IAEA-NS-2020/03 ORIGINAL: English



INTEGRATED REGULATORY REVIEW SERVICE (IRRS) FOLLOW-UP MISSION TO REPUBLIC OF LITHUANIA

10 November to 2 December 2020

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY





INTEGRATED REGULATORY REVIEW SERVICE (IRRS) **FOLLOW-UP REPORT**

TO

REPUBLIC OF LITHUANIA

Mission date: 10 November to 2 December 2020

Regulatory body: State Nuclear Power Safety Inspectorate (VATESI) and Radiation

Protection Centre (RSC)

Location: Virtual

Regulated facilities Radiation Sources in Industrial and Medical Facilities, Waste and activities:

Management Facilities, Decommissioning, Transport, Emergency Preparedness and Response, Medical Exposure, Occupational

Exposure, Public and Environmental Monitoring

Organized by: *IAEA*

IRRS REVIEW TEAM

Team Leader (United Kingdom) **HART Anthony**

ARENDS Patrick Reviewer (Netherlands) CHRISTINA DODKIN Reviewer (Canada) JÄRVINEN MARJA-LEENA Reviewer (Finland) **HUSSAIN Muhammad Nadeem** Reviewer (Pakistan) SLOKAN DUŠIČ Darja Reviewer (Slovenia)

TAIT Colin Reviewer (United Kingdom) MANSOUX Hilaire IAEA Team Coordinator

MACSUGA Géza IAEA Deputy Team Coordinator AGHAJANYAN Nelli IAEA Review Area Facilitator **BOSNJAK Jovica** IAEA Review Area Facilitator IAEA Administrative Secretary SWOBODA Zumi

The number of recommendation of the status of the regulatory be	ns, suggestions and good	practices is in no way a measure
of the status of the regulatory bo from different countries should	not be attempted.	numbers between IKKS reports

TABLE OF CONTENTS

EXE	CUTIVE SUMMARY	1
II.	INTRODUCTION	3
III.	OBJECTIVE AND SCOPE	4
IV.	BASIS FOR THE REVIEW	5
1.	RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	7
	 1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY 1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY 1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE 1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS 1.5. COORDINATION OF AUTHORITIES WITH RESPONSIBILITIES FOR SAFETY WITHIN THE REGULATORY FRAMEWORK 1.6. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE EXISTING OR UNREGULATED RADIATION RISKS 1.7. PROVISIONS FOR THE DECOMMISSIONING OF FACILITIES AND THE MANAGEMENT OF RADIOACTIVE WASTE AND OF SPENT FUEL 1.8. COMPETENCE FOR SAFETY 1.9. PROVISION OF TECHNICAL SERVICES 	8 10 11 11 11 11 13
•	THE GLOBAL SAFETY REGIME	
2.	2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION 2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE.	16
3.	RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	17
4.	3.1. ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND ALLOCATION OF RESOURCES	17 18 22 324 24 24 25
4.	4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT	21
	4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM	31 32 32
5.	AUTHORIZATION	
	 5.1. GENERIC ISSUES	34 34 38 40

6.	REVII	EW AND ASSESSMENT	. 42
	6.1.	GENERIC ISSUES	. 42
	6.2.	REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS	
	6.3.	REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES	
	6.4.	REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND	. 15
	0.4.	ACTIVITIES	16
	6.5.	REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES	
	6.6.	REVIEW AND ASSESSMENT FOR TRANSPORTREVIEW AND ASSESSMENT FOR TRANSPORT	
	0.0.	REVIEW AND ASSESSIMENT FOR TRAINSPORT	. 40
7.	INSPE	CTION	. 47
	7.1.	GENERIC ISSUES	. 47
	7.2.	INSPECTION PROGRAMME	. 47
	7.3.	INSPECTION PROCESS AND PRACTICE	
	7.4.	INSPECTORS	
	7.5.	INSPECTION OF NUCLEAR POWER PLANTS	
	7.6.	INSPECTION OF WASTE MANAGEMENT FACILITIES	
	7.7.	INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES	
	7.7.	INSPECTION OF DECOMMISSIONING ACTIVITIES	
	7.9.	INSPECTION OF TRANSPORT	
	7.5.	INSTECTION OF TRANSFORT	
8.	ENFO	RCEMENT	. 52
	8.1.	ENFORCEMENT POLICY AND PROCESS	52
	8.2.	ENFORCEMENT IMPLEMENTATIONS	
	0.2.	EN ORCEVIENT IVII ELIVIENTATIONS	. 52
9.	REGU	LATIONS AND GUIDES	. 53
	9.1.	GENERIC ISSUES	. 53
	9.2.	REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS	. 53
	9.3.	REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES	. 54
	9.4.	REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND	
	,	ACTIVITIES	
	9.5.	REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES	
	9.6.	REGULATIONS AND GUIDES FOR TRANSPORT	
10.	EMER	GENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS	62
10.			
	10.1.	GENERAL EPR REGULATORY REQUIREMENTS	
	10.2.	FUNCTIONAL REGULATORY REQUIREMENTS	. 65
	10.3.	REGULATORY REQUIREMENTS FOR INFRASTRUCTURE	. 65
	10.4.	ROLE OF REGULATORY BODY DURING RESPONSE	. 67
11.	ADDI	ΓΙΟΝΑL AREAS	. 68
	11.1.	CONTROL OF MEDICAL EXPOSURES	68
	11.2.	OCCUPATIONAL RADIATION PROTECTION	
	11.3.	CONTROL OF RADIOACTIVE DISCHARGES, MATERIALS FOR CLEARANCE, AND	. 70
	11.5.	EXISTING EXPOSURES SITUATIONS; ENVIRONMENTAL MONITORING FOR PUBL	IC
		RADIATION PROTECTION	
		RADIATION I ROTLE HON	. 12
12.	INTERI	FACE WITH NUCLEAR SECURITY	. 74
	12.1.	LEGAL BASIS	74
	12.2.	REGULATORY OVERSIGHT ACTIVITIES	
	12.2.	INTERFACE AMONG AUTHORITIES	
13.		ORED MODULE FOR COUNTRIES EMBARKING ON NUCLEAR POWER (SSG	
	•		
	13.1.	INTRODUCTION TO TAILORED MODULE FOR COUNTRIES EMBARKING OF NUCLEAR POWER	
		110CLL/IKTOWLK	. 13

13.2.	CONSIDERATION OF ELEMENTS OF SSG-16	75
13.2.1.	SSG-16 ELEMENT 01NATIONAL POLICY AND STRATEGY	75
13.2.2.	SSG-16 ELEMENT 02 GLOBAL NUCLEAR SAFETY REGIME	76
13.2.3.	SSG-16 ELEMENT 03 LEGAL FRAMEWORK	76
13.2.4.	SSG-16 ELEMENT 04 REGULATORY FRAMEWORK	76
13.2.5.	SSG-16 ELEMENT 05 TRANSPARENCY AND OPENNESS	76
13.2.6.	SSG-16 ELEMENT 06 FUNDING AND FINANCING	76
13.2.7.	SSG-16 ELEMENT 07 EXTERNAL SUPPORT ORGANIZATIONS AND CONTRACTORS	76
13.2.8.	SSG-16 ELEMENT 08 LEADERSHIP AND MANAGEMENT FOR SAFETY	77
13.2.9.	SSG-16 ELEMENT 09 HUMAN RESOURCES DEVELOPMENT	77
13.2.10.	SSG-16 ELEMENT 10 RESEARCH FOR SAFETY AND REGULATORY PURPOSES	77
13.2.11.	SSG-16 ELEMENT 11 RADIATION PROTECTION	
13.2.12.	SSG-16 ELEMENT 12 SAFETY ASSESSMENT	77
13.2.13.	SSG-16 ELEMENT 13 SAFETY OF RADIOACTIVE WASTE, SPENT FUEL MANAGEMENT	AND
	DECOMMISSIONING	79
13.2.14.	SSG-16 ELEMENT 14 EMERGENCY PREPAREDNESS AND RESPONSE (REGULATORY	
	ASPECTS)	
13.2.15.	SSG-16 ELEMENT 15 OPERATING ORGANIZATION	
13.2.16.	SSG-16 ELEMENT 16 SITE SURVEY, SITE SELECTION AND EVALUATION	
13.2.17.	SSG-16 ELEMENT 17 DESIGN SAFETY	
13.2.18.	SSG-16 ELEMENT 19 TRANSPORT SAFETY	
13.2.19.	SSG-16 ELEMENT 20 INTERFACES WITH NUCLEAR SECURITY	79
APPENDIX I	LIST OF PARTICIPANTS	80
APPENDIX II	LIST OF COUNTERPARTS	82
A DDENIDIY III	I MISSION PROGRAMME	00
APPENDIX II	MISSION PROGRAMME	00
APPENDIX IV	RECOMMENDATIONS (R) AND SUGGESTIONS (S) FROM THE 2016 IRRS MISSIG	ON
THAT RE	MAIN OPEN	92
APPENDIX V	RECOMMENDATIONS (RF) AND SUGGESTIONS (SF) AND GOOD PRACTICE	75
	OM THE 2020 IRRS FOLLOW UP MISSION	
APPENDIX VI	REFERENCE MATERIAL USED FOR THE REVIEW	94
APPENDIX V	I IAEA REFERENCE MATERIAL USED FOR THE REVIEW	97
APPENDIX VI	TI ORGANIZATION CHART	99

EXECUTIVE SUMMARY

At the request of the Government of the Republic of Lithuania, an international team of senior safety experts met with representatives of the State Nuclear Power Safety Inspectorate (VATESI) and the Radiation Protection Centre (RSC) from 16 November to 2 December 2020 to conduct a virtual Integrated Regulatory Review Service (IRRS) follow-up mission. The purpose of the IRRS follow-up mission was to review Lithuania's progress against the recommendations and suggestions identified in the initial IRRS mission, which was carried out from 17 to 29 April 2016. The follow-up mission took place virtually, due to the travel restrictions imposed by the COVID-19 pandemic. The scope of the IRRS follow-up mission was the same as the scope of the initial mission in 2016, namely the regulatory framework for all nuclear and radiation facilities and activities in Lithuania.

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

The IRRS team carried out a review of the progress made on each recommendation and suggestion that was documented in the 2016 IRRS mission report. These recommendations and suggestions cover the following areas: responsibilities and functions of the government; the global safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body, including authorization, review and assessment, inspection, enforcement and the development and content of regulations and guides; emergency preparedness and response; control of medical exposure; occupational radiation protection; control of radioactive discharges, materials for clearance and control of existing exposure situations and remediation; environmental monitoring for public radiation protection and the tailored module for countries embarking on nuclear power.

To assess progress, the IRRS team conducted a series of online interviews and discussions with VATESI and RSC and reviewed the advance reference material provided by them.

The IRRS team concluded that Lithuania, has been responsive to each recommendation and suggestion made in 2016, and continues to place appropriate focus on implementing a framework that provides for effective nuclear and radiation safety for workers, patients, the public and the environment. 26 out of the 27 recommendations and 31 out of the 32 suggestions identified in 2016 have been closed. 1 new recommendation and 2 new suggestions were formulated on the basis of analysis of current situation.

The IRRS team noted that the Lithuanian Government, VATESI and RSC have shown a strong commitment to nuclear and radiation safety.

Achievements since 2016 have been impressive and include:

- The legal framework on Radiation Protection now takes better into account IAEA safety standards on several key elements;
- The legal framework and approaches have been changed to allow increased public information on and involvement in regulatory decision-making;
- The graded approach is now well-embedded in both the legal framework and regulatory practices;
- Publicly announced written consultations to provide further guidance, where needed, on legal compliance, e.g. on the requirements of periodic safety reviews at nuclear facilities;

- Alignment of predisposal and disposal requirements for radioactive waste with IAEA safety standards;
- Improvements to regulatory requirements and approaches for the preparedness and response to a nuclear or radiological emergency;
- Ensuring that referral guidelines for radiodiagnostic procedures are used by medical practitioners in the justification of individual medical exposures;
- Improvements in how environmental monitoring is regulated.

The Government, VATESI and RSC are encouraged to continue their efforts to:

- Strengthen the effective independence of RSC's regulatory functions from its expert services to licensees;
- Increase the range of inspection guidance that VATESI provides to its nuclear inspectors and further develop the framework for regulating the eventual closure of radioactive waste repositories;
- Complete the revision of the National Radioactive Waste Management Programme and define more clearly when the different exemption values for practices and sources should be applied.

The specific findings of the follow-up mission are summarized in Appendices IV and V. A press release was issued by the IAEA at the end of the IRRS follow-up mission.

II. INTRODUCTION

At the request of the Government of Lithuania, an international team of senior safety experts met representatives from the State Nuclear Power Safety Inspectorate (VATESI) and the Radiation Protection Centre (RSC) from 16 November to 2 December 2020 to conduct a virtual Integrated Regulatory Review Service (IRRS) follow-up mission.

The purpose of the follow-up mission is to review the implementation of the recommendations and suggestions given to the Government of Lithuania during the IRRS Mission in April 2016. The follow-up mission was formally requested by the Government of Lithuania in February 2019. A preparatory meeting was conducted on 4 December 2019 at the 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.

The IRRS review team consisted of seven senior regulatory experts from six IAEA Member States, and 5 IAEA staff members. The IRRS review team carried out the review in the areas covered by the initial mission in 2016.

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

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

III. OBJECTIVE AND SCOPE

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

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

IV. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Lithuania, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted on 4 December 2019. The preparatory meeting was carried out by the appointed Team Leader Mr Ingmar Lund, and IAEA Team Coordinator Mr Hilaire Mansoux and Deputy Team Coordinator Mr Geza Macsuga and the VATESI and RSC representatives.

The IRRS Follow-up mission preparatory team had discussions regarding regulatory programmes with the senior management of VATESI and RSC represented by Mr Ovidijus Šeštokas as the Liaison Officer for VATESI and Ms Ramunė Marija Stasiūnaitienė as the Liaison Officer for RSC. The discussions resulted in agreement that the regulatory functions covering the following facilities and activities were to be reviewed by the IRRS follow-up mission:

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

Mr Michail Demčenko and Ms Ramunė Marija Stasiūnaitienė made presentations on the national context, the current status of the VATESI and RSC and the progress made since the initial mission of April 2016.

IAEA staff presented the process and methodology of conducting an IRRS mission follow-up. This was followed by a discussion on the tentative work plan for the implementation of the follow-up mission in Vilnius in 2020.

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

The Liaison Officers for the preparatory meeting and the IRRS follow-up mission were Mr Ovidijus Šeštokas, VATESI and the Liaison Officer for RSC to be Ms Ramunė Marija Stasiūnaitienė.

VATESI and RSC provided the IAEA (and the review team) with the advance reference material for the review in March 2020 and additional materials. In preparation for the mission, the IRRS review team members conducted a review of the advance reference material and provided their initial review comments to the IRRS Team Coordinator and Team Leader prior to the follow-up mission.

B) REFERENCES FOR THE REVIEW

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

C) CONDUCT OF THE REVIEW

An initial IRRS team meeting was conducted on Tuesday 10 November 2020 by the IRRS Team Leader and IAEA Team Coordinator to discuss the general overview, the focus areas and the specific issues of the mission; to clarify the basis for the review and the background and objectives of the IRRS; and to agree on the methodology for the review. The agenda for the mission was also presented.

The Liaison Officers, Mr Ovidijus Šeštokas and Ms Ramunė Marija Stasiūnaitienė were present at the initial IRRS team meeting in accordance with the IRRS guidelines, and presented logistical arrangements planned for the mission.

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

The IRRS entrance meeting was held on Monday 16 November 2020, with the participation of senior management and staff of VATESI and RSC. Opening remarks were made by Mr Michail Demčenko, Head of VATESI, and the IRRS Team Leader Mr Anthony Hart. On behalf of VATESI Mr Michail Demčenko gave an overview of the VATESI and on behalf of RSC Ms Ramunė Marija Stasiūnaitienė, Acting Head and Deputy Director of RSC gave an overview of the RSC activities and response to the 2016 initial mission findings.

During the mission, a review was conducted for all the mission scope areas with the objective of reviewing the Government and VATESI and RSC's response to the recommendations and suggestions identified during the initial mission. The review was conducted virtually, due to the travel restrictions imposed by the COVID-19 pandemic and included meetings, interviews and discussions on the national practices and activities.

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

The IRRS exit meeting was held on 2 December 2020 where the IRRS Team Leader Mr Anthony Hart presented the results of the follow-up mission highlighting the main findings. This was followed by a statement by Mr Michail Demčenko, Head of VATESI in response to the Team Leader's presentation. Closing remarks were made by Mr. Peter Johnston Director of the Division of Radiation, Transport and Waste Safety, Department of Nuclear Safety and Security.

A press release was issued by the IAEA at the end of the IRRS follow-up mission.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

2016 Original mission RECOMMENDATIONS and SUGGESTIONS

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 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.

Changes since the original IRRS mission

Recommendation 1: During the initial mission in 2016, it was observed that the Lithuanian policy and strategy for safety had been established through provisions of several laws; in particular through the Law on Nuclear Safety and the Law on Radiation Protection. However, the Fundamental Safety Principles of IAEA SF-1 were not fully embedded in the Law on Radiation Protection.

Since the initial mission, all legal acts regulating nuclear and radiation safety in Lithuania have been systematically reviewed and updated. The most significant changes have been made in the legal framework for radiation safety, as the Law on Radiation Protection has been completely replaced by a new edition, which was adopted by the Lithuanian Parliament in June 2018.

The Law on Radiation Protection (2018) in Article 1 includes specification of the scope of the governmental, legal and regulatory framework for safety, and also states the fundamental safety objective to protect people and the environment from harmful effects of ionizing radiation. In Article 3, all ten safety principles of IAEA SF-1 are systematically addressed. Safety principles referred to in the 2016 IRRS mission report, such as prime responsibility for safety, leadership and management for safety and protection of present and future generations, are addressed in paragraphs 1, 3 and 7 respectively.

Status of Recommendation 1

Recommendation (R1) is closed as the Law on Radiation Protection (2018) takes into account the fundamental safety objective and all fundamental safety principles of IAEA SF-1.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

2016 Original mission RECOMMEN	NDATIONS AND SUGGESTIONS

Observation: The Lithuanian framework for safety does not set out general provisions for the involvement of public in the process of decision-making.

involvem	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.	

Changes since the original IRRS mission

Recommendation 2: In response to this recommendation, VATESI and RSC have taken several activities to include provisions for involvement of the public in the decision making process of the regulatory body. The legal basis under the jurisdiction of VATESI was established in the amendment to the Law on Nuclear Safety (2017). New Article 39(1) provides for public participation in the adoption of major decisions; for example, approval of the assessment report for the siting for construction of new nuclear facilities and the issuance of certain licenses

VATESI developed regulations titled Nuclear Safety Requirements BSR-1.1.5-2017 "Rules of Procedure for Public Participation in Decision-making in the Area of Nuclear Energy", approved by the Head of State Nuclear Power Safety Inspectorate (Order No. 22.3-182, October 23rd, 2017). The regulations describe the whole process, including the receipt of the application, the schedule of submission of documents, publication of the draft decision and the time for public comments, evaluation of public comments, and information on the final decision.

Additional provisions regarding public involvement in decommissioning have been included in the updated Nuclear Safety Requirements BSR-1.5.1-2019, "Decommissioning of Nuclear Facilities". The input from the public is taken into consideration while preparing the final decommissioning plan and final decommissioning report.

In radiation safety legislation, the legal basis for the involvement of the public in the decision making process was established in Article 34 of the Law on Radiation Protection (2018). The implementation of this provision is further supported by RSC's quality management system procedure, "Authorization of Practices", which describes the process of involving the public in the decision making process during the authorization process.

Several other instruments deal with the involvement of the public in decision making, such as the Law on Environmental Impact Assessment of the Proposed Economic Activity (implements Convention on ESPO), and Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention), which take into account input from the public during an environmental impact assessment process.

The IRRS team was informed that VATESI and RSC jointly organize regular meetings with representatives of the public, such as annual meetings with the population living in the vicinity of the nuclear facility, and biennial meetings to raise awareness of the public about safety issues. VATESI's public website contains information about these events, as well as a list of actual license applications in which the public may participate in the decision making process.

Status of Recommendation 2

Recommendation (R2) is closed as the legal basis, implementing regulations and supporting internal processes regarding public participation in the decision making process have been developed and implemented.

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS	
Observation: A graded approach is not reflected clearly in the Law on Radiation Protection for radiation safety.	
	BASIS: GSR Part 1 Requirement 2, paras. 2.5(3), (8) and (10) states that "The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:
(1)	(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.

Changes since the original IRRS mission

Recommendation 3: The recommendation relates to the introduction of the graded approach principle into legislation for radiation safety, as a graded approach was already addressed in the nuclear legislation. Article 3 in paragraph 2 of the Law on Radiation Protection (2018) states that "the graded approach should be applied to the regulation and supervision of radiation protection, which should be commensurate with the magnitude and likelihood of exposures resulting from the certain practices, and commensurate with the impact that regulation and supervision of radiation protection may have in reducing such exposures or improving the radiation protection".

The application of the regulatory functions following a graded approach is further considered in several articles of the Law on Radiation Protection (2018). For example, the application of a graded approach is addressed in Article 10, which introduces the notification process; Article 11, which establishes criteria for exemption and clearance; and Article 17, which specifies responsibilities of the undertakings, depending on whether it is authorized by registration or license. A graded approach is not introduced in the provisions on inspection activities, are set out in Article 8, but it is emphasized that supervision will be conducted in accordance with the procedure established by the Minister of Health and VATESI. This procedure takes into account a graded approach, in particular, regarding the frequency of inspections.

Article 12 establishes the graded system of authorization, which takes the form of either a registration or a licence. In Article 14, the graded approach is not explicitly mentioned; however, it is highlighted that the nature of the intended practice and the risks involved therein are factors that need to be considered by the applicant when submitting the information relevant to radiation protection.

The implementation of a graded approach in specific regulatory functions is further addressed in section 5.

Status of Recommendation 3

Recommendation (R3) is closed as the graded approach principle has now been introduced through the Law on Radiation Protection and adopted within the processes of the regulatory bodies.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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.

R4	Recommendation: The Government should ensure that VATESI is only asked to comment on nuclear safety issues regarding national policy and
(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

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

strategy on the use of nuclear power.

Changes since the original IRRS mission

Recommendation 4: During the 2016 IRRS mission, Sub-Paragraph 12 of Paragraph 1 of Article 22 of the Law on Nuclear Energy was identified as potentially conflicting (*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"). VATESI's function could potentially compromise its mandate as the nuclear safety regulator.

During the revision of the Law on Nuclear Energy (2019), the identified conflicting requirement was considered and modified accordingly. The revised paragraph is in line with the mandate of a regulator and states that: "State Nuclear Power Safety Inspectorate submits proposals regarding ensuring nuclear safety, radiation protection, physical protection and implementation of obligations for non-proliferation of nuclear weapon to the Government and other relevant institutions or agencies during forming and (or) implementing State's policy and strategy in nuclear energy sector".

With this amendment, the role of VATESI as the nuclear safety regulator related to the State's policy and strategy in the nuclear energy sector is no longer compromised.

Status of Recommendation 4

Recommendation (R4) is closed as the conflicting requirement on the role of VATESI concerning nuclear energy policy and strategy has been removed.

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

There were no findings in this area in the original IRRS mission.

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

There were no findings in this area in the original IRRS mission.

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

There were no findings in this area in the original IRRS mission.

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

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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.

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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."

- **(1)**
- (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, establishing required research and development programmes, and securing the appropriate financial provisions for all planned activities.

Changes since the original IRRS mission

Recommendation 5: In order to address the recommendation regarding the decommissioning of facilities and the management of radioactive waste in Lithuania, several activities have been initiated by the Ministry of Energy, VATESI and state enterprise Ignalina NPP.

Significant changes to the Law on Radioactive Waste Management were introduced in 2018. These were related to the management of used sealed sources, shipment of radioactive waste and spent nuclear fuel, and principles for the management of radioactive waste. The changes also addressed coordination of the approval of the final closure plan for radioactive waste repositories, and the interdependencies between steps of the radioactive waste management process. Further amendments to the Law on Radioactive Waste Management were introduced this year and relate to better integration of the radioactive waste management programme approved by the Government and the wider system of strategic planning within Lithuania.

State enterprise Radioactive Waste Management Agency (RATA) was reorganized by way of a merger with state enterprise Ignalina NPP. State enterprise Ignalina NPP became an operating organization of Maišiagala radioactive waste storage facility from the beginning of 2019.

In November 2020, the Lithuanian Parliament adopted a package of laws that provide funding for the management of radioactive waste and implementation of the Deep Geologic Repository (DGR) project. They include an amendment to the Law on State Treasury of the Republic of Lithuania and amendment to the Seimas (Parliament) Resolution on the Approval of the Reserve (Stabilization) Fund Regulations. These laws establish the legal framework for the accumulation of funds for the management of radioactive waste, including decommissioning of RW storages and closure of RW repositories and for the implementation of the DGR project.

However, the most important strategic document, the National Radioactive Waste Management Programme, is still under revision. The IRRS team was informed that the draft (Development Programme of Radioactive Waste Management and Decommissioning of Nuclear Energy Facilities for 2021–2030) is in the final phase of development, and Governmental approval is expected by the end of 2020.

The revised programme will take into account information from the revised Final Ignalina NPP Decommissioning Plan regarding the radioactive waste management infrastructure that will remain after Ignalina NPP decommissioning and which may be suitable for the future management of radioactive waste. The programme will fully address interdependencies between steps of the radioactive waste management.

The IRRS team did not have an opportunity to evaluate the draft of the National Radioactive Waste Management Programme. This will however be evaluated in detail during the forthcoming ARTEMIS mission, planned for 2021. The mission will also review provisions for the decommissioning of facilities, management of radioactive waste, research and development programmes; the source and mechanisms for the funding of a DGR facility, and the maintenance of spent fuel and radioactive waste management infrastructure after decommissioning of the Ignalina NPP.

Status of Recommendation 5

Recommendation (R5) is open as the provisions regarding the interdependencies of the steps involved in the entire radioactive waste management process, and the required research and development programmes are not yet fully embedded in the legislative framework. This issue will be addressed in the National Radioactive Waste Management Programme, which is currently under revision.

1.8. COMPETENCE FOR SAFETY

2	2016 Original mission RECOMMENDATIONS AND SUGGESTIONS	
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."	
	BASIS: GSR Part 3 Requirement 2, para. 2.21 states that "The government shall ensure that requirements are established for:	
(2)	(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.	

Changes since the original IRRS mission

Recommendation 6: The requirements specifying the roles and responsibilities, and the legal basis for the recognition of qualified experts for radiation protection (radiation protection expert, RPE), are set out in Article 29 of the Law on Radiation Protection (2018). An RPE must hold a certificate issued by RSC or VATESI.

Detailed criteria for education, training and qualification, and procedures for recognition of qualified experts for radiation protection are set in two Orders: Order No. V-1059 (2018), "On Approval of Issue on Recognition of Radiation Protection Experts Except Activities with Sources of Ionizing Radiation in Nuclear Energy Area", approved by the Minister of Health, and Order No. 22.3-204, (2018), "On the Approval of Nuclear Safety Requirements BSR 1.9.6-2018, "Recognition of Radiation Protection Expert for Activities with Sources of Ionizing Radiation in Nuclear Energy Area and Duties of Undertakings carrying out Aforementioned Activities to Consult with Radiation Protection Expert", approved by the Head of State Nuclear Power Safety Inspectorate.

The requirements for recognition of qualified experts in medical physics (medical physics expert, MPE) are set in Order No. V-901 (2017), "On Approval of Requirements for Activities of Medical Physicists", approved by the Minister of Health, and Order No. V-86 (2017), "On Assessment of Professional Preparedness of Medical Physics Expert", approved by the Director of Radiation Protection Centre.

The IRRS team was informed that the process for formal recognition of qualified expert is fully functioning. Currently, there are 6 RPE certified for various practices and 6 MPE (3 in radiotherapy, 1 in nuclear medicine and 2 in diagnostic radiology). The list of certified experts is available on RSC's public webpage.

Status of Recommendation 6

Recommendation (R6) is closed as the requirements and implementing procedures for formal recognition of qualified experts have been established for radiation protection and medical physicists.

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS	
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, 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.

Changes since the original IRRS mission

Suggestion 1: There are two components of this suggestion. The first refers to the assessment of human resource needs of the regulatory bodies (RSC and VATESI), and the second refers to existing and possible future facilities and activities. This is particularly important for future increased activities in nuclear decommissioning and waste management, as well as the planned construction and operation of waste repositories.

RSC established the QMS procedure, "Rules of Procedure for Planning of Human Resources", in 2017. Based on this procedure, RSC's assessment of human resource needs was performed in 2018. The assessment considered RSC functions set in the Law on Radiation Protection and the Statute of RSC, existing human resources, workload, and activities planned in the near future. The IRRS team was informed that based on the results of the assessment, the plan for engagement of new staff for RSC and relocation of existing staff to new positions was developed. According to the requirements, the assessment of existing and future human resource needs should be performed every three years.

As part of the integrated management system, VATESI issued "Rules of Procedure for Planning of Human Resources", establishing the following tools for better long-term management of human resources: the procedure for management turnover of personnel, the tool for tracking of working time, and different methodologies for evaluating number and competence of employees needed in the long-term perspective. In 2017 and 2019, VATESI carried out an assessment of existing and future needs of human resources and subsequently established a plan for further action.

During the development of the revised Final Decommissioning Plan of Ignalina NPP, an analysis report on the human resources needs by 2028 was prepared. The report provides the analysis of the preliminary human resource needs based on the Ignalina NPP decommissioning megaproject schedule and evaluation of the impact of retiring employees and ensuring sufficient number of employees. Long-term plans related to human resources will be updated by the end of 2021, taking into account the revised Final Plan for the decommissioning of the Ignalina NPP and recent developments.

Status of Suggestion 1

Suggestion (S1) is closed as the necessary quality management procedures have been developed, and assessments of existing and future human resource needs performed.

1.9. PROVISION OF TECHNICAL SERVICES

There were no findings in this area in the original IRRS mission.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

There were no findings in this area in the original IRRS mission.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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.

Changes since the original IRRS mission

Suggestion 2: RSC's quality management system procedure, "Management of International Operating and Regulatory Experience", has been developed and issued. This procedure systematically documents the process for sharing operating and regulatory experience in the area of radiation protection. This includes the steps taken for reviewing international and national experience on regulatory activities and the safe use of radiation sources, as well as the sharing of experiences and information on lessons learned both within RSC and with operators.

RSC holds meetings every three months for all staff to disseminate relevant information on lessons learned. RSC staff participating in training courses or at meetings domestically or abroad are obliged to submit a report that contains, inter alia, topics of interest that can be selected and presented at these quarterly meetings. Identified good practices during inspections are shared with other licensees, and the information related to radiological incidents and accidents is provided to the target audience for which that information could be important. The relevant information on operating and regulatory experience are shared during national seminars and training courses.

Status of Suggestion 2

Suggestion (S2) is closed as a procedure describing the process for reviewing and evaluating regulatory and operating experience and disseminating relevant information on lessons learned has been developed and implemented.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

There were no findings in this area in the original IRRS mission.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

2016 Original Mission RECOMMENDATIONS AND SUGGESTIONS

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."
S 3	Suggestion: RSC should consider further strengthening the effective independence of its regulatory functions from its expert services to licensees.

Changes since the original IRRS mission

Suggestion 3: Since the IRRS mission in 2016, RSC has updated its quality management process for authorizations (P-9). The updated process emphasizes the importance of maintaining independence between occasionally needed support for the review of applications and RSC's authorization decision making. This support for review is undertaken by specialists in its Division of Emergency Management and Training; Division of Radiation Protection

Supervision Expertise and the divisions of the Department of Expert Services and Monitoring (Division of Expertise and Medical Exposure Monitoring; Division of Occupational Exposure Monitoring; Division of Public Exposure Monitoring); and, all of the divisions of Department of Expert Services and Monitoring provide services to operators. The support for review is principally in regard to radiation monitoring, but also include expertise in aspects such as the uncertainties regarding radiation protection and physical protection of radioactive sources.

At the time of the IRRS mission, RSC had plans to seek accreditation (in 2017) of its regulatory functions against LST/ISO/IEC/EN 17020:2012 *Conformity assessment. Requirements for the operation of various types of bodies performing inspection*. Though RSC completed a self-assessment of its management systems against this standard, the accreditation process was not completed due to competing priorities. Areas of improvement to enhance the independence of RSC's regulatory functions in line with IAEA requirements and recommendations from services provided were nevertheless identified.

A number of these services, including personal dosimetry, gamma spectrometry and radiochemistry, are accredited by the Lithuanian National Accreditation Bureau in accordance with the updated standard LST/ISO/IEC/EN 17025:2018, *General requirements for the competence of testing and calibration laboratories*. In addition, RSC's management system procedure REI-3 requires that all these services are managed as accredited services. RSC also provides a number of non-accredited services such as measuring whole-body activity, gross alpha and beta activity, radon concentration, uranium and plutonium and surface contamination as well as radiation protection expertise for designs of premises using ionizing radiation sources. RSC does not however provide any consultation on radiation protection.

RSC's expertise in premises design is a public service required by Lithuanian construction law. The applicant is required to submit a review of its construction project demonstrating compliance with regulatory requirements, including in respect of radiation protection and the physical protection of radiation sources. RSC is the only organization nominated by Government to provide the necessary services needed for applicants to perform such reviews. In 2019 RSC provided this service on 339 occasions (267 for dental practices; 57 for X-ray diagnostics; 10 for veterinary services; 2 for radiotherapy; 1 in nuclear medicine and 1 other).

RSC is still planning to continue to seek the accreditation of its regulatory functions against LST/ISO/IEC/EN 17020 in line with common practice in Lithuania where regulatory bodies are providing services to their licensees.

Status of Suggestion 3

Suggestion (S3) is open as RSC has yet to complete its work to strengthen the effective independence of its regulatory functions from its expert services to licensees.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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

	2016 Original mission RECOMMENDATIONS AND SUGGESTIONS	
	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 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.	

Changes since the original IRRS mission

Recommendation 7: Since the IRRS mission in 2016 VATESI has issued Rules of Procedure for Planning of Human Resources (PR-14) establishing the tools for better long-term management of human resources in its integrated management system. Analysis of the VATESI functions and associated employee turnover, working time tracking and workload follow up are used to assesses resource needs. The personal and competence needs are estimated for short and long-term perspective. In 2017 a long-term (5 years) plan and related action plan was developed and approved by the head of VATESI. Systematic approach is applied for long-term planning and competence management (see also S4).

The process for management of employee turnover requires a detailed annual of changes in personnel and associated risks. Compensatory measures are identified to ensure expertise from the organization point of view. At the moment there are 49 positions described in this plan subject to approval by the head of VATESI. The practice has been in place since 2017.

Tool for working time tracking and workload assessment allows monitoring of the distribution of functions between positions and divisions as well as appropriate of workload. It may be used for estimating the needs to enhance competence or training. Annual evaluation of information has started in 2017. Information is also used for VATESI's quarterly reporting of regulatory functions to the government.

The operating environment of VATESI has changes after the IRRS mission in 2016. Current National Energy Independence Strategy does not foresee development of nuclear power in Lithuania. The changes in the operating environment have been considered in the planning of human resources and competences.

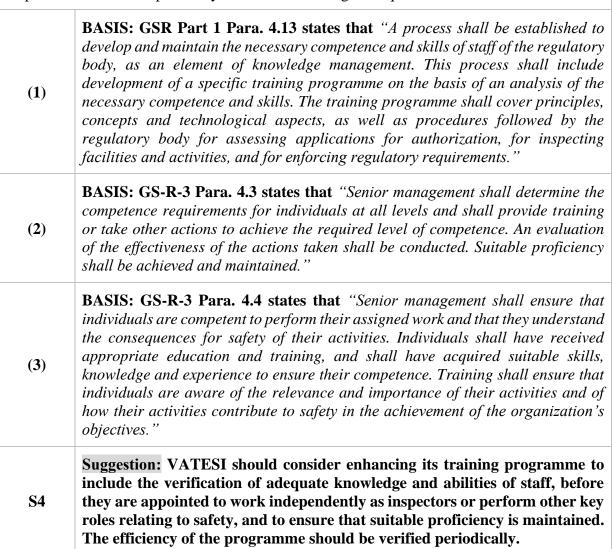
Status of Recommendation 7

Recommendation (R7) is closed as VATESI now has systematic means in its IMS for managing its short and long-term human resource and competence needs for delivering its

regulatory functions. VATESI has demonstrated implementation of a systematic approach for managing human resources and competences.

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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.



Changes since the original IRRS mission

Suggestion 4: The Statute of Training of VATESI Personnel has been amended in 2016. According to amended statute inspectors are required to have extended introductory training and pass a written test before allowed to carry out inspections independently. The inspectors are required to attend refresher courses organized internally and pass a written test every five years. The written test is developed by an independent internal committee nominated by the head of VATESI each time there is need for a such test. The composition of the committee varies case by case. To pass the test 24 questions out of 30 questions should be answered 20

correctly. In 2017 tests for all the inspectors (39) were carried out. Since 2017 four tests have been carried out for new inspectors.

Key competences were developed in 2017 and associated individual plans to develop those were established for all of the personnel. Each job description incudes the associated competence needs. A systematic approach has been adopted for the planning of the VATESI human resources, competences and training.

Statute of Training of VATESI Personnel has been supplemented with provisions on evaluation of efficiency of training programme. The requirements for the evaluation every five years (prior to next evaluation of key competences) and criteria for such evaluation are set. The first evaluation is to take place before the end of year 2021.

Status of Suggestion 4

Suggestion (S4) is closed on the basis of progress and confidence in effective completion in due time. VATESI has improved its processes for verifying and maintaining staff competencies. The efficiency of the overall programme is planned to be evaluated before the end of 2021.

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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.

Changes since the original IRRS mission

Suggestion 5: Since IRRS mission in 2016 RSC Quality Management System Procedure "The Rules of Procedure for Planning of Human Resources" has been developed to evaluate human resources and competences needed for RSC over the short and long-term. The comprehensive

assessment of the resource need, responsibilities, workload and employee turnover has been made for all RSC functions. The first long term plan was made in 2018 providing a 3 year lookahead. The plan is to be updated in 2021. Now there are 58 positions available at RSC. For each position primary and secondary expertise has been defined. The annual evaluation of the training and associated training plans for each employer are made systematically.

Status of Suggestion 5

Suggestion (S5) is closed as RSC now has a systematic approach 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.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS	
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 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.

Changes since the original IRRS mission

Suggestion 6: The revised National Energy Independence Strategy was approved by the Parliament of the Republic of Lithuania on the 21st of June 2018. The revised strategy establishes four main directions of Lithuanian energy policy – energy security, the development of green energy, efficient energy consumption, competitiveness and innovation. The revised National Energy Independence Strategy does not foresee development of nuclear power in Lithuania.

As the development of a new nuclear power plant, namely the Visaginas NPP, project has been suspended, no actions were taken by VATESI. The suggestion 6 is not considered relevant by VATESI in the new circumstances. In the IRRS mission report the suggestion is especially justified by new build.

In the field of waste management, the Ministry of Energy established in 2017 a national working group for monitoring of management of spent nuclear fuel and radioactive waste management. As a continuation for that working group in April 2020 Ministry of Energy

established a working group on strategic questions on waste management. Members of the working group are representatives of the following institutions: Ministry of Energy, Ministry of Environment, Ministry of Finance, Radiation protection centre under Ministry of Health Care, VATESI, Lithuanian Geology Service as well as representatives of Ignalina NPP. VATESI may bring strategic questions to this group and ask for advice. The group may also engage external experts as necessary.

Related to decommissioning of the Ignalina NPP funded by the Ignalina Decommissioning Programme (EU support for decommissioning of INPP). It is foreseen that two expert groups will be established related to the dismantling of the reactor core structures: an expert group to advise Ignalina NPP and a Technical Advisory Group for all stakeholders involved in the project (except Ignalina NPP). The second Technical Advisory Group will consist of high-level international experts and it will be accountable to the Ministry of Energy and EC.

The Advisory body for the new build is no longer relevant. In the field of waste management and decommissioning there is a national working group and plans for international groups that VATESI may use for strategic advice as necessary.

Status of Suggestion 6

Suggestion (S6) is closed as VATESI's operating environment has now changed due to changes in national energy policy and no new build is planned.

	2016 Original mission RECOMMENDATIONS AND SUGGESTIONS	
	tion: There are no provisions for RSC to obtain technical or other expert professional 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.	

Changes since the original IRRS mission

Suggestion 7: RSC's new (2019) statute gives it the right to use the services of experts and advisors, scientific and technical support organizations and others to assist with implementing its functions, provided these are independent from the facilities planning or conducting activities with ionizing radiation.

Status of Suggestion 7

Suggestion (S7) is closed as the statue of RSC has been updated to allow it the option to use expert services.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

There were no findings in this area in the original IRRS mission.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

There were no findings in this area in the original IRRS mission.

3.7. SAFETY RELATED RECORDS

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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, 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.

Changes since the original IRRS mission

Suggestion 8: The internal information management system (VAIS) has been updated. The safety reviews and assessments as well safety justification documentation Safety Evaluation Report are stored into VAIS. The information is available for all the employees of VATESI "INSPECTIONS, SAFETY REVIEW AND ENFORCEMENT" section. Several types search functions are available and links between related documents exist. The list of licensing documents and the documents themselves are in VAIS. There is interlink between VAIS licensing documents and the Register of Incoming documents. The licensee's submissions are indicated by document number in the Reports on Review of Application Documents. The modules of Inspection reports are the most advanced in the VAIS system. The development of VAIS and content or review reporting continues.

The management of documents is described in the IMS procedure PR-5 "Review and assessment of safety justifying documents". In addition, the previous Safety Evaluation Reports (2009 - 2017) are systemised and located in the defined folder for internal usage.

Status of Suggestion 8

Suggestion (S8) is closed as VATESI has updated its information management system VAIS and information is easily accessible for relevant staff.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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 communication in the vicinity of the nuclear facilities.

the vicini	ty 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.

Changes since the original IRRS mission

Recommendation 8: The VATESI public communication requirements are stipulated in the amended Law on Nuclear Safety Article 39. VATESI management system includes a procedure controlling communications (PR-11) and communication requirements are considered in the organization's annual planning cycle. The practice has been applied since 2017. The communication events are well planned and informative. They cover extensively all aspect of regulatory oversight and its outcome at the nuclear facility. The concerns raised by public are discussed. The events are well received by public (see also S9).

Status of Recommendation 8

Recommendation (**R8**) is closed as risk and related communication in the vicinity of nuclear facilities is now stipulated in law, described in VATESI's IMS and has been implemented since 2017.

Changes since the original IRRS mission

Suggestion 9: The legal bases for the public communication in the vicinity of the nuclear facilities by VATESI and RSC is laid down in the Law on Nuclear Safety Article 39 and in the Law on Radiation Protection Article 34.

VATESI and RSC have various means of communication such as websites, press releases, annual reports and meetings with local public and government representatives. During 2018–2019, five meetings with the local public in Visaginas, Ignalina, Zarasai municipalities have been convened by VATESI and RSC. In the meeting VATESI and RSC present the status of safety issues and annual results from the state radiation monitoring. An extensive review of the regulatory oversight outcome, assessment of exposure of workers, public and environment is presented and discussed with public.

Common communication at the vicinity of nuclear facilities has become a practice for both regulatory authorities. VATESI annual stakeholder survey results (2019) also show positive feedback from communication with municipalities near vicinity of Ignalina NPP.

Status of Suggestion 9

Suggestion (S9) is closed as VATESI and RSC now coordinate, and where appropriate combine, their public communication in the vicinity of nuclear facilities.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS	
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.

Changes since the original IRRS mission

Suggestion 10: The advance reference materials provide information and refer to "Manual of Integrated Management System" which describes the VATESI's vision.

Since 2016 VATESI has put significant effort into improving its managment system to align with IAEA Safety Standard GSR Part 2. Part of this work was also related to the definition of the VATESI's vision. The VATESI's vision is defined in paragraph 5 of the "Manual of Integrated Management System" of November 2019. The first VATESI's vision was defined and approved in September 2016. Later on, it was reviewed and the new version was approved in September 2019. In discussion with the VATESI's counterpart, the IRRS team understood that VATESI senior management and other employees were involved and actively participated in the preparation of the VATESI's vision. Special meetings for the development and improving of the VATESI's vision were organized using the brainstorming materials, prepared in advance.

The VATESI's vision is related to the protection of the public and the environment (reliably protected in accordance with the highest modern standards), setting nuclear safety regulations (explicit and prudent) and work at VATESI (highly respected, valued and motivating).

The VATESI's vision has been communicated to interested parties. A large framed poster, dedicated to VATESI's vision and values, hangs on the wall in the VATESI's entrance hall. Information about the VATESI's vision is also presented in its annual report.

Status of Suggestion 10

Suggestion (S10) is closed as VATESI has defined its vision and implemented the requirements of relevant IAEA Safety Standards related to the vision.

2	2016 Original mission RECOMMENDATIONS AND SUGGESTIONS
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

2	2016 Original mission RECOMMENDATIONS AND SUGGESTIONS	
	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.	

Changes since the original IRRS mission

Recommendation 9: The RSC "Quality Policy" of 2016 was amended in 2017 with the statement that one of the main objectives of RSC is "to ensure that safety is an overriding priority for all radiation protection issues" and "to strengthen the safety culture".

RSC further updated its "Quality Policy" in 2019. The requirement for safety to be an overriding priority is still retained.

The IRRS team noted that RSC uses terms that are aligned with requirements of ISO 9000 standards, in its management system. Although the content of "Quality Policy" corresponds to "Safety Policy" which is required by IAEA standards, it would be preferable to use the term "Safety Policy" instead of Quality Policy" and "Management System Manual" instead of "Quality Manual" since a management system covers more than just quality management.

Chapter 5.2 of the RSC "Quality Manual" is dedicated to the "Quality Policy". It states that the RSC management is responsible for establishing the "Quality Policy" and for its implementation.

The IRRS team was informed that the RSC employees were involved in preparation of the "Quality Policy". The "Quality Policy" is communicated to all RSC employees and is annually reviewed and assessed at the management reviews meetings.

The "Quality Policy" is available to the public and other interested parties through the RSC websites and also through features in a poster which is located in the entrance hall of the RSC premises.

Status of Recommendation 9

Recommendation (**R9**) is closed as RSC has improved its Quality Policy to include specifically that safety is an overriding priority in all activities related to radiation protection issues.

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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.

2	2016 Original mission RECOMMENDATIONS AND SUGGESTIONS	
(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."	
	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 the organization;	
(2)	—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."	
(4)	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."	

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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.

Changes since the original IRRS mission

Recommendation 10: Following the initial IRRS mission in 2016, RSC has worked to improve its management system to align it with the latest IAEA Safety Standard GSR Part 2. The work has included improvements to its "Quality Manual" relating to safety culture, application of a graded approach, organizational change management, management system reviews and documenting processes.

The requirement for strengthening the safety culture is addressed in RSC's "Quality Policy" and RSC's "Quality Manual" Chapter 4.5. Additionally, RSC has developed the procedure P-32 "Development of Safety Culture". According to the procedure a self-assessment of safety culture is performed once per two years. The first self-assessment was performed in 2020. Three recommendations were made and implemented. The results of self-assessment are also evaluated during the reviews of the management system.

The provisions for organizational changes are captured in the Chapter 4.7 of the "Quality Manual". The IRRS team was informed that senior management of RSC plans, manages and monitors the implementation of RSC organizational changes and their impact on safety. The organizational changes and their impact on safety are assessed during the review of the management system. The records on organizational changes, if any, are captured in the management system review report.

Requirements on graded approach are defined in the legislation related to radiation safety, in Section 4.6 of the RSC's "Quality Manual" and in RSC's procedures. In addition, the requirement of graded approach is applied in the RSC processes. Management system documents are prepared according to requirements of graded approach defined in the RSC "Quality Manual". The application of graded approach is identified in management system procedures such as:

P-08 "Maintenance of the state register of ionizing radiation and exposure of workers" different requirements (the quantity and content of provided documents) depending on the source category.

- P-09 "Registration or licencing of practices with sources of ionizing radiation" licensing or registration is applied for practices; for different types of authorization, different requirements are applied.
- P-10 "Performance of state radiation safety supervision". The periodicity and complexity of state radiation safety supervision, the number of requirements, the number of requirements determined during inspections depends on the type and the risk of practices or the category of sources of ionizing radiation.
- P-12 "Issue of permissions for the shipment of radioactive materials and radioactive waste" different requirements (the quantity of provided documents) depending on the source category.

RSC "Quality Manual" subsection 9.3 "Review of the management system" provides that the senior management conducts the management system reviews once a year.

During the reviews of the management system the implementation of areas of improvement of the last review of the management system are checked.

During the reviews of the management system the efficiency and effectiveness of the management system and its processes are reviewed and implementation of possible improvements is discussed. At the management system review meetings also review of lessons learned from other organizations is foreseen.

The management representative prepares the report on the review meeting which will be approved by the director.

The RSC management system is based on processes. In the RSC "Quality Manual" RSC identified 3 management processes, 7 core processes and 2 supporting processes which are documented in 31 procedures and 67 instructions. The IRRS team was informed that for each of the processes a responsible person is appointed for implementing and improving the process via job description.

Status of Recommendation 10

Recommendation (R10) is closed as RSC has developed and implemented improvements to its management system to align with the latest IAEA Safety Standard, GSR Part 2, including in regard to safety culture, application of a graded approach, organizational change management, management system review and documenting of processes.

4.2. MANAGEMENT RESPONSIBILITY

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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.

Changes since the original IRRS mission

Suggestion 11: The VATESI's "Manual of Integrated Management System" defines the ultimate responsibility of senior management for the establishing, applying, sustaining and continually improving the management system to ensure safety.

After the initial mission in 2016 the "Manual of Integrated Management System" was revised and supplemented with the provision that "VATESI top management is responsible for the development, implementation, maintenance, effectiveness and continual improvement of integrated management system in order to ensure nuclear power safety."

VATESI provided evidence that the head of VATESI supports implementation and continual improvement of the management system. He approves all management system procedures personally and is proactive in discussing on proposed findings and necessary improvements. Head of VATESI participates together with management system representative, managers and process owners in management system reviews where discussions are held about the identified problems related to the management system and its processes and activities for improvements are defined.

Status of Suggestion 11

Suggestion (S11) is closed as VATESI has supplemented its "Manual of Integrated Management System" with provisions clarifying senior management's ultimate responsibility for maintaining and developing the management system.

4.3. RESOURCE MANAGEMENT

There were no findings in this area in the original IRRS mission.

4.4. PROCESS IMPLEMENTATION

There were no findings in this area in the original IRRS mission.

4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

There were no findings in this area in the original IRRS mission.

5. AUTHORIZATION

5.1. GENERIC ISSUES

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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.

Changes since the original IRRS mission

Suggestion 12: Following consideration of the benefits of introducing licence conditions, the Government has amended the Law of Radiation Protection to make provision for VATESI and RSC to identify conditions in licences and temporary permits authorising practices involving sources of ionising radiation or transportation of radioactive waste.

Rules on Authorization of Practices with Sources of Ionizing Radiation (approved by Resolution No. 918 of the Government of the Republic of Lithuania) defines specific limited conditions which may be identified in licences and temporary permits issued by the regulatory body. Furthermore, the Resolution requires the holder of these licences or permits to perform the activity in accordance with the conditions defined and in accordance with the provisions described within their application documentation.

Subsequent to the original IRRS mission, the Law on Nuclear Safety was amended, removing VATESI's ability to attach conditions to nuclear facility licences. However, other powers remain available to it under the Law on Nuclear Safety, which are judged to provide an equivalent outcome. Specifically, by maintaining a controlled list of approved (technical) application documents, the provisions of which are legally enforceable, VATESI has sufficient powers to ensure limits and conditions necessary in the interests of safety are adopted to control the authorized party's activities.

Status of Suggestion 12

Suggestion (S12) is closed as the Government has granted additional powers to RSC and VATESI to identify specific conditions in licences and temporary permits and requiring operators to conduct their activities as described within their application documentation.

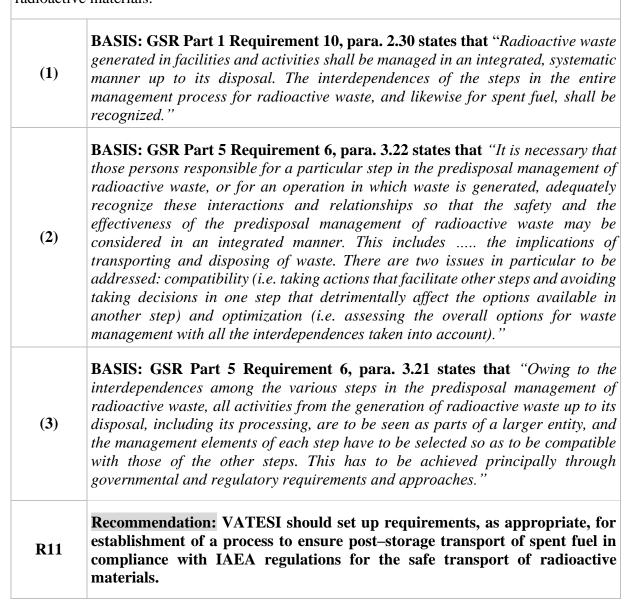
5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

There were no findings in this area in the original IRRS mission.

5.3. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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.



Changes since the original IRRS mission

Recommendation 11: Though there have been no amendments to the licensing and operational requirements for spent fuel storage facilities since the original mission, VATESI nevertheless

revised its Nuclear Safety Requirements BSR-3.1.1-2010 "Management of spent nuclear fuel in dry-type storage facilities" under Order No. 22.3-149 of the Head of VATESI, approved in June 2018.

Annex 3 of BSR-3.1.1-2016 was supplemented with new paragraph 4.5, which specifies that the periodic safety evaluation report shall contain "the description and assessment of compliance with the requirements for transportation of casks with spent nuclear fuel beyond the site boundaries (if such transportation is envisaged)".

The same provision is also established in Annex 5 of Nuclear Safety Requirements BSR-3.1.2-2017 "Pre-disposal management of radioactive waste at nuclear installations" with regard to the content of a periodic safety evaluation report.

Until there is a decision on the location of a deep geological repository for LILW-LL and HLW (including spent fuel), it is not yet known whether there will be a need to transport spent nuclear fuel beyond Ignalina NPP site boundaries. As such, apart from assessment of the transportability provided by the design of a cask, the existing provisions of the legal framework do not require any measures for maintaining the post–storage transport of storage casks.

Article 22¹ of the Law on Nuclear Safety establishes provisions for issuing different types of certificates relating to the supervision of transportation of nuclear fuel cycle materials, nuclear and fissile materials.

Furthermore, Nuclear Safety Requirements BSR-4.1.1-2017 "Rules of issuing certificates for transportation of nuclear fuel cycle materials, nuclear and fissile materials" include requirements for applications for transport package design approval certificates, as well as for applications for the endorsement of certificates issued by a competent authority in another country.

As the design lifetime of the spent nuclear fuel casks, as well as that of the dry storage facilities, will be reached before the envisaged commissioning of a deep geological facility, Ignalina NPP (licence holder) may need to take further steps as part of its ageing management programme to ensure the continuing safety of spent nuclear fuel storage, including its potential post—storage transportation, as appropriate.

Nuclear Safety Requirements BSR-3.1.1-2016 establishes provisions for the assessment of the effects of ageing of structures, systems and components important to safety on storage facilities. In addition, VATESI has developed new Nuclear Safety Requirements BSR-1.8.4-2018 "Ageing management of structures, systems and components important to safety of nuclear facility", which was approved by Order No 22.3-169 of the Head of VATESI of July 2018.

The IRRS team noted the similar issues on the post-storage transport of dual-purpose casks in other Member States and that in consequence IAEA's Transport Safety Standards Committee (TRANSSC) is in the process of agreeing appropriate safety standards. Given this, the team supports VATESI's regulatory strategy to manage this regulatory issue through the periodic safety review process, thereby ensuring storage is maintained at suitable standards and in line with developing international practice.

To help it remain up to date with and contribute to developments in transport safety standards, and in particular concerning the post-storage transport of dual purpose casks, VATESI is shortly to become a member of TRANSSC.

Status of Recommendation 11

Recommendation (R11) is closed on the basis of progress and confidence in effective completion in due time, as future periodic safety reviews of spent nuclear fuel storage undertaken by Ignalina NPP will provide a suitable means for VATESI to ensure the ongoing ageing management of the spent fuel casks and, if needed, their off-site transportability, in compliance with existing and developing IAEA safety standards.

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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.

- 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."
- 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."
 - 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."
- **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.

(3)

Changes since the original IRRS mission

Recommendation 12: Though Article 22 of the Law on Nuclear Safety, which specifies types of licences and permits for the activities in the nuclear field, has not been amended since the original mission, VATESI nevertheless initiated the amendment of the Law on the Management of Radioactive Waste in cooperation with the Ministry of Energy. As such, Article 21 of the Law has been amended to introduce new provisions to coordinate the approval process for the Final Closure Plan of a disposal facility.

The newly introduced paragraph 1¹ of Article 21 requires that "The final plan for the closure of the radioactive waste disposal facility shall be developed and submitted for approval to the State Nuclear Power Safety Inspectorate no later than two years before the closure of the radioactive waste disposal facility.After being agreed upon with the State Nuclear Power Safety Inspectorate, the final plan for the closure of the disposal facility shall be forwarded by the operator of the radioactive waste disposal facility to the Ministry of Energy for approval in accordance with Article 32 of the Law on Nuclear Energy."

The approval is formalized by Order of the Head of VATESI and the applicant is informed by letter.

In this regard VATESI refers to para 11. Article 2 of the Law on Public Administration, which defines "Administrative decision shall mean an administrative act or any other document of the established form adopted in accordance with the established procedure where the will of an entity of public administration is expressed."

The Law on Nuclear Safety requires a licence for decommissioning of a nuclear installation, such as a radioactive waste storage facility, however for closure of radioactive waste disposal facility no authorization (licence, permit) is required.

"Regulations on the issue of licences and permits for activities in the nuclear energy area" approved by Resolution No 722 of the Government of the Republic of Lithuania of 20 June 2012 requires submission of the safety analysis report along with the application for combined licence for construction and operation of a disposal facility. In this context, the safety analysis report provides the description and initial assessment of the closure of disposal facility.

However, there are no legal provisions stipulating that the organization operating the disposal facility must submit a safety assessment with the application for authorization of the closure of radioactive waste disposal facility.

Status of Recommendation 12

Recommendation (R12) is closed as VATESI has initiated the necessary amendments to the Law on the Management of Radioactive Waste.

New observations from the follow-up mission

The Final Closure Plan of the radioactive waste disposal facility is required to be prepared by the organization operating the disposal facility for the review and approval of VATESI.

In the granting of an authorization for closure of the radioactive waste disposal facility VATESI does not require the applicant to submit a safety assessment.

FU Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: There are currently no provisions in the legal framework that oblige the applicant to update assessment of all associated risks and hazards, including non-radiological hazards, that arise under normal and emergency conditions, before applying for an authorization for the closure of a disposal facility, and thus provide assurance of the adequacy of the safety of all activities associated with the closure of the disposal facility.

(1)	BASIS: GSR PART 1 (Rev.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."
(2)	BASIS: GSR PART 1 (Rev.1), Requirement 24 para 4.33 states that "Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures."
RF1	Recommendation: VATESI should revise the regulatory framework and associated procedures to require the prior submission of an updated safety

assessment to inform its decision-making on the granting of an authorization

5.4. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

for the closure of radioactive waste disposal facilities.

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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.

uses a sigi	inicant 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.

Changes since the original IRRS mission

Suggestion 13: Authorization processes were improved with the implementation of a graded approach, established in following legal acts:

1. The new edition of Law on Radiation Protection, adopted on 21st June 2018, established the principle of the graded approach, in Article 3, Paragraph 2. Article 12 and the Annex 1 establish

the system of authorization, taking into account the risk of practices (registration, licensing, temporary permits). Provisions of Articles 17, 25 and 26 determine the categories of sources.

- 2. Chapters IV, V, VI and VII of the new edition of the *Rules on Authorization of Practices with Radiation Sources*, approved by Government Resolution No. 918 in September 2018 determine the mandatory set of documents to be submitted for authorization in respect to the practices and its risk.
- 3. Procedure of Preparation the Documents to be Presented for Authorization of Practices with the Radiation Sources, approved by the Order No V-62 of the Director of the Radiation Protection Centre in October 2018.

In addition, revisions to the Law on Radiation Protection for the authorization of practices with radiation sources allow for licensing or registration (for the practices, specified in Annex 1 of the Law). It also defines which practices can be performed without authorization, with registration being applicable to lower risk activities and practices. Dependent on whether a practice is licenced or registered, different safety requirements are required (on qualification of workers, training and instruction, physical safety, individual dose monitoring of workers, requirements for radiation protection measures etc.). As a result of these changes in legislation and regulations, RSC has changed several hundred licences to registrations.

To apply for a licence, temporary permit or registration requires different levels of detail to be submitted to the licensing authority. Then after registration is granted, no more documents need to be submitted to RSC if there are changes in operational conditions. Instead operators are now only required to send declarations to the State Register.

For existing authorized activities/practices, these legislative changes have resulted in significantly reduced levels of review and assessment work by RSC. For new applications for a license or registration, the amount of work for RSC is also reduced since the review and assessment work of documents for registration applications is less detailed and extensive compared with the ones for license applications. Furthermore, the process for issuance of registrations and licenses is different. Therefor there is less work for issuance of a registration. Typically, no Annexes have to be produced by RSC.

Currently, RSC is improving its processes, to include registrable sources in a licence for operators who have both types of sources/activities.

Inspection processes have also been amended in legislation. This has shifted RSC's inspection effort away from lower risk activities and onto higher risk ones. The *Regulations of State Radiation Protection Supervision* from the Ministry of Health, Annex 1 lists different frequencies for the inspection of different authorized practices. This list takes into account the entity's activity risk, nature of hazard, the probability of occurrence of damage or danger to persons, society or the environment, previous data on how the entity complied with legal requirements for the safety and security of sources and other relevant aspects. Annex 1 is currently being updated based on RSC's recent experience working within the new legislation.

Status of Suggestion 13

Suggestion (S13) is closed as a graded approach has now been introduced, both in radiation protection legislation and in RSC's processes, including for authorization, review and assessment and inspection.

5.5. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

There were no findings in this area in the original IRRS mission.

5.6. AUTHORIZATION OF TRANSPORT

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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.

802 arc no	of 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.

Changes since the original IRRS mission

Recommendation 13: By changing the Law on Nuclear Safety and the Law on Radiation Protection, the Government defined clearly all the responsibilities of VATESI and RSC for transport-related approvals. At the time of the initial mission, the general responsibilities were assigned in the Governmental Resolution on Granting the authorization for carriage of dangerous goods by roads and rail and related activities.

The Law on Nuclear Safety was amended to clarify provisions on authorization of transport of nuclear fuel cycle, nuclear and fissionable material (Article 22 of the Law) and to establish types of certificates for transport of nuclear fuel cycle, nuclear and fissionable material, including certificates for special arrangement transport, issued by VATESI as well as the procedure for issuing, suspending and revoking these certificates (Articles 22¹, 24¹ and 26¹ of the Law). Following amendments to the Law on Nuclear Safety, Nuclear Safety Requirements BSR-4.1.1-2017 "Rules on the Issue of Certificates for Transport of Nuclear Fuel Cycle, Nuclear and Fissionable Materials" were adopted by the Head of VATESI in order to set requirements for applications for the certificates and the content of the certificates. In these 'Rules' there are important references to SSR-6 and they also specify which information should be listed in the certificate, also referencing SSR-6. Standard application forms, which were approved by the Head of VATESI, are available on the VATESI website.

The Law on Radiation Protection was also amended to clarify the provision for transport related approvals (Article 32). The Article regulates the issuance of the certificate for recognition of the design compliance for transport packages (for type B(M), B(U) and C-type packages) and for the cancelation of the validity of issued certificate for recognition of the design compliance for transport packages. Shipments of radioactive material and/or radioactive waste have to be authorized by RSC by issuance of a licence or temporary permit. The process for authorization is clearly defined in the Law.

Status of Recommendation 13

Recommendation (R13) is closed as the Government has changed the Law on Nuclear Safety and the Law on Radiation Protection to define clear responsibilities for transport-related approvals by VATESI and RSC, aligning Lithuanian law with IAEA safety standards.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

There were no findings in this area in the original IRRS mission.

6.2. REVIEW AND ASSESSMENT FOR nuclear power plants

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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 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.

Changes since the original IRRS mission

Recommendation 14: VATESI has continued to enhance its process for the review and assessment of safety justification documentation. Specifically, VATESI has introduced a new type of report, the simplified Safety Evaluation Report. This compliments the existing full Safety Evaluation Report and is completed in circumstances where completing a full report is judged by line managers to be disproportionate. The revised process requires a record of each instance of review and assessment be made, recording the names of the specialists involved, the applicable standards against which the safety evaluation was judged, and the issues raised.

This approach to review and assessment adopts the sort of graded approach sought by GSR Part 1. Specifically, it provides an adequate approach for review and assessment of safety documentation appropriate to the decommissioning, spent fuel and radioactive waste management programmes currently envisaged within Lithuania.

The approach does not however evidence the extent of consideration given, or justify why particular aspects are considered acceptable, to a depth consistent with international regulatory norms for high hazard programmes. Consequently, this recommendation should be

reconsidered in the event of a future policy change to develop a nuclear power programme in Lithuania.

Status of Recommendation 14

Recommendation (R14) is closed as VATESI has revised its process for review and assessment of safety justification documents, requiring a record be prepared documenting each relevant case. The process is appropriate to the types of review and assessment that it is envisaged VATESI will need to undertake.

Changes since the original IRRS mission

Suggestion 14: Peer review is a mechanism widely used within academia and engineering to ensure the quality and consistency of technical work.

Since the original IRRS mission 2016, VATESI have amended its process for review and assessment to enable the formation of a temporary commission to assess the results of specific regulatory review and assessment activities independently. The intent is that a temporary commission would be formed, at the order of the Head of VATESI in accordance with a graded approach, to assist with the most significant reviews and assessments. It is envisaged these commissions would independently evaluate the quality of the review and assessment performed by VATESI officials, considering matters such as the resources allocated, whether the work complied with internal rules and procedures, and the overall quality of technical decision making.

This new concept is considered by the IRRS team to be a positive enhancement to VATESI's management system. However, we note it has not yet been applied to a review and assessment activity.

Status of Suggestion 14

Suggestion (S14) is closed as a result of VATESI developing a peer review mechanism to examine the quality and consistency of its most significant review and assessment activities.

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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

all levels within its organization and perform necessary training.

Changes since the original IRRS mission

Suggestion 15: VATESI has developed its procedures for review and assessment supplementing the guidance to technical specialists on the application of a graded approach that existed at the time of the original mission. Procedures for review and assessment have been enhanced by the definition of an overarching principle of proportionality, applying to all

elements of review and assessment, including resource allocation and scope. The principle of proportionality defined within VATESI's review and assessment processes is judged to be analogous to the graded approach defined within IAEA Safety Requirements.

In addition, VATESI has requested IAEA assistance to inform further development of its procedures. This has included training in the form of an IAEA workshop on the application of graded approaches to the regulation of nuclear installations held in December 2019. Following this workshop VATESI has explored other sources of relevant good practice in respect to application of graded approaches for review and assessment. It intends to capture learning from this work in future revisions to its processes, managed as part of normal business.

Status of Suggestion 15

Suggestion (S15) is closed as a result of the development of VATESI's procedures for review and assessment which has taken place following the original mission and the training provided by IAEA on application of the graded approach.

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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, 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."

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

Changes since the original IRRS mission

integrated within this process.

Suggestion 16: VATESI has amended its process for integrated safety assessment to improve the integration of the outputs from its nuclear power plant review and assessment work. VATESI has also amended its arrangements to require results from the integrated safety assessment to be published and distributed to stakeholders (including the State Enterprise Ignalina NPP).

Status of Suggestion 16

Suggestion (S16) is closed as a result of improvements made to VATESI's process for the Oversight of Economic Entities.

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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.

Changes since the original IRRS mission

Suggestion 17: The Government has amended the Law on Nuclear Safety to require licensees to seek to implement nuclear and radiological safety requirements, together with non-radiological safety requirements in a manner which is mutually supportive and harmonious. Furthermore, VATESI has included within a number of its regulations and guides, explicit requirements for consideration of non-radiological risks within licensee safety submissions.

The IRRS team was informed how VATESI works with other domestic regulators to deliver a harmonised approach to regulation of nuclear facilities. For example, VATESI have agreed a formal protocol for cooperation with the State Inspectorate for Spatial Planning and Construction. This protocol is further supported by administrative processes which, for example, ensure that prior to VATESI authorizing construction of new facilities, the State Inspectorate for Spatial Planning and Construction has completed its own review and approvals, ensuring an integrated approach to the regulation of construction safety.

Status of Suggestion 17

Suggestion (S17) is closed as VATESI's processes and the legal framework have been improved so that non-radiological risks are now considered explicitly both in licensee safety submissions and in VATESI's review and assessment.

6.3. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

There were no findings in this area in the original IRRS mission.

6.4. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

There were no findings in this area in the original IRRS mission.

6.5. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

There were no findings in this area in the original IRRS mission.

6.6. REVIEW AND ASSESSMENT FOR TRANSPORT

There were no findings in this area in the original IRRS mission.

7. INSPECTION

7.1. GENERIC ISSUES

There were no findings in this area in the original IRRS mission.

7.2. INSPECTION PROGRAMME

There were no findings in this area in the original IRRS mission.

7.3. INSPECTION PROCESS AND PRACTICE

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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.

Changes since the original IRRS mission

Recommendation 15: The Government has amended the legislative framework to provide VATESI and RSC additional powers to conduct unplanned inspections beyond the basis set by the Law on Public Administration. The regulatory bodies are now empowered to conduct unplanned inspections, both announced and unannounced in specific circumstances (for example following the occurrence of an unusual event). The IRRS team was informed, these new powers to conduct unplanned inspections are consistent with IAEA safety requirements and guidance.

In addition, the Law on Radiation Protection has been amended to allow RSC and VATESI powers to conduct planned unannounced radiation protection inspections in restricted cases in their respective areas of interest. These cases are significantly limited, i.e. to circumstances where it is not feasible to announce the inspection in advance, for example when conducting planned inspection of imported goods and the responsible person, location or time is not known in advance. Although these limitations mean that planned unannounced inspection is unlikely to be used frequently, the new powers are judged to add value, enabling planned unannounced inspection to form part of baseline inspection programmes.

In respect to planned unannounced nuclear safety inspection at nuclear facilities, no legislative changes have taken place. However, it is noted that VATESI has resident inspectors based at the Ignalina NPP and other inspectors who visit Maišiagala. These inspectors are able to freely access all parts of the site important to safety and routinely verify the way in which operations are being conducted. Oversight by these inspectors is considered by the IRRS team to provide an equally effective alternative approach, achieving outcomes consistent with GSR Part 1 Requirement 28.

Status of Recommendation 15

Recommendation (R15) is closed as the Government has amended the legislative framework to provide VATESI and RSC additional powers to conduct both unplanned and planned unannounced inspections. Though in practice neither VATESI nor RSC are likely to conduct many unannounced inspections, the options available to them within the overall framework are considered by the IRRS team to provide equally effective alternative approaches, achieving outcomes consistent with IAEA safety standards.

Changes since the original IRRS mission

Suggestion 18: The Government has amended the Law on Nuclear Safety to broaden the legal basis for conducting unplanned inspection beyond the basis set by the Law on Public Administration. The revised legalisation enables VATESI to conduct unplanned announced inspections in all safety areas within its regulatory competence.

Status of Suggestion 18

Suggestion (S18) is closed as VATESI can conduct unplanned announced inspections in the circumstances defined in the revised Law on Nuclear Safety, in all safety areas within the regulatory body's competence.

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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."
 - 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

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS	
	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.

Changes since the original IRRS mission

Suggestion 19: In accordance with general state policy, VATESI is in the process of supplementing its generic inspection processes, where appropriate, with the development of standard guidelines, in the form of Control Questionnaires, to provide a consistent structure and format for inspections. VATESI is targeting those inspections (for example those conducted frequently) where the approach will add the most value with inspection of radiation protection practices providing an initial focus for development. The approach is now increasingly being developed for inspection at nuclear facilities. To date, thirteen Control Questionnaires have been published.

VATESI has amended its management system to identity requirements for future Control Questionnaires via a continuous improvement process. VATESI has also made amendments to provide and analyse feedback learning from its inspection programme to drive continuous improvement.

Status of Suggestion 19

Suggestion (S19) is closed as VATESI's management system has been improved to provide for the development and application of Control Questionnaires, which are helping to provide a more consistent structure and format for inspections. A range of Control Questionnaires has been developed, as appropriate, for inspection of activities with radiation sources. The availability of specific guidance for VATESI inspectors conducting inspection of nuclear facilities is currently limited.

New observations from the follow-up mission

The provision of inspection guidance is an important element within the system of regulatory control, providing a framework for objective regulatory decision making and ensuring stability and consistency. In addition to the provision of generic inspection guidance, many regulatory bodies provide specific inspection guidance aligned, where relevant, to inspection areas identified within baseline inspection plans, specific regulations or topics. The overarching objective is to define a consistent structure and format for regulatory inspections, while providing sufficient flexibility for inspectors to exercise professional judgment and take the initiative.

The IRRS team recognizes the work already undertaken by VATESI to develop Control Questionnaires, which support delivery of this objective for inspection of activities involving radioactive sources. However, the availability of inspection area-specific guidance for VATESI inspectors conducting inspection of nuclear facilities, in the form of Control Questionnaires, is currently limited. The provisional of additional inspection area-specific guidance has potential to improve the regulatory system of control.

FU MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The availability of specific guidance for VATESI inspectors conducting inspection of nuclear facilities is currently limited.

(1)	BASIS: GSR PART 1 (Rev.1) Requirement 22 Stability and consistency of regulatory control states that "The regulatory body shall ensure that regulatory control is stable and consistent."
(2)	BASIS: GSG-13 para 3.221 states that "Specific responsibilities of the regulatory body with respect to inspection should include the following: [] Developing procedures and directives as necessary for the effective conduct and administration of the inspection programme."
(3)	BASIS: GSG-13 para 3.262. states that "The regulatory body should issue internal guidance for its inspectors on performing regulatory inspections in order to ensure a consistent approach to inspection while allowing sufficient flexibility for inspectors to take the initiative in dealing with new concerns that arise."

Suggestion: VATESI should consider broadening the range of available guidance for inspection of nuclear facilities, taking into account the benefits of such guidance for each inspection area.

7.4. INSPECTORS

SF₁

There were no findings in this area in the original IRRS mission.

7.5. INSPECTION OF NUCLEAR POWER PLANTS

There were no findings in this area in the original IRRS mission.

7.6. INSPECTION OF WASTE MANAGEMENT FACILITIES

There were no findings in this area in the original IRRS mission.

7.7. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

There were no findings in this area in the original IRRS mission.

7.8. INSPECTION OF DECOMMISSIONING ACTIVITIES

There were no findings in this area in the original IRRS mission.

7.9. INSPECTION OF TRANSPORT

There were no findings in this area in the original IRRS mission.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

There were no findings in this area in the original IRRS mission.

8.2. ENFORCEMENT IMPLEMENTATIONS

2	2016 Original mission RECOMMENDATIONS AND SUGGESTIONS
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.

Changes since the original IRRS mission

Recommendation 16: The Government has amended the Law on Nuclear Safety to place new legal duties on VATESI inspectors who identify violations at nuclear facilities which present an imminent threat to nuclear or radiological safety. In such circumstances, inspectors are required to order the authorized party to take corrective action to protect members of the public, workers or the environment.

Such orders issued by VATESI officials are enforceable. In the event that a legal order is disobeyed, VATESI has a range of proportionate sanctions available in line with international norms.

Status of Recommendation 16

Recommendation (R16) is closed as a result of changes made to the legal and regulatory framework that allow VATESI to require corrective actions in cases where an imminent likelihood of a safety significant event is identified during an inspection.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

There were no findings in this area in the original IRRS mission.

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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.

S20	Suggestion: VATESI should consider developing guides to help in how to comply with the safety requirements.
(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."

Changes since the original IRRS mission

Suggestion 20: VATESI has considered the legislative basis for providing regulatory guidance on how operators should comply with safety requirements and has set up a publicly announced written consultation process for instances where further clarity appears to be needed. These consultations may be initiated either by VATESI or by its stakeholders (for example, by the operator).

Since the initial mission in 2016, VATESI has applied this written consultation process six times, providing advice on a range of topics, chiefly in respect to authorization and enforcement. Each case has resulted in the publication of guidance on VATESI's website. The consultation most relevant to this suggestion involved clarification of safety requirements for duty holders conducting Periodic Safety Review of nuclear facilities. The scope of the advice provided in respect of Periodic Safety Review provides confidence in the wider approach. VATESI intends to continue to use this mechanism to provide guidance and advice as and when this is judged to be necessary.

The IRRS team was informed that the Lithuanian regulatory regime places greater reliance on regulations than some other regulatory regimes. These define in detail the principles, requirements and criteria upon which VATESI's regulatory judgements, decisions and actions are based. Consequently, less effort is required to provide supplementary guidance. VATESI's response to Suggestion S20 is judged to be appropriate to the context in which it operates.

Status of Suggestion 20

Suggestion (S20) is closed as VATESI has considered how to develop guidance to operators appropriate to its regulatory context and has implemented a process of publicly announced written consultations that is being applied as circumstances demand.

9.3. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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.

Changes since the original IRRS mission

Recommendation 17: Nuclear Safety Requirements BSR-3.1.2-2010 "Predisposal management of radioactive waste at the nuclear facilities" and Nuclear Safety Requirements BSR-3.1.1-2010 "Management of spent nuclear fuel in dry-type storage facilities" were amended in 2017 and 2018, respectively.

The amendments make provisions for integrated management of radioactive waste considering interdependencies among all the steps; for safety evaluation of a site for a radioactive waste management facility; for design of radioactive waste management facility; for programme of commissioning; and, for safety assessment and periodic safety review. The revised BSR-3.1.2-2017 also includes provisions on monitoring, inspection and maintenance of the waste package and of the storage facility to ensure their continued integrity; on periodical review of the

adequacy of the storage capacity against predicted waste arising, the expected lifetime of the storage facility and the availability of disposal options; etc.

The amendments made to BSR-3.1.2-2017 also introduce WENRA safety reference levels for conditioning of radioactive waste.

In addition, Nuclear Safety Requirements BSR-1.8.3-2017 "Technical specification for a nuclear facility" and BSR-1.8.5-2018 "For commissioning of a nuclear facility" were established by Orders of the Head of VATESI No. 22.3-222 of 24 November 2017 and No. 22.3-295 of 4 December 2018, respectively. BSR-1.8.3-2017 establishes requirements for the content of the technical specification for a nuclear facility and BSR-1.8.5-2018 sets out requirements for the content of a commissioning report and for the analysis of the test results at each stage of the commissioning of a nuclear facility.

Status of Recommendation 17

Recommendation (R17) is closed as amendments made to the regulatory framework on predisposal of radioactive waste to ensure its compliance with the IAEA safety standard GSR Part 5.

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

Observation: The IRRS team found several inconsistencies of the regulatory framework on disposal of radioactive waste with the IAEA SSR-5.

- 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."

 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,

2	2016 Original mission RECOMMENDATIONS AND SUGGESTIONS	
	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.	

Changes since the original IRRS mission

Recommendation 18: VATESI has developed new Nuclear Safety Requirements BSR-3.2.2-2016 "Radioactive waste disposal facilities", which was approved by Order No. 22.3-188 of the Head of VATESI dated 30 November 2016.

BSR-3.2.2-2016 makes provisions for siting, design, construction, commissioning, operation, closure and period after closure of a disposal facility. The requirements are relevant for different types of disposal facilities, otherwise the specific requirements are explicitly defined. The document also establishes requirements for the content of a safety analysis report and a safety justification report; for the content of site evaluation report of a disposal facility; for the content of periodic safety assessment report; for the final plan for closure of a disposal facility; for the report on termination of surveillance of the disposal facility; for the content of radioactive waste acceptance criteria and for the annual report on activities carried out in the disposal facility.

In addition, Nuclear Safety Requirements BSR-1.8.3-2017 "Technical Specification for a Nuclear Facility" and BSR-1.8.5-2018 "For Commissioning of a Nuclear Facility" were established by Orders of the Head of VATESI No. 22.3-222 of 24 November 2017 and No. 22.3-295 of 4 December 2018, respectively. BSR-1.8.3-2017 establishes requirements for the content of the technical specification for a nuclear facility and BSR-1.8.5-2018 sets out requirements for the content of a commissioning report and for the analysis of the test results of each stage of the commissioning of a nuclear facility.

Status of Recommendation 18

Recommendation (R18) is closed as amendments VATESI has made to the regulatory framework on disposal of radioactive waste to ensure its compliance with the IAEA Safety Standard SSR-5.

9.4. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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.

Changes since the original IRRS mission

Recommendation 19: Since the initial mission, RSC and VATESI have updated the existing regulations for radiation safety; not only according to GSR Part 3 but also by implementing the EU Directive 2013/59.

In the nuclear area, the specific radiation protection requirements BSR-1.9.3-2016, "Radiation Protection at Nuclear Facilities", were amended by the Head of VATESI by Order No. 22.3-38 of 7th of February 2018. Radiation protection requirements are transposed to the new edition of the Lithuanian Hygiene Standard HN 73:2018, "Basic Standard of Radiation Protection", approved on 3rd August 2018 by the Order No. V-886 of the Minister of Health.

