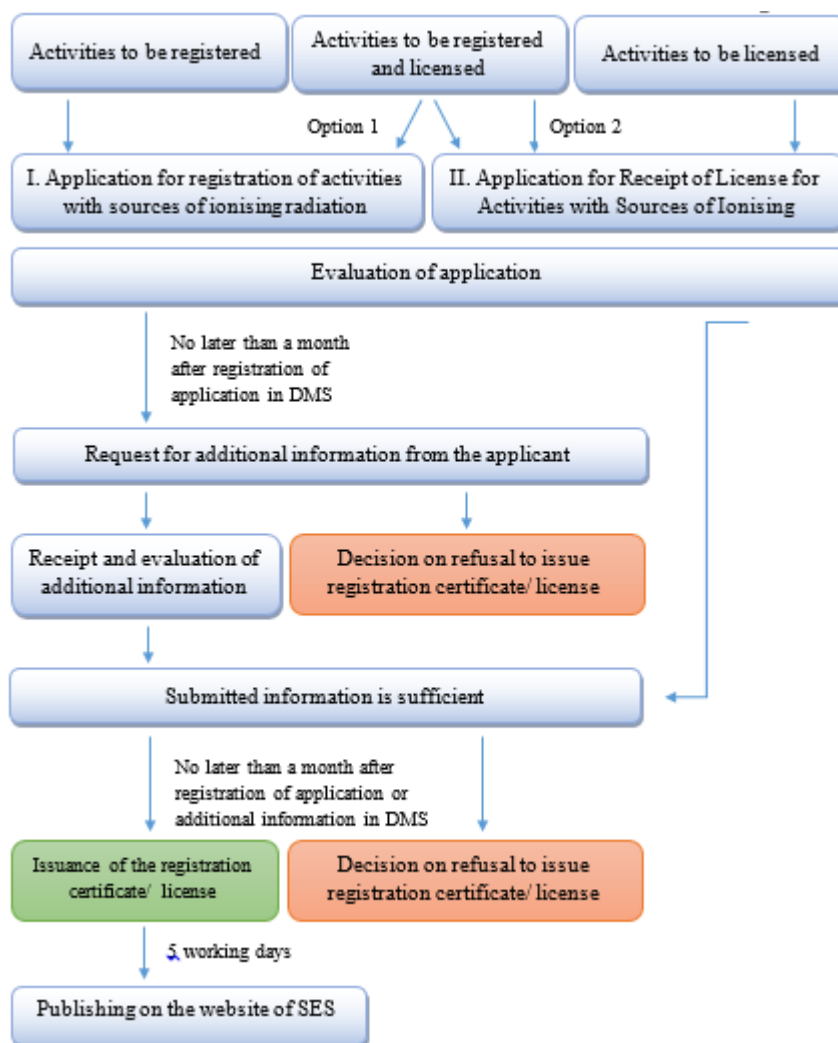
The Law does not provide for notification however amendments to the Law concerning the introduction of the concept of notification have been drafted in 2018.

RSC SES performs authorizations following the “Procedure for Licensing and Registration of Activities with Sources of Ionising Radiation”. Applicants have useful information available online by RSC SES, such as guidance for safety assessment, radiation protection programme and the application process.

The IRRS Team was informed that RSC SES is reviewing the authorization process to make it more efficient and effective. RSC SES Licensing and Registry Division staff process the application, which is then reviewed by the Head of Licensing and Registry Division and approved by the Director of RSC SES. For some applications, the inspection division of the RSC SES may be required to carry pre-authorization inspections prior to issuing a license or registration.

After 5 working days, relevant parts of the license or registration are published on the SES website.

Authorization process for Licensing and Registration, taken from “Procedure for Licensing and Registration of Activities with Sources of Ionising Radiation” guideline



For certain facilities, Regulation No. 752 prescribes different types of authorizations taking in consideration the different stages in lifetime like site evaluation, design, construction, commissioning, operation, shutdown and decommissioning. This is limited to facilities of national significance, however this concept is not used in authorizing other complex facilities (e.g. radiotherapy etc.).

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Observation: *There is no system for notification in place. Amendments to the law in order to implement the concept of notification have been drafted in 2018. This finding has been recognized in the self-assessment.*

(1) **BASIS:** **GSR Part 3 Requirement 7, para. 3.7 states that** “Any person or organization intending to carry out any of the actions specified in para. 3.5 shall submit a notification to the regulatory body of such an intention. Notification alone is sufficient provided that the exposures expected to be associated with the practice or action are unlikely to exceed a small fraction, as specified by the regulatory body, of the relevant limits, and that the likelihood and magnitude of

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	<i>potential exposures and any other potential detrimental consequences are negligible.”</i>
R9	Recommendation: The government should include provisions in the legislation for notification.

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Observation: *RSC SES is providing different types of authorization for the different stages in the lifetime of a facility or the duration of an activity only for some facilities in the country (objects of national significance), however this concept is not used in authorizing other complex facilities (e.g. radiotherapy etc.)*

(1)	BASIS: GSR Part 1 Requirement 24, para. 4.29 states that “ <i>Different types of authorization shall be obtained for the different stages in the lifetime of a facility or the duration of an activity. The regulatory body shall be able to modify authorizations for safety related purposes. For a facility, the stages in the lifetime usually include: site evaluation, design, construction, commissioning, operation, shutdown and decommissioning (or closure). This includes, as appropriate, the management of radioactive waste and the management of spent fuel, and the remediation of contaminated areas. For radioactive sources and radiation generators, the regulatory process shall continue over their entire lifetime.</i> ”
(2)	BASIS: GSG 13, para. 3.115 states that “ <i>... the regulatory body should carry out authorization in several steps for complex facilities or activities, with an application usually being required for each step (see Appendix II). For nuclear facilities, industrial irradiation installations and facilities for industrial radiography, nuclear medicine and radiotherapy, the regulatory body may require a multistep process of authorization (e.g. it might require the submission of an application to construct the facility before construction can begin). The regulatory body might also prohibit the procurement of nuclear material or radiation sources (including their import) until a particular stage of construction has been completed and the safe and secure storage of the nuclear material or radiation sources can be ensured.</i> ”
(3)	BASIS: GSG 13, para. 3.115 states that “ <i>The authorization process for a complex facility or activity should be considered to consist of a series of steps, each subject to the need for regulatory input to allow progress from one step to the next. These steps may depend on national legislation but are normally as follows:</i> <i>(a) Siting and site evaluation (which may include the environmental impact assessment);</i> <i>(b) Design;</i> <i>(c) Construction;</i> <i>(d) Commissioning;</i> <i>(e) Operation;</i> <i>(f) Decommissioning (or closure);</i> <i>(g) Release from regulatory control.</i> ”
S5	Suggestion: RSC SES should consider applying the system for different types of authorization for all complex facilities, taking into account different stages

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in lifetime.

5.2. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

Authorization requirements for radioactive waste management facilities are defined in Regulation No.752 “Procedures for Licensing and Registering Activities with Sources of Ionising Radiation”. In addition, Regulation No.661 provides authorization requirements for construction of facility of national significance, including waste management facilities. For authorization of a radioactive waste management facility, RSC SES requires submission of documents prescribed by Regulation No.752. Authorization for the current radioactive waste management facility is issued for 10 years.

RSC SES requires the submission of safety assessment as a main component for authorization of radioactive waste management facilities. Regulation No.129 provides requirements for conducting a safety assessment of radioactive waste management facilities. This regulation requires a safety assessment to be performed using a deterministic approach. However, this is not consistent with article 85 of the Regulation No.129 that makes references to IAEA safety guides, which provide for conduct of safety assessment using deterministic and probabilistic approaches.

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Observation: *The regulation only provides for conduct safety assessment using deterministic approach. This is in contradiction to another provisions in the same regulation to use the Agency’s guide for using both the deterministic and the probabilistic approaches for safety assessment.*

(1)	<p>GSR Part.5 Req.4 Responsibilities of the operator <i>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.</i></p> <p>Para 3.11 states <i>“Depending on the complexity of the operations and the magnitude of the hazards associated with the facility or the activities concerned, the operator has to ensure an adequate level of protection and safety by various means, including: ...</i> <i>—Derivation of operational limits, conditions and controls, including waste acceptance criteria, to assist with ensuring that the predisposal radioactive waste management facility is operated in accordance with the safety case”</i></p>
(2)	<p>GSR Part 4 Req.15 Deterministic and probabilistic approaches <i>Both deterministic and probabilistic approaches shall be included in the safety analysis</i></p>
(3)	<p>SSR-5 Req. 13 Scope of the safety case and safety assessment <i>The safety case for a disposal facility shall describe all safety relevant aspects of the site, the design of the facility and the managerial control measures and regulatory controls. The safety case and supporting safety assessment shall</i></p>

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	<i>demonstrate the level of protection of people and the environment provided and shall provide assurance to the regulatory body and other interested parties that safety requirements will be met.</i>
(4)	GSG-3 para 5.8 states that <i>The safety assessment should be performed using an appropriate selection of approaches that, when used in a complementary manner, can increase confidence in the safety of the facility or activity. The different approaches that can be considered include: reasoned arguments, the use of simple conservative models, probabilistic and deterministic approaches, and the use of more complex and more realistic models.</i>
(5)	SSG-23 para 3.10 states that “ <i>...The safety assessment has to include a safety analysis, which consists of a set of different quantitative analyses for evaluating and assessing challenges to safety in various operational states, anticipated operational occurrences and accident conditions, by means of deterministic and also probabilistic methods.</i> ”
S6	Suggestion: The Government should consider revising the regulation to enable the use of both deterministic and probabilistic approaches for safety assessment.

5.3. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

RSC SES apply the graded approach for authorization of radiation sources facilities and activities. For example, that use of x-ray devices in medicine have to be licensed, while use of x-ray devices in dentistry have to be registered. Similarly, use of mobile x-ray devices in non-medical applications have to be licensed, while use of stationary x-ray devices have to be registered. Activities with radioactive sources that exceed the exemption level more than 1 000 times have to be licensed, while activities with sources that exceed the exemption level less than 1 000 times have to be registered. The registration limit for each radionuclide as well as exemption levels are prescribed in Regulations No.752. Clearance levels are listed in regulation 129.

RSC SES has established a set of guidelines which include No.7 “Completing an Authorization Application for Activities with Ionising Radiation Sources”, No. 1 “Safety Assessment” and No. 4 “Development of radiation safety quality assurance programme (radiation protection programme)”. These guidelines describe the information which needs to be submitted to RSC SES when applying for a license or registration. The application forms are adjusted to different practices. However, specific guidelines for industrial radiography are not established. **See Suggestion 10 in Section 9.3.**

5.4. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

Regulation No.752 “Procedures for Licensing and Registering Activities with Sources of Ionising Radiation” provides requirements for issuing authorization. RSC SES Guidelines No. 7 “Completing an Authorization Application for Activities with Ionising Radiation Sources” includes guidance for content of decommissioning plan (both preliminary plan and final plan). However, Regulations do not include specific requirements for an authorization for decommissioning **See Recommendation 4 Section 1.7.** The IRRS Team was informed that authorization for decommissioning of nuclear research reactor, facility of national significance, will be conducted in accordance of requirements of Regulation No.661.

A main component of the authorisation for decommissioning is the final decommissioning plan. In accordance with IAEA safety standards, a decommissioning plan must be supported by a safety assessment.

5.5. AUTHORIZATION OF TRANSPORT

Law on the Movement of Dangerous Goods provides that each transport mode is regulated by the pertinent modal regulation (ADR, RID, IMDG, ICAO). The transport of radioactive material is considered an activity. Therefore, the graded approach in the authorisation of the transport of radioactive material is introduced by Regulation 752 that sets the value of 1 000 times exemption level, below which registration applies; if this value is exceeded, a license is required.

Type A and Type B packages, as well as industrial packages and excepted packages are mainly transported by land. Special form radioactive material, low dispersible radioactive material, packages containing 0.1 kg or more of uranium hexafluoride, Type B(U), Type B(M) packages or Type C packages are currently not designed or manufactured in Latvia. According to Regulation No. 307 RSC SES has the authority to issue approvals based on the SSR-6 (Rev.1) for all modes.

There is no internal guidance on the contents of the approval certificates. Nevertheless, these are set in Regulations No. 307 and in the modal regulations. The RSC SES could benefit from the development of the certificate template as it would facilitate the approval procedure, although it appears very rare until to date.

5.6. AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE

The Licensing and Registry Division at RSC SES reviews and assesses during the authorization process a safety assessment submitted by the applicant which is prepared by a radiation protection expert. A list of Radiation Protection Experts (RPE) is available on the SES website.

