

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

Bratislava, the Slovak Republic

5-16 September 2022

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



Integrated
Regulatory
Review Service

IRRS



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Mission dates:	<i>5-16 September 2022.</i>
Regulatory bodies involved:	<i>Nuclear Regulatory Authority of the Slovak Republic (ÚJD SR), the Public Health Authority (UVZ SR), Ministry of Transport and Construction (MDV SR), National Labour Inspectorate (NIP, IP Nitra), Slovak Hydrometeorological Institute (SHMÚ), Ministry of Environment (MZP SR) and the Ministry of Interior (MV SR).</i>
Location:	<i>Bajkalská 27, 820 07 Ružinov, the Slovak Republic.</i>

Regulated facilities, activities, and exposure situations in the mission scope:	<i>Decommissioning of facilities; fuel cycle facilities; nuclear power plants; waste management facilities; disposal of radioactive waste; Predisposal management of radioactive waste; transport of radioactive material; radiation sources facilities and activities; occupational exposure; medical exposure; public exposure; emergency preparedness and response.</i>
Organized by:	<i>IAEA</i>

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IAEA-2022

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

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EXECUTIVE SUMMARY

At the request of the Government of the Slovak Republic, an international team of senior safety experts met representatives of the Nuclear Regulatory Authority of the Slovak Republic (ÚJD SR) along with representatives from the different institutions that legally and collectively provide the full scope of the national regulatory responsibilities and functions. These authorities include the Public Health Authority (ÚVZ SR), Ministry of Transport and Construction (MDV SR), National Labour Inspectorate (NIP, IP Nitra), Slovak Hydrometeorological Institute (SHMÚ), Ministry of Environment (MZP SR) and the Ministry of Interior (MV SR). The mission took place mainly at the headquarters of the ÚJD SR and the ÚVZ SR, in Bratislava between 5-16 September 2022.

The purpose of this IRRS mission was to review the effectiveness of the Slovak regulatory framework for nuclear and radiation safety.

The review assessed the Slovak regulatory framework for nuclear and radiation safety against IAEA safety standards as the international benchmark for safety. The mission was also used as an opportunity to exchange information and experience between the IRRS team members and Slovak counterparts in the areas covered by the IRRS. The IRRS team commends the Slovak Republic for hosting this very comprehensive peer review which included 7 regulatory authorities with responsibilities in nuclear safety and radiation protection in the area of facilities and activities.

The IRRS team consisted of 14 senior regulatory experts from 13 IAEA Member States and four IAEA staff members. The IRRS team carried out the review in the following areas: responsibilities and functions of the Government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the functions of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, patient protection, public and environmental exposure control, transport, waste management and decommissioning.

The IRRS mission also included a special session for discussion: 1) Regulatory implications of the COVID-19 pandemic and 2) Independence of the Regulatory Body.

The IRRS review addressed the facilities and activities regulated by the national regulatory authorities on nuclear and radiation safety.

The mission included observations of regulatory activities and a series of interviews with the national regulatory authorities, including discussions with licensee personnel and management, to help assess the effectiveness of the regulatory system. In addition, the mission Team Leads met with His Excellency Mr Lengvarský, the Slovak Minister of Health.

These activities included observations of inspections at Mochovce Nuclear Power Plant (NPP) site and Cyclotron Centre of the Slovak Republic in Bratislava (BIONT). The IRRS team members observed the working practices during inspections carried out by ÚJD SR and ÚVZ SR.

ÚJD SR and ÚVZ SR and other regulatory authorities provided the IRRS team with advanced reference material and documentation including the results of self-assessment in all areas within the scope of the mission, including the initial action plan for improvements established after the self-assessment. Throughout the mission, the IRRS team was extended full cooperation in its review of regulatory, technical and policy issues by all parties. The staff of all regulatory authorities were very open in their discussions and provided the fullest practicable assistance.

The Government of the Slovak Republic has adopted the “Policies, principles and strategies for further development of nuclear safety” as the national policy and strategy on nuclear safety through government resolution No. 256/2014 in the year 2014.

The IRRS team identified the following issues warranting attention and action by the Government of the Slovak Republic:

- Development and implementation of a national nuclear emergency plan to respond to radiological or nuclear emergencies
- Ensuring effective cooperation and coordination between the different regulatory authorities in charge of oversight of nuclear, radiological and transport safety

- Ensuring that ÚVZ SR, is effectively independent from the organizational entities that are under regulatory control in the field of radiation protection
- Ensuring that ÚVZ SR and MDV SR are adequately resourced
- Consideration of implementing a comprehensive programme to identify all exposure situations with potential impact on the public and ensure that strategies and measures against radon exposures as it is laid out in the National Action Radon Plan are implemented
- Revising the Act 87/2018 Coll. to assign the prime responsibility for safety to the authorized party, including the assessment and authorization of Type B and Type C package designs containing radioactive material.

ÚJD SR has legal responsibilities to regulate nuclear safety and the ÚVZ SR, organizationally and financially dependent on the Ministry of Health, is the main authority responsible for radiation safety. In addition, the functions for radiation safety have also been assigned to the Ministry of Transport and Construction, Ministry of Defence, Ministry of Interior and Slovak Information Service (SIS).

Overall, the IRRS team concluded that the regulatory programme of the Slovak Republic is mature, but the regulatory oversight of nuclear and radiation safety is disproportionate and inconsistent across authorities. The complexities in the legislation, structure, and interactions among the various regulatory authorities may reduce the effectiveness of the programme and risk overlap and potential gaps in the delivery of the regulatory functions.

The IRRS team identified several areas of good performance and made recommendations and suggestions to the regulatory authorities. Appropriate adoption of these will enhance the effectiveness of the regulatory framework and functions in line with the IAEA Safety Standards. The main areas for further improvement are as follows:

- The regulatory authorities should clearly establish and document the interfaces among themselves in their management system.
- The regulatory authorities should ensure that application of graded approach to the delivery of their regulatory functions.
- The regulatory body should develop and implement an enforcement policy covering the entire range of possible enforcement actions and implement a procedure to inform each authority of relevant enforcement actions being taken.

To effectively perform their regulatory functions, the ÚVZ SR and its respective Regional Public Health Authorities and MDV SR should:

- Establish, implement, and continuously improve an integrated management system.
- Develop and implement a human resources plan to have an adequate number of appropriately qualified and competent resources to support inspections and independent verification of safety assessments.
- Ensure that the staff training programme is tailored to their regulatory functions.
- Develop and implement a comprehensive risk-based inspection programme.
- Establish or adopt guidance to support applicants and licensees in complying to the relevant requirements.

The IRRS team findings are summarized in Appendices V and VI.

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

I. INTRODUCTION

At the request of the Government of the Slovak Republic, an international team of senior safety experts met, from 5 to 16 September 2022 in Bratislava, with representatives from the different institutions that legally and collectively provide the full scope of the national regulatory responsibilities and functions to conduct an IAEA Integrated Regulatory Review Service (IRRS) mission. The involved Slovak organizations include representatives of the Nuclear Regulatory Authority of the Slovak Republic (ÚJD SR) the Public Health Authority of the Slovak Republic (ÚVZ SR), respective regional public health authorities (RÚVZs), Ministry of Transport and Construction (MDV SR), National Labour Inspectorate and the Labour Inspectorate Nitra (NIP, IP Nitra), Slovak Hydrometeorological Institute (SHMÚ), Ministry of Environment (MZP SR) and the Ministry of Interior (MV SR). The mission took place mainly at the headquarters of both the ÚJD SR and the ÚVZ SR.

The purpose of this peer review was to review the Slovak governmental, legal and regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of the Slovak Republic on 20 January 2020. A preparatory meeting was conducted from 21 to 22 March 2022 at ÚJD SR Headquarters in Bratislava to discuss the purpose, objectives, and detailed preparations, and agree upon the scope of the IRRS mission in connection with regulated facilities and activities in the Slovak Republic.

This mission was organized back-to-back to an Integrated Review Service for Radioactive Waste and Spent Fuel, Decommissioning and Remediation (ARTEMIS) mission scheduled for early 2023. To avoid unnecessary duplications between the IRRS and the ARTEMIS missions, the preparation and conduct of the IRRS mission was carried out in a coordinated manner with the ARTEMIS mission and included an IRRS team member who will also be part of both missions. Thus, the provisions for the decommissioning of facilities and the management of radioactive waste and of spent fuel, subject of Section 1.7., are to be reviewed by the upcoming ARTEMIS mission.

The IRRS team consisted of 14 senior regulatory experts from 13 IAEA Member States and 4 IAEA staff members. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, control of medical exposure, public and environmental exposure control, transport of radioactive material, waste management and decommissioning. The IRRS mission also included the following regulatory policy issues for discussion: 1) Regulatory implications of the COVID-19 pandemic and 2) Independence of the Regulatory Body.

The state authorities, with the leadership of ÚJD SR and ÚVZ SR conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of the self-assessment and supporting documentation were provided to the IRRS team as Advance Reference Material (ARM) for the mission. During the mission the IRRS team performed a systematic review of all topics within the agreed upon scope by performing a thorough review of the Slovak ARM, conducting interviews with management and staff from the state authorities and direct observation of the ÚJD SR and ÚVZ SR regulatory inspections at regulated facilities. In addition, the mission Team Leads met with His Excellency Mr Vladimír Lengvarský, the Slovak Minister of Health.

Throughout the mission, the IRRS team received excellent support and cooperation from the state authorities.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review Slovak radiation and nuclear safety governmental, legal and regulatory framework and activities against the relevant IAEA safety standards to report on effectiveness of the regulatory system and to exchange information and experience in the areas covered by the IRRS. The agreed scope of this IRRS review included all facilities and activities regulated in the Slovak Republic. It is expected that this IRRS mission will facilitate regulatory improvements in the Slovak Republic and other Member States, using the knowledge gained and experiences shared between Slovak Republic regulatory authorities and IRRS reviewers and the evaluation of the Slovak regulatory framework for nuclear and radiation safety, including its good practices.

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

- a) providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;
- b) providing the host country (regulatory body and governmental authorities) with a review of its regulatory technical and policy issues;
- c) providing the host country (regulatory body and governmental authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;
- d) promoting the sharing of experience and exchange of lessons learned among senior regulators;
- e) providing key staff in the host country with an opportunity to discuss regulatory practices with IRRS team members who have experience of other regulatory practices in the same field;
- f) providing the host country with recommendations and suggestions for improvement;
- g) providing other states with information regarding good practices identified in the course of the review;
- h) providing reviewers from Member States and IAEA staff with opportunities to observe different approaches to regulatory oversight and to broaden knowledge in their own field (mutual learning process);
- i) contributing to the harmonization of regulatory approaches among states;
- j) promoting the application of IAEA Safety Requirements;
- k) providing feedback on the use and application IAEA safety standards.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IRRS TEAM

At the request of the Government of the Slovak Republic, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 21 to 22 March 2022. The preparatory meeting was carried out by the IRRS representatives, and Mr Miguel Santini and Mr Ronald Pacheco Jimenez as IAEA Team Coordinators.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management from the different institutions that legally and collectively provide the full scope of the national regulatory responsibilities and functions, namely the Nuclear Regulatory Authority of the Slovak Republic (ÚJD SR), the Public Health Authority of the Slovak Republic (ÚVZ SR), Ministry of Transport and Construction of the Slovak Republic (MDV SR), National Labour Inspectorate and the Labour Inspectorate Nitra (NIP, IP Nitra), Slovak Hydrometeorological Institute (SHMÚ), Ministry of Environment of the Slovak Republic (MŽP SR) and the Ministry of Interior of the Slovak Republic (MV SR). The preparatory meeting took place at the ÚJD SR.

It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides:

- Decommissioning of facilities;
- Fuel cycle facilities;
- Nuclear power plants;
- Waste Management facilities;
- Disposal of radioactive waste;
- Predisposal management of radioactive waste;
- Transport of radioactive material;
- Radiation sources facilities and activities;
- Occupational exposure;
- Medical exposure;
- Public exposure;
- Emergency preparedness and response; and
- Selected policy issues.

Ms Marta Žiaková, Chairperson, ÚJD SR, other senior management and staff of the regulatory authorities (ÚVZ SR) made presentations on the national context, the current status of the regulatory programme and the self-assessment results to date.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in the Slovak Republic in September 2022.

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

The ÚJD SR Liaison Officer for the IRRS mission was confirmed as Mr Mikuláš Turner, Director General of the Department of Regulatory Activities and International Relations. Mr Jakub Konečný, Senior Officer, Division of International Relations and European Affairs, was confirmed as Deputy Liaison Officer.

In preparation for the mission, ÚJD SR and the other regulatory authorities provided the IAEA with the ARM for the review at the end of June 2022, which was reviewed by the IRRS team in order to provide their initial impressions.

B) REFERENCES FOR THE REVIEW

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

C) CONDUCT OF THE REVIEW

The initial IRRS team meeting took place on Sunday, 4 September 2022 in Bratislava, directed by the IRRS Team Leader and the IRRS IAEA Team Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and provided the background, context and objectives of the IRRS programme. The understanding of the IRRS methodology for review was reinforced by the Deputy Team Coordinator. The agenda for the mission was presented to the team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

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

The IRRS entrance meeting was held on Monday, 5 September 2022, with the participation of the different institutions that legally and collectively provide the full scope of the national regulatory responsibilities and functions, including the ÚJD SR, ÚVZ SR, RÚVZ SR, MDV SR, NIP, IP Nitra, SHMÚ, MŽP SR and MV SR. The mission took place mainly at the headquarters of both the ÚJD SR and the ÚVZ SR.

Ms Marta Žiaková, Chairperson, ÚJD SR gave an overview of the Slovak Republic context, and Mr Mikuláš Turner, Director General of the Department of Regulatory Activities and International Relations presented the action plan prepared as a result of the pre-mission self-assessment.

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

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

The IRRS exit meeting was held on Friday, 16 September 2022. The opening remarks at the exit meeting were presented by Ms Marta Žiaková, Chairperson, ÚJD SR and were followed by the presentation of the results of the mission by the IRRS Team Leader Ms Dana Drábová, Chairperson of the Czech Republic State Office for Nuclear Safety (SÚJB). Closing remarks were made by Ms Kirsi Alm-Lytz, Section Head, Regulatory Activities Section, Division of Nuclear Installation Safety, IAEA.

An IAEA press release was issued.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY

The Government of the Slovak Republic adopted the “Policies, principles and strategies for further development of nuclear safety” as national policy and strategy on nuclear safety through government resolution No. 256/2014 in the year 2014. The document provides a comprehensive summary of national policies, principles, and strategies for nuclear safety of nuclear facilities constructed or operated in the Slovak Republic. The safety principles are based on IAEA Safety Fundamentals. The aim of Policy, Principles and Strategy for Further Development of Nuclear Safety is to provide material and reinforcement principles to protect the public and the environment from harmful effects of ionizing radiation associated with peaceful uses of nuclear energy. The principles stipulated in the document with reasonable limits apply also to institutions engaged in research activities, medical and industrial applications. For radiation protection the Government has further detailed the national policy and strategy for safety in the Act on Radiation Protection.

The IRRS team has noted that the policy document is largely consistent with the Fundamental Safety Principles (SF-1) however, principles 2, 3 and 9 may need to be strengthened. Requirements such as establishment and sustainability of an effective legal and governmental framework for safety, including an independent regulatory body, is missing in principle 2 of the national policy. Furthermore, effective leadership and management for safety is not covered in principle 3, while principle 9 of national policy states that arrangements for emergency plans and response to radiation incidents and accidents must be made in accordance with SF-1 and shall be designed to ensure an effective response.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The national policy “Policies, principles and strategies for further development of nuclear safety” is not fully consistent with the safety principles in SF-1.*

(1)

BASIS: GSR Part 1 (Rev. 1) Requirement 1 states that *“The government shall establish a national policy and strategy for safety...to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals”.*

S1

Suggestion: The Government should consider reviewing and updating the national policy “Policies, principles and strategies for further development of nuclear safety” to ensure it is fully consistent with the safety principles of SF-1.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The legal system of the Slovak Republic includes the Constitution, Constitutional laws, Acts/Governmental ordinances, Decrees, Slovak Technical Standards, Guidelines, and by-laws (such as directives/procedures and orders). The Government of the Slovak Republic has established a framework for assuring nuclear and radiation safety through the promulgation of acts (e.g., Atomic Act No. 541/2004 Coll. and Act No. 87/2018 Coll. on Radiation Protection, etc.). The basic objective is the protection of humans and the environment against the harmful effects of ionizing radiation. This is achieved through the authorization of facilities and activities and continuous regulatory oversight, in order to ensure compliance with the legal provisions. Only peaceful uses of nuclear energy are allowed.

Duties and responsibilities for the ministries and other state bodies in the Slovak Republic are stipulated in the Act No. 575/2001 Coll. as amended. Nuclear safety in the Slovak Republic is regulated by the ÚJD SR; and radiation protection is primarily regulated by the ÚVZ SR, and other regulatory authorities as mandated by the Act on Radiation Protection.

The Act on Radiation Protection prescribes a list of considerations which are specific for the type of radiation source activity or facility. The use of prescriptive safety requirements has the potential to limit the scope and rigour of safety assessment undertaken by the regulatory body, especially when assessing novel radiation practices or unforeseen modifications to facilities; long term stability over the lifetime of the facility including best practice.

The International safety standards have specified safety objectives which allow for broad consideration and factors in the review and assessment of radiation source facilities and activities by the regulatory body. It is therefore proposed that appropriate regulations and guides to address such considerations be developed. **Recommendation R18 in Section 9.1. addresses this issue.**

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

ÚJD SR was established on 1 January 1993 as the nuclear safety regulatory authority of the Slovak Republic, in accordance with the previous Act on Activities of Ministries and Other Central Governmental Bodies No. 347/1990 Coll. as amended. ÚJD SR supervises nuclear safety of nuclear installations including supervision of the treatment of radioactive waste, nuclear spent fuel management and further stages of the fuel cycle, as well as nuclear materials, including their control and accountancy. ÚJD SR is a central governmental body. It reports directly to the Slovak government. It is independent of organizations and bodies dealing with the promotion of nuclear technologies or responsible for facilities or activities. It is also independent from any other Ministries.

ÚJD SR has an advisory body – the Council for Nuclear Safety. This body provides independent non-binding advice to the chair of ÚJD SR in matters of nuclear safety and state supervision over nuclear installations as well as its assessment.

Under the Act on Radiation Protection a number of state authorities are responsible for radiation protection and radiation safety, with the primary one being ÚVZ SR and the Regional Public Health Authorities (RÚVZ BA, RÚVZ BB, RÚVZ NR and RÚVZ KE). However, the Ministry of Transport and Construction of the Slovak Republic, Ministry of Defence of the Slovak Republic, and Slovak Information Service, are also assigned responsibility of the regulatory body under circumstances specified under the Act. The Act clearly delineates the roles and responsibilities of the various state authorities. The IRRS team has noted that there is overlapping of responsibilities between some of the authorities.

The IRRS team was informed that the regulatory authorities perform their responsibility with independence and objectivity. However, the IRRS team noted that the organisational structure of the regulatory authorities (ÚVZ SR and RÚVZs) organizationally and financially dependent on the Ministry of Health has potential for conflict of interest in regulatory oversight. For example, hospitals owned and operated by the Ministry of Health are authorized by ÚVZ SR and respective RÚVZs which are organizations established and funded by the Ministry of Health.

The International Safety Standards states that the government should ensure that the regulatory body is effectively independent of persons and organizations using or promoting radiation sources so that it is free from any undue influence by interested parties and any conflicts of interest.

From the discussions, the IRRS team concluded that ÚVZ SR and respective RÚVZs do not have adequate human and financial resources to effectively perform the full suite of responsibilities assigned under the Act.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *ÚVZ SR issues licences to some hospitals which are established and financed by the Ministry of Health which may cause a potential conflict of interest.*

(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 4 states that <i>“The government shall ensure that the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making”.</i>
(2)	BASIS: GSR Part 1 (Rev. 1) Requirement 4, para. 2.11 states that <i>“In the event that a department or agency of government is itself an authorized party operating an authorized facility or facilities, or conducting authorized activities, the regulatory body shall be separate from, and effectively independent of, the authorized party”.</i>
R1	Recommendation: The Government should ensure that ÚVZ SR and respective RÚVZs, are

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

effectively independent from the organizational entities that are under its regulatory control in the field of radiation protection.

From various discussions and observations during this mission, the IRRS team has also noted that ÚVZ SR and MDV SR do not have adequate human and financial resources to effectively perform the full suite of responsibilities assigned to it under the Act. This has impacted a number of areas of its regulatory responsibilities such as authorisation and inspection programmes including acquisition of external technical expertise for assessment of complex technical and safety matters relating facilities and activities. Details of this are addressed in a number of modules in this report.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *ÚVZ SR and MDV SR do not have adequate number of appropriately qualified staff including facilities, equipment and services to effectively discharge its obligations under the Act on Radiation Protection.*

(1)	<p>BASIS: GSR Part 1 (Rev. 1) Requirement 4, para.2.8 states that <i>“To be effectively independent from undue influences on its decision making, the regulatory body:</i></p> <p><i>(a) Shall have sufficient authority and sufficient competent staff;</i></p> <p><i>(b) Shall have access to sufficient financial resources for the proper and timely discharge of its assigned responsibilities;</i></p> <p><i>(c) Shall be able to make independent regulatory judgements and regulatory decisions, at all stages in the lifetime of facilities and the duration of activities until release from regulatory control, under operational states and in accidents”</i></p>
(2)	<p>BASIS: GSR Part 3 Requirement 2, para. 2.17 states that <i>“The government shall ensure that the regulatory body has the legal authority, competence and resources necessary to fulfil its statutory functions and responsibilities”.</i></p>
R2	<p>Recommendation: The Government should ensure that ÚVZ SR, respective RÚVZs and MDV SR are effectively resourced to fulfil their regulatory responsibilities.</p>

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

Under section 23 (1) of the Atomic Act, authorised parties are assigned the prime responsibility for safety and includes actions of contractors and subcontractors whose activities may affect the safety of a nuclear installation. It is further stated in Section 23 (1) of the Atomic Act that the licensee cannot waive or transfer the prime responsibility for safety.

International safety standards require the Atomic Act and the Act on Radiation Protection to assign the prime responsibility for safety to the authorised person or organisation, responsible for a facility or activity.

The IRRS team review of the Act on Radiation Protection revealed that it does not assign prime responsibility for safety to the authorised person or organisation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The Act on Radiation Protection does not assign the prime responsibility for safety to the authorised party.*

(1)	<p>BASIS: GSR Part 1 (Rev. 1) Requirement 5 states that <i>“The government shall expressly assign the</i></p>
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RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>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”.</i>
R3	Recommendation: The Government should amend the Act on Radiation Protection to clearly assign the prime responsibility for safety to the authorised party.

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

Authorities and general fields of competence among the different governmental regulatory bodies are assigned by the Act No. 575/2001 Coll. on Organization of Governmental Activities and of Central State Administration. More specific details are stipulated in the relevant Acts and subsequent legally binding documents, such as decrees. Apart from this, there is no specific formal coordination mechanism in this matter. The § 38 of the Competence Act stipulates that the ministries and other central governmental bodies cooperate as appropriate in the performance of their responsibilities under the Act. The regulatory bodies exchange information and documents, negotiate the issues that may impact on safety. To ensure more efficient performance of individual activities, ministries and other central state administration bodies may enter into a written agreement on cooperation, in which the type and scope of cooperation activities are defined in particular.

While the Act on Radiation Protection has mainly bestowed the powers of the regulatory body to, ÚVZ SR and the respective RÚVZ SR, other national bodies such as MDV SR, MV SR, Slovak Information Services and the Ministry of Defence of the Slovak Republic may also perform the functions of the regulatory body as specified under the Act on Radiation Protection. The IRRS team has been informed that these bodies have issued authorizations for facilities and activities operating in their premises. There have been limited consultations or cooperation in this regard with the ÚVZ SR or RÚVZs.

The IRRS team has also observed gaps in cooperation and coordination in the responsibilities between ÚJD SR and ÚVZ SR. Some examples are provided below.

- Both ÚJD SR and ÚVZ SR perform inspections of nuclear facilities. While the focus of the inspections is different, there is limited coordination between the two regulatory bodies in the conduct of inspections or sharing of inspection findings. For example, in case of significant violations ÚVZ SR or ÚJD SR may take enforcement actions independently of each other without coordination.
- The operator of the nuclear facility is required to obtain licences/authorizations from different authorities. Multiple licensing without appropriate coordination between the Authorities involved may lead to conflicting requirements being imposed on the licensees. Furthermore, for some authorisations, the licensee has to submit separate applications for the same activity to ÚJD SR, ÚVZ SR, and perhaps other authorities.
- Under the Atomic Act, ÚJD SR is required to inform the public of any incidents or accidents while the same responsibility is also assigned to ÚVZ SR and regional authorities by the Act on Radiation Protection.

The International Safety Standards recognize that a number of agencies may have responsibilities for safety within the regulatory framework for safety. However, the lack of an integrated management system to support the safety assessments within and between the regulatory bodies, could result in regulatory controls being applied inconsistently.

Due to the number of regulatory authorities responsible for regulating nuclear and radiation safety, there is a strong need for coordination and cooperation, including the establishment of formal arrangements such as memoranda of understanding. This will remove the potential conflict of interest and confusion among certain interested parties which may adversely affect safety.

The IRRS team noted that there are two authorities involved in the regulatory framework related to the transport of nuclear radioactive material and radioactive material which does not comply with GSR Part 1 (Rev. 1) Requirement 7

as there is no documented process to provide effective coordination between the authorities and their regulatory oversight functions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>There is limited coordination and cooperation between the various regulatory authorities having responsibilities for safety.</i>	
(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 7 states that “Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties”.
(2)	BASIS: GSR Part 1 (Rev. 1) Requirement 7, para 2.18 states that “This coordination and liaison can be achieved by means of memoranda of understanding, appropriate communication and regular meetings. Such coordination assists in achieving consistency and in enabling authorities to benefit from each other’s experience”.
(3)	BASIS: GSR Part 1 (Rev. 1) Requirement 7, para 2.19 states that “If responsibilities and functions do overlap, this could create conflicts between different authorities and lead to conflicting requirements being placed on authorized parties or on applicants. This, in turn, could undermine the authority of the regulatory body and cause confusion on the part of the authorized party or the applicant”.
R4	Recommendation: The Government should establish a means for effective coordination and cooperation between the different regulatory authorities, which may include the development of formal agreements, to ensure consistency in the regulatory requirements and avoid any omissions, undue duplication, and conflicting requirements, being placed on authorized parties.

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

The government has established an effective system for protective actions to reduce existing or unregulated radiation risks in the Act on Radiation Protection. This Act sets conditions and requirements for protection of workers and the population against exposure from consequences of nuclear or radiological events.

ÚVZ SR published the “National Action Radon Plan” and has issued the guideline “Policy of handling orphan sources” that sets the requirements, conditions, and manuals, for handling orphan sources.

The IRRS team was informed that exposure to radon is identified as an existing exposure situation with potential impact on the public. However, except of regulation of exposure from building materials or drinking water, no consideration has been given for the need to have a comprehensive programme to identify other possible existing exposure situations considered significant from a public protection aspect.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>A comprehensive programme to identify existing exposure situations with potential impact on the public has not been conducted.</i>	
(1)	BASIS: GSR Part 3 Requirement 29, para. 3.124 states that “The government shall ensure that existing exposure situations that have been identified are evaluated to determine which occupational exposures and public exposures are of concern from the point of view of radiation protection”.
S2	Suggestion: The Government should consider implementing a comprehensive programme to identify all possible existing exposure situations considered significant from a public protection aspect.

Although, the “National Radon Action Plan” is a comprehensive document laying down a strategy to address occupational and public exposures in relation to radon, including identification of radon-prone areas, workplaces, dwellings, awareness, and proposes preventive and corrective measures to reduce exposure to radon, it has not been implemented.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>The National Action Radon Plan has not been implemented.</i>	
(1)	BASIS: GSR Part 3 Requirement 50, para. 5.20 states that <i>“Where activity concentrations of radon that are of concern for public health are identified on the basis of the information gathered, the government shall ensure that an action plan is established comprising coordinated actions to reduce activity concentrations of radon in existing buildings and in future buildings”.</i>
(2)	BASIS: GSR Part 3 Requirement 52, para. 5.27 states that <i>“The regulatory body or other relevant authority shall establish a strategy for protection against exposure due to 222Rn in workplaces, including the establishment of an appropriate reference level for 222Rn. ...”.</i>
R5	Recommendation: The Government should ensure that strategies and measures against radon exposures, as laid down in the National Action Radon Plan, are implemented.

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

Government provisions concerning decommissioning are regulated primarily through resolutions of the Government of the Slovak Republic. Specific measures concerning decommissioning and ensuring the management of radioactive waste are based on the Resolution of the Government of the Slovak Republic No. 387/2015, which approved the National Policy and the National Programme for the management of spent nuclear fuel and radioactive waste in the Slovak Republic.

The framework for the National Programme is based on the categorization of radioactive waste in accordance with the ÚJD SR Decree No. 30/2012 Coll. laying down details of requirements for the handling of nuclear materials, radioactive waste, and spent nuclear fuel (hereinafter „Decree No. 30/2012 Coll.”), which is based on the approaches in the relevant IAEA safety standards.

ÚVZ SR performs state supervision over activities leading to exposure, including nuclear installations, spent nuclear fuel and radioactive waste management, and release of radioactive substances and radioactively contaminated objects from administrative control. According to the Act on Radiation Protection, authorizations from ÚVZ SR are required for decommissioning of facilities, the management and disposal of radioactive waste, and the management of spent fuel.

According to para 8 section 19 of the Atomic Act, the licensee is obliged to provide funding to cover the costs associated with decommissioning. Financial means are managed by the National Nuclear Fund in accordance with the Act No. 308/2018 Coll. on National Nuclear Fund. The conditions for the utilization of the funding from the National Nuclear Fund are set out in §12 of the Act.

The main emphasis of the radioactive waste management system is placed on the interdependencies of the technologies within the individual stages of radioactive waste management, the storage of radioactive waste is considered only in case of time or technological necessity. In the long term, all activities within the radioactive waste management system are aimed at their disposal in a suitable type of repository.

It has been observed that the fundamental safety principles have not been addressed in the national policy and strategy on spent nuclear fuel and waste handling.

The provisions for the decommissioning of facilities and the management of radioactive waste and of spent fuel, are to be reviewed by the upcoming ARTEMIS mission, which is organized back-to-back to this IRRS mission.

1.8. COMPETENCE FOR SAFETY

ÚJD SR and other state administration bodies provide requirements for building and maintaining the necessary competences and training facilities through the legislation. For example, the ÚJD SR Regulation on Professional Competence stipulates details about professional competence for employees of the licensees in the area of nuclear safety.

Training on the representative full-scope simulator ensures effective training of selected employees of nuclear facilities for normal operation, abnormal operation, and emergency conditions. Systematic technical cooperation is carried out in cooperation with the IAEA and the EU, based on bilateral agreements, as well as multilateral agreements.

Academic research and development are carried out at universities, mostly with a technical and scientific focus, by the Slovak Academy of Science or by commercial organizations.

The IRRS team concluded that ÚJD SR has put in place programmes to ensure that in operating organizations the key positions for nuclear and radiation safety are staffed by competent personnel.

There are no effective arrangements for building and maintaining the competence of other parties having responsibilities relating to the safety of facilities and activities.

1.9. PROVISION OF TECHNICAL SERVICES

In accordance with the Act on Radiation Protection and relevant regulations, the ÚVZ SR is the headquarters of the national radiation monitoring network. The monitoring networks of the MV SR, MDV SR, MO SR, MZP SR, Ministry of Education, Science, Research and Sport, the Ministry of Agriculture and Rural Development, and MH SR, are part of the national radiation monitoring networks. ÚVZ SR is responsible for environmental monitoring and the collection of data within the territory of the Slovak Republic. Requirements for monitoring during normal radiation situations, and during radiation accidents, are defined in the relevant ÚVZ SR regulations.

The calibration and verification of equipment is required by the Slovak Metrological Institute. It is carried out in accordance with the Act on Metrology and Regulation on Measures and Measurement Control, wherein lists of equipment to be legally verified as well as other provisions on legal verification are specified. ÚVZ SR authorizes the technical services related to radiation safety.

The IRRS team concluded that the technical services related to nuclear and radiological safety, such as services for personal dosimetry, environmental monitoring and the calibration and testing of equipment, are available.

POLICY DISCUSSION: REGULATORY IMPLICATIONS OF THE COVID-19 PANDEMIC

The main objective in this policy discussion was to have a debate on the impact of the COVID-19 pandemic on the regulatory activities for the nuclear and radiation safety and having an overview of the reaction of the regulatory bodies present in the discussion.

ÚJD SR made a brief introduction of the pandemic measures and approaches, expanded with the experience of ÚVZ SR, which was heavily involved in the public health response by the Slovak Republic.

The Government ordered everyone who was able to work from home to do so. The regulator as an employer had to schedule the need of staff necessary to be present at work on the weekly basis, and, for the emergency preparedness on the daily basis (due to possible illness or quarantine). Requirements were established to have a negative COVID

test for re-entry into the workplace (regulator or operator). During the vaccination period, the operational staff at NPPs were part of the critical infrastructure and given priority for vaccination to ensure safe operations.

The IRRS Team Leader described in general terms the response by the regulators in many countries, and information collected through surveys from different international organizations such as IAEA and IEA.

The scheduled replacement in January 2020 of desktop computers with laptops to all U.S. Nuclear Regulatory Commission (USNRC) staff, approximately two months before the pandemic, supported mandatory telework by staff.

Regarding authorization, the discussion revealed other countries used exemptions or licence extensions for specific facilities and activities.

Pakistan Nuclear Regulatory Authority (PNRA) has explained that the construction activities of two NPPs under construction by Chinese contractors in Karachi were also affected by the lockdown. The inspectors allowed to enter the plant premises were quarantined for fourteen days and then cleared the PCR tests. To cope with this condition, PNRA inspectors used to stay for three months in the plant once entered into the premises.

During the COVID-19 pandemic, PNRA performed review and assessment of Karachi-2/Karachi-3 (NPP sites) safety analysis report by observing reduced office timings and 50% of staff to work from home. Review meetings with authorized parties were conducted through video conferencing.

ÚJD SR stated that emergency exercises were not rescheduled during pandemic lockdowns.

The USNRC expert stated that a summary of all the COVID-19-related exemptions and activities were posted at NRC's website at <https://www.nrc.gov/about-nrc/covid-19/index.html>. Examples included temporary flexibilities related to licensed nuclear and radiation protection activities, i.e., emergency response exercises, periodic training, inspection plan schedule adjustments, calibration or radiation leak test requirements. Licensees still had to demonstrate that their licensed facilities and activities were still safe despite variances to the regulations that were temporarily permitted.

The Finnish regulatory body, Radiation and Nuclear Safety Authority (STUK) mentioned that they had a site emergency case (false alarm) at a NPP in December 2020. Despite the COVID-19 pandemic, both the licensee and STUK were able to start and maintain their emergency operations as planned.

STUK mentioned that two new-build projects were underway as the pandemic started. At the construction site of Olkiluoto 3, commissioning and finishing works were underway. The pandemic affected the project as some commissioning activities were postponed because foreign contractors were not allowed to access the site. STUK also mentioned that in the second project, Hanhikivi-1 project, construction licence reviews were mainly performed remotely as well as inspections, also to foreign organisations.

Participants highlighted that the role of the site inspectors during the lockdown was very important for regulatory oversight.

In Australia some states have mandated that staff be vaccinated unless it can be justified on medical grounds. The other countries also express the mandate for those who has to inspect or related with medical facilities, like the regulatory staff from the health authority in the Slovak Republic, which were forced to test every week and some were not allowed to work from home.

The Canadian Nuclear Safety Commission (CNSC) expert mentioned that nuclear power plants were identified as critical infrastructure, with CNSC inspectors as essential workers, which facilitated access to the vaccine for inspectors. It was also mentioned that when they were required to work from home when the pandemic was declared and initially there were network limitations restricting access, until tablets could be issued to all staff. Network access and regulatory oversight were prioritized to ensure safety was maintained. Other countries also expressed issues with IT platforms at the beginning experienced by most regulators.

The ÚJD SR counterpart inquired about whether regulatory bodies had lessons learned that could be applied in the future. The CNSC expert mentioned lessons learned on remote inspection practices and surveillance monitoring activities, as well as the practice of sharing and receiving lessons learned through international fora. Additionally, in response to a question from ÚVZ SR, CNSC shared that a municipal, provincial and federal working group on potassium iodide (KI) pill distribution in an emergency was considering how lessons learned on misinformation and public trust could be addressed.

The reviewer from Hungary present, commented that medical procedures not deemed essential were postponed during the pandemic, effectively halting screening programmes. This resulted in dwindling number of registered cancer patients. Due to prohibition to quit jobs in the medical sector, many people felt overburdened, leaving this profession after the prohibitions were lifted. These causes may have safety implications.

POLICY DISCUSSION: INDEPENDENCE OF THE REGULATORY BODY

In preparation for the discussion, ÚVZ SR sent to IRRS team a document providing an overview of the current situation related to the regulatory independence seen from its perspective. This document listed a series of elements, such as the composition of the regulatory body (authorities), the competences of each of these authorities, the budgetary limitations faced by ÚVZ SR and RÚVZs that could affect the effective performance of their regulatory functions and the fact that all legal documents prepared by the ÚVZ SR and respective RÚVZ SR must pass through the Ministry of Health of the SR (MZ SR) before being submitted to the government, among others.

The discussion started with a short presentation by a representative of ÚJD SR on the general concepts of regulatory independence established in both the EU Directive and the Code of Conduct on the Safety and Security of Nuclear Sources that support, in its view, the idea of an effectively independent regulatory body. It mentioned the high level of independence of ÚJD SR highlighted by IRRS mission in 2012. Regarding ÚVZ SR, it was recognized that while the MZ SR is one of the largest operators of sources, at the same time the ÚVZ SR is organizationally and financially dependent on the MZ SR. ÚVZ SR believes that requirements on independence in the European directives are met. At this point the IRRS Team Leader introduced the definition of independence of the regulatory body as stated in the IAEA Safety Standards.

After this initial exchange of ideas, some of the members of the IRRS team talked about the experiences on the topic in their respective countries. Examples were provided on the grouping of authorities in one body (Netherlands) and on separation of the regulatory body from organizations using radiation sources or promoting their use (Hungary). The example of the Dutch Authority for Nuclear Safety and Radiation Protection (ANVS) was very applicable to the present situation of the regulatory programme in the Slovak Republic presently. For instance, before the amendment of the nuclear law in the Netherlands to create ANVS there were several organizations who shared responsibility in the regulation of nuclear and radiation activities. The expert from ANVS concluded that consolidation of many of the regulatory responsibilities increased efficiency and minimized the risks of duplication or gaps in the regulatory functions.

An example was provided on a single regulatory body for all radiation sources with high degree of independence in discharging its regulatory functions (Pakistan). Finally, the Australian expert noted that the regulatory authorities within each state jurisdictions were either under the health or environmental authorities.

During the final interventions, it was recognized that the regulatory body is always part of the governmental structure, and it is never fully independent. But the effective independence means that decisions should be taken in an independent way and with no undue influences from the Government or the industry.

1.10. SUMMARY

The Government of the Slovak Republic has established a national policy and strategy as well as regulatory framework for nuclear and radiation safety. The Slovak legal framework for nuclear and radiation safety includes binding legal acts (laws, decrees) as well as non-binding guidelines (safety guides).

The Slovak legal framework covers all types of nuclear facilities, radiation activities and exposure situations. It covers all phases of nuclear facilities and sources lifetime. The Slovak regulatory framework is composed of several organizations.

Nuclear safety in the Slovak Republic is regulated by the ÚJD SR; and radiation protection is primarily regulated by the ÚVZ SR and other regulatory authorities as mandated by the Act on Radiation Protection. There are also other regulatory bodies involved in the regulation of nuclear facilities and facilities with radiation sources (e.g., area of off-site emergency preparedness).

Some deficiencies are highlighted in the coordination between different regulatory authorities including duplication in responsibilities regarding nuclear and radiation safety.

The IRRS team recommended that the effectiveness of the regulatory framework should be further enhanced by the effective arrangements for cooperation among regulatory authorities.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

The Government of the Slovak Republic has expressed their political commitment in the application of the code of conduct on safety and security of radioactive sources (Code). However, the IRRS team was informed that no political commitment has been yet expressed on the supplementary guidance on the Import and Export of Radioactive Sources to provide for an adequate transfer of responsibility when a source is being transferred from the Slovak State to another and to the Guidance on the Management of Disused Radioactive Sources regarding the establishment of a national policy and strategy for the management of disused sources, and on the implementation of management options such as recycling and reuse, long term storage pending disposal and return to a supplier.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Although the Government of the Slovak Republic has provided a commitment to the Code of Conduct on Safety and Security of Radioactive Sources, no written political commitment has been sent to the IAEA's Director General for the supplementary Guidance on Import and Export of Radioactive sources and Guidance on the Management of Disused radioactive sources.*

(1)	<p>BASIS: GSR Part 1 (Rev. 1) Requirement 14, para. 3.2 states that <i>“The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation and assistance to enhance safety globally.</i></p> <p><i>3.2. The features of the global safety regime include:</i></p> <p><i>(b) Codes of conduct that promote the adoption of good practices in the relevant facilities and activities...”.</i></p>
(2)	<p>BASIS: Code of Conduct on Safety and Security of Radioactive Sources para. 31 states that <i>“Every State should, as appropriate, inform persons involved in the management of radioactive sources, such as industry, health professionals, and government bodies, and the public, of the measures it has taken to implement this Code, and should take steps to disseminate that information”.</i></p>
R6	<p>Recommendation: The Government should express the political commitment to the supplementary guidance on Import and Export of Radioactive sources and Guidance on the Management of Disused radioactive sources.</p>

The legal framework for the fulfilment of commitments of the Slovak Republic arising from international agreements concerning nuclear safety of nuclear installations and management of nuclear materials is laid down in Section 29 (2) of Act No. 575/2001 Coll. on the Organization of Government Activities and the Organization of the Central State Administration. Section 4 (1) (f) and (g) of the Atomic Act further specifies that ÚJD SR shall ensure international cooperation in the areas falling within the scope of the Atomic Act.

According to para 5 letter a) of Act No. 87/2018 Coll. the Ministry of Health of the Slovak Republic coordinates cooperation of central authorities of state administration and international cooperation in the area of radiation protection.

ÚVZ SR is a contact point for communication with the regulatory authorities in radiation protection of other Member States and it is responsible for international cooperation with international and European organizations.

The Slovak Republic participates in all relevant international arrangements for enhancement of nuclear safety globally.

The Slovak Republic has been actively participating in the international nuclear and radiation safety and peer reviews. Since its foundation, Slovak Republic has hosted or invited tens of various peer review services including OSART, IRRS/IRRT, TSR, ORPAS or ARTEMIS. The experts from ÚJD SR and ÚVZ SR participate regularly as members of the mission teams abroad.

The IRRS team concluded that the Government of the Slovak Republic effectively fulfils their international obligations, participates in the relevant international arrangements, including international peer reviews, and promotes international cooperation to enhance safety globally.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

There are legal requirements in place in the Slovak Republic requiring the licensee to establish and implement an operating experience feedback programme. There are also requirements in place to draw lessons and improve after operating experience feedback analysis.

ÚJD SR participates in a number of international activities where nuclear safety operational events and related data is collected and disseminated. They also contribute information about events in the Slovak Republic to the IRS database. Any relevant information is reviewed by the specialists, who present findings at regular meetings of the special board. At regular intervals, foreign operating experience is shared with all ÚJD SR inspectors.

Representatives of ÚVZ SR are delegated responsibilities for specific areas in bodies of international institutions where they represent the Slovak Republic and thus contribute with their expertise to increase health quality, strengthen diseases prevention and fight against health risks and health protection of EU citizens and radiation protection.

There are several authorities with regulatory oversight responsibilities of the authorized parties and facilities involved in the scope of transport as defined in SSR-6 (Rev. 1). It is therefore considered necessary for all Ministries and Authorities who issue authorizations and/or conduct inspections for the transport of nuclear radioactive material or radioactive material, to consider routinely informing each other of their inspection findings, authorizations issued, and enforcement actions taken; this should also include the Police and Border Officials and authorities responsible for conventional safety. Furthermore, to improve the effectiveness of the information exchange, consideration should be given to convening meetings on a regular basis between all the aforementioned entities.

2.3. SUMMARY

Both ÚJD SR and ÚVZ SR contribute to the effort of the Slovak Republic to fulfil its respective international obligations, in the relevant international arrangements. ÚJD SR and ÚVZ SR have a strong presence at international level and gain significant feedback experience from this to manage their own organisation.

The IRRS team concluded that both ÚJD SR and ÚVZ SR are active contributors to the global nuclear safety regime. The value of international exchange of information and experience is also well recognized. Compliance with the relevant IAEA standards (requirements) and international undertakings is observed.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

Authorities and fields of competence for ÚJD SR are based on Act No. 541/2004 Coll. on Peaceful Uses of Nuclear Energy (Atomic Act). As the ÚJD SR is the authority for nuclear safety, including management of radioactive waste and spent fuel and other phases of fuel cycle, it is responsible for nuclear materials control and registration, as well as for physical protection of nuclear installations and nuclear materials. ÚJD SR assesses applicant requests for use of nuclear energy, quality of safety-related equipment, instruments used in nuclear technology, and fulfils the Slovak Republic's international nuclear safety treaties obligations for nuclear installations and management of nuclear materials. ÚJD SR performs state supervision over nuclear safety of nuclear installations in order to demonstrate to the public and the international community that nuclear safety is assured in all aspects of the use of nuclear energy.

ÚJD SR is an independent authority and reports directly to the Government of the Slovak Republic. ÚJD SR uses human and financial resources necessary for the fulfilment of obligations under the Atomic Act in accordance with the resources allocated from the State budget. ÚJD SR is headed by a chairperson appointed by the Government, and the chairperson reports the performance of his/her duties directly to the Government. The responsibilities assigned by the law to the ÚJD SR are indicated in the Quality Manual (S 500 006_21), for each function of their organizational chart. Responsibilities and regulatory authority of the organizational units and the staff of ÚJD SR are listed in the following documents: organizational requirements of ÚJD SR, ÚJD SR staff requirements, and internal procedures of ÚJD SR.

Related to the financial resources of the regulatory body, the State budget is organizationally arranged into chapters (lines in the budget). ÚJD SR as a central administration body has its own chapter within the State budget and is budgetary independent from other administrative bodies and entities.

According to the Act on Radiation Protection, in the field of radiation protection, state administration is performed by various State administration authorities: MZ SR, ÚVZ SR, RÚVZ BA, RÚVZ BB, RÚVZ NR, RÚVZ KE, MDV SR, Ministry of Defence of the Slovak Republic, MV SR and the Slovak Information Service.

ÚVZ SR, as the Radiation Protection Authority, is the regulatory authority that is responsible for the approval and authorization of practices leading to occupational or public exposures from: nuclear installations; management of spent nuclear fuel; management of radioactive waste; authorized release (within regulatory limits) of radioactive substances and effluents; and any radioactive contaminated objects that have been created or are used in activities leading to exposure.

The Radiation Protection Department is part of the ÚVZ SR Section of Protection and Promotion of Health in the area of Living and Working Environment from the ÚVZ SR.

The ÚVZ SR is funded by MZ SR with responsibilities in the territory of the Slovak Republic. The ÚVZ SR is managed by the Chief Public Health Officer of the Slovak Republic who is also the Director of ÚVZ SR. The Director is appointed by Minister of Health. ÚVZ SR's budget is dependent upon the allowed budget from MZ SR. The Radiation Protection Department is one of the departments of ÚVZ SR.

ÚVZ SR is responsible for managing the National Radiation Monitoring Network. Accordingly, ÚVZ SR monitors the ambient radiation conditions, collects and processes data on the results of monitoring in the Slovak Republic for evaluation of potential exposure, and performs assessment of the impact of radiation on the health of population. ÚVZ SR is required to recommend the reference levels to optimize exposure in an emergency situation or for long-term exposures in existing exposure situations, and determines the conditions for transition from emergency situation to the existing exposure situation, including transition to recovery.

In 2021, the radiation protection authorities from, ÚVZ SR and RÚVZs, had approximately 70 employees. The decision-making process together with the distribution of responsibilities between ÚVZ SR and RÚVZs are provided in the Act on Radiation Protection and the resources are allocated according to preestablished rules, identified needs, and appropriated State budgets.

The ÚVZ SR has the following main responsibilities:

- issues notifications, registrations and authorizations,
- conducts State supervision,
- maintains the following registries:
 - National Registry of Doses
 - National Registry of Sources of Ionizing Radiation
 - National Registry of Radiation Protection Officers (RPOs)
 - National Registry of Radiation Protection Experts (RPE)
 - National Radiation Monitoring Network
- provides expert guidance, information, dose assessment and cooperation, contact point and National Focal Point for international organizations, European Commission, and other member states in radiation protection.

The state administration in the field of radiation protection is carried out by the ÚVZ SR through its Radiation Protection Department that comprises 23 staff and is enforced through four RÚVZ SR located in Bratislava, Banská Bystrica, Košice, and Nitra. ÚVZ SR has the following structure:

- Nuclear Fuel Cycle and Radioactive Waste Management
- Radioactive Sources used in Medicine, Industry, Education, Research, etc.
- Natural Sources of Ionizing Radiation
- Assessment and Evaluation of Exposure and Associated Health Risks
- Registry of Doses and Radioactive Sources
- Environmental Monitoring, Emergency Preparedness, and Response.

The Ministry of Labour, Social Affairs and Family of SR manages and controls the NIP. The NIP manages and controls labour inspectorates and is responsible to unify and rationalise working methods of the labour inspectors. The IP NR supervises the compliance with laws and other regulations to ensure occupational health and safety at the workplaces of nuclear and radiation protection installations in the Slovak Republic and is responsible for performance of labour inspection.

MV SR, the responsible coordinating body for civil protection, is the National Contact point for emergency notifications. MV SR is responsible for: implementation of protective actions recommended by ÚVZ SR and ÚJD SR; civil protection measures during the threat or occurrence of a radiological accident and providing the public overall direction and assistance in the event of a nuclear accident or radiological emergency. As stated in Module 10, in the event of a nuclear incident or accident, the operator must immediately notify MV SR, ÚJD SR, UVZ SR and other governmental bodies.

The ÚJD SR's management system has been developed using a graded approach. The basis for this graded approach in ÚJD SR activities is formally required by the Atomic Act and is incorporated into the internal regulatory documents. Specific criteria are found in generally binding legal documents, safety guides, and in the ÚJD SR procedures. The overall responsibility of how to apply these processes resides with ÚJD SR.

The Atomic Act, the Act on Radiation Protection and related decrees set strict requirements for what the regulatory authority must approve, or provide authorization for, regardless of the actual risk associated with the request. This has led to a relatively large number of approvals for matters that are not necessarily of great safety importance which ÚJD SR has noticed and has started measures to improve it. Neither ÚJD SR's nor ÚVZ SR's internal procedures for review, assessment or inspection practices provide guidance as to how to apply the graded approach. However, ÚJD SR has requirements on graded approach in the decrees and some guidelines.

Although ÚVZ SR develops an annual inspection list for some activities, the IRRS team noted that ÚVZ SR does not have processes or internal guidance to develop and implement the programme of inspection in accordance with a graded approach. Additionally, ÚVZ SR does not regularly conduct or plan unannounced inspections.

The IRRS team observed that ÚVZ SR lacks a documented process to be used and followed during each emergency response and preparedness (EPR) inspection that would describe the inspection process criteria, from the decision to initiate an inspection (reactive or programmed), through to the follow-up stage, which would include criteria for a graded approach based on the risk posed by the radiation facilities and sources. No guidance for the application of graded approach exists in the framework, nor have written inspection instructions been developed. Separately, although ÚJD SR stated that they do have specific details in the legislation and regulation that serve as guidance for

its annually planned inspection programme, written procedures for determining a graded approach for these inspections have not been developed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Some of the regulatory functions for nuclear and radiation safety are not commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach.*

(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 19 states that: <i>“The performance of regulatory functions shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach”.</i>
(2)	BASIS: GSR Part 1 (Rev. 1) para 4.3 states that: <i>“The objective of regulatory functions is the verification and assessment of safety in compliance with regulatory requirements. The performance of regulatory functions shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach”.</i>
S3	Suggestion: The regulatory body should consider ensuring that the performance of the regulatory functions is commensurate with the magnitude of the radiation risks arising from facilities and activities. The graded approach takes into account any exposures to radiation, in normal operation, anticipated operational occurrences and accident conditions, as well as the possibility of events with a very low probability of occurrence.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

Functional separation of ÚJD SR is based on the Atomic Act and the Chairperson of ÚJD SR reports to the Government on the performance of his/her function. Annually on or about 30 April, ÚJD SR must present to the National Council of the Slovak Republic a report on the status of nuclear safety of nuclear installations in the Slovak Republic activities for the past year. ÚJD SR has a separate budget, which is connected by its revenues and expenditures to the state budget of the Slovak Republic. The chairperson of ÚJD SR can make informed decisions without the need of consent or approval of any other body or organization and is therefore independent in its decision making. The Statute of ÚJD SR provides details on the scope of powers, tasks, responsibilities of activity, internal organization of ÚJD SR, and its relations with ministries, other central state administration bodies, and other organizations.

ÚVZ SR, as radiation protection authority, is functionally dependent on the MZ SR.

ÚVZ SR’s staff are considered civil servants who must follow the requirements that are documented in the Civil Service Act, Code of Ethics for Civil Servants, and internal ÚVZ SR staff rules.

ÚJD SR, ÚVZ SR and NIP have their own internal procedures for development of the personnel application process when selecting civil servants. There is a limitation on the interchange between the executive staff of the nuclear industry and the regulators, which is addressed in the Constitutional Act No. 357/2004 Coll. and the Act No. 55/2017 Coll.

ÚJD SR can use external expertise, and scientific and technical resources to support its regulatory functions. Provisions on preventing the conflict of interest are presented in the internal public procurement procedure (Code S 120 048: 22) and is based on the Act No. 343/2015 Coll.

Any employee of the public authorities of the Slovak Republic must follow State regulations such as the Act on Civil Service. According to these regulations, a civil servant has to perform the civil service in a politically neutral and impartial manner. Moreover, a civil servant is obliged to notify their administrative office without undue delay of any actual or potential conflict of interest, as well as of teaching or lecturing activities that are identical or similar to the activity specified in the description of their civil service position. According to the same act, a civil servant cannot conduct business or perform any other gainful activity, which is identical or similar to the activity specified in the description of his/her civil service position. The Code of Ethics for civil servants defines the principles of ethical

behaviour when performing public service. The principles for preventing and resolving conflict of interest situations for ÚJD SR are implemented in the Quality Manual: Chapter 2.6 Civil Servant Ethics, and 2.7 Impartiality in the Decision-making.

The ÚJD SR document, "Directive determining the details of the training of employees of the Nuclear Regulatory Authority of the Slovak Republic," (S 401 040:22) establishes the details of the training of civil servants and employees in the performance of work in the public interest.

ÚVZ SR follows the rules applicable to all state administration: Act No. 55/2017 Coll. on Civil Service; Act No. 552/2003 Coll. on Service in Public Interest in the field of conflict of interest; and the Code of Ethics, document code VD-04, updated in 2020.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

The document "Policies, principles and strategies for further development of nuclear safety" establishes as a permanent task the commitment within the Slovak educational programmes of secondary schools and universities to support scientific and technical orientations supporting research, development and use of nuclear energy for the benefit of society and to provide training for new professionals.

Recruitment and training of staff of the regulatory bodies are defined in the Act on Civil Service. ÚJD SR, ÚVZ SR, and NIP have their own internal procedures for recruitment of civil servants. ÚJD SR may also use external scientific and technical resources and expertise to support its regulatory functions. The recruitment process is conducted in accordance with the legal requirement applicable to civil servants and internal procedures.

ÚJD SR has an annually approved plan of continuous education and training of all employees. As of 31 December 2021, ÚJD SR had 118 employees with a budgeted total number of 125 employees. Of this number, 110 were civil service positions and 15 employees worked in public interest areas and from 2022, ÚJD SR has increased the total number of its employees to 130.

From 2015-2016, ÚJD SR conducted a competence analysis (knowledge, skills and abilities) for each position under its purview that is related to the licensing, review, assessment, and control of nuclear installations. All individuals' performance at ÚJD SR is evaluated on a yearly basis and each evaluation is performed by the direct supervisor, taking into account the results of the competency analysis. ÚJD SR's personnel office keeps records of individual's performance and maintains these records until retirement. The IRRS team identifies the competence analysis as a **good performance**.

ÚVZ SR, together with RÚVZs, has up to 70 employees that are responsible for radiation protection activities in 2020. Currently, there are only 55 people employed by the radiation protection departments at ÚVZ SR and RÚVZs. From this total, 22 are from Radiation Protection Department of the ÚVZ SR. The Labour Inspectorate Nitra (IP NR) has 14 employees.

Currently, the activities implemented for the development and maintenance of the necessary competence and skills of staff of the regulatory body, ÚVZ SR, are set in the framework of the ÚVZ SR programme on training and consist mainly of training and individual plans for competencies and evaluation of individuals. Based on the catalogue of training requirements from Ministry of Health of the SR, for each position hired, qualification criteria, duties and responsibility for each specific type of job are established. This document is not tailored for the specific needs of the Radiation Protection Department. Within ÚVZ SR and respective RÚVZs, training of staff is bound by the MZ SR rules and procedures which are not specifically tailored to the scope of performing regulatory functions (e.g., licensing, inspection, and enforcement) in the field of radiation safety. Similar resource concerns have been observed for MDV SR. There are four staff in MDV SR, three of which are inspectors with responsibility for transport safety who oversee several thousand shipments of radioactive material each year.

In addition, the IRRS team was informed that financial resources of ÚVZ SR, RÚVZs and MDV SR are insufficient and have impacted the ability of both authorities to: recruit new staff; purchase equipment; provide training, consider and conduct new activities; use external scientific and technical expertise when needed; and participate in national and international forums.

Since the declaration of the COVID-19 pandemic, three out of five ÚVZ SR inspectors responsible for oversight of NPPs have left work for other external (non-governmental) positions (e.g., licensees). ÚVZ SR does not have a formal knowledge management process that could assist in limiting the impact of inspectors leaving the ÚVZ SR. It was noted that the current financial and human resources have been insufficient to ensure all planned inspections are conducted, but the limited financial and human resources may inhibit the ability of ÚVZ SR to properly train or conduct reactive and unplanned inspections.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *ÚVZ SR, its respective RÚVZ SR, and MDV SR, do not have a human resources plan to have an adequate number of appropriately qualified and competent staff to effectively perform their regulatory functions.*

(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 18, para. 4.11 states that <i>“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”.</i>
(2)	BASIS: GSR Part 1 (Rev. 1) Requirement 18, para. 4.12 states that <i>“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”.</i>
R7	Recommendation: The ÚVZ SR, RÚVZs and MDV SR should develop and implement a human resources plan to have an adequate number of appropriately qualified and competent staff to effectively perform their regulatory functions.

Inspectors of ÚVZ SR/RÚVZs and MDV SR perform their inspections according to the Act on Radiation Protection. Their education and training include passing a training course, on the Act on Radiation Protection and on-the-job training, however there is no formal programme to ensure inspectors have the necessary competences. Education of the inspectors however is decided on the basis of their education, experience and expertise.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Within ÚVZ SR, RÚVZ SR and MDV SR, the training programme does not provide the necessary knowledge, skills and abilities relevant to radiation safety to perform their regulatory functions.*

(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 18, para. 4.11 states that <i>“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”.</i>
(2)	BASIS: GSR Part 1 (Rev. 1) Requirement 18, para. 4.13 states that <i>“A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills. The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements”.</i>
R8	Recommendation: ÚVZ SR, RÚVZ SR and MDV SR should ensure that the existing staff training programme includes the necessary knowledge, skills and abilities in radiation safety to perform the regulatory functions.

ÚJD SR has defined its Knowledge Management programme as a management process and has in place a Strategy of Knowledge Management through 2024. The scope of this strategy is to fulfil the competencies through qualified personnel and the preservation and development of its knowledge. Currently, ÚJD SR is running a project “Implementation of Knowledge Management”, to ensure that knowledge between experienced and less-experienced regulator’s staff is transferred and to maintain critical knowledge within the regulatory authority. There are currently provisions related Knowledge management in the Quality Manual and associated procedure.

For the NIP and MDV SR, there is no formal process of knowledge management implemented, however, there are measures in place for preserving the organizational data in the form of a database.

Within ÚVZ SR, a formal process has not yet been established that would ensure that knowledge relevant for the activities of the regulatory body is acquired, stored, preserved, distributed and managed as a resource of the regulatory body. The document management system within ÚVZ SR and respective RÚVZ SR should support all activities related to the information management processes, knowledge management processes and competence management processes.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *ÚVZ SR and respective RÚVZ SR have not developed a process of knowledge management that would maintain the necessary competence and skills of staff of the regulatory body.*

(1)

BASIS: BASIS: GSR Part 1 (Rev. 1) Requirement 18, para. 4.13 states that “A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management”.

R9

Recommendation: ÚVZ SR and respective RÚVZs should develop and implement a process for knowledge management that will ensure that knowledge relevant for the activities of the regulatory body is acquired and retained.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

In order to provide technical support to the ÚJD SR decision making process, different advisory bodies and/or committees have been formed. The establishment of such advisory bodies is specified in the Statute of ÚJD SR in article 5. This Statute entitles the Chairperson of ÚJD SR to establish advisory bodies to evaluate and resolve important questions related to regulatory duties with the aim to ensure fulfilment of essential tasks. Until now, ÚJD SR has established one permanent advisory body, the ÚJD SR Council for Nuclear Safety. This body advises the head of ÚJD SR in the matters of nuclear safety and state supervision over the nuclear installations as well as its assessment. Except for ÚJD SR Chairperson and council secretary, the Council for Nuclear Safety is composed of external experts coming from the Academy of Science, universities, research institutions, industries, finance, and partner regulatory bodies, and cannot be from companies regulated by ÚJD SR or institutions owned by regulated companies. When needed, the ÚJD SR Council for Nuclear Safety can form working groups from within its members and/or ad hoc invited specialists to resolve very specific problems. Resulting positions and recommendations are submitted to the Council. In such cases, invited ad hoc specialists may be invited to work on temporary basis. In some cases, specific temporary advisory bodies assist in solving specific tasks, e.g., the Chairperson's Advisory Committee on commissioning of the new unit of the Mochovce Nuclear Power Plant. The selection of technical organizations and consultants for ÚJD SR support is governed by the rules used in the public procurement process. Purchasing for these ÚJD SR activities (including technical support) is outlined in the Quality Manual (Chapter 8.3.4) and relevant management system procedures. Communication with foreign organizations to get technical support for ÚJD SR is described in the Quality Manual (Chapter 8.3.2 or 7.3.4.2). Principles for the selection of experts for Chairperson's advisory bodies are provided in the document Statute of bodies.

The Act No. 343/2015 Coll. on public procurement defines a conflict of interest as a situation in which an involved person, who may influence the outcome or conduct of a public procurement, has a direct or indirect financial, economic or other personal interest, which could be considered as a threat to his/her impartiality and independence in relation to public procurement.

ÚJD SR has access to technical or other expert professional advice or services as necessary in support of its regulatory functions, but the final responsibility of the decision-making process remains with ÚJD SR. Some forms of external support require a formal contract between ÚJD SR and the provider of services according to procedure on the preparation, assessment and monitoring of the performance of contracts (S 500 002:21). In certain specific cases, when ÚJD SR does not have the required technical-analytical expertise to support the decision-making process, it uses technical support from various organizations such as research institutes, academic organizations operating in the Slovak Republic, and also from abroad. ÚJD SR's internal procedure on public procurement requires possible conflicts of interest to be taken into account when obtaining external technical support. However, the use of external technical assistance and advice does not release ÚJD SR from liability in the performance of regulatory activities and in issuing decisions towards licensees.

ÚVZ SR has an advisory council lead by the chair of the Main Adviser on Radiation Protection in the Slovak Republic that provides advice in the field of radiation protection to the Director of ÚVZ SR. The members of this advisory bare ÚVZ SR and RÚVZ SR representatives.

According to article 87 art. 46 from the Act on Radiation Protection, an examination committee is established for providing exams for radiation protection officers. The statute of the Examination Board, document code PO-06 / 2018, establishes, in Chapter 3.2, providing of the rules for the composition and activity of examination group for radiation protection experts and is comprised of only ÚVZ SR staff. Examination committees are established for examining radiation protection experts, according to document code PO-13. The document establishes that these examination committees are composed of three independent external specialists, each with at least 10 years of experience.

RÚVZs SR use a dosimetry service as well as some services for measuring and testing devices, including metrological services. Some of these services are provided by external authorizations that are licensed by ÚVZ SR. Special consideration is not given when using the services of the organizations licensed by ÚVZ SR.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

The decision-making process is a formal regulatory process required by the regulatory requirements related to nuclear safety, radiological protection, physical protection, quality assurance, or emergency preparedness. The regulatory process of issuing an authorization in the field of nuclear energy is governed by the provisions of the Atomic Act, pursuant to the Administrative Procedure Code.

The communications between ÚJD SR and the licensees is established and described in the Quality Manual and internal procedures. The communication with the interested parties is also governed by the Communication Strategy and are used several communication channels such as: official notice board stationed at the entrance to ÚJD SR headquarters, official notice board in the adjacent municipalities to respective nuclear installations, electronic notice board located on ÚJD SR web page, as well as on the Central Public Administration Portal at www.slovensko.sk. One of the main objectives of the commitments of ÚJD SR established under the Quality Policy, annex 1 of the Quality manual, is "Open communication with the stakeholders including licensees". Chapter 7.3.4.2 External communication from the quality manual describes communication with regulated entities and with other bodies of state and public administration, other external communication as well as communication with foreign organizations.

Regarding the activity of ÚVZ SR, the formal communication channel consists of various forms of notification as obligations for the entrepreneur, employer of external staff, legal person who performs registered activity leading to exposure, licensee, etc. Informal communication channel consists of information network based on phone numbers and e-mail addresses.

The decisions issued by the Regulatory Authorities are based on internal established rules, like ÚJD SR – Procedure on Issuance of Decision by ÚJD SR and / or legal requirements, and Act on Administrative Procedure No. 71/1967 Coll. for issuing any decision. When issuing authorization or registration, ÚVZ SR provides the legal basis based on which the document was issued.

According to Act No. 125/2006 Coll. on labour inspection, the labour inspector is obliged to discuss their findings from the inspection with the employer. The methodology for the performance of labour inspection implies the obligation to invite also employee representatives to discuss the results.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

The safety regulatory authorities have defined policies, principles, criteria, and safety objectives for implementation of the main activities and responsibilities assigned to them by the national and international framework.

In the decision-making process, the regulatory bodies use the same common legislation - Administrative Procedure Code, and Act on drafting of legislation and on the Collection of Laws, which sets the rules for drafting and preparation of generally binding legal requirements.

At the same time, all governmental organizations must apply the principles of ethical behaviour, as mentioned in the Code of Ethics for civil servants, to include: political neutrality, impartiality, public interest, dignity and respect in interpersonal relationships, and professionalism.

The ministries and other government bodies may issue generally binding legal regulations if they are empowered to do so by law, therefore ministries and other central government bodies have to ensure that matters falling within their competence are properly regulated. The process of issuance of laws and regulations is a flexible process that allows all interested parties to participate.

Act on the organization of government activities and the organization of the central state administration, indicates that the Government Office of the Slovak Republic provides legislative activities for other central state administration bodies related to preparation and approval of constitutional laws, laws and other generally binding legal regulations.

3.7. SAFETY RELATED RECORDS

ÚJD SR has established and maintains the following main registers and inventories:

1. Records relating to the safety of facilities and activities (e.g., ÚJD SR Groups of Event Analysis);
2. Records that might be necessary for the shutdown and decommissioning (or closure) of facilities;
3. Records of events, including non-routine releases of radioactive material to the environment;
4. Inventories of radioactive waste and of spent fuel.

ÚVZ SR has established and maintains the following main central registers, databases, and inventories:

1. Central registry of sources of ionizing radiation (including radiation sources, RTG devices, accelerators, unsealed sources, etc.);
2. Central registry of doses (monitored workers of Category A and B);
3. National register of radiation protection officers;
4. National register of radiation protection experts;
5. National register of operators of sources of ionizing radiation;
6. National register of technical service providers (dosimetry services, testing services, calibration services, etc.);
7. National register of operators of workplaces with increased exposure to natural sources of ionizing radiation;
8. Information system on monitoring of radiation situation;
9. Register of approved types of sources of ionizing radiation;
10. Register of approved types of consumer products with added radionuclide;
11. Database of results of measurements of volume activity of radon at the workplace, in dwellings and results of assessments of radon index;
12. Database of results of measurements of radiological indicators of quality of drinking water and radiological indicators in construction material;
13. Records of events, incidents, and accidents, including non-routine releases of radioactive material to the environment;
14. Records of radioactive wastes produced and spent fuel stored.

MDV SR has established and maintains the following main central registers, databases, and inventories:

1. Central register of holders of authorizations for transport of radioactive material;
2. Central register of notifications on transport of radioactive material;

3. Central register of approved packages for transport of radioactive material;
4. Central register of radiation protection officers for transport of radioactive material;
5. National register of doses of air crew members due to cosmic radiation exposure.

Records and documentation are managed and used in accordance with the principles of registration and archiving, required by the Act on Archives and Registries and detailed in the internal procedures of the regulatory bodies. For the other authorities, NIP and MŽP SR, there are internal procedures in place that describe the management of internal documents, that observe the national regulatory framework.

Safety related records stored by licensee are controlled, analysed, and evaluated by regulatory body during inspection activity. The types of records that the licensee has to maintain are indicated in the Atomic Act, Act on Radiation Protection and decrees (Decree No. 430/2011 Coll. on nuclear safety requirements and Decree No. 431/2011 Coll. on a quality management system).

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

The ÚJD SR Public Communication Strategy (2019-2023) sets the general framework for communication process with the interested parties. The objective of communication with the public is to inform the domestic and foreign public about the activities under the competence of the regulatory body and to build public confidence in the activities of the ÚJD SR. The strategy identifies objective and means to achieve the objectives and provides the principles of communication with the public. The strategy also identifies interested parties, the target groups – general public, media, stakeholders and employees of ÚJD SR. There are in place communication plans elaborated for specific time periods.

According to this Strategy, the key target group of ÚJD SR communication are citizens of the Slovak Republic, mainly those from regions with nuclear installations. In order to reach this target group, ÚJD SR organizes press conferences, compiles and disseminates annual reports, leaflets, articles, issues press releases, publishes news on its website, and posts information on its Facebook page. ÚJD SR also has a special e-mail address that enables members of the public to send questions. ÚJD SR also communicates with the public in the vicinity of the nuclear installations through organizing meetings with representatives of local authorities and public, participation in sessions of civic information committees, or organizing lectures allowing face-to-face discussions.

The public communications activities of ÚVZ SR are governed by the rules on public communication, department of communication within the Section of International Relations and Communication. The department of communication uses communication rules, document code SM-11 and communication rules for emergency situations document code SM-36. The mentioned documents only include general guidelines and are not tailored to specific activities under the responsibility of the Radiation protection department and do not detail the communication obligations that are required by the Act on Radiation Protection. This document does not take into account the specific communication responsibilities from the Act on Radiation Protection nor the interfaces that should be used when working together with ÚJD SR.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: ÚVZ SR does not have a public communication strategy, specifically tailored to the activities of the radiation protection department and does not provide for interface with other authorities.

(1)	BASIS: GSG-6 para 4.3 states that “A communication strategy appropriate for the role and functions of the regulatory body should be developed and implemented. This strategy should be integrated within the overall strategy of the regulatory body”.
(2)	BASIS: GSG-6 para. 4.32 states that “The communication and consultation process should be flexible enough so that specific communication plans can be tailored to target audiences, depending on the types of interested party that are involved in a particular issue, facility or activity”.
S4	Suggestion: ÚVZ SR should consider preparing a public communication strategy, specifically

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

tailored to the activities of the radiation protection department, taking into account interfaces with other authorities.

ÚJD SR publishes on its internet site laws and regulations in the field of nuclear safety, related legislation, the full text of safety guides and reports as they relate to nuclear safety of nuclear installations in the Slovak Republic, and all ÚJD SR decisions. Information on the ÚJD SR administrative proceedings and decisions are published also on the Official Electronic Notice Board of ÚJD SR, or on the Central Official Electronic Board (CUET) of Central Portal of Public Administration (www.slovensko.sk) and when appropriate, also on the Official Boards of the communities in the vicinity of the nuclear installations. The communication with the public is performed by participating in the local Civic Information Committees. Regarding the activities regulated by ÚVZ SR, all the operators must inform the public about radiation risks and radiation situation, about production of radioactive waste and impact on the population and the environment, using information centre, periodical leaflets, journals, brochures and leaflets, websites of licensees, social media or through regular meetings of the members of the Civic Information Committees.

The competent authority for the assessment of transboundary environmental impacts within the Slovak Republic is the MŽP SR.

The Atomic Act establishes that the regulatory body must ensure that authorized parties inform the public about possible radiation risks associated with their facilities and activities. According to the Atomic Act, the licensee has to inform ÚJD SR on events in the operated nuclear installations and in case of incident or accident has the obligation of informing the public.

3.9. SUMMARY

The structures of the ÚJD SR and ÚVZ SR are established with the scope of fulfilling the responsibilities set by the regulatory framework. However, some regulatory functions for nuclear and radiation safety are not commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach

The national legislation, as well as internal procedures and rules of ÚJD SR and ÚVZ SR provide requirements to ensure the independence in performing the regulatory functions, from the point of view of preventing a potential conflict of interest.

Within ÚJD SR there is a stable number of staff that is provided with a continuous training programme, based on competency analysis. However, within ÚVZ SR and respective RÚVZs, there is not implemented a human resource plan. The ÚVZ SR training programme is not tailored so as to ensure the necessary knowledge, skills and abilities for the staff to perform the assigned regulatory functions. In the same manner, ÚVZ SR has not implemented a knowledge management process that could be useful in maintaining the necessary skills of the staff.

In the management activities related to public communication, ÚJD SR uses a public communication strategy and communication plans. ÚVZ SR fulfils its responsibility of communicating, as indicated in the Act on Radiation Protection, using the rules of the ÚVZ SR on public communication. The framework set by the ÚVZ SR is not tailored as per the specific issues on radiation safety and does not include interfaces with ÚJD SR.

4. MANAGEMENT OF THE REGULATORY BODY

4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

The strategic safety goals and objectives of the Slovak Republic are summarised in the “Policy, Principles and Strategy for Further Development of Nuclear Safety”. The strategic plan, and the main tasks to ensure the enhancement of nuclear safety are based on sixteen actions involving nine institutions.

ÚJD SR and ÚVZ SR, the main regulatory authorities for nuclear and radioactive activities and facilities, operate independently and have developed separate quality management documentation. Most of the information included in the ARM and Self-Assessment is related to ÚJD SR. During the mission, the IRRS team gathered information from the other regulatory authorities, especially from the ÚVZ SR.

The mission, vision, and values of ÚJD SR are established in the Quality Manual (S-500 006:21) which states that “safety is paramount, overriding all other demands”. The ÚJD SR aims at providing a framework for individual and organizational expectations. ÚJD SR strategies, with goals, objectives, and plans, are part of the management system documentation and are reviewed every year.

ÚVZ SR has also established a Quality Manual that is binding for all employees. This manual contains the “Strategic Health Care Framework for 2014-2030”, which does not specifically align with the activities of the ÚVZ SR in the field of radiation protection.

4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

ÚJD SR has established, implemented, and is continually improving their management system, based on standard ISO 9001:2015 and IAEA Safety Standard Series GSR Part 2 (Leadership and Management for Safety). Additionally, the requirements of standard ISO 9004:2018 have been partially applied.

The ÚJD SR’s management system includes national provisions of generally binding legal documents on such activities as occupational health and safety, fire protection, risk management, public procurement, public information, financing and accounting, information security and cyber security and anti-corruption activities.

The senior management is responsible for establishing organizational policies, objectives/goals, strategies, and plans that set out principles, rules, and expectations to guide the direction of the work and management system development. ÚJD SR has established a “Board for the Management System” which represents an internal advisory body for the Chairperson.

The Plan-Do-Check-Act (PDCA) cycle approach is implemented in the ÚJD SR management system to ensure that the processes and activities are planned, controlled, and improved.

The IRRS team noticed that no provisions for the integration of safety into a management system exist for ÚVZ SR, due to the lack of a management system as explained in Section 4.3.

4.3. THE MANAGEMENT SYSTEM

ÚJD SR has developed and implemented an integrated management system, aligned with its safety goals. This management system integrates different elements, including safety, health, environmental-, security-, quality-, human-and organizational-factors, societal, and economic elements, so that safety is not compromised. Regulatory requirements and guidance are defined within the management system as part of the regulatory framework and include decrees, safety guides, decisions, decision conditions, formal letters, etc.

The ÚJD SR Quality Manual specifies the organizational structure, responsibilities and accountabilities at different levels of the organization. The processes have their owners, who are responsible for their management, monitoring, review, and improvement of their efficiency.

ÚJD SR is responsible for establishing, applying, sustaining, and continuously improving the management system to ensure safety. The management system is periodically reviewed, and the report is submitted to the ÚJD SR Board for the Management System before its approval by the Chairman.

ÚJD SR staff members shall ensure that their decision-making is objective, impartial and that the adopted solution is always consistent with the public interest and applicable legislation. The approach is based on generally binding legal documents and international agreements.

Arrangements are established in the management system for an independent review before significant decisions related to safety are made. Where there is a need for resolution of conflicts arising in decision-making processes, the ÚJD SR applies a policy concerning internal communication among the parties and experts as a first approach.

The ÚJD SR management system is required to be developed and implemented using a graded approach. Criteria for the application of graded approach is documented in the Quality Manual but the responsibility for the application of graded approach lies on the judgement of the process owners.

The management system documentation includes, among others:

- the policy statement on safety
- a description of the structure, functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing, and assessing work
- a description of the core and support processes and supporting information
- a description of how the management system follows regulatory requirements

ÚJD SR develops, maintains, and preserves management system documentation in paper and electronic form. Retention times for several types of documents are prescribed in the relevant provisions of generally binding legal documents and ÚJD SR internal procedures.

ÚJD SR recognises the challenge of improving the existing management system portal. The procurement of a new management system portal is currently in progress. Every employee of the ÚJD SR is obliged to conduct a self-assessment of their own work periodically, identify possible deficiencies and submit proposals to management.

The ÚVZ SR Quality Manual is certified in accordance with ISO 9001: 2015. Laboratories of the ÚVZ SR and the RÚVZ SR are either certified in accordance with ISO 9001: 2015 or accredited in accordance with ISO 17025: 2017. To complement and apply the Quality Manual, a set of documents have been developed. However, the Quality Manual and supporting documents are not in compliance with IAEA GSR Part 2.

MDV SR has developed and also implemented a management system to the extent that the responsibilities of each of the divisions within MDV SR are defined. This does not amount to an integrated management system for MDV SR in relation to its obligations for radiation safety.

The IRRS team has observed that the interfaces between regulatory authorities to ensure an effective coordination and cooperation among them are not adequately considered in the current management systems. Coordination and cooperation between the various regulatory authorities having responsibilities for safety could be improved.

Recommendation R4 in Section 1.5. addresses this issue.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *ÚVZ SR and MDV SR have not yet established and implemented an integrated management system that integrates elements, including safety, health, environmental, security, quality, human-and-organizational-factors, societal and economic elements in line with IAEA safety requirements.*

(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 19 states that <i>“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”.</i>
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(2)	BASIS: GSR Part 2 Requirement 6 states that <i>“The management system shall integrate its elements, including safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements, so that safety is not compromised”.</i>
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RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(3)	BASIS: GSR Part 2 Requirement 6 para 4.11 states that <i>“The organizational structures, processes, responsibilities, accountabilities, levels of authority and interfaces within the organization and with external organizations shall be clearly specified in the management system”.</i>
(4)	BASIS: GSR Part 2 Requirement 13 states that <i>“The effectiveness of the management system shall be measured, assessed and improved to enhance safety performance, including minimizing the occurrence of problems relating to safety”.</i>
R10	Recommendation: The ÚVZ SR and MDV SR should establish, implement, and continuously improve an integrated management system with processes and procedures to cover the core regulatory functions in line with IAEA safety requirements.

4.4. MANAGEMENT OF RESOURCES

The number of employees of ÚJD SR is set by the Ministry of Finance of the Slovak Republic for each calendar year. The human resources plan considers medium- and long-term needs, as well as possible changes in the organization.

ÚJD SR funds come from a separate chapter of the state budget which is approved annually by the National Council. The allocation of funds is approved to mainly cover the priority areas in the given year. Special provisions are made for the training programme.

The Head of the Radiation Protection Department of ÚVZ SR develops an annual plan of resources requirements (human and material) and submits it to the ÚVZ SR director for review and approval. The budget of ÚVZ SR is determined by the Ministry of Health. **As stated in Recommendation R1 and R2 in Section 1.3.**, the IRRS team concluded that the resources assigned to the Radiation Protection Department of ÚVZ SR are not sufficient and that they are not financially independent from MZ SR.

4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

ÚJD SR has included a “Process Map” in its Manual System. The Map includes all the processes covering all the activities and their mutual interfaces. The processes are identified as key, management and support process, in line with the typical grouping of processes proposed by GSG-12.

Processes are developed into related guidelines and operating procedures to further describe the activities carried out in implementing each process. Processes are aligned with the safety goals and strategies of the ÚJD SR, and each process has an assigned process owner.

ÚJD SR uses technical support to discharge some of their responsibilities. There are procedures in the management system to guarantee that suppliers of products are selected based on specified criteria. Their performance and delivered outputs are evaluated.

ÚJD SR staff have an understanding and knowledge of the product or service being supplied. ÚJD SR retains responsibility for safety when contracting out any processes and when receiving any product or service.

Regarding the ÚVZ SR, the IRRS team observed that there is no “Process Map” developed that covers the radiation protection activities. The IRRS team also identified the absence of internal guides and procedures, except for working instructions that are established for activities related to the laboratories. **Recommendation R10 in Section 4.3. addresses this issue.**

4.6. CULTURE FOR SAFETY

ÚJD SR states its commitment to the implementation of safety culture principles in ÚJD SR activities and the importance to foster and sustain a strong safety culture.

The management system fosters and sustains a strong safety culture by:

- ensuring a common understanding of the key aspects of safety culture within the ÚJD SR.
- providing the means by which the ÚJD SR supports individuals and teams in carrying out their tasks safely and successfully, considering the interactions between individuals, technology and the organization.
- reinforcing a learning and questioning attitude at all levels of the ÚJD SR.
- providing details on how the ÚJD SR continually seeks to develop and improve its safety culture.

The ÚJD SR project concerning the knowledge management process is currently in progress with a clear and well-structured plan.

ÚVZ SR promotes the safety culture through self-assessment questionnaires conducted annually by staff. However, there is no systematic approach in place to foster and sustain a strong safety culture in the organization.

IRRS team also noted that MDV SR does not have a systematic approach to foster and sustain safety culture in the organization.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>ÚVZ and MDV SR do not have a systematic approach to foster and sustain a strong safety culture.</i>	
(1)	BASIS: <i>GSR Part 2, Requirement 8 states that “Individuals in the organization, from senior managers downwards, shall foster a strong safety culture. The management system and leadership for safety shall be such as to foster and sustain a strong safety culture”.</i>
R11	Recommendation: <i>ÚVZ SR and MDV SR should implement a systematic approach to foster a strong safety culture.</i>

4.7. MEASUREMENT, ASSESSMENT, AND IMPROVEMENT

Several mechanisms are used by ÚJD SR to monitor, measure, and assess the implementation of the management system and to confirm its ability to achieve its goals and identify opportunities for improvement.

Internal audits are performed in accordance with the “Annual audit plan”. The auditors are trained and certified and are given sufficient independence and authority. A system for external audits which are performed every three years has also been established.

Several indicators have been established to measure the different process and activities. These results are evaluated, and trends are included into yearly management review. Senior managers review the management system regularly at planned intervals to confirm its suitability and effectiveness and its ability to enable the objectives of the regulatory body. This review is documented and evaluated by the Board for Management System. Measures to improve the management system are discussed and adopted as tasks. The monitoring of improvement is a subject of the management system review by senior management next year. Lessons learned are implemented.

A self-assessment of leadership for safety and safety culture took place in 2019 and in 2022 following the methodology given in the IAEA Safety Report Series No. 83, “Performing Safety Culture Self-Assessments”, the results were considered to be satisfactory and ÚJD SR has committed to conduct the next assessment in 2025.

The ÚVZ SR mechanisms and approaches to assess and improve its quality system are limited and are not systematic.

4.8. SUMMARY

ÚJD SR has established an integrated management system, in line with GSR Part 2, and in accordance with ISO 9001, which is subject to a continuous improvement process. The PDCA cycle approach is implemented. The knowledge management process is currently in progress with a clear and well-structured plan. Some elements of the management system, like interactions between the regulatory authorities in Slovak Republic are not adequately treated.

Regarding ÚVZ SR, its Quality Manual is elaborated in accordance with ISO 9001, and they have developed several documents for managing its main activities. However, an integrated management system, in accordance with GSR Part 2 has not been developed yet.

5. AUTHORIZATION

5.1. GENERIC ISSUES

5.1.1. REGULATORY FRAMEWORK FOR AUTHORIZATIONS

The authorization of nuclear and radiation facilities is undertaken by a number of authorities, the principal ones being ÚJD SR, ÚVZ SR and RÚVZs. Authorization for the transport of radioactive materials in packages, other than excepted packages, is the responsibility of MDV SR. IP Nitra performs oversight to ensure compliance with laws and other decrees for the safety and protection of health at workplaces, however, it does not have responsibilities for authorization. MDV SR is one of the authorities that participates in the authorization process for shipments of fresh and spent nuclear fuel, as well as RAW.

The Atomic Act requires that nuclear energy may only be used if permissions or authorizations are issued by the regulatory authorities. The licensing and approval processes, as well as related authorizations for nuclear facilities and activities are prescribed in the Atomic Act, including the responsibilities for ÚJD SR. The regulatory authorities shall issue authorizations, check whether the conditions are met, and have the power to revoke authorizations. Detailed requirements and recommendations for matters and documents to be presented at different authorization stages are presented in the regulations and safety guides.

Nuclear and waste management facilities are authorized under both the Atomic Act and the Act on Radiation Protection which encompasses the whole lifecycle of the facility from siting, construction, commissioning, decommissioning or closure of the facility.

The Atomic Act stipulates that relevant authorizations are sequential. The licensee is responsible to seek authorizations in the proper sequential order. The IRRS team was informed that provisions in legislation in the area of authorization are stand alone and do not foresee any interactions between institutions during the authorization processes. Decisions are made independently, except for the building permit, where ÚJD SR acts as a construction authority for nuclear installations and compiles all relevant authorizations by all involved regulatory authorities under the umbrella of a single building permit.

The IRRS team was informed that Decree No. 58/2006 Coll. establishes the requirements for sets of documentation concerning spent nuclear fuel management during commissioning and operation, prior to carrying out the planned activity for authorization. Based on these sets of documentation, two authorizations pursuant to Sec. 5 (3) of the Atomic Act are issued at the same time, for example: authorizations for commissioning or operation combined with spent nuclear fuel management.

In 2021, ÚJD SR issued 390 authorizations. ÚVZ SR with its regional offices issued 2 341 authorizations in 2020; IP NR (Nitra Labour Inspectorate) issued 15 decisions imposing fines on nuclear power plants in the administrative procedure in 2021.

According to the Act on Administrative Procedure, the authorized party has a right to appeal all written decisions to the regulatory body and further to the court, if necessary. For the authorizations that are given based on the Act on Radiation Protection, the first licensee has the right to appeal to the Ministry of Health of the Slovak Republic, in case when the authorization has been issued by the ÚVZ SR.

ÚVZ SR has not yet developed application forms that identify the necessary information for the application for authorization. This could assist the applicants in gathering the required information and supporting documentation. ÚVZ SR is planning to develop a web platform to manage applications for authorizations.

However, MDV SR has prepared and published all necessary application forms for the applicants within their premises as well as several guides on different activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *ÚVZ SR has not adopted application forms for authorization of facilities and activities.*

(1) **BASIS:** **GSG13 para. 3.74 states that** *“The notification and, as appropriate, the application for*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>authorization should be submitted on forms prescribed by the regulatory body with information that is commensurate with the level of radiation risk associated with operating the facility or conducting the activity”.</i>
S5	Suggestion: ÚVZ SR should consider developing application forms for authorization of facilities and activities.

5.1.2 THE VALIDITY OF AUTHORIZATIONS

The regulatory body primarily issues authorizations without an expiry date. The authorizations include conditions that are set for the duration of the validity period. For instance, in the case of nuclear power plants, a systematic safety assessment takes place in connection with Periodical Safety Reviews. However, this is not applied by every regulatory authority, for example, the regulatory framework for radiation protection does not require periodic safety reviews or a revalidation of safety assessments at predetermined time intervals. **Recommendation R14 in Section 6.1.4 addresses this issue.**

If the authorization conditions are not met, the authorities have the power to reduce the activity, stop it or revoke the authorization.

ÚVZ SR provides authorizations for nuclear installations and activities, in accordance with the Act on Radiation Protection. This includes the authorization of any activity related to occupational and public exposures. The ÚVZ SR has the right to impose restrictions and to define operational limits or constraints.

Time limits for the issuance of authorizations to nuclear installations are formally defined in the Atomic Act and the Act on Radiation Protection. For nuclear installations, time limits are 4 months for siting (except for NPPs, research reactors and repositories); 6 months for commissioning or decommissioning; and, 1 year for construction, siting or closure of NPPs, research reactors and repositories. For any other authorizations in relation to the Atomic Act the time limit is 60 days. The chairperson of ÚJD SR has the authority to extend any regulatory review period, when it is justifiable.

Authorizations granted by a regulatory authority do not replace or repeal a licence, permit, authorization or certification issued by other regulatory authorities pursuant to other acts.

5.1.3 COMMUNICATION WITH THE INTERESTED PARTIES AND PUBLIC

ÚJD SR and ÚVZ SR communicate with interested parties and the public on several levels. They participate in meetings between local authorities, authorized parties and the public in the vicinity of nuclear installations, and report annually on their tasks and status to the government, parliament, and the public. Communication channels with the licensees include inspections and meetings at different organisational levels. ÚJD SR makes its authorization decisions publicly available for feedback through ÚJD SR's web page, as well as the Slovak Central official electronic board. The feedback received is processed and justified in the decision to be made.

5.1.4 GRADED APPROACH IN AUTHORIZATIONS

The Atomic Act stipulates that in using nuclear energy, safety aspects must get priority over any other aspects of such activities. The approach to safety aspects shall be graded according to the type of nuclear installation, nuclear material inventory, radioactive waste and spent nuclear fuel and all associated activities. However, the Atomic Act, the Act on Radiation Protection and related decrees set strict requirements for what the authority must approve or give authorization to, regardless of the actual risk factors. This has led to a relatively large number of approvals for matters that are not necessarily of great safety importance, such as during construction of nuclear installations. ÚJD SR has noticed this trend and has initiated measures to change it. However, neither ÚJD SR's nor ÚVZ SR's internal

procedures for review and assessment, as well as ÚJD SR's procedures for inspection practices, provide much guidance on how to apply the graded approach. Regarding ÚJD SR, the overall description of the quality manual recognizes the graded approach and requires the process owners to take it into account in their processes. **Suggestion S3 in Section 3.1 addresses this issue.**

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

Based on the Atomic Act, authorization is required for siting, construction, commissioning, operation and decommissioning of NPPs. Authorizations are issued by ÚJD SR after verification that the applicant fulfilled all the conditions stipulated by the Atomic Act and associated regulations. Requirements for the scope and content of the documentations submitted within the licensing process are described in Annex No. 1 of the Atomic Act and Decree No. 58/2006 Coll. The regulatory framework also contains some non-binding safety guides, like safety guide BN 5/2022, "Format and content of the safety analysis report". Nuclear safety requirements throughout the life cycle of NPPs are governed by Decree No. 430/2011 Coll. The fulfilment of these requirements is verified by ÚJD SR by reviewing the required documentation and conducting regular inspections.

Based on the Act on Land-use Planning and Building Order (the Building Act) ÚJD SR is the Civil Construction Authority at NPPs. The Building Act obliges ÚJD SR to collect statements and decisions from other authorities before giving authorization for each phase of the lifecycle of the facility.

The major authorization phase for a new NPP is the authorization for construction. Prior to giving the authorization (issuing a permit), ÚJD SR collects decisions and statements from other authorities as required by the Building Act. In addition to safety reviews and assessment, ÚJD SR also evaluates applicant's organizational and financial capability for the construction project.

ÚJD SR authorizes modifications during the different lifecycle phases of the NPP as required by the Atomic Act. They also authorize several job positions at NPPs (e.g., control room operators and shift supervisors) whose work has a direct impact on nuclear safety. The required professional competencies are attained after successful completion of professional training and passing the final state exam in front of an Examination Committee appointed by ÚJD SR. The scope and content of the training is subject of authorisation by ÚJD SR. The authorization of special professional competence is valid five years from the date of issue.

Authorizations for the operation of NPPs are issued without an expiration date. As a result, Periodic Safety Reviews (PSRs) are a key mechanism to ensure safety over the lifetime of the NPP. According to the Atomic Act, the first PSR shall be submitted to the authority eight years after obtaining the operation authorization and every ten years after that. Detailed requirements for the content of the application and regulatory expectations are presented in Decree No. 33/2012 Coll. and in regulatory guide BN 1/2020 "Comprehensive Periodic Safety Review". ÚJD SR evaluates the self-assessment and action plan that the licensee submits and ensures its validity with an inspection. One key area that is described in the review report of facilities that are reaching their original lifetime is ageing management. The IRRS team concluded that the ÚJD SR's approach to periodic safety review is commensurate with IAEA Safety Standards.

ÚVZ SR performs its evaluations prior to the authorization of construction activities as stated in the Act on Radiation Protection. ÚVZ SR does not review or assess the technical design of the facility but relies on applicant conclusions on the fulfilment of the requirements like operational limits. There is no co-ordination between the authorities regarding the regulatory review. This may result in one crucial area of design (optimization of radiation doses) receiving less attention. **Recommendation R4 in Section 1.5. addresses this issue.**

5.3. AUTHORIZATION OF FUEL CYCLE FACILITIES

Authorizations are issued by ÚJD SR pursuant to Sec. 5 (3) and required for all stages of life cycle of spent nuclear fuel management facilities (construction, commissioning, operation, decommissioning phase). Authorization is required for siting of a nuclear installation, the commissioning phase and trial operation.

Details of the scope of the documentation to be submitted for authorization are stipulated in the Annex 1 of the Atomic Act. Further details concerning the scope, content and manner for maintaining documentation of spent nuclear fuel management facilities necessary for the issuance of individual decisions are laid down in Decree No. 58/2006 Coll.

Modifications to nuclear installation affecting nuclear safety during its construction, commissioning, operation and decommissioning can be implemented only upon prior consent or approval from the Authority.

Requirements on quality management for classified equipment are provided in Decree No. 431/2011 Coll. as amended on a quality management system.

5.4. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

Authorizations are issued by ÚJD SR pursuant to Sec. 5 (3) of the Atomic Act and are required for all stages of life cycle of radioactive waste management facilities (construction, commissioning, operation, decommissioning, closure and institutional control of repository). The IRRS team acknowledged that in accordance with provisions of Decree No. 58/2006 Coll. as amended a description of waste management during commissioning, operation and decommissioning shall be prepared and submitted prior to authorization of planned activities. Based on this set of documentation authorization for radioactive waste management activities pursuant to Sec. 5 (3) f) of the Atomic Act is issued. Authorization is required for siting of a construction of a nuclear installation, the commissioning phase and trial operation as well.

Details on the scope of the documentation are stipulated in the Annex 1 of the Atomic Act. Further details concerning the scope, content and manner for maintaining documentation of radioactive waste management facilities necessary for the issuance of individual decisions are laid down in Decree No. 58/2006 Coll. This includes regulatory requirements for the development, operation, closure and institutional control of radioactive waste disposal facilities.

The Act on Radiation Protection (Section 28) also includes provisions for authorization of activities within nuclear installations and stipulates authorizations issued by ÚVZ SR from the aspect of radiation protection for operation and decommissioning, as well as for handling, storage and manipulation with fresh nuclear fuel, treatment of spent nuclear fuel and management of radioactive waste, transport of radioactive substance or fission substance, radiation source, radioactive waste, spent nuclear fuel and radioactively contaminated objects, releasing of radioactive substances and radioactively contaminated objects.

Details on submissions for operation and decommissioning authorizations of nuclear installations are provided in Annex 6 Part II (a) and (b) of the Act, and clearance values are set in Annex 5 of the Act on Radiation Protection.

In accordance with the provisions of the Act on Radiation Protection it is an obligation of the licensee to safely terminate the activity concerning the source of ionising radiation. Radioactive sources shall be returned to the manufacturer or supplier, or transferred to another licensee, to treat it safely (Sec. 36 Part 1 u).

5.5. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The Act on Radiation Protection requires a graded approach for the authorization of sources and facilities. The Act has specified criteria and/or activities for which notification, registration or authorization is required. The Act also provides criteria for exemption and clearance of sources from regulatory control. The criteria for exemption of sources and activities are consistent with the IAEA Safety Standards.

The Act requires that different types of authorization to be obtained for the different stages in the lifetime of a facility, for example construction, commissioning, operation and decommissioning. This is on the basis of the risk of the facility. The scope of activities to be authorized are consistent with IAEA International Standards and includes distribution, sale, rent, export or import of sources.

The Act has detailed requirements for applicants on how to notify the regulatory authorities of the intention to conduct an activity or operate a facility. The documentation to be provided is prescribed under the Act, taking into consideration the nature and magnitude of risk of the facility or activity.

While there are no application forms for notification or authorization, a list of documents to be submitted is prescribed in the Act. Applicants are required to submit legal, organisational and the safety assessment of the facility and activity including nominating a suitably qualified and authorized radiation protection officer. Time frames for submitting applications including decision making by the regulatory body are specified under the Act. The format of authorizations issued by the regulatory body is prescribed under the Act and specifies the name of a radiation protection officer or the expert, as appropriate. Authorizations are issued for an indefinite period of time. The authorized party has obligations to notify any changes in circumstances or variations to conditions of authorization to the regulatory authorities.

For sources prescribed as high activity sources under the Act on Radiation Protection, the authorized parties are required to provide commercial insurance to cover cost of management of sources in case of bankruptcy. JAVYS is the sole service provider authorized to receive and store disused sources which are not able to be returned to the manufacturer.

Persons performing the functions of a radiation protection officer or a radiation protection expert, including for quality assurance/testing and environmental monitoring, are required to undergo rigorous assessment prior to being authorized on the basis of their knowledge and skills to certify safety requirements for specific facilities or activities.

Persons conducting activities such as import, distribution, sale or rent of sources are required to provide safety certification for sources, and instructions for safe use and maintenance, including safe disposal. Only sources that are certified to meet European Safety Standards are able to be supplied and used. Specific details such as unique identifying details and location of radiation generators and sealed sources are recorded and tracked on the national register maintained by ÚVZ SR. This also applies to sources following their disposal to the authorized technical service provider.

Authorization by notification and registration may be issued by ÚVZ SR or the relevant RÚVZ SR. However, the Act has prescribed requirements about the type of facility or activity that is to be authorised by licensing and the regulatory authority (i.e., ÚVZ SR or the RÚVZ SR, MDV SR) responsible for authorization. For example, ÚVZ SR is authorized to issue licences for manufacturing of sources, including consumer products, handling of orphan sources, and handling of radioactive waste and non-medical irradiation outside of health facilities. The regional radiation protection authorities issue licences for particle accelerators used for research and development; radiation generators; sealed and unsealed sources; sealed sources used for food irradiation or other technical purposes; unsealed sources for veterinary purposes; medical irradiation using radiation generators; and, unsealed sources and sealed sources. Only ÚVZ SR may grant authorization for distribution, sale, renting or import of sources. Authorization from MDV SR is needed for transport of specific radioactive material.

The IAEA Safety Standards recognise that a number of authorities may have responsibilities for safety within the regulatory framework for safety. However, the division of roles and responsibilities between many authorities, while permitted under the Act on Radiation Protection, has created an undue overlap of responsibilities in the authorization of facilities and activities operating within then premises of agencies such as the MDV SR, Slovak Information Services and the Ministry of Defence of the Slovak Republic. Further, this has the potential for an inconsistent approach to authorization, review and assessment and inspection of sources and facilities including the perception of potential conflict of interest and confusion among authorised parties. It may be appropriate to review and amend the law due to the number of regulatory bodies responsible for safety. There is a strong need for coordination and liaisons including the establishment of formal arrangements such as memoranda of understanding, appropriate communication, and regular meetings, to ensure safety requirements are effectively met.

Recommendation R4 in Section 1.5. addresses this issue.

5.6. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

According to the Atomic Act, decommissioning of a nuclear installation requires an authorization. The IRRS team was informed that the State company JAVYS performs decommissioning of nuclear installations as a licensee for decommissioning and shall fulfil all responsibilities of licensee as prescribed in the Atomic Act and relevant Decrees including the obligation to ensure availability of properly trained, qualified and competent staff.

Prior to the scheduled shutdown of a nuclear installation for the purpose of termination of the operation, the holder of an operating authorization is required to submit, for approval to the Regulatory Body, a conceptual plan for decommissioning according to the current knowledge at the time of shutdown of a nuclear installation.

The decommissioning plan is prepared based on a conceptual plan for decommissioning during the transition period of a nuclear installation from operation to decommissioning.

Details of the scope of the documentation are stipulated in the Annex 1 point D of the Atomic Act. Further details of the content of the documentation are specified in Decree No. 58/2006 Coll. as amended.

If decommissioning requires the construction and use of new technological units within the defined boundaries of a nuclear installation, under decommissioning, those nuclear installations are subject of authorizations in accordance with provisions of Atomic Act.

During operation, the licensee shall collect and preserve all data and information needed for decommissioning. Also, the holder of the authorization is required, prior to transition of such nuclear installation to the decommissioning phase, to remove the spent nuclear fuel from a nuclear installation, as well as to manage radioactive waste.

The final description of a decommissioned nuclear installation site and of all work performed in decommissioning shall contain demonstration of achievement of the objectives of decommissioning and compliance with the requirements of regulatory authorities, and shall provide conditions if restrictions of site use are envisaged.

As stated, in the conceptual decommissioning plan, a calculation of the costs of decommissioning according to the recommended international cost structure for the decommissioning of nuclear installations, considering the decommissioning strategy must be analysed (Decree No. 58/2006 Coll. as amended) and submitted for regulatory review.

In accordance with the Act on the National Nuclear Fund No. 308/2008 Coll. as amended, the Board of Governors shall issue upon request of the ÚJD SR, the opinion on the adequacy of the estimated cost in the conceptual plan for decommissioning of a nuclear installation. The opinion is binding for the ÚJD SR.

5.7. AUTHORIZATION OF TRANSPORT

Authorizations on transport issued for the transport of nuclear and radioactive material in the Slovak Republic must comply with the European ADR regulations which adopt the entire requirements stated in the IAEA SSR 6 (Rev. 1).

ÚJD SR issues authorizations for the transport of packages containing nuclear and/or radioactive material in accordance with the Atomic Act. MDV SR issues authorizations for the transport of packages containing radioactive material in accordance with the Act on Radiation Protection. The findings from ÚJD SR and MDV SR inspections are considered in the respective Authorization processes.

ÚVZ SR issues authorization for the transport of all radioactive materials that are transported within the premises of nuclear installations.

Currently MDV SR does not have a legal basis, due to an omission in the Act on Radiation Protection, to issue authorizations for Type B and Type C packages containing radioactive material. This will be rectified when a revision of the Act is enacted, which is currently in the legal process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *There is no legal basis in the Act on Radiation Protection for MDV SR to assess and issue authorizations relating to Type B and Type C package designs for the transport of radioactive material.*

(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”.*

R12

Recommendation: *The proposed revision of the Act on Radiation Protection, which is currently*

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going through due process for enactment, should include the requirement for MDV SR to assess and issue authorizations relating to Type B and Type C package designs for the transport of radioactive material.

The authorization process should include the assessment of ageing management mechanisms as defined in the package design safety case. The ageing management mechanisms are important for packaging intended for transport after storage and for packaging that will have an operational life for which the timescales are considered by MDV SR as appropriate, to necessitate the consideration of ageing management mechanisms. **Recommendation R15 in Section 6.7. addresses this issue.**

5.8. AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE

The ÚVZ SR and RÚVZ SR, are responsible for the authorization of practices which may give rise to occupational exposures, according to the Act on Radiation Protection. The same applies for services assessing exposure to radon and its progenies, personal dosimetry, assessment of intake of radionuclides and external exposures. Service providers of radiation protection training and education are also authorised and recognised as such by the ÚVZ SR. Their training programme, extent and scope of education must conform to the minimum requirements laid down in the Act on Radiation Protection. Occupational health surveillance is carried out by service providers, recognized by a different division in the ÚVZ SR.

All authorizations issued by the ÚVZ SR do not have an expiry date. Authorizations are only valid after a pre-authorization inspection. However, there are no formal mechanisms in place to regularly review, assess authorizations, and review operating experience. **Recommendation R14 in Section 6.1.4 addresses this issue.**

Supporting documents are required to be submitted to the ÚVZ SR and RÚVZ SR for every authorization procedure, however, forms are not available. **Suggestion S5 in Section 5.1.1 addresses this issue.**

Depending on the type of activity to be authorized, the scope and extent of the documents are different, but these must address justification, optimisation, dose limits, dose constraints, and a clear description of responsibilities. Depending on the facility or activity to be authorized, a safety assessment and a radiation protection programme must also be submitted, for which the Act on Radiation Protection has a detailed list of requirements.

5.9. AUTHORIZATION ISSUES FOR MEDICAL EXPOSURE

The authorization of facilities and activities related to medical exposures are carried out by ÚVZ SR and RÚVZs.

None of the RÚVZ SR have adopted a form for the request of authorizations (licence or registry) in medical applications of ionising radiation. **Suggestion S5 in Section 5.1.1. addresses this issue.** The requests for authorization are formalized through a letter, and the submission of the supporting documentation is defined in the Act on Radiation Protection. The information that is required in the request letter is defined in Part four, sections §23 to §29. The supporting documentation is defined in documentation to application Part 1 and Part 2. The Decree of MZ SR No. 101/2018 Coll. provides information on what should be the content of the supporting documentation.

A graded approach is applied to the definition of the supporting documentation for authorization requests, and on the content of such documentation. Prior to issuing the authorizations the RÚVZ SR conducts an inspection, to assess if the radiation protection measures put in place by the applicant are in compliance with the requirements of the regulatory framework. If a non-compliance is identified the evaluation of the application may be suspended to allow the applicant to make the necessary corrections.

5.10. AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE

The Act on Radiation Protection establishes the provisions for applicants for an authorization shall comply with to ensure adequate protection of the public. Requirements related to dose limits in compliance with GSR Part 3 and the establishment of a generic effective dose constraint value of 0.25 mSv/year for the public are included in the Act. The Act also includes requirements for limiting the release of radioactive material to the environment. According to the Act, applicants for a discharge authorization for nuclear facilities should demonstrate compliance with dose constraint values of 0.2 mSv/year for discharges to the air and 0.05 mSv/year for discharges to surface waters. If there are several facilities in an area these values relate to total exposure from all nuclear installations in the area or region and specific to each facility, constraints should be imposed. For the authorization of facilities releasing radioactive materials to the environment, the Act requires the authorization to include the maximum values of material that can be released in terms of each radionuclide, and expressed in Bq/year or Bq/day.

Facilities discharging radioactive material to the environment are required to implement a monitoring programme to demonstrate compliance with these values. They are required as well to report periodically to ÚVZ SR on the results of these programmes. ÚVZ SR carries out an independent monitoring programme to verify compliance with authorized discharge limits. The radiological monitoring of the environment is complemented with an environmental monitoring network with measuring stations distributed over the Slovak territory. Results of monitoring programmes are made available to the public through periodic reports which are published on the ÚVZ SR web page (https://www.UVZSRsr.sk/docs/vs/vyrocnna_sprava_SR_2020.pdf).

5.11. SUMMARY

The Slovak Republic has a well-established system of granting authorizations that mostly fulfils IAEA Safety Standards. Authorization of nuclear and radiation facilities is undertaken by a number of regulatory authorities, therefore, co-operation between the authorities is crucial for comprehensive safety assessment, as well as for using a graded approach to authorizations that ensures an efficient usage of regulatory resources.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

The regulatory body is empowered by law to conduct review and assessment of facilities and activities to cover all stages of the lifetime of the facility (siting, construction, commissioning, operation, decommissioning, and closure) or activity. The Act on Radiation Protection and the Atomic Act have specified the documents to be submitted by licensees and applicants including time frames for regulatory review by the regulatory body. The review and assessment of complex facilities or activities may be undertaken in a series of steps, to allow progress from one stage to the next.

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

ÚJD SR performs review and assessment for matters related to nuclear safety of nuclear installations including treatment of radioactive waste, nuclear spent fuel management and further stages of the fuel cycle, as well as nuclear materials, including their control and accountancy.

ÚJD SR prepares a programme for major review and assessment activities to effectively manage the resources available and document the systematic approach to the review and assessment. The programme uses the applicants' intentions for submissions to be delivered to the regulatory body as an input. The programme is prepared by the management of ÚJD SR and presented in ÚJD SR staff meetings, division meetings and ÚJD SR Board meetings. The programme is specific for each particular review and assessment activity. Results and decisions deriving from the review and assessment are recorded. ÚJD SR takes appropriate actions, as necessary, and the results of review and assessment are used as feedback information for regulatory process.

Requirements related to graded approach are defined in the Atomic Act and further developed in Decree No. 430/2011 Coll., Decree No. 431/2011 Coll., Decree No. 33/2012 Coll., Decree No. 48/2006 Coll., Decree No. 58/2006 Coll., etc. Specification on application of graded approach is provided in the regulatory guides. Principles of graded approach in ÚJD SR activities are summarised in Quality Manual (S 500 006:21) including clear assignment of responsibilities for its application. According to the Decrees, the graded approach is required for the categorization of classified equipment, safety assessment, definition and application of radiological criteria and technical acceptance criteria for protection of barriers of defence in depth concept, safety margins, investigation of events, training of the staff, management system documentation, in preparing decommissioning plans, etc. The IRRS team discussed the application of graded approach in authorization, and review and assessment, and found that ÚJD SR internal procedures do not detail the application of the graded approach during the performance of review and assessment. **Suggestion S3 in Section 3.1. addresses this issue.**

The ÚVZ SR has implemented processes for undertaking review and assessment which are included as part of its process for the management of the regulatory programme. Review and assessment of applications for authorizations are overseen and granted by the head of the regulatory body. Regulatory staff are required to follow the requirements set out in the Act, but there are no documented requirements regarding review and assessment. There are no management processes for feedback from other regulatory processes (e.g., inspection or enforcement into review and assessment processes). There is heavy reliance on regulatory authority staff to follow-up and take appropriate actions, however, there does not appear to be a systematic approach that enables this.

The lack of an integrated management system has impacted the ability of the regulatory body to implement a review and assessment process that ensures a graded approach including consistency in the application of regulatory requirements on safety checks performed by the regulatory body. **Recommendation R10 in Section 4.3. addresses this issue.**

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

The ÚJD SR human resources and knowledge management for review and assessment strongly depends on the technical areas and stages of the NPPs. ÚