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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

REPUBLIC OF LITHUANIA

Vilnius, Lithuania

17 – 29 April 2016

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

IAEA Integrated Regulatory Review Service IRRS

Integrated
Regulatory
Review Service

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

IRRS TEAM MEMBERS

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INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
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REPUBLIC OF LITHUANIA

Mission dates:	*17 to 29 April 2016*
Regulatory body visited:	*State Nuclear Power Safety Inspectorate (VATESI) and Radiation Protection Centre*
Location:	*Vilnius, Lithuania*
Regulated facilities and activities in the mission scope:	*Radiation Sources in Industrial and Medical Facilities, Nuclear Power Plant, Radioactive Waste Management facilities, Transport, Emergency Preparedness and Response, Medical Exposure, Occupational Exposure, Public and Environmental Monitoring.*
Organized by:	*IAEA*

IRRS REVIEW TEAM	
LUND Ingemar	Team Leader (Sweden)
KILOCHYTSKA Tetiana	Deputy Team Leader (Ukraine)
AGHAJANYAN Nelli	Reviewer (Armenia)
ALTEN Serhat	Reviewer (Turkey)
ARENDS Patrick	Reviewer (Netherlands)
BOSNJAK Jovica	Reviewer (Bosnia and Herzegovina)
DODKIN Christina	Reviewer (Canada)
PRENDES ALONSO Miguel	Reviewer (Cuba)
GUTTERRES Ricardo	Reviewer (Brazil)
HART Anthony	Reviewer (United Kingdom)
HUSSAIN Muhammad Nadeem	Reviewer (Pakistan)
HUTRI Kaisa-Leena	Reviewer (Finland)
KENNY Tanya	Reviewer (Ireland)
LORÁND Ferenc	Reviewer (Hungary)
JARVINEN Marja-Leena	Reviewer (Finland)
SLOKAN DUŠIČ Darja	Reviewer (Slowenia)
REICHE Ingo	Reviewer (Germany)
HULSMANS Mark.	Observer (European Commission)

PUSKAR Ilmar	Observer (Estonia)
MANSOUX Hilaire	IAEA Team Coordinator
MACSUGA Géza	IAEA Deputy Team Coordinator
BACIU Adriana	IAEA Review Area Facilitator
SWOBODA Zumi	IAEA Administrative Secretary

IAEA - June 2016

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

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EXECUTIVE SUMMARY

At the request of the Government of the Republic of Lithuania, an international team of senior nuclear safety and radiation safety experts met with representatives of the Government, State Nuclear Power Safety Inspectorate (VATESI) and the Radiation Protection Centre (RSC) from 18 to 29 April 2016 to conduct an Integrated Regulatory Review Service (IRRS) mission. The mission took place at the VATESI and RSC Headquarters in Vilnius. Meetings were organized with the Ministry of Health and with the Office of the Government. The purpose of the IRRS mission was to perform a peer review of Lithuania's national regulatory framework for nuclear and radiation safety.

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

The IRRS team consisted of 17 senior regulatory experts from 16 IAEA Member States, 3 IAEA staff members, 1 IAEA administrative assistant and 2 observers. 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; control of medical exposures, occupational radiation protection, control of radioactive discharges and materials for clearance, environmental monitoring, transport, waste management and decommissioning.

The IRRS mission included one policy issue discussion on regulatory policy for authorization of dismantling activities during transitional period from operation to decommissioning.

The mission included observations of regulatory activities, interviews and discussions with staff of VATESI and RSC. Activities included visits to: Ignalina NPP, the Heating network facility Vilniaus Energija UAB, the Vilnius University Hospital Santariškių Klinikos. The IRRS team members observed regulated activities and performance of inspection activities, including discussions with the licensee personnel and management.

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

The IRRS team observed that all Lithuanian counterparts were committed to provide effective oversight of regulatory functions covering its nuclear programme and a diverse range of activities with radiation sources.

It was recognized that a challenge for Lithuania was the potential construction of a new NPP unit and the preparations needed for this, including the infrastructure for safety. In this regard, at the request of Lithuania, the scope of the IRRS mission included a review specific to this issue. The review resulted in suggestions on coordination, needed national resources and regulations, when the project of new built is further developed.

The most significant challenges for the regulatory authorities at the time of the mission were implementation of new international standards on radiation protection and nuclear safety, and securing resources and skills necessary to ensure the appropriate regulatory oversight of the ongoing decommissioning activities at Ignalina NPP.

The IRRS team identified a number of good practices and made recommendations and suggestions that indicate where improvements are necessary or desirable to continue enhancing the effectiveness of regulatory functions in line with IAEA safety standards.

The good practices identified by the IRRS review team include:

- Lithuania is actively engaged in international cooperation; including international arrangements, peer reviews and international support programmes;
- RSC employees undergo training that is systematically planned and followed up on, including self-assessment. The lessons learned in international courses and seminars are disseminated and used in planning;
- VATESI conducts self-assessment of safety culture.

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

- The Government should:
  - continue improving its legal and regulatory framework for nuclear, radiation, and waste safety to ensure full consistency with the latest IAEA safety standards;
  - conduct a comprehensive assessment of existing and future human resource needs in relation to safety; and
  - further develop the existing provisions of the legal framework and national policy and strategy for the decommissioning of waste management facilities and for the management of radioactive waste;
- VATESI and RSC should:
  - improve the information to the public in the vicinity of nuclear facilities;
  - strengthen the regulatory framework related to Emergency Preparedness and Response with regards to the assessment of hazards and the conduct of on-site exercises;
- VATESI should:
  - improve its inspection programme to ensure systematic and consistent approach to inspection;
  - initiate amendment of the legal framework to ensure there are distinct steps for authorizing the closure of repositories;
  - ensure that the assumptions used for calculating the environmental impact of INPP are up-to-date;
  - have the possibility to establish advisory bodies.
- RSC should:
  - revise its integrated management system;

- ensure that clinical audits are performed regularly and that referral guidelines for justification of individual medical exposures are being used;
- support the use of dose constraints in optimization of occupational exposure;
- initiate amendment of the legal framework to ensure the possibility to use technical support to carry out its regulatory activities.

The IRRS review 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 the Republic of Lithuania, an international team of senior nuclear and radiation safety experts met representatives of the State Nuclear Power Safety Inspectorate (VATESI) and the Radiation Protection Centre (RSC) from 18 to 29 April 2016 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the Lithuanian regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of the Republic of Lithuania to the International Atomic Energy Agency (IAEA) in January 2012. A preparatory mission was conducted from 3 to 4 November 2015 at VATESI Headquarters in Vilnius to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in Lithuania and their related safety aspects and to agree the scope of the IRRS mission.

The IRRS team consisted of 17 senior regulatory experts from 16 IAEA Member States, 2 observers, 3 IAEA staff members and 1 IAEA administrative assistant. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, control of medical exposure, public and environmental exposure control, transport of radioactive material, waste management and decommissioning. The tailored module for countries embarking on nuclear power was also included in the scope of the mission.

In addition, a policy issue was discussed, namely: regulatory policy for authorization of dismantling activities during transitional period from operation to decommissioning.

In preparation for the mission, VATESI and RSC conducted a self-assessment and prepared a preliminary action plan. The results of VATESI's and RSC's self-assessment and supporting documentation were provided to the IRRS review team as advance reference material for the mission. During the mission, the IRRS team performed a systematic review of all topics within the agreed scope by reviewing the advance reference material, conducting interviews with management and staff from VATESI and RSC and direct observation of working practices during conduct of a regulatory inspection. Meetings with representatives of the Ministry of Health and the Office of the Government of the Republic of Lithuania were also organized.

All through the mission, the IRRS team received excellent support and cooperation from VATESI and RSC.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to conduct a review Lithuania's radiation and nuclear safety regulatory framework and activities to review its effectiveness and to exchange information and experience in the areas covered by the IRRS. The IRRS review scope included all facilities and activities regulated by VATESI and RSC. The review was carried out by comparison of existing arrangements against the IAEA safety standards.

It is expected that the IRRS mission will facilitate regulatory improvements in Lithuania and other Member States from the knowledge gained and experiences shared between VATESI, RSC and IRRS reviewers and through the evaluation of the effectiveness of the Lithuania regulatory framework for nuclear safety and its good practices.

The key objectives of this mission were to enhance nuclear and radiation safety, and national arrangements for emergency preparedness and response:

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

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

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

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

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

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

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

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

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

j) promoting the application of IAEA Safety Requirements; and

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

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of the Republic of Lithuania, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 3 to 4 November 2015. The preparatory meeting was carried out by the appointed Team Leader Mr Ingemar Lund, Deputy Team Leader Ms Tetiana Kilochytska and the IRRS IAEA Team representatives, Mr Ahmad Al Khatibeh and Mr Jean-Rene Jubin.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of VATESI and RSC represented by Michail Demčenko, Head of VATESI, Ramunė Marija Stasiūnaitienė, Deputy Director of RSC and other senior management and staff. It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides:

- Nuclear power plants;
- Waste management facilities;
- Radiation sources facilities and activities;
- Decommissioning;
- Transport of radioactive materials;
- Control of medical exposure;
- Occupational radiation protection;
- Public and Environmental exposure control;
- Waste management (policy and strategy, predisposal and disposal);
- Selected policy issues.

Mr. Michail Demčenko and Mrs. Ramunė Marija Stasiūnaitienė made a presentation on the national context, the current status of VATESI and RSC 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 Lithuania in April 2016.

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 VATESI Liaison Officer for the IRRS mission was confirmed to be Mr Ovidijus Šeštokas and the Liaison Officer for RSC to be Ms Ramunė Marija Stasiūnaitienė.

VATESI and RSC provided IAEA with the advance reference material (ARM) for the review at the end of February 2016. In preparation for the mission, the IAEA team members reviewed the Lithuania advance reference material and provided their initial impressions to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

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

C) CONDUCT OF THE REVIEW

The initial IRRS team meeting took place on Sunday, 17 April, 2016 in Vilnius, directed by the IRRS Team Leader and the IRRS IAEA Team Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS programme. The understanding of the methodology for review was reinforced. The agenda for the mission was presented to the team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

The host Liaison Officers were 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, 18 April, 2016, with the participation of VATESI and RSC senior management and staff, government officials Ms Jadvyga Zinkevičiūtė, Viceminister of the Ministry of Health and Ms Lina Žongolavičiūtė, Adviser of the Office of the Government of the Republic of Lithuania. Opening remarks were made by Mr Tomas Garasimavičius, Energy Policy Adviser to the Prime Minister of the Republic of Lithuania, Mr Ingemar Lund, IRRS Team Leader and Mr Hilaire Mansoux, IRRS Team Coordinator. Mr Michail Demčenko gave an overview of the VATESI activities and Mr Albinas Mastauskas an overview of the RSC activities.

During the IRRS mission, a review was conducted for all review areas within the agreed scope with the objective of providing VATESI and RSC 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 II.

The IRRS exit meeting was held on Friday, 29 April, 2016. The opening remarks at the exit meeting were presented by Mr Michail Demčenko and Mr Albinas Mastauskas and were followed by the presentation of the results of the mission by the IRRS Team Leader Mr Ingemar Lund. Closing remarks were made by Mr Peter Johnston, IAEA, Director, Division of Radiation, Transport and Waste Safety.

An IAEA press release was issued.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

The Government of Lithuania has established a legal framework for radiation and nuclear safety through the provisions of the Laws on Nuclear Energy, Nuclear Safety, Radiation Protection and Radioactive Waste Management. Governmental policy and strategy for safety does not exist as a separate document; however, through provisions of these laws policy and strategy, fundamental objectives and principles for safety are established.

The fundamental safety objective to protect people and the environment from harmful effects of ionizing radiation is set out in the provisions of the Laws on Nuclear Safety and Radiation Protection. To achieve the fundamental safety objective of the IAEA Safety Fundamentals, ten fundamental safety principles were established. In the existing Lithuanian legal framework for safety, the fundamental safety principles are fully addressed in the Law on Nuclear Safety. The Law on Radiation Protection addresses the basic radiation protection principles of justification, optimization and dose limitation, however the safety principles such as: prime responsibility for safety, leadership and management for safety, protection of present and future generations are not fully addressed into the existing framework for radiation safety. The counterpart has identified this in its performed self-assessment and the associated action plan.

Provisions for human and financial resources, corresponding with the nature and scope of the activities, are addressed in the Law on Nuclear Energy and in the Law on Radiation Protection. Provisions for research and development are endorsed in the National Strategy for Independence of Energy Sector, approved by the Parliament. Provisions of the Law on Nuclear Safety require effective leadership and management for safety to be put in place and maintained by all parties responsible for the activities related to the use of nuclear energy.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Policy and strategy objectives and principles established in IAEA SF-1 are mainly achieved through different laws. However, some of the safety principles, such as prime responsibility for safety, leadership and management for safety, protection of present and future generations, are not addressed in the Lithuanian legal framework for radiation safety.	
(1)	**BASIS: GSR Part 1 Requirement 1, para. 2.3 states that** *"National policy and strategy for safety shall express a long term commitment to safety. The national policy shall be promulgated as a statement of the government's intent. The strategy shall set out the mechanisms for implementing the national policy. In the national policy and strategy, account shall be taken of the following:* *(a) The fundamental safety objective and the fundamental safety principles established in the Fundamental Safety Principles [1];"*
(2)	**BASIS: GSR Part 1 Requirement 5 states that** *"The government shall expressly assign the prime responsibility for safety to the person or organization responsible for a facility or an activity, and shall confer on the regulatory body the authority to require such persons or organizations to comply with stipulated*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	regulatory requirements, as well as to demonstrate such compliance."
R1	**Recommendation: The Government should ensure that the fundamental safety objective and all fundamental safety principles of IAEA SF-1 are accounted for in the Lithuanian legal framework for radiation safety.**

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

A national framework for the nuclear and radiation safety has been established. It consists of primary and secondary legal acts. The main primary acts are:

a) Law on Radiation Protection;

b) Law on Nuclear Energy;

c) Law on Nuclear Safety;

d) Law on Radioactive Waste Management.

These Laws determine, inter alia, functions and responsibilities of governmental bodies, policy makers, state institutions and regulatory bodies. Safety principles, regulations and oversight of the activities in field of nuclear and radiation safety are also addressed.

The Ministry of Energy is responsible for the state policy in the area of nuclear energy and organizes, coordinates and controls implementation of the national energy policy and strategy.

The Ministry of Health, in the area of radiation protection and public health, prepares policies regarding the protection of members of the public, workers and the environment from harmful effect of ionizing radiation. It is also responsible for the implementation of directives and provisions of the European Union and other agreed international arrangements and obligations, and the preparation of laws and governmental resolutions in radiation safety.

The State Nuclear Power Safety Inspectorate (VATESI) is the national regulatory and supervisory authority for nuclear safety and radiation safety within the areas of nuclear energy, physical protection of nuclear facilities and materials.

The Radiation Protection Centre (RSC) is the national regulatory and supervisory authority in the areas of radiation safety and physical protection of radiation sources, except at nuclear facilities.

Other authorities involved in radiation and nuclear safety are: the Ministry of Environment, the Ministry of Interior, the Environmental Protection Agency, the State Food and Veterinary Service, the State Border Guard Service, the Custom Department, and the Fire and Rescue Department.

The legal framework for nuclear safety considers all stages of the life-cycle of nuclear installations: siting, design, construction, commissioning, operation, decommissioning, management of radioactive waste, closure of disposal facilities as well as supervision of disposal facilities after closure. However, the IRRS team identified some weaknesses in the framework which are described below.

According to the Law on Radiation Protection, RSC issues licences and temporary permits for practices, and permits to ship radioactive materials and radioactive waste generated by facilities outside the nuclear fuel cycle, and regulates practices such as the production,

processing, use, storage, transport, import, export of radiation sources and the management of associated radioactive waste.

A number of lower level, legally binding documents are approved to regulate nuclear and radiation safety. The system of requirements and rules issued by VATESI includes two types of regulations: firstly, basic requirements and rules that apply to all nuclear facilities and secondly topical requirements and rules, which apply to specific facilities or activities.

The IRRS team was informed by the counterpart that in order to establish procedures for public participation in the process of making decisions, amendments to the Law on Nuclear Safety and implementing legislation are to be adopted. This is to ensure, in the area of nuclear safety, compliance with IAEA safety standards as well as provisions of the Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters. The counterpart has identified this in its performed self-assessment and the associated action plan.

While there is provision for the use of a graded approach in the nuclear legislation, there are no similar provisions in the Law on Radiation Protection.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Lithuanian framework for safety does not set out general provisions for the involvement of public in the process of decision-making.	
(1)	**BASIS: GSR Part 1 Requirement 2, para. 2.5 states that** *"The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:* *... (5) Provision for the involvement of interested parties and for their input to decision making."*
(2)	**BASIS: GSR Part 1 Requirement 36 states that** *"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."*
(3)	**BASIS: GSR Part 6 Requirement 15 para. 9.6 states that** *"Inputs from the public shall be addressed before authorization for decommissioning is terminated."*
R2	**Recommendation: The Government should amend the legal framework for safety to include provisions for involvement of the public in the decision making process of the regulatory body.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: A graded approach is not reflected clearly in the Law on Radiation Protection for radiation safety.	
(1)	**BASIS: GSR Part 1 Requirement 2, paras. 2.5(3), (8) and (10) states that**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	"The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following: *(3) The type of authorization that is required for the operation of facilities and for the conduct of activities, in accordance with a graded approach;* *(8) Provision for the review and assessment of facilities and activities, in accordance with a graded approach;* *(10) Provision for the inspection of facilities and activities, and for the enforcement of regulations, in accordance with a graded approach."*
R3	**Recommendation: The Government should introduce the principle of a graded approach for radiation safety in the Law on Radiation Protection.**

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

VATESI sets safety requirements and rules, supervises whether they are complied with, issues licences, permits and temporary permits, performs safety assessments of nuclear facilities, and conducts inspections, among other functions. VATESI reports directly to the President of the Republic of Lithuania and the Lithuanian Government and it has its own state budget as decided by the Parliament.

VATESI makes decisions autonomously and its functions are separated from the functions of other authorities, institutions or organizations engaged in the development of nuclear power or use of nuclear energy, including the production of electricity. However, the IRRS team observed that according to Article 22 of the Law on Nuclear Energy VATESI "*shall prepare and submit to the Government or its authorized institution proposals regarding the national policy and strategy in the sector of nuclear power and implementation thereof"*. This function could compromise VATESI and be in conflict with its mandate as a nuclear safety regulator.

RSC is supervised by the Ministry of Health. Its functions as a regulatory body are described in the Law on Radiation Protection, Statute of the Radiation Protection Centre approved by Order of Ministry of Health. The allocation of the financial resources for RSC is provided on a yearly basis by the budget of the Ministry of Health, based on the annual plan prepared by RSC.

The IRRS team observed that RSC provides expertise and services for radiation measurement in homes and workplaces but it also has certain regulatory functions that require licensees to perform measurements and has the power to prosecute non-compliances. This could lead to possible conflicts of interest. The IRRS team was informed that RSC has established an organizational structure in such a way that the department of regulatory functions and department of expertise are separated. Also, as part of the system of management, the Director of RSC has signed a statement that he will not unduly influence the professional work of the staff in the Department of Expertise and Exposure Monitoring. Considering the information provided, the team concluded that the effective independence of RSC's regulatory functions is not jeopardized.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Sub-Paragraph 12 of Paragraph 1 of Article 22 of the Law on Nuclear Energy states that VATESI has been assigned to "…*prepare and submit to the Government or its authorized institution proposals regarding the national policy and strategy in the sector if nuclear power and implementation thereof",* which might constitute a conflict of interest for VATESI.	
(1)	**BASIS: GSR Part 1 Requirement 4, para. 2.9 states that** *"No responsibilities shall be assigned to the regulatory body that might compromise or conflict with its discharging of its responsibility for regulating the safety of facilities and activities."*
R4	**Recommendation: The government should ensure that VATESI is only asked to comment on nuclear safety issues regarding national policy and strategy on the use of nuclear power.**

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

The Government has explicitly assigned prime responsibility for nuclear safety to the persons in charge of the nuclear installation or to the activities posing a risk of exposure to ionizing radiation in the provisions of the Law on Nuclear Safety.

However, the prime responsibility for safety of the person or organization responsible for a facility or an activity is not clearly expressed in the Law on Radiation Protection. It is nevertheless stated in this Law that anyone carrying out radiation activities requires RSC authorization. Also, according to Lithuanian Basic Standard of Radiation Protection HN73:2001, bullet 26, the "*Licensee is responsible for compliance with requirements on protection. It may delegate functions on radiation protection to person (service) responsible for radiation protection, but the responsibility shall not be delegated.*" During the process of authorization, the applicant is obliged to demonstrate compliance with stipulated safety requirements by providing a suitable set of documents. This observation is addressed in Recommendation 1 in Section 1.1.

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

Although VATESI has responsibility for the regulation of nuclear and radiation safety at nuclear facilities, other regulators and bodies are involved. For example, the State Territorial Planning and Construction Inspectorate under the Ministry of Environment is responsible for oversight of civil constructions of nuclear installation's buildings; the Fire and Rescue Department under the Ministry of Interior is responsible for oversight of fire safety, emergency preparedness and response (civil protection), and extinction of fire; and the Environmental Protection Agency (EPA) under the Ministry of Environment is responsible for performing matters regarding environmental monitoring and oversight.

Coordination exists between VATESI and EPA, and the State Territorial Planning and Construction Inspectorate through Memoranda of Understanding.

Similarly, RSC has primary responsibilities for the regulation of radiation safety, however RSC cooperates with other authorities. This is primarily with the Ministry of Health and the

Ministry of Environment, which is responsible for coordination of a state environmental monitoring; the Fire and Rescue Department under the Ministry of Internal Affairs, which acts as a national co-ordinating authority in the field of emergency preparedness and response; the State Border Guard Service, which is responsible for radiation control by persons and vehicles crossing the border and cargo; the Customs Department, for identification and collection of orphan sources of ionizing radiation; and with the State Food and Veterinary Service in the area for food safety.

RSC has established formal arrangement for coordination in the form of memoranda with the State Border Guard Service and the Customs Department, the Fire and Rescue Department, the State Food and Veterinary Service and the State Security Department.

Both counterparts informed the IRRS team that their respective roles and responsibilities are defined in detail in the legislation and that there is no need for additional documents to formalize their cooperation. The legal framework specifies the responsibilities of VATESI and RSC in the field of radiation sources. However, the legal framework cannot deal with all the circumstances of the use of radiation sources at the nuclear facilities, such as oversight of sources licensed for applications outside the nuclear facility but used as service also at nuclear facility. The IRRS team observed that for the preparation of the IRRS mission their cooperation worked well, however for further strengthening and sustaining the cooperation between VATESI and RSC the IRRS team is of the view that formal arrangements for coordination would be helpful.

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

The system for protective actions to reduce existing or unregulated radiation risks in Lithuania is established on the basis of the Law on Radiation Protection. According to the Law on Radiation Protection, RSC has the mandate to organize and exercise national regulation and supervision of persons who are not subject to licences, but whose operations may result in exposure of population or the environment or are likely to discover an orphan source of ionising radiation or an object contaminated with radionuclides.

The Law on Radiation Protection sets out practices where radiation risks from natural sources need to be taken to account. The reference levels for radon concentrations in old and new living accommodation and workplaces, as well as levels for natural gamma dose rate in living and working premises and activity indexes for building materials are established in the legislation.

The IRRS team was informed that annual campaigns searching for orphan sources are organized by RSC. These campaigns mainly cover former Soviet military bases, factories and conventional waste management facilities. RSC also carries out a comprehensive programme for indoor radon measurements (individuals, kindergartens, schools, flats). Practices where NORM might be a problem are identified and investigated.

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

According to the Lithuanian legislation spent nuclear fuel and substances contaminated with or containing radionuclides at concentrations higher than the established clearance levels and for which no further use is foreseen, are defined to be radioactive waste (RW).

The national RW management policy is mainly set out in the Law on Radioactive Waste Management. The strategy on RW management is established by the Development Programme of Radioactive Waste Management (governmental resolution No. 1427 of 23.12.2015), which is valid since the 1st of January 2016.

This programme sets out four objectives to achieve the strategic goals of the programme which are the safe management of all radioactive waste and spent nuclear fuel available in Lithuania; the protection of people and the environment from harmful effects of ionizing radiation; and avoiding undue burdens on future generations. The aforementioned objectives are:

1. to reduce generation of RW;
2. to achieve a high level of nuclear and radiation safety and environmental protection of spent nuclear fuel and RW;
3. to ensure sustainable management of spent fuel and long-lived RW in the long-term safety; and
4. to ensure transparency of spent nuclear fuel and radioactive waste management.

The IRRS team was informed that the Government has decided to start, during 2016-2017, preparatory work for the project for the development of a geological repository. In this project the schedule of implementation, research and development requirements, and the administration of design, construction and operation will be addressed.

The effective and efficient management of waste requires planning in advance for the whole waste management process, until and including disposal. The interdependencies of the steps of the waste management need to be taken into account in such planning. As an example, in compliance with the transport regulations, the ability to transport casks containing spent fuel from interim storage to the site of further processing or disposal (if and when such transport would be needed) depends on the design of the cask, the conditions of loading and storage as well as establishment of a process of a periodic safety review focused on transport and, as required, a research program on ageing effects. Currently the advance planning process is not complete, which can negatively influence the overall safety system.

The principal objective of the decommissioning fund, established in compliance with the Law on Nuclear Energy, is the accumulation of resources required for safe decommissioning of a nuclear installation and safe management of RW, including spent nuclear fuel.

There are several funding sources, both nationally and from the EU and other donors, to cover activities related to the decommissioning of INPP units 1 and 2 including management of RW and spent fuel:

1. the Enterprise INPP Decommissioning Fund;
2. the Ignalina International Decommissioning Support Fund; and
3. the Ignalina Programme.

New RW management facilities, which are planned as part of the INPP decommissioning process, such as a solid RW management and storage facility, an interim spent nuclear fuel storage facility, and near surface repositories are being financed by the funds listed above. However, there are no yet clear solutions for funding to cover the operational costs of the planned repositories. In addition, currently there are no provisions for funding of the disposal of long-lived RW and spent nuclear fuel. However, during above-mentioned preparatory works for the long-lived radioactive waste disposal project solutions for funding will be proposed.

The Final Decommissioning Plan, approved by the Ministry of Energy, provides an estimation of INPP decommissioning costs, In the Development Programme of Radioactive Waste Management there is demand of financial resources for certain tasks and activities included in the programme. The IRRS team noted that the decommissioning funding mechanism largely relies on the European Union assistance as a result of the accession agreements while radioactive waste management plan short-term funding is established in Interinstitutional Action Plan (approved by the Government). However, the IRRS team consider that further attention should be given to ensure the long-term availability of financial resources for decommissioning, taking into consideration the timeframe of it implementation.

According to the Law on Nuclear Safety, a separate licence is required to conduct decommissioning of a nuclear installation and supervision of a closed RW repository. According to the Law on Radioactive Waste Management, following a recommendation of the Ministry of Energy, the government has the mandate to decide on the closure of a disposal facility (the same as "repository"; in original documents the same one Lithuanian word is used) as well as the termination of post-closure surveillance. However, no separate licence or permit is required to conduct activities related to closure of RW repositories. Moreover, in the Law on Radioactive Waste Management, "closure of radioactive waste disposal facility" is defined but there are no provisions for the closure of a RW repository.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The existing provisions for decommissioning of facilities and the management of radioactive waste are not fully complete. The long-term management of radioactive waste, including interdependencies between different management steps, construction and operation of disposal facilities, provisions for the needed research and development programmes and the financing of all future waste management activities are issues needing further attention.	
(1)	**BASIS: GSR Part 1 Requirement 10, paras 2.30, 2.32 and 2.33 states that** *(2.30) "Radioactive waste generated in facilities and activities shall be managed in an integrated, systematic manner up to its disposal. The interdependences of the steps in the entire management process for radioactive waste, and likewise for spent fuel, shall be recognized."* *(2.32) "The Government shall make adequate provisions for appropriate research and development programme in relation to the disposal of radioactive waste, in particular programmes for verifying safety in the long term."* *(2.33) "Appropriate financial provisions shall be made for:* *(a) Decommissioning of facilities;* *(b) Management of radioactive waste, including its storage and disposal;* *(c) Management of disused radioactive sources and radiation generators;* *(d) Management of spent fuel."*
R5	**Recommendation: The Government should further develop the existing provisions of legal framework and national policy and strategy for the decommissioning of waste management facilities, for the management of radioactive waste (including spent fuel) regarding interdependencies of the steps in the entire management process, closure of disposal facilities,**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	establishing required research and development programmes, and securing the appropriate financial provisions for all planned activities.

Policy issue discussion

The policy issue discussions took place on 22 April 2016 from 14:00. Experts of VATESI and interested IRRS team members participated in the discussions. VATESI wished to collect the international experience and views of the IRRS team regarding authorization of activities of decontamination and dismantling during transition from operation to decommissioning period.

The discussion goal was to identify regulatory policy aspects and criteria for authorization of license holder activities during transition from operation to decommissioning period.

Background information was attached to the Summary Report of the IRRS Advance Reference Material and was presented at the beginning of discussions by Vidas Paulikas (VATESI). The main points that VATESI was interested to get inputs on were:

- The main technical and safety justification documentation submitted for authorization of activities of transition period;
- Regulatory Policy for decision making during transition period;
- Criteria for authorization of dismantling of not anymore needed systems and components during transition period.

Following the introductory presentation questions were raised and answered in order to clarify the current status of INPP decommissioning, including on the scope of operation licence of INPP, the major phases of the transition period between operation and decommissioning.

Based on the discussions and experience shared by the IRRS team, it was concluded in general that the design basis should be identified for each major stage of the full decommissioning process, and accordingly major safety functions and corresponding safety systems have to be defined. Safety assessment, technical specifications and safety analyses report should be prepared and submitted to the regulatory body for review and assessment and licensing. VATESI experts said the Lithuanian approach follows a similar process. For different decommissioning stages different permits may be granted under the licence. In the UK a single licence is issued by the regulatory body for the site that covers its entire lifecycle (including the construction, operation and decommissioning stages) and all the plants on the site. Authorization of decommissioning is achieved under the site licence by providing individual authorizations for specific hold-points and activities within the decommissioning plan, applying a graded approach.

Decommissioning process requires new approaches, new competences, knowledge and skills from both the regulatory body and the operator. These new competences may significantly differ from those that were required during the operational phase of the facility. An overarching planning is also needed to optimize the entire process of decommissioning. Therefore beyond the safety issues related to the current stage and/or activities, adequate attention shall be paid to safety issues in long term. In this the regulatory body may benefit from the cooperation with other authorities at national and international level. Specific experiences and practices of countries represented by the IRRS experts were presented during the discussion. It was concluded that priorities for ensuring nuclear safety, radiation

protection and security are changing from stage to stage during the entire decommissioning process; therefore, cooperation amongst regulatory bodies is essential.

It was also discussed that before granting a decommissioning license, it is important that the regulatory body verifies the readiness of the operator for the decommission stage. In addition to technical issues attention needs to be paid to e.g. functionality of the management system, level of safety culture, training of personnel, personnel resources, and management of chains of subcontractors.

It was mentioned during the discussions that the timing and the deadlines defined in the license for the implementation of decommissioning activities have high importance. Due to different phenomena (like aging and wear out) beyond the specified deadlines the components' capabilities may significantly be reduced to with-stand those circumstances that they were planned to withstand in the decommissioning plans. Thus delay in conducting necessary activities and steps of the decommissioning stage may cause an increase of risk for the public and the environment.

During the decommissioning phase the regulatory body's power may weaken to enforce its regulation and requirements. This phenomenon requires special attention from the government. The government seems to play also a significant role in following up the decommissioning process: implementation of stages, successes, delays and problems have to be regularly reported to and if necessary, actions to be taken by the government. In the practice of several countries the funding of decommissioning is collected from the operator during the operational phase. Therefore, that is also the role of the government to establish in due time the funding policy for decommissioning.

1.8. COMPETENCE FOR SAFETY

The competencies for all parties with nuclear safety responsibilities are addressed in the Law on Nuclear Energy. The Law sets out requirements on ensuring the adequate general and professional competencies.

The Ministry of Education and Science is responsible for implementing education and science programmes, as well as establishing curricula and take other necessary measures, so that adequate competence and knowledge in the field of nuclear safety is ensured.

The regulator VATESI has to employ qualified personnel with experience and special knowledge, based on the qualification, education and other criteria established for certain positions, necessary to perform its functions. Qualification requirements for personnel working at nuclear installations are set out by requirements approved by VATESI.

The IRRS team noted that education of specialists for the national infrastructure for safety was performed, for a period of time, at Lithuanian education and research institutions: Kaunas University of Technology, Vilnius University, Lithuanian Energy Institute and the Centre for Physical Sciences and Technology.

The counterpart informed the IRRS team that VATESI has initiated an amendment of the Law on Nuclear Energy which will address both the required qualifications of top managers and personnel at nuclear power plants.

To build and maintain the competences in the radiation protection area, the Minister of Health approved the procedure: "*Compulsory Radiation Protection Training and Instruction Procedure*", which is based on the Law on Radiation Protection. The requirements of education for persons dealing with ionizing radiation sources are determined by this approved

procedure. RSC assures and implements the national supervision and control of the compulsory radiation protection training. RSC participates in research and training, financed by national budget, in the field of radiation protection and cooperates with foreign institutions on a bilateral basis.

The IRRS team observed that in the area of radiation safety in Lithuania there are competent experts in many specialisms including, radiation protection, medical, public and occupational exposure, and quality assurance. Some of them are involved in the authorization process. However, there is no formal recognition of medical physicists and no unified formal recognition of qualified experts for radiation protection in accordance with the requirements of the IAEA safety standards GSR Part 3.

The IRRS team was informed that the regulatory authorities (VATESI and RSC) have sufficient staff. However, at the time of the IRRS mission, actions to achieve a more systematic and holistic management of resources and competences were pointed out (See Section 3.3). Furthermore, for the national needs, the team was informed that in the area of medical exposures and public health care, long-term human resources planning is realized and implemented.

Taking into account factors like generational shifts, possible nuclear new-build, future increased activities in nuclear decommissioning and waste management as well as the planned construction and operation of waste repositories, the IRRS team is of the view that a national and integrated review of competence needs could be useful.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no requirement for formal recognition of qualified experts for radiation protection and medical physicists in the existing regulatory framework.	
(1)	**BASIS: GSR Part 1 Requirement 11 states that** *"The government shall make provision for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities."*
(2)	**BASIS: GSR Part 3 Requirement 2, para. 2.21 states that** *"The government shall ensure that requirements are established for:* *(a) Education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety;* *(b) The formal recognition of qualified experts..."*
R6	**Recommendation: The Government should establish a process of formal recognition of qualified experts for radiation protection and for medical physicists.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The team could not find evidence of comprehensive review and assessment of existing and future human resources needs in relation to safety.	
(1)	**BASIS: GSR Part 1 Requirement 11, para. 2.36 (c) states that** *"The Government shall make provisions for adequate arrangements for increasing,*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	maintaining and regularly verifying the technical competence of persons working for authorized parties."
(2)	**BASIS: GSR Part 1, Requirement 11, 2.34 states that** *"As an essential element…. the necessary professional training for maintaining the competence of a sufficient number of suitably qualified and experience staff shall be made available"*
S1	**Suggestion: The Government should consider performing a comprehensive assessment of existing and future human resource needs in relation to the safety of facilities and activities.**

1.9. PROVISION OF TECHNICAL SERVICES

Technical services such as personal dosimetry services, instrument calibration services and environmental monitoring are provided for.

The State Metrology Service operates a calibration laboratory for dose rate and dose survey meters, is accredited according to ISO 17025. Other equipment is sent abroad for calibration at international secondary standard laboratories.

Ministry of Environment is responsible to identify organizations performing national environmental monitoring and to set up provisions on performing environmental monitoring measurements. RSC operates a laboratory for this purpose which is accredited according to ISO 17025.

There are three personal dosimetry laboratories covering the national needs, one of which is operated by RSC. Personal dosimetry services and working place monitoring services should be accredited according to ISO 17025 or approved by the RSC in accordance with the order of the Director of RSC No. V-42 of 28 May 2013 "*Performance criteria for approval of Non-accredited dosimetry laboratories (services) performing measurements of exposure of workers and workplaces and assessment of exposure*".

1.10. SUMMARY

Lithuania has established a comprehensive legal framework for radiation and nuclear safety, including establishing effectively independent regulatory authorities, VATESI and RSC, with clearly defined responsibilities.

Areas of improvement identified by the IRRS team are:

- all the fundamental safety principles of IAEA SF-1, including the principle of prime responsibility for safety and the principle of a graded approach, should be addressed into the legal framework for radiation safety;
- the provisions for involvement of the public in the decision making process should be included into legal framework for safety;
- the government should ensure that VATESI is only be asked to comment on nuclear safety issues regarding the national policy and strategy on the use of nuclear power;

- consideration should be given to further development of the existing provisions for decommissioning of facilities and the management of radioactive waste regarding some specific issues;

Finally, it is pointed out that, the government should consider assessing existing and future human resources needs, and should make the necessary provision for formal recognition of all parties having responsibilities in relation to the safety.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Lithuania is a contracting party of relevant international treaties and conventions that establish the common obligations and mechanisms for ensuring safety in the utilization of nuclear energy and ionizing radiation, for peaceful purposes, and provide for an effective coordinated international response to a nuclear or radiological emergency.

Lithuania has expressed support for the IAEA 'Code of Conduct on the Safety and Security of Radioactive Sources' and implements the associated 'Guidance on the Import and Export of radioactive sources' in practice.

There are a number of bilateral international agreements, at a government and regulatory body level, for the cooperation on and exchange of information in the field of radiation protection with respect to emergency preparedness and the combating of illicit trafficking.

RSC has agreed bilateral arrangements with other regulatory authorities for the cooperation on and exchange of information including safety regulation, operational experience and crises.

VATESI is involved in working groups that are developing international requirements and rules for facilitating exchange of experience and best practice in the regulation and supervision of the activities in the nuclear energy area. VATESI works in cooperation with a number of international organizations including the International Atomic Energy Agency (IAEA), the European Nuclear Safety Regulators Group (ENSREG), the Western European Nuclear Regulators Association (WENRA) and the European Nuclear Security Regulators Association (ENSRA).

RSC is a member of various working groups, societies and networks, such as the Heads of European Radiological Protection Competent Authorities (HERCA), the Group of Experts under the Article 31 of the European Treaty, the Council of the Baltic Sea States (CBSS) Experts Group on Nuclear and Radiation Safety, the European Training and Education in Radiation Protection Platform (EUTERP) and the European Study of Occupational Radiological Exposure (ESOREX).

Lithuanian experts participate in a number of IAEA committees as follows; Commission on Safety Standards (CSS), Committee on Nuclear Safety Standards (NUSSC), Radiation Safety Standards Committee (RASSC), Transport Safety Standards Committee (TRANSSC), Radioactive Waste Safety Standards Committee (WASSC), Emergency Preparedness and Response Standards Committee (EPRSC) and Nuclear Security Guidance Committee (NSGC).

A number of international peer reviews of both the regulatory system and of the safety of facilities have been carried out in Lithuania (for example, IPPAS, IRRT, OSART, RaSSIA, INSARR, EPREV, EduTA). VATESI and RSC staff have also participated in IAEA international peer reviews including IRRS, IPPAS, OSART, WANO, RaSSIA, EPREV, EduTA.

RSC in cooperation with IAEA organize a number of training courses and workshops for professionals from other countries to promote international cooperation for the purpose of enhancing safety globally.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Lithuania actively participates in a number of international bodies, working groups, committees and international peer reviews, also Lithuania hosted many peer reviews missions and training courses and workshops for professionals from other countries especially in the radiation protection field to promote international cooperation and assistance to enhance safety globally.	
(1)	**BASIS: GSR Part 1 Requirement 14 states that** *"The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation and assistance to enhance safety globally."*
GP1	**Good practice: Lithuania is actively engaged in international cooperation; including international arrangements, peer reviews and international support programmes.**

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

A framework for sharing operating and regulatory experience for the purpose of the prevention of nuclear and radiological accidents and incidents and further safety improvement is established in the Law on Nuclear Safety. Furthermore, detailed requirements for reporting, use and exchange of operating experience are established in VATESI regulations, 'General requirements for the event reporting system at NPP' and 'Requirements on the Operational Experience Feedback in the field of Nuclear Energy'. The process for the use of operating and regulatory experience is defined and documented in the VATESI`s management system procedure 'Management of the regulatory and operating experience'.

Information about unusual events and the subsequent implemented safety measures is published in annual VATESI reports. National reports on international conventions include information with respect to safety measures taken as the result of lessons learned from operating experience.

With respect to the exchange of nuclear safety-related information, VATESI is assigned to be the contact institution with international organizations and foreign institutions regulating nuclear safety. VATESI has nominated a national coordinator to IAEA/NEA IRS, FINAS and INES.

Sharing of operating and regulatory experience in the area of radiation protection is established by RSC, according to the Law on Radiation Protection and the 'HN 73:2001 Basic Standards of Radiation Protection'. The RSC has developed and maintains a radiation protection information system (RSIS) which contains a component on radiation safety events. All events are registered, analysed and used for improvement of the legislation in radiation protection and physical security of the sources of ionizing radiation. During inspections, RSC evaluate how authorized parties implement new requirements. RSC prepare a number of reports including an annual report and a report of programmes performed. RSC also prepare information bulletins and leaflets that are disseminated to relevant parties.

In accordance with an Order issued by the Director, all RSC specialists are obliged to submit proposals for improvement of activities to ensure occupational, public and environmental radiation protection as well as improvement of legislative base, after participation at

international events. However, the process of the use of operating and regulatory experience is not defined and documented in the management system procedure. The counterpart informed the IRRS team that the Quality management procedure "Management of the regulatory and operating experience" which details the process for the use of operating and regulatory experience is under preparation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RSC use operational and regulatory experience for improvement of existing system as well as for sharing information with other authorities and licensees, however a procedure describing the process for reviewing and evaluating international operating and regulatory experience and disseminating relevant information on lessons learned is to be developed by RSC.	
(1)	**BASIS: GSR Part 1 Requirement 15 states that** *"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."*
S2	**Suggestion: RSC should consider developing a procedure for systematic review and evaluation of international operating and regulatory experience and the dissemination of relevant information on lessons learned.**

2.3. SUMMARY

Lithuania is a contracting party of all relevant international treaties and conventions. VATESI and RSC have a number of a bilateral agreements in place, furthermore, their staff represent Lithuania in a wide variety of international fora. Sharing of relevant information such as operational and regulatory experience from other States, and from authorized parties through its participation at regional and international meetings, is used to enhance safety by both regulators. The IRRS team suggested that the counterpart should consider establishing a formal procedure for systematic review and evaluation of feed-back experience and its dissemination.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

VATESI is the regulatory body for the oversight of nuclear installations. Its responsibilities cover nuclear safety, radiation safety in nuclear installations, physical security and implementation of non-proliferation regime. While VATESI was established in 1991, it should be noted, that in 2011 the regulatory oversight of radiation safety and radiation sources in nuclear installations was transferred from RSC to VATESI.

The independent position of VATESI is ensured by several means. VATESI's independence is stipulated in the Law on Nuclear Energy, the Law on Nuclear Safety, the Law on Radioactive Waste Management, the Law on Radiation Protection and in the Statute of VATESI. VATESI reports to the President of Republic of Lithuania and to the Government. The budget of VATESI is part of the state budget which is decided by the Parliament. The strategic plan of VATESI is approved by the Head of VATESI. The Head of VATESI is appointed by the President of Republic of Lithuania and the deputy heads are appointed by the Prime Minister.

The maximum number of positions at VATESI are defined in a Government Decree. There are currently 75 positions at VATESI. In 2008 the number of positions was increased by 15 due to the new NPP project. At the time of the IRRS mission, the NPP project was on hold.

VATESI has an Administration Department and two groups of divisions: responsible for radiation safety matters, and responsible for nuclear safety matters. There are also divisions related to internal auditing, public communication, project management, finance and accounting as well as nuclear material control and physical security. The Head of VATESI decides on the structure of the organization and the allocation of resources.

RSC is the regulatory body for the use of radiation sources in medical applications, research and industry, etc. Its responsibilities cover, inter alia, regulatory oversight, emergency preparedness and environmental monitoring as well as training on radiation protection. RSC was established in 1997.

The independence of RSC is stipulated in the Law on Radiation Protection. RSC is supervised by the Ministry of Health. RSC's budget is decided by the Ministry of Health. The number of positions at RSC is defined in a Government Decree. There are currently 59 positions at RSC, of which 31 positions are for the regulatory functions where 14 positions are for inspections. The Annual plan of RSC is approved by the Minister of Health. The number or positions was decreased by four in 2008-2009 due to the reduction of the state budget.

The RSC structure is based on the functions established in the Law on Radiation Protection and the Statute of the Radiation Protection Centre. There is a Department of Expertise and Exposure Monitoring which has three divisions for medical, occupational and public exposure. Deputy Director of RSC is coordinating the activities of the five divisions responsible of licensing, management of the State Register of Sources of Ionizing Radiation and Occupational Exposure and oversight of the radiation facilities and activities. Three surveillance divisions are located in other main cities of Lithuania than Vilnius. The senior specialists and the matters regarding emergency preparedness, public information and administration are under the Director of RSC.

The State Metrology Services is responsible for calibration matters and operates a national metrology laboratory.

The Environmental Protection Agency, under the supervision of the Ministry of Environment, is responsible for the radiological monitoring of environmental.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

The independence of VATESI and RSC is stipulated in the Law on Nuclear Energy and Law on Radiation Protection, respectively. VATESI reports directly to the President and to the Government. RSC reports to the Minister of Health.

The decision making is based on the Laws on Nuclear Energy, Nuclear Safety, Radiation Protection, Radioactive Waste Management and lower-level legislation. There are several persons involved in the preparation of decisions at VATESI.

The Head of VATESI and the director of RSC and their deputies are public and civil servants. Most of the employees of VATESI and RSC are also civil servants. Public and civil servants have to give a "Private Interest Declaration". The Lithuanian civil service and public administration legislation set strict requirements for the impartiality of the public and civil servants.

VATESI has resident inspectors at Ignalina NPP site. There is no rotation of inspectors in place. In the Law of Nuclear Safety there are provisions ensuring the independence of the TSO support provided to VATESI.

At RSC inspections are standardised and there are formal checklists for each type of inspection. There are frequent contacts between the RSC Vilnius office and the local divisions. A number of services, including personal dosimetry, gamma spectrometry and radiochemistry, are provided by the RSC department of Expertise and Exposure Monitoring; which are accredited by the Lithuanian National Accreditation Bureau in accordance with the standard LST/ISO/IEC/EN 17025:2005, *General requirements for the competence of testing and calibration laboratories.* RSC also has the capability to provide measurements of gross alpha and beta activities in various samples. The majority of RSC's clients; particularly for the services for individual dosimetry and measurement of workplace contamination; are licensees and temporary permit holders. This results in a situation in which the regulatory body responsible is also providing services that may be essential, in part, to demonstrate compliance with regulatory requirements.

There are arrangements made to ensure the independence of the department of Expertise and Exposure Monitoring. However there is an option to perform inspection together with others divisions of RSC (e. g. Division of Radiation Emergency Management and Training, Division of Expertise and Medical Exposure Monitoring, Division of Occupational Exposure Monitoring) in order to provide for deeper evaluation of the medical, occupational, public and environmental exposures. RSC is planning to apply accreditation for its regulatory functions according to standard LST/ISO/IEC/EN 17020:2012 in 2017. This standard includes further requirements concerning the management of risks related to impartiality and independence, applicable to the supervision functions in RSC. (See Section 1.3, 5.4, 11.1, 11.2)

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RSC, responsible for the regulation and oversight of facilities and activities is also providing services that may be essential, in part, to demonstrate compliance with regulatory requirements. RSC is planning to apply for accreditation for its regulatory functions according to standard LST/ISO/IEC/EN 17020:2012 in 2017. This standard includes further requirements concerning the impartiality and independence.	
(1)	**BASIS: GSR Part 1 Requirement 4 para. 2.9 states that** "*No responsibilities shall be assigned to the regulatory body that might compromise or conflict with its discharging of its responsibility for regulating the safety of facilities and activities.*"
(2)	**BASIS: GSR Part 1 Requirement 17 states that** "*The regulatory body shall perform its functions in a manner that does not compromise its effective independence.*"
(3)	**BASIS: GSR Part 1 Requirement XX para. 4.6 states that** "*The government establish and maintain a regulatory body that is effectively independent in its decision making and that has functional separation from entities having responsibilities or interests that could unduly influence its decision making. This imposes an obligation on the regulatory body to discharge its responsibilities in such a way as to preserve its effective independence.*"
(4)	**BASIS: GSR Part 1 para. 4.6 states that** "*The regulatory body shall prevent or duly resolve any conflicts of interests or.*"
S3	**Suggestion: RSC should consider further strengthening the effective independence of its regulatory functions from its expert services to licensees.**

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

The maximum number of positions of the government organizations are defined in Government Resolution No. 1329, 2015. In VATESI, there is a strategic and annual planning of the activities. VATESI may, as needed, use TSO support.

The management of resources and competences of VATESI is based on the Strategic Activities Plan and the Annual Plan. However there is no systematic formalized approach for managing the VATESI resources and competences, so that the delivery of VATESI statutory responsibilities in long term can be ensured. The IRRS team made an observation that several areas rely on a single expert in the organization e.g. Probabilistic Safety Assessment, civil engineering. The IRRS team was informed that it is more and more difficult to recruit nuclear safety experts with adequate knowledge of the Russian language (language of some technical documentation at INPP). The redundancy of expertise, ageing of staff and the future needs of the VATESI oversight activities should be considered in the resource and competence planning in a timely manner.

The training programme of VATESI covers four types of training activities: in-class training, practical training, self-studies, and on-the-job training. The training needs are assessed in the annual evaluation of the employees and the annual training plan is developed accordingly. For the nuclear safety training the services provided by IAEA are widely used. The training plan includes also the follow up of the training received by the employees. However, there is no formal periodic, systematic assessment of the effectiveness of the training programmes. There is no formal system of appointing inspectors to be able to work independently, and no system for the follow-up of their needed qualification.

The IRRS team was informed that a systematic management of the resources and competences at VATESI is being developed, and this measure is included in the VATESI action plan resulting from its self-assessment.

Knowledge management is considered in VATESI management system. Information related to the many defined external and internal sources of information is documented and registered. (See Section 4.3)

The planning of the resources of RSC is based on the strategy plan and the annual planning of the activities. The planning is based on the number of staff allocated to RSC in the government resolution. There is annual evaluation of the employees, description of the position containing primary and secondary expertise. However a holistic, documented view of the resources and competences needed, taking into account the development of the current and future use of radiation sources and their oversight, is not developed.

At RSC the initial training of all staff is 40 hours. RSC has four training programmes: Radiation protection in medicine, Radiation protection in industrial and scientific facilities, Radiological measurements and methods to assess the exposure, and Radiological accidents and their management. There is an exam before the inspector can start the work. Each staff member is expected to have at least 120 h of training in every five years. The annual planning of the RSC training is based on the annual evaluation of the employees. The plan specifies training for each staff member. There is follow up of the training and quarterly seminars on dissemination of the lessons learned. The training is evaluated by the participants after training activities and after one year the participant assesses the usefulness of the training.

RSC has three local divisions for the supervision of radiation safety outside of the Vilnius region. There are frequent contacts between employees of the local divisions and RSC Vilnius office staff.

The concept of knowledge management is not used at RSC. However there are a lot of activities related to knowledge management. (see Section 4.3)

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Human and other resources at VATESI are defined as an output of the process of strategic planning of VATESI's activities. A long term strategy for human resource development is currently not in place in order to ensure the discharge of regulatory duties in the future.	
(1)	**BASIS: GSR Part 1 Requirement 18 states that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSR Part 1 Requirement 18 para. 4.11 states that** *"The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions."*
(3)	**BASIS: GSR Part 1 Requirement 18 para. 4.12 states that** *"The human resources plan for the regulatory body shall cover recruitment and, where relevant, rotation of staff in order to obtain staff with appropriate competence and skills, and shall include a strategy to compensate for the departure of qualified staff."*
R7	**Recommendation: VATESI should establish and implement a systematic approach to management of human resources and competences, including both a short and long term strategy, to ensure future delivery of its regulatory functions.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is an annual assessment of the employees that includes the assessment of training needs of the employees. However, systematic periodic assessment of the effectiveness of the overall training programme at VATESI is not included in the management system processes of training. Furthermore, VATESI has no formal system for appointing the inspectors to work independently and for maintaining their qualification.	
(1)	**BASIS: GSR Part 1 Para. 4.13 states that** *"A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include development of a specific training programme on the basis of an analysis of the necessary competence and skills. The training programme shall cover principles, concepts and technological aspects, as well as procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements."*
(2)	**BASIS: GS-R-3 Para. 4.3 states that** *" Senior management shall determine the competence requirements for individuals at all levels and shall provide training or take other actions to achieve the required level of competence. An evaluation of the effectiveness of the actions taken shall be conducted. Suitable proficiency shall be achieved and maintained."*
(3)	**BASIS: GS-R-3 Para. 4.4 states that** *"Senior management shall ensure that individuals are competent to perform their assigned work and that they understand the consequences for safety of their activities. Individuals shall have received appropriate education and training, and shall have acquired suitable skills, knowledge and experience to ensure their competence. Training shall ensure that individuals are aware of the relevance and importance of their*

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	activities and of how their activities contribute to safety in the achievement of the organization's objectives."
S4	**Suggestion: VATESI should consider enhancing its training programme to include the verification of adequate knowledge and abilities of staff, before they are appointed to work independently as inspectors or perform other key roles relating to safety, and to ensure that suitable proficiency is maintained. The efficiency of the programme should be verified periodically.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The planning of the human resources of RSC is based on the strategy plan and the annual planning of the activities. There is an annual evaluation of the employees and a description of the position, specifying primary and secondary expertise. A holistic, documented view of the human resources and competences needed is not developed.	
(1)	**BASIS: GSR Part 1 Requirement 18 states that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."*
(2)	**BASIS: GSR Part 1 para. 4.11 states that** *"The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions."*
(3)	**BASIS: GSR Part 1 para. 4.12 states that** *"The human resources plan for the regulatory body shall cover recruitment and, where relevant, rotation of staff in order to obtain staff with appropriate competence and skills, and shall include a strategy to compensate for the departure of qualified staff."*
S5	**Suggestion: Taking into account the current and future needs of oversight of radiation sources, RSC should consider enhancing its practices for managing resources and competences so that the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions can be quantified.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The systematic approach includes evaluation of the training, the quarterly seminars for disseminating the lessons learned and, after one year the assessment of usefulness of the training by the participating individuals.	
(1)	**BASIS: GSR Part 1 Para. 4.13 states that** *"A process shall be established to*

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	develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include development of a specific training programme on the basis of an analysis of the necessary competence and skills. The training programme shall cover principles, concepts and technological aspects, as well as procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements."
GP2	**Good Practice: All RSC employees are included in systematic planning and follow up of training. The dissemination of information of the lessons learned in international courses and seminars, and the self-assessment of the usefulness of received training is an integral part of the management of training.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

At the time of the IRRS mission VATESI had no advisory body.

In the Law on Nuclear Safety it is required that the TSO support provided to VATESI should be independent from these persons or organizations who prepare the documentation to be assessed. The TSO support is accounted for when defining fees for performing activities to be reviewed and assessed. Recently a few TSO contracts have been signed. The procurement of services is made case-by-case based on national or international competition. The TSO support has been provided both by Lithuanian and foreign TSOs and consultants.

The advisory body of RSC was established in 2015 by an order of the Director of RSC. There are 11 experts from a variety of stakeholder organizations in the advisory body. It is expected to give advice to RSC on, inter alia, safety policy, legislation, analysis of radiation safety issues, interface with physical protection and initiation of radiation safety research. The advisory body had its first meeting in March 2016. It has planned to have meetings twice a year.

At the time of the IRRS mission there is no provision in the legislation that allows RSC to use TSO support. RSC has identified this in the performed self-assessment and there is a plan to change the Law on Radiation Protection in this regard.

For special cases, such as illicit trafficking of, or nuclear forensics connected with, very high activity sources or nuclear materials, RSC has agreements for support with the Institute of Transuranium Elements (ITU) in Karlsruhe, Germany and the Institute of Physics in Lithuania.

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Observation: VATESI for the time being has no permanent advisory body.	
(1)	**BASIS: GSR Part 1 Requirement 20 states that** *"The regulatory body shall obtain technical or other expert professional advice or services as necessary in support of its regulatory functions, but this shall not relieve the regulatory body*

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	of its assigned responsibilities."
(2)	**BASIS: GSR Part 1 Requirement 20, para. 4.18 states that** *"The regulatory body may decide to give formal status to the processes by which it is provided with expert opinion and advice. If the establishment of advisory bodies, whether on a temporary or a permanent basis, is considered necessary, it is essential that such bodies provide independent advice, whether technical or non-technical in nature."*
S6	**Suggestion: For further development of nuclear programme VATESI should consider establishing the provisions for an advisory body to obtain technical or other expert professional advice in support of its regulatory functions.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no provisions for RSC to obtain technical or other expert professional services as necessary in support of its regulatory functions in the legislation.	
(1)	**BASIS: GSR Part 1 Requirement 20 states that** *"The regulatory body shall obtain technical or other expert professional advice or services as necessary in support of its regulatory functions, but this shall not relieve the regulatory body of its assigned responsibilities."*
S7	**Suggestion: RSC should consider suggesting changes to the present legislation to establish provisions for obtaining technical or other expert professional services, as necessary, in support of its regulatory functions.**

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

There are regular quarterly meetings between the VATESI management and the Ignalina NPP management. A protocol is produced and the information is disseminated within VATESI. Other liaison means are the use of official letters, meetings with or without recorded minutes (reports). The changes of the regulatory requirements are effectively distributed to all stakeholders. The licensees (Ignalina NPP – quarterly, other licensees – after every inspection) evaluate performance of VATESI inspection activities by a questionnaire organized by the Ministry of Economy. The report is published.

RSC has an extensive program of seminars for the licensees and there are contacts with professional societies in the field of radiation protection. The communication with licence holders is through official letters and as needed meetings to resolve safety issues. RSC sends a questionnaire to the licensees annually. The licensees evaluate the performance of RSC after each inspection by a questionnaire organized by the Ministry of Economy. The monthly performance report of RSC is published.

The information on VATESI and RSC licences/decisions is public.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

VATESI and RSC follow the national practices when new requirements are issued. There is a five-year planning of the changes in the legislation, regulations and guides. The drafts for new regulations are available for comments at the Seimas data systems. The impact assessment of the changes is included in the preparation of new regulations. As necessary, meetings are arranged with the concerned parties to resolve the comments received on the draft regulations.

In the management system of VATESI and RSC one of the core processes is the preparation of the regulations.

3.7. SAFETY RELATED RECORDS

At VATESI there are 24 safety related registers. Half of the registers contain safety related information and other records (e.g. the incoming documentation) and the other half contains exclusively safety related records. The decisions of VATESI are archived and kept in hard copies and most of the documents are also kept electronically in an older IT system. VATESI is in the transition from the use of the current system to an integrated ICT system, called VATESI Internal Administration Information System (VAIS) which is to include all non-classified registers.

The initial commissioning of VAIS was planned to be in 2015. At the time of the IRRS mission the VAIS system was in use, except for the parts which were being further improved due to technical issues. VAIS has been used for the record keeping of inspection documents from the beginning of the year 2016.

RSC is responsible to have and manage the State register of radiation sources and occupational exposure called RSC Register. This register also includes the information on licensing and the related inspections. There is a wide selection of reporting possibilities that can be directly extracted from the database and which later can be used for planning, inspections and assessment of the performance of the licensees and the regulator.

The information in RSC Register is available on-line for any licensee who wants get an actual overview of data for their sources, workers, occupational exposure records, licenses, permits, inspection report, non-compliances and time limits thereof. The system allows also for the on-line updating of the licensees data.

The RSC document management system “KONTORA” includes official letters, orders and tasks.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: VATESI is changing its management of records including the safety related records to a new VATESI Internal Administrative Information System (VAIS). At the time of IRRS mission the VAIS system was partially in use.	
(1)	**BASIS: GSR Part 1 Requirement 35 states that** *“The regulatory body shall make provision for establishing, maintaining and retrieving adequate records relating to the safety of facilities and activities.”*
(2)	**BASIS: GS-R-3 para.5.21 states that** *“All records shall be readable,*

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	complete, identifiable and easily retrievable."
S8	**Suggestion: VATESI should consider ensuring the completion of its internal information management system and easy access of the relevant staff to appropriate safety related information.**

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

The decisions of the regulatory organizations are public, and anyone can request the decision and the related justification in Lithuania. The drafts of legislation, regulations and orders of the regulatory bodies are available for public comments. For the environmental impact assessment process the Ministry of Environment organize public hearings and related meetings at the local level. VATESI takes part in meetings addressing issues which are related to its formal competence. A recommendation on legal provisions for involvement of the public in the decision making process of the regulatory body is made in Section 1.2 Recommendation 2.

VATESI has a website were extensive information on the nuclear facilities in Lithuania and the regulatory oversight is provided, including licences granted, annual reports on the oversight activities, emergency preparedness, data on nuclear facilities, incidents at the nuclear facilities, regulations relevant to safety and events at VATESI. The VATESI reports are also being sent to the local authorities. At the time of the IRRS mission, no activities for communication to the people living in the vicinity of the nuclear facilities were performed. The IRRS team was informed that VATESI has plans to start such communication activities. As RSC is responsible for the environmental monitoring and public exposure, both VATESI and RSC should be involved in the communication activities to the people living in the vicinity of nuclear facilities.

When needed, VATESI directly provides necessary information to the President or the Prime Minister. Since 2009 VATESI has organized, every other year, a survey on the public awareness of issues related to nuclear safety and the expectations of citizens regarding nuclear safety oversight in Lithuania.

RSC has considerable amount of information on its website, including annual reports, forms for applying different types of licences, monthly performance assessment of RSC. RSC organizes about 30 seminars or training events during a year for the licensees. RSC organizes various types of public communication on radiation sources with the Ministry of Health and municipal organizations in Lithuania. Information events are regularly organized in the vicinity of Ignalina NPP. Co-operation between RSC and VATESI would be helpful while organizing public communication in the vicinity of nuclear facilities. At the time of IRRS mission, there were no provisions for public involvement, as appropriate, in the licensing of radiation sources.

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Observation: There is information on the website on the safety of the nuclear facilities. However at the moment there are no activities that focused on the information of public in the vicinity of the nuclear installations. RCS organizes various types of public

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communication in the vicinity of the nuclear facilities.	
(1)	**BASIS: GSR Part 1 Requirement 36 states that** *"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."*
(2)	**BASIS: GSR Part 1 para. 4.66 states that** *"The regulatory body shall establish, either directly or through authorized parties, provision for effective mechanisms of communication, and it shall hold meetings to inform interested parties and the public and for informing the decision making process. This communication shall include constructive liaison such as."*
(3)	**BASIS: GSR Part 1 para. 4.67 states that** *"In particular, there shall be consultation by means of an open and inclusive process with interested parties residing in the vicinity of authorized facilities and activities, and other interested parties, as appropriate [1]. Interested parties including the public shall have an opportunity to be consulted."*
R8	**Recommendation: VATESI should develop provisions for informing the public in the vicinity of the nuclear facilities about the radiation risks associated with facilities, the requirements for protection of people and the environment, and the processes of VATESI.**
S9	**Suggestion: VATESI and RSC should consider together organizing periodic, and as needed specific, public information in the vicinity of nuclear facilities.**

3.9. SUMMARY

The functions and responsibilities of the regulatory bodies VATESI and RCS have been defined in the legislation and are implemented in practice. There is room for enhancement of the regulatory functions at VATESI in resource and competence management, appointment of inspectors to work independently, management of safety records and public communication in the vicinity of nuclear facilities. For RSC a good practice was identified by the team in relation to its training programme. For RSC there is room for enhancement in ensuring the independence of regulatory oversight and expert services, management of resources and competencies, in the contracting of expert services and for public communication in the vicinity of nuclear facilities.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

The Lithuanian Law on Public Administration requires that quality management of public administration at state level and at the level of an entity of the public administration should be implemented.

VATESI and RSC have both obtained the ISO 9001:2008 certification.

The VATESI management system is developed in accordance with the standard ISO 9001:2008 and with the requirements of IAEA standards, namely GS-R-3 and to a great extent with GS-G-3.1.

A detailed structure of the VATESI integrated management system is defined in the management system documentation which consists of the "Management System Policy", the "Manual of Integrated Management System", 30 different procedures which define the VATESI processes, and other related documents defined in the "Manual of Integrated Management System". The manual is the essential document which describes the VATESI management system and provides guidance to the work of VATESI staff. The Quality Policy is available for stakeholders on the VATESI website; the management system documentation is available on the VATESI intranet. The VATESI procedures are very extensive. During the interviews it was however found out that the management system documentation is not always consistent, not all procedures are user friendly and detailed enough in all areas. For example, "Procedure Document for Review and Assessment of Safety Justification Documents" is insufficient and does not give all the necessary instructions; this issue is addressed in Recommendation 14 and Suggestion 14 in Section 6.2. The procedure describing the inspection process might also be improved, as observed by the IRRS team during the site visit. This issue is addressed in Suggestion 19 in Section 7.1.2.

Moreover, the IRRS team noted that VATESI has not defined a vision as a part of the management system documentation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: VATESI's vision is not defined in the management system documentation.	
(1)	**BASIS: GS-G-3.1 para. 2.54 states that** *"Information on the following should be provided at level 1:* *—Vision, mission and goals of the organization;"*
S10	**Suggestion: VATESI should consider defining a regulatory body vision.**

Priority to safety is stated in the VATESI "Management System Policy". VATESI has developed procedure for the process "Development of Organizational Culture", which describes the elements of safety culture and VATESI values.

The requirements for graded approach are defined in the VATESI "Management System Policy" and in the Manual. The concept of a graded approach is used for the core processes and its application is defined in each procedures describing single core process. In some procedures, i.e. "Procedure Document for Review and Assessment of Safety Justification

Document", the graded approach is mentioned but its application remains difficult. This issue is addressed in Suggestion 15 in Section 6.2.

RSC has established and developed a comprehensive management system in line with standard ISO 9001:2008. The RSC management system is certified. However, the RSC management system does not meet the additional requirements set by the IAEA standards GSR Part 1, Requirement 19, GS-R-3 and GS-G-3.1. For example, the RSC quality policy, does not state clearly that safety is an overriding priority. RSC management system is based on a process approach which is described in the management system documentation, consisting of a vision, a mission, a quality policy, a management manual, 29 procedures describing processes and related work instructions. The documentation of the management system is readily accessible by intranet. Formal training on access, use and familiarization with its functions is given to all new staff. All RSC employees use approved management system documents when performing their activities. Although a graded approach process is not defined in the management system documentation, RSC applies, to some extent, a graded approach when carrying out its activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The RSC quality policy does not state clearly that safety is an overriding priority.	
(1)	**BASIS: SF-1, Principle 3 states that** *"Safety has to be achieved and maintained by means of an effective management system. This system has to integrate all elements of management so that requirements for safety are established and applied coherently with other requirements, including those for human performance, quality and security, and so that safety is not compromised by other requirements or demands."*
(2)	**BASIS: GS-R-3 para. 2.2 states that** *"Safety shall be paramount within the management system, overriding all other demands."*
R9	**Recommendation: RSC should revise its quality policy in order to emphasize that safety is an overriding priority.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RSC management system is in line with ISO 9001:2008 standard. However, the additional requirements set by IAEA standard GSR Part 1 and GS-R-3 are not included in the RSC management manual.	
(1)	**BASIS: GSR Part 1 Requirement 19 states that** *"The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement."*
(2)	**BASIS: GS-R-3 para. 2.5 states that** *"The management system shall be used to promote and support a strong safety culture by:* *—Ensuring a common understanding of the key aspects of safety culture within*

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	the organization; *—Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization;* *—Reinforcing a learning and questioning attitude at all levels of the organization;* *—Providing the means by which the organization continually seeks to develop and improve its safety culture."*
(3)	**BASIS: GS-R-3 para. 2.6 states that** *"The application of management system requirements shall be graded so as to deploy appropriate resources, on the basis of the consideration of:* *—The significance and complexity of each product or activity;* *—The hazards and the magnitude of the potential impact (risks) associated with the safety, health, environmental, security, quality and economic elements of each product or activity;* *—The possible consequences if a product fails or an activity is carried out incorrectly."*
(4)	**BASIS: GS-R-3 para. 2.7 states that** *"Grading of the application of management system requirements shall be applied to the products and activities of each process."* **BASIS: GS-R-3 para. 5.28 states that** *"Organizational changes shall be evaluated and classified according to their importance to safety and each change shall be justified."*
(5)	**BASIS**: **GS-R-3 para. 6.8 states that** *"The review shall cover but not be limited to:* *—Outputs from all forms of assessment;* *—Results delivered and objectives achieved by the organization and its processes;* *—Non-conformances and corrective and preventive actions;* *—Lessons learned from other organizations;* *—Opportunities for improvement."*
(6)	**BASIS: GS-G-3.1 para. 5.4 states that** *"Where it is necessary to document processes, appropriate methods should be used, such as graphical representations, written instructions, checklists, flow charts, methods using visual media and electronic methods."*
R10	**Recommendation: RSC should upgrade its management system to comply with the IAEA Safety Requirements, in particular with respect to safety culture, application of a graded approach, organizational change management, management system review, and documenting processes.**

4.2. MANAGEMENT RESPONSIBILITY

The VATESI management demonstrates its commitment to the establishment, implementation, assessment and continual improvement of its management system through quality policy, demonstrating leadership and allocation of adequate resources.

The VATESI individual values, institutional values and behavioural expectations for the organization to support the implementation of the management system are defined in procedure "Development of Organizational Culture". All VATESI employees sign and confirm that they are familiar with the procedure. VATESI has developed several communications channels to familiarize the employees with integrated management system documents.

VATESI identified interested parties and their expectations in the "Manual of Integrated Management System" and in the "Procedure document for monitoring of interested parties". Expectations of interested parties have been monitored yearly using appropriate questionnaires. Feedback from interested parties is also possible by using website questionnaires.

The VATESI strategic planning group has been developing a "Strategic Plan" every year for the period of three years on the basis of the "Methodology for Strategic Planning" approved by the Government. VATESI has also developed a "Procedure Document for Strategic Management". On the basis of the strategic plan, the necessary resources, including human resources, are acquired. The strategic plan is the main document where strategic objective, annual goals, tasks and measures of VATESI are defined. VATESI Annual Activity Plan details the implementation of the Strategic plan. Annual Work Plans of VATESI Divisions detail the implementation of Strategic Plan and Annual Activity Plan. The strategic planning group reviews the realization of the plans. The effectiveness of the implementation of strategies, plans and objectives is measurable at different level of the organization.

VATESI management responsibility for the management system is defined in the "Manual of Integrated Management System", however the IRRS team noted that the ultimate responsibility of the senior management for establishing, implementing and assessing the management system is not clearly stated. VATESI appointed a management representative for the management system, who reports directly to the Head of VATESI.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: VATESI's "Manual of Integrated Management System" does not clearly state that senior management is ultimately responsible for establishing, implementing, assessing and continually improving the management system.	
(1)	**BASIS: GS-R-3 para. 3.12 states that** *"Senior management shall be ultimately responsible for the management system and shall ensure that it is established, implemented, assessed and continually improved."*
S11	**Suggestion: VATESI should consider clearly expressing in the management system documentation the senior management ultimate responsibility for establishing, implementing, assessing and continually improving the management system.**

RSC senior management commitment to the establishment, implementation, assessment and continual improvement of the management system is expressed by developing the Quality Policy, organizational goals and processes and in providing adequate resources for the development of management system.

RSC individual values, institutional values and behavioral expectations are not defined in an individual document. However, RSC developed several internal rules where RSC values are defined, i.e. "Rules on behavior on work", "Statute on work in organization". RSC quarterly organizes whole day meetings with the staff were issues like mission, vision, strategic plan, annual plan, management system review conclusions are discussed.

The RCS interested parties are defined in RSC "Quality Manual". The IRRS team noted that the RSC defined as interested parties customers and workers using radiation sources. However, other stakeholders such as the public and other regulatory bodies and public administration are not recognized as interested parties. Feedback from interested parties and public is possible by using a website questionnaire. Feedback is analyzed once a year. Responsible persons prepare a report on analyzed feedback, and the report is later evaluated by the Director. The report is presented to all employees. The IRRS team noted that RSC uses feedback information and implements corrective measures. However, trends from feedback information are not analyzed.

RSC defines a "Strategic Plan" which constitutes a part of the "Strategic plan of the Ministry of Health". In accordance with the strategic plan, the "Annual Working Plan" is prepared. The annual working plan is reviewed quarterly. Each employee has his/her own plan with the defined working tasks, time limits and trainings. The senior management periodically reviews the implementation of the strategic and annual working plans. The realization of individual plans is presented in the individual reports.

RSC management responsibility for the management system is defined in the "Management Manual". A management representative for quality within advance defined responsibilities and who directly reports to the senior management, is appointed.