When applying for a license or registration or when modifying the practice, the applicant is required to submit technical documentation describing the main design and parameters of the radiation source. Requirements for the Radiation Protection Programme (RPP) are set in Regulation No. 149 and detailed guidelines are available on the SES website. This includes requirements for facility layout plan, workplace monitoring programme and radiation safety instructions. The application has to contain information on the arrangements for individual dosimetry both for category A and category B workers. Individual dosimetry service is provided by State Ltd. "State Environment, Geology and Meteorology Centre" (LEGMC) which reports all doses received by workers wearing TLDs to RSC SES on a quarterly basis. Authorized parties report doses received by workers using EPDs to RSC SES. Doses are checked and followed up by RSC SES, as necessary.

RPPs are also reviewed during the authorization process with regard to changes in the facility. RPPs are reviewed and approved by RSC SES in accordance with the criteria published in the Guidelines on RPP. Dose limits for occupational exposure in planned exposure situations are set in Regulations No.149. The dose limits are in accordance with the Schedule III of GSR Part 3 for planned exposure situations except for the equivalent dose to the lens of the eye. **Recommendation R21 in Section 9.6 addresses this issue.**

Requirements for the necessary level of education and experience for radiation protection officers and workers, with regard to the practice or activity, are set out in Regulation No. 752 which also includes requirements for periodic re-training of workers. Periodic re-training in radiation protection and safety shall be done once every 5 years. The training programmes are approved by RSC SES and reviewed periodically. If the worker duties change or if new equipment or a new procedure with sources of ionising radiation is introduced at work, extracurricular training is required.

A radiation protection officer (RPO) is required to be appointed in the facility in order for an authorization to be granted. The task of the RPO is to ensure that workers are sufficiently trained in the performance of protective measures, and they have adequate knowledge of the conditions and legal requirements and are aware of potential risks related to their work including ionizing radiation. The RPO facilitates consultation of and co-operation with workers with regard to protection and safety on all measures necessary to achieve the efficient implementation of the regulations.

Regulation No. 149 requires the licensees and registrants to develop and enforce a radiation protection instruction. The instruction requires that personal protective equipment be used properly implying that workers are informed about it.

Regulation No.149 contains requirements on area classification, demarcation and marking. It covers appropriate classification in controlled and supervised area, marking of work-space, routines on workplace control and radiation monitoring as well as marking with a radiation label and an indication whether the area is a controlled or supervised area. However, there is no requirement concerning the access to a controlled area by persons under the age of 18 as stated in GSR Part 3.

In addition, there is no requirement concerning the display instructions at access points to and at appropriate locations within controlled areas, which is also mentioned in the preliminary action plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *There are no requirements for persons under the age of 18 years to be under supervision when accessing a controlled area. This finding is identified in the preliminary action plan.*

(1) **BASIS:** GSR Part 3 Req. 28 para. 3.116 states that “Employers, registrants and licensees shall ensure that persons under the age of 18 years are allowed access to a controlled area only under supervision and only for the purpose of training for employment in which they are or could be subject to occupational exposure or for the purpose of studies in which sources are used.

R10 **Recommendation:** The government should review the regulation to include requirements for employers, registrants and licensees to make special arrangements for protection and safety for persons under 18 years of age who are undergoing training.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Regulation 149 has requirements on area classification, demarcation and marking. This covers classification in controlled and supervised area. However, there are no requirements concerning the display instructions at access points to and at appropriate locations within controlled areas. This finding is identified in the preliminary action plan.*

(1)	<p>BASIS: GSR Part 3 Req. 24 para. 3.90 states that “Employers, registrants and licensees</p> <p><i>(f) Shall provide, as appropriate, at entrances to controlled areas:</i></p> <ul style="list-style-type: none"> <i>(i) Personal protective equipment;</i> <i>(ii) Equipment for individual monitoring and workplace monitoring;</i> <i>(iii) Suitable storage for personal clothing.</i> <p><i>(g) Shall provide, as appropriate, at exits from controlled areas:</i></p> <ul style="list-style-type: none"> <i>(i) Equipment for monitoring for contamination of skin and clothing;</i> <i>(ii) Equipment for monitoring for contamination of any objects or material being removed from the area;</i> <i>(iii) Washing or showering facilities and other personal decontamination facilities;</i> <i>(iv) Suitable storage for contaminated personal protective equipment</i>
R11	<p>Recommendation: The government should review the regulation to include requirements for employers, registrants and licensees to ensure protection and safety in controlled areas and provide for the following as appropriate:</p> <p>(1) at entrances to controlled areas:</p> <ul style="list-style-type: none"> (i) Personal protective equipment; (ii) Equipment for individual monitoring and workplace monitoring; (iii) Suitable storage for personal clothing. <p>(2) at exits from controlled areas:</p> <ul style="list-style-type: none"> (i) Equipment for monitoring for contamination of skin and clothing; (ii) Equipment for monitoring for contamination of any objects or material being removed from the area; (iii) Washing or showering facilities and other personal decontamination facilities; (iv) Suitable storage for contaminated personal protective equipment

5.7. AUTHORIZATION ISSUES FOR MEDICAL EXPOSURE

Activities involving medical exposure are licensed in Latvia, apart from mammography, bone densitometry and dental radiology which are registered. Most of these activities are applied for diagnosis. There are few radiotherapy facilities with linear accelerators, one stereotactic radiosurgery facility, one brachytherapy facility and one nuclear medicine facility that delivers treatments with radiopharmaceuticals.

Diagnostic reference levels (DRLs) for medical exposures incurred in several medical imaging modalities, are set at Annex 1 in Regulations No. 482, and in RSC SES Guideline No. 6

“Diagnostic Reference Levels for Radiological Procedures”. These DRLs are based on published values and there is no evidence that they are appropriate for the local circumstances. The IRRS Team was informed that RSC SES has launched a survey for establishing national DRLs for diagnostic X-ray imaging and computed tomography. The IRRS Team was also informed that Latvia has developed a four-year action plan for medical exposure (2018-2021), as part of the IAEA regional project RER9147, which includes the establishment of national DRLs in mammography and interventional radiology, until 2022.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: <i>The established diagnostic reference levels are based on published values and there is no evidence that they are appropriate for the local circumstances.</i></p>	
(1)	<p>BASIS: GSR Part 3 Requirement 34, para. 3.148 states that “<i>The government shall ensure, as part of the responsibilities specified in para. 2.15, that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a set of diagnostic reference levels is established for medical exposures incurred in medical imaging, including image guided interventional procedures. In setting such diagnostic reference levels, account shall be taken of the need for adequate image quality, to enable the requirements of para. 3.169 to be fulfilled. Such diagnostic reference levels shall be based, as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstances.</i>”</p>
R12	<p>Recommendation: The government should ensure that the establishment of diagnostic reference levels for medical exposures is based, as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstances.</p>

Dose constraint for carers and comforters and criteria for the release of patients who have undergone therapeutic radiological procedures using unsealed sources are established in Regulation No 482. The IRRS Team was informed that criteria for the release of patients who still retain implanted sealed sources are not established, as treatments that involve permanent implants of sealed sources are, as at date, not delivered in Latvia. Dose constraint for volunteers participating in a programme of biomedical research and guidelines for the release of patients who have undergone therapeutic radiological procedures using unsealed sources have also not been established.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: <i>Dose constraint for volunteers participating in a programme of biomedical research is not set in the Regulations. Guidelines for the release of patients who have undergone therapeutic radiological procedures using unsealed sources have not been established. These findings have been identified in the preliminary action plan.</i></p>	
(1)	<p>BASIS: GSR Part 3 Requirement 34, para. 3.149 states that “<i>The government shall ensure that, as a result of consultation between the health authority, relevant professional bodies and the regulatory body, the following are established:</i></p> <p>(a) <i>Dose constraints, to enable the requirements of paras 3.173 and 3.174, respectively, to be fulfilled for:</i></p> <p style="margin-left: 40px;">(i) <i>Exposures of carers and comforters⁴⁰;</i></p> <p style="margin-left: 40px;">(ii) <i>Exposures due to diagnostic investigations of volunteers</i></p>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>participating in a programme of biomedical research.</i>
	<i>(b) 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.</i>
R13	Recommendation: The government should ensure that dose constraint for volunteers participating in a programme of biomedical research and guidelines for the release of patients who have undergone therapeutic radiological procedures using unsealed sources are established.

Regulations No. 482 set requirements for justification and optimisation of medical exposure, including paediatric and pregnant or breast-feeding patients, unintended and accidental medical exposures, radiological reviews and records. Although access of carers and comforters to radiation safety instructions is provided for, there is no specific requirement for them to indicate an understanding of the received instructions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: <i>There is no requirement for carers or comforters to indicate an understanding of the received instructions relating to information on radiation protection and on the radiation risks, prior to providing care and comfort to an individual undergoing a radiological procedure. This has been identified in the preliminary action plan.</i>	
(1)	BASIS: GSR Part 3 Requirement 36, para. 3.153 states that “Registrants and licensees shall ensure that no individual incurs a medical exposure as a carer or comforter unless he or she has received, and has indicated an understanding of, relevant information on radiation protection and information on the radiation risks prior to providing care and comfort to an individual undergoing a radiological procedure. Registrants and licensees shall ensure that the requirements specified in para. 3.173 are fulfilled for the optimization of protection and safety for any radiological procedure in which an individual acts as a carer or comforter.”
R14	Recommendation: The Government should establish and RSC SES should verify requirements to ensure that carers and comforters indicate an understanding of, relevant information on radiation protection and information on the radiation risks prior to providing care and comfort to an individual undergoing a radiological procedure.

Regulations No.149 and Regulations No. 482 include requirements for assignment of responsibilities to a sufficient number of trained workers for work with radiation sources. Nevertheless, there is no specific requirement for the relevant delegation of responsibilities to be documented and maintained.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: <i>There is no specific requirement in Regulation 482 for documentation of any delegation of responsibilities by the principal party. Moreover, registrants and licensees are not required to maintain records of any delegation of responsibilities by a principal party.</i>	
(1)	BASIS: GSR Part 3 Requirement 36, para. 3.154 states that “Registrants and licensees shall ensure that:

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>...(f) Any delegation of responsibilities by a principal party is documented.”</i>
(2)	BASIS: GSR Part 3 Requirement 42, para. 3.183 states that <i>“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)); ...”</i>
R15	Recommendation: The Government should establish and RSC SES should verify requirements to ensure the documentation of any delegation of responsibilities by a principal party.

5.8. AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE

According to regulation No.752, an authorization requires a safety assessment be performed by a radiation protection expert considering RSC SES Guidelines No 1 “An opinion of a radiation safety, nuclear safety or medical physics expert on the adequacy of the premises, building or site operating conditions and planned activities with sources of ionizing radiation”. In accordance with this guidance, the safety assessment includes an assessment of possible public exposure. This guidance suggests that the safety assessment include criteria for acceptance based on reference levels or limits defined by Latvian regulations. For example, regulation No. 149 “Regulations for Protection against Ionising Radiation” defines annual dose limit for population as 1 mSv. Similarly, the same regulation identifies doses for public exposure by radon as well as limits for annual discharges. Regulation No. 1284 “Procedures for Control and Registration of the Exposure of Workers” identifies dose limit 0.1 mSv for critical group of population.

5.9. SUMMARY

RSC SES applies a well described authorization process. Facilities and practises can be authorized by licensing or registration depending on radiation source and practice. During the authorization process safety assessment and a Radiation Protection Programme of the applicant are reviewed and assessed. The issued licenses are valid 10 years, registrations do not need to be renewed.

The IRRS Team identified a few areas of improvement and some of them are already part of the preliminary action plan of RSC SES. Latvia needs to develop requirements to address the identified gaps, mainly in radioactive waste management, occupational exposure and medical exposure.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

The Licensing and Registry Division of RSC SES performs review and assessment during the authorization process, including the process of amending the issued licenses and reviews the annual reports provided by the authorized parties. RSC SES carries out review and assessment to verify that the authorized party complies with regulatory requirements and authorization conditions applying a graded approach.

Review and assessment is performed in accordance with RSC SES Quality Guidelines for Procedure No 4 “Procedure for Review of Operators Radiation Protection Programmes” and guidelines No 1 concerning safety assessment. The application for authorization and the supporting documentation that have to be submitted by the applicant, are prescribed by Regulations No 752.

During authorization process, the radiation protection programme and the safety assessment submitted by the applicant are reviewed and assessed by RSC SES.

The IRRS Team was informed that RSC SES applies the graded approach in the review and assessment process by considering the type and content of information that has to be submitted. Requirements concerning emergency preparedness and response, security, civil liability insurance, and workplace monitoring frequency are commensurate with the risks associated with the facility or activity, such as use of x-ray equipment or radioactive materials, high activity sealed sources (HASS), non-medical or medical exposure.

RSC SES documents results and decisions deriving from review and assessment. During the authorization process, the identified non-compliances, inaccuracies or incomplete content of the submitted documents are communicated to the applicant and are recorded in the register of received applications.

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

The review and assessment of applications for authorization are carried out by RSC SES Licensing and Registry Division. The staff of the Division have a background in physics, chemistry, geology and administration. The division maintains good cooperation with the Inspection Division. Training and education of the staff is ensured according to the training scheme in Quality Guidelines for Procedure “RSC SES Training Module”.

The Licensing and Registry Division may participate in pre-authorization inspections together with the Inspection Division, in order to clarify issues identified during review and assessment.

In order to ensure consistency of the review and assessment process, RSC SES has developed and documented a set of internal procedures.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

Regulation No. 752 establishes requirements concerning “Procedures for Licensing and Registering Activities with Sources of Ionising Radiation”. Requirements on environmental impact assessment are applicable for facilities of national significance.

The bases for review and assessment are the Safety Assessment Report, the Radiation Protection Programme, and other documents that may be required by the Regulations. Safety Assessment guidelines define the scope and content of the safety assessment prepared by the Radiation Protection Expert (RPE) to assess the risk associated with the proposed activity involving the use of radiation sources. Guideline No.4 describes in detail different aspects of Radiation Protection Programme that has to be submitted by applicant.

The “Procedure for Review of Operators Reports” and “Procedure for Review of Operators Radiation Protection Programmes” developed and implemented by RSC SES ensures consistency in the conduct of review and assessment.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

The comprehensiveness and quality of the documents and information submitted by the applicant is verified by the Licensing and Registry Division of RSC SES. Findings of the review and assessment of applications are verified by the Head of the Division prior to the submission of decision on the application to the Director for approval.

According to Regulations No. 752, authorization is conducted in several steps for facilities of national significance, and consequently the review and assessment of applications for such facilities are performed in several steps.

6.2. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

Regulation No.129 includes requirements for conducting a safety assessment for radioactive waste management facilities. Regulation No.129 requires a safety assessment be submitted to the RSC SES for authorization and reviewed every 10 years or whenever there is a significant change at the facility.

The requirements for the review and assessment of waste management facilities are provided in Regulation No.752 which are common for authorization for all activities. The IRRS Team was informed that in 2012, an independent review and assessment of the safety case of the waste management facility was performed, however there are no separate requirements for the independent review and assessment of radioactive waste management facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *In 2012, an independent review and assessment of the safety case of the waste management facility was performed. However, there is no regulatory requirement for independent review of safety case.*

(1) **GSR Part 3 Req. 13, para 3.34 states that** “Registrants and licensees shall ensure that the safety assessment is documented and, where appropriate, that it is independently reviewed under the relevant management system”

(2) **SSR-5 Req. 14 Documentation of the safety case and safety assessment**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>The safety case and supporting safety assessment for a disposal facility shall be documented to a level of detail and quality sufficient to inform and support the decision to be made at each step and to allow for independent review of the safety case and supporting safety assessment</i>
(3)	GSG-3 para. 4.97 states that “Independent peer review should play an important role in building confidence in the safety case..”
R 16	Recommendation: The Government should establish requirements for the licensees to conduct independent review of safety case and supporting safety assessment for waste management facilities.

6.3. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The Regulations No. 752 set out the requirements for the review and assessment for radiation sources facilities and activities. Checklists for review and assessment have been developed by RSC SES for various activities involving medical exposure, use of radioactive sources and use of radiation generators. The RSC SES requires the licensee to develop their RPP commensurate with risk associated with the practice to be carried out. For example, for high risks practices the RPP can be extensive while for dental radiography the RPP is limited to standardized form of four pages.

Graded approach is applied in the review and assessment process. For registrations, the review and assessment is only carried at the time of application, whereas for a licence it is carried out at the time of application and at the time of renewal of the licence, that is at least once every 10 years. A review and assessment is also carried out for change to any licence or registration activity, for example, when a new sources is acquired or change in the location where the practice is carried out.

6.4. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

Regulation No. 752 has general requirements for applicants performing activities with sources of ionising radiation, including dismantling. RSC SES Procedure No KV_Lic_1 of Licensing and Registry Division provides guidance for RSC SES staff to review and assess decommissioning plans (both preliminary plan and final plan) for authorization. However, there is no specific requirement documented for operators to update decommissioning plans and submit supporting safety assessment. **See Recommendation 4 in Section 1.7.**

6.5. REVIEW AND ASSESSMENT FOR TRANSPORT

Applications for transport authorisation and supporting documentation are reviewed and assessed by RSC SES according to its internal procedure as for all other facilities and activities.

The IRRS Team was informed that the main document reviewed and assessed for the safe transport of radioactive material is the radiation protection programme.

Annual report templates specific to the transport of radioactive material have not been developed by RSC SES. The IRRS Team noted that the annual reports provided by the transport operators to RSC SES mainly focus on the supply of radioactive material.

Oversight of transport aspects, such as evidence of compliance of the package design and conditions of reusable transport packages that do not require competent authority approval, are not included in the review and assessment processes. **See Recommendation 18 in section 9.5.**

6.6. REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE

The regulations require that a description of the assessment of occupational exposure be included in the RPP. During the review and assessment of authorization applications, RSC SES requires licensees to demonstrate compliance with the occupational exposure dose limits.

Prior to authorization, RSC SES review and assess relevant sections of the safety assessments and RPP, more specifically those providing information on monitoring programme, classification of workers, and classification of area, etc.

Regulation No. 1284 specifies requirements concerning individual monitoring of workers and workplace monitoring as well as dose assessment for workers. Authorized parties are required to categorize their workers and provide relevant justification.

The Law and regulations stipulate requirements about dose limits and dose measurements. According to the guideline for the RPP, the applicant should describe how the principle of dose limitation is achieved. Optimisation is required in Regulation No. 482 on medical exposure, but there is no requirement in place on optimisation of protection and safety of workers. **See Recommendation 20 in Section 9.6.**

6.7. REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE

The IRRS Team was informed that the main document reviewed and assessed, as part of the medical facilities authorization process, is the RPP which includes the quality assurance programme. The IRRS Team reviewed several RPPs submitted by licensees and noted that arrangements for pregnant or breast feeding patients are missing. This finding is further discussed in section 9.7.

The IRRS Team noted that medical exposure related elements are not included in the annual reports provided to RSC SES by the licensees. The regulatory oversight of medical exposure would benefit from the review and revision of the annual reports' templates, in order to encompass elements relating to the control of medical exposure.

6.8. REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE

Public exposure is reviewed and considered as part of various activities according to established RSC SES standards. The review of public exposure is conducted against the standards established by regulations as described in section 5.8

6.9. SUMMARY

Prior to authorization, RSC SES performs review and assessment of relevant documentation, in accordance with a graded approach to determine whether facilities or activities comply with regulatory requirements. Review and assessment is performed in accordance with RSC SES Quality Guidelines for Procedures (internal procedures). Pre-authorization inspections are conducted in some cases, to clarify issues identified during the review and assessment.

The IRRS Team identified areas for improvement regarding review and assessment of facilities and activities, mostly concerning regulatory requirements for independent review and assessment for radioactive waste management facilities, preparing and revising decommissioning plans, optimisation of protection and safety of workers, access to controlled areas, enhanced focus on the control of medical exposure and on certification of transport packages by competent authority.

7. INSPECTION

7.1. GENERIC ISSUES

The Inspection Division at RSC SES consists of 5 inspectors who are required to complete training according to the internal training procedure. RSC SES Quality Guidelines for Procedures include “Inspection procedure” that specifies the different types of inspections. This procedure also describes the categorization of the authorized parties for inspection, inspection planning and frequency. Inspection may be either planned or unplanned and be carried out on a full scope or thematic basis.

Furthermore, there are detailed procedures for “Preparation for the inspections”, “Performance of Inspections” as well as a procedure for “Compilation of inspections results”, describing how to document inspection results. The procedures also define the actions that inspectors need to perform after an inspection, which includes, the preparation of an inspection report within a month and sending it to the authorized party. RSC SES has developed an online system for preparing inspection reports in order to facilitate the sharing of inspection report with the authorized party.

Each inspector is expected to carry out 60 inspections per year imposed by the SES requirements. RSC SES has developed and implemented a documented inspection programme. The annual inspection plan is mainly based on the inspection programme taking into account the criteria for the inspection frequency for different practices and according to the inspection procedure the analysis of authorized parties' previous activity, potential risks, analysis of violations statistics.

Inspections are carried out in accordance with documented internal procedures that are supplemented by practice specific checklists. Checklists used by the RSC SES for its inspections are made available on its website, to ensure openness and transparency. The IRRS Team consider that as good performance. The inspection checklists also ensures consistency for RSC SES to verify compliance with regulatory requirements.

An internal procedure defines when to do planned inspections (announced or unannounced), follow-up inspections, pre-authorization inspections or reactive inspections. In practice, several unannounced planned inspections have been carried out by RSC SES. There were also unplanned unannounced inspections carried out.

7.2. INSPECTION OF WASTE MANAGEMENT FACILITIES

The inspection of radioactive waste management facilities is conducted according to existing requirements set out in procedure established by the RSC SES for inspection.

Radioactive waste repository “Radons”, a facility of national significance, is inspected four times a year. The inspection frequency may be reduced to at least once per year inspection as continuous video surveillance is provide to RSC SES office. The inspectors have sufficient qualifications to conduct the inspection at “Radons”. The inspections checklist for waste management facility is prepared and effectively being used. The inspection comprises interviews, verification of documents and record, waste inventory, site monitoring and operator waste inspection results. The inspectors have access to all required documents and areas of the facility where they are enable conduct field measurement and assessment. The inspection

findings are usually discussed with operator following the inspection and submitted as part of the inspection report.

The IRRS Team was informed that currently radioactive waste is stored in vaults intended for both storage and disposal. There is no requirement to store waste in such a manner that it can be inspected and monitored.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation <i>The existing regulations contain requirements for the safe storage of radioactive waste, however there is no requirement to store waste in such a manner that it can be inspected and monitored.</i>	
(1)	GSR part 5 Requirement 11 states that <i>“Waste shall be stored in such a manner that it can be inspected, monitored, retrieved and preserved in a condition suitable for its subsequent management. Due account shall be taken of the expected period of storage, and, to the extent possible, passive safety features shall be applied. For long term storage in particular, measures shall be taken to prevent degradation of the waste containment.”</i>
S7	Suggestion: The Government should consider establishing requirements for storing radioactive waste in such manner that the waste can be inspected and monitored.

Site visit to radioactive repository “Radons”

The IRRS Team visited radioactive waste repository site to observe performance of the inspection conducted by two inspectors of RSC SES. The inspection was conducted in accordance with established rules using developed checklists covering whole area of the storage and disposal of radioactive waste. The inspectors were also able to conduct on site measurement to assess the situation with radiation exposure and possible contamination. A separate meeting also was organized with representatives of “Radon” facility to discuss the possible problems and their views to solve them.

7.3. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The IRRS Team was informed that RSC SES carries out inspections following a scheme ranging from twice per year for facilities of national importance or radioactive sources with high activity (HASS) to once every seven years for low risk activities, such as dental radiology. Inspection procedures include observing facility installations and activities at workplaces, carrying out interviews of different workers and verification of documents and review of the RPP. Inspectors carry out measurements such as to verify workplace monitoring results, and quality control measurements. The measuring equipment available at the RSC SES is listed in the Procedure “Performance of Inspections”.

7.4. INSPECTION OF DECOMMISSIONING ACTIVITIES

The IRRS Team was informed that decommissioning activities may be inspected in accordance with RSC SES procedure “Inspector Activities”. However, there is no specific requirement for inspection of decommissioning activities. **See Recommendation 4 in Section 1.7.**

7.5. INSPECTION OF TRANSPORT

The inspection frequency for licensees who systematically transport radioactive material is two years. RSC SES has recently developed a transport specific inspection checklist. The IRRS Team observed an inspection for transport at the radioactive waste repository “Radons” of the State limited liability company "Latvian Environment, Geology and Meteorology Centre". The inspectors were well prepared, and the inspection was conducted with the use of the newly developed checklist. The inspection comprised interviews, direct observation of the vehicle and the available equipment, surface contamination measurements and verification of documents and records.

The IRRS Team noted that the carrier has spare industrial packages (Type IP) in good condition, but could not demonstrate evidence of compliance of the package design with the regulatory requirements.

The IRRS Team has also noted, during the inspection carried out at the Latvian Oncology Centre of Riga East University Hospital, that although the licensee act as consignor of the used Mo-99/Tc-99m generators being sent back to their suppliers, the inspection did not include transport specific requirements. **See Recommendation 19 in section 9.5.**

7.6. INSPECTION OF OCCUPATIONAL EXPOSURE

According to RSC SES the main focus in the inspection process is on verifying the implementation of the radiation protection programme, observing the authorized party’s actual practices and analysing the data that has been accumulated during operation.

The inspector requires the authorized party during the inspection to present results of workplace monitoring, information on staff’s professional qualification and training in radiation protection, dose passbook, compulsory health examination of staff, the justification of the workers categorization into category A or B and the radiation safety instruction. Inspectors also verify compliance during inspections with the RPP, which include the radiation safety instruction. RSC SES inspectors also observe the use of individual protective equipment, the classification and marking of areas, radiation warning signs and lights. Inspectors check the labelling of a source wherever possible. All these aspects are part of the inspections’ checklists that are made available by the RSC SES on website. Inspectors may carry out dose rate and contamination measurements in order to verify the results of the workplace monitoring.

Site visit to the hospital

The IRRS Team observed that both inspections of the radiotherapy and the nuclear medicine departments of the Latvian Oncology Centre of Riga East University Hospital were performed adequately using the checklist developed by RSC SES. The inspectors were well prepared. The inspection comprised interviews with several workers as well as observation of radiation protection arrangements and verification of documents and records related to occupational exposure.

7.7. INSPECTION OF MEDICAL EXPOSURE

Planned inspections for radiotherapy facilities and nuclear medicine facilities are conducted once per year. For interventional radiology, diagnostic radiology and dental facilities the inspection frequencies range from two to seven years.

RSC SES has developed specific inspection checklists that address medical exposure for the majority of the medical practices. The IRRS Team observed an inspection to the radiotherapy and the diagnostic nuclear medicine departments of the Latvian Oncology Centre of Riga East University Hospital. During the discussion with the licensee staff, about the effectiveness of the regulatory inspections, the IRRS Team was informed that the RSC SES initiative to upload the inspection check lists to its website is highly welcomed by the licensee staff, as it offers them the opportunity to be conversant of the inspection procedure in advance of the inspection.

7.8. INSPECTION OF PUBLIC EXPOSURE

The IRRS Team was informed that public exposure is also assessed during the inspections carried out by the RSC SES at the various radiation facilities. The assessment covers all aspects of public exposure including discharges of radioactive substances into environment as described at section 5.8 .

7.9. SUMMARY

The RSC SES conducts inspections in accordance with established processes and procedures. These include planned, unplanned, announced and unannounced inspections.

Planned inspections are conducted according to the approved annual plan. Practice specific checklists have been developed by RSC SES and are in use by its inspectors for the conduction of inspections. This ensures a consistent approach to inspections. There is currently no checklist for the inspection of decommissioning facilities.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

According to Section 6 of the Law, RSC SES has the right to prohibit activities with sources of ionising radiation if the requirements of radiation safety and nuclear safety are not met. In accordance with Section 7 of the Law, RSC SES inspectors have the rights to inspect places where activities with sources of ionising radiation are performed and to take the necessary samples for verification of compliance. In case of violations of the regulatory requirements, inspectors may examine materials and if necessary hold the responsible persons liable.

Regulations No. 752 empowers RSC SES to issue temporary suspension or cancellation of the operation of the licence or registration if necessary.

Administrative Violations Code Section 87¹ defines administrative violations with regard to regulatory non-compliance as well as the related applicable fines. RSC SES may impose fines for administrative violations specified in Section 87¹ or apply confiscation. Enforcement Procedure No. KV Insp 5 “Methods of enforcement actions and the Principles for the Application Thereof” provides details of the methods of enforcement to be applied while adopting the graded approach based on the seriousness of the non-compliance or violation. The procedure describes for instance when suspension of activities with sources of ionising radiation is to be applied, also when the license or registration is revoked.

The authorized party has the right to appeal the administrative acts, and the actual action thereof, depending on its nature of the regulatory decision, to the director general of SES or to the State Environmental Bureau. The law regulates the rights on how to appeal regulatory decisions.

8.2. ENFORCEMENT IMPLEMENTATIONS

RSC SES inspectors follow the internal procedure “Methods of enforcement actions and the Principles for the Application Thereof” and communicate non-compliances verbally to the authorized party, preferably to the head of the organization.

The IRRS Team was informed that the majority of enforcement actions carried out by RSC SES consist of issuing written reports listing the non-compliances and relevant corrective actions to be implemented within a certain timeframe for remedial action. According to the methodology described in the enforcement procedure, RSC SES regularly follows up the implementation status of the corrective actions. In cases where corrective actions are not addressed within the deadline set, the RSC SES issues warning letters to the licensee. If the authorized party fails to comply with the requirements of the RSC SES, a penalty is applied in accordance with the Administrative Procedure Law.

Enforcement methods include confiscation of a source of ionising radiation, suspension of distribution or withdrawal from the market are relevant only if the activity being carried out poses an imminent radiation risk. This might include situations where the location of such radiation source at the place of violation poses a direct threat to human life and health or could lead to radioactive pollution of the environment. In such case, the RSC SES requests the source of ionising radiation to be handled in a safe manner and the party who committed the administrative violation to pay all related costs for securing the source.

The procedure for issuing the administrative violation protocol forms is specified in the SES Internal Regulations No 11 “Procedure for Issuing the Administrative Violation Protocol Forms”. In cases when information on a potential violation is received by the RSC SES, an administrative violation must be initiated within three working days.

RSC SES inspectors are trained in enforcement procedures and general legislative framework including the Administrative Procedure Law and Latvian Administrative Violations Code as per the training planned by the RSC SES. Such training courses are organised in SES locally, as well by the Latvian School of Public Administration.

8.3. SUMMARY

An enforcement policy has been established to deal with non-compliances. Enforcement actions for non-compliances are governed by Law, Latvian Administrative Violations Code and Administrative Procedure Law.

RSC SES inspectors have the right to prohibit activities with sources of ionising radiation if the requirements of radiation safety and nuclear safety are being violated.

The RSC SES has established internal procedure for enforcement by adopting the graded approach. The enforcement action is commensurate with the seriousness of the non-compliance.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

According to the legal system of Latvia, only the Parliament and the Cabinet of Ministers are entitled to issue mandatory binding documents intended to operators. The RSC SES does not have rights to issue regulations with mandatory requirements to operators. All requirements to be complied with in order to ensure radiation and nuclear safety are outlined in laws and Cabinet of Ministers regulations. The MEPRD is responsible for the drafting of regulations in the field of radiation safety. The concept of the graded approach is been applied for the development of the different set of regulations.

The RSC SES has established a process for the development of proposals for regulations and it is documented at Annex 3 of the RSC SES Quality Guidelines for Procedure No KV_Vis_Rokasgramata “Quality Management System Manual”. For the development of any set of regulations under the Law on Radiation Safety and Nuclear Safety, the RSC SES has to submit its proposal to the MEPRD for consideration, after preliminary consultations with relevant stakeholders and Radiation Safety Council (Law Section 8 Article (3)). The MEPRD do arrange for wider consultations with all involved parties, including the public, on the proposed regulations on radiation safety prior to its finalisation and approval by the Cabinet of Ministers.

In line with the provisions made in the Section 4.5.2 of the Quality Management System Manual, the RSC SES has established procedures for the periodic review of the regulations to ensure that they are in line with the IAEA Safety Standards and the EU directives.

The RSC SES also develop and issue guides to facilitate the implementation of the requirements of the law and regulations made thereunder. The guides are developed and approved by the Director of RSC SES. These guides are developed by the regulatory body using the graded approach and are recommendatory in character. However, as mentioned in Section 4.3, the procedure for the development of guides is not documented in the management system.

The RSC SES does organise several activities, including meetings with the stakeholders, for the promotion of the regulations and guides. The RSC SES do also promote the regulations and guides during its inspections of radiation facilities.

9.2. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

Regulation No. 129 sets general requirements for radioactive waste management. Chapter VIII of the regulations set out the requirements for acceptance of radioactive waste for disposal or long-term storage. The radioactivity range for storage and disposal packages is based on annual dose limit of 300 μ Sv. The ranges are stipulated in Annex 3 and form the basis of the Waste Acceptance Criteria (WAC).

Regulation No. 752, at Annex 1, defines the minimum activity ranges for authorization of radioactive materials (exemption limits). In parallel, the Regulation No.129, at Annex 1 defines minimum significant activities for radioactive waste as clearance levels. However, these levels do not correspond to IAEA requirements for clearance criteria.

In addition, there is no guidance to release a site from regulatory control, which is an important element for completing of decommissioning or decontaminating a site or building structures and for identifying the conditions for further use.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>The existing regulations define clearance levels and clearance criteria, however these are not in line with IAEA clearance criteria. In addition, there is no guidance to define site release criteria to release the site from regulatory control.</i>	
(1)	GSR Part 3 Req. 8 Exemption and clearance ... <i>The regulatory body shall approve which sources, including materials and objects, within notified practices or authorized practices may be cleared from regulatory control”</i> Para. 3.12 states that <i>“The regulatory body shall approve which sources, including materials and objects, within notified or authorized practices may be cleared from regulatory control, using as the basis for such approval the criteria for clearance specified in Schedule I or any clearance levels specified by the regulatory body on the basis of these criteria.”</i>
(2)	GSR part 5 Req. 3 Responsibilities of the regulatory body Para.3.8 states that <i>“To facilitate compliance with regulatory requirements, the regulatory body has to do the following: ... - Establish criteria for the clearance of material from regulatory control, in accordance with national policy”</i>
(3)	GSR Part 5 Req. 10 Processing of radioactive waste <i>“Radioactive material for which no further use is foreseen, and with characteristics that make it unsuitable for authorized discharge, authorized use or clearance from regulatory control, shall be processed as radioactive waste” ...</i>
(4)	RS-G-1,7 para. 3.4 say that <i>“The primary radiological basis for establishing values of activity concentration for the exemption of bulk amounts of material and for clearance is that the effective doses to individuals should be of the order of 10 μSv or less in a year.”</i>
(5)	WS-G-5.1, para 3.7 says that <i>“The regulatory body should establish safety requirements and guidelines for the planning, approval and conduct of clean-up activities, for the management of contaminated material and the waste that arises from this process, and for the release of land, buildings and structures from regulatory control. The responsibilities of the regulatory body should also include: a. Establishing, promoting and adopting criteria and guidance for the cleanup and release of sites as a part of decommissioning activities;”</i>
R17	Recommendation: The Government should establish clearance criteria in line with international safety standards.
S8	Suggestion: RSC SES should consider developing guidance for site release criteria from regulatory control.

The Articles 5-7 of Regulation No. 129 provides a classification system of radioactive waste, which is not in line with the IAEA classification system. However, the IRRS Team was informed that, in practice, the IAEA classification for radioactive waste is typically used in the country.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The radioactive waste classification established in the regulation is not in line with IAEA safety standards. However, in practice the IAEA waste classification is being used in Latvia.*

(1)	GSR Part 5 Req. 3, para. 3.8 states that “To facilitate compliance with regulatory requirements, the regulatory body has to do the following: ...” - <i>Establish an appropriate definition and/or classification of radioactive waste”</i>
(2)	GSG-1, para 2.2 states that “In accordance with the approach outlined in the Appendix, six classes of waste are derived and used as the basis for the classification scheme ...”
S9	Suggestion: The Government should consider updating existing regulation concerning classification of radioactive waste in accordance with IAEA Safety Standards.

9.3. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The main regulations covering requirements for radiation sources, facilities and activities are Regulation No. 752 on authorization, Regulation No. 149 on basic safety requirements, Regulation No 482 on medical exposure and Regulation No. 1284 on occupational exposure. These regulations cover all activities that are subject to licensing or registration. Regulation No 588 “Procedures for the Certification of Welders and Fault Detectors in the Regulated Sphere” covers qualitative technical aspects of non-destructive techniques within industrial radiography. However, there are no specific requirement for industrial radiography concerning education and training and dose monitoring of workers.

The guidelines developed by RSC SES, which are available online, cover all main aspects of authorisation, assessment, inspection and enforcement and provide detailed information on the requirements of the regulations. The guidelines are useful for RSC SES staff to assure a common understanding of the regulatory requirements and a consistency in the regulatory function. The guidelines have also proven to be very useful for the authorized parties for a better understanding of the requirements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Existing regulations and guidelines describe the requirements for practices with ionising radiation. However, there are no specific guidelines for radiation safety in industrial radiography.*

(1)	BASIS: SSG 11 states that “This Safety Guide provides recommendations for ensuring radiation safety in industrial radiography used for purposes of non-destructive testing.”
S10	Suggestion: RSC SES should consider establishing guidelines for industrial radiography taking into account IAEA Safety Standards SSG 11.

9.4. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

At present, there are no specific regulation for decommissioning. However, there are some requirements included in Regulations No.129, 752 and 661. A decommissioning concept is issued for the decommissioning of Salaspils nuclear research reactor (Order of cabinet No.612). Decommissioning is considered in the national program for radioactive waste management. **See Recommendation 4 in Section 1.7.**

9.5. REGULATIONS AND GUIDES FOR TRANSPORT

Law on the Movement of Dangerous Goods provides that each transport mode is regulated by the pertinent modal regulation (ADR, RID, IMDG, ICAO). Detailed requirements for the transport of radioactive material are included in Regulation No. 307. Law on Carriage by Road and Regulations No. 541 and No.674 include requirements that apply to the transport of radioactive material, which is one of the nine classes of dangerous goods and assign responsibilities for the control of the movement of dangerous goods.

Given that Regulation No. 307 is based on early versions of the IAEA Regulations for the Safe Transport of Radioactive Material (IAEA Safety Series No. 6 and ST-1), several provisions of the current edition of the IAEA SSR-6 are missing, such as SCO-III and basic radionuclide values for additional radionuclides. Moreover, there is not full consistency between the currently existing regulatory requirements for the transport of radioactive material in Latvia.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>Regulations No.307 is based on early versions of the IAEA Regulations for the Safe Transport of Radioactive Material (Safety Series No. 6 and ST-1). This has been identified in the preliminary action plan. Moreover it is inconsistent with other current requirements for the transport of radioactive material.</i>	
(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 33 states that “ <i>The Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained.</i> ”
(2)	BASIS: SSR-6 (Rev. 1), para. 307 states that “ <i>The competent authority shall assure compliance with these Regulations.</i> ”
R18	Recommendation: The Government should revise the current regulatory framework for the transport of radioactive materials to provide for an updated set of requirements which are fully consistent with the international regulatory framework.

There is no specific guide prepared by RSC SES for the transport of radioactive material. Guideline No 4 on radiation protection programme and Guideline No 7 on authorization application applies to the activity of transport. The emergency preparedness and response (EPR) plan for the transport of radioactive material is required by Regulation No.152. Nevertheless, guidance concerning, inter alia, evidence of compliance of the package design and conditions of re-usable transport packages not requiring competent authority approval, EPR plan, segregation from other dangerous goods during transport, are not included in the existing guidelines.

The development and dissemination of transport specific guidance is anticipated to facilitate the RSC SES regulatory oversight and enhance the awareness of the licensees and registrants,

especially the ones who act as consignors, although they are mainly authorised to apply activities other than the transport of radioactive material.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>There is no specific guide prepared by RSC SES for the transport of radioactive material. This has been mentioned in the advanced summary report.</i>	
(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 32, para. 2.30 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”.
R19	Recommendation: RSC SES should establish a guide for the transport of radioactive material.

9.6. REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE

The Law on Radiation Safety and Nuclear Safety describes the activities which have to be licensed and Regulations No. 752 “Procedures for Licensing and Registering Activities with Sources of Ionising Radiation” describes the activities to be registered or exempted. The existing legislation contains an extensive set of requirements, with the aim to provide adequate protection to workers. There are detailed requirements concerning both individual and workplace monitoring. However, there are no specific requirements concerning optimisation of protection and safety and dose constraints.

Regulation No. 1284 “Procedures for Control and Registration of the Exposure of Workers” contains requirements for occupational protection monitoring workers, workplaces and control and recording of exposure. The regulations, inter alia, require that special monitoring shall be used by the operator if the dose to the lens of the eye for the worker significantly exceeds the annual limit of 20 mSv. According to Regulation No.149 “Regulations for Protection against Ionising Radiation” the dose limit to the lens of the eye for workers is set to 150 mSv per year. A revision of this regulation is under process and doses to the lens of the eye will be adjusted to be in line with the IAEA standard GSR Part 3 (Schedule III). The guidelines No.4 “Development of radiation safety quality assurance programme (Radiation Protection Programme)” give the operator useful information on how to establish a radiation protection programme. It also provides information on occupational radiation protection.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *There are no requirements for optimization of protection and safety for workers.*

(1)	BASIS: GSR Part 3 Requirement 11, para. 3.22 (a) states that “ <i>The government or the regulatory body shall establish and enforce requirements for the optimization of protection and safety.</i> ”
(2)	BASIS: GSR Part 3 Requirement 11, para. 3.22 (b) states that “ <i>The government or the regulatory body shall require documentation addressing the optimization of protection and safety.</i> ”
(3)	BASIS: GSR Part 3 Requirement 11, para. 3.22 (c) states that “ <i>The government or the regulatory body 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.</i> ”
R20	Recommendation: The Government should establish requirements for optimization of protection and safety for workers.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The dose limits for the lens of the eye for workers within the Regulations No 149 does not comply with GSR Part 3. This finding has been identified in the preliminary action plan.*

(1)	BASIS: GSR Part 3 Requirement 12, para. 3.26 states that “ <i>The government or the regulatory body shall establish and the regulatory body shall enforce compliance with the dose limits specified in Schedule III for occupational exposures and public exposures in planned exposure situations.</i> ”
(2)	BASIS: GSR Part 3 Requirement 19, para. 3.71 states that “ <i>The government or the regulatory body shall establish, and the regulatory body shall enforce compliance with, the dose limits specified in Schedule III for occupational exposure.</i> ”
(3)	BASIS: GSR Part 3 Requirement 21, para. 3.76 (a) states that “ <i>Occupational exposure is controlled so that the relevant dose limits for occupational exposure specified in Schedule III are not exceeded.</i> ”
R21	Recommendation: The Government should review its regulations concerning dose limits for the lens of the eye to be consistent with GSR Part 3 (Schedule III).

9.7. REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE

Regulation No. 149 set the basic safety standards for radiation and nuclear safety and Regulation No. 482 provide specific requirements for protection and safety in medical exposure. The IRRS Team was informed that Regulations No 268, No. 193, No. 468 and No 689 also include requirements that apply to medical exposure, such as registration and certification of medical physicists, approval of medical technologies including generic justification of medical exposure, registration of medical devices.

Moreover, several guidelines that apply to medical exposure are available on SES website, namely, Guidelines No 4 “Development of Radiation Protection Programme”, No 5 “Assessment of Patient Doses in Radiodiagnostic Practices and Analysis Thereof in Medical Treatment Institutions” and No 6 “Diagnostic Reference Levels for Radiological Procedures”

and “Clinical Audit Guidelines in Respect of Medical Exposure in Radiodiagnostic Practices and Radiotherapy” developed in cooperation with professional societies in 2017.

Radiation protection of patients in medical exposure is described in Guideline No 4. However, procedures for ascertaining the pregnancy status of a female patient or that is not currently breast-feeding before the administration of radiopharmaceuticals, are missing. Guideline 5 does not address nuclear medicine or interventional radiology.

The RSC SES guidelines that apply to medical exposure may be reviewed and updated for more attention to be paid to the control of medical exposure aspects in Latvia.

9.8. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE

The main requirement for public exposure is set by Regulation No.149, which defines 1mSv as annual dose limit for public. At the same time Regulation No.1284 defines the dose limit for critical group to be ten times less than the dose limit in Regulation No.149. The Regulation No.149 also sets different dose constraints for population considering drinking water, different type of buildings. Radon exposure is also considered. Exposure from consumer products is also considered. Further detailed description on public exposure requirements are given in Section 5.8.

9.9. SUMMARY

Latvia has established and implemented regulations under the Law on Radiation Safety and Nuclear Safety. These regulations are rather comprehensive and were developed by adopting the graded approach. A few gaps in the regulatory framework were identified and consequently the IRRS Team has recommended the development of requirements, more specifically in the following areas: radioactive waste management, transport of radioactive materials, occupational and medical exposure.

The RSC SES has also developed and issued a series of guides to facilitate the implementation of the Law and regulations. These guides have proven to be very useful for the operators in promoting safety and a safety culture. The IRRS Team has also suggested the development of some additional guidance documents, such as a guide for industrial radiography and the transport of radioactive material.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

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

The regulatory mandate and responsibilities of the RSC SES for emergency preparedness and response is provided in the Latvian legal framework. The Law on Radiation and Nuclear Safety in Chapter II Section 9 provides that RSC SES conduct inspections of the readiness for potential emergencies and has the right to request and receive information regarding any radiation emergencies and accidents. RSC SES also ensures operation of radiation monitoring stations and exchange of information in accordance with international agreements. For operating organisations, the responsibilities related to safety measures, notification and reporting in case of nuclear or radiological emergencies are stipulated in the Law and regulations.

According to the Law, the Cabinet specifies requirements in relation to the readiness for radiological emergency and actions in the event of such emergency. RSC SES submits proposals for requirements on emergency preparedness and response. Regulations No. 152 specifying the principles, requirements and associated criteria for emergency preparedness and response has been issued. Regulations No. 149, 752 and 563 also contain emergency preparedness and response aspects. In accordance with Regulation No. 752, to obtain a license an applicant has to ensure readiness for radiation accidents and elimination of its consequences. The authorization application has to be accompanied by a “plan on the readiness for radiation accidents and action in situations of a radiation accidents” which is coordinated with the local government and State Fire and Rescue Service (SFRS) of Latvia. The IRRS Team was informed that the Latvian legal framework makes provision for the approval of the operating organisation’s emergency plans by RSC SES following review and assessment against requirements and criteria in the regulations.

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

GENERAL REQUIREMENTS

Regulation No. 152 stipulates the conduct of a hazard assessment by operating organisations to define the boundaries of the protection measure areas, which needs to be updated taking into account significant changes in operations. There are no requirements for assessed hazards to be grouped in accordance with emergency preparedness categories for developing generically justified and optimized arrangements for preparedness and response for a nuclear or radiological emergency.

There is no requirement for a protection strategy to be developed in Latvia at the preparedness stage based on the hazard assessment for taking protective actions and other response actions effectively in a nuclear or radiological emergency. Reference levels and generic criteria consistent with international standards for taking protective actions and other response actions have not been established.

FUNCTIONAL REQUIREMENTS

There are requirements that the operating organisations perform intervention activities without delay to guarantee the safety of the source of ionising radiation. The operating organisations shall manage the on-site emergency response during the transition from normal operations to operations under emergency conditions.

In accordance with the legislation, the RSC SES has the right to receive information without delay regarding any emergencies and accidents. The RPO authorised by an operator for the work with ionising radiation sources must inform RSC SES and where applicable the SFRS regarding any emergencies and accidents that may affect radiation safety and nuclear safety. Regulation No. 152 specify the need to inform persons within the object and off-site, and makes provision for notifying and informing workers and relevant stakeholders as well as specifies the criteria above which an emergency is declared.

Regulations No. 152 stipulate that the operating organisation and the RPO shall immediately take the necessary radiation safety measures and conduct investigation if any radiation safety and nuclear safety operational parameter exceeds the permitted level or does not comply with the foreseen operating conditions, or in case of a nuclear or radiological emergency. There is provision in Regulations No. 149 for producers, suppliers and other operators to perform notifications, intervention and other measures to ensure the safety of a radioactive source.

Urgent protective actions to be implemented by the operator and the local government are listed in Regulations No. 149 and 152. The criteria for protective actions to be performed during the emergency for sheltering, evacuation and iodine prophylaxis are not in accordance with the latest IAEA standards.

SFRS in accordance with Regulations No. 152, advises public regarding nuclear and radiological emergencies. The RSC SES provides relevant institutions with information on the consequences of a possible radiological emergency, the damage of ionizing radiation to health and the individual protection measures that must be taken in case of an emergency.

Ionising radiation dose limits for specially authorised exposure of workers are specified in Regulations No. 149. The operator shall provide worker who is intended to be involved in elimination of the consequences of a radiation accident with appropriate information, instructions and preparedness.

The State Disaster Medicine Plan has been developed in accordance with the Ministry of Health Order No. 239 by the State Emergency Medical Service in cooperation with institutions involved in emergency response. Regulations No. 149 provides requirements for health care management in case of an emergency, including special health examinations and reduction of internal radioactive contamination. Regulations No. 152 provides for an operator, local government, and the SFRS to rescue members of public who have suffered in the radiological emergency and the provision of emergency medical assistance.

In terms of Regulations No.152 the SFRS shall notify and warn public in the event of a nuclear or radiological emergency by using the mass media and the notification and alarm system. The operator in case of emergency shall provide the necessary information for public instructions in their territory and warnings to the RSC SES, which will in turn provide recommendations to the SFRS.

Requirements are in place for the implementation of measures to avert or reduce the immediate damage, affected areas shall be determined, and long-term protection measures shall be performed after the nuclear or radiological emergency. However the associated criteria for protective actions in Regulations No. 149, are not aligned with the latest IAEA standards. (See **Recommendation R22**)

Regulations No. 152 provides that if a radiological emergency has occurred in the area controlled by an operator, the radiation protection officer shall collect, package and prepare for transportation the radioactive waste that has emerged as the result of the radiological emergency. Regulations No. 129 provides for waste volumes and accumulation and labelling of radioactive waste after elimination of the consequences of a nuclear or radiological emergency. It also provides for large quantities of radioactive waste which has been generated when eliminating the consequences of radiation emergencies, to be conveyed. The storage of radioactive waste management during a nuclear or radiological emergency has been considered in Cabinet Order 414, “Radioactive Waste Storage Concept”, however other aspects in GSR Part 7 for management of radioactive waste during emergencies have not been included in the national waste management programme.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>The national radioactive waste management programme does not specify provisions for the management of radioactive waste generated in a nuclear or radiological emergency.</i>	
(1)	BASIS: GSR Part 7 Req 5.84 states that “ <i>The national policy and strategy for radioactive waste management [19] shall apply for radioactive waste generated in a nuclear or radiological emergency, with account taken of paras 5.85 to 5.88.</i> ”
S11	Suggestion: The Government should consider to make provision in the national programme for the safe management of radioactive waste generated in a nuclear or radiological emergency.

The team was informed that although there are no explicit requirements for operators to have arrangements for workers dealing with non-radiological consequences, the State Civil Protection Plan and the Disaster Medicine Plan make provision for response organisations such as SFRS and State Emergency Medical Service to provide relevant support. Operating organisations can also request required support from RSC SES upon notification of a nuclear or radiological emergency, who could request assistance for addressing non-radiological aspects of a nuclear or radiological emergency in accordance with the State Civil Protection Plan.

One of the main functions of the RSC SES as stipulated in the Law on Radiation Safety and Nuclear Safety is to ensure the 24-hour readiness for early notification of nuclear accidents and to perform the functions of a contact point in accordance with the Convention on Early Notification of a Nuclear Accident. Regulations No. 152 makes provision for the RSC SES in co-operation with the Ministry of Foreign Affairs to request assistance where necessary from the International Atomic Energy Agency if due to a nuclear or radiological emergency, in line with specific situations indicated in the regulation. Bilateral agreements between the Government of the Republic of Latvia and Ukraine, Lithuania and Belarus on Early Notification of Nuclear Accidents, Exchange of Information and Co-operation in the Field of Nuclear Safety and Radiation Protection have been established.

Regulations No. 149 makes provision for the termination of an activity with a source of ionising radiation by the operator if a fault therein or a violation of laws and regulations in activity with sources of ionising radiation has been determined and rectify the relevant deficiencies. Regulations No. 152 states that during the liquidation of the radiological emergency the RSC SES shall update and supplement the information regarding the expansion of the nuclear accident or emergency, the anticipated and actual termination thereof. Detailed requirements, objectives and prerequisites for transition from an emergency exposure situation to an existing or planned exposure situation are not included in the existing regulations. (See **Recommendation R22**)

Regulations No. 149 states that if a radiation accident takes place which may cause the ionising radiation dose limits to be exceeded, the operator and the radiation protection officer shall immediately take the necessary radiation safety measures and conduct investigation. Detailed requirements for consideration of the causes of the accident, measures taken and any other substantial information during the analysis process are not provided for. (See **Recommendation R22**)

REQUIREMENTS FOR INFRASTRUCTURE

The operator is required to develop a plan of civil protection measures co-ordinated with the National Civil Protection Plan for preparedness to radiological emergencies and actions in the event of radiological emergency in an object which might cause radiological emergency damage. There is provision in Regulations No. 149 for the operator and the RPO to immediately take the necessary radiation safety measures in case of a radiation emergency and to conduct investigations. The operator is not required to request approval by the RSC SES in the course of implementing such actions on the site therefore sufficient operator's authority is ensured.

The Regulations determine that operators shall establish a radiation safety unit which shall be responsible for the activities with sources of ionising radiation within the operator's controlled area if in case of an emergency human life may be endangered. An RPO shall, without delay, report to the operator, the RSC SES and the SFRS regarding all emergencies and accidents that have occurred when performing activities in an ionising radiation object of national significance.

The regulatory requirements for coordination between on-site and off-site response organizations are defined. According to Regulations No. 149, the plan of civil protection measures in case of nuclear or radiological emergencies has to be coordinated with the local government. The Republic city and district structural units of the SFRS in co-operation with local governments shall analyse the hazard of the possible radiological emergency and develop a plan of civil protection measures in the relevant administrative territory.

Regulations No. 752 requires that where relevant based on regulatory criteria, the authorization application has to be supported by a "plan on the readiness for radiation accidents and action in situations of a radiation accidents" which is coordinated with the local government and SFRS of Latvia. Regulations No. 152 requires that the operator shall establish an emergency plan for objects that can cause an emergency i.e. an installation, a room or the complex in the area controlled by the operator where the activities with radioactive sources are carried out, or a vehicle that transports radioactive sources. RSC SES reviews and approves the plan, after evaluation and acceptance from SFRS and local government.

Regulations No. 149 contains the requirements for the necessary means and resources which should be available for emergency preparedness and response. In order to assess the quality and efficiency of the implementation of protection measures, the operating organisation shall ensure regular calibration of measuring instruments, as well as regular checking of their readiness for use and correct use. RPO in accordance shall maintain measuring instruments and protective means in an appropriate condition, maintain an inventory and ensure record keeping.

Regulations No. 152 provides that the SFRS in co-operation with RSC SES shall develop recommendations regarding radiation safety and nuclear safety topics to be included in study programmes, as well as regarding the preparedness for a radiological emergency and actions during radiological emergency. Regulations No. 152 includes provisions for qualifications, examinations of knowledge and further training with regard to emergency preparedness and response. There is also provision for state-wide training on protection measures and the practical implementation thereof, to be conducted once every four years. Regulations No. 563 requires the conduct of emergency exercise by operating organisations, once every 3 years for objects of national significance.

Regulations No. 752 requires that the operators establish a general Radiation Protection programme. Regulation No. 149 sets out the requirement for radiation protection programme to be developed. Guidelines No 4 “Development of Radiation Safety Quality Assurance Programme (Radiation Protection Programme)” have been published by RSC SES on its website. Regulations No. 152 also requires that the operator shall assess the quality and efficiency of the implementation of protection measures, through regular calibrations and regular checking of their readiness for use and correct use of the protective devices, auxiliary devices, and materials used for radiation safety and nuclear safety.

Regulations No. 152, 149, 752 and 563 contain requirements for emergency preparedness and response arrangements for operating organisations. The existing regulations are not fully consistent with the provisions of GSR Part 7.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>Some of the existing requirements for emergency preparedness and response are not fully in compliance with the requirements of IAEA safety standards GSR Part 7, for example provision for the grouping of hazards in accordance with emergency preparedness categories, development and implementation of a protection strategy, termination of a nuclear or radiological emergency, and for operating organisations to analyse the emergency and the emergency response with the aim to identify actions to be taken to avoid other emergencies and to improve emergency arrangements.</i>	
(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 33 states that “ <i>The Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained.</i> ”
(2)	BASIS: GSR Part 7 para. 4.19 states that “ <i>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</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<i>and response for a nuclear or radiological emergency.”</i>
(3)	BASIS: GSR Part 7 requirement 5 states that <i>“The government shall ensure that protection strategies are developed, justified and optimized at the preparedness stage for taking protective actions and other response actions effectively in a nuclear or radiological emergency.</i>
(4)	BASIS: GSR Part 7 requirement 18 states that <i>“The government shall ensure that arrangements are in place and are implemented for the termination of a nuclear or radiological emergency, with account taken of the need for the resumption of social and economic activity.</i>
(5)	BASIS: GSR Part 7 requirement 19 states that <i>“the government shall ensure that the nuclear or radiological emergency and the emergency response are analysed in order to identify actions to be taken to avoid other emergencies and to improve emergency arrangements.”</i>
R22	<p>Recommendation: The Government should revise the regulations for emergency preparedness and response in accordance with GSR Part 7 such as provisions for</p> <ul style="list-style-type: none"> • the grouping of hazards in accordance with emergency preparedness categories; • development and implementation of a protection strategy; • termination of a nuclear or radiological emergency; and • operating organisations to analyse the emergency and the emergency response with the aim to identify actions to be taken to avoid other emergencies and to improve emergency arrangements.

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

During the authorisation process, the emergency preparedness and response arrangements are reviewed by RSC SES against the provisions of the regulations. The Law defines the right of RSC SES inspectors to inspect places where activities with sources of ionising radiation are performed. RSC SES carries out regular inspections of facilities and activities requiring emergency plans to verify the operator’s emergency preparedness and response arrangements using KV_Insp_Inc “Actions During Local Radiological Emergencies”. The frequency for conducting emergency preparedness and response inspections is based on the RSC SES Order on criteria for the planning of inspections. Inspections are prepared and conducted using procedures KV_Insp_2 and KV_Insp_3 and inspection checklists have been developed. RSC SES monitors the implementation of corrective actions by operating organisations and has in place an enforcement procedure KV-Insp_5. In case of radioactive sources being detected at border controls, notification of elevated levels from State Border Guards shall be transmitted to RSC SES via Customs Service. If necessary the RSC SES inspector on duty may be requested to perform an inspection of cargo at the border.

In accordance with the Law, RSC SES in co-operation with authorised institutions of the Ministry of the Interior, shall inspect the readiness for potential emergencies in places where activities with sources of ionising radiation are performed. SFRS performs both on- and off-site emergency preparedness and response inspections. There is no liaison between RSC SES

and the SFRS on exchange of inspection findings or joint inspections to ensure the operating organisation's arrangements for nuclear and radiological emergencies are adequate.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: <i>The RSC SES performs inspections of the operating organisations' arrangements for emergency preparedness and response, however for some inspections there is no liaison and coordination with other authorities.</i></p>	
(1)	<p>BASIS: GSR Part 1 (Rev 1) para. 4.53 states that <i>"In conducting inspections, the regulatory body shall consider a number of aspects, including:</i></p> <ul style="list-style-type: none"> <i>-Structures, systems and components and materials important to safety;</i> <i>-Management systems;</i> <i>-Operational activities and procedures;</i> <i>-Records of operational activities and results of monitoring;</i> <i>-Liaison with contractors and other service providers;</i> <i>-Competence of staff;</i> <i>-Safety culture;</i> <i>-Liaison with the relevant organization for joint inspections, where necessary.</i>
S12	<p>Suggestion: RSC SCS should consider to liaise where necessary, with other organisations involved in the inspection of operating organisations' emergency preparedness and response arrangements to ensure compliance with the regulatory requirements.</p>

RSC SES involves the operator in the international exercises such as IAEA Convex exercises in which the RSC SES participates. Following the exercises, improvements of emergency preparedness and response arrangements are identified. For facilities of national significance the conduct of emergency exercises are required in accordance with Regulations No. 563. The RSC SES has not been evaluating the performance of specified functions during such exercises.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: <i>The RSC SES does not systematically evaluate the exercises conducted by operating organisations to ensure that all specified functions and interfaces can be performed effectively during a nuclear or radiological emergency.</i></p>	
(1)	<p>BASIS: GSR Part 7 para. 6.30 states that <i>"Exercise programmes shall be developed and implemented to ensure that all specified functions required to be performed for emergency response, all organizational interfaces for facilities in category I, II or III, and the national level programmes for category IV or V are tested at suitable intervals. These programmes shall include the participation in some exercises of, as appropriate and feasible, all the organizations concerned, people who are potentially affected, and representatives of news media. The exercises shall be systematically evaluated (see para. 4.10(h)) and some exercises shall be evaluated by the regulatory body. Programmes shall be subject to review and revision in the light of experience gained (see paras 6.36 and 6.38).</i></p>
R23	<p>Recommendation: RSC SES should systematically evaluate the operator's on-site exercises to ensure that response functions can be implemented effectively during a nuclear or radiological emergency.</p>

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

The role of the RSC SES in a nuclear or radiological emergency includes provision of support, advice and recommendations regarding mitigatory actions and implementation of protection measures to operating organisations, SFRS and local authority officials. The RSC SES shall also where delegated direct operations in the Action and Information Centre in accordance with MEPRD Order 202. RSC SES is mandated to operate an early warning and notification system as well as receiving and issuing notifications.

The Director of RSC SES is overall responsible for emergency preparedness and response in RSC SES. Inspection Division and Early Warning Group staff are available to promptly respond to nuclear or radiological accidents, and Licensing and Registry Division are available for support. The notification process is documented in procedures Insp-OBG_1 and 2. The Early Warning Group (EWG) duty officer is available 24/7, and communication means available include an external fax line, landlines and mobile phones. Inspector standby rosters and EWG schedules are prepared before the end of every month and approved by the RSC SES director.

The Early Warning Group operates 20 gamma radiation monitoring stations, which are used for early warning and notification purposes. RSC SES has a contract in place with a company to perform system maintenance and to provide quarterly reports to RSC SES. Data from the stations are accessible to the public, as well as the SFRS through the SES website. Radiological data from the stations are provided to EURDEP.

Regarding the logistical support and facilities to respond to a nuclear or radiological emergency, the necessary equipment, instrumentation and supplies are available and stored by RSC SES. Calibrations are performed and inventories are reviewed annually as part of RSC SES management system. In case of a nuclear or radiological emergency, the Action and Information Centre at the RSC SES offices will be activated from where the response to a nuclear or radiological emergency will be directed. RSC SES has the capability of modelling dispersion involving accidental radioactive releases. Necessary manuals and checklists have been developed for modelling.

In responding to a nuclear or radiological emergency, RSC SES implements procedure KV_Insp_Inc “Actions During Local Radiological Emergencies”. In the case of a nuclear or radiological emergency, RSC SES prepares the information, advice and recommendations for SES and to the SFRS (including public information and technical information). Forms for providing information to other stakeholders are part of the KV_Insp procedure, and requires approval by the RSC SES Director.

All RSC SES staff members are trained and competent to respond to a nuclear or radiological emergency. An emergency preparedness and response training programme for RSC SES staff has been developed in KV_training_module and a training plan for 2018-2022 to cover functions, training requirements and training topics. If necessary local Radiation Protection Experts can be utilized to support RSC SES during the response to a nuclear or radiological emergency.

RSC SES has organised national training courses for medical preparedness for response to nuclear and radiological emergencies for over 50 personnel from the State Emergency Medical Service. The IAEA pocket guide for medical responders to a radiation emergency resulting in

a mass casualty event is being translated to Latvian language for publication in State Emergency Medical Service facilities. The State Emergency Medical Service through RSC SES cooperates with IAEA and US DOE TC regarding strengthening medical aspects in case of a nuclear or radiological emergency.

RSC SES has established its own emergency exercise programme, and also participates in IAEA CONVEX exercises. Internal orders specify the types of exercises, and are approved by the RSC SES director. A procedure is in place to plan, conduct and evaluate RSC SES exercises. Following the conduct of exercises, feedback is provided by staff members through compilation of reports and corrective actions are implemented within specified timeframes to improve internal arrangements.

10.5. SUMMARY

The legislative framework defines the regulatory mandate and responsibilities of RSC SES in the field of emergency preparedness and response.

The Law and regulations make provision for requirements for the operating organisations to establish emergency plans and arrangements for a response to nuclear and radiological emergencies. Some of the requirements are not fully consistent with IAEA safety standards.

RSC SES verifies the adequacy of the operating organisations' emergency preparedness and response arrangements through review and assessment as well as the inspections, which are well established. Areas for improvement that have been identified during the IRRS mission include the liaison with other institutions responsible for emergency preparedness and response inspections, as well as evaluation by RSC SES of some emergency exercises conducted by operating organisations.

The response functions of RSC SES during a nuclear and radiological emergency have been documented. Internal training and exercise programmes are in place and implemented to ensure staff are prepared to respond upon notifications and to provide advice to the operating and response organisations.

Policy Issues

Justification, Optimization and clinical audits in medical exposure

RSC SES introduced IRRS Team to their effort in the field of radiation safety in medical exposure that is considered as one of the biggest challenges right now. Control of medical exposure is of great importance in Latvia because of the large number of medical radiological equipment, especially in diagnostics. The plan to control patient doses to avoid unnecessary risk to population is necessary. It has been recognized that awareness of radiation risks from medical exposure is low in Latvia. Therefore, RSC SES has established working group for this matter and developed a 4-year action plan (2018-2022) to improve the situation regarding medical exposure. Also, a lot of work has been done to train RSC SES staff to perform high quality inspections in this field. The RSC SES is currently focussing on two main aspects, the practical implementation of optimization and justification of medical exposure practices.

- Practical implementation of referral guidelines and justification of examinations in medical exposure from the perspective of regulatory body.

RSC SES recognises implementation of justification principle as one of the biggest challenges in medical exposure. Several guidelines have been developed regarding justification, for example the “Referral Guidelines” and the “Guidelines for Referring to and Performing Medical Exposure to Children”, however efforts should be made by relevant stakeholders for their practical implementation.

The IRRS Team also recognised this as a challenge in many countries. The IRRS Team mentioned the HERCA survey regarding justification as a mean to raise awareness about justification during inspections. RSC SES may implement some of HERCA survey questions into its checklists. It was highlighted that the implementation of justification principle and raising awareness is a long-term process.

- The practice of establishing national DRLs, practical approaches for different types of examinations, optimization of patient doses.

RSC SES has initiated the process of developing national DRLs based on national survey for the first time. It has been recognized as one of the main tools for dose optimization. National DRLs are especially necessary in Latvia because current DRLs were taken from published values therefore they may not be appropriate for Latvia. It was recognized that the process of collecting data for establishing national DRLs, is challenging.

The IRRS Team discussed methods for collecting data, such as requesting for typical doses from hospitals, and collecting data during inspections. The RSC SES pointed out that it is hard to collect typical doses from all hospitals because it creates additional work for hospital staff. The IRRS Team highlighted that it is not necessary for all licensees to be included in the survey and that a representative sample may be used. Regional surveys of appropriate scale taking into account type of practices and examinations may be adopted. In addition, collection of typical doses may be included as a requirement in the regulation. The IRRS Team noted that optimization of doses is part of quality system and strong safety culture that need to be enhanced.

APPENDIX I LIST OF PARTICIPANTS

IRRS REVIEW TEAM			
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Dace Satrovska

Nancy Greencom

Jolanta Malnace

Natalija Slaidina

GLOBAL SAFETY REGIME

Igor Osojnik

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RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

Igor Osojnik

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Faradally Ollite

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Inese Martinsone
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EMERGENCY PREPAREDNESS AND RESPONSE

Alan Muller

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Aija Lazdane
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APPENDIX III MISSION PROGRAMME

LATVIA IRRS MISSION PROGRAMME 20 to 30 October 2019		
Sunday 20 October 2019		
IRRS Initial IRRS Review Team Meeting		
14:00 - 18:00	<p>Opening remarks by the IRRS Team Leader</p> <p>IRRS Team Members - Self-introduction: <i>Each team member to give a brief statement of their careers and current responsibilities (2 min each)</i></p> <p>Presentation of the IRRS Process and Guidance for Reporting (TC)</p> <p>Review of Mission Schedule (TC, LO) Logistical Arrangements (LO)</p> <p>Report of Initial Review of Advance Reference Material: <i>Reviewers to briefly present (10 min each) their initial impressions of the advance reference material. This is also an opportunity to raise any initial concerns or specific requests for clarification with the liaison officer.</i> <i>The order of the presentations is that of IRRS Modules</i></p> <p>Closing Remarks/Questions Preparation for daily Interviews: <i>(The team members may continue working in their subject areas, after the closure of the meeting,</i></p>	<p>Venue: Hestia Hotel Jugend</p> <p>Participants: the IRRS Team + the LO</p>
Monday 21 October 2019		
IRRS Entrance Meeting		

LATVIA IRRS MISSION PROGRAMME 20 to 30 October 2019

09:00 – 11:00	09:00 Arrival, registration, coffee 09:15 Welcoming Address by the Hosts 09:30 Expectations for the Mission and introduction of the IRRS Team by Ilmar Puskar (Team Leader) 09:45 Introduction of the Main Latvia Counterparts by Liaison Officer 10:15 Regulatory Overview, Self Assessment results by LO 10:45 Group photo 11:00 Moving to RSC	Venue: RSC SES office Participants: Government Officials, RSC Management and staff, Officials from relevant organizations, the IRRS Team + the LO
11:30 – 17:00	Interviews and Discussions with Counterparts (parallel discussions) with the break for standing lunch from 12:00 to 13:00	Venue: RSC SES office IRRS interviews schedule Participants: IRRS Team + Counterparts
17:00 - 18:00	Daily IRRS Review Team meeting	Venue: Hestia Hotel Jugend meeting room Participants: the IRRS Team + the LO
18:30 -	Writing the report	IRRS Team
Tuesday 22 October 2019		
Daily Discussions / Interviews		
09:00 – 17:00	Interviews and Discussions with Counterparts (parallel discussions)	Location RSC SES office Participants: IRRS Team Reviewers + Counterparts
12:00 – 13:00	Lunch	
13:00 – 16:00	Meeting with Government officials TL, TC, M1-3 reviewers	Venue: according to the Governmental officials meeting schedule Participants: IRRS TL, TC Reviewer Modules 1,2, and 3
17:00 – 18:00	Daily IRRS Review Team meeting. Preliminary findings discussions	Venue: Hestia Hotel Jugend Participants: the IRRS Team + the LO
18:30-	Writing the report	IRRS Team

LATVIA IRRS MISSION PROGRAMME 20 to 30 October 2019

Wednesday 23 October 2019

Daily Discussions / Interviews		
09:00 – 12:00	Interviews	Venue: RSC SES office
09:00 – 15:00	Site Visits	RSC Inspectors and IRRS Team Members for Modules 5-9 for sources
12:00 – 13:00	Lunch	
13:00 – 16:00	Writing first draft of preliminary findings (Rs, Ss and GPs)	Venue: RSC SES office IRRS Team
16:00 – 17:00	Deliver First draft of written preliminary finding Rs, Ss and GPs to be compiled to report	
17:00 – 18:00 extended as needed	Quick briefing on site visits Daily IRRS Review Team meeting: discussion of findings (Rs, Ss and GPs)	Venue: Hestia Hotel Jugend Participants: the IRRS Team + the LO.
18:30 -	Writing the report	Venue: Hestia Hotel Jugend

Thursday 24 October 2019

Daily Discussions / Interviews		
9:00 -16:00 extended as needed	Follow-up Interviews and Discussions with Counterparts (parallel discussions), as appropriate	Venue: RSC SES office Participants: the IRRS Team
09:00 – 15:00	Site Visits	Inspectors and IRRS Team
12:00 – 13:00	Lunch	
16:00 – 18:00 extended as needed	Daily Team Meeting: Briefing from site visits Discussion of findings – feedback from discussion with Counterparts	Venue: Hestia Hotel Jugend Participants: IRRS Team + the LO.

Friday 25 October 2019

Daily Discussions / Interviews		

LATVIA IRRS MISSION PROGRAMME 20 to 30 October 2019

09:00 – 12:00	Follow up interviews and discussion of the report text with counterparts	Venue: RSC SES office Participants: IRRS Team
09:00 – 12:00	AA and TC writers introductory part	TC + AA
12:00 -13:00	Lunch	
13:00 – 14:00	Report preparation	IRRS Team
14:00 – 16:00	Policy issue discussion:	Venue: RSC SES office Participants: Reviewers and Counterparts
16:00 – 18:00 Extended as needed	Daily Team Meeting: Finalization of the “boxes”: observations, basis, R/S/GP	Venue: Hestia Hotel Jugend Participants: IRRS Team + LO

Saturday 26 October 2019

09:00 – 11:00	Individual report inputs finalizing and submission to AA	Venue: TBD IRRS Team TL, DTL, TC and DTC
11:00 – 12:00	AA compiles the report	
12:00 – 13:00	Lunch	
13:00 – 18:00	Cross reading and report editing	
18:00 –	TL, TC and AA continue to edit the report	

Sunday 27 October 2019

09:00	IRRS Team. Rest day and Social Event Official Dinner	Full day trip outside of capital city
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LATVIA IRRS MISSION PROGRAMME 20 to 30 October 2019

Monday 28 October 2019

Report commenting and discussions

09:00 – 11:00	TL, TC, AA and ‘editors’ finalise the report	Venue: RSC SES office IRRS Team
11:00	Submission of draft report to RSC	
12:00 – 13:00	Lunch	
13:00 – 18:00	TL, TC draft executive summary	

Tuesday 29 October 2019

Report reviewing and finalization

09:00 – 11:00	TL, TC draft exit presentation and coordinate press release preparation	Venue: RSC SES office
11:00 – 12:00	RSC submits written comments IRRS Team reviews RSC comments individually	Venue: RSC SES office
12:00- 13:00	Lunch	
13:00- 16:00	IRRS team revises report online	
16:00 – 18:00	Discussion with Hosts on findings, if required	Venue: RSC SES office
18:00 – 20:00	Report editing and executive summary finalization IAEA official briefing	Venue: Hestia Hotel Jugend

Wednesday 30 October 2019

IRRS mission exit meeting

9:00 -11:00	<ul style="list-style-type: none"> • Main findings of the IRRS mission (Team Leader) • Remarks by RSC in response to the mission findings • Closing remarks by IAEA Official (TC) IAEA press release	Venue: RSC SES office Participants: Government officials, RSC management and staff, officials from relevant organisations, the IRRS Team + LO
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APPENDIX IV SITE VISITS

1. Latvian Oncology Center of Riga East University Hospital
2. Radioactive waste repository “Radons” of State limited liability company "Latvian Environment, Geology and Meteorology Centre"

APPENDIX V 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 include all safety fundamentals in a national policy and strategy for safety that covers all facilities and activities that takes into account graded approach. This policy and strategy should express a long term commitment to safety.
	R2	RSC SES should develop a programme for the promotion of leadership and management for safety culture
	R3	The government should develop national policy to define long term goals for safe management of all classes of existing and future radioactive waste streams.
	R4	The Government should include in the national legal framework provisions for safe planning and conduct of decommissioning activity. This includes requirements for identifying decommissioning strategy, periodical update of decommissioning plans, and providing financial support for decommissioning activity.
2. GLOBAL SAFETY REGIME	S1	The Government should consider a commitment to implement the supplementary guidance under the Code of Conduct entitled “Guidance on the Management of Disused Radioactive Sources”.

Area	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	S2	RSC SES should consider within its management system to establish procedures for analysing events, ensuring corrective actions, operating experience and disseminating the lessons learned within the country and internationally.
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	R5	RSC SES should prepare assessment of the necessary number of staff including competence and skills to perform its functions and to discharge its responsibilities, and based on this analysis to develop and implement a comprehensive human resources plan including, specific training programme, which is based on assessment of the necessary staff.
4, MANAGEMENT SYSTEM OF THE REGULATORY BODY	S3	The RSC SES should consider to document, in its management system, the strategy and means for interaction with interested parties.
	R6	The RSC SES should include in its management system details on the arrangements for the resolution of conflicts arising in decision making processes, most specifically those related to potential impacts of security measures on safety and potential impacts of safety measures on security.
	R7	The RSC SES should identify in its management system any changes, including organizational changes, that could have significant implications for safety and to ensure that they are appropriately analysed
	R8	The RSC SES should establish in its management system the arrangements for independent review to be made before decisions significant for safety are made, and to specify the requirements on the independent nature of the review and on

Area	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		the necessary competences of the reviewers.
	S4	The RSC SES should consider to identify, develop and document all its processes.
5. AUTHORIZATION	R9	The government should include provisions in the legislation for notification.
	S5	RSC SES should consider applying the system for different types of authorization for all complex facilities, taking into account different stages in lifetime.
	S6	The Government should consider to review the regulation to enable the use of both deterministic and probabilistic approaches for safety assessment.
	R10	The government should review the regulation to include requirements for employers, registrants and licensees to make special arrangements for protection and safety for persons under 18 years of age who are undergoing training
	R11	<p>The government should review the regulation to include requirements for employers, registrants and licensees to ensure protection and safety in controlled areas and provide for the following as appropriate:</p> <p>(1) at entrances to controlled areas:</p> <ul style="list-style-type: none"> (i) Personal protective equipment; (ii) Equipment for individual monitoring and workplace monitoring; (iii) Suitable storage for personal clothing. <p>(2) at exits from controlled areas:</p> <ul style="list-style-type: none"> (i) Equipment for monitoring for contamination of skin and clothing;

Area	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		(ii) Equipment for monitoring for contamination of any objects or material being removed from the area; (iii) Washing or showering facilities and other personal decontamination facilities; (iv) Suitable storage for contaminated personal protective equipment
	R12	The government should ensure that the establishment of diagnostic reference levels for medical exposures is based, as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstances.
	R13	The government should ensure that dose constraint for volunteers participating in a programme of biomedical research and guidelines for the release of patients who have undergone therapeutic radiological procedures using unsealed sources are established.
	R14	The Government should establish and RSC SES should verify requirements to ensure that carers and comforters indicate an understanding of, relevant information on radiation protection and information on the radiation risks prior to providing care and comfort to an individual undergoing a radiological procedure.
	R15	The Government should establish and RSC SES should verify requirements to ensure the documentation of any delegation of responsibilities by a principal party.
6. REVIEW AND ASSESSMENT	R16	The Government should establish requirements for the licensees to conduct independent review of safety case and supporting safety assessment for waste management facilities.

Area	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
7. INSPECTION	S7	The Government should consider establishing requirements for storing radioactive waste in such manner that the waste can be inspected and monitored.
8. ENFORCEMENT		
9. REGULATION AND GUIDES	R17	The Government should establish clearance criteria in line with international safety standards.
	S8	RSC SES should consider developing guidance for site release criteria from regulatory control.
	S9	The Government should consider updating existing regulation concerning classification of radioactive waste in accordance with IAEA Safety Standards.
	S10	RSC SES should consider to establish guidelines for industrial radiography taking into account IAEA Safety Standards SSG 11.
	R18	The Government should revise the current regulatory framework for the transport of radioactive materials to provide for an updated set of requirements which are fully consistent with the international regulatory framework.
	R19	The RSC SES should establish a guide for the transport of radioactive material.
	R20	The Government should establish requirements for optimization of protection and safety for workers.

Area	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R21	The Government should review its regulations concerning dose limits for the lens of the eye to be consistent with GSR Part 3 (Schedule III).
10.EMERGENCY PREPAREDNESS AND RESPONSE	S11	The Government should consider to make provision in the national programme for the safe management of radioactive waste generated in a nuclear or radiological emergency.
	R22	<p>The Government should revise the regulations for emergency preparedness and response in accordance with GSR Part 7 such as provisions for</p> <ul style="list-style-type: none"> • the grouping of hazards in accordance with emergency preparedness categories; • development and implementation of a protection strategy; • termination of a nuclear or radiological emergency; and • operating organisations to analyse the emergency and the emergency response with the aim to identify actions to be taken to avoid other emergencies and to improve emergency arrangements.
	R23	RSC SES should systematically evaluate the operator`s on-site exercises to ensure that response functions can be implemented effectively during a nuclear or radiological emergency.
	S12	RSC SCS should consider to liaise where necessary, with other organisations involved in the inspection of operating organisations` emergency preparedness and response arrangements to ensure compliance with the regulatory requirements.

APPENDIX VI REFERENCE MATERIAL USED FOR THE REVIEW

REFERENCE MATERIAL PROVIDED BY RSC SES

Law on Radiation Safety and Nuclear Safety (adopted 26.10.2000.)
Environmental Policy Guidelines for 2014-2020 (adopted with 26.03.2014. Cabinet Order No 130)
Annex No 5 to Environmental Policy Guidelines for 2014-2020 “Radioactive Waste Management Programme” (adopted with 10.05.2017. Cabinet Order No 233)
Regulations No 752 “Procedures for Licensing and Registering Activities with Sources of Ionising Radiation” (adopted 22.12.2015.)
Regulations No 149 “Regulations for Protection against Ionising Radiation” (adopted 09.04.2002.)
Regulations No 1284 “Procedures for Control and Registration of the Exposure of Workers” (adopted 12.11.2013.)
Regulations No 482 “Regulations Regarding Protection Against Ionising Radiation in Medical Exposure” (adopted 19.08.2014.)
Regulations No 129 “Requirements for Operations with Radioactive Waste and Materials Related Thereto” (adopted 19.03.2002.)
Regulations No 152 “Requirements for Preparedness for Radiological Emergency and Actions in the Event of Such Emergency” (adopted 08.04.2003.)
Regulations No 307 “Regulations Regarding Protection against Ionising Radiation when Transporting Radioactive Materials” (adopted 03.07.2001.)
Regulations No 661 “Construction Regulations in Respect of Structures Related to Radiation Safety” (adopted 24.11.2015.)
The Constitution of the Republic of Latvia (adopted 15.02.1922.)
Cabinet Structure Law (adopted 15.05.2008.)
Regulations No 300 “Rules of Procedures of the Cabinet of Ministers” (adopted 07.04.2009.)
State Administration Structure Law (adopted 06.06.2002.)
Law on Prevention of Conflict of Interest in Activities of Public Officials (adopted 25.04.2002.)
State Civil Service Law (adopted 07.09.2000.)
Administrative Procedure Law (adopted 25.10.2001.)
Regulations No 402 “Procedures for the completion and sending of the safety data sheet of sources of ionising radiation” (adopted 18.09.2001.)
Latvian Administrative Violations Code (adopted 01.07.1985.)
Criminal Law (adopted 17.06.1998.)
Medical Treatment Law (adopted 12.06.1997.)
Law on Environmental Impact Assessment (adopted 14.10.1998.)
Law on Official Publications and Legal Information (adopted 31.05.2012.)
Archives Law (11.02.2010.)
Regulations No 748 “Regulations Regarding Records and Archives Management” (adopted 06.11.2012.)
Law on Carriage by Road (adopted 23.08.1995.)
Law on the Movement of Dangerous Goods (adopted 14.10.2010.)

Regulations No 541 "Procedures for Control of the Movement of Dangerous Goods" (adopted 05.07.2001.)

MEPRD 14.06.2014. Order No 202 "On co-operation of the Ministry of Environmental Protection and Regional Development and its subordinate institutions and the circulation of information in accidents and emergency situations"

05.08.2008. Cabinet Order No 12 "Instruction Regarding Actions of Responsible Institutions in the Event of Finding a Substance or Object of Unknown Origin if It is Suspected that It Contains Explosive, Radioactive, Dangerous Chemical or Biological Substances, as well as if Indications of Terrorist Attack are Detected""

Radioactive Waste Storage Concept (adopted with 26.06.2003. Cabinet Order No 414)

Concept for the Decommissioning of Salaspils Research Reactor (adopted with 30.11.2004. Cabinet Order No 958)

01.07.2009. Cabinet Order No 448 "On Liquidation of State Agency "Latvian Environment, Geology and Meteorology Agency" and Hazardous Waste Management State Agency and Establishment of the State Limited Liability Company "Latvian Environment, Geology and Meteorology Centre""

03.12.2008. Cabinet Order No 769 "On Approval of the Construction of Two New Radioactive Waste Vaults and Long-Term Storage for Spent Sealed Sources in Radioactive Waste Repository "Radons""

24.08.2016. Cabinet Order No 478 "On Determining the Status of an Object of National Interest to Radioactive Waste Repository "Radons" in the Territory of Baldone Parish in Baldone Municipality"

26.07.2007. Cabinet Order No 467 "On Approval of the Decommissioning and Dismantling of Salaspils Nuclear Research Reactor"

Regulations No 535 "Procedures for Performing the Radiometric Control of Goods, Luggage, Persons and Vehicles at the Border Crossing Points, and the Requirements for Training of the Persons Involved in Radiometric Control in Radiation Safety Matters" (adopted 22.09.2015.)

Regulations No 960 "Regulations Regarding the Procedures for Purchasing and Selling Ferrous and Non-ferrous Metal Cuttings and Scrap and for Issuing Licences for the Purchase of Metal Cuttings and Scrap in Latvia, and also the Rate of the State Fee for a Licence for the Purchase of Ferrous and Non-ferrous Metal Cuttings and Scrap and the Payment Procedures of the State Fee" (adopted 13.12.2011.)

Regulations No 219 "Procedures for Performance of Mandatory Health Examinations" (adopted 10.03.2009.)

Regulations No 943 "Procedures for Certification of Medical Practitioners" (adopted 18.12.2012.)

Regulations No 468 "Procedures for Approving Medical Technologies to be Used in Medical Treatment and the Procedures for Introducing New Medical Technologies" (adopted 28.06.2005.)

Regulations No 891 "Procedures for the Clinical Trial of Medical Devices Intended for Human Use" (adopted 21.09.2010.)

Regulations No 289 "Regulations Regarding the Procedures for Conduct of Clinical Trials and Non-interventional Trials of Medicinal Products, Labelling of Investigational Medicinal Products and the Procedures for Assessment of Conformity of Clinical Trial of Medicinal Products with the Requirements of Good Clinical Practice" (adopted 23.03.2010.)

Regulations No 265 “Procedures for Keeping Medical Documents” (adopted 04.04.2006.)

Country Action Plan for Medical Exposure (IAEA RER9147 Enhancing Member States' Capabilities for Ensuring Radiation Protection of Individuals Undergoing Medical Exposure)

Regulations No 671 „Mandatory Harmlessness and Quality Requirements for Drinking Water, and the Procedures for Monitoring and Control Thereof” (adopted 14.11.2017)

National Environmental Monitoring Programme (approved by the MEPRD 16.02.2015 Order No 67 “Environmental Monitoring Programme”)

SES Annual Public Report for 2018

National Report on the implementation of the obligations under the Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (October 2017)

Republic of Latvia National Report on the implementation of the obligations under the Convention on Nuclear Safety (August 2019)

SARIS report

ARM report

APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW

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APPENDIX VIII ORGANIZATION CHARTS