In addition to these basic safety standards, RSC has implemented, Hygiene Standard HN 99:2019, "Protective Actions of the Public in Case of Nuclear or Radiological Emergency", approved by Order No. V-1398, 5 December 2019, of the Minister of Health Lithuania. In particular it has published a list of justified practices on its website along with a new procedure for justifying practices that aligns with IAEA standard GSG-5 and introduced new legislation and regulations on Radiation Protection Expert recognition, Medical Expert recognition and radiation protection training.

Status of Recommendation 19

Recommendation (R19): is closed as RSC and VATESI have extensively updated their regulations on radiation safety to comply with IAEA Safety Standard GSR Part 3 and EU Directive 2013/59.

New observations from the follow-up mission

In the process of changing the Radiation Safety Regulations to align with GSR Part 3 and the EU (BSS) Directive, the Hygiene Standard HN73:2018 was updated by adopting the Exemption and Clearance levels from the EU-BSS, which are consistent with Schedule I of GSR Part 3.

These Exemption and Clearance levels are listed in Annex 4 of the HN73:2018, in which Table 1 is applicable for the Exemption and Clearance of any quantity of radioactive material and Table 4 is applicable for the Exemption of moderate amounts of radioactive material. However, RSC has not clearly defined the amounts of material above which the concentration values in Tables 1 and 4 should be applied.

FU Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: In setting exemption levels, the Ministry of Health did not clearly define the amounts of material above which the different concentration values in Table 4 of Annex 4 of Hygiene Standard HN73:2018, "Basic Radiation Protection Standards", should be applied.

	BASIS: GSR Part 3 Requirement 8 para. 3.10 states that "The government
	or the regulatory body shall determine which practices or sources within
	practices are to be exempted from some or all of the requirements of these
(1)	Standards, including the requirements for notification, registration or licensing,
	using as the basis for this determination the criteria for exemption specified in
	Schedule I or any exemption levels specified by the regulatory body on the basis
	of these criteria.

SF2 Suggestion: The Ministry of Health should consider amending the Hygiene Standard HN73:2018 to define the amounts of material below which the different concentration values, listed in Table 4 of Annex 4 should be used to exempt practices or sources from regulatory control.

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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.

There is nowever no requirement for needsing of multiple small (exempted) sources.	
(1)	BASIS: Safety Standards Series No GSR Part 3, schedule I, I.3 (a) States that "Under the criteriaapplicable 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.

Changes since the original IRRS mission

Recommendation 20: The requirement for notification is set in Article 10 of the new edition of the Law on Radiation Protection, adopted on 21st June 2018, and in Paragraph 11.1 of the new version Statute of State Register of Radiation Sources and Occupational Exposure, approved by the resolution of the Government of the Republic of Lithuania, No. 844, on 29th

of August, 2018. Article 10 of the Law sets criteria for exemption of notification which do not apply for multiple sources which together do not meet the criteria for exemption of practice and clearance of materials and the exemption levels are exceeded.

Status of Recommendation 20

Recommendation (R20) is closed as changes in the Law on Radiation Protection have removed the requirement for notification of single exempted sources except where multiple exempted sources in combination should be authorized.

9.5. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

Observation: VATESI approved Nuclear Safety Requirements BSR-1.5.1-2015 "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 posts and particles are stated as not again, because while the the requirements for
	fine 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.

Changes since the original IRRS mission

Suggestion 21: VATESI developed new regulation Nuclear Safety Rules BST-1.5.1-2016 "The evaluation of compliance with free release criteria of buildings and site of nuclear facilities", which was approved by Order of the Head of VATESI No. 22.3-206 of 20 December 2016.

BST-1.5.1-2016 was subsequently amended in January 2020 to include provisions on engineering structures. The version currently in force is entitled "The evaluation of compliance with free release criteria of buildings, engineering structures and site of nuclear facilities".

BST-1.5.1-2020 uses the Multi-Agency Radiation Survey and Site Investigation Manual (MARSIM) methodology for free release of buildings, engineering structures and site, and prohibits areas of elevated activity. The Nuclear Safety Rules establishes provisions for classification of buildings, engineering structures and the site with respect to the level of residual activity, requirements for entities to carry out free release measurements, and requirements on the content of radiological survey reports, including final status radiological survey.

Criteria for clearance of material are established in Nuclear Safety Requirements BSR-1.9.2-2018 "Establishment and application of clearance levels of radionuclides for the materials and

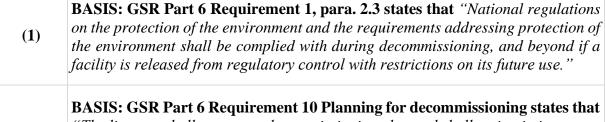
waste generated during the activities with the sources of ionizing radiation in the area of nuclear energy".

Status of Suggestion 21

Suggestion (S21) is closed as criteria for clearance of buildings and the site of a facility and methodologies for the use of them are now established.

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

Observation: The regulatory framework on decommissioning of non-nuclear facilities is not fully consistent with GSR Part 6.



- "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".
 - **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.

Changes since the original IRRS mission

Recommendation 21: "The procedure for decommissioning of the facilities using radiation sources" has been amended by the Order No. V-785 of the Minister of Health of the Republic of Lithuania dated 09 April 2020 (effective 30 October 2020).

The amendments introduced provisions for planning for decommissioning; application of graded approach; preparation of a decommissioning plan for facilities with an intermediate decommissioning complexity and maintaining it throughout the lifetime of the facility; review

(3)

of the initial decommissioning plan and updates, review and approval of the final decommissioning plan and final decommissioning report; release of a facility from regulatory control with or without restrictions on its future use; and, the format and content of documents to be submitted by the applicant.

Status of Recommendation 21

Recommendation (R21) is closed as amendments made to the regulation on decommissioning of non-nuclear facilities to ensure its compliance with the IAEA Safety Standard GSR Part 6.

9.6. REGULATIONS AND GUIDES FOR TRANSPORT

There were no findings in this area in the original IRRS mission.

10. EMERGENCY PREPAREDNESS AND RESPONSE - REGULATORY ASPECTS

10.1. GENERAL EPR REGULATORY REQUIREMENTS

2016 Original mission RECOMMENDATIONS AND SUGGESTIONS

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 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.

Changes since the original IRRS mission

Recommendation 22: VATESI has revised the regulatory requirements for emergency preparedness and response for nuclear installations and issued Nuclear Safety Requirements BSR-1.3.1-2020 in January 2020 by Order No. 22.3-18. The revised requirements have been updated and brought into line with GSR Part 7.

Similarly, regulatory requirements for the sources used in facilities and activities other than nuclear installations have also been revised by the Ministry of Health. The Ministry has updated regulations on "Basic Standards of Radiation Protection" and "Protective Actions of the Public in Case of Nuclear or Radiological Emergency" in August 2018 and December 2019 respectively taking into account the GSR Part 7 as well as other relevant IAEA safety standards.

Status of Recommendation 22

Recommendation (R22) is closed as VATESI and RSC have updated the regulatory requirements for preparedness and response to a nuclear or radiological emergency in line with IAEA Safety Standard 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.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(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.

Changes since the original IRRS mission

Suggestion 22: To improve its internal process for the evaluation of operating organization's onsite emergency plans, RSC has amended its quality management system procedure "Authorization of Practices". Under this procedure, its Division of Radiation Protection Supervision shares emergency plans for facilities and activities using Category I - III radiation sources with the Division of Emergency Management and Training for evaluation and feedback. The Division of Emergency Management and Training provides feedback on these plans through email or telephone, advising whether the plans are acceptable.

In 2017, RSC issued internal working instructions for the assessment of emergency exercises conducted by operating organizations. According to these instructions, representatives of the Divisions of Radiation Protection Supervision and Emergency Management and Training jointly evaluate the exercises once every three years.

A regulatory requirement for review and revision of emergency plans based on lessons learned from exercises and past emergencies has been set in the revised regulations on Basic Standards of Radiation Protection issued by Ministry of Health.

During its inspections and evaluations of forthcoming exercises, RSC verifies that the emergency plans are being reviewed and updated in the light of lessons learned.

Status of Suggestion 22

Suggestion (S22) is closed as improvements made to RSC's internal processes for the evaluation of emergency plans, exercises and use of lessons learned.

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.

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 [...]."

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.

Changes since the original IRRS mission

Recommendation 23: RSC has now issued a regulatory guide for setting criteria to define Emergency Preparedness Categories (EPCs) for facilities and activities using radiation sources (except for the sources used in Nuclear Energy). These criteria are in line with the basis for EPCs defined in GSR Part 7. The guide also requires operating organizations to perform and periodically review their on-site hazard assessments and then make justified arrangements for the preparedness and response to a nuclear or radiological emergency commensurate with the hazards.

A legal obligation has been included in the amended Law on Nuclear Energy requiring operating organizations of nuclear installations to analyze the consequences of possible nuclear or radiological accidents and submit the results to VATESI. Similarly, by amending the "Law on Nuclear Safety", a legal obligation has been set for VATESI to prepare an assessment of the hazards posed by all the nuclear installations located within the country, taking into account the results of the analysis performed by operating organizations. According to this law, VATESI is also required to assess the hazard posed by installations located in neighboring countries.

Regulatory requirements for performing the hazard assessments by operating organizations of facilities using fissile materials have been established in Nuclear Safety Requirements BSR-1.8.7-2020 approved by VATESI.

VATESI has also prepared Nuclear Safety Requirements for the "Analysis of the Consequences of the Possible Nuclear and Radiological Accidents at Nuclear Installations". Once approved, these requirements will set out obligations and provide guidance for operating organizations to perform and periodically review on-site hazard assessments and make suitable arrangements for preparedness and response to a nuclear or radiological emergency. The requirements are currently in the final stages of the approval process.

Status of Recommendation 23

Recommendation (R23) is closed on the basis of progress and confidence in effective completion in due time as RSC has completed and VATESI has made good progress towards setting and promulgating requirements, criteria and guidance for operating organizations to perform and periodically review their on-site hazard assessments in support of their emergency preparedness arrangements.

10.2. FUNCTIONAL REGULATORY REQUIREMENTS

There were no findings in this area in the original IRRS mission.

10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE

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 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.

Changes since the original IRRS mission

Suggestion 23: RSC has initiated a process to review the exercise scenarios prepared by operating organizations and evaluate which emergency response functions should be covered in future exercises based on what has been tested in previous exercises. In this way, RSC ensures that all critical functions are tested systematically within the operator's overall annual exercise programmes.

RSC has also developed exercise assessment forms as part of its internal working instructions on "Assessment of Radiological Incidents or Accidents Response Exercises organized by the Holders of the License or Temporary Permits", issued in December 2017. These assessment forms include exercise evaluation criteria as well as providing means for recording whether the exercise objectives were achieved, other major findings and recommendations. At end of the exercise, the completed form is jointly signed by RSC and the operating organization. The operating organization later submits a compliance report setting out how it has addressed the recommendations and made improvements in its arrangements for responding to a nuclear or radiological emergency. RSC then verifies compliance by conducting inspections.

Status of Suggestion 23

Suggestion (S23) is closed as RSC has introduced processes to ensure the testing of all critical emergency response functions in annual exercises and to set criteria for the effective evaluation of these exercises.

Changes since the original IRRS mission

Recommendation 24: VATESI has set a regulatory requirement in Section 25.11 of its revised "Requirements for Emergency Preparedness and Response for Nuclear Installations (BSR-1.3.1-2020) for the participation of all nuclear installation staff responsible for critical response functions in training exercises at least once per year. Compliance with this requirement is verified by VATESI through evaluation of trainings and exercises record.

In the original IRRS Mission in 2016, it was recommended that VATESI should set a regulatory requirement for establishing criteria for the effective evaluation of annual on-site exercises. Although a direct regulatory requirement for establishing criteria is not in place however Section 25.9 of VATESI's Nuclear Safety Requirement BSR-11.3.1-2020 requires the operating organizations to assess the effectiveness of its training and exercises. VATESI uses this requirement as a basis to ensure that operating organizations have suitable mechanisms for evaluating their onsite exercises.

VATESI has elaborated that a mechanism in place for developing evaluation criteria by operating organizations before conduct of an exercise. The criteria are developed, on case to case basis, considering the exercise scope and objectives, and taking into account the actions defined in emergency plans, procedures and different type of instructions developed by operating organizations. Very well before conducting an exercise, operating organizations share the evaluation criteria along with exercise plan/scenario with VATESI who assesses the suitability of the criteria and also use them for evaluation of the exercise, as a regulatory body.

Status of Recommendation 24

Recommendation (**R24**) is closed as VATESI has now established a regulatory requirement for at least annual participation of staff responsible for critical response functions in training exercises and has developed processes to ensure exercises are evaluated effectively.

10.4. ROLE OF REGULATORY BODY DURING RESPONSE

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.

Changes since the original IRRS mission

Suggestion 24: VATESI installed a diesel generator in December 2019 with an output power sufficient to provide backup electricity both for its Emergency Operations Centre as well to the whole office. Performance of the diesel generator is tested on monthly basis.

Status of Suggestion 24

Suggestion (S24) is closed as VATESI has ensured an adequate supply of backup power by installing a diesel generator.

11. ADDITIONAL AREAS

11.1. CONTROL OF MEDICAL EXPOSURES

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."			
(2)	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.			

Changes since the original IRRS mission

Recommendation 25: The updated Law on Radiation Protection (No. XIII-1283, dated June 21, 2018) continues to include provisions regarding the justification of medical exposures, with requirements for referrals to be made using guidelines approved by the Minister of Health.

Lithuanian Hygiene Standard HN 31:2020, "Requirements of Radiation Protection in Medical Radiodiagnostics", has been revised to correspond to the provisions established in the Law on Radiation Protection. Specifically, Paragraph 21 requires the prescriber (referral practitioner) to use referral guidelines for radiodiagnostic procedures, prepared by the European Society of Radiology, or referral guidelines recognized by international organizations, when assessing the individual justification of the prescribed radiodiagnostic procedure. This legislation is to be adopted by Order of the Minister of Health of the Republic of Lithuania before the end of 2020.

RSC continues to be delegated supervision of compliance with the requirements of HN 31:2020.

Status of Recommendation 25

Recommendation (R25) is closed, on the basis of progress made and confidence in the effective completion as the legal and regulatory framework is being revised to ensure that international referral guidelines are used by prescribers (referral practitioners) in the justification of individual medical exposures.

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

lacinities.		
(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."	
(2)	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.	

Changes since the original IRRS mission

Suggestion 25: The updated Law on Radiation Protection (No. XIII-1283, dated June 21, 2018) continues to include the provision requiring undertakings having activities related to medical exposures to ensure clinical audits are conducted (Article 21, Paragraph 2, Item 5).

Additionally, Paragraph 104.4 of the new edition of the Lithuanian Hygiene Standard HN 73:2018, "Basic Standard of Radiation Protection", requires undertakings conducting activities related to medical radiological procedures to ensure that external clinical audits are performed at least once per 5 years in accordance with the procedure established by the Minister of Health. There is now a corresponding procedure established for the organization and conduct of clinical audits, described in the Order of the Minister of Health of the Republic of Lithuania, No. V-2390, Order On the Approval of the Organisation and Conduct of the Clinical Audit Procedure for Medical Radiology. The Order was approved on October 28, 2020, with a coming into force date of November 21, 2021. Order V-2390 also establishes that the control of the implementation of clinic audit recommendations by the undertaking shall be enforced by RSC.

The IRRS team was informed that RSC has processes and procedures to provide the necessary oversight and enforcement of the conduct of clinical audits at medical radiation facilities.

Status of Suggestion 25

Suggestion (S25) is closed as revisions to the legal and regulatory framework, which provides requirements for the organisation and conduct of its clinical audits, and establishes the means for RSC to enforce the conduct of clinical audits at medical radiation facilities.

11.2. OCCUPATIONAL RADIATION PROTECTION

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 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 occupations radiation protection and take appropriate action.		

Changes since the original IRRS mission

Recommendation 26: Provisions have been established in the new edition of the Lithuanian Hygiene Standard HN 73:2018, "Basic Standard of Radiation Protection". Specifically, Paragraph 46 requires undertakings to record any report received from a worker that identifies circumstances that could affect compliance with legislated requirements established for radiation protection, and take appropriate actions.

Status of Recommendation 26

Recommendation (**R26**) is closed as given that requirements have now been established in legislation for undertakings to record any report received from a worker that identifies circumstances that could affect compliance with legislated requirements established for radiation protection, and take appropriate action.

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.	

Changes since the original IRRS mission

Suggestion 26: Provisions are established in the new edition of the Lithuanian Hygiene Standard HN 73:2018, "Basic Standard of Radiation Protection". Specifically, Paragraph 22

includes the requirement for the undertaking to establish dose constraints for the purpose of optimization of safety and protection of occupational exposures, as agreed with the regulatory body.

A dose constraint is defined in HN 73:2018 as a value of prospective individual dose, set to define the options considered in the process of optimization for a given radiation source in a planned exposure situation. Typically, dose constraints are established at the design and planning stages for practices involving radiation sources. In later stages of operation, licensees of sealed sources of category I, II and III are required to review occupational exposures against the established dose constraints and evaluate the adequacy of implemented measures for optimization. According to the procedure set in the Order of the Director of the Radiation Protection Centre, No. 68V, approved on October 7, 2011, "On The Procedure of Safety Assessment of the Practice Involving Sources of Ionizing Radiation", the licensee must conduct this review and prepare a report for submission to RSC every 3 years. There are plans to amend this Order by the end of 2021 to include higher-risk practices involving X-ray equipment.

It is RSC's opinion that for low risk facilities and activities, dose constraints are addressed in the design stage, and through later stages of operation, optimization is based on the use of investigation levels. Investigation levels are used by licensees to ensure occupational exposures will not reach or exceed dose constraints that were set during the design stage. When Investigation Levels are reached or exceeded, the causes must be investigated and identified, and the results must be reported to RSC. This aspect is also checked by RSC during inspections.

Status of Suggestion 26

Suggestion (S26) is closed as the legal and regulatory framework now includes mechanisms for licensees to include dose constraints as part of optimization of protection and safety beyond the design and planning stage, and RSC includes these aspects as part of its regulation of compliance.

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.

ASIS: GSR Part 3, Requirement 20, subparagraphs 3.73 (a) and (c) state "The regulatory body shall be responsible, as appropriate, for: stablishment and enforcement of requirements for the monitoring, recorded control of occupational exposures in planned exposure situations excordance with the requirements of these Standards; (c) Authorization opproval of service providers for individual monitoring and calibrate ervices."
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Recommendation: VATESI should adopt in regulation the requirements for authorization or approval of dosimetry services for the nuclear energy sector.

Changes since the original IRRS mission

Recommendation 27: Article 28, Item 1 of the Law on Radiation Protection (No. XIII-1283, dated June 21, 2018) establishes the recognition of dosimetry services within nuclear facilities, which is delegated to VATESI. Nuclear Safety Requirements BSR-1.9.7-2018, "Rules of Procedure for Recognition of Dosimetry Services at Nuclear Facilities", was also enacted on

August 30, 2018 (Order No. 22.3-203), which establishes VATESI's procedure for the recognition and approval of dosimetry services in nuclear facilities.

Status of Recommendation 27

Recommendation (R27) is closed as given that VATESI has now legislated suitable requirements for the recognition and approval of dosimetry services for nuclear facilities.

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

Environmental monitoring

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 periodical review of the monitoring programme results and dose assessment.

periodical review of the monitoring programme results and dose assessment.		
	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	
(1)	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 mecha for common review of the periodic reports of environmental monitor programmes, results and dose assessments made by nuclear installation	

Changes since the original IRRS mission

Suggestion 27: The licensee is required to provide monthly and quarterly reports on discharges from the nuclear installations, which are submitted to VATESI, RSC and the Environmental Protection Agency (EPA, under the Ministry of Environment). An annual report is also required to be submitted by the licensee, which includes calculated dose estimates for a representative person based on the discharges from the facility over the calendar year.

VATESI, as the regulatory body responsible for nuclear installations, reviews and verifies the licensee's compliance with authorized discharge limits. It presents information on the reported environmental monitoring results and estimated doses annually to RSC. In turn, RSC presents annually to VATESI information on its independent evaluation of doses to members of the public from discharges from the nuclear installations, as well as estimated doses to the public based on results of environmental radiological monitoring data obtained by state institutions.

VATESI and RSC evaluate the exchanged information, and specific meetings on these issues are organized if needed. The mechanism for the review and exchange of information is incorporated into RSC's and VATESI's annual work plans.

Status of Suggestion 27

Suggestion (S27) is closed as VATESI and RSC have implemented a mechanism for common review of the periodic reports from 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.	

Changes since the original IRRS mission

Suggestion 28: Order No. 22.3-198 approved updates to Nuclear Safety Requirements BSR-1.9.1-2017, "Standards of Release of Radionuclides from Nuclear Installations and Requirements for the Plan on Release of Radionuclides", on October 31, 2017. Updates included removal of the assumptions that were previously defined for the evaluation of environmental impact and public exposure. Instead, there is now a requirement for nuclear licensees to apply modern, internationally recognized scientific models for assessing radionuclide dispersion and their impacts in the environment. A requirement is also included for licensees, not less than once every 10 years, to revise and evaluate the assumptions, parameters and values used to determine and choose the representative person.

Section 10 of the *Regulations on the Environmental Monitoring of Operators*, approved by Order No. D1-546, on September 19, 2009, by the Minister of Environment also requires nuclear operators to review their environmental monitoring programmes every five years. These reviews must consider operating experience from the previous monitoring period, as well as the most recent monitoring methods and means, and any changes in facility operation and environmental conditions.

Status of Suggestion 28

Suggestion (S28) is closed as there are now legislated requirements for nuclear facility licensees to verify the adequacy of assumptions made for the assessment of public exposure and the assessment of radiological environmental impacts, taking into account, inter alia, the results of radiological monitoring.

12. INTERFACE WITH NUCLEAR SECURITY

12.1. LEGAL BASIS

There were no findings in this area in the original IRRS mission.

12.2. REGULATORY OVERSIGHT ACTIVITIES

There were no findings in this area in the original IRRS mission.

12.3. INTERFACE AMONG AUTHORITIES

There were no findings in this area in the original IRRS mission.

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

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

At the time of the initial IRRS mission in 2016, Lithuania was considering the construction of a new nuclear power plant at Visaginas. The Republic of Lithuania requested that the mission specifically consider the readiness of its nuclear and radiological safety infrastructure to support this proposed development and provide advice on resilience. This was included within the scope of the mission via the development of a tailored module aligned to IAEA Safety Guide SSG-16 ("Establishing the Safety Infrastructure for a Nuclear Power Programme").

In 2018, a revised National Energy Independence Strategy was approved by the Parliament of the Republic of Lithuania which no longer foresees development of nuclear power in Lithuania. Given this change in circumstances, the Suggestions made by the IRRS mission for the tailored module are no longer relevant. As such, work to address these Suggestions was suspended.

There were no findings in this area in the original IRRS mission.

13.2. CONSIDERATION OF ELEMENTS OF SSG-16

There were no findings in this area in the original IRRS mission.

13.2.1. SSG-16 Element 01National Policy and Strategy

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.		

Changes since the original IRRS mission

Suggestion 29: In view of the revised National Energy Independence Strategy, which no longer foresees the development of nuclear power in the Republic of Lithuania (including the

suspension in the development of the Visaginas nuclear power plant), no action was taken to implement this Suggestion.

Status of Suggestion 29

Suggestion (S29) is closed as it is no longer relevant. The Suggestion should be reconsidered if a future policy change is made to develop a nuclear power programme.

13.2.2. SSG-16 Element 02 Global nuclear safety regime

There were no findings in this area in the original IRRS mission.

13.2.3. SSG-16 Element 03 Legal framework

There were no findings in this area in the original IRRS mission.

13.2.4. SSG-16 Element 04 Regulatory framework

There were no findings in this area in the original IRRS mission.

13.2.5. SSG-16 Element 05 Transparency and openness

There were no findings in this area in the original IRRS mission.

13.2.6. SSG-16 Element 06 Funding and financing

There were no findings in this area in the original IRRS mission.

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

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.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

This should happen when the new build project is further developed.

Changes since the original IRRS mission

Suggestion 30: In view of the revised National Energy Independence Strategy, which no longer foresees the development of nuclear power in the Republic of Lithuania (including the suspension in the development of the Visaginas nuclear power plant), no action was taken to implement this Suggestion.

Status of Suggestion 30

Suggestion (S30) is closed as it is no longer relevant. The Suggestion should be reconsidered if a future policy change is made to develop a nuclear power programme.

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

There were no findings in this area in the original IRRS mission.

13.2.9. SSG-16 Element 09 Human resources development

There were no findings in this area in the original IRRS mission.

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

There were no findings in this area in the original IRRS mission.

13.2.11. SSG-16 Element 11 Radiation protection

There were no findings in this area in the original IRRS mission.

13.2.12. SSG-16 Element 12 Safety assessment

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."

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."

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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.

Changes since the original IRRS mission

Suggestion 31: In view of the revised National Energy Independence Strategy, which no longer foresees the development of nuclear power in the Republic of Lithuania (including the suspension in the development of the Visaginas nuclear power plant), no action was taken to implement this Suggestion.

Status of Suggestion 31

Suggestion (S31) is closed as it is no longer relevant. The Suggestion should be reconsidered if a future policy change is made to develop a nuclear power programme.

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 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.	

Changes since the original IRRS mission

Suggestion 32: In view of the revised National Energy Independence Strategy, which no longer foresees the development of nuclear power in the Republic of Lithuania (including the suspension in the development of the Visaginas nuclear power plant), no action was taken to implement this Suggestion.

Status of Suggestion 32

Suggestion (S32) is closed as it is no longer relevant. The Suggestion should be reconsidered if a future policy change is made to develop a nuclear power programme

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

There were no findings in this area in the original IRRS mission.

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

There were no findings in this area in the original IRRS mission.

13.2.15. SSG-16 Element 15 Operating Organization

There were no findings in this area in the original IRRS mission.

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

There were no findings in this area in the original IRRS mission.

13.2.17. SSG-16 Element 17 Design safety

There were no findings in this area in the original IRRS mission.

13.2.18. SSG-16 Element 19 Transport Safety

There were no findings in this area in the original IRRS mission.

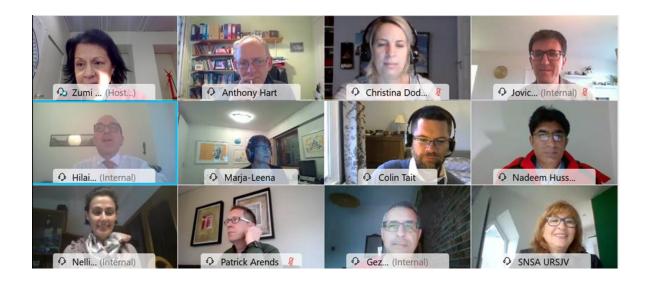
13.2.19. SSG-16 Element 20 Interfaces with nuclear security

APPENDIX I LIST OF PARTICIPANTS

	INTERNATIONAL EXPERTS				
1.	HART Anthony	Office for Nuclear Regulation (ONR) UNITED KINGDOM	Anthony.Hart@onr.gov.uk		
2.	ARENDS Patrick	Authority for Nuclear Safety and Radiation Protection NETHERLANDS	patrick.arends@anvs.nl		
3.	DODKIN Christina	Canadian Nuclear Safety Commission CANADA	christina.dodkin@canada.ca		
4.	JÄRVINEN Marja- Leena	Nuclear Reactor Regulation Department Radiation and Nuclear Safety Authority (STUK) 00881 HELSINKI FINLAND	Marja- Leena.Jarvinen@stuk.fi		
5.	HUSSAIN Muhammad Nadeem	Pakistan Nuclear Regulatory Authority (PNRA) PAKISTAN	m.nadeem@pnra.org		
6.	SLOKAN DUŠIČ Darja	Slovenian Nuclear Safety Administration SLOVENIA	Darja.Slokan-Dusic@gov.si		
7.	TAIT Colin	Office for Nuclear Regulation (ONR) Redgrave Court Merton Road BOOTLE L20 7HS UNITED KINGDOM	Colin.Tait@onr.gov.uk		
	IAEA STAFF MEMBERS				
1.	MANSOUX Hilaire	Division of Radiation, Transport and Waste Safety	H.Mansoux@iaea.org		
2.	MACSUGA Geza	Division of Nuclear Installation	G.Macsuga@iaea.org		

INTERNATIONAL EXPERTS			
3.	BOSNJAK Jovica	Division of Radiation, Transport and Waste Safety	J.Bosnjak@iaea.org
3.	AGHAJANYAN Nelli	Division of Radiation, Transport and Waste Safety	N.Aghajanyan@iaea.org
4.	SWOBODA Zumi	Division of Radiation, Transport and Waste Safety	Z.Swoboda@iaea.org

	LIAISON OFFICERS				
1.	ŠEŠTOKAS Ovidijus	Lisiaan Officens	Ovidijus.Sestokas@vatesi.lt		
2.	STASIUNAITIENE Ramune	Liaison Officers	ramune.stasiunaitiene@rsc.lt		



APPENDIX II LIST OF COUNTERPARTS

IRRS EXPERTS	COUNTERPART			
RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT				
Jovica BOSNJAK	VATESI : Vidas PAULIKAS Participate: Laura RAZGUTĖ-POVILAVIČIENĖ RSC : Ramunė Marija STASIŪNAITIENĖ Participate: Julius ŽILIUKAS			
GLOBAL SAFETY REGIME				
Jovica BOSNJAK	VATESI: Dainius BRANDISAUSKAS Participate: Laura RAZGUTĖ-POVILAVIČIENĖ RSC: Ramunė Marija STASIŪNAITIENĖ Participate: Julius ŽILIUKAS			
RESPONSIBILITIES AND FUNCTION	ONS OF THE REGULATORY BODY			
Marja-leena JARVINENTUK	VATESI: Laura RAZGUTĖ-POVILAVIČIENĖ Sigitas ŠLEPAVIČIUS RSC: Ramunė Marija STASIŪNAITIENĖ Participate: Julius ŽILIUKAS			
MANAGEMENT SYSTEM				
Darja SLOKAN DUSIC	VATESI: Vida JAKIMAVIČIENĖ Participate: Ovidijus ŠEŠTOKAS RSC: Auksė TANKEVIČIŪTĖ			
AUTHORIZATION				
For radioactive waste, decommissioning Nelli AGHAJANYAN	VATESI: Birutė PURLIENĖ Participate: Asta NEKRASOVAITĖ, Ovidijus ŠEŠTOKAS, Nerijus BUCEVIČIUS, Rimantas DAUBARAS, Asta NAVAGROCKIENĖ			
For radiation sources and transport Patrick ARENDS	RSC: Gintautas BALČYTIS Participate: Vaidas STATKUS			

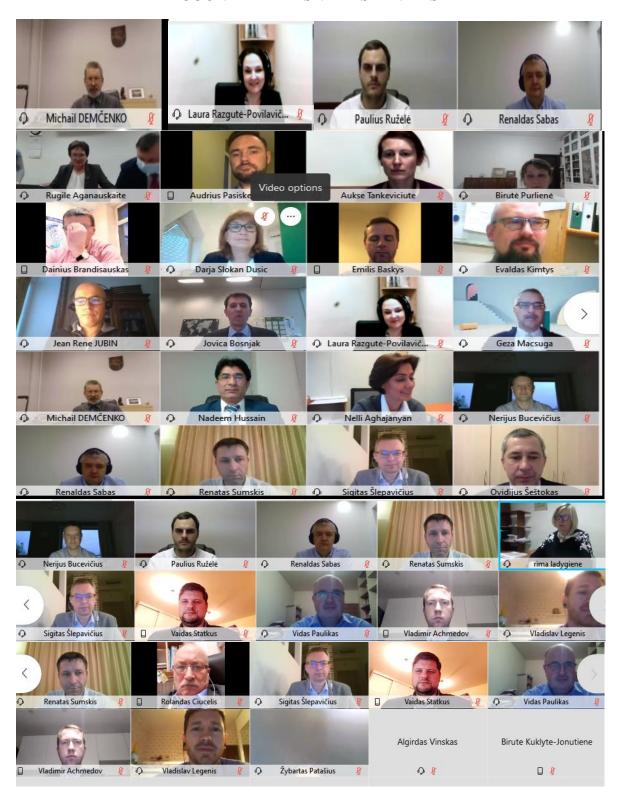
IRRS EXPERTS	COUNTERPART
	Transport:
	RSC Vaidas STATKUS Participate: Rugilė AGANAUSKAITĖ (participate Kristina TUMOSIENĖ, VATESI)
For NPP	Nuclear Power Plants: Evaldas KIMTYS (VATESI) Participate: Vilmantas LAŠIŪNAS
Colin TAIT	Fuel cycle facilities (Spent fuel storage facilities): Vidas PAULIKAS (VATESI) Participate: Sigizmundas STYRO
	Waste management facilities: Vidas PAULIKAS (VATESI) Participate: Algirdas VINSKAS, Vaida TIMINSKIENĖ, Žybartas PATAŠIUS
REVIEW AND ASSESSMENT	
For radioactive waste, decommissioning: Nelli AGHAJANYAN For radiation sources and transport	VATESI: Vladislav LEGENIS Participate: Nerijus BUCEVIČIUS, Dainius BRANDIŠAUSKAS, Asta NEKRASOVAITĖ
Patrick ARENDS	Transport: RSC Vaidas STATKUS Participate: Rugilė AGANAUSKAITĖ (participate Kristina TUMOSIENĖ, VATESI)
For NPP Colin TAIT	Nuclear Power Plants: Evaldas KIMTYS (VATESI) Participate: Vilmantas LAŠIŪNAS
	Fuel cycle facilities (Spent fuel storage facilities): Vidas PAULIKAS (VATESI Participate: Sigizmundas STYRO
	Waste management facilities: Vidas PAULIKAS (VATESI) Participate: Algirdas VINSKAS, Vaida TIMINSKIENĖ, Žybartas PATAŠIUS

IRRS EXPERTS	COUNTERPART
INSPECTION	
For radioactive waste, decommissioning: Nelli AGHAJANYAN	VATESI: Evaldas KIMTYS Participate: Asta NAVAGROCKIENĖ,
For radiation sources and transport Patrick ARENDS	Asta NEKRASOVAITĖ
	RSC: Vaidas STATKUS Participate: Rugilė AGANAUSKAITĖ
	Transport:
	RSC Vaidas STATKUS Participate: Rugilė AGANAUSKAITĖ Kristina TUMOSIENĖ (VATESI)
For NPP Colin TAIT	Nuclear Power Plants: Evaldas KIMTYS (VATESI) Participate: Vilmantas LAŠIŪNAS)
	Fuel cycle facilities (Spent fuel storage facilities): Vidas PAULIKAS (VATESI Participate: Sigizmundas STYRO
	Waste management facilities: Vidas PAULIKAS (VATESI) Participate: Algirdas VINSKAS, Vaida TIMINSKIENĖ, Žybartas PATAŠIUS
ENFORCEMENT	
For radioactive waste, decommissioning: Nelli AGHAJANYAN For radiation sources and transport	VATESI: Laura RAZGUTĖ-POVILAVIČIENĖ Participate: Sigitas ŠLEPAVIČIUS
Patrick ARENDS	Transport:
	RSC Vaidas STATKUS Participate: Rugilė AGANAUSKAITĖ (participate Kristina TUMOSIENĖ, VATESI)
	Nuclear Power Plants: Evaldas KIMTYS (VATESI)

ADDG TANDDDWG	
IRRS EXPERTS	COUNTERPART
	Participate: Vilmantas LAŠIŪNAS)
For NPP Colin TAIT	Fuel cycle facilities (Spent fuel storage facilities): Vidas PAULIKAS (VATESI Participate: Sigizmundas STYRO
	Waste management facilities: Vidas PAULIKAS (VATESI) Participate: Algirdas VINSKAS, Vaida TIMINSKIENĖ, Žybartas PATAŠIUS
REGULATIONS AND GUIDES	
For radioactive waste, decommissioning: Nelli AGHAJANYAN For radiation sources and transport	VATESI: Laura RAZGUTĖ-POVILAVIČIENĖ Participate: Evaldas KIMTYS, Vilmantas LAŠIŪNAS
Patrick ARENDS	RSC: Vaidas STATKUS Participate: Gintautas BALČYTIS
	Transport:
	RSC Vaidas STATKUS Participate: Rugilė AGANAUSKAITĖ (participate Kristina TUMOSIENĖ, VATESI)
For NPP Colin TAIT	Nuclear Power Plants: Evaldas KIMTYS (VATESI) Participate: Vilmantas LAŠIŪNAS)
	Fuel cycle facilities (Spent fuel storage facilities): Vidas PAULIKAS (VATESI Participate: Sigizmundas STYRO
	Waste management facilities: Vidas PAULIKAS (VATESI) Algirdas VINSKAS, Participate: Vaida TIMINSKIENĖ, Žybartas PATAŠIUS
EMERGENCY PREPAREDESS AND R	ESPONSE
Muhammad NADEEM HUSSAIN	VATESI: Emilis BAŠKYS Participate: Audrius PAŠIŠKEVIČIUS

IRRS EXPERTS	COUNTERPART	
	RSC: Paulius RUŽELĖ Participate: Danutė ŠIDIŠKIENĖ	
ADDITIONAL AREAS - Medical Exposure		
Christina DODKIN,	RSC Julius ŽILIUKAS Participate: Vaida GRIGONIENĖ	
ADDITIONAL AREAS - Occupational Exp	oosure	
Christina DODKIN,	RSC Vaidas STATKUS Participate: Rugilė AGANAUSKAITĖ Vladimir ACHMEDOV, VATESI)	
	ctive discharges and materials for clearance, a authorized practices for public radiation	
Christina DODKIN,	VATESI: Audrius PAŠIŠKEVIČIUS (participate Darius LUKAUSKAS) RSC:	
TAIL OPEN MODILLE SSC 16	Rima LADYGIENĖ	
TAILORED MODULE SSG 16		
Anthony HART Colin TAIT	VATESI: Evaldas KIMTYS Participate: Participate: Sigitas ŠLEPAVIČIUS	

COUNTERPARTS VATESI AND RSM



APPENDIX III MISSION PROGRAMME

IRRS FOLLOW-UP MISSION TO LITHUANIA

10 November – 2 December 2020

* Timing below is referring to Vienna time

IRRS FOLLOW-UP MISSION PROGRAMME					
	10 to 13 November 2020				
	Tuesday 10 November				
IRRS Initial 7	Team Meeting				
14:00 - 16:00	Opening remarks by the IRRS Team Leader	Participants: IRRS			
	Introduction by IAEA	Team, Liaison Officer			
	Self-introduction of all attendees				
	IRRS Process and report writing (IAEA)				
	Schedule (TL, IAEA)				
	First impression from team members arising				
	from the Advanced Reference Material				
	(ARM) (all Team members): Presentations				
	Administrative arrangements				
	(VATESI/RSC Liaison Officer, IAEA):				
	Detailed Mission Programme				
	Wednesday 11 November				
	Each Reviewer finalizes his/her First	Participants: IRRS			
	Impressions Report, considering comments	Team			
	from the Review Team and sends it to the				
	IRRS Team Leader and IAEA Coordinator.				
	Thursday 12 November				
12:00	IAEA sends the First Impressions Reports to	Participants: IRRS			
	the Host for their preparation.	Team			

Week 1 - 16 – 20 November 2020 Monday 16 November 2020			
IRRS Entrance M	leeting		
14:00 – 15.45 14:0	00 - 1415	Opening remarks by	Participants: High
		Lithuania / VATESI / RSC	Level Government
14:1	15 - 14:30	Opening remarks by the	Official,
		Team Leader – Mr Anthony	VATESI/RSC
		Hart	Management, Liaison
14:3	30 - 14:40	Self-introduction of IRRS	Officer and staff,
		team members	Official from relevant
14:4	40 - 14:50	Self-introduction of EB	organizations, the
		counterparts of each module	IRRS Team
14:5	50 - 15:30	Overview of the Lithuania	
		regulatory framework,	
		changes since the initial	
		mission, main results of the	

	self-assessment by	
	VATESI/RSC	
	15:30-15-45 Review of the mission	
	agenda by IAEA Team	
	Coordinators	
16:00 -18:00	Reviewers/Counterparts discussions in	Participants: the IRRS
	parallel, through WebEx and emails, no time	Team / VATESI/RSC
	limit. Detailed schedule to be arranged in	Counterparts
	advance between reviewers and counterpart	1
	Tuesday 17 November 2020	
Daily Discussi	ons / Interviews	
	Reviewers/Counterparts discussions in	Participants: the IRRS
	parallel, through WebEx and emails, no time	Team/ VATESI/RSC
	limit. Detailed schedule to be arranged in	Counterparts
	advance between reviewers and counterpart	Counterparts
	Report drafting by reviewers	Participants: IRRS
	Report draining by reviewers	Team
15:00 – 17:00	Doily IDDS toom mosting to review as	
15:00 – 17:00	J 2	Participants: the IRRS
	and address any challenge	Team + the LO
	IAEA Admin support compiles the draft	
	report	
	Wednesday 18 November 2020	
Daily Discussi	ons / Interviews	
	Reviewers/Counterparts discussions in	Participants: the IRRS
	parallel, through WebEx and emails, no time	Team/ VATESI/RSC
	limit. Detailed schedule to be arranged in	Counterparts
	advance between reviewers and counterpart	
	Report drafting by reviewers	IRRS Team
14:00 – 16:00	Daily IRRS Review Team Meeting:	Participants: the IRRS
	conclusions discussions	Team + the LO
	IAEA Admin support compiles the draft	
	report	
	Thursday 19 November 2020	
Daily Discussi	ons / Interviews	
	Reviewers/Counterparts discussions in	Participants: the IRRS
	parallel, through WebEx and emails, no time	Team/ VATESI/RSC
	limit. Detailed schedule to be arranged in	Counterparts
	advance between reviewers and counterpart	Country parts
	Report drafting by reviewers	Participants: the IRRS
	Report draiting by reviewers	Team
15:00 – 17:00	Daily IRRS team meeting, to review progress	Participants: the IRRS
13.00 – 17.00		Team+ the LO
	and address any challenge	ream⊤ me LU
	IAEA Admin support compiles the draft	
	report	

Friday 20 November 2020			
Daily Discussi	Daily Discussions/ Interviews (if needed)		
	Reviewers/Counterparts discussions in	Participants: the IRRS	
	parallel, through WebEx and emails, no time limit. Detailed schedule to be arranged in	Team/VATESI/RSC Counterparts	
	advance between reviewers and counterpart	Counterparts	
	Report drafting by reviewers	Participants: IRRS	
		Team	
14:00 – 16:00	Daily IRRS team meeting, to review progress	Participants: the IRRS	
	and address any challenge	Team+ the LO	
	IAEA Admin support compiles the draft		
	report		

Week 2 – 23 – 27 November 2020				
Monday 23 November 2020				
	Report drafting by reviewers	Participants: IRRS Team		
14:00 – 16:00	IRRS Team meeting to review the draft	Participants: IRRS Team		
	report			
	Tuesday 24 November 2020			
	Report drafting by reviewers	Participants: IRRS Team		
14:00 – 16:00	IRRS Team meeting to review the draft report	Participants: IRRS Team		
	Wednesday 25 November 2020			
	Reviewers/Counterparts parallel discussions on the draft report, duration 2 hours max per module	Participants: IRRS Team/ VATESI/RSC Counterparts		
	Thursday 26 November 2020			
14:00 – 16:00	IRRS Team meeting to finalize the draft report	Participants: IRRS Team		
EOB	Submission of the draft report to the host	Participants: IRRS Team		
Friday 27 November 2020				
	Lithuania to review the draft report and to	Participants:		
	provide written comments by COB	VATESI/RSC		
	TL/TC write executive summary and the			
	press release			

Week 3 –30 November to 2 December 2020			
	Monday 30 November 2020		
14:00 - 16:00	IRRS Team meeting to resolve the IRRS Team		
	comments		
Tuesday 1 December 2020			
14:00 – 16:00 to be extended if required	Plenary discussion of the report. IRRS Team/VATESI/RSC		

Wednesday 2 December 2020				
Exit Meeting				
14:00 - 16:00	Government official opening remarks	Participants:		
	Main findings of the IRRS mission (Team	Government Officials,		
	Leader)	VATESI/RSC		
	Remarks by VATESI/RSC in response to	Management, LO and		
	the Mission findings.	staff, the IRRS Team		
	IAEA Official Closing remarks delivery			
	by IAEA Official			
	Publication of the press release, after			
	IAEA and Lithuania clearances.			

APPENDIX IV RECOMMENDATIONS (R) AND SUGGESTIONS (S) FROM THE 2016 IRRS MISSION THAT REMAIN OPEN

Section	Module	R/S	Recommendations/Suggestions
1.7	1	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.
3.2	3	S3	RSC should consider further strengthening the effective independence of its regulatory functions from its expert services to licensees.

APPENDIX V RECOMMENDATIONS (RF) AND SUGGESTIONS (SF) AND GOOD PRACTICES (GPF) FROM THE 2020 IRRS FOLLOW UP MISSION

Section	Module	RF/SF/GPF	Recommendations, Suggestions or Good Practices
5.3	5	RF1	VATESI should revise the regulatory framework and associated procedures to require the prior submission of an updated safety assessment to inform its decision-making on the granting of an authorization for the closure of radioactive waste disposal facilities.
7.3	7	SF2	VATESI should consider broadening the range of available guidance for inspection of nuclear facilities, taking into account the benefits of such guidance for each inspection area.
9.4	9	SF2	The Ministry of Health should consider amending the Hygiene Standard HN73:2018 to define the amounts of material above which the different concentration values, listed in Table 4 of Annex 4 should be used to exempt practices or sources from regulatory control.

APPENDIX VI REFERENCE MATERIAL USED FOR THE REVIEW

1.	Quality policy document				
	Referral to CT and MRI examinations.docx				
	Statute of RSC (new)-2019-LT.DOCX				
	Statute of RSC (old).doc				
	DRAFT of Order of Minister of Health on Issue of Clinical Audits.docx				
	Kokybes vadovas LT Quality manual.doc				
2	Acts of Parliament				
	Law on Public Administration.docx				
	Law on Radiation Protection.docx				
	Law on Radioactive Waste Management (with all amendments).docx				
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	Law on Control of Strategic Goods.doc				
	Law on Environmental Impact Assessment.doc				
	Law on Environmental Monitoring.doc				
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3	Resolution of the Government				
	Radioactive Waste Management Development Programme.docx				
	Regulations on the Issue of Licences and Permits for Activities in the Nuclear Energy Area.docx				
	Rules on Authorising Activities with Sources of Ionising Radiation.docx				
	Rules on the Handling of Orphan Radioactive Sources.DOCX				
	State Emergency Management Plan.doc				
	Statute of VATESI.doc				
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	National Plan for Protection of Population in Case of a Nuclear or Radiological Accident.docx				
4	Orders of VATESI				
	BSR-3.2.2-2016_Radioactive Waste Disposal Facilities.DOCX				

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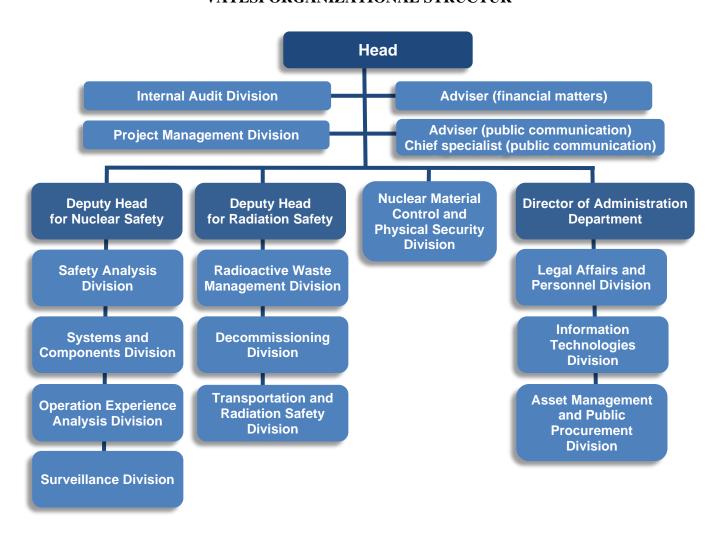
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8	List of legal acts available in English
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7	Internal VATESI documents
	Environmental Monitoring of Operators.doc
	Action Plan for the Implementation of Recommendations and Suggestions of the IRRS Mission Report.docx
	Rules on Inport Export and Transport of Radioactive Material.doc
	Recommendations for Determining Criteria for Emergency Preparedness.docx
6	Orders of other institution
	Description of the Procedure for Decommissioning of the Facilities Using Radiation Sources.docx
	HN 99 2019_Protective Actions of the Public in Case of Nuclear or Radiological Emergency.docx
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APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW

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APPENDIX VIII ORGANIZATION CHART VATESI ORGANIZATIONAL STRUCTUR



STRUCTURE OF THE ADMINISTRATION OF THE RADIATION PROTECTION CENTRE