4.3. RESOURCE MANAGEMENT

VATESI has defined that resources include financial resources, human resources, competences, know how, knowledge, infrastructure and working environment. The senior management is responsible for provision of adequate resources.

The amount of resources necessary to carry out activities are defined in the "Strategic Plan" and in the "Annual Plan".

The maximum number of positions in VATESI is established by the Government. The education, experience and skills needed for particular positon are set in job descriptions for employees. Competence requirements are determined according to the tasks and duties for each position. Detailed training requirements based on the competence needs are under development.

Different methods of trainings are used in order to keep and improve competences of employees. Annual evaluation of employees' competences and activities is conducted according to the requirements of the Law on Civil Service. During this evaluation, the training needs are established and defined in the "Annual Training Plan". However, the IRRS team noticed that there is no periodical assessment of the effectiveness of employees training.

Such assessment is not addressed by the management system process for training; this observation is addressed in Suggestion 4 of Section 3.3.

VATESI developed a procedure "Personnel and Knowledge Management". Most of the information needed for implementing the knowledge management process has been identified already. However, the IRRS team noticed that the database used for knowledge management is not easily accessible for all employees.

VATESI infrastructure includes vehicles, office equipment, IT hardware and software. To provide, maintain and re-evaluate infrastructure and working environment VATESI has developed the process "Management of Working Environment and Infrastructure".

The RSC resources include staff, facilities, services and logistic support. The RSC quality policy states that senior management is responsible for provision of resources for the implementation and continual improvement of management system. Such resources are defined in the annual working plan.

RSC has developed a "Personal Management Strategy" which defines the staff management system. Work duties for each employee are defined in the work descriptions. A work description includes position and main activities, special requirements (education, knowledge of languages) tasks and responsibilities. However, skills and trainings needed for obtaining and improving competences are not defined in this document. RSC has created a system for the recruitment of new staff with appropriate requirements for individuals, on the job training after starting the work and periodical trainings. For the training of staff, RSC has developed a process described in the procedure "Human Resource Management", and a working instruction "Recruitment of the Civil Servants and Employees Working Under an Employment Contract. Qualification Improvement". The training also includes familiarizing newcomers with the main principles of the management system. Each training of newcomer finishes with an exam.

Maintaining the required level of competence and proficiency is performed by regular trainings that are planned annually. The needs for training are also defined during the annual evaluation of employee competences. The personnel manager is responsible for preparing an annual plan of the training and improvement of the personal skills. All planning actions are described in procedure "Human Resource Management" and working instruction "Recruitment of the Civil Servants and Employees Working Under an Employment Contract Qualification Improvement". After any training, each employee is required to prepare report on the training which is later assessed by the senior management.

RSC carries out a lot of activities which refer to knowledge management, however it seems that these activities are not managed in a systematic way. The procedure "Human Resource Management" also describes the system for measuring the effectiveness of training.

A description of the infrastructure and work environment is given in chapter 6.4 "Working Environment" of the RSC quality manual. The needs for equipment and goods for work and plans for purchasing are analyzed weekly in each division. Senior staff is responsible to ensure the proper and safe working environment that promotes employees motivation.

4.4. PROCESS IMPLEMENTATION

VATESI's integrated management system is based on a process approach. VATESI has identified 30 processes which are grouped into core, management and supporting processes. Each process is documented by a procedure. The processes are evaluated through indicators

measuring their effectiveness and efficiency. The performance indicators are reviewed, and possibly improved each year. An appointed management representative is responsible for the establishment of processes map and for suggesting improvements when needed. Each process has its designated process owner, assigned by an order of the Head of VATESI. The responsibilities of process owner are defined in the "Manual of Integrated Management System".

VATESI has established and documented the process "Documents and Records Management". This procedure provides a "Documentation Plan" where the retention time for each group of documents and record is stated.

The management policy and the general objectives of the integrated management system are periodically communicated to the staff. The management policy is published on the website of VATESI and is accessible to other stakeholders. External communication with interested parties is defined and specified in the procedure "Document for Monitoring of Interested Parties" as well as in procedure documents of individual processes that have direct connection to interested parties.

Very intensive internal communications take place via face-to-face communication among the staff, during meetings on different levels, by e-mail and intranet, in training and educational events, and by mobile and stationary means of communication.

The process "Control of organizational changes" is not described in a separate document. However, the procedure to perform organizational change is described in the "Project Management Procedure". The organizational changes which have an impact on the organization and are of potential importance to safety are managed as projects.

RSC management system is based on a process approach. RSC has identified 29 processes which are described in procedures. The implementation of the processes is supported by 67 working instructions which explain how the work is to be prepared, reviewed, carried out, recorded, assessed and improved. Processes are divided into management, executive and supporting processes. RSC has prepared a schematic process map. Each process has a designated processes owner. The IRRS team noted that the responsibilities of process owner are not defined in the management system documentation. A standard format for description of procedures and working instruction was developed and approved by RSC and it is used by all staff that prepare management system documents. However, flowcharts for presenting the flow of the processes are not required. This observation is addressed in Recommendation 10 in Section 4.1 above.

RSC has prepared a process description "Management of Records" where all record keeping issues relevant to the activities of RSC are described. RSC is using an efficient software program for documents and records management "Kontora" in which copies of all documents and records received and sent are stored. Each worker can access and use "Kontora".

For communication of information on radiation protection, health and environment related goals to the stakeholders and public, many channels are used by RSC. Those channels include the RSC website, seminars, conferences, trainings, fellowships, publications, meetings with public, work with school children and students from universities and colleges.

RSC has not developed a special procedure which describes the method for internal communication However, within RSC the extensive internal official and unofficial communications are provided through different meetings and during daily work. Every week there is a management meeting and meetings in separate units, and every quarter there is a meeting with all the employees.

RSC has no procedure for managing organizational changes. However, organizational changes can be made only after an analysis of the situation. Such changes could be done due to foreseen additional work, changes in the national budget rules or for other reasons. Upon suggestions of RSC, the Minister of Health is reviewing and approving any new organizational structure.

4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

The effectiveness of the VATESI integrated management system is monitored and measured using independent evaluation, monitoring of interested parties, internal audits, monitoring of processes, self-assessment, performance indicators and management review. VATESI management system is also checked yearly by a certification organization.

Internal audits are performed by trained auditors on the basis of the audit program covering the three year period and annual audit plans. The audits are performed in accordance with the procedure "Internal Audit of the Management System". VATESI is also performing joint audits of different processes where the most critical elements of the management system such as the interaction and interfaces of different processes are reviewed. Each process is audited at least once per three years.

VATESI management, at all levels, perform self-assessment through the evaluation of the implementation of Work Plans of Divisions and by the assessment of the staff.

VATESI introduced the self-assessment of safety culture. The procedure "Development of Organizational Culture", inter alia, describes the elements of safety culture and VATESI values. A questionnaire for self-assessment of safety culture, prepared in accordance with GS-G-3.1 (para 2.36), is a part of this procedure. VATESI has twice performed a self-assessment of the safety culture using this questionnaire. Based on the feedback information from the answers, areas of concern were identified and appropriate measures have been taken.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: VATESI introduced the self-assessment of safety culture.	
(1)	**BASIS: GS-R-3 para. 6.2 states that** *"Senior management and management at all other levels in the organization shall carry out self-assessment to evaluate the performance of work and the improvement of safety culture."*
GP3	**Good practice: VATESI conducts self-assessment of safety culture.**

Management review meetings are conducted at least once per year in VATESI. The purpose of a management review is to ensure that the integrated management system complies with requirements, policy and performance objectives. The process of management review is defined in the procedure "Management System Review and Improvement".

VATESI established the process managing of non-conformances and corrective actions. The process of identification of non-conformances, determination of their causes and remedial actions is described in the procedure "Managing of Non-conformances and Corrective Actions". The evidences of all non-conformances are kept in the VATESI database.

RSC performs measurement, assessment and review processes through internal audits, external audits, collection of information from interested parties, self-assessments, and by management system reviews.

RSC prepares a yearly plan for internal audit. Each year at least 21 internal audits are organized. IRRS team noted that internal audits are organized separately for each process. However, joint audits of interacting processes are not foreseen.

RSC has implemented arrangements for the review and improvement of its management system. RSC conducts the assessment of the effectiveness of management system on annual management system review. The scope of a management system review is described in the management manual. The IRRS team noted that management system review do not systematically cover "Lessons learned from other organizations", which is one of the requirements of GS-R-3 (para 6.8). This observation is addressed in Recommendation 10 in Section 4.1 above.

The RSC procedure "The Management of the Non–conformances" sets requirements for the reporting of non–conformances affecting its processes and activities, determining the causes of the non–conformances and taking corrective actions (assessment of the effectiveness of the corrective actions). Non-conformances can be reported by each RSC employee.

4.6. SUMMARY

VATESI has established an integrated management system which is in line with the IAEA standard GS-R-3 and ISO standard 9001:2008. In 2015, VATESI successfully passed the external audit and acquired the certification according to the requirements of the standard ISO 9001:2008. VATESI management system is very well documented. The introduction of effective safety culture self-assessment is undoubtedly a good practice. According to the requirements of IAEA standard GS-R-3 continual improvement of the management system is needed. Special attention should be paid to consistency of management system documents and continuous improvement of management systems based on relevant IAEA standards, including the application of a graded approach.

RSC has developed a comprehensive management system which is in force since 2009 when RSC gained its first certificate according to the requirements of ISO standard 9001:2008. The RSC management system defines all RSC activities, and is process oriented. However, the RSC management system does not consider some additional requirements set by the IAEA standard GS-R-3, particularly safety culture, graded approach and requirements on defining the process of organizational change.

5. AUTHORIZATION

5.1. GENERIC ISSUES

The IRRS team has reviewed approaches to authorization as defined in the Lithuanian legal system and regulated by VATESI and RSC and found that, other than in a small number of cases, they generally meet IAEA safety standards. Details are provided in the following sections.

One generic issue was however identified during the mission, namely in regard to attaching conditions to the licences issued by VATESI and RSC. VATESI's approach of attaching conditions to operating licences in order to ensure appropriate standards of safety has provided a flexible and efficient method of regulation consistently over many years. Although RSC includes details in annexes of its licences regarding sources, workers and premises, it does not use operational licence conditions at present. RSC recognized in this review that it can see advantages of efficiency and effectiveness from adopting licence conditions as an alternative to using Safety Requirements in some situations.

Using licence conditions provides a good means of regulating according to a graded approach and is fully in line with established international practice. However, the approach adopted in the nuclear sector is not in line with standard regulatory approaches in use across the Lithuanian economy and therefore licence conditions are not used for radiation sources and may be discontinued in nuclear regulation.

Not using, or discontinuing the option of attaching licence conditions would mean VATESI and RSC would not be compliant with IAEA Safety Requirements and for nuclear facilities, discontinuing would be a retrograde step for effective regulation of nuclear and radiological safety. In consequence, the following suggestion is made.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Attaching conditions to licences in order to ensure appropriate standards of safety provides a flexible and efficient method of regulation consistent with a graded approach and in line with established international practice. Not using, or discontinuing the use of licence conditions would mean national regulators are not compliant with IAEA Safety Requirements and for nuclear facilities, would be a retrograde step for effective regulation of nuclear and radiological safety.	
(1)	**BASIS: GSR Part 1 Requirement 23 states that** *"Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process."*
S12	**Suggestion: The government should consider introducing licence conditions to support VATESI and RSC's authorization processes regulated by the Law on Radiation Protection.**

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

The Lithuanian system for regulating the safety of nuclear power plants appears to meet IAEA Safety Requirements in all important respects. Specifically, VATESI uses a range of

types of authorization as a prerequisite for all facilities and activities affecting safety and all types of authorization require the applicant to submit an adequate demonstration of safety in support of its application. VATESI applies a graded approach to authorization, issuing licences in line with Lithuanian legal requirements, as well as permits and licence conditions under these licences and Orders and regulatory letters in line with relevant Nuclear Safety Requirements and Nuclear Safety Rules. VATESI's use of licence conditions is considered by the review team to be a particularly important component of the regulatory framework for NPPs.

The legal framework within which VATESI regulates caters explicitly for regulating all six lifetime stages set out in IAEA Safety Requirements (e.g. from site evaluation through operation and into final shutdown and decommissioning). The Law on Nuclear Safety is very thorough in this regard and all the legal and regulatory possibilities explored during this review appeared to have been foreseen and enacted within the legislation.

Some areas of the IAEA safety standards relevant to nuclear power plant operation could however, not be explored in detail during the mission in view of the time that has elapsed since the Ignalina NPP was in power operation, i.e. those we spoke to had no personal experience of authorizing an NPP in power operation. However, VATESI recognizes that this is an area that will need development in the event that new NPPs are constructed in Lithuania and this is reflected in the action plan developed following VATESI's self-assessment. More generally, the IRRS team was satisfied that any refinements to the current approaches to authorizing operating NPPs can be implemented within the timescales available before any new NPP would become operational.

The two items in VATESI's action plan relevant to this section reflect these sentiments. The items relate to establishing requirements on the format and content of Technical Specification documents (i.e. requirements relevant to other designs of NPP other than RBMKs) and preparing the Nuclear Safety Requirements document "Operation of Nuclear Power Plant" to align with recent changes in IAEA safety standards. Both these items are supported and neither is considered to represent a shortfall important enough to merit a specific suggestion or recommendation.

The IRRS team looked in detail at how VATESI applies a graded approach to authorization. As noted above, the IRRS team observed an overall graded approach that appears to be in line with established international practice for regulating NPPs. One minor exception to this general rule however, was in how VATESI uses regulatory letters to authorize all categories of safety-significant modifications to NPPs, irrespective of their importance to safety. However, noting that a graded approach is applied to a limited extent (i.e. the signatory of the letter depends on the category of the modification) and VATESI's scope to change its approach is limited by the national legal framework, the IRRS team made no suggestions to further develop this process.

5.3. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

Lithuania has ratified both the Espoo and Aarhus conventions and public involvement takes place in the Environmental Impact Assessment related to siting, construction and operation of facilities.

Regulations and requirements for design and safety assessment of Radioactive Waste Management Facilities (RWMFs) and Radioactive Waste Disposal Facilities (RWDFs)

related to particular facility life-stages (e.g. siting, design, construction and operation, as well as the closure and post-closure stages for RWDFs, are the following:

- Nuclear Safety Requirements BSR-3.1.2-2010 "Regulation on the Pre-disposal Management of Radioactive Waste at the Nuclear Facilities";
- Nuclear Safety Requirements BSR-3.1.1-2010 "General Requirements for Spent Nuclear Fuel Storage Facility of the Dry Type";
- P-2002-2: "Regulation on Disposal of Low and Intermediate Level Short Lived Radioactive Waste"; and,
- P-2003-02: "Regulation on Disposal of Very Low Level Radioactive Waste".

Some of the above-mentioned requirements and regulations are being updated as part of an improvement programme begun in 2015 and running to 2019.

The requirements regarding licences and permits in the area of nuclear safety are defined in the Law on Nuclear Safety. In addition, the Law on Radioactive Waste Management stipulates that "*the radioactive waste generator, engaged in activities in the area of nuclear energy subject to licensing and in activities involving nuclear and/or nuclear fuel cycle materials …shall not be required to obtain a separate licence or a temporary permit to manage radioactive waste".*

The Law on Nuclear Safety stipulates that "*A [single] general type licence may be issued with respect to several nuclear installations, if those installations are anticipated in one general design. At the applicant's request, it is possible to issue separate licences for separate nuclear power plant units*".

Closure of a disposal facility is regulated under the operational (or combined construction and operation) licence. The IRRS team was informed that revisions to Nuclear Safety Requirements (currently in draft) will require that the final closure plan (with an updated safety analysis report) will have to be submitted to VATESI two years prior to the proposed closure. However, the current version of these Nuclear Safety Requirements has no specification for these timescales.

The scope and content of safety cases for disposal facilities is not fully in line with IAEA safety standard SSR-5 (see Section 5.3 where a Recommendation is made). After closure, a separate licence is needed for the post-closure institutional control and this activity will be carried out by the Radioactive Waste Manager (currently Radioactive Waste Management Agency (RATA)) in compliance with the Law on Nuclear Safety.

A combined licence for construction and operation of a Very Low Level Waste (VLLW) disposal facility has been granted to the Ignalina NPP operator but following closure, surveillance of this repository will be carried out by the Radioactive Waste Manager.

The IRRS team was informed that the first storage facility for spent fuel at Ignalina was licensed in 2000. Currently there are 20 CASTOR and 98 CONSTOR casks storing spent fuel. VATESI requirements stipulate the need for a maintenance and testing programme at spent fuel dry storage facilities. Under this programme the casks undergo maintenance (corrosion, dose measurement, etc.) and testing (e.g. helium concentration monitoring, leak tightness).

The oldest casks date from 1999. The certificate on transportability of these casks was issued by Skoda (Czech Republic) for 10 years and is therefore no longer valid. In addition, the licensing provisions at both the first and second spent fuel storage facilities at Ignalina do not

include provisions to enable the eventual transportation of the casks for either further processing or final disposal.

Taking into account the requirement in GSR Part 1 to manage radioactive waste in an integrated, systematic manner up to its disposal, VATESI will need to establish (in due time) measures to ensure the post-storage transportability of all spent fuel casks used now and in future. This may include planning and carrying out periodic safety reviews focusing specifically on compliance with the transport regulations and related activities for obtaining the necessary information regarding ageing of the cask components and the spent fuel for transport after decades of storage. Recent IAEA activities including the formation of a Spent Fuel Management Network may provide further insights, e.g. into international practices in ensuring that dual purpose casks for storage and transport of spent nuclear fuel may be transported in compliance with the IAEA safety standard SSR-6. A recommendation on maintaining the suitability of spent fuel casks for post-storage transport is made below.

Licences for non-nuclear facilities using radiation sources are granted by RSC. The licence applicant is required to provide information about its arrangements to collect and store spent sources and other radioactive wastes unless these are below clearance levels, or the spent sealed sources can be returned to supplier. Spent sources and other radioactive wastes that are above clearance levels will go to RATA's buffer storage facility (regulated by RSC). Later, these items will be transported to a store at Ignalina (regulated by VATESI).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The licensing and operational requirements for spent fuel storage facilities do not require measures for maintaining the transportability (i.e. for the entire storage period) of dry interim storage casks in compliance with IAEA regulations for the safe transport of radioactive materials.	
(1)	**BASIS: GSR Part 1 Requirement 10, para. 2.30 states that** "*Radioactive waste generated in facilities and activities shall be managed in an integrated, systematic manner up to its disposal. The interdependences of the steps in the entire management process for radioactive waste, and likewise for spent fuel, shall be recognized."*
(2)	**BASIS: GSR Part 5 Requirement 6, para. 3.22 states that** *"It is necessary that those persons responsible for a particular step in the predisposal management of radioactive waste, or for an operation in which waste is generated, adequately recognize these interactions and relationships so that the safety and the effectiveness of the predisposal management of radioactive waste may be considered in an integrated manner. This includes ..... the implications of transporting and disposing of waste. There are two issues in particular to be addressed: compatibility (i.e. taking actions that facilitate other steps and avoiding taking decisions in one step that detrimentally affect the options available in another step) and optimization (i.e. assessing the overall options for waste management with all the interdependences taken into account)."*
(3)	**BASIS: GSR Part 5 Requirement 6, para. 3.21 states that** *"Owing to the interdependences among the various steps in the predisposal management of*

	radioactive waste, all activities from the generation of radioactive waste up to its disposal, including its processing, are to be seen as parts of a larger entity, and the management elements of each step have to be selected so as to be compatible with those of the other steps. This has to be achieved principally through governmental and regulatory requirements and approaches."
R11	**Recommendation: VATESI should set up requirements, as appropriate, for establishment of a process to ensure post–storage transport of spent fuel in compliance with IAEA regulations for the safe transport of radioactive materials.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: A combined construction and operation licence for a disposal facility may cover a very long time period from construction until post-closure surveillance start and there is no clear specified step in legal framework between operation and closure of a disposal facility.	
(1)	**BASIS: SSR 5, Requirement 1 states that** *"The government is required to establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities shall be clearly allocated for disposal facilities for radioactive waste to be sited, designed, constructed, operated and closed. This shall include: confirmation at a national level of the need for disposal facilities of different types; specification of the steps in development and licensing of facilities of different types; and clear allocation of responsibilities, securing of financial and other resources, and provision of independent regulatory functions relating to a planned disposal facility."*
(2)	**BASIS: GSR PART 1, Requirement 24 states that** *"The applicant shall be required to submit an adequate demonstration of safety in support of an application for the authorization of a facility or an activity."*
(3)	**BASIS: GSR PART 1, Requirement 24 para 4.29. states that** *"Different types of authorization shall be obtained for the different stages in the lifetime of a facility or the duration of an activity. The regulatory body shall be able to modify authorizations for safety related purposes. For a facility, the stages in the lifetime usually include: site evaluation, design, construction, commissioning, operation, shutdown and decommissioning (or closure). This includes, as appropriate, the management of radioactive waste and the management of spent fuel, and the remediation of contaminated areas. For radioactive sources and radiation generators, the regulatory process shall continue over their entire lifetime."*
(4)	**BASIS: SSR 5 Requirement 11 states that** *"Disposal facilities for radioactive waste shall be developed, operated and closed in a series of steps. Each of these steps shall be supported, as necessary, by iterative evaluations of the site, of the options for design, construction, operation and management, and of the performance and safety of the disposal system."*

R12	**Recommendation: VATESI should initiate amendment of the legal framework to ensure there are distinct steps for authorizing the closure of repositories.**

5.4. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

Lithuanian legislation requires the authorization of facilities and activities involving radiation sources and RSC is the competent regulatory authority on these matters (other than for activities involving sources at NPPs, where VATESI is the competent authority). The legislation also establishes the administrative and safety requirements for obtaining an authorization, the types of authorization needed and provides for amending, suspending and revoking authorizations.

The process of review and assessment in support of the authorization process follows the requirements established in legislation and RSC QMS procedures. Documentation recording RSC authorizations is produced following a specific RSC QMS procedure and all amendments, suspensions and revocations are duly recorded. The licensee is informed in writing every time a licence is amended, suspended or revoked and the list of licences and temporary permits issued by RSC is available on RSC's website.

VATESI has implemented an equivalent authorization process for sources used in nuclear facilities and applies the same legal framework as used by RSC.

Lithuania has written to the IAEA Director General expressing its support for IAEA's Code of Conduct on the Safety and Security of Radioactive Sources and the associated 'Guidance on the Import and Export of Radioactive Sources'.

According to Lithuanian legislation, all activities and practices involving radiation sources need to be authorized, with the exception of practices involving sources below exemption levels, shipment and storage of radiation generators and shipping of radioactive materials in excepted packages as specified in international agreements. Radiation facilities and activities involving exempted practices need to be notified to RSC for the purposes of registration.

The legislation, including Government Decrees on Rules on Licensing, also establishes the requirements for obtaining an authorization and the associated demonstration of safety that needs to be submitted. Two forms of authorizations are defined in the legislation for activities with sources: licences and temporary permits that can be granted for specific practices and circumstances. As noted above in Section 5.1, RSC is not however allowed to attach any additional conditions to licences.

When applying for an authorization, RSC requires applicants to provide an explanation and justification of the practices to be authorized, details of the worker radiation protection programme in place and information about the radiation sources requiring authorization. The legislation also provides for additional information that needs to be supplied for various different types of practice.

Information supporting the authorization process appears to be adequately registered and recorded by RSC. This includes issued authorizations, inspection reports, requests and documentation provided by the licensees, adopted enforcement actions and accident and incident registers. All amendments, renewals, suspensions and revocations are registered in the Radiation Protection Information System (RSIS) and are also kept in paper form.

Inspections and periodic reports are used for verifying the optimization of safety. Information in RSIS and RSC Register is available on-line to licensees, who can get an up-to-date overview of their sources, workers, occupational exposures, licences, permits, inspection reports, non-compliances and time limits thereof.

Though the legislation requires that all practices must be authorized and conducted in accordance with the basic principles of radiation protection, no scope is provided for generic justifications of practices. This means that every applicant has to justify its practices on a specific basis, even for relatively common and replicated practices such as in nuclear medicine or radiation therapy. The IRRS team considers there would be no detriment to safety and considerable scope for efficiencies if generic justifications were to be introduced.

In regulating radiation sources, the graded approach is partly applied, through categorization of sources, based on the risk posed by the different types of sources, through the use of two different inspection frequencies taking into account the risk of the radiation sources, through compulsory training programmes of distinct extent on radiation protection for workers and RPO, through the process of review and assessment, when the applicants have to demonstrate compliance with stipulated safety requirements depending on the type of practice. Although these instruments are available, RSC takes partial account of a graded approach in its authorization processes and supporting review, assessment at inspection activities. Consequently RSC uses a significant amount of its resources on regulating low risk practices.

Since the notification and registration of lower risk sources are not yet part of the Lithuanian authorization system, these sources also require a licence. In addition, based on the current legislation, details of the licenced sources and all personnel working with them have to be listed in an annex to the licence. This means that every change in personnel, and even minor technical changes to the information on the sources, requires the annex of the licence to be amended, creating a significant administrative burden both on RSC and on the applicants with little benefit to safety. These matters lead to the following suggestion:

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RSC takes account of a graded approach in a limited way in its authorization processes and supporting review, assessment and inspection activities. Consequently RSC uses a significant amount of its resources on regulating low risk practices.	
(1)	**BASIS: GSR Part 3 Requirements 3, item 2.31 states that** *"The regulatory body shall adopt a graded approach to the implementation of the system of protection and safety, such that the application of regulatory requirements is commensurate with the radiation risks associated with the exposure situation."*
S13	**Suggestion: RSC should consider improving its implementation of a graded approach in the system of protection and safety.**

5.5. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

According to the Law on Nuclear Safety, decommissioning a nuclear installation requires a licence. The licence can be amended at the request of licensee when a nuclear facility moves to the next stage of its lifecycle (e.g. from operation to decommissioning) or if the licensee seeks to carry out dismantling works at the facility. For NPPs, an operational licence has to be

kept and maintained during the shutdown period while nuclear fuel (including spent nuclear fuel) remains in the nuclear reactor unit.

The documents that need to be submitted in the authorization process for decommissioning are listed in the Law on Nuclear Safety and in the regulations. Detailed Nuclear Safety Requirements are also set, including the need for a decommissioning strategy, and for planning and conducting decommissioning activities, performing safety analysis, justification of the decommissioning, radiological surveys, and for a final report on decommissioning for demonstration of compliance with end-state criteria.

The IRRS team was informed that there is no requirement to update the decommissioning plan for non-nuclear licensees. However, when a non-nuclear facility renews its licence for use and storage of a sealed source, all relevant documents are required to be updated in accordance with Government Order No 653.

5.6. AUTHORIZATION OF TRANSPORT

The requirements for approval related to the design and shipment of packages are established through a range of legislative measures. The measures enact international agreements and apply to national as well as international transport of radioactive material. The international agreements include the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). Regulation concerning the International Carriage of Dangerous Goods by Rail (RID), the Agreement on International Goods Transport by Rail (SMGS), the International Maritime Code for Dangerous Goods (IMDG Code) and International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air. The requirements apply to specific circumstances including special form radioactive material, fissile material (including fissile material excepted under para. 417(f) of SSR-6), packages of Types B(U), B(M) and C, packages containing more than 0.1 kg of uranium hexafluoride and certain shipments and transports under special arrangements.

RSC and VATESI are established by Government Resolution as the competent authorities for authorization (design or shipment approval) for the transport of radioactive material. However, their exact responsibilities are not defined in the Law on Nuclear Safety and the Law on Radiation Protection in all areas. VATESI has identified a corrective action for this in its action plan.

RSC has a written procedure for the validation of package designs approved by foreign countries. The procedure requires that documents supporting such applications have to include a detailed description of the packaging and content and a demonstration of compliance with the regulations. VATESI could improve the efficiency of its approval process by defining and publishing procedures for the main types of approvals it issues related to dangerous goods transport regulations. This is already included in VATESI's action plan.

Besides the above-mentioned approvals, carriers wishing to transport radioactive material other than in excepted packages in Lithuania need a licence (or a temporary permit) issued by RSC or VATESI. These licences are the basis for supervision of the operations. Procedures for application for and issuing of licenses are well-defined. Additionally, each shipment of radioactive material (other than for excepted packages) in, into or out of Lithuania requires a transport permit from RSC or VATESI. Depending on the assessment of safety and security of the proposed transport, this permit may place special conditions on the shipment.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The responsibilities of RSC and VATESI for approval required in SSR-6, para. 802 are not fully defined in the legal system of Lithuania.	
(1)	**BASIS: SSR-6, para. 802 states that** *"802. Competent authority approval shall be required for the following:* *(a) Designs for:* *(i) Special form radioactive material (...);* *(ii) Low dispersible radioactive material (...);* *(iii) Fissile material excepted under para. 417(f) (...);* *(iv) Packages containing 0.1 kg or more of uranium hexafluoride (...);* *(v) Packages containing fissile material, unless excepted by para. 417, 674 or 675 (...);* *(vi) Type B(U) packages and Type B(M) packages (...);* *(vii) Type C packages (...).* *(b) Special arrangements (...).* *(c) Certain shipments (...).* *(d) Radiation protection programme for special use vessels (...).* *(e) Calculation of radionuclide values that are not listed in Table 2 (...).* *(f) Calculation of alternative activity limits for an exempt consignment of instruments or articles (...)."*
(2)	**BASIS: TS-G-1.5, para. 2.6 states that** *" The responsibilities and duties of the competent authority (regulatory body) are required to be defined within the national legal framework of a State, ... The responsibilities of the competent authority include:* *(b) Activities in connection with discharging these responsibilities for the safe transport of radioactive material, such as:* *(iii) Issuing approvals."*
R13	**Recommendation: The government should revise the Law on Nuclear Safety and the Law on Radiation Protection to define all the responsibilities of VATESI and RSC for the transport-related approvals.**

5.7. SUMMARY

The IRRS team found that the approaches to authorization followed by VATESI and RSC are generally in accordance with IAEA Safety Requirements.

There were however exceptions in a few areas, leading to recommendations and suggestions relating to the attaching of licence conditions; authorizations to ensure the suitability of spent fuel casks for post-storage transport; authorizing the closure of repositories; RSC's application of a graded approach and omissions in the regulatory framework for transport-related approvals.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

The IRRS team observed no generic safety issues under Section 6 on Review and Assessment.

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

VATESI's approach to review and assessment of information important to safety appears to meet IAEA Safety Requirements in all important respects. Specifically, VATESI reviews and assesses relevant information to determine whether NPPs and activities undertaken at these plants comply with legal and regulatory requirements in order to inform its authorization and other regulatory decisions, applying a graded approach. These legal and regulatory requirements include all expected aspects, such as in regard to submissions for authorizations, periodic safety analysis reviews, and in response to adverse inspection findings and following incidents and events.

VATESI applies a comprehensive and detailed process in managing its review and assessment activities. Procedure PR-5 (Procedure Document for Review and Assessment of Safety Justification Documents) describes how work is assigned (to different VATESI divisions) and the goals that the work needs to achieve. PR-5 also describes the process for resolving review and assessment issues with the operators and how review and assessment conclusions feed into different types of authorization decisions VATESI makes.

PR-5 is a relatively new process and as such, VATESI's self-assessment identifies the need to make further improvements in light of its experience in applying it. Further to these, the review team recommends that improvements should also be made in how reviews and assessments are reported. Specifically, we consider greater detail should be recorded describing the technical reasons for the conclusions made in the review or assessment, including the reasons for not making particular conclusions. The team also suggests that a process of peer review should be added to PR-5 for the most significant reviews and assessments VATESI performs. Further details are provided in the recommendation below.

VATESI employs nuclear safety experts in all the usual technical disciplines relevant to nuclear safety. Moreover, its processes allow for technical support organizations to supply further resources in the event that there is insufficient internal resource or capability available. The IRRS team however notes that in some areas, VATESI only employs single experts and that further recruitment will therefore likely prove necessary if and when Lithuania takes forward proposals for new NPPs. This is addressed in Recommendation R7 in Section 3.

VATESI carries out its reviews and assessments primarily against Lithuanian Nuclear Safety Requirements and Nuclear Safety Rules (as provided for in the Law on Nuclear Safety). VATESI also uses relevant IAEA safety standards, applying these through the Law on Nuclear Safety as so-called Normative Technical Standards (standards which it has required the licensee to adopt as its own, so that adhering to the standard becomes a legally enforceable Nuclear Safety Requirement). VATESI's use of standards and guidance are discussed further in Section 9.

As noted above, VATESI performs its reviews and assessments in accordance with its internal procedure PR-5. PR-5, in accordance with IAEA Safety Requirements, is clear that a graded approach must be applied in VATESI reviews and assessments. However, this aspect

of the process is only described towards the end of the procedure and then only in regard to sub-process P (i.e. when the technical specialists perform their reviews) rather than to the review and assessment process as a whole. Based on our discussions held, VATESI staff noticed that, there are no explicit IAEA safety standards published, dedicated for practical application of a graded approach for reviews and assessments. VATESI staff also emphasized that in accordance with requirements BSR-1.1.1-2014 "Rules of Procedure for Drafting Nuclear Safety Requirements and Nuclear Safety Rules" (para 13) and internal procedure, the nuclear safety requirements and rules shall be drafted taking into account graded approach, so the review and assessment against such regulation automatically applies the graded approach. The application of a graded approach for reviews and assessments described in PR-5 was based mainly on national experience. This suggests that the PR-5 process needs further development and a suggestion has been made.

In accordance with Lithuanian law, VATESI only regulates matters relating to nuclear and radiological safety, with other regulatory bodies having responsibility for regulating non-radiological safety matters at NPPs. Interfaces between radiological and non-radiological safety aspects are managed through bilateral arrangements between these regulators so that VATESI is invited to comment on NPP reviews and assessments completed by other regulators and vice-versa. These arrangements ensure that each regulator is made aware of issues of relevance to other regulators. However, in its self-assessment, VATESI recognizes that its current approach falls short of IAEA requirements for nuclear and radiological safety assessments to take direct account of non-radiological risks and for this matter to be considered explicitly by licensees. The IRRS team, noting the importance of non-radiological risks in regulating decommissioning activities at NPPs in a holistic manner, supports VATESI's proposals for corrective action and has made a suggestion below to affirm this.

VATESI's "Oversight of Economic Entities" process provides a systematic approach to performing integrated annual safety assessments of licensee safety performance over the previous year. The process tabulates how each licensee has performed on a requirement by requirement basis and assigns a Red, Amber or Green rating accordingly. This then leads to explicit recommendations for VATESI's regulatory priorities for the following year. In its self-assessment however, VATESI has recognized that further work is needed to better integrate the outputs from its nuclear power plant review and assessment work into the Oversight process. In addition, the process is at present only an internal one and its conclusions are not shared with the licensees. This latter aspect falls short of IAEA Safety Requirements and so a suggestion is made below.

In view of proposals in Lithuania for new build NPPs, the review team looked at how VATESI will ensure that its reviews and assessments of the design and operation of any new NPPs will be optimized in line with wider international experience and regulatory decisions. A suggestion in Module 13 has been therefore been made to encourage VATESI to further develop its relationships with overseas regulators regulating plants of similar designs to that proposed in Lithuania.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: Other than recording the conclusions of its completed reviews and assessments, VATESI not always makes records documenting this work. Specifically, there are no records of the issues considered during the work, the depth of these considerations, the name of the specialist performing the work and justifications for why particular aspects were considered acceptable. Consequently there is no written basis to support decisions on

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
the conclusions and no means for undertaking peer reviews of completed reviews or assessments. In contrast, when the work is performed by an external contractor, full records are made.	
(1)	**BASIS: GS-R-3 para. 5.16 states that** *"The organization shall confirm that products meet the specified requirements."*
(2)	**BASIS: GS-R-3 para. 5.17 states that** *"Products shall be provided in such a form that it can be verified that they satisfy the requirements."*
R14	**Recommendation: VATESI should, as part of its planned work to further develop its review and assessment procedures, include specific requirements for recording the review and assessment work undertaken.**
S14	**Suggestion: VATESI should consider a possibility of adding formal peer review to its review and assessment processes, applying a graded approach.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Though VATESI's procedure PR-5 governing its review and assessment activities is explicit in requiring a graded approach from those carrying out such activities, the procedure does not appear to encourage or detail the practical application of a graded approach in determining what and how review and assessment tasks should be assigned and undertaken.	
(1)	**BASIS: GSR Part 1 Requirement 26 states that** *"Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."*
S15	**Suggestion: VATESI should consider further developing its procedures for review and assessment so that it is clear that the graded approach applies at all levels within its organization and perform necessary training.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: VATESI's Oversight of Economic Entities process provides a systematic process for performing integrated annual safety assessments of Operating Organization safety performance over the previous year. VATESI has nevertheless recognized in its self-assessment that further work is needed to better integrate the outputs from its nuclear power plant review and assessment work into this process. In addition, the process is at present only an internal one, and its conclusions are not shared with the licensees.	
(1)	**BASIS: GSR Part 1 Requirement 26, para. 4.46 states that** *"For an integrated safety assessment, the regulatory body shall first organize the results obtained in a systematic manner. It shall then identify trends and conclusions drawn from inspections, from reviews and assessments for operating facilities,*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	and from the conduct of activities where relevant. Feedback information shall be provided to the authorized party. This integrated safety assessment shall be repeated periodically, with account taken of the radiation risks associated with the facility or activity, in accordance with a graded approach."
S16	**Suggestion: VATESI should consider further developing its Oversight of Economic Entities process to provide feedback to the Operating Organization and improve how its review and assessment outputs are integrated within this process.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: VATESI has identified that the current Nuclear Safety Requirements do not require licensees to assess explicitly how nuclear and radiological risks are affected by non-radiological risks and also that its review and assessment processes do not take this interrelation directly into account. In consequence it has added an item to its action plan to improve how this aspect of its regulation is achieved in practice.	
(1)	**BASIS: GSR Part 1 Requirement 26, para. 4.47 states that** *"Risks that are not related to radiation may arise in the operation of facilities or the conduct of activities, and these risks shall also be taken into account in the decision making process of the regulatory body."*
(2)	**BASIS: SSR2/2 Requirement 23 para. 5.26 states that** *"The operating organization shall establish and implement a programme to ensure that safety related risks associated with non-radiation-related hazards to personnel involved in activities at the plant are kept as low as reasonably achievable. The non-radiation-related safety programme shall include arrangements for the planning, implementation, monitoring and review of the relevant preventive and protective measures, and it shall be integrated with the nuclear and radiation safety programme."*
S17	**Suggestion: VATESI should consider improving its processes and associated national legal framework so that non-radiological risks are taken into account explicitly in licensee safety submissions and its associated reviews and assessments.**

6.3. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

The following Nuclear Safety Requirements and Regulations define requirements for the safety assessment of radioactive waste management facilities as well as requirements related to particular facility life-stages (e.g. siting, construction, operation, including closure and post-closure stages for disposal facilities):

- Nuclear Safety Requirements BSR-3.1.2-2010, "Regulation on the Pre-disposal Management of Radioactive Waste at the Nuclear Facilities";

- Nuclear Safety Requirements BSR-3.1.1-2010, “General Requirements for Spent Nuclear Fuel Storage Facility of the Dry Type”;
- P-2002-2, “Regulation on Disposal of Low and Intermediate Level Short Lived Radioactive Waste”; and
- P-2003-02, “Regulation on Disposal of Very Low Level Radioactive Waste”.

In addition, a periodic safety evaluation report is required at least every 10 years after a permit for industrial operation of the radioactive waste management facility has been issued.

The IRRS team was informed that as part of its authorization processes, VATESI reviews, assesses and approves technical specifications for the design of a RWMF or RWDF, utilizing external experts. The technical specifications have to be met according to requirements established by the competent authorities, including VATESI.

6.4. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

Under Lithuanian legislation, RSC is responsible for authorization of practices involving radiation sources, control of compliance with the standards of emission of radionuclides into the environment from radiation facilities and control of compliance with radiation protection requirements. VATESI has equivalent responsibilities and duties for activities involving sources in nuclear facilities.

RSC and VATESI perform reviews and assessments to determine whether the licensees comply with applicable safety requirements and regulatory conditions. The supporting documentation required for an authorization application is specified in the legislation which, together with QMS procedures, is used as the basis for regulatory review and assessment. A pre-operational inspection is carried out prior to issuing an authorization and is used for verifying if the safety framework presented by the applicant is in place and adequate.

RSC reviews and assesses activities related to authorization matters falling under its regulation, safety evaluation and for facilities performing activities with radiation sources of categories I, II and III, security requirements. Design requirements are included in the assessed information and, in some cases, approval of construction or reconstruction is provided for in the legislation. Permission to import, export, transit and transport radioactive materials is also covered in legislation. In addition, an Order of Ministry of Health requires that licensees apply for discharge authorization. In general, regulations detail the requirements to be followed by licensees and RSC QMS procedures define the review and assessment procedure.

For the case of sources in nuclear facilities, VATESI has implemented an equivalent review and assessment process to that adopted by RSC, noting that VATESI issues consents for RSC authorized facilities that, from time-to-time, perform activities under VATESI’s regulatory control.

RSC’s Division of Licensing and State Register leads its authorization activities, while other RSC Divisions play a supporting role if it is necessary.

Technical or other expert professionals advise RSC as necessary. RSC cooperates with relevant professional bodies, accredited laboratories and other relevant governmental and non-governmental organizations, who provide support to its activities. In addition, an Advisory Committee for radiation protection also gives RSC independent advice for review

and assessment. Formal agreements among state organizations have been established in order to deal with orphan or uncontrolled sources, and a working group on nuclear security has been established by the Prime Minister, involving representatives of the Prosecutor General's Office, State Border Guard Service, Customs Department, Fire and Rescue Department, VATESI and RSC.

RSC's authorization process is supported, if necessary, by reviews and assessments provided by its Division of Expertise and Medical Exposure Monitoring.

Legislation, regulation and RSC QMS procedures are established and form the basis for reviews and assessments performed by RSC.

As established in regulations, and in accordance with Requirement 25 of GSR Part 1, RSC reviews and assesses the information submitted prior to issuing any authorizations and also over the lifetime of the facility, or the duration of the activity.

Legislation establishes that RSC has the right to require from licensees all necessary information, documents, materials, research and personal data, which could be useful for the regulatory control of the safety and security of radiation sources.

RSC has already implemented the Safety Requirement for a periodic safety assessment of Category I, II and III sources. The safety assessment needs to include a description of the facility and activities and planned changes thereof, an assessment of radiation protection, optimization measures, exposure and area monitoring, discharges, the quality assurance programme, staff qualifications and training, prevention measures for incidents and accidents, incident reports, vulnerability of physical protection and possible areas for improvement. The safety assessment has to be performed periodically (every 3 years) throughout the lifetime of the facility, or the duration of the activity and has to be submitted to RSC. There is also a (inspection) process to follow-up on identified areas for improvement. It is recognized by the IRRS team that implementation of this requirement contributes to the continuous improvement of safety.

The main aspects considered in RSC reviews and assessments are defined in RSC QMS procedures and are consistent with the relevant legislation. The format and content of the documentation to be submitted in support of authorization applications is described in an official procedure made available to the licensees. In addition, legislation establishes the deadlines for completing the assessment and authorization processes.

Inspections are carried out to verify compliance with applicable safety requirements before deciding whether to issue an authorization, or an amendment to an authorization. These inspections cover the issues raised in the reviews and assessments of the supporting documentation.

In general, the items evaluated in RSC authorization processes for radiation sources are: the basic design of the facility; technical and safety data for the sources; the system of management of radioactive waste; safety and security of sources; the system of quality assurance; and emergency preparedness.

The process of review and assessment in support of authorization decisions follows the requirements established in the Law on Radiation Protection, Government Decrees on Rules on Licensing and RSC QMS procedures, among others. It includes assessments of justification, the design of the facility or equipment, radiation protection programme, including radiation protection measures, operational and technical provisions, predicted occupational doses and doses to members of public and other relevant information provided

to demonstrate safety. The review and assessment documentation is registered according to assessment and expertise protocols and a paper copy is filed in accordance with RSC QMS procedures.

RSC has not fully implemented a graded approach: RSC's approach is mainly based on the categorization of sources (as established by a Health Ministry Order) and is related to the amount of documents sent to RSC in support of the application. The IRRS team notes that a significant amount of resources is spent in the review and assessment of low risk practices. This observation forms part of the basis of the suggestion made in Section 5 that RSC should apply a more graded approach to its authorization activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RSC has implemented the requirement for a periodic safety assessment of Category I, II and III sources.	
(1)	**BASIS: Safety Standards Series No GSR Part 1, Requirement 26, paragraph, 4.46 states that** *"This integrated safety assessment shall be repeated periodically, with account taken of the radiation risks associated with the facility or activity, in accordance with a graded approach."*
GP4	**Good Practice: The required completion of Periodic Safety Assessments for Category I, II and III sources contributes significantly to continuous safety improvement.**

6.5. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

The legal framework requires that the strategy for decommissioning a nuclear facility has to be selected during planning for its construction and forms part of the decommissioning plan which the licensee has to review and update (if necessary) every ten years. The decommissioning strategy must also be reviewed and updated if another nuclear facility is planned to be constructed on the same site.

Information regarding new methods proposed for use during decommissioning has to be presented by the licensee in the decommissioning plan and in the safety analysis report on decommissioning. The required content of the safety analysis report is defined in Nuclear Safety Requirements.

For the final decommissioning plan, experience gained during earlier stages of the decommissioning, changes in Nuclear Safety Requirements and Rules, technologies to be used, reasons for selecting the proposed decommissioning strategy, the decommissioning schedule, and financial aspects, must be taken into consideration. After the approval of the final decommissioning plan, the licensee must review it at least every five years and, if necessary, update it.

After carrying out a decommissioning project at a nuclear facility, the licensee has to prepare a report of the project and submit it to VATESI for review and assessment. The report must include the results of the tests of any new methods, equipment or devices employed in the nuclear energy sector. The requirements for report content are again set out in Nuclear Safety Requirements.

6.6. REVIEW AND ASSESSMENT FOR TRANSPORT

At present neither RSC nor VATESI assesses any package designs or materials for an approval under the dangerous goods regulations. This is because no packages are designed or shipped in Lithuania that would require competent authority approval of design or shipment according to these regulations.

RSC and VATESI have, related to their responsibilities, access to their own experts for dose rate and criticality safety assessments. For assessments in other areas, VATESI can contract external experts or technical support organizations who are independent of the applicant. In addition, RSC has contracts with external organizations for assessments not covered by its own experts.

6.7. SUMMARY

The IRRS team found that the approaches to reviews and assessments undertaken by VATESI and RSC are generally in accordance with IAEA Safety Requirements. This includes a Good Practice for the conduct of Periodic Safety Assessments for Category I, II and III radiation sources.

There were however exceptions in a few areas, leading to recommendations and suggestions relating to VATESI's review and assessment processes. These related to the recording of reviews and assessments and their peer review; use of a graded approach; aspects of the "Oversight of Economic Entities process" and taking non-radiological risks into account.

7. INSPECTION

7.1. GENERIC ISSUES

VATESI is the responsible body, defined in the law, to inspect the compliance with legal requirements, government and ministerial orders for nuclear facilities and activities. The legal requirements include the Nuclear Safety Requirements and Nuclear Safety Rules issued by the Head of VATESI, the issued licences and the attached conditions. Since 2011 VATESI also inspect the radiation safety of activities with ionizing radiation sources in the nuclear power area. Furthermore, VATESI is the competent authority for inspecting transport of nuclear material.

Legal provisions define clearly that inspections performed by VATESI do not impact upon the licensees' prime responsibility for safety. In addition, VATESI inspections do not substitute for any supervision or inspection required to be carried out by the licensee itself.

RSC is the responsible body for carrying out inspections of radiation facilities and activities in order to verify independently the compliance, with the legal and regulatory requirements and/or with the details of sources and workers specified in the authorization. All regulated facilities and activities as well as facilities or persons who are not subject to RSC authorization, but whose operation, however, may result in public or environmental exposure or the discovery of an orphan source or contaminated material, like scrap yards, are subject to inspection.

7.1.1. INSPECTION PROGRAMME

The inspection programme and procedure are defined in a binding safety requirements document and in a VATESI procedure document, both issued by the Head of VATESI. The inspections are categorized as planned and unplanned, announced and unannounced and by type. The determined types are: regular, special and technical. The annual plan of inspections, approved by the Head of VATESI, is compiled by the inspection process owner from the Safety Analysis Division based upon the input from the relevant VATESI divisions. The planned inspections constitute the vast majority of the executed inspections. On average, there are about 2 unplanned inspections conducted annually.

On the INPP site, the distribution and frequency of these inspections amongst the different facilities, systems, activities and other inspection areas is included in the annex of Nuclear Safety Requirements BSR-1.1.3-2016 "Inspections Conducted by State Nuclear Power Safety Inspectorate". The inspection frequency is set implementing a graded approach as it takes account of the different aspects of safety (system and equipment classification, former inspection findings, etc.). The annual inspection plan is published on the VATESI website. The annual inspection plan can be modified not less than ten working days before the time limit planned for the inspection and with the approval of the Head of VATESI.

Within RSC, inspections may be planned or unplanned. Planned inspections are performed according to the RSC annual plan, which is provided for in regulation and approved by director of RSC. Unplanned inspections may be carried out: as result of relevant request or assignment, to verify information or suspicion on the illegality and irregularity of the activities carried out by the licensee, to verify the correction of non-compliances identified in a previous inspection or documentation assessment prior the issuance of an authorization or

authorization amendment; and for legal reasons. Unplanned inspections can also be carried out when a licensee reports an incident or accident. All planned inspections shall be announced at least ten days prior to the conduction of the inspection. Unannounced planned inspections are not included in the inspection programme, according to legislation.

All regulated facilities and activities including, import, export, transit and transport of radioactive material substances and radioactive waste, as well as facilities or persons who are not subject to RSC authorization, but whose operation, however, may result in public or environmental exposure or the discovery of an orphan source or contaminated material, are subject to inspection. RSC inspections cover all areas of RSC responsibilities, including occupational, medical, public and environmental exposures. Assignment and conduct of RSC inspections are established in legislation and specific regulation.

As determined in the regulation, the annual inspection plan includes a list of legal entities to be inspected, the preliminary extent of inspections, necessary radiological measurements and the period in the year the inspections will be conducted. Regulation also defines extension, responsibilities, rights and duties and general procedures of inspections. QMS procedures are in place for ensuring quality and efficiency of the inspections.

The frequency of inspections is established in the regulation. Basically, inspections are carried out annually or every three years, depending on the radioactive source risk classification or, carried out every two years or every three years, depending on the specifications of the radiation generator.

Regulation defines inspection methods including: examination of records; observation of work activities, work areas, equipment, facilities, area warning signs and labelling, check interlocks, radioactive waste store; interviews and discussions with radiation protection officers and workers; on-site measurements of radiation and contamination levels.

According to regulation inspections may be carried out together with third parties and other authorities. It also defines the operational condition for implementing these kinds of inspection. Additionally, RSC cooperates with other parties on radiation protection issues.

RSC carries out pre-licensing inspection prior the issuance of an authorization. Pre-licensing inspections are also carried out for every change in licensed sources, equipment and design of the facility. This is also extensively done in the case of low risk facilities. During these inspections the information submitted by the licensee to RSC for obtaining the authorization is verified.

In 2015, 645 inspections were performed across all divisions of RPC of which 347 were of dental facilities. Approximately 40% of inspections carried out are pre-licensing unplanned inspections. The inspection programme therefore only applies, partially a graded approach.

In general, the existing registers and records are used for preparation and conduction of the inspection where the information filed in RSC is confirmed and verified. Inspections can involve specialists from other divisions of RSC to evaluate the medical, occupational, public and environmental exposures.

Even though the information system (RSIS) provides detailed information about the sources, radiation workers, occupational exposure etc., the licence application documents are filed on paper and are available, by request, to inspectors in the regional divisions for the preparation of inspections.

7.1.2. INSPECTION PROCESS AND PRACTICE

There are about 40 inspections conducted on average annually by VATESI inspectors. The prior ten day notification to the economic entity contains the main data of the planned inspection, including listing the documents and equipment required from the inspected organization for successful conduction of the inspection. The economic entity shall furnish the required information to VATESI. The procedure establishes the content of the inspection plan to be prepared and communicated with the organization to be inspected. The inspection begins with an introductory meeting and finishes with an exit meeting. During the exit meeting the main observations and findings are presented to the inspected organization. As agreed at the exit meeting, additional information may be requested by VATESI and submitted by the inspected organization following the inspection. Once the report is finalized and approved by the Head of VATESI it is issued to the licensee. A mandatory feedback mechanism, for continuous improvement purposes, is in place for all national inspection authorities where it is necessary to submit data about all conducted inspections into a centralized system. This system was introduced one year ago.

The IRRS team was informed that according to the Law on Public Administration, planned inspections may not be unannounced, and there are only four predetermined cases when unplanned unannounced inspections may take place.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Executing planned unannounced inspections is excluded by the Public Administration Law and is not considered in the nuclear and radiation safety regulations. In addition, VATESI has conducted unplanned unannounced inspection in 2014, in the area of safeguards. RSC have not conducted unplanned unannounced inspections for several years. Conducting of unplanned unannounced inspections is restricted to a few cases.	
(1)	**BASIS: GSR Part 1 Requirement 28 states that** *"Inspections of facilities and activities shall include programmed inspections and reactive inspections, both announced and unannounced."* **Furthermore para. 4.50 to GSR Part 1 Requirements 28 and 29 contains, that** *"The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections)."* **para. 4.52 to GSR Part 1 Requirements 28 and 29 contains, that** "*Regulatory inspections shall cover all areas of responsibility of the regulatory body, … These inspections may include, within reason, unannounced inspections."*
R15	**Recommendation: VATESI and RSC should initiate amendment in appropriate legislation to allow for planned unannounced inspections and broaden the basis for conducting unplanned unannounced inspections.**
S18	**Suggestion: VATESI should consider making the necessary arrangements to be able to conduct unplanned announced inspections in all safety areas.**

The IRRS team observed a VATESI inspection, which was conducted at the INPP site. During this inspection of dismantling and decontamination activities, the VATESI inspectors observed some non-compliances with respect to the wearing of personal protective equipment and the labelling of dismantled waste. These observations were discussed during the exit meeting with the representatives of the licensee organization. During the inspection in the turbine hall of the NPP there was an unlabelled small ventilator put aside and not having any labelling. INPP staff explained to VATESI's inspector that this small ventilator was dismantled recently. Further a worker not wearing the required breath protection was observed as well. Although in these cases the inspectors asked some questions, but later were not mentioned in the exit meeting as non-compliances. Representatives of the licensee on the spot did not take corrective actions in this cases, what should be considered as improper implementation of the management system (partly as well of the radiation protection arrangements) and of the safety culture. Although the inspection procedure allows the inspector(s) to make observations and initiate actions related to all safety related issues, the inspectors did not mention these additional issues in the exit meeting, too.

The VATESI self-assessment report reveals shortcomings with the inspection procedures for waste management facilities and decommissioning. For instance, no pre-defined check-lists or questionnaires are used during the inspection process and there is a need to improve the mechanism in place to incorporate feedback from the inspection for the purposes of improving the regulatory control. The IRRS team was informed that these deficiencies with respect to inspection procedures apply to all areas of regulatory control of VATESI.

The IRRS team was also informed that general requirements for conducting inspections in different life-cycle phases of the nuclear facilities are in place. However, there are no systematic planned inspections associated to the different licensing steps. Provision for this could enhance safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: VATESI's inspections procedures are generic and do not include pre-defined check lists or questionnaires to be used during inspections. The mechanism in place to incorporate the inspections feedbacks for the purpose of improving the regulatory control is not effective.	
(1)	**BASIS: GSR Part 1 Requirement 22 Stability and consistency of regulatory control sates that** *"The regulatory body shall ensure that regulatory control is stable and consistent."*
(2)	**BASIS: GS-G-1 para.4.1 states that** *"To ensure that all nuclear facilities in a State are inspected to a common standard and that their level of safety is consistent, the regulatory body should provide its inspectors with written guidelines in sufficient detail. The guidelines should be followed to ensure a systematic and consistent approach to inspection while allowing sufficient flexibility for inspectors to take the initiative in dealing with new concerns that arise."*

(3)	**BASIS: GS-G-1.3 para. 4.15 states that** *"Preparations should be made by the individual or team [...] who will be conducting the inspection. Furthermore, it may be useful to establish a special plan for the inspection and to compile a questionnaire and a list of the documents to be reviewed with the operator. [...]Appropriate subjects for guidance and instructions for inspectors could include [...]relevant technical information and questionnaires[...]."*
S19	**Suggestion: VATESI should consider improving the inspection procedures for all areas subjected to regulatory control to ensure systematic and consistent approach to inspection.**

Inspections are supported by regulations issued by RSC and Ministry of Health which cover requirements for radiation protection training; radiological measurements and equipment tests; enforcement measures and inspection questionnaires and reports. On this theme, specific RSC Orders approved 11 inspection questionnaires and reports for different practices and subjects. RSC also have established QMS procedures related to inspection procedures.

Instrumentation is available to perform inspections and includes dose rate monitors (gamma, X-ray, neutron), surface contamination monitors, portable spectrometer, laser distance meter, photo and video cameras and equipment for taking samples for radiological measurements.

Regulation establishes the steps for the inspection process, including an exit briefing, with the facility representative, in which the findings and results are discussed as well as the preparation of the inspection report. The report detailing the findings, results, measurements, tests, requirements to eliminate identified non compliances, suggestions and timeframes to solve the observed non-compliances, is issued to the licensee. The licensee must submit to RSC, for review and assessment, a formal communication on the adopted measures to eliminate the observed non-compliances together with evidentiary documents. A follow up inspection can be carried out for onsite verification of the corrective actions adopted by the licensee. Records of every inspection are maintained at the respective divisions and copies are uploaded to the Information System RSIS.

RSC has a QMS procedure to review inspection findings and issues which includes periodic meetings and communication of relevant issues to the RSC Director and/or his deputy. The information related to inspections is used for improvement of the regulatory system.

7.1.3. INSPECTORS

There are about 45 inspectors within VATESI. Following introductory, on-the-job training and participating in inspections as an observer VATESI staff may be given the rights of inspectors by the Head of VATESI. VATESI has a Surveillance Division at the INPP site. This division has five positions of which 4 are currently filled.

An RSC Director order designates RSC inspectors who have the regulatory power to carry out inspections and apply enforcement measures. If inspectors are impeded by the inspected legal entity of discharging their duties, RSC has the right to impose sanctions established in the Legislation.

Inspectors are subject to a training plan that is established by the RSC Division in which the inspector acts, in accordance with their assigned functions. The training period should not be

less than 120 hours in 5 years. Compulsory programs are included in the training plan and international standards are considered in the preparation of them.

7.2. INSPECTION OF NUCLEAR POWER PLANTS

There are 18 different kinds of inspections defined which are to be conducted at the INPP site. Four of these are not related to the NPP. (The latter category includes inspections which are related to more than one nuclear facility at the NPP site – e.g. inspection of the management system of the common operating organization of the facilities on the site.) Therefore, the information given in chapter 7.1 is relevant to the inspection of the NPP. About 75% of the inspections are related to the two NPP units which are shut down.

During the IRRS mission, team members accompanied VATESI inspectors on an inspection at the INPP site. The inspection objectives were to check:

- the safety of INPP unit 2 turbine hall equipment dismantling and decommissioning activity of project B9-1(2) and the correspondence of working zones to the project, including radiation safety issues;
- the operation of radioactive waste accounting and control system and the management of radioactive waste packagings documents at B-10 and B-19 buildings.

After the opening meeting, inspectors followed the inspection plan, which was prepared and provided to the operator 2 weeks before the inspection.

Dismantling, decontamination, and activity/dose measurement works were checked by VATESI inspectors. They recognized questionable practices related e.g. to fire protection and at the exit meeting required to give further clarifications and prove of safety from the licensee. They noted issues related to a set aside and not labelled dismantled waste and some problems with the required personal protective equipment.

The findings and observations of inspection group were summarized and discussed with the operator in the closing meeting.

The IRRS team observers had an opportunity as well to meet representatives of the INPP management and clarify the way of contacts they have with the regulators**.** At the end of the site visit the IRRS team held as well a short debriefing with the VATESI inspectors in order to clarify some questions arising during the observation of the inspection.

7.3. INSPECTION OF WASTE MANAGEMENT FACILITIES

Inspections may be planned and unplanned and inspections of WMF are carried out in accordance with the Nuclear safety requirement.

The IRRS team was informed that in planning and conducting inspections at WMF and on decommissioning a graded approach is applied taking into account doses, safety classification of systems, complexity of the activity, etc. VATESI inspectors have unlimited access to the licensed facilities. The IRRS team was also informed that VATESI Headquarter inspectors conduct three inspections annually while on-site inspectors conduct two annually. However, there are no specific procedures of waste management facilities inspections. This observation is addressed in Suggestion 19 in Section 7.1.

The IRRS team was also informed that upon finding a violation of the rules it is recorded in the inspection report and provided to the Head of VATESI with identification of the specific

requirements violated. The Head of VATESI decides whether or not to apply enforcement measures suggested in the inspection report. If the decision is to apply, a draft of the relevant document for applying of enforcement measures is prepared and provided for the review to the Legal Affairs and Personnel Division.

The IRRS team was informed that there is a practice (usually once per year) that VATESI invite external experts to take part in VATESI's inspections. For example, representatives of the Environmental Protection Agency were invited to participate in the inspections carried out in 2013 and 2014 related to application of free release levels in case of removal material and waste from the INPP controlled area. But it should be stated that such inspections are considered to have the status as the VATESI's inspections, i.e. they are under VATESI's responsibility.

The objectives and introductory meeting details of the Ignalina NPP inspection are provided in the Section 7.2. The inspection started from the waste accounting and control system operation building where the accuracy and comprehensiveness of input data were checked, in addition the inspectors took printout data from the database on the randomly chosen package for further check of the validity of the information by their own comparative/verifying dose measurements. Afterwards, the inspectors went to the free release facility (B-10) and the buffer storage facility of very low level waste (B-19), where the verifying measurments were performed by the inspectors. No inconsistency on the data were found out. The information on the exit meeting and further activites of IRRS team is provided in Section 7.2.

The IRRS team notices from witnessing the inspection and corresponding suggestions are elaborated in the Section 7.1.

7.4. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

RSC QMS procedures are used to inspect radiation facilities. Questionnaires, for all practices, are in place to facilitate the preparation and conduct of the inspections. Security issues are verified through a specific questionnaire for facilities which operate with sealed sources. All steps of RSC inspections are defined and the related tasks are established.

During the IRRS mission, team members accompanied RPC inspectors on two inspections which included an industrial and medical facility.

During the inspection of the industrial facility inspectors checked on the rules for non-destructive testing (NDT) sources and visited the storage location of the sources. While conducting the hospital inspection, inspectors visited the blood irradiator facility, two interventional radiology rooms and the nuclear medicine department.

Based on the observations during these visits, together with the contents of the RPC inspection checklists, it can be concluded that the inspection visits are well structured and professionally conducted. The format of the inspections observed incorporated an initial meeting with the licensee's representatives, including the Radiation Protection Officer (RPO). At these meetings the regulatory and licence requirements of the facility were scrutinized and discussed.

After the initial meeting, the inspection continues with a check of all the required documentation, including licensed sources, radiation protection training records, personnel records, occupational exposure records of exposed workers, monitoring records, waste management records, records on emergency exercises, the periodical safety assessment, and

the quality assurance programme for the sources and in case of the hospital for the radiation protection of the patients.

The documentation checks were followed by a visit to each of the areas relevant to the inspection. The inspectors checked on radiation levels and also performed contamination wipe tests. In the case of the hospital these were taken of staff member's hands and of certain areas in the nuclear medicine department. A close-out meeting was held at the end of the inspection where the inspector advised the facility they were working to all regulatory requirements and that an inspection report will be issued within five days.

The IRRS team noted from witnessing the inspection that there were no major non-compliances identified at the time of the inspection. However the inspector reserved the right to hold judgement on non-compliances until a review of all recent paperwork submitted to RSC had taken place.

During the inspection at the hospital, the RPO advised the inspectors that the hospital last performed a clinical audit of nuclear medicine procedures in 2011. This reflects the shortcoming identified in Section 11 whereby RSC does not currently enforce the legal requirement for clinical audits to be performed by the licensee. Concerning this issue a suggestion is included in Section 11.

In the opinion of interviewed licensees, RSC could pay additional attention to the comments they provide on draft regulations and the opportunity to discuss further.

For the case of the sources at nuclear area, VATESI implements an equivalent inspection program. From the discussions between the VATESI representatives and the IRRS team it is observed that VATESI does not include in its inspection plan the inspections on the RSC authorized licensees that, from time to time, perform activities in the area under VATESI control.

7.5. INSPECTION OF DECOMMISSIONING ACTIVITIES

There are no specific procedures for the inspection of decommissioning activities. These inspections are carried out in accordance with Nuclear safety requirements BSR-1.1.3-2016 "Inspections conducted by the State Nuclear Power Safety Inspectorate" and Procedure document for inspections PR-6 (VATESI's management system's document).

7.6. INSPECTION OF TRANSPORT

Inspections of carriers transporting radioactive material is done by inspectors from RSC or VATESI, depending on the information obtained in the licensing process. Inspections are based on internal procedures and, in case of RSC, on questionnaires. Inspections cover all important areas like condition of vehicles and packages, marking and labelling, compliance with radiation protection and training requirements for workers, status of emergency response arrangements, written instructions, radiation protection programme and security measures. Inspections are conducted once every three years. Inspections also include measurements of dose rates on the surface of the packages.

Further improvement of the inspection procedures is included in the VATESI action plan.

The result of the inspection is reported to the licensee, and for RSC the information about reports and non-compliances is recorded in the information system accessible by RSC and the licensee.

7.7. SUMMARY

In general the inspection programme, process and practice of the regulatory organizations are in line with the requirements of the safety standards. However in the legal circumstances there were shortcomings identified (legal framework for the unannounced inspections) and therefore one recommendation and one suggestion was formulated for both VATESI and RSC.

Suggestions related to the amendment of its inspection procedures were formulated by the IRRS team to enhance the effectiveness of inspections and to improve supervision of safety.

It was noted that in these fields there is an opportunity to improve graded approach in the planning of inspections by considering the frequency and necessity of inspecting low risk source facilities. The graded approach could also be considered in the context of the existing requirement to perform pre-licensing inspections in all facilities and for all changes to the licence thereof. Concerning these issues a recommendation was included in Section 5.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

At the NPPs the system of enforcement measures applied by VATESI is defined by the laws and other legal documents. These set out a framework which allows taking the enforcement measures according to a graded approach, depending on the nature of the violation. It ensures that the enforcement measures will be applied according to the gravity of the non-compliance. The enforcement measures in these facilities are governed differently dependent upon whether the activity falls under the authorization by the Law on Nuclear Safety or by the Law on Radiation Protection.

In accordance with the Law on Nuclear Safety the Head of VATESI can take the following enforcement actions through a mandatory requirement to eliminate detected violations of nuclear safety, to suspend works within the time-limits set by him and/or to shut-down the nuclear reactor, to decrease its capacity and to discontinue the operation of other equipment or activities.

If the mandatory requirement is not complied with, the licensee or permit holder is warned about the consequential suspension of an authorization.

If even after the suspension the licence or permit holder fails to eliminate the violations within the prescribed time-limits, the Head of VATESI can revoke the authorization.

In both cases of suspension and revocation, the licensee's or permit holder's responsibility for safety and the related duties remain unchanged.

Similar system is established in the Law on Radiation Protection according enforcement measures applied for holders of licences or temporary permits foreseen in the Law on Radiation Protection.

Also VATESI is authorized to take enforcement measures established in the Code of Administrative Offences in the cases when violation is committed by natural person.

In the cases of severe violations due to which the safety barriers are or might be breached and/or as a result of which the activity of radionuclides discharged into environment exceeds the allowed limit and/or the doses of exposure of workers exceed the allowed limits, and which fails to comply with the requirements arising out of the international obligations on non-proliferation of nuclear weapons assumed by the Republic of Lithuania, and this is related to significant quantities of nuclear materials defined by IAEA, economic sanctions (fines) can be applied. In addition to the fines a legal person may be subject to mandatory requirements as described above.

By law there are established two possibilities for legal appeal of decisions (including enforcement actions) of VATESI: to raise the issue before at Administrative Disputes Commission or to seek remedy in the court.

VATESI's QMS PR7 "Procedure document for application of enforcement measures" establishes the enforcement procedures. The IRRS team was informed that some years ago all VATESI's inspectors had an 8 days training on enforcement tools. All inspectors (having inspections in that quarter) get quarterly an e-mail (with guidance) from VATESI's Legal Affairs and Personnel Division with information on the inspection implementation process and corresponding enforcement tools.

RSC's regulatory enforcement policy which applies to all facilities and practices outside of the nuclear facilities is supported by legislation, regulation and RSC QMS provisions. The legislation also establishes the enforcement actions that are applied, depending on the crime committed. Procedures and requirements for the application of penalties are in place.

Most restrictive regulatory enforcement actions include suspension and revocation of the authorization, seal of the facility and complaint presentation for prosecution in court. Regulation specifies the non-compliances that are liable to penalties, corresponding enforcement actions and the criteria for the adoption of penalties. Regulation also empowers RSC officers to seal premises equipment or devices with sources.

RSC decision making process applied for enforcement is defined in Regulation and RSC QMS Procedure and includes: the internal communication of the identified non-compliance to the hierarchic competent levels; adoption of preventive measures; presentation of a warning for the licensee on need of corrective actions and the possible enforcement actions to be adopted in case of non-adoption of these corrective actions; suspension of the licensed activity; in accordance with the regulation, issuing a protocol on administrative law violations for court prosecution; propose to the RSC Director to adopt a decision on suspension of validity of the authorization. Notification for the licensee of the non-compliance, violations, corrective actions and correspondent time frames for their implementation, is done through the inspection report which is also documented, filed and maintained by RSC. The licensee shall notify RSC in writing on the measures adopted to eliminate the non-compliance and violations and provide together evidentiary documentation.

It was observed that an appeal against a licence suspension, or withdrawal by the Director of RSC is evaluated and decided on by the same officer (Director RSC). As the authorized parties may seek legal remedy in the court as well, it is considered that there is no necessity for a recommendation or suggestion.

For the case of the activities in the area of nuclear energy involving sources of ionizing radiation, VATESI is able to implement some of the enforcement actions available for RSC. VATESI could apply enforcement measures described in the Code of Administrative Offences.

8.2. ENFORCEMENT IMPLEMENTATIONS

VATESI inspectors have the right to give an oral remark on the spot in case of minor violations when it could be corrected instantly.

In the area of nuclear installations in the last few years VATESI issued 2-7 mandatory requirements a year. There were no appeals against any enforcement decisions of the VATESI for many years. In line with the improvement of the enforcement process VATESI plans to propose amendments to the relevant part of the LNS by introduction of minimal time (from 1 to 60 days in different cases) within which VATESI may require a mandatory requirement (to suspend the works and (or) to shut-down the nuclear reactor, to decrease its capacity, to discontinue operation of equipment or activities) issued by the Head of the VATESI. Accordingly a proposed amendment of the law has been drafted already.

The IRRS team considers that if this amendment is approved, immediate elimination of a detected violation that could lead to a safety significant event would not be possible. In such cases preset minimum time for execution may impact safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: During inspections, VATESI's inspectors are not empowered to require corrective actions if an imminent likelihood of a safety significant event is identified.	
(1)	**BASIS: GSR Part 1 Requirements 30 and 31, para. 4.58 states *that*** *"On-site inspectors, if any, shall be authorized to take corrective action if there is an imminent likelihood of safety significant events."*
R16	**Recommendation: VATESI should initiate changes in the legal system to authorize inspectors to require corrective actions in case an imminent likelihood of a safety significant event is identified during inspection.**

According to the Legislation, RSC can adopt different types of enforcement actions. RSC identifies and documents the nature and all relevant information of observed non-compliances and the time frame for correcting them. RSC communicates in writing to the licensees for correcting identified non-compliances within a specified time frame and for taking all necessary measures to avoid recurrences.

The RSC designated inspectors have the regulatory power to carry out inspections and apply regulatory enforcement measures as mentioned above.

Records of every inspection are maintained at respective RSC divisions and copies are uploaded to the Information System (RSIS). In RSIS the data about the inspection findings, non-compliances, measures of enforcement are collected and stored. The inspector controls the set time frames for correcting non-compliances and violations until the authorized party confirms all corrective actions were implemented. Authorized parties can access the RSIS to get an overview of their non-compliances and the applicable time limits for correction.

The inspection report includes requirements to eliminate identified non-compliances and violations, suggestions and reasonable time frames for the adoption of corrective actions by the licensee. The inspector after having conducted the inspection and upon agreement with the Senior Controller can take the decision to suspend activities with the radiation source or sources.

RSC inspectors are also responsible for evaluating and assessing the licensee notification on the adopted corrective actions, including the documentary evidence and, after agreement with the RSC Senior Controller, provide conclusions on the acceptability of the notification.

RSC periodically organizes trainings and seminars on enforcement issues, during which the chief specialist jurist analyses inadequacies observed in documentation in which the application of enforcement measures is registered. Moreover, for training purposes RSC invites lawyers licensed by the Ministry of Justice of the Republic of Lithuania who are well experienced in applying legislation.

The IRRS team was informed that VATESI inspectors do not have the same enforcement powers if compared to RSC inspectors. It was observed that a legal entity authorized by RSC, which performs activities within nuclear area, would be enforced through different instruments by VATESI inspectors.

8.3. SUMMARY

In general, VATESI and RSC has established and implemented an enforcement policy in accordance with the legal framework of the Lithuania. The policy allows for enforcement measures to be taken according to severity of risks and the severity of non-compliance. However some of the requirements of the IAEA safety standards are not complied fully or partially in the area of nuclear installations, therefore a recommendation was formulated.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

In accordance with legislation, requirements and associated safety criteria for nuclear power plants (NPPs) are further elaborated on in secondary legislation (nuclear safety requirements and nuclear safety rules), established by VATESI. Regulatory judgements, decisions and actions are mainly based on this secondary legislation. In 2008, VATESI conducted a comprehensive evaluation of the topics covered by their nuclear safety regulations and compared with the content of IAEA safety standards and established at that time. VATESI has in place a process to to systematically plan and issue new or amended regulations with due consideration of current and relevant international requirements. In its self evaluation process VATESI identified the actual needs and included them in its draft action plan. The process established by VATESI enables the plan to be kept up-to-date in light of new international requirements.

RSC establishes the principles and criteria for the regulation of radiation protection, control of radiation sources, and the safety and security of radiation sources. The safety and security regulatory framework is established in accordance with international treaties ratified by the Republic of Lithuania and taking into account IAEA safety standards, European Union legislation and best practices. RSC also applies its experience as a member of various international forums (HERCA, IRPA, CBSS, etc.) for the development of the regulatory framework covering safety and security of radiation sources.

All legal acts that should be prepared by RSC are included in its annual work plan, approved by the Minister of Health. This annual work plan is presented on the RSC's website. RSC reviews and updates regulations periodically according to the regulatory framework review and update plan, approved by an Order of the Director of RSC.

The process for drafting, adopting, publishing and amending safety and security regulations and guides follows a QMS procedure. The developed drafts and additional explanations are submitted to stakeholders and publicized on the Legislative Information System. Stakeholder feedback is documented and, according to the regulatory bodies, discussed with all interested parties. Use of an electronic environment enables transparency and public participation in the standards-setting process.

Consistency within the extensive legal framework is ensured by the Law on Fundamentals of Legislative Procedures. The Law sets the basic principles for drafting of legislation with the principles of harmonization.

In case of changes in administrative burden for authorized parties which would be introduced by new or revised legislation, the Ministry of Economy is consulted.

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

There is an extensive set of regulations in force, including a number of regulations in the drafting or planning stages. Currently, VATESI does not use guidance documents in areas of its regulatory oversight. In the past, some regulatory guides (recommendations) did exist but the system was changed, as VATESI explained, on the basis that the guides were used by the authorized parties as being mandatory content and not for guidance purposes. The IRRS team

was informed that currently there are paragraphs in regulations which are formulated as recommendations and are not enforced as requirements. In addition, there exists a number of means by which VATESI provides guidance information to authorized parties in case of need. These include posting on their website draft regulatory documents for information prior to issuance, allocating the time for solicitation of comments from stakeholders, review of feedback received, and, if needed, organization of meeting(s) for contentious issues. According to the general legislation in place, any authorized party may request consultation regarding adequate ways of implementing requirements, or even on the interpretation or explanation of the content of the requirements. These consultations are in practice conducted as requested, and may be initiated as-needed by VATESI. As an example; consultation was initiated by VATESI on the content of the periodic safety review process. It was recognized by the IRRS team that not issuing formal guidance documents is not in line with IAEA requirements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: VATESI does not prepare and issue guides, as a part of a comprehensive regulatory framework, to provide guidance on how to comply with the safety requirement.	
(1)	**BASIS: GSR Part 1 Requirement 32 States that** *"The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."*
S20	**Suggestion: VATESI should consider developing guides to help in how to comply with the safety requirements.**

9.3. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

Secondary legislation on the regulatory supervision of waste management facilities covers all types of waste management facilities except disposal of high-level radioactive waste and long-lived low- and intermediate level radioactive waste (RW) to be disposed in deep geological formations.

The IRRS team found that there is a lack of several explicit provisions in regulations, for example:

- the periodic review of the adequacy of RW storage facility capacity;
- the documentation of decisions and assumptions made in the safety assessment of RW management facilities;
- the content of a final commissioning report for waste pre-disposal management facilities;
- the development of disposal facilities for long lived waste, high level waste and spent fuel;
- the siting of a disposal facility away from significant known mineral resources, geothermal water and other valuable subsurface resources;
- the consideration of heat production in the case of heat generating waste;
- the level of detail and quality of disposal facility safety analysis report, including: the requirement on documentation of decisions and assumptions made in the

development and operation of a disposal facility; the models and data used, in the demonstration of containment capability of waste package in safety assessment and its appropriateness for the waste type and the overall disposal system; safety aspects related to surface and underground excavation, construction and mining work, waste emplacement, and backfilling, sealing and closing operations, etc.

VATESI has identified deficiencies in its performed self-assessment and the associated action plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The IRRS team found several inconsistencies of the regulatory framework on RW predisposal management with the IAEA GSR Part 5.	
(1)	**BASIS: GSR Part 5 Requirement 11, para. 4.22 states that** *"Provision has to be made for the regular monitoring, inspection and maintenance of the waste and of the storage facility to ensure their continued integrity. The adequacy of the storage capacity has to be periodically reviewed, with account taken of the predicted waste arising, both from normal operation and from possible incidents, of the expected lifetime of the storage facility and of the availability of disposal options."*
(2)	**BASIS: GSR Part 5 Requirement 15, para. 5.9 states that** *"For the purposes of both justification and traceability, a well-documented record is necessary of the decisions and assumptions that were made in the development and operation of the facility, and of the models and data used in the safety assessment to obtain the set of results."*
(3)	**BASIS: GSR Part 5 Requirement 18, para. 5.17 states that** *"Upon the completion of commissioning, a final commissioning report is usually produced by the operator. …. The regulatory body has to assess this report to ensure that all conditions and requirements are satisfied before agreeing to the operation of the facility. The safety case has to be updated, as necessary, to reflect the as-built status of the facility and the conclusions of the commissioning report."*
(4)	**BASIS: GSR Part 1 Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained."*
R17	**Recommendation: VATESI should revise the regulatory framework on predisposal management of radioactive waste to ensure its compliance with the GSR Part 5.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The IRRS team found several inconsistencies of the regulatory framework on disposal of radioactive waste with the IAEA SSR-5.	
(1)	**BASIS: SSR-5 Requirement 2, para. 3.8 states that** *"The regulatory body has to develop regulatory requirements specific to each type of disposal facility for radioactive waste, including each type that is envisaged, on the basis of national policy and with due regard to the safety objective and criteria."*
(2)	**BASIS: SSR-5 Requirement 4, para. 3.20 states that** *"Consideration has to be given to locating the facility away from significant known mineral resources, geothermal water and other valuable subsurface resources. This is to reduce the risk of human intrusion into the site and to reduce the potential for use of the surrounding area to be in conflict with the facility."*
(3)	**BASIS: SSR-5 Requirement 8, para. 3.40 states that** *"The containment of the radionuclides in the waste form and the packaging over a defined period has to ensure that the majority of shorter lived radionuclides decay in situ. … For high level waste, it also has to be ensured that any migration of radionuclides outside the disposal system would occur only after the heat produced by radioactive decay has substantially decreased."*
(4)	**BASIS: SSR-5 Requirement 8, para. 3.40 states that** *"The containment capability of the waste package has to be demonstrated by means of safety assessment to be appropriate for the waste type and the overall disposal system."*
(5)	**BASIS: SSR-5 Requirement 13, para. 4.15 states that** *"All aspects of operation relevant to safety are considered, including surface and underground excavation, construction and mining work, waste emplacement, and backfilling, sealing and closing operations."*
(6)	**BASIS: GSR Part 1 Requirement 24, para. 4.34 states that** *"The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization. The applicant shall be required to submit or to make available to the regulatory body, in accordance with agreed timelines, all necessary safety related information as specified in advance or as requested in the authorization process*."
(7)	**BASIS: GSR Part 1 Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical*

	standards and of relevant experience gained."
R18	**Recommendation: VATESI should revise the regulatory framework on disposal of radioactive waste to ensure its compliance with the SSR-5.**

9.4. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

RSC is the regulatory body responsible for regulation and supervision of safety and security, and control of radiation sources, except for regulation and supervision of the practices involving radiation sources in the area of nuclear energy; these last functions are assigned to VATESI.

The established regulations, by Minister of Health and RSC cover the basic standards of radiation protection, safety in medical X-ray diagnostic, industrial radiography, nuclear medicine, outside workers, non medical equipment containing radioactive sources use, radiotherapy and veterinary. Various Orders cover requirements in the following areas:

- quality control in medical diagnostic and radiotherapy;
- monitoring of internal exposure;
- equipment for radiation protection;
- high activity sealed radioactive sources and orphan radioactive sources;
- security of radiation sources;
- radiation protection assessment for radiation facilities;
- import, export, transit and transport of radioactive material and waste and spent nuclear fuel;
- required data on radiation sources and workers working with radiation sources;
- danger categories of equipment with the radiation sources and their control and supervision;
- information on transport of nuclear, radioactive material and other radiation sources;
- compulsory radiation protection training and instruction procedure;
- control of radioactive contamination in procurement and processing places of scrap metal, waste and processed metal production;
- determination of persons responsible for the physical protection of sealed radioactive sources.

For the control of orphan sources, dedicated rules are established in legislation. It was noted during the IRRS review that there are extensive requirements for scrap yards, e.g. requirements for training and requirements to perform measurements on all the loads of scrap. However, the IRRS team was informed that in Lithuania, there are a lot of small scrap dealers and only a few large scrap yards. The small scrap dealers perform measurements of scrap loads with handheld radiation detection instruments.

Within the legal framework, it is a requirement for notification to be made to RSC regarding exempted sources for the purpose of notification, which is not fully consistent with the concept of exemption. Depending on accumulation of multiple exempted sources within a premises, they are regulated correspondingly.

There is a recognized need to update the regulatory framework taking into account the new safety requirements established by the European Union Directives and the IAEA Radiation

Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3 (GSR Part 3), in terms of the concepts of protection, introduction of notification and registration and updating of factors, limits and other conditions. RSC has identified this in its performed self-assessment and associated action plan. In addition, these particular gaps in legislation are currently being addressed by VATESI through revisions to BSR-1.9.3-2011, *Radiation Protection at Nuclear Facilities*; tracked also through VATESI's Action Plan #35. These findings form the basis for the following recommendation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: It was observed that the legal framework for radiation safety is based on the former International BSS (SS-115) and does not reflect the latest requirements of GSR Part 3.	
(1)	**BASIS: GSR Part 1 Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained."*
R19	**Recommendation: RSC and VATESI should update existing regulations in radiation safety according to the Safety Standards Series No GSR Part 3.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Individual exempted sources are required to be notified by the legal entity. There is however no requirement for licensing of multiple small (exempted) sources.	
(1)	**BASIS: Safety Standards Series No GSR Part 3 , schedule I, I.3 (a) States that** *"Under the criteria…….applicable exemption level given in Table I.1."*
R20	**Recommendation: RSC should revise the existing regulation not to require the notification of a single exempted source but to account for the accumulation of exempted sources.**

9.5. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

Regulatory supervision of decommissioning is covered by Nuclear Safety Requirements BSR-1.5.1-2015 "Decommissioning of Nuclear Facilities". This legislation, approved by VATESI, establishes the requirements for conducting decommissioning of nuclear facilities. According to this legislation, VATESI must specify criteria for free release radioactive levels for individual buildings, engineering structures of the facility and to the site of the facility. The IRRS team was informed that a draft of BSR-1.5.1-2016 "Clearance Levels of Buildings and the Site of the Facility" is prepared; however, it has not yet been enacted.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: VATESI approved Nuclear Safety Requirements BSR-1.5.1-2015

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
"Decommissioning of Nuclear Facilities", however corresponding criteria for clearance of buildings and the site of the facility has not approved yet.	
(1)	**BASIS: GSR Part 3 Requirement 8, para. 3.12 states that** *"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. By means of this approval, the regulatory body shall ensure that sources that have been cleared from regulatory control do not again become subject to the requirements for notification, registration or licensing unless it so specifies."*
S21	**Suggestion: VATESI should consider establishing criteria for clearance of buildings and the site of a facility and methodologies for the use of them.**

The IRRS team observed that there is a lack of several explicit provisions in legislation, including the requirements of addressing protection of the environment if a facility is released from regulatory control with restrictions on its future use, and the update of an initial decommissioning plan throughout the lifetime of non-nuclear facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The regulatory framework on decommissioning of non-nuclear facilities is not fully consistent with GSR Part 6.	
(1)	**BASIS: GSR Part 6 Requirement 1, para. 2.3 states that** *"National regulations on the protection of the environment and the requirements addressing protection of the environment shall be complied with during decommissioning, and beyond if a facility is released from regulatory control with restrictions on its future use."*
(2)	**BASIS: GSR Part 6 Requirement 10 Planning for decommissioning states that** *"The licensee shall prepare a decommissioning plan and shall maintain it throughout the lifetime of the facility, in accordance with the requirements of the regulatory body, in order to show that decommissioning can be accomplished safely to meet the defined end state".*
(3)	**BASIS: GSR Part 6 Requirement 5 para.3.3 states that** *"The responsibilities of the regulatory body shall include....* – *Review of the initial decommissioning plan and updates, review and approval of the final decommissioning plan and supporting documents, and review and approval of updates after the final decommissioning plan has been approved."*
(4)	**BASIS: GSR Part 1 Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due*

	consideration taken of relevant international safety standards and technical standards and of relevant experience gained."
R21	**Recommendation: RSC should revise and update its decommissioning regulations to ensure its compliance with GSR Part 6.**

9.6. REGULATIONS AND GUIDES FOR TRANSPORT

Lithuania applies to national as well as international shipments of radioactive material the regulations set in the international agreements for road, rail, sea and air transport that Lithuania has signed. Lithuania is member of IMO and ICAO and has signed ADR, RID and SMGS. This ensures that the regulations for safety of transport of radioactive material in Lithuania comply with SSR-6.

Review and revision of regulations regarding the transport of radioactive material includes drafting of text by RSC and VATESI, consultation with stakeholders and approval by the Ministry of Health and the Head of VATESI.

Based on the transport needs in Lithuania, RSC and VATESI have not yet issued extensive guidance for applicants for transport-related approvals. Taking into account potential transport needs arising from the existing nuclear installations and the possible renewal of the nuclear program, VATESI might benefit from making available such guidance. VATESI informed the IRRS team that it planned drafting some legislation defining application procedures and documents. As one basis for specifying application documents the international experience collected in the European PDSR guide could be used.

RSC and VATESI require training to workers of carriers according to ADR and check if this training is completed. In addition to the training required by ADR, radiation protection training and examination is required. Training centers and programs for this radiation protection training for RSC licensees are approved by RSC. The IRRS team was informed that VATESI would organize an equivalent function regarding VATESI licensees.

RSC and VATESI co-operate with other national organizations involved in the transport of dangerous goods, as the Ministry of Transport and Communication, the Border Guard Service and the Customs Department.

RSC and VATESI are involved in international cooperation projects. Nevertheless, both authorities would benefit from a more intensive and coordinated involvement in activities of Transport Safety Standards Committee (TRANSSC) and the European Association of Competent Authorities (EACA) for optimizing exchange of information and improving uniformity of the application of the IAEA transport regulations in all member states.

9.7. SUMMARY

In general, RSC and VATESI have established and implemented Regulations covering the areas under their regulatory oversight. There were however exceptions in a few areas, leading to recommendations and suggestions.

It is recognized that the updating of the legal and regulatory framework, taking into account the IAEA Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3 is timely.

For national and international transport of radioactive material, the regulations from the international agreements for road, rail, sea and air transport are applied. This complies with the IAEA standards.

VATESI regulations for radioactive waste management are not completely in line with the appropriate IAEA safety requirements (GSR part 5 and SSR 5), which were partly revealed in the self-assessment report and included in the action plan.

VATESI is drafting new safety rules on clearance of buildings and site to be used in the decommissioning of nuclear facilities; however, the criteria for clearance and the methodologies for the use of such criteria are to be established.

RSC rules on decommissioning of non-nuclear facilities need to be updated to comply with GSR part 6.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

Although the new IAEA Safety Requirements on Emergency Preparedness and Response have been recently published (Nov 2015) as General Safety Requirements Part 7 (GSR Part 7), superseding GS-R-2 (2002), during this mission the appraisal on Emergency Preparedness and Response (EPR) has been performed against GS-R-2 (2002) requirements, to be consistent with the self-assessment performed by host organizations RSC and VATESI.

Revised terminology of some concepts has been introduced in GSR Part 7. For consistency purposes, the important concepts will be referred as included in both GS-R-2 and GSR Part 7: the threat (hazard) assessment and threat (emergency preparedness) categories (EPC) will be mentioned in both old and revised terminology, to be in line with the basis used for this review (GS-R-2 requirements) and also with the new GSR Part 7.

According to the IAEA categorization of radiation related threats (hazards), Lithuania is currently a country with facilities and activities belonging to EPC I, III and IV.

Using the graded approach of IAEA safety standards on EPR, facilities in EPC III are facilities using radioactive sources in category 1, 2 or 3 (at fixed locations); activities in EPC IV are activities using mobile radioactive sources in category 1, 2 or 3 (so called “dangerous sources”, as per IAEA safety standards).

10.1. GENERAL EPR REGULATORY REQUIREMENTS

Basic responsibilities

Lithuania has in place a comprehensive legislative framework that clearly defines and allocates the regulatory mandate and responsibilities of RSC and VATESI in the field of EPR.

According to the Law on Radiation Protection, RSC is the regulatory authority in the area of radiation protection, excluding nuclear facilities, responsible with issuing requirements for EPR for operating organizations in EPC III and IV and to exert regulatory control over these facilities and activities.

According to Law on Nuclear Safety, VATESI is the national regulatory authority in charge with regulatory control of nuclear installations and activities related to nuclear power and nuclear fuel cycle materials, responsible with establishing and enforcing regulatory requirements for EPR for these facilities.

The existing legislation establishes in detail the responsibilities of operating organizations to ensure EPR. During authorization and inspections, RSC and VATESI evaluate and verify the compliance of licensees under their regulatory oversight with the regulatory requirements to ensure that EPR arrangements are in place and the authorization conditions are fulfilled at the facility or activity level.

The existing regulatory requirements for EPR for operating organizations are in line with GS-R-2. In the future there is a need to update them in line with the newly published GSR Part 7. A similar finding has been identified by VATESI in the self-assessment (Action #26 of the Action Plan).

The obligation for the users of radiation sources to establish an emergency plan is set out in Governmental Decree No. 653 Rules on the Licensing of Practices with Sources of Ionizing Radiation. Other requirements for EPR for operating organizations in EPC III and IV are addressed in a number of legislative acts, such as Law on Radiation Protection, and a number

of Hygiene Standards: HN 73:2001, HN 99:2011 and Hygiene Standards for different types of activities with Sources of Ionizing Radiation (HN 31:2008, HN 52:2012, HN 77:2002, HN 86:2005, HN 95:2015).

The responsibility to prepare regulatory acts on EPR in RSC belongs to the Division for Radiation Emergency Management and Training. According to the discussions held, this division is involved only from time to time in the evaluation of on-site emergency plans for EPC III and EPC IV and does not participate in on-site emergency exercises organized by these licensees. During the licensing process, Division for authorization uses the RSC Director's Order V-82 which contains specific requirements for on-site emergency plans. For inspection purposes, RSC Division for inspection developed general and specific questionnaires, based on existing EPR requirements included in the legislative framework, which are used for checking the compliance of the on-site emergency plans with the required content. Although these questionnaires are very useful and provide a good basis for evaluation, during the interviews the IRRS team noticed that there is no systematic cooperation between Divisions for authorization and inspections with the Division for Radiation Emergency Management and Training, for evaluating on-site emergency plans for EPC III and EPC IV. As a consequence, some particular aspects related to the on-site emergency plan are not covered by RSC during the evaluation process.

One aspect considered for review was the involvement of RSC in the on-site emergency exercises of EPC III and EPC IV, in order to observe and evaluate on-site staff performance and adequacy of on-site EPR arrangements versus regulatory requirements. According to the legal requirements the operating organizations using dangerous sources have to perform annually one exercise to test the on-site arrangements. During these exercises, only some parts of the on-site emergency plan are tested. During the interviews it was noticed that RSC seldom participate as observers and evaluators in the on-site emergency exercises and there are no effective evaluation criteria for the exercises they observe. RSC performs mainly one inspection per year in relation to the EPR arrangements of EPC III and IV. In relation to on-site exercise evaluation, during the annual inspections, RSC inspectors only check the report of the previous conducted exercise. The feedback resulting from the on-site emergency exercises is not systematically considered by RSC and there is no verification of how lessons learned are incorporated and transposed into improved on-site EPR arrangements.

With respect to nuclear facilities, the requirements on EPR for the operating organization are set out in the Law on Nuclear Energy, Law on Nuclear Safety, the VATESI Order P-2008-1 and in the Plan on Protection of State Residents in case of Nuclear Accident. The responsibility to prepare regulatory acts on EPR in VATESI belongs to the Division for Transportation and Radiation Safety. This same Division is also responsible to evaluate the on-site emergency plans and associated instructions for nuclear facilities during the authorization process or whenever is needed, and to inspect and supervise the nuclear facility in the EPR area.

Based on VATESI requirements, the nuclear facility has the responsibility to prepare an on-site emergency plan that has to be submitted to VATESI during the authorization process. During the review process of the on-site emergency plan, every three years, VATESI inspectors check for compliance of the on-site emergency plan and the associated instructions with the required content. The on-site emergency plan is approved by the management of the operating organization after receiving the formal agreement from VATESI.

VATESI inspectors perform 1 or 2 inspections per year at nuclear facilities, in which they check instructions, arrangements, and the availability and condition of required supplies,

equipment and communication systems for adequate emergency response. No pre-defined check lists or questionnaires are used during the inspection process. These observations support the basis for Suggestion 20 in Section 7.1. During inspections, also the reports of previous exercises are evaluated and the inspectors check for the implementation of corrective actions resulted from the evaluation of exercises.

During interviews, the IRRS team discussed the involvement of VATESI staff in the evaluation of on-site emergency exercises of nuclear facilities. According to the discussions held, the operating organization of nuclear facilities organizes once in three years a full scale on-site emergency exercise with the participation of entire on-site emergency organization. On an annual basis, only some parts of the on-site plan are tested. After each full scale on-site exercise conducted once every three years, a report is prepared by the operating organization, in which all recommendations, suggestions and observations coming from all observers and evaluators (VATESI, RSC, Fire and Rescue Department, local officials) are gathered. Based on exercise report, an action plan with corrective actions is prepared by the nuclear facility and this plan is inspected by VATESI for implementation. The feedback from exercises is consistently and systematically considered by VATESI inspectors for enforcing the regulatory control over improvement of on-site EPR arrangements.

Assessment of threats

In 2011 the threat (emergency preparedness) categories have been adopted in the HN 99:2011 in line with GS-R-2 (Table 1), but they are not actually used for providing a graded approach to on-site EPR planning. For example, the regulatory requirements for operating organizations using radioactive sources apply to all radioactive sources, irrespective of their activity and the associated radiological risk.

A similar situation exists in relation to EPC I facilities. Although some requirement exists for nuclear facilities on conducting safety analysis of potential accident prior the elaboration of the on-site emergency plan (VATESI Order P-2008-1), there are no specific requirements, criteria or guidance for operating organizations for developing and periodical review of the threat (hazard) assessment as basis for on-site planning, with due consideration of any changes to the on-site hazards. This is the case especially for INPP site, during the transitional phase from operation to decommissioning.

The threat (emergency preparedness) categorization has to be updated and regulatory requirements on hazard assessment have to be prepared by RSC and VATESI, in line with GSR Part 7. Similar finding has been identified by RSC and VATESI in the self-assessment (Action #44 of the Action Plan). During discussions held, the IRRS team has been informed that a draft version of a common Order of RSC and VATESI is already prepared and should be soon promulgated, which includes requirements, criteria and guidance for the operating organizations to perform their hazard assessment as planning basis for their preparedness and response arrangements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Lithuania has a number of legislative acts (laws, governmental decrees, ministerial orders, and hygiene norms) including regulatory requirements for operating organizations on preparedness and response for a nuclear or radiological emergency, which do not meet the latest relevant IAEA Safety Standard GSR Part 7.	
(1)	**BASIS: GS-R-2 para. 3.9 states that** "*In fulfilling its statutory obligations, the*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	regulatory body shall establish, promote or adopt regulations and guides upon which its regulatory actions are based; [...].”
(2)	**BASIS: GSR Part 1 Requirement 33 states that** *“Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained.”*
R22	**Recommendation: RSC and VATESI should jointly review, update and complete, in line with their assigned responsibilities, the regulatory requirements for preparedness and response for a nuclear or radiological emergency, in line with GSR Part 7.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RSC Divisions for authorization and inspections do not systematically cooperate with the Division for Radiation Emergency Management and Training for evaluating on-site emergency plans and for observing and evaluating the on-site emergency exercises of facilities in EPC III and activities in EPC IV.	
(1)	**BASIS: GS-R-2 para. 3.8 states that** “*The regulatory body shall require that arrangements for preparedness and response be in place for the on-site area for any practice or source that could necessitate an emergency intervention. For a facility in threat category I, II or III [...] The regulatory body shall ensure that such emergency arrangements provide a reasonable assurance of an effective response, in compliance with these requirements, in the case of a nuclear or radiological emergency. [...]”*
(2)	**BASIS: GS-R-2 para. 5.33 states that** *“The Exercise programmes shall be conducted to ensure that all specified functions required to be performed for emergency response and all organizational interfaces for facilities in threat category I, II or III and the national level programmes for threat category IV or V are tested at suitable intervals. [...] The exercises shall be systematically evaluated and some exercises shall be evaluated by the regulatory body. The programme shall be subject to review and updating in the light of experience gained.”*
S22	**Suggestion: RSC should consider improving its internal process for evaluation of on-site emergency plans and exercises of operating organizations in EPC III and IV, and to ensure that lessons learned are considered and transposed into improved on-site EPR arrangements.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Although threat (emergency preparedness) categories are adopted in HN99:2011 in line with the international requirements, the current regulatory framework does not explicitly include requirements, criteria or guidance for operating organizations to perform and periodically conduct on-site threat (hazard) assessment as basis for their on-site planning.	
(1)	**BASIS: GS-R-2 para. 3.15 states that** *"The nature and extent of emergency arrangements for preparedness and response shall be commensurate with the potential magnitude and nature of the threat… associated with the facility or activity.[...] The threat assessment shall be so conducted as to provide a basis for establishing detailed requirements for arrangements for preparedness and response [...]."*
R23	**Recommendation: RSC and VATESI should jointly prepare and promulgate requirements, criteria and guidance for operating organizations, in line with their assigned responsibilities, to perform and periodically review the on-site hazard assessment as basis for a graded approach to emergency preparedness arrangements.**

10.2. FUNCTIONAL REGULATORY REQUIREMENTS

All requirements, including those identified as missing in this sub-chapter should be considered for compliance when the legislative framework will be updated and completed in line with GSR Part 7 (see Recommendation 22 in Section 10.1).

Establishing emergency management and operations

The regulatory requirements for nuclear facilities are in place for establishing the structure of emergency preparedness organization, coordinating actions at different levels of the organization, defining the responsibilities of each member of the organization, and transition from normal to emergency operations. Similarly, the requirements for emergency management and operations are also established in HN 73:2001, which are applicable for nuclear facilities and users of ionizing radiation sources.

Identifying, notifying and activating

As per regulatory requirements established by VATESI, the licensee of nuclear facility should define the emergency class based on the classification system described in GS-R-2. Similarly, HN 99:2011 also addresses the requirement for prompt classification of an emergency and emergency classes listed in the standards are same as in GS-R-2. As observed during the interviews, predefined Emergency Action Levels for classifying an emergency situation are included in the on-site emergency plan of a nuclear facility.

Regulatory requirements for notification of an emergency to the regulatory bodies and other relevant authorities are in place for all operating organizations. Timing requirements for classification and notification of an emergency are included in the State Residents Protection Plan in Case of a Nuclear Accident. VATESI also requires immediate notification by licensees regarding all safety significant events.

Requirements for notifying the RSC and activating the response in situations related to scrap metal facilities are addressed under the Rules on the handling of orphan sources nuclear material and contaminated objects. Similarly, requirements for radioactive control of scrap metal recycling and processing facilities are also established.

Taking mitigatory actions

Provisions are included in the regulatory requirements for operating organizations to take mitigatory actions in case of a nuclear or radiological emergency.

VATESI and RSC have established the requirements for provision of external emergency services to operating organizations for mitigating the on-site consequences of a nuclear or radiological emergency. The compliance with this requirement is checked by VATESI during the on-site exercises. It was noticed during the discussions held with the RSC inspectors that for operating organization in EPC III these arrangements are rarely tested.

Taking urgent protective action

Generic Criteria and Operational Intervention Levels for taking urgent protective actions and other response actions in emergency exposure situations are addressed in HN 99:2011, in line with GSG-2. Regulatory requirements for emergency planning zones are also addressed in HN 99: 2011 and these zones are in line with GS-G-2.1. Regulatory requirements for establishing criteria for terminating the urgent protective actions are missing. Similar finding has been identified by RSC in the self-assessment (Action #45 of the Action Plan).

Providing information and issuing instructions

Regulatory requirements in VATESI Order P-2008 and HN 99:2011 ask for operating organizations to assist the State authorities and institutions in disseminating information to the public. As per requirements, the operating organization of nuclear facilities shall establish instructions on how and what information to be provided to the public.

Protecting emergency workers

Protection of emergency workers is regulated under the Law on Radiation Protection, HN 73:2001 and RSC Director's Order No. 57. The requirements on guidance values for emergency workers are consistent with GS-R-2. VATESI has established separate requirements for the nuclear facility on: designation of emergency workers; provision of information about health risks, hazardous conditions under which the workers have to perform different jobs; monitoring and evaluation of received doses during intervention.

Assessing the initial phase

VATESI explicitly requires licensees to have capability for promptly assessing the situation during the initial phase of an emergency. There is a requirement that the licensee must classify the emergency and have the ability to promptly evaluate the emergency situations and advise protective actions in the urgent phase of an emergency. Accordingly, the licensee shall be adequately prepared by having relevant instructions, necessary instruments and software to assess the urgent phase of the emergency. The regulatory requirement for assessing the initial phase of a radiological are described in HN 73:2001, which requires the licensees to make an initial provisional assessment of circumstances and consequences of an emergency and initiate intervention.

Managing the medical response

Regulatory requirements for the operating organizations in relation to the medical response in case of nuclear or radiological emergency are in place. Instructions for medical services and evacuation arrangements are issued for the nuclear facility. As per discussions held with VATESI EPR inspectors, the operating organization, besides on-site decontamination and first aid, has arrangements in place for transportation of injured persons to special medical facilities.

Other activities in emergency preparedness

The criteria for taking agricultural countermeasures and countermeasures to reduce ingestion doses are established in HN 99:2011, while criteria for long term protective actions are defined in HN 73:2001. These criteria are consistent with IAEA safety standards.

VATESI requires the nuclear facility to clearly define the transition from the emergency phase to long term recovery operations. Generically, requirements for addressing the non-radiological consequences of an emergency by operating organizations are included in HN 73:2001. However, these are not addressed in the requirements for nuclear facilities. A similar finding has been identified by VATESI in the self-assessment (Action #26 of the Action Plan).

Although requirements are in place for RSC to assess public exposure in case of a nuclear or radiological emergency, however, there is no clear requirement in the legal framework for making the results of these assessments publicly available.

10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE

All requirements, including those identified as missing in this sub-chapter should be considered for compliance when the legislative framework will be updated and completed in line with GSR Part 7. (see Recommendation 22 in Section 10.1)

Authority

Both VATESI and RSC have authority for regulating the EPR activities of respective operating organizations.

Organization

Functional regulatory requirements on staffing of licensee's response organization are established in the requirements issued by VATESI and in the Order No. 82V issued by RSC. The licensees are required to assign a sufficient number of employees to promptly staff the positions necessary following the declaration and notification of a nuclear or radiological emergency and for longer term operation.

Coordination of emergency response

The regulatory requirements for coordination between on-site and off-site response organizations are defined. Coordination of emergency response for nuclear facility is described in "Instruction on cooperation with organizations, companies and services in liquidation emergencies at INPP.

Plans and procedures

The Law on Nuclear Safety and HN 73:2001 establish the requirements for preparation of emergency plans by the operating organizations and their submission to regulatory bodies for review and approval. For the nuclear facility, a requirement is in place that the plan should be

tested through exercise prior to bringing the nuclear fuel to the site. When the on-site emergency plan is revised at every three years, as part of approval process, the plan has to be tested through one full scale on-site emergency response exercise. As per requirements in place, the emergency plans of operating organizations using radiation sources have to be revised every year.

It was revealed during the discussion with RSC that the on-site emergency plans for EPC III facilities and EPC IV activities are partially tested during the exercise, as described in section 10.1.

Logistical support and facilities

The regulatory requirement on logistical support and facilities for emergency preparedness and response are clearly defined in VATESI P-2008-01 for nuclear facilities and in Order No. 82 V of RSC for EPC III and EPC IV.

Training, drills and exercises

VATESI requires the operating organization to identify the knowledge and skills necessary for the workers involved in emergency preparedness and response. The licensees are required to prepare training and exercise program for each group of emergency preparedness organization. Conducting periodic refresher training is also mandatory for the operating organization.

Under the Law on Radiation Protection, compulsory training is mandatory on radiation protection including training on emergency preparedness and response for all the relevant on-site personnel.

According to existing requirements in VATESI Order P-2008-1, full scale on-site emergency exercises are conducted for the nuclear facility once every three years, while limited parts of the on-site emergency plan are tested in yearly exercises.

The exercises for the EPC III facilities and EPC IV activities are conducted on an annual basis. Most exercises are not observed or evaluated by RSC inspectors. Based on discussions held, there is no systematic control by RSC to ensure that all aspects (e.g. receiving external support from off-site emergency services and public information) of the on-site plans are regularly tested.

As a general observation revealed during interviews, no specific criteria are in place for the evaluation of the on-site exercises for facilities and activities in EPC I, III and IV.

Quality assurance programme

VATESI has established the requirements for operating organization to establish and implement quality management program which should cover all types of operations that can make an impact on the emergency response.

The operating organization of the nuclear facility is required to review the existing emergency plan and procedures at least once every three years, while for radiation sources this review is done at least once in every year.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: (i) The on-site emergency response plans of facilities in EPC III or activities in EPC IV are partially tested in the annual on-site exercises. There is no systematically control of RSC and evaluation criteria to ensure that the all aspects (e.g. receiving external

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
support from off-site emergency services and public information) of the on-site plans are regularly tested and effectively evaluated. (ii) According to the existing requirements, INPP shall organize once every three years a full scale on-site emergency response exercise with the participation of whole on-site emergency response organization. On an annual basis, only some parts of the on-site plan are tested. No specific criteria are in place at VATESI or at INPP for the evaluation of the on-site exercises.	
(1)	**BASIS: GS-R-2 para. 5.33 states that** *"The Exercise programmes shall be conducted to ensure that all specified functions required to be performed for emergency response and all organizational interfaces for facilities in threat category I, II or III [...]are tested at suitable intervals. [...] The exercises shall be systematically evaluated and some exercises shall be evaluated by the regulatory body. The programme shall be subject to review and updating in the light of experience gained."*
(2)	**BASIS: GS-R-2 para. 5.34 states that** "*The staff responsible for critical response functions for a facility in threat category I, II or III shall participate in a training exercise or drill at least once every year. [...]."*
S23	**Suggestion: RSC should consider ensuring that all critical functions of the on-site emergency plans for EPC III and IV are tested through the annual on-site exercises and that criteria are in place for effective evaluation of annual on-site exercises.**
R24	**Recommendation: VATESI should set a requirement and oversee that staff responsible for critical response functions within the on-site emergency organization for facilities in EPC I shall participate in a training exercise or drill at least once every year. VATESI should also set a requirement and oversee that criteria are in place for effective evaluation of annual on-site exercises.**

10.4. ROLE OF REGULATORY BODY DURING RESPONSE

Both regulatory authorities have clearly allocated roles and responsibilities as response organizations within the national system for emergency management. The main responsibilities of RSC and VATESI as response organizations are defined in the legal framework.

The expertise and services in radiation protection available to local officials and first responders dealing with emergencies for activities in EPC IV is ensured by the RSC, which has adequate capabilities and trained staff to provide these services. The RSC can provide support by sending a team of 2–3 experts at the scene. In addition, RSC is responsible for radiological consequence assessment, conduct and coordination of emergency radiation monitoring, and formulation of recommendations for population and emergency workers protection in case of a nuclear or radiological emergency. In case of state-level radiological emergency, RSC shall be appointed as "responsible institution" for coordinating the

radiological emergency response. In such situations, all other responsible ministries and State Institutions including VATESI shall provide support to RSC.

For nuclear emergencies, the role of VATESI as a response organization is specifically addressed in the State Residents Protection Plan in case of Nuclear Accident. In case of nuclear emergency VATESI shall assess the situation and make prognosis on facility conditions evolution in INPP or other nuclear facilities under its jurisdiction and may recommend actions for on-site consequences management. In addition, VATESI has specific roles for international notification and information exchange, in line with the provisions of International Conventions for Early Notification. With respect to this, VATESI is the National Warning Point and the National Competent Authority for Accidents Abroad and shares the responsibility as National Competent Authority for Domestic Accidents with the Fire and Rescue Department (FRD). For domestic accidents VATESI is responsible with international notification and exchange of information, while FRD is responsible with requesting international assistance.

Both regulatory authorities have established emergency operations centres, in terms of suitable facilities and equipment for carrying out their response functions. The emergency operations centres are endowed with basic communication systems and IT systems. The RSC's emergency operations centre is provided with backup electricity for operation in case of electricity breakdown. VATESI's emergency operations centre has computer codes for INPP parameters collection and analysis, and also for technological and radiological consequences assessment. The emergency operation centre of VATESI is provided with short term backup electricity, but not for long term operation, and this could negatively affect its functionality in case of emergency.

RSC and VATESI have in place their own emergency plan, an established emergency organization (ERO) and emergency procedures for performing their response functions. The EROs of RSC and VATESI have well defined groups and assigned positions for their response functions. While the positions of RSC's ERO are staffed with sufficient number of experts, for VATESI it appears that there is a lack of staffing the positions within the ERO for long term operation in case of severe emergency at INPP. Taking into consideration of future developments, VATESI may investigate means to receive support from external organizations for staffing its ERO.

RSC and VATESI have in place annual internal training programmes to increase the knowledge, skills and abilities of their staffs for the roles within the EROs. In addition, every year RSC and VATESI staffs participate in national training on emergency management, together with experts from other response organizations.

In addition, RSC is very active in conducting and supporting training at national level on radiation protection and EPR areas. As an example, in 2015 RSC conducted the training at national level of 266 first responders in different counties of the country: Visaginas hospital, police in Panevezys county, the specialists of the VIP Protection Department under the Ministry of the Interior of the Republic of Lithuania, the firefighters from Fire and Rescue Department under the Ministry of the Interior, firefighters in Klaipeda county, civil protection specialists in Vilnius county. This observation supports the basis for Good Practice 2 in Section 3.3.

To test their staff for roles within the ERO and the adequacy of existing EPR arrangements, RSC and VATESI participate in internal drills and exercises, and in exercises conducted at national level. In addition, RSC and VATESI participate annually according with their roles and responsibilities in drills and exercises at international level (CMX NATO crisis

management exercises; IAEA ConvEx exercises; EC ECUREX exercises; Baltic state exercises).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The emergency operations centre of VATESI is not provided with backup electricity for long term operation, which could negatively affect its functionality in case of emergency.	
(1)	**BASIS: GS-R-2 para. 5.25 states that** *"5.25. Adequate tools, instruments, supplies, equipment, communication systems, facilities and documentation (such as procedures, checklists, telephone numbers and manuals) shall be provided for performing the functions [...].These support items shall be located or provided in a manner that allows their effective use under postulated emergency conditions."*
S24	**Suggestion: VATESI should consider all possible ways for ensuring backup electricity at the emergency operations centre.**

10.5. SUMMARY

A comprehensive legislative framework is in place, in line with GS-R-2 (2002), which defines and allocates the regulatory mandate and responsibilities of both regulatory authorities in the field of EPR. As the IAEA safety standards on EPR have been recently published as GSR Part 7 (2015), the existing regulatory requirements for EPR for operating organizations have to be revised for compliance with GSR Part 7.

Although threat (emergency preparedness) categories are adopted in HN 99:2011 in line with the international requirements, there are no requirements, criteria or guidance on how to use them. RSC and VATESI should jointly prepare and promulgate requirements, criteria and guidance for operating organizations on how to perform and periodically review the on-site hazard assessment as basis for a graded approach to planning for EPR.

The regulatory system, as well as the inspection system, are well established and properly functioning for both regulatory authorities. Areas for improvement have been identified during the IRRS mission, for both RSC and VATESI, to strengthen their regulatory control over on-site emergency plans and on-site emergency exercise evaluation.

Both RSC and VATESI have in place emergency plans, emergency organizations (ERO) and emergency procedures for performing their response functions within the national system for emergency management. The EROs of both RSC and VATESI have well defined groups and positions for their respective response functions. In terms of logistics, VATESI should consider all possible ways for ensuring the functionality of its emergency operations centre under postulated emergency conditions.

The active involvement and commitment of both regulatory authorities for training of their staff and for knowledge sharing and capacity building within the national system for emergency management is recognized by the IRRS team as a good practice.

11. ADDITIONAL AREAS

11.1. CONTROL OF MEDICAL EXPOSURES

Responsibilities

Responsibility for establishing legislation with respect to medical exposures is assigned to the Ministry of Health through the 'Law on Radiation Protection'. The Law assigns RSC the responsibility for regulating practices involving radiation including medical exposures. All medical practices are authorized by RSC's licensing system and the licences are issued according to the 'Rules on licensing the practices with sources of ionizing radiation'. RSC has sole responsibility for the protection of patients undergoing medical radiological exposures.

The Law specifies the responsibilities and requirements for the licence holder which include the appointment of qualified responsible persons and ensuring that workers meet the qualification requirements established by the legislation. Health professionals who work with sources of ionizing radiation must pass compulsory training on radiation protection before commencing their work. As part of the licensing process, RSC requires a list of employees who have the right to work with or in the environment of sources, and their certificates confirming their professional qualification and radiation protection training.

Medical Exposures are specifically dealt with in the Hygiene Standard, 'Basic Standards of Radiation Protection' and apply to the use of ionizing radiation for all medical applications including radiology, radiotherapy, nuclear medicine and dental. In the Law on Radiation Protection it is specified that medical licence holders must make arrangements to ensure that appropriate quality assurance programmes are developed and implemented and that the patient exposure is as low as reasonably achievable and registered in the manner required by the Ministry of Health.

The responsibilities of the prescriber and practitioners are also set out in these Basic Standards. Clinical responsibility regarding individual medical exposures is attributed to the practitioner; specifically, with respect to justification, optimization, clinical evaluation of outcome and co-operation with other practitioners, as appropriate. The medical physicist shall be involved in radiation therapy procedures. Medical physicists are permitted by RSC to work independently in specific radiation applications once confirmation has been received from the Medical Physicists Association of Lithuania that they have sufficient competence and experience. There is no formal recognition of medical physicists and the current recognition practice is not in line with IAEA recommendations. Draft legislation has been prepared to address this issue which has been submitted to the Ministry of Health but is yet to be approved. Furthermore, while there are mandatory, RSC-approved radiation protection training courses for medical radiation technologists, it should be noted there is no professional recognition or approval mechanism for these staff. These issues are addressed in Recommendation 6 in Section 1.8.

Justification

The legislation states that both the prescriber and practitioner, according to their competence, shall be involved in the justification of medical exposures for patients. Individual justification of medical exposures must be performed in advance under prescription of the prescriber and the practitioner is responsible for the medical exposure. Referral criteria that can be taken into

account in this justification process are not available in Lithuania and therefore the requirements of GS-R-3 are not being met.

A Ministerial Order specifies mandatory requirements with respect to the information to be obtained in the justification process of a medical exposure. These requirements are related to the National Health Insurance Fund as payment to hospitals is provided only if this Order is followed. These requirements do not fulfil the function of referral guidelines and are an administrative record of information to be obtained in the justification process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The legislation specifies that all exposures must be justified. In practice, there are no international or national referral guidelines that can be taken into account for the justification of a medical exposure for an individual patient.	
(1)	**BASIS: GSR Part 3 Requirement 36, states that** *"Registrants and licensees shall ensure that no person incurs a medical exposure unless there has been an appropriate referral, responsibility has been assumed for ensuring protection and safety, and the person subject to exposure has been informed as appropriate of the expected benefits and risks."* **BASIS: GSR Part 3 Requirement 37, para. 3.158 states that** *"Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure."*
R25	**Recommendation: RSC should require that referral guidelines are being used in the justification of individual medical exposures.**

According to the Basic Standards, generic justification of new types of practice can be evaluated by RSC on a case by case basis. In practice, hospitals must use diagnostic and treatment methods which are developed by procedures approved by the Minister of Health. If there are no nationally developed and approved techniques, the hospital must prepare protocols that are important to ensure the quality of health care provider's services. For this process, the hospital must meet the requirements of the Order on 'Minimal Quality Requirements for Health Care requirements'. This process usually involves the establishment of a working group composed of the relevant stakeholders and professional bodies. Where radiation is involved, RSC is represented in the working group. It should be ensured that this process is formally documented.

The licensee can perform health screening only according to the procedure established by the Law. Justification of medical exposure of healthy individuals and patients, which voluntarily take part in research programmes, must be scrutinized by Lithuanian Committee of Bioethics.

Optimization

The regulations explicitly establish the principle of optimization and include provisions on establishing diagnostic reference levels (DRLs), dose constraints and quality assurance programmes. The appropriate medical physicist shall also give advice to members of staff on optimization of radiation protection, including patients' dosimetry. Before first using the radiological equipment for diagnostics or therapy, acceptance tests shall be carried out on this

equipment. The criteria for quality control of the medical X-ray, therapy and nuclear medicine equipment are adopted by the Orders of Minister of Health.

National DRLs have been established by the Minister for Health. RSC is currently conducting a 5 year national study to assess patient dosimetry. This study serves the dual purpose of verifying the national DRLs and also of providing feedback to hospitals on how their patient doses compare to the national DRLs. This study is due to be completed next year.

Dose constraints for comforters and carers have also been set by RSC at 5mSv per patient.

Pregnant women and breast feeding women

Requirements regarding pregnant and breast feeding patients are included in the legislation. Licensees are required to place signs (in appropriate languages) in relevant areas requesting patients to notify staff in the event that they are or might be pregnant or breast-feeding. Licensees must ensure that procedures are in place for ascertaining the pregnancy status of female patients before performing radiological procedures that could result in a significant dose to the fetus, so that this information can be considered in the justification process and in the optimization of protection and safety. It is mandatory for licensees to ensure before therapy procedures that a woman is not pregnant. Instructions are also provided to nursing mothers who have undergone a nuclear medicine procedure for the protection of the infant.

Unintended Medical Exposures

According to the legislation, the licensee is responsible for taking all necessary preventive actions regarding the occurrence of unintended and accidental medical exposures. There are also requirements to notify RSC without delay in the case of such incidents and within seven days in written form. In the event of an incident, the licensee shall investigate the incident including performing a calculation of an estimate of the dose received. A Ministerial Order requires that unintended or accidental medical events must be registered and that RSC must analyse this information and present a report quarterly to the Ministry of Health. There are further requirements for the reporting of radiotherapy incidents specified and approved by the Director of RSC.

Release of patients

The legislation provides for written instructions to be supplied to patients released following radionuclide therapy to ensure the protection of family and members of the public. Release criteria 400 MBq for I-131 are set that doses to persons who come into contact with these patients should not exceed 5mSv and 1mSv (per patient) in the case of children and pregnant women.

Review and records

RSC require licensees to maintain appropriate records in line with the requirements of G-SR-3.

There is provision in the legislation that clinical audits must be performed by the licensee, this is enforced by RSC. In practice, radiotherapy departments have arranged their own internal and external clinical audits. Some external audits have also been performed in nuclear medicine departments. Ministry of Health has not developed a framework specifying how systematic clinical audit programmes should be performed and who is qualified to perform clinical audits.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: While there is provision in the legislation that clinical audits shall be carried out by licensees, RSC does not enforce the conduct of clinical audits consistently in medical facilities.	
(1)	**BASIS: GSR Part 3 Requirement 38, para. 3.172 states that** *"Registrants and licensees shall ensure that regular and independent audits are made of the programme of quality assurance for medical exposures, and that their frequency is in accordance with the complexity of the radiological procedures being performed and the associated risks."* **BASIS: GSR Part 3 Requirement 42, states that** *"Registrants and licensees shall ensure that radiological reviews are performed periodically at medical radiation facilities and that records are maintained."*
S25	**Suggestion: RSC should consider enforcing that radiological reviews (clinical audits) are performed periodically at medical radiation facilities.**

11.2. OCCUPATIONAL RADIATION PROTECTION

Legal and regulatory framework

The fundamental legislation for occupational radiation protection is established in the *Law on Radiation Protection.* This Law establishes the legal framework for radiation protection in the Republic of Lithuania, for the protection of people and the environment from the harmful effects of ionizing radiation. The Law also introduces the fundamental principles of radiation protection: justification, optimization and limitation. As well, the Law establishes the competence of the regulatory bodies responsible for the regulation and supervision of occupational radiation protection in practices in the nuclear energy sector (VATESI) and all other practices involving sources of ionizing radiation (RSC).

RSC's legislation for regulation of occupational radiation protection includes the Hygiene Standards approved by the Ministry of Health; specifically HN73:2001. Requirements related to occupational radiation protection are also provided in additional Hygiene Standards for specific areas and practices, including X-ray diagnostics, nuclear medicine, industrial radiography, and radiotherapy.

The *Law on Nuclear Safety* also provides the main responsibilities for licensees engaged in practices in the nuclear energy sector, including radiation protection. VATESI has been granted the authority to draft and approve corresponding legislation for occupational radiation protection for the nuclear energy sector. VATESI also has supervisory powers over how provisions established in legislation are implemented. The main legislation for occupational radiation protection for Lithuania's nuclear energy sector includes VATESI's Nuclear Safety Requirements BSR-1.9.3-2011. As stated in the ARM, Hygiene Standards approved by the Ministry of Health have also been adopted for the nuclear energy sector, and VATESI has the authority to supervise and enforce how these standards are implemented by licensees.

HN73:2001 establishes the dose limits for effective and equivalent doses for workers and apprentices (students). Occupational dose limits for planned exposure situations and dose limits for emergency workers are prescribed. The occupational dose limits are in line with GSR Part 3, including the new equivalent dose limits for the lens of the eye following an

amendment to legislation in September 10, 2014. Tissue weighting factors and radiation weighting factors; used in the calculation of effective dose; are established in HN73:2001. The IRRS team identified that revisions are necessary of these weighting factors in order to align with those provided in GSR Part 3. This observation supports the basis for Recommendation 19 in Section 9.4.

Workers undertaking interventions are not to be exposed in excess of the occupational dose limits specified in HN 73:2001, except in special cases of intervention and when doing so voluntarily. The intervention levels for special cases of intervention (i.e. to save life or prevent serious injuries; to avert large collective dose; and, to prevent development of catastrophic conditions) are in line with GSR Part 3. It is noted that the intervention level for preventing the development of catastrophic conditions is more restrictive than what is recommended in GSR Part 3.

General responsibilities of registrants, licensees and employers

Main responsibilities for employers, registrants and licensees for the protection of all workers (including outside workers) for all practices involving ionising radiation and in the nuclear energy sector are established in the *Law on Radiation Protection.*

Additional responsibilities for employers, registrants and licensees in the nuclear energy sector are established in the *Law on Nuclear Safety* and BSR-1.9.3-2011. As reported in the ARM, VATESI identified a number of areas in its legislation where general responsibilities of registrants, licensees and employers need to be strengthened in order to fully align with GSR Part 3. Action Plan #35, which involves revisions to BSR-1.9.3-2011, was raised by VATESI to address these areas. These observations support the basis for Recommendation 19 in Section 9.4.

With regards to radiation protection training and instruction; RSC is responsible for assessing and approving training centres as per the requirements of the Order No. V-1001 of the Minister of Health of the Republic of Lithuania. As reported in the ARM, VATESI identified that currently there is no comprehensive legislation to ensure appropriate radiation protection training of workers in the nuclear energy sector; although this was regulated by RSC up until 2011. Recently, VATESI was granted the right to draft and approve legislation related to radiation protection training among the amendments to the *Law on Radiation Protection*, No. XII-2190, dated December 15, 2015. The amended legislation comes into force on May 1, 2016, as well as new legislation, BSR-1.9.4-2016.

For practices involving sources of ionizing radiation, responsibilities and requirements for employers, registrants and licensees regarding radiation protection and the protection of workers are detailed in HN73:2001 and the Resolution No. 653 of the Government of the Republic of Lithuania. These requirements align quite well with those dictated by GSR Part 3. Although HN73:2001 obliges workers to promptly notify the licensee upon identifying instances of non-compliance with radiation protection requirements, there is no legislated obligation for the licensee to generate a record of such a notification.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no requirement in RSC's regulations which explicitly requires licensees to record notifications of instances of non-compliances made by workers.	
(1)	**BASIS: GSR Part 3, Requirement 21, paragraph 3.80 states that** *"Employers, registrants and licensees shall record any report received from a*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	worker that identifies circumstances that could affect compliance with the requirements of these Standards, and shall take appropriate action."
R26	**Recommendation: RSC should require licensees to record any report received from a worker that identifies circumstances that could affect compliance with legislated requirements established for occupational radiation protection and take appropriate action.**

Requirements for dose constraints and exposure investigation levels for workers in the nuclear energy sector are well defined and prescribed in VATESI's BSR-1.9.3-2011. Similarly, requirements for the use of dose constraints and investigation levels are prescribed in HN73:2001 and Order No. 63 of the Director of the Radiation Protection Centre. The IRRS team identified that in practice, there is typically no use of dose constraints as a tool for optimizing worker doses beyond the design and planning stage for practices involving sources of ionizing radiation. Investigation levels are used and established for the purposes of controlling operations and exposures, and as triggers for investigations when reached.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RSC does not enforce the requirement for licensees to use dose constraints for the optimization of safety and protection for occupational exposures beyond the design and planning stages for practices involving sources of ionizing radiation.	
(1)	**BASIS: GSR Part 3, Requirement 11, subparagraph 3.22 (c) states that** "*The Government or the Regulatory Body shall establish or approve dose 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."*
S26	**Suggestion: RSC should consider encouraging the use of dose constraints by licensees for optimization of occupational exposures.**

Compliance by workers

Main responsibilities of all workers for protection and safey, in practices involving ionizing radiation and in the nuclear energy sector, are established in the *Law on Radiation Protection*. Additional responsibilities for workers are prescribed in BSR-1.9.3-2011 and HN73:2001, including obligations for workers to follow radiation protection requirements and local rules established by the licensee or permit holder, and proper use of equipment for radiation protection purposes. These comprehensive responsibilities for protection and safety align with the requirements of GSR Part 3.

Requirements for radiation protection programmes

A radiation protection programme is required for the issuance of licences or temporary permits for all practices involving ionizing radiation and the nuclear energy sector, as prescribed in the *Law on Radiation Protection.*

For practices involving sources of ionizing radiation, detailed requirements for radiation protection programmes are prescribed in HN 73:2001, which align well with those dictated by GSR Part 3.

In the nuclear energy sector, VATESI's BSR-1.9.3-2011 details the requirements for radiation protection programmes. As reported in the ARM, VATESI identified a number of areas regarding radiation protection programme arrangements and requirements where improvements are necessary to fully align with GSR Part 3. These gaps in legislation are currently being addressed through VATESI's Action Plan #35, with revisions to BSR-1.9.3-2011. These observations support the basis for Recommendation 19 in Section 9.4.

Assessment of occupational exposures and workers' health surveillance

The main requirements related to monitoring and recording of occupational exposures are prescribed in Resolution No. 651 of the Government of the Republic of Lithuania and Order No. V-675 of the Minister of Health of the Republic of Lithuania.

The *Law on Radiation Protection* empowers the Government of the Republic of Lithuania to establish the State Register of Sources of Ionizing Radiation and Exposure of Workers, through Government Resolution No. 651. RSC is responsible for the management of the State Register, in accordance with the *Law on Radiation Protection*. Data submission to the State Register must be provided in the manner required by the *Law on Radiation Protection* and the Order No. V-675.

BSR-1.9.3-2011 details requirements for the nuclear energy sector regarding the individual monitoring of workers, outside workers and visitors visiting controlled areas. This legislation also obliges the licensee or permit holder to organize health surveillance of workers .

For practices involving sources of ionizing radiation; HN 73:2001 and Order No. 63 of the Director of the Radiation Protection Centre detail the requirements for the assessment of occupational exposures. Licensees or temporary permit holders are also required to organize medical surveillance.

Monitoring programmes and technical services

The *Law on Metrology* establishes the State Metrology Service, which is responsible for the approval of calibration and metrology laboratories in Lithuania. Calibration services must be accredited by the Lithuanian National Accreditation Bureau in accordance with ISO/IEC 17025. The accredited calibration service provider in Lithuania is the Metrology Centre of Vilnius, which provides calibration services for active personal dosimeters and radiation dose rate meters. Foreign Secondary Standard Dosimetry Laboratories provide calibration services for passive personal dosimeters and other equipment (i.e., alpha, beta and X-ray measuring instrumentation).

There are commercial passive dosimetry services available through RSC and INTA (Information Technologies Application). The dosimetry services of RSC and INTA are accredited according to ISO/IEC 17025. The Ignalina Nuclear Power Plant (NPP) provides dosimetry services to their workers. *In vivo* measurements are conducted by RSC and at Ignalina NPP.

Service providers for individual monitoring must be accredited by the Lithuanian National Accreditation Bureau according to ISO/IEC 17025, or approved by RSC in accordance with the Order No. V-42 of the Director of the Radiation Protection Centre. Prior to 2011, the dosimetry service at Ignalina NPP was under the supervision of RSC and in compliance with the corresponding requirements for dosimetry services. As reported in the ARM; following

the amendment of the *Law on Radiation Protection* in 2011 which assigned supervisory responsibilities for radiation protection at Ignalina NPP to VATESI, RSC requirements for dosimetry services were no longer applicable. To address this issue, VATESI will adopt the requirement in legislation for dosimetry services in the nuclear energy sector to be accredited in accordance with the ISO/IEC 17025 standard. This is to be accomplished through revisions to BSR-1.9.3-2011, as per VATESI's Action Plan #35.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The requirements for authorization or approval of dosimetry services for the nuclear energy sector are not formally defined in VATESI's legislation.	
(1)	**BASIS: GSR Part 3, Requirement 20, subparagraphs 3.73 (a) and (c) state that** "*The regulatory body shall be responsible, as appropriate, for: (a) Establishment and enforcement of requirements for the monitoring, recording and control of occupational exposures in planned exposure situations in accordance with the requirements of these Standards; (c) Authorization or approval of service providers for individual monitoring and calibration services."*
R27	**Recommendation: VATESI should adopt in regulation the requirements for authorization or approval of dosimetry services for the nuclear energy sector**.

Conditions of Service

Requirements for conditions of service are established in HN73:2001 for all practices involving ionizing radiation and in the nuclear energy sector. The *Law on Radiation Protection* requires employers to provide a worker with alternative work in circumstances where symptoms of a disease related to the effects of ionizing radiation have been identified, or it is confirmed or suspected that a dose limit has been exceeded. In these instances, RSC has the authority to authorizes the worker to continue working.

Special arrangements for protection and safety for female workers and for persons under 18 years of age undergoing training

The *Law on Radiation Protection* establishes restrictions on adolescents, and pregnant and breastfeeding women on engaging in work activities involving sources of ionizing radiation. HN73:2001 additionally prescribes requirements for information to be contained in local rules for pregnant and breastfeeding workers and apprentices (students), obligations for female workers (pertaining to notifications), and provisions for dissemination of risk information to female workers and apprentices (students) on the influence of occupational exposures on a foetus and breast-fed infants. VATESI is also strengthening the requirements for dissemination of risk information to female workers in the nuclear energy sector through revisions to BSR-1.9.3-2011.

11.3. Control of RADIOACTIVE discharges, MATERIALS FOR clearance, AND EXISTING EXPOSURES SITUATIONS; environmental monitoring FOR PUBLIC RADIATION PROTECTION

Control of discharges

Both VATESI, which regulates activities of the nuclear facilities and RSC which regulates the activities of all other installations using radiation sources (including medical services), establish regulations that require the users to obtain an authorization for releasing radioactive materials to the environment. In accordance with these regulations, applicants have to submit the following information to the relevant regulatory body for approval:

- the characteristics and activity of the material to be discharged;
- the potential points and methods of discharge, the significant exposure pathways by which discharged radionuclides can deliver public exposure;
- the estimated doses to the critical groups (representative person) due to the planned discharges.

Conditions to be applied in each installation with regard to discharges (records, source monitoring, release procedures, etc.) are included in the authorization licence and compliance is verified by regulatory authorities during the inspections. Taking in to account that RSC is responsible at the national level for the control of the public exposure, the VATESI authorization process for discharges requires users to submit the plan of discharges to RSC for approval. VATESI issues the authorization after receiving RSC approval of the discharge plan. The conditions established in the authorizations issued by both regulatory authorities set discharge limits which are based on a dose constraint of 200 μSv/y for the members of the public.

Presently there is only one non-nuclear facility in Lithuania discharging radioactive materials to the environment and requiring an authorization. The licensee of the nuclear facility and the other users releasing radioactive materials below the exemption criteria are required to provide reports to RSC periodically on their discharges. RSC has provisions for collecting and storing such reports. Although information on releases made is available within RSC, there is no national recording system or database in place that could facilitate any assessment of data and the retention period required.

Clearance of materials

With respect to clearance of radioactive materials, both regulatory authorities are establishing specific regulations addressing the main concepts and relevant procedures to be applied. The relevant regulations establish dosimetric criteria in line with the GSR Part 3, which defines that the effective dose expected to be incurred by any individual owing to the cleared material is of the order of 10 μSv or less in a year. The regulations also consider conditional clearance requirements and relevant criteria for such cases.

A draft is in progress to update Order No. V-892 "Determination and application of procedure of clearance levels", applying for non-nuclear installations, that would include clearance criteria in agreement with requirements of GSR Part 3. See Recommendation 19 in Section 9.4 for the updating of regulations according to the requirements of GSR Part 3.

Environmental monitoring

In Lithuania, the main facilities releasing radioactive materials to the environment (NPP, radioactive waste management facilities) are located at the same site. Radiation facilities, such as nuclear medicine departments, educational and research facilities do not have significant releases to the environment. The structure of environmental monitoring in Lithuania is described in the Law on Environmental Monitoring and the Order of the Minister of Environment "On approval of regulation of environmental monitoring of economic entities" then establishes the requirements in this respect. Based on this Order, there are two levels of monitoring in the case of the nuclear facilities:

- National monitoring,
- Monitoring of economic entities.

A graded approach is considered in the regulations when justifying the pertinence of a radiological monitoring programme. The regulations establish that such a programme is not required if the estimated annual effective dose to the representative person is less than 0.1 mSv per year. Currently, based on this, the only ongoing environmental monitoring program at a local level (monitoring of economic entities) is carried out by the operator of nuclear facilities.

The main technical concepts and requirements of the radiological monitoring programme around installations releasing radioactive materials are established in the Order of the Minister of Environmental D1-546 (Annex 5 and 6). Complementary regulations are issued by the Ministry of Health which address the specific aspects with respect to the monitoring of food and drinking water. Although VATESI is responsible for the final approval of the environment programme, the design has to be previously evaluated and approved by the Environmental Protection Agency (EPA) and RSC. In addition, RSC and EPA carry out independent radiological monitoring.

An annual report, detailing the results of the environmental programme, is submitted by the licensees to EPA and RSC for the evaluation. The EPA is evaluating the radiological impact, if any, on local ecosystems and the possible accumulation of radioactive materials in the physical environment. The RSC verifies compliance with authorized discharge limits and any other regulatory requirements concerning the impact on the public. Nevertheless, according to the information provided there is a lack of appropriate interaction between both regulatory authorities (VATESI and RSC) regarding the result of assessment of the environmental programme. Consequently, nuclear facility licensees are not required to verify the adequacy of the assumptions made for the assessment of public exposure and the assessment for radiological environmental impacts. In this case, such verification could be considered important as the assumptions for the environmental impact are established in the regulation issued by VATESI some years ago are still being used for the assessment of the environmental impact. During this time, the period of the operation of the nuclear facilities and its discharges has changed and it certainly could be expected that some possible pathways of exposure or parameters used in the impact assessment could have also changed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: The data and results of the environmental monitoring program around the nuclear facilities are evaluated by RSC, as part of its responsibility in relation to control of public exposure. No information on such evaluation and analysis is used by VATESI in the

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
periodical review of the monitoring programme results and dose assessment.	
(1)	**BASIS: GSR Part 3 Requirement 32, para. 3.135 states that** *"The regulatory body shall be responsible, as appropriate, for:* *b) Review of periodic reports on public exposure (including results of* *monitoring programmes and dose assessments) submitted by registrants and licensees.* *(d) Assessment of the total public exposure due to authorized sources and practices in the State on the basis of monitoring data provided by registrants and licensees and with the use of data from independent monitoring and assessments."*
S27	**Suggestion: VATESI and RSC should consider implementing a mechanism for common review of the periodic reports of environmental monitoring programmes, results and dose assessments made by nuclear installations.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The evaluation of the public exposure due to the impact of the nuclear installations is made based on the assumptions previously defined in the related regulation. These assumptions, were established many years ago. The results of the radiological environmental monitoring are not used by licensees to verify the adequacy of these assumptions.	
(1)	**BASIS: GSR Part 3 Requirement 32, para. 3.137 states that** *"Registrants and licensees shall, as appropriate:* *g) Verify the adequacy of the assumptions made for the assessment of public exposure and the assessment for radiological environmental impacts."*
S28	**Suggestion: VATESI should consider requiring licensees to verify the adequacy of assumptions made for the assessment of public exposure and the assessment for radiological environmental impacts taking into account, inter alia, the results of the radiological monitoring.**

Existing exposure situations

The regulatory framework includes provisions for the management of existing exposure situations. In the case of natural radioactivity there are regulations establishing references levels for indoor radon concentrations and radon in water. Dose constraints are defined for external radiation due to construction materials, gamma emitters inside buildings and members of aircrews. Dose constraints are also set for public exposure due to NORM industries.

The main institution responsible for the control of public exposure is RSC. In this regard the RSC leads a very comprehensive programme for the monitoring of public exposure due to

any source (natural, medical, occupational and emergency). The annual report of the results obtained, including dose assessments, are made available to the competent authorities and given to the public through the RSC website.

The so called National Dedicated Programme for Radon is ongoing in the country. In the framework of this programme a very extensive survey of indoor radon levels is performed continuously, covering the areas and scenarios with highest risk. The results of this Lithuanian survey are published on the RSC website and an indoor radon risk map is available. There is no evidence on radon indoor problem so far.

11.4. SUMMARY

The IRRS team considers that RSC meets the requirements with respect to regulatory control of medical exposures. Some shortcomings were identified and a recommendation is made in the area of referral criteria for the justification of individual medical exposures. It is also suggested that RSC should consider ensuring that clinical audits are performed periodically at medical radiation facilities.

This module should also be read in conjunction with section 1.9 (Competence for Safety) where it is recommended that the Government should establish a process of formal recognition for medical physicists. The observation in Section 5.4 (Authorization of Radiation Sources facilities and Activities) is applicable to medical facilities and the recommendation that RSC should consider improving its implementation of a graded approach in the system of protection and safety, should be noted here. (Please refer to S13 in Section 5.4).

Legislation for occupational radiation protection in Lithuania is mainly in line with IAEA GSR Part 3. Improvements have been identified by the regulatory bodies and through the IRRS review which will ensure full alignment with IAEA Requirements, for the generation of records and use of dose constraints in practices involving ionizing radiation, and formalization of requirements for dosimetry services in the nuclear energy sector. These improvements will further strengthen the regulatory framework for occupational radiation protection

Existing regulations require users to obtain an authorization for discharges. Authorizations establish the conditions for release and discharge limits. For non-nuclear installations the regulatory body doesn´t have an appropriate system to ensure and maintain records of discharges made by the licensees. Specific regulations exist to address clearance criteria for radioactive materials. In the case of non-nuclear facilities, the regulations could be updated in order to meet IAEA GSR Part 3. Lithuanian regulations establish requirements for the implementation of environmental monitoring programs for facilities that release radioactive materials to the environment. A system exists for verifying the validity of the monitoring results and a nationwide environmental monitoring program is carried out by RSC and the Environmental Protection Agency. Nevertheless, there is a lack of appropriate interaction between both regulatory authorities (VATESI and RSC) with respect to the assessment of the radiological environmental programme results. The regulations also include safety requirements to deal with existing situations. A comprehensive programme is in place to assess the public exposure due to any source of radiation.

12. INTERFACE WITH NUCLEAR SECURITY

12.1. LEGAL BASIS

According to the Laws on Nuclear Safety and on Nuclear Energy, VATESI performs the State regulatory and supervision functions related the safety, security and the control of and accounting for nuclear material. Some provisions concerning nuclear security (in Lithuania the term “Physical security” is used in the same context as “Physical protection” in the IAEA documents. Physical security is a part of overall nuclear security) are also provided in the Laws mentioned above.

The requirements regarding physical security for nuclear facilities are established for the different stages of the planning for and during the lifetime of a facility: siting, design, construction, operation and decommissioning.

An explicit statement that the physical security measures must not compromise safety is given in the document BSR-1.6.1-2012, however, the similar provision for the safety measures must not compromise security is missing. Further on, the interface of safety with physical security is established through provisions in management systems of VATESI, which ensures that safety and security issues is being reviewed in an integrated manner to avoid any conflicts between safety and security. According to the Quality Management Procedure PR-05, ‘Procedure document for review and assessment of safety justification documents’, review and assessment is taking into account the undue influence of security system to the safety of the facility and safety to the security regime.

According to the Law on Radiation Protection, RSC is responsible for regulatory and supervision related to the physical protection of radioactive sources, except for radiation sources used in the area of nuclear facilities. Basic requirements regarding physical protection are set in ‘HN 73:2001 chapter XII and in the Order of the Minister of Health on ‘Rules of physical protection of sources of ionizing radiation’.

Additionally, the interface of safety with nuclear security in the radiation protection area is established through provisions in management systems requirements of RSC. Based on the Quality Management Procedure P-09, ‘Issue of licenses and temporary permits for practices using ionizing radiation sources’, and the Quality Management Working Procedure DI-12, ‘Vulnerability assessment of physical protection system in activities with the sources of ionizing radiation’, assessment and evaluation of documents regarding vulnerability of physical protection system the influence of security measures to safety and vice versa are taking into account.

12.2. REGULATORY OVERSIGHT ACTIVITIES

The governmental and legal framework provides for VATESI in its area of competencies the responsibility to authorize activities, perform inspections, apply enforcement measures, use operational experience feedback, and to assess the configuration of facilities and activities for optimization of safety with factors relating to nuclear security.

According to Lithuanian legislation, the nuclear or radiological accident/incident could be initiated by a security event but the emergency response would be the same. However, in case of a “security event” in addition to emergency response, the contingency plan (as a part of security plan) is activated. The emergency and contingency response responsibilities are coordinated during the process of the approval of emergency and security plans, respectively.

A practical exercise covering both these aspects was conducted two years ago on the Ignalina NPP site.

RSC has established the principles and criteria for state regulation of the sources of ionizing radiation, and for ensuring radiation protection and physical protection of the sources of ionizing radiation. Also, RSC prepares and approves the description of the procedure and recommendations for implementing these principles and criteria. Furthermore, the RSC inspectors check both aspects: safety and security, during the inspection. RSC may refer to the competent authorities in order to verify whether there are any circumstances, which could prevent a particular natural person from being entrusted with the physical protection of the sealed sources of ionizing radiation with danger categories I, II, III or from being accepted to work involving shipment of the sealed sources within these categories.

12.3. INTERFACE AMONG AUTHORITIES

VATESI is a single state institution, which has responsibility for integrated regulation and oversight of nuclear safety and physical security. However, there are several institutions involved in the assurance of physical security. Cooperation and interface among different authorities and organizations involved in activities within the security is demonstrated in the document "Provisions of Ignalina NPP Physical Protection" that needs to be revised and updated. A draft of the amendment to the Law on Nuclear Energy is prepared by VATESI and coordinated with relevant institutions. When approved by the Parliament, it will prescribe the responsibility of Government to develop a resolution regarding the functions and coordination of activities of competent authorities and organizations involved in assurance of physical security of all nuclear facilities and nuclear material in transport.

To enhance cooperation, RSC has signed a set of Memorandums of Understanding with authorities involved in activities for physical protection of the radioactive sources, such as: State Border Guard Service, Customs Department and State Security Department.

12.4. SUMMARY

VATESI and RSC have developed a regulatory system for safety, designed and implemented in an integrated manner with arrangements for nuclear security and with the State system of accounting for, and control of, nuclear material.

The requirement that security measures should not compromise safety and safety measures should not compromise security is implemented through requirements of the management systems of VATESI and RSC.

Regulatory over site activities to maintain arrangements for safety and security, including: authorization, inspections, enforcement measures, operational experience feedback, and assessment of the configuration of facilities and activities for optimization of safety with factors relating to nuclear security, are performed.

Cooperation and interface within different authorities and organizations involved in activities within the security area is established, also updates for improvement of existing arrangements are in progress.

13. TAILORED MODULE FOR COUNTRIES EMBARKING ON NUCLEAR POWER (SSG–16)

13.1. INTRODUCTION TO TAILORED MODULE FOR COUNTRIES EMBARKING ON NUCLEAR POWER

The IAEA has developed a safety guide (SSG-16, Establishing the Safety Infrastructure for a Nuclear Power Programme) with the objective to provide guidance on the establishment of a national safety infrastructure, in accordance with the IAEA safety standards, to countries considering or preparing to embark on a national nuclear power programme. SSG-16 constitutes a road-map of safety-related actions to be taken in the first three phases of the development of the nuclear power programme, in order to achieve a high level of safety throughout the lifetime of nuclear power plants, including decommissioning and waste management.

This tailored module comprises a review against actions set out in SSG-16 and the IAEA requirements on which the actions are based. The host country Lithuania, when agreeing the scope of the mission, requested the review to be performed for first two phases defined in SSG-16 based on their self-assessment on the level of development of the national safety infrastructure. Subsections of the tailored module is reflected in the following section of this module.

Nuclear Power in Lithuania

The decision to build 4 units of 1500 MWe RBMK type nuclear reactors near the town of Visaginas in Lithuania SSR was made in 1974 by the former USSR. Site preparation for Ignalina Nuclear Power Plant (Ignalina NPP) was initiated in 1978. The first unit of Ignalina NPP was commissioned by the end of 1983. At the time of the Chernobyl accident, the second unit of Ignalina NPP was ready for commissioning, the third unit was under construction, and the fourth unit was in the preparation stage. After a short delay in commissioning, unit 2 of Ignalina NPP was put into operation at the end of August 1987. The Government of Lithuania SSR requested suspending the activities of other units from USSR. Construction of other units was suspended in 1989, which was followed by the decision to cancel the construction of further units.

After Lithuania became independent in 1990, the nuclear regulatory body, VATESI, was established in 1991 to take over the regulatory oversight of Ignalina NPP, in addition to the oversight of Maišiagala Waste Storage Facility near Vilnius which was closed in 1989.

VATESI requested the Ignalina NPP to apply for operating licenses for each unit in accordance with international practice. The Safety Analysis Report (SAR) of Unit 1 was prepared by the Ignalina NPP with technical support from international organizations and companies, including those from the Russian Federation. The SAR of Ignalina NPP Unit 1 was reviewed by VATESI with technical support from international expert organizations and companies, including Lithuanian Energy Institute and Kurchatov Institute of Russia. Unit 1 of Ignalina NPP was granted an operating license in 1999. For the second unit, the SAR was prepared by Ignalina NPP with technical support provided by the Lithuanian Energy Institute. VATESI reviewed this application with the technical support of national expert organizations, such as Kaunas Technology University, Institute of Physics and ITECHA and granted an operating license in 2004.

Lithuania became part of the global safety regime by ratifying and being party to all relevant international conventions. The list of these international and bilateral agreements can be found on VATESI's website.

Ignalina NPP Units 1 and 2 were shut down in accordance with the protocol signed between the Lithuanian Government and the European Union in 2004 and 2009, respectively. Since then, activities at Ignalina NPP have been focused on decommissioning and radioactive waste management issues. Currently, the fuel from Unit 1 is removed from the core and is in temporary storage within spent fuel pools and fuel casks and Unit 2 is in a shutdown state with fuel inside.

Meanwhile, the possibility of further use of nuclear power has been considered by the Government and in 2007 the Law on Nuclear Power Plant was enacted in accordance with the relevant mandate of the Law on Nuclear Energy, to initiate the activities for a new build. In 2008, VAE UAB (Visagino Atominė Elektrinė UAB) company was established for performing preparatory works for new build; mainly the site selection and environmental impact assessment. In 2009, the Government approved Resolution 300 on "Strategic Directions for Project Implementation For New Nuclear Power Plant In Lithuania" demonstrating the commitment of the Government.

For the new build, sites in close vicinity of Ignalina NPP were considered based on the availability of technical infrastructure. Two potential sites were further investigated. The environmental impact assessment was performed for both sites in accordance with the national requirements and procedures of ESPOO convention, which have been completed with affirmative decision in 2009.

Potential sites for Visaginas NPP have been further investigated with new requirements to identify any exclusion criteria. The Site Evaluation Report was prepared by VAE UAB (currently VAE SPB) and submitted to VATESI for review in 2011. After communicating its findings with VAE and revisions made to the report by VAE, VATESI approved the submitted the Report on the Site Evaluation of Visaginas Nuclear Power Plant. VATESI approval was awarded upon review of the report regarding meteorology, hydrology, geology, cooling reliability, emergency preparedness and others, with the positive conclusions on report given by Lithuanian Geological Survey, Lithuanian Hydrometeorological Service, Fire Safety and Rescue Department, Ministry of Health and Civil Aviation Administration, to determine the suitability of site for nuclear installation.

Currently, the Government is in the process of updating the National Energy Policy for the approval of Parliament, which is expected to reflect the governmental commitment to nuclear power and position on further development of the project.

13.2. CONSIDERATION OF ELEMENTS OF SSG-16

This chapter presents the review of the SSG-16 elements with respect to potential new build within the country. Lithuania has been performing regulatory oversight on Ignalina NPP since 1991. However, the siting, construction, commissioning and operation of the Ignalina NPP has been authorized by the former USSR authorities.

Furthermore the self-assessment for SSG-16 was performed based only on VATESI's regulatory responsibilities and did not involve other bodies relevant to the safety infrastructure. Consequently, the self-assessment and the review are limited in scope and content. Within these circumstances, identification of issues that may have direct impact on new build project was the primary purpose of the review.

As the safety element 18 addresses the issues regarding the commissioning of nuclear power plants and has no action requirements prior to phase 3, this element is considered as out of scope for the purposes of this review.

13.2.1. SSG-16 Element 01National Policy and Strategy

Lithuania has been using nuclear power since the 1980s, and regulating the Ignalina NPP since 1991. In this respect, the main elements of the nuclear safety infrastructure for a new build is mostly in place. The main legal document establishing the national infrastructure is the Law on Nuclear Energy (LNE), establishing the regulatory body VATESI. The Law on Nuclear Safety (LNS) addresses the main safety related issues.

Within the legal system, no document was identified which directly addresses the nuclear safety strategy of the government. Lithuania bases nuclear safety strategy on nuclear safety principles embedded into its legal system to ensure the safety of nuclear activities, therefore no separate document is adopted. Safety principles can be found in LNS, while the fundamental safety objective is implemented in the integrated management system of VATESI and in its policy statement.

The legal system established by the Lithuanian Parliament (Seimas) and the Government identifies the responsibilities of the State, the regulators, the implementing organizations and other organizations within the safety infrastructure. As LNE clearly states responsibilities of various governmental entities, that are considered to be part of a new build project. In this respect, to ensure the safety in the long term, it is the Government's responsibility to coordinate these activities, to provide for development of all necessary organizations of the safety infrastructure, and to address their needs on financing and human resources in early stages of the project.

The IAEA guidelines suggest delegation of these responsibilities to an organization specifically assigned for the implementation of the new build project. Further guidance on this issue can be found on SSG-16.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The organizations taking part in the safety infrastructure should be efficiently developed regarding the new nuclear power programme, and their activities should be properly coordinated to ensure long term safety.	
(1)	**BASIS: SSG-16 Safety Element 1 Action 2 states that** *"The government should provide for the coordination of all activities to establish the safety infrastructure."*
(2)	**BASIS: SSG-16 Safety Element 1 Action 8 states that** *"The government should ensure that all the necessary organizations and other elements of the safety infrastructure are developed efficiently and that their development is adequately coordinated."*
S29	**Suggestion: The Government should consider to enhance coordination of activities of different organizations within the safety infrastructure for the new build and the efficient development of these organizations. This should happen when the new build project is further developed.**

13.2.2. SSG-16 Element 02 Global nuclear safety regime

After established as a sovereign state in 1991, the Republic of Lithuania demonstrated a strong commitment to be part of the international nuclear community, which included global nuclear safety regime. Lithuania became party to all relevant international treaties, conventions, and bilateral agreements, established its membership in relevant international organizations and communities. The requirements laid out by these international instruments were implemented in early stages of the new nuclear power program, particularly during the environmental impact assessment of the project. In addition to international conventions, Lithuania signed bilateral agreements on early notification of nuclear accidents with most of its neighbours, including overseas neighbours.

VATESI is also quite active in terms of being part of the international community. They become members of WENRA, ENSREG, and similar other organizations and participate in various activities of the IAEA. Furthermore, VATESI has signed agreements with NRC of USA, NRA of Japan, and SNRC of Ukraine on information exchange and cooperation. Lithuania and VATESI extensively uses peer review activities of IAEA to ensure that the safety of ongoing nuclear activities is not compromised.

13.2.3. SSG-16 Element 03 Legal framework

Based on the Ignalina NPP experience, Lithuania has its main legal framework established for a new build.

The LNE clearly identifies the responsibilities of all relevant entities within the state administration of Lithuania, from the parliament to ministries and to municipalities. The LNE also establishes the State Nuclear Power Safety Inspectorate (VATESI) as an independent regulatory body reporting to the President and the Government. The LNE defines the necessary competences for VATESI and lays out its main human resource arrangements. The law further addresses the main requirements on design, construction, operation, and decommissioning, and main responsibilities of license holder.

The fundamental safety principles of IAEA have been embedded in the LNS, addressing the main safety requirements. The LNS further details the competence and responsibilities of VATESI, and lays out provisions on licenses and permits, assessment of nuclear safety, prevention of accidents, emergency preparedness, technical support and enforcement.

These laws are complemented by the Law on Nuclear Power Plant, needed to be enacted for building an NPP, the Law on Radiation Protection, the Law on Environmental Impact Assessment, and various other laws which indirectly contribute to the legal framework on nuclear safety.

These legal provisions were reviewed by the IRRS team and the subsequent requirements and suggestions are listed under relevant module, if needed. For re-establishing the nuclear power in Lithuania, the legal aspects for a new build project can be considered as addressed properly.

13.2.4. SSG-16 Element 04 Regulatory framework

The independence of the regulatory body, authorities assigned to VATESI to execute its regulatory functions and its responsibilities were reviewed under Module 1 and 3.

The establishment of the independent regulatory body on nuclear safety in Lithuania is dating back to 1991, following the independence of the country for taking over the regulatory oversight of the existing Ignalina NPP. The main authorities and competencies of VATESI were laid out in the LNE, and these are further detailed in the LNS. The assigned competencies of VATESI are covering the main regulatory functions for NPPs.

However, in addition to its regulatory functions, VATESI has been defined in Article 22.1.12 of Law on Nuclear Energy as the competent authority to prepare the proposals for national policy and strategy in the sector of nuclear power and its implementation and submit these proposals to the Government or its authorized institutions. Such a competence will establish a conflict of interest with its regulatory duties when it is used or requested to be used. Such a competence should belong to an entity responsible from the coordination of implementation of the nuclear power project. The competency of VATESI regarding a national policy and strategy of nuclear power and its implementation should not be more than contributing to it with safety and security aspects of nuclear power. Based on the characteristics of this non-conformance, this issue has been addressed in Recommendation No 4 in Section 1.3.

With regards to developing the regulatory basis for the authorization activities of NPPs, types of technical regulatory documents were defined in Article 5 of LNS and VATESI has the procedure in place on drafting and approval safety requirements in its integrated management system. The regulatory approach was already established for regulatory oversight of the Ignalina NPP. The same approach is used for the new build project. Most of the safety issues related to ongoing activities are regulated by VATESI, while further draft regulations are under preparation for a new build, including design safety. This need was identified by VATESI and included in draft Action Plan.

13.2.5. SSG-16 Element 05 Transparency and openness

VATESI is authorized in LNS for informing the public and other interested parties with due respect to Law on Provision of Information to the Public. However, there is no provision in legislation ensuring the involvement of public and other interested parties in the decision making process of VATESI.

Action 39 of SSG-16 lays the responsibility on Government to establish a policy and guidance for ensuring such involvement, and Action 40 emphasizes the need for establishing a process for consideration of comments arisen from such involvement and communicating the outcome of this consideration to relevant parties. No legal or regulatory provision was identified during the IRRS review which ensures the involvement of the public and interested parties in the decision making process regarding the nuclear power program and regulatory decision making of VATESI. Only the development of regulatory requirements are open to public comments through the website announcements. The same non-conformance was identified under various Modules of the review and issue is addressed in Recommendation 2 in Section 1.2. Addressing this issue requires measures to be taken at a legal level. Upon implementation of an action regarding the Recommendation No 2, VATESI should consider implementing legal provisions within its regulatory system. This implementation should also consider Action 40 of SSG-16 and include mechanisms for ensuring consideration of comments arising from consultation with interested parties, and for communicating the outcome of the consideration of review comments to relevant parties.

VATESI continues to inform the public when the need is identified, or upon request. There is no other institution providing such activities, which is considered as another indication for the

need of coordination of activities at the Government level as addressed in Suggestion No 31 of this Module.

13.2.6. SSG-16 Element 06 Funding and financing

There are four aspects of funding and financing that need to be reviewed regarding a new build project. Financing the development activities of human resources at a national level, financing the regulatory body to ensure proper conduct of regulatory activities, ensuring finances for the operating organization for safe operation of the NPP, and ensuring finances for the long term radioactive waste management, spent fuel management and decommissioning.

The human resource development for the new build has been addressed in the "National plan for preparation of nuclear energy specialist" which was approved by the joint order No.V-906/1-133 of Minister of Education and Science and Minister of Energy in 25 May 2011. The funding for the implementation of this plan has to be provided by the state according to the Article 47 of LNE. The same article also requires the operator to have enough funds for performing its functions. The Government may consider to include the notion of ensuring safety as the purpose of such funding during next revision of Law on Nuclear Energy.

Financial issues of the regulatory body are provided in the Statute of VATESI (which constitutes an annex to a Governmental Resolution), and funding comes directly from the state budget. Even though VATESI requests fees for its authorization activities, these fees are directly deposited into the state budget.

Funding issues regarding safe management of radioactive wastes and spent fuel are addressed in the Law on the Management of Radioactive Waste. The Government is responsible for funding relevant research activities and human resource development for this purpose. According to Article 9.2 of the Law, the generator of the radioactive waste, and hence the spent fuel, is responsible for all expenses incurred from the safe management of such waste. On the other hand, the Government is responsible for appointment of an organization as the national radioactive waste manager and for ensuring necessary financial support in order for the manager to execute its responsibilities according to Article 10.2 of the Law.

Funding issues regarding decommissioning activities are addressed in Article 48 of Law on Nuclear Energy in general terms, which require enactment of the Law for Decommissioning Funds. This Law addresses general principles for the funds, and the Law on Nuclear Power Plant ensures that decommissioning costs can be included in the selling price of the electricity produced. However, the Law on Managing Decommissioning Funds was not enacted. Considering a new build, the Government of Lithuania should consider to establish necessary provisions for the management of decommissioning funds. This topic is addressed in Recommendation No 5 in section 1.7. This need was identified by VATESI and included in draft Action Plan.

13.2.7. SSG-16 Element 07 External support organizations and contractors

Due to the existence of nuclear power in Lithuania, there are national support organizations developed at various levels. Additionally, there is a specific section of the Law on Nuclear Energy ensuring the possibility to receive scientific technical support to the operator and the regulatory body, if necessary. These organizations are mainly universities or research centres and governmental organizations; namely Lithuanian Energy Institute, Kaunas University of

Technology, Vilnius Gediminas Technical University and Centre for Physical Sciences and Technology.

Some of these organizations participated in the review of the safety assessment performed for Ignalina NPP in the 1990s, and Lithuanian Energy Institute participated in conduct of that safety assessment. However, no current study has been identified to determine the expertise areas of these organizations, to identify the gaps in which expertise would be needed, and to determine the actions necessary to address such needs for further development.

VATESI is relying on its ability to procure such support services according to public procurement rules which allows participation from abroad. However, there is a need to further develop a national technical support organization for ensuring the long term safety of operation of an NPP and regulatory oversight through knowledge transfer.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Competence of existing organizations that can provide technical support to the VATESI or the operating organization have not been assessed by the government to identify the gaps with respect to competence needed for licensing of new builds and to ensure safe operation of nuclear power plants.	
(1)	**BASIS: SSG-16 Safety Element 7 Action 62 states that** *"The government should assess the need to create or to enhance national organizations to provide technical support to the regulatory body and the operating organization for the safe operation of nuclear power plants."*
(2)	**BASIS: SSG-16 Safety Element 10 Action 100 states that** *"The government should identify gaps in the capabilities of domestic research centres to meet needs in core areas, and should plan to establish new research centres for core areas as necessary."*
S30	**Suggestion: The Government should consider regularly assessing the competence of existing organizations that can provide technical support to VATESI or operating organization, and performing a gap analysis to identify areas in which these organizations need further support of the Government. This should happen when the new build project is further developed.**

13.2.8. SSG-16 Element 08 Leadership and management for safety

With the existence of Ignalina NPP prior to the new build project, it is ensured that there is an independent regulatory body in Lithuania and the safety issues are recognized at the Government level, in general. In this respect, VATESI has its top management in place for the new build under discussion. In addition to the existing situation, VATESI has an integrated management system in place which has been reviewed by the IRRS team. As for the new build project, the requirements for having a management system has been identified for the operator.

For the purposes of new build project, the leadership and management for safety concerns were properly addressed.

13.2.9. SSG-16 Element 09 Human resources development

Since the development of necessary human resources to implement a new build project and to ensure safety during the implementation requires comprehensive planning, efforts and financial arrangements, the human resource issues have to be addressed in the early stages of the project. In this respect, the Government is expected to be aware of needs regarding the human resources for implementation of the project and for ensuring that the proper regulatory oversight can be exercised for all activities. The Government should plan on the actions required to address the needs and implement human resource development activities in advance of a new build.

The Government has established the national policy regarding the development of human resources through the "National plan for preparation of nuclear energy specialists" in 2011, but no evidence could be provided on the implementation of the plan. This issue has been combined with the competence issues in safety assessment area and formalized in a suggestion under the Element 12 of this Chapter.

VATESI has such planning activities within the framework of its integrated management system, which addresses allotment of new posts as need arises, within the boundary conditions on maximum allowable positions allocated to VATESI by the Government. VATESI's annual strategic plan determines the need for new staff. If the need can be addressed within VATESI itself, then the Head of VATESI is authorized to make the necessary assignments. If the need requires an increase in the maximum allowable positions, then it is communicated through the proper channels of Government.

13.2.10. SSG-16 Element 10 Research for safety and regulatory purposes

According to SSG-16, the Government must identify which safety issues would need further scientific research, implement a gap analysis, and initiate the relevant research. Initiation, coordination and control of the research for safety and regulatory purposes is under the auspices of VATESI, according to Article 11.6 of the LNS. However, it is mostly implemented by the research centres and universities which are also considered as technical support organization.

No study has been identified to address the need for safety research, and no gap analysis was performed by VATESI, relying on the existing infrastructure of safety for Ignalina NPP. This observation establishes another basis for Suggestion 30 made under the Element 7 of this Section.

13.2.11. SSG-16 Element 11 Radiation protection

By using nuclear power since the 1980s, Lithuania has the necessary awareness on radiation protection in nuclear facilities and activities. Adequacy of the regulatory structure for radiation protection was reviewed in detail by the IRRS team. Radiation protection in nuclear facilities and activities are within the jurisdiction of VATESI. However, VATESI and RSC, which oversees practices involving radiation sources, should consider establishing coordination on issues that may have an effect within and outside of NPPs.

For the purposes of the new build project, Lithuania has necessary measures in place. Radiation protection issues were considered during development of the energy strategy, and radiological impact of the project was considered and assessed within the context of the environmental impact assessment.

13.2.12. SSG-16 Element 12 Safety assessment

There are two crucial actions for the safety assessment at early phases of a new build project. For Government, it is to gain an understanding of the resources needed to conduct and review safety assessment, and for implementing organizations, such as the regulatory body, operator and technical support organization, it is to acquire necessary expertise in a timely manner.

Having no operator identified for the new build project, it is the VATESI's and the technical support organization's responsibility to prepare themselves for conducting and reviewing the safety assessment. The National Plan on providing necessary expertise in the nuclear area is the tool established by the Government. However, no implementation of this plan could be identified during the IRRS review to prepare for the safety assessment. Combining with a similar finding in safety element 9, the Suggestion No 31 has been formalized.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Even though there is a "National plan for preparation of nuclear energy specialists", which was approved by the joint order of Minister of Education and Science and Minister of Energy on 25 May 2011 No.V-906/1-133, for training purposes, no evidence was identified on implementation of this plan. Additionally, no gap analysis has been performed to identify the needs for training the personnel to prepare for conduct and review of safety assessment by technical support organizations and/or VATESI.	
(1)	**BASIS: SSG-16 Safety Element 9 Action 94 states that** *"All relevant organizations should commence the education and training in academic and vocational institutions of the necessary number of persons for ensuring safety."*
(2)	**BASIS: SSG-16 Safety Element 12 Action 118 states that** *"The operating organization, the regulatory body and external support organizations, as appropriate, should develop the expertise to prepare for the conduct or review of safety assessments."*
S31	**Suggestion: The Government should consider coordinating and urging all relevant organizations for implementation of National Plan and to commence with the education and training of their personnel to ensure safety and to prepare for the conduct and review of safety assessments. This should happen when the new build project is further developed.**

Additionally, the IRRS team, reviewing the review and assessment for NPP under Module 6, identified a need for enhancing international cooperation to ensure that the safety assessment is performed with proper input on safety concerns from international practices.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Regulating the optimization of protection provided for in the design of any new NPP which might be constructed in Lithuania will require VATESI to understand the options considered, issues raised and regulatory decisions made by regulatory bodies regulating plants of a similar design.	
(1)	**BASIS: SSG-16 para. 2.28 states that** *"To gain feedback from regulatory bodies in other States, the regulatory body should extend its contacts, in*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	particular through its participation in bilateral, multilateral and international cooperation on the subject of a nuclear power programme."
(2)	**BASIS: GSR Part 1 para. 4.42 states that** *"In performing its review and assessment of the facility or activity, the regulatory body shall acquire an understanding of the design of the facility or equipment, the concepts on which the safety of the design is based and the operating principles proposed by the applicant, to satisfy itself that, among other factors:* *(a) The available information demonstrates the safety of the facility or the proposed activity and the optimization of protection."*
S32	**Suggestion: VATESI should consider extending its contacts with regulatory bodies engaged with regulating NPPs of similar designs to that proposed to be constructed in Lithuania. This should happen when the new build project is further developed.**

13.2.13. SSG-16 Element 13 Safety of radioactive waste, spent fuel management and decommissioning

Rather than a new build, the safe management of radioactive waste and spent fuel, and safety of decommissioning are current issues for Lithuania due to the decision made to shut down the two units of Ignalina NPP. The requirements on safety of decommissioning has been addressed in VATESI Orders, and safe management of radioactive waste and spent fuel are addressed in the Law on Management of Radioactive Waste. The responsibilities of parties important to safe management of radioactive waste and spent fuel management were also defined in the relevant law. The governmental strategy regarding radioactive wastes was recently established in the "Development Programme of Radioactive Waste Management (resolution No. 1427 of 23.12.2015)", valid since the 1st of January 2016. As a more urgent issue than new build, the IRRS review focused on these details in relevant Modules. For the purposes of the new build project, the issue is considered as being properly addressed.

13.2.14. SSG-16 Element 14 Emergency preparedness and response (regulatory aspects)

The responsibilities of all relevant governmental organizations in the nuclear energy area have been identified in the LNE. It is the Ministry of Interior's responsibility to ensure that a state plan is available for protection of the population in the event of nuclear and/or radiological accidents, and it is the municipality's responsibility to take measures for ensuring preparedness and implementation of off-site emergency plans. The system is in place for a new build project.

However, the self-assessment of VATESI states that there is a need for reestablishment of hazard categorization to ensure the compliance with GS-R-2 of IAEA. This need was identified by VATESI and included in draft Action Plan.

13.2.15. SSG-16 Element 15 Operating Organization

This element of SSG-16 has not been assessed by VATESI, stating that the operating organization has not been identified yet. However, there is a state owned company called

VAE (Visagino Atominė Elektrinė), which has been established for performing preparatory works for new build in 2008; mainly the site selection and environmental impact assessment. This company is currently inactive regarding the new build project.

13.2.16. SSG-16 Element 16 Site survey, site selection and evaluation

After the Law on Nuclear Power Plant has been enacted in 2007, which can be considered as the initial decision on new build, the VAE UAB was established in 2008 to perform site activities and environmental impact assessment. The regulatory requirements for the site have been laid out by VATESI.

For the new build project, two potential sites have been considered near Ignalina based on the existence of technical infrastructure to support construction and operation of an NPP. Alternative sites were investigated for identification of any characteristic that would lead to rejection of site. Being geological studies the most extensive one, meteorology, hydrology, geology, cooling reliability and emergency preparedness were the main factors considered in site evaluation.

Having the necessary requirements laid out by VATESI, the environmental impact assessment process of sites has been completed with a positive decision made in 2009. The Site Evaluation Report for both sites was agreed on after positive decisions have been received from other relevant governmental organizations involved in review.

The Site Evaluation Report does not include all the site-related design parameters, but the agreement given by VATESI has additional requirements for performing further studies to determine the parameters to be used in design. For the purposes of a new build project, the actions of SSG-16 are considered as implemented.

13.2.17. SSG-16 Element 17 Design safety

Having operated Ignalina NPP for over 10 years and addressing the back-end issues after the shutdown, the Government has considered the safety requirements and availability of technical infrastructure during the decision made for new build and for siting.

Based on the existing situation, VATESI has begun drafting design requirements for new build; however, this is still in draft form and needs to be enhanced on issues regarding aircraft crash, WENRA positions, and IEAE SSR 2/1(Rev. 1) on design safety of NPPs.

According to the authorization process for NPPs, the next stage is the approval of the technical specifications of the bid for procuring the NPP, which requires establishment of an operating organization following the governmental policy announced with the new Energy Strategy document. Therefore, VATESI has time to finalize these requirements but should consider paying more attention on resolving the issues at hand to prepare for comments from interested parties in advance of a potential bid.

13.2.18. SSG-16 Element 19 Transport Safety

Regulating the transport of nuclear materials, radioactive waste originated from nuclear activities and spent fuel is within the scope of responsibility of VATESI. However, VATESI may need further authorization powers through law in order to regulate this area and define the authorization requirements for transport casks as -recommended by SSR-6. At the same time, competence needs to be developed for the review and assessment that needs to be performed by VATESI for these authorizations. This topic is addressed in Recommendation No 13 in Section 5.6. This need was identified by VATESI and included in draft Action Plan.

13.2.19. SSG-16 Element 20 Interfaces with nuclear security

The security of nuclear facilities and activities is mainly addressed under the LNE, defining the responsibilities of stakeholders for ensuring security of nuclear facilities and activities. Further requirements are in VATESI regulations for the Physical Security of Nuclear Facilities, Nuclear Material and Nuclear Fuel Cycle Material. The interface between the nuclear safety and security is addressed in VATESI regulations, ensuring physical security system is to be in compliance with the nuclear, technical, and work safety, radiation protection, fire safety and civil safety.

The interface between the safety and security is further discussed in detail in Section 12.

13.3. SUMMARY

The decision to build a new NPP in Lithuania was made in a National Energy Strategy paper published in 2007. Initial steps were taken regarding the new build, such as completing the siting and EIA process, and issuing the Law on Nuclear Power Plant in accordance with the mandate of the LNE. However, the decision has not been implemented any further.

The Ignalina NPP has ensured that many aspects of legal and regulatory infrastructure established before the new build was on the agenda of the Government, and also ensured that the Government has made informed decisions with due consideration of safety and technical infrastructures of the Government, radiological concerns, etc., as required by SSG-16.

The regulatory body, VATESI, was established before the new build project was initiated. VATESI prepared and implemented an integrated management system for its regulatory activities and already has most of the regulatory requirements in place for ensuring long term safety of NPPs.

Currently, the new build project is on hold, waiting for the Government's update to the Nuclear Energy Strategy expected this year. VATESI has taken a considerable amount of initiative to prepare itself for the new build project, by ensuring implementation of most of the SSG-16 actions. However, there are additional efforts needed, such as coordinating the activities of new build project and ensuring necessary competence is gathered in relevant organization with dedicated implementation of the "National Plan for preparation of nuclear energy specialists".

The IRRS team emphasizes the benefit of repeating the self-assessments based on the IAEA guidance in SSG-16 as the nuclear power programme progresses in order to monitor progress at different stages.

APPENDIX 1 LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS			
1.	LUND Ingemar	Swedish Radiation Safety Authority (SSM),	ingemar.lund@ssm.se
2.	KILOCHYTSKA Tetiana	State Nuclear Regulatory Inspectorate of Ukraine	kilochytska@hq.snrc.gov.ua
3.	AGHAJANYAN Nelli	Armenian Nuclear Regulatory Authority (ANRA)	n.aghajanyan@anra.am
4.	ALTEN Serhat	Turkish Atomic Energy Authority (TAEK)	Serhat.Alten@taek.gov.tr
5.	ARENDS Patrick	Authority for Nuclear Safety and Radiation Protection	patrick.arends@anvs.nl
6.	BOSNJAK Jovica	State Regulatory Agency for Radiation and Nuclear Safety	jovica.bosnjak@darns.gov.ba
7.	DODKIN Christina	Canadian Nuclear Safety Commission	christina.dodkin@canada.ca
8.	GUTTERES Ricardo	National Nuclear Energy Commission (CNEN),	rgutterr@cnen.gov.br
9.	HART Anthony	Office for Nuclear Regulation (ONR)	Anthony.Hart@onr.gsi.gov.uk
10.	HUSSAIN Muhammad Nadeem	Pakistan Nuclear Regulatory Authority (PNRA)	m.nadeem@pnra.org
11.	HUTRI Kaisa-Leena	Radiation and Nuclear Safety Authority (STUK)	kaisa-leena.hutri@stuk.fi
12.	KENNY Tanya	Environmental Protection Agency (EPA) of Ireland	t.kenny@epa.ie
13.	LORÁND Ferenc	Hungarian Atomic Energy Authority (HAEA),	lorand@haea.gov.hu
14.	MARJA-LEENA Jarvinen	Radiation and Nuclear Safety Authority (STUK),	marja-leena.jarvinen@stuk.fi
15.	SLOKAN DUŠIČ Darja	Slovenian Nuclear Safety Administration	darja.slokan-dusic@gov.si
16.	PRENDES ALONSO Miguel	Centro de Protección e Higiene de las Radiaciones	prendes@cphr.edu.cu
17.	REICHE Ingo	Bundesamt für	ireiche@bfs.de

INTERNATIONAL EXPERTS			
		Strahlenschutz (BfS)	
18.	HULSMANS Mark	European Commission – Joint Research Center – Institute for Energy and Transport (EC-JRC-IET)	Mark.HULSMANS@ec.europa.eu
19.	PUSKAR Ilmar	Estonia Environmental Board	Ilmar.Puskar@keskkonnaamet.ee
IAEA STAFF MEMBERS			
1.	MANSOUX Hilaire	Division of Radiation, Transport and Waste Safety	H.Mansoux@iaea.org
2.	MACSUGA Géza	Division of Nuclear Installation Safety	G.Macsuga@iaea.org
3.	BACIU Adriana	Incident and Emergency Centre	A.C.Baciu@iaea.org
4.	SWOBODA Zumi	Division of Radiation, Transport and Waste Safety	Z.Swoboda@iaea.org
LIAISON OFFICERS			
1.	ŠEŠTOKAS Ovidijus	State Nuclear Power Safety Inspectorate (VATESI)	Ovidijus.Sestokas@vatesi.lt
2.	STASIŪNAITIENĖ Ramunė Marija	Radiation Protection Centre (RSC)	ramune.stasiunaitiene@rsc.lt

APPENDIX II MISSION PROGRAMME

IRRS MISSION PROGRAMME		
Sunday 17 April		
Initial IRRS Review Team Meeting		
13:30 - 17:00	Opening remarks by the IRRS team Leader (Mr Ingemar Lund) Introduction by IAEA Self-introduction of all attendees IRRS Process (IAEA) Report writing (IAEA) Schedule (TL, IAEA, LO) First impression from team members arising from the Advanced Reference Material (ARM) (all team members): Presentations Administrative arrangements (VATESI/RSC IRRS Liaison Officer(s), IAEA): Detailed Mission Programme	Venue Hotel conference room Participants: the IRRS team + the LO(s)
Monday 18 April		
IRRS Entrance Meeting		
09:00 – 12.00	09:00 Arrival, registration, 09:30 Energy Policy Adviser to the Prime Minister of the Republic of Lithuania – Welcoming Address 09:45 IRRS Coordinator – The IRRS programme 10:00 IRRS Team Leader –	Venue Hotel conference room Participants: High Level Government Officials, VATESI and RSC Management and staff, Officials from relevant organizations, the IRRS Team + the LO(s)

IRRS MISSION PROGRAMME		
	Expectations for the Mission and introduction of the IRRS Team Introduction of the Main Lithuanian Counterparts 10:15 Group photo of the meeting participants 10:30 Coffee 10:45 VATESI and RSC presentation(s) – Regulatory Overview, SARIS results (strength, challenges, action plan)	
12:00 – 13:00	Lunch	Hotel restaurant
13:00 – 17:00	Interviews and Discussions with Counterparts (parallel discussions)	Counterparts and Offices: Module 1: Michail Demčenko, Vidas Paulikas, Kristina Ramonienė (VATESI), Albinas Mastauskas (RSC) - VATESI room 253 Module 2: Dainius Brandišauskas, Vidas Paulikas, (VATESI), Albinas Mastauskas, Ramunė Stasiūnaitienė (RSC) - VATESI room 253 Module 3: Ugnė Adomaitytė, VATESI room 246 Module 4: Vida Jakimavičienė, VATESI room 238 Module 5 for NPP: Birutė Purlienė, Nerijus Bucevičius, VATESI room 251

		Module 7 for NPP: Sigitas Šlepavičius, VATESI room 242 Modules 5 to 9 for Waste Management facilities, decommissioning: Darius Lukauskas (Waste management facilities), VATESI room 231 Saulius Stravinskas (Decommissioning), VATESI room 233 Modules 5 to 9 for Radiation Sources: Gintautas Balčytis, Vaidas Statkus, Ramunė Stasiūnaitienė, RSC room 208 Modules 5 to 9 for Transport: Vaidas Statkus (RSC), Kristina Tumosienė (VATESI) - RSC room 106 Module 10: Danutė Šidiškienė (RSC), Emilis Baškys (VATESI) - RSC room 210 Module 11 on Occupational Exposure: Irena Račienė (RSC), Vladimir Achmedov (VATESI) – RSC room 108 Module 11 on Medical Exposure: Jonas Marcinkevičius, RSC room 206 Module 11 Environ. & contr. of discharges, public exposure, existing exposure situations: Rima Ladygienė, RSC room 124 Tailored Module SSG 16: Evaldas Kimtys, VATESI room 240

IRRS MISSION PROGRAMME		
17:00 - 18:00	Daily IRRS team meeting	Venue VATESI conference room Participants: the IRRS Team + the LO(s)
Tuesday, 19 April		
Daily Discussions / Interviews		
09:00 – 17:00	Interviews and discussions with counterparts (parallel discussions)	Counterparts and Offices: Module 2: Dainius Brandišauskas, VATESI room 241 Module 3: Albinas Mastauskas, RSC room 102 Module 4: Albinas Mastauskas and supporting staff, RSC room 102 Module 5 for NPP: 9:00-12:00 Birutė Purlienė, Nerijus Bucevičius, VATESI room 251 Module 6 for NPP: 13:00 – 17:00 Vladislav Legenis, VATESI room 251 Module 8 for NPP: 9:00-12:00 Kristina Palevičienė, VATESI room 237 Module 9 for NPP: 13:00 – 17:00 Ugnė Adomaitytė, VATESI room 246 Modules 5 to 9 for Waste Management facilities, decommissioning: Darius Lukauskas (Waste management facilities), VATESI room 231 Saulius Stravinskas (Decommissioning), VATESI room 233

IRRS MISSION PROGRAMME		
		Modules 5 to 9 for Radiation Sources: Gintautas Balčytis, Vaidas Statkus, Ramunė Stasiūnaitienė, RSC room 208 Modules 5 to 9 for Transport: Vaidas Statkus, RSC room 106 Module 10: Danutė Šidiškienė, RSC room 210 Module 11 on Occupational Exposure: Irena Račienė (RSC), Vladimir Achmedov (VATESI) – RSC room 108 Module 11 on Medical Exposure: Jonas Marcinkevičius, RSC room 206 Module 11 Environ. & contr. of discharges, public exposure, existing exposure situations: Audrius Pašiškevičius (VATESI), Beata Vilimaitė Šilobritienė (Environmental Protection Agency) – VATES room 230 Module 12, Interface with Nuclear Security: Renaldas Sabas (VATESI), Rugilė Aganauskaitė (RSC) - VATESI room 249 Tailored Module SSG 16: Evaldas Kimtys, VATESI room 240
12:00 – 13:00	Lunch	

IRRS MISSION PROGRAMME		
15:00 –	Visit Government/Ministry(ies)[1]	IRRS TL, DTL, TC, Meeting at the Ministry of Health – Albinas Mastauskas, RSC
17:00 – 18:00	Daily IRRS team meeting	Venue VATESI conference room Participants: the IRRS Team + the LO(s)
Wednesday 20 April		
Daily Discussions / Interviews		
09:00 – 17:00	Interviews and discussions with counterparts for all modules	Counterparts and Offices: Module 1, Module 2: Albinas Mastauskas, RSC room 102 Module 3: Ugnė Adomaitytė (VATESI), VATESI room 246 Module 4: Vida Jakimavičienė, VATESI room 238 Module 6 for NPP: Vladislav Legenis, VATESI room 251 Module 7, 8, 9 for NPP: Sigitas Šlepavičius (Module 7), VATESI room 242 Kristina Palevičienė (Module 8), VATESI room 237 Ugnė Adomaitytė (Module 9), VATESI room 246

[1] *Meeting with the state officials that the Regulatory Body reports to.

IRRS MISSION PROGRAMME		
		Modules 5 to 9 for Waste Management facilities, decommissioning: Darius Lukauskas (Waste management facilities), VATESI room 231 Saulius Stravinskas (Decommissioning), VATESI room 233 Modules 5 to 9 for Radiation Sources: Gintautas Balčytis, Vaidas Statkus, Ramunė Stasiūnaitienė, RSC room 208 Modules 5 to 9 for Transport: Kristina Tumosienė, VATESI room 231 Module 10: Emilis Baškys, VATESI room 230 Module 11 on Occupational Exposure: Irena Račienė (RSC), Vladimir Achmedov (VATESI) – RSC room 108 Module 11 on Medical Exposure: Jonas Marcinkevičius, RSC room 206 Module 11 Environ. & contr. of discharges, public exposure, existing exposure situations: Rima Ladygienė, RSC room 124 Module 12, Interface with Nuclear Security: Rugilė Aganauskaitė, RSC room 107 Tailored Module SSG 16: Evaldas Kimtys, VATESI room 240
12:00 – 13:00	Lunch	
13:00 – 17:00	Writing first draft of preliminary	The IRRS Team

IRRS MISSION PROGRAMME		
	findings (Observations, Rs, Ss, GPs)	
17:00 – 18:00	Daily IRRS team meeting	Venue VATESI conference room Participants: the IRRS team + the LO(s)
Thursday 21 April		
Daily Discussions / Interviews		
09:00 – 17:00	Follow-up Interviews and discussions with counterparts (parallel discussions)	Counterparts and Offices: TBD
06:30 – 18:00	Site Visit to Ignalina NPP (observation of inspection to the NPP and waste management facility; meeting with NPP management)	IRRS experts: Géza Macsuga, Mark Hulsmans, Ferenc Lóránd, Kaisa-Leena Hutri-Aspholm, Nelli Aghajanyan. VATESI: Saulius Stravinskas (Inspection team leader), Edmundas Vaitkus, Ričardas Krujalskis, Darius Lukauskas, Pavel Mikulan
09:00 –12:00	Site visit to Heating network facility "Vilniaus Energija" UAB (Industrial Radiography). Observation of inspection, meeting with management	IRRS experts: Christina Dodkin, Ricardo Gutterres, Patrick Arenda RSC: Rugilė Aganauskaitė, Dovilė Šerėnaitė
13:00 – 16:00	Site Visit toVilnius University Hospital Santariškių Klinikos (With Radiology, Nuclear Medicine and Blood Irradiator). Observation of inspection, meeting with management	IRRS experts: Tanya Kenny, Ricardo Gutterres, Patrick Arenda, Ilmar Puskar RSC: Rugilė Aganauskaitė, Dovilė Šerėnaitė, Vaidas Statkus
17:00 – 18:00	Daily IRRS team Meeting: 1st complete draft of boxes (observations, recommendations, suggestions and good practices)	Venue VATESI conference room Participants: the IRRS team + the LO(s)

IRRS MISSION PROGRAMME		
Friday 22 April		
Daily Discussions / Interviews		
09:00 – 17:00	Follow-up Interviews as needed	Counterparts and Offices: TBD
10:30 – 11:30	Visit Government/Ministry(ies)[2]	IRRS TL, DTL, TC Meeting at the Office of the Government of the Republic of Lithuania – Michail Demčenko, Vidas Paulikas, VATESI
16:00 – 17:00	Report preparation: finalize observations, basis, recommendations, suggestions and good practices	Venue VATESI conference room Participants: the IRRS team + the LO(s)
17:00 – 18:00	Daily IRRS team meeting	Venue VATESI conference room Participants: the IRRS Team + the LO(s)
Saturday, 23 April		
Daily Discussions/		
09:00 – 17:00	Team members write draft report. Finalize Observations, Recommendations and Good Practices, Cross reading.	Venue VATESI conference room IRRS team
19:00	Text sent to Admin Assistance	

[2] *Meeting with the state officials that the Regulatory Body reports to.

IRRS MISSION PROGRAMME		
Sunday 24 April		
Team rest day + cultural events		
10:00 – 16:00	Cultural event: visit to Trakai	Participants: IRRS team + the LO(s)
Monday 25 April		
Daily Discussions		
09:00-12:00	Discussion of mission report by Module	IRRS team and module counterparts
12:00 – 17:00	Report amendment following morning discussions	Venue : VATESI conference room Participants: The IRRS + the LO(s).
12:00 – 13:00	Lunch	
17:00 – 18:00	Daily IRRS team meeting	Participants: the IRRS team + the LO(s)
18:00	Cross reading if required	IRRS team
Tuesday 26 April		
Daily Discussions		
09:00 – 13:00	Finalize report text	Venue : VATESI conference room Participants: Tl, DTL, TC and DTC and The IRRS team (as needed)
12:00 – 13:00	Lunch	

IRRS MISSION PROGRAMME		
13:00	Draft to be sent to LO (VATESI and RSC) for review	
Wednesday 27 April		
Daily Discussions		
09:00 – 17:00	VATESI and RSC review the draft	
17:00	Comments from VATESI and RSC are submitted to the IRRS team.	
Thursday 28 April		
Daily Discussions		
09:00 – 12:00	Discussion with the counterparts on findings (the submitted comments).	IRRS team Module counterparts and LO(s)
12:00 – 13:00	Lunch	
13:00-	Report finalization by the team and handover the report to VATESI and RSC.	VATESI Conference Room
18:00	Dinner	

IRRS MISSION PROGRAMME		
Friday 29April		
Exit Meeting		
09:00 – 11:00	Main findings of the IRRS mission (Team Leader)	Venue Hotel conference room Participants: Government Officials, VATESI and RSC Management and staff, Officials from relevant organizations, the IRRS Team + the LO(s)
	Remarks by VATESI and RSC in response to the Mission findings. IAEA Official (TBD): Closing Remarks Group photo of the meeting participants	
	Publication of the IAEA press release	

APPENDIX III SITE VISITS

1. Ignalina NPP and waste management facility
2. Vilnius University Hospital Santariškių Klinikos
3. Heating network facility “Vilniaus Energija” UAB

APPENDIX IV LIST OF COUNTERPARTS

IRRS EXPERTS	COUNTERPART
RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	
Ingemar Lund Tetiana Kilochytska Jovica Bosnjak Hilaire Mansoux	Vidas Paulikas, VATESI Dainius Brandišauskas , VATESI Albinas Mastauskas, RSC
GLOBAL SAFETY REGIME	
Ingemar Lund Tetiana Kilochytska Jovica Bosnjak Hilaire Mansoux	Vidas Paulikas, VATESI Dainius Brandišauskas , VATESI Albinas Mastauskas, RSC
RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	
Marja-Leena Jarvinen	Ugnė Adomaitytė, VATESI Albinas Mastauskas, RSC
MANAGEMENT SYSTEM	
Darja Slokan-Dusic	Vida Jakimavičienė, Ovidijus Šeštokas, VATESI Albinas Mastauskas, RSC
AUTHORIZATION	
Anthony Hart Géza Macsuga	Birutė Purlienė, Nerijus Bucevičius, Ovidijus Šeštokas, VATESI
Nelli Aghajanyan Kaisa-Leena Hutri	Darius Lukauskas, VATESI (Waste management facilities) Saulius Stravinskas, VATESI (Decommissioning)
Patrick Arends Ricardo Gutterres	Gintautas Balčytis, Vaidas Statkus, Ramunė Stasiūnaitienė, RSC
Ingo Reiche	Vaidas Statkus, RSC Kristina Tumosienė, VATESI

IRRS EXPERTS	COUNTERPART
REVIEW AND ASSESSMENT	
Anthony Hart Géza Macsuga	Vladislav Legenis, VATESI
Nelli Aghajanyan Kaisa-Leena Hutri	Darius Lukauskas, VATESI (Waste management facilities) Saulius Stravinskas, VATESI (Decommissioning)
Patrick Arends Ricardo Gutterres	Gintautas Balčytis, Vaidas Statkus, Ramunė Stasiūnaitienė, RSC
Ingo Reiche	Vaidas Statkus, RSC Kristina Tumosienė, VATESI
INSPECTION	
Ferenc LORÁND Géza Macsuga	Sigitas Šlepavičius, VATESI Asta Navagrockienė, VATESI Kristina Palevičienė, VATESI Ugnė Adomaitytė, VATESI
Nelli Aghajanyan Kaisa-Leena Hutri	Darius Lukauskas, VATESI (Waste management facilities) Saulius Stravinskas, VATESI (Decommissioning)
Patrick Arends Ricardo Gutterres	Gintautas Balčytis, Vaidas Statkus, Ramunė Stasiūnaitienė, RSC
Ingo Reiche	Vaidas Statkus, RSC Kristina Tumosienė, VATESI
ENFORCEMENT	
Ferenc Loránd Géza Macsuga	Kristina Palevičienė, VATESI Ugnė Adomaitytė, VATESI
Nelli Aghajanyan Kaisa-Leena Hutri	Darius Lukauskas, VATESI (Waste management facilities) Saulius Stravinskas, VATESI

IRRS EXPERTS	COUNTERPART
	(Decommissioning)
Patrick Arends Ricardo Gutterres	Gintautas Balčytis, Vaidas Statkus, Ramunė Stasiūnaitienė, RSC
Ingo Reiche	Vaidas Statkus, RSC Kristina Tumosienė, VATESI
REGULATIONS AND GUIDES	
Ferenc LORÁND Géza Macsuga	Ugnė Adomaitytė, VATESI
Nelli Aghajanyan Kaisa-Leena Hutri	Darius Lukauskas, VATESI (Waste management facilities) Saulius Stravinskas, VATESI (Decommissioning)
Patrick Arends Ricardo Gutterres	Gintautas Balčytis, Vaidas Statkus, Ramunė Stasiūnaitienė, RSC
Ingo Reiche	Vaidas Statkus, RSC Kristina Tumosienė, VATESI
EMERGENCY PREPAREDESS AND RESPONSE	
Adriana Celestina Baciu Géza Macsuga Nadeem Hussain	Emilis Baškys, VATESI Danutė Šidiškienė, RSC
ADDITIONAL AREAS - Medical Exposure	
Tanya Kenny	Jonas Marcinkevičius, RSC
ADDITIONAL AREAS - Occupational Exposure	
Christina Dodkin	Irena Račienė, RSC Vladimir Achmedov, VATESI

ADDITIONAL AREAS **Environmental monitoring associated with authorized practices for public radiation protection purposes, Control of chronic exposure remediation**	
Miguel Prendes Alonso	Audrius Pašiškevičius, VATESI Rima Ladygienė, RSC
MODULE 12 INTERFACE WITH NUCLEAR SECURITY	
Ingemar Lund Tetiana Kilochytska Jovica Bosnjak Hilaire Mansoux	Renaldas Sabas Rugilė Aganauskaitė
SSG 16	
Serhat Alten Géza Macsuga	Evaldas Kimtys, VATESI

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 ensure that the fundamental safety objective and all fundamental safety principles of IAEA SF-1 are accounted for in the Lithuanian legal framework for radiation safety.
		R2	The Government should amend the legal framework for safety to include provisions for involvement of the public in the decision making process of the regulatory body.
		R3	The Government should introduce the principle of a graded approach for radiation safety in the Law on Radiation Protection.
		R4	The government should ensure that VATESI is only asked to comment on nuclear safety issues regarding national policy and strategy on the use of nuclear power.
		R5	The Government should further develop the existing provisions of legal framework and national policy and strategy for the decommissioning of waste management facilities, for the management of radioactive waste (including spent fuel) regarding interdependencies of the steps in the entire management process, closure of disposal facilities, establishing required research and development programmes, and securing the appropriate financial provisions for all planned activities.
		R6	The Government should establish a process of formal recognition of

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			qualified experts for radiation protection and for medical physicists.
		S1	The Government should consider performing a comprehensive assessment of existing and future human resource needs in relation to the safety of facilities and activities.
2.	**GLOBAL SAFETY REGIME**	GP1	Lithuania is actively engaged in international cooperation; including international arrangements, peer reviews and international support programmes.
		S2	RSC should consider developing a procedure for systematic review and evaluation of international operating and regulatory experience and the dissemination of relevant information on lessons learned.
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**	S3	RSC should consider further strengthening the effective independence of its regulatory functions from its expert services to licensees.
		R7	VATESI should establish and implement a systematic approach to management of human resources and competences, including both a short and long term strategy, to ensure future delivery of its regulatory functions.
		S4	VATESI should consider enhancing its training programme to include the verification of adequate knowledge and abilities of staff, before they are appointed to work independently as inspectors or perform other key roles relating to safety, and to ensure that suitable proficiency is maintained. The efficiency of the programme should

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			be verified periodically.
		S5	Taking into account the current and future needs of oversight of radiation sources, RSC should consider enhancing its practices for managing resources and competences so that the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions can be quantified.
		GP2	All RSC employees are included in systematic planning and follow up of training. The dissemination of information of the lessons learned in international courses and seminars, and the self-assessment of the usefulness of received training is an integral part of the management of training.
		S6	For further development of nuclear programme VATESI should consider establishing the provisions for an advisory body to obtain technical or other expert professional advice in support of its regulatory functions.
		S7	RSC should consider suggesting changes to the present legislation to establish provisions for obtaining technical or other expert professional services, as necessary, in support of its regulatory functions.
		S8	VATESI should consider ensuring the completion of its internal information management system and easy access of the relevant staff to appropriate safety related information
		R8	VATESI should develop provisions for informing the public in the vicinity of the nuclear facilities about the radiation risks associated

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			with facilities, the requirements for protection of people and the environment, and the processes of VATESI.
		S9	VATESI and RSC should consider together organizing periodic, and as needed specific, public information in the vicinity of nuclear facilities.
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**	S10	VATESI should consider defining a regulatory body vision.
		R9	RSC should revise its quality policy in order to emphasize that safety is an overriding priority.
		R10	RSC should upgrade its management system to comply with the IAEA Safety Requirements, in particular with respect to safety culture, application of a graded approach, organizational change management, management system review, and documenting processes.
		S11	VATESI should consider clearly expressing in the management system documentation the senior management ultimate responsibility for establishing, implementing, assessing and continually improving the management system.
		GP3	VATESI conducts self-assessment of safety culture.
5.	**AUTHORIZATION**	S12	The government should consider introducing licence conditions to support VATESI and RSC's authorization processes regulated by the Law on Radiation Protection.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R11	VATESI should set up requirements, as appropriate, for establishment of a process to ensure post–storage transport of spent fuel in compliance with IAEA regulations for the safe transport of radioactive materials.
		R12	VATESI should initiate amendment of the legal framework to ensure there are distinct steps for authorizing the closure of repositories.
		S13	RSC should consider improving its implementation of a graded approach in the system of protection and safety.
		R13	The government should revise the Law on Nuclear Safety and the Law on Radiation Protection to define all the responsibilities of VATESI and RSC for the transport-related approvals.
6.	**REVIEW AND ASSESSMENT**	R14	VATESI should, as part of its planned work to further develop its review and assessment procedures, include specific requirements for recording the review and assessment work undertaken.
		S14	VATESI should consider a possibility of adding formal peer review to its review and assessment processes, applying a graded approach.
		S15	VATESI should consider further developing its procedures for review and assessment so that it is clear that the graded approach applies at all levels within its organization and perform necessary training.
		S16	VATESI should consider further developing its Oversight of

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			Economic Entities process to provide feedback to the Operating Organization and improve how its review and assessment outputs are integrated within this process.
		S17	VATESI should consider improving its processes and associated national legal framework so that non-radiological risks are taken into account explicitly in licensee safety submissions and its associated reviews and assessments.
		GP4	The required completion of Periodic Safety Assessments for Category I, II and III sources contributes significantly to continuous safety improvement.
7.	**INSPECTION**	R15	VATESI and RSC should initiate amendment in appropriate legislation to allow for planned unannounced inspections and broaden the basis for conducting unplanned unannounced inspections.
		S18	VATESI should consider making the necessary arrangements to be able to conduct unplanned announced inspections in all safety areas.
		S19	VATESI should consider improving the inspection procedures for all areas subjected to regulatory control to ensure systematic and consistent approach to inspection.
8.	**ENFORCEMENT**	R16	VATESI should initiate changes in the legal system to authorize inspectors to require corrective actions in case an imminent likelihood of a safety significant event is identified during inspection.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
9.	**REGULATION AND GUIDES**	S20	VATESI should consider developing guides to help in how to comply with the safety requirements.
		R17	VATESI should revise the regulatory framework on predisposal management of radioactive waste to ensure its compliance with the GSR Part 5.
		R18	VATESI should revise the regulatory framework on disposal of radioactive waste to ensure its compliance with the SSR-5.
		R19	RSC and VATESI should update existing regulations in radiation safety according to the Safety Standards Series No GSR Part 3.
		R20	RSC should revise the existing regulation not to require the notification of a single exempted source but to account for the accumulation of exempted sources.
		S21	VATESI should consider establishing criteria for clearance of buildings and the site of a facility and methodologies for the use of them.
		R21	RSC should revise and update its decommissioning regulations to ensure its compliance with GSR Part 6.
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**	R22	RSC and VATESI should jointly review, update and complete, in line with their assigned responsibilities, the regulatory requirements for preparedness and response for a nuclear or radiological emergency, in line with GSR Part 7.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		S22	RSC should consider improving its internal process for evaluation of on-site emergency plans and exercises of operating organizations in EPC III and IV, and to ensure that lessons learned are considered and transposed into improved on-site EPR arrangements.
		R23	RSC and VATESI should jointly prepare and promulgate requirements, criteria and guidance for operating organizations, in line with their assigned responsibilities, to perform and periodically review the on-site hazard assessment as basis for a graded approach to emergency preparedness arrangements.
		S23	RSC should consider ensuring that all critical functions of the on-site emergency plans for EPC III and IV are tested through the annual on-site exercises and that criteria are in place for effective evaluation of annual on-site exercises.
		R24	VATESI should set a requirement and oversee that staff responsible for critical response functions within the on-site emergency organization for facilities in EPC I shall participate in a training exercise or drill at least once every year. VATESI should also set a requirement and oversee that criteria are in place for effective evaluation of annual on-site exercises.
		S24	VATESI should consider all possible ways for ensuring backup electricity at the emergency operations centre.
11.1	**CONTROL OF MEDICAL EXPOSURES**	R25	RSC should require that referral guidelines are being used in the justification of individual medical exposures.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		S25	RSC should consider enforcing that radiological reviews (clinical audits) are performed periodically at medical radiation facilities.
11.2	**OCCUPTIONAL RADIATION PROTECTION**	R26	RSC should require licensees to record any report received from a worker that identifies circumstances that could affect compliance with legislated requirements established for occupational radiation protection and take appropriate action.
		S26	RSC should consider encouraging the use of dose constraints by licensees for optimization of occupational exposures.
		R27	VATESI should adopt in regulation the requirements for authorization or approval of dosimetry services for the nuclear energy sector.
11.3	**Control of RADIOACTIVE discharges, MATERIAL FOR clearance, AND EXISTING EXPOSURES SITUATIONS; environmental monitoring FOR PUBLIC RADIATION PROTECTION**	S27	VATESI and RSC should consider implementing a mechanism for common review of the periodic reports of environmental monitoring programmes, results and dose assessments made by nuclear installations.
		S28	VATESI should consider requiring licensees to verify the adequacy of assumptions made for the assessment of public exposure and the assessment for radiological environmental impacts taking into account, inter alia, the results of the radiological monitoring.
12.	**INTERFACE WITH NUCLEAR SECURITY**	NA	

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
13.	**TAILORED MODULE FOR COUNTRIES EMBARKING ON NUCLEAR POWER (SSG–16)**	S29	The Government should consider to enhance coordination of activities of different organizations within the safety infrastructure for the new build and the efficient development of these organizations. This should happen when the new build project is further developed.
		S30	The Government should consider regularly assessing the competence of existing organizations that can provide technical support to VATESI or operating organization, and performing a gap analysis to identify areas in which these organizations need further support of the Government. This should happen when the new build project is further developed.
		S31	The Government should consider coordinating and urging all relevant organizations for implementation of National Plan and to commence with the education and training of their personnel to ensure safety and to prepare for the conduct and review of safety assessments. This should happen when the new build project is further developed.
		S32	VATESI should consider extending its contacts with regulatory bodies engaged with regulating NPPs of similar designs to that proposed to be constructed in Lithuania. This should happen when the new build project is further developed.

APPENDIX VI REFERENCE MATERIAL USED FOR THE REVIEW

1.	**Acts of the Parliament**
a)	Law on Civil Protection.doc
b)	Law on Environmental Impact Assessment.doc
a)	Law on Environmental Monitoring.doc
b)	Law on Granting Consession.doc
c)	Law on Nuclear Energy.docx
d)	Law on Nuclear Safety.docx
e)	Law on Public Administration.docx
f)	Law on Radiation Protection.docx
g)	Law on Radioactive Waste Management.docx
h)	Law on Strategic Goods.doc
i)	Code of Administrative Offences (ANK)_relevant articles.docx
j)	Criminal Code.doc
k)	Law of Nuclear Power Plant.docx
l)	Law on Carriage of Dangerous Goods_relevant articles.docx
2.	**Resolutions of the Government**
a)	Rules on the Handling of Orphan Sources.doc
b)	State Emergency Management Plan.doc
c)	Statute of VATESI.doc
d)	Granting the Authorization for Carriage of Dangerous .doc
e)	Order on Informing the Public in Case of Emergency.doc
f)	Regulations on Issue of Licenses for Nuclear Energy Activities .doc
g)	Rules on Licensing Practices with Sources of Ionizing Radiation.doc
3.	**Orders of VATESI**
a)	BSR-1.9.1-2011_Release of Radionuclides from Nuclear Installations.docx
b)	BSR-1.9.2-2011_Clearance Levels.doc
c)	BSR-1.9.3-2011_Radiation Protection at Nuclear Facilities.docx
d)	BSR-3.1.1-2010_Dry storage Facility of Spent Nuclear Fuel.docx
e)	BSR-3.1.2-2010_Pre-Disposal Management of Radioactive Waste.doc
f)	BST-1.5.1-____Free Release Criteria.docx
g)	P-2002-02_Disposal of Low and ILSL Radioactive Waste.doc
h)	P-2003-02_Disposal of VLL Radioactive Waste.doc
i)	P-2008-01_Requirements for Emergency Preparedness.doc
j)	P-2009-04_Operational Experience Feedback.doc
k)	BSR-1.1.1-2014_Drafting Nuclear Safety Requirements.docx
l)	BSR-1.1.3-2016_Inspections Conducted by VATESI.doc
m)	BSR-1.1.4-2011_Enforcement Measures.docx
n)	BSR-1.5.1-2015_Decommissioning.docx
o)	BSR-1.6.1-2012_Physical Security.docx
p)	BSR-1.7.1-2014_Fire Safety.doc
q)	BSR-1.8.2-2015_Requiremenst for modifications.docx
4.	**Orders of the Ministry of Health**
a)	HN 73 2001_Basic Standards of Radiation Protection.doc
b)	HN 99 2011_Protective actions.doc

c) Issuing the Permissions for the Discharges from the Medical, Industrial Installations.doc
d) Regulation on State Radiation Protection Supervision.doc
e) Rules of Decommissioning.doc
f) Statute of RSC.doc
g) Determination and Application of the Clearance Levels.doc
5. Orders of other institutions
a) Rules on Import Export and Transport of Radioactive Material.doc
b) Environmental Monitoring of Operators.doc
6. Internal administrative VATESI and RSC documents
a) VATESI Manual of Integrated Management System.docx
b) VATESI Procedure for Inspections PR-6.doc
c) VATESI Procedure for Review and Assessment_PR-5.docx
d) VATESI Procedure for Strategic Management_PR-21.docx
e) RSC QMS_List of procedures and work instructions.docx
f) RSC_List of legal acts related to radiation protection.doc
g) VATESI Management System Policy.docx
7. Documents for Ignalina NPP
a) Ignalina NPP Instruction on Emergency Planning.docx
b) Ignalina NPP Instruction on Notification of EPO.docx
c) INPP Instruction on Cooperation with Organizations in Liquidation Emergencies.doc
d) Ignalina NPP Emergency Classification Instruction.doc
e) Ignalina NPP Emergency Preparedness Plan. General part.doc
8. List of legal acts available in English_2016-02-15.doc
9. List of legal acts available in English_updated 2016-03-21.doc
10. Self Assessment Report
Module areas
Responsibilities and Functions of the Government.doc
Global Nuclear Safety Regime.docx
Responsibilities and Functions of the Regulatory Body.doc
Management System of the Regulatory Body.docx
Authorization.docx
Review and Assessment.doc
Inspection.doc
Enforcement.doc
Regulations and Guides.doc
Emergency Preparedness and Response.docx
Interface with Nuclear Security.doc
Additional areas
Control of Medical Exposure
Justification.doc
Optimization.docx
Patient Release.doc

Pregnant and Breast Feeding Women.doc
Responsibilities of Registrants and Licensees.doc
Responsibilities of the Government.doc
Responsibilities of the Regulatory Body.doc
Reviews and Records.docx
Unintended Exposures.doc
Control of Radioactive Discharges and material for clearance
Environmental Monitoring Associated with Authorized Practices for Public Radiation Protection Purposes
Environmental monitoring
Regulatory Framework
Occupational Radiation Monitoring
Legal Regulatory Framework.doc
Monitoring Programmes Technical Services.docx
Requirements for Radiation Protection Programmes.docx
General Responsibilities of Registrants, Licensees and Employers.doc
General Responsibilities of Workers.docx
Transport
Issuing of Approvals.doc
Monitoring and Inspections of Transport Operations.doc
Regulatory Review and Maintenance of Effective Legal Framework.docx
Training and Distribution of Information.docx
Witnessing Manufacture.docx
Witnessing Testing.doc
Audits of Management System.doc
Design Assessment.docx
Emergency Planning and Exercises.doc
Enforcement Actions and Investigations of Incidents.doc
Examination of Maintenance and Servicing Arrangements.doc
International Liaison.doc
11. Safety Requirements for Decommissioning of Nuclear and Other Facilities.doc
12. Fuel Cycle Facilities
Regulation of FCF.doc
Review and Assessment.doc
Development of Regulations and Guides.doc
Inspection and Enforcement.docx
Licensing.docx
13. Nuclear Power Plants
a) Safety of NPP - Design.doc
b) Safety of NPP - Commissioning and Operation.docx
c) Development of Regulations and Guides.doc
d) Inspection and Enforcement.doc
e) Licensing of NPPs.docx
f) Review and Assessment.doc

14.	**Safety of Radiation Sources**
15.	**SSG 15**
Interim report 2016-02-15	
16.	**Waste facilities**
a)	Safety Requirements for Predisposal Management of Radioactive Waste.doc
b)	Safety Requirements for Disposal of Radioactive Waste.doc
17.	**IRRS ARMS Summary**
18.	**VATESI and RSC Action plan**
19.	**EMERGENCY**
a)	Regarding the approval of the requirements for emergency preparedness to the organization operating the nuclear facility
b)	Lithuanian hygiene norm hn 99:2011 ,,protective actions of general public in case of radiological or nuclear accident
20.	**Safety requirements for Existing (Chronic) Exposure and RADON**

APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1. No. SF-1 - Fundamental Safety Principles
2. INTERNATIONAL ATOMIC ENERGY AGENCY - Governmental, Legal and Regulatory Framework for Safety General Safety Requirement Part 1(Rev 1) (Vienna2016)
3. INTERNATIONAL ATOMIC ENERGY AGENCY - Preparedness and Response for a Nuclear and Radiological Emergency Safety Requirement Series No. GS-R-2 IAEA Vienna (2002)
4. INTERNATIONAL ATOMIC ENERGY AGENCY- The Management System for Facilities and Activities. Safety Requirement Series No. GS-R-3 IAEA, Vienna (2006)
5. INTERNATIONAL ATOMIC ENERGY AGENCY – Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, (2014)
6. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety assessment for facilities and activities, General Safety Requirements Part 4, No. GSR Part 4 (Rev 1), IAEA, Vienna (2016)
7. INTERNATIONAL ATOMIC ENERGY AGENCY – Predisposal Management of Radioactive Waste General Safety Requirement Part 5, No. GSR Part 5, IAEA, Vienna (2009)
8. INTERNATIONAL ATOMIC ENERGY AGENCY – Decommissioning of Facilities General Safety Requirement Part 6, No. GSR Part 6, IAEA, Vienna (2014)
9. INTERNATIONAL ATOMIC ENERGY AGENCY – Preparedness and Response for a Nuclear or Radiological Emergency General Safety Requirement Part 7, No. GSR Part 7, IAEA, Vienna (2015)
10. INTERNATIONAL ATOMIC ENERGY AGENCY - Regulations for the Safe Transport of Radioactive Material Specific Safety Requirements 6, No. SSR 6, IAEA, Vienna (2012)8.
11. INTERNATIONAL ATOMIC ENERGY AGENCY - Organization and Staffing of the Regulatory Body for Nuclear Facilities, Safety Guide Series No. GS-G-1.1, IAEA, Vienna (2002)
12. INTERNATIONAL ATOMIC ENERGY AGENCY - Review and Assessment of Nuclear Facilities by the Regulatory Body, Safety Guide Series No. GS-G-1.2, IAEA, Vienna (2002)
13. INTERNATIONAL ATOMIC ENERGY AGENCY - Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, Safety Guide Series No. GS-G-1.3, IAEA, Vienna (2002)
14. INTERNATIONAL ATOMIC ENERGY AGENCY - Documentation for Use in Regulatory Nuclear Facilities, Safety Guide Series No. GS-G-1.4, IAEA, Vienna (2002)
15. INTERNATIONAL ATOMIC ENERGY AGENCY- - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)
16. INTERNATIONAL ATOMIC ENERGY AGENCY – Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna (2011)
17. INTERNATIONAL ATOMIC ENERGY AGENCY– Assessment of Occupational Exposure Due to Intake of Radionuclides Safety Guide Series No. RS-G-1.2, IAEA, Vienna (1999)

18. INTERNATIONAL ATOMIC ENERGY AGENCY - Assessment of Occupational Exposure Due to External Sources of Radiation Safety Guide Series No. RS-G-1.3, IAEA, Vienna (1999)

19. INTERNATIONAL ATOMIC ENERGY AGENCY - Building Competence in Radiation Protection and the Safe Use of Radiation Sources, Safety Guide Series No. RS-G-1.4, IAEA, Vienna (2001)

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

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

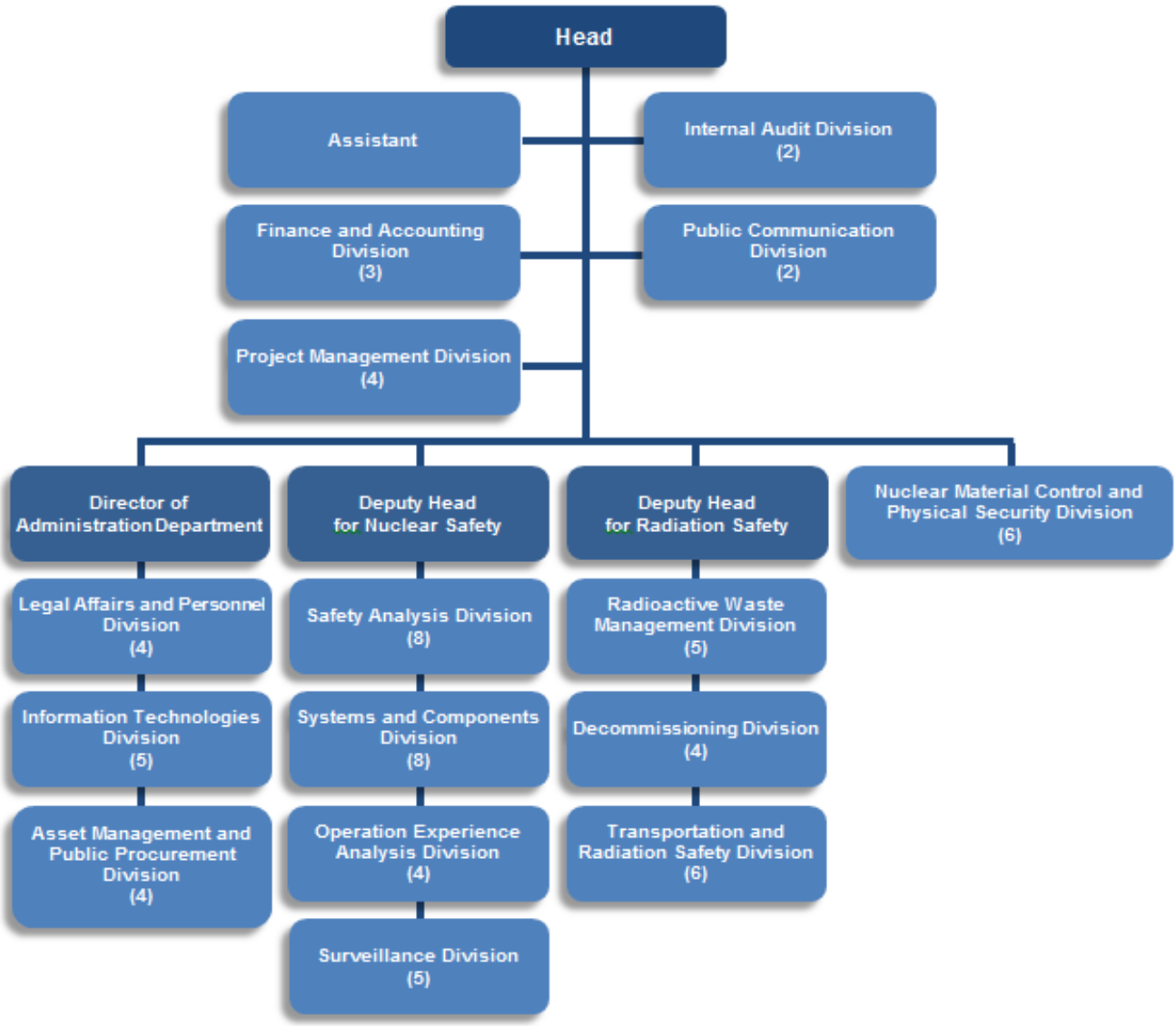
22. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No. WS-G.5.2, IAEA, Vienna (2009)

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

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

APPENDIX VIII ORGANIZATIONAL CHART

VATESI ORGANIZATIONAL CHART



RSC ORGANIZATIONAL CHART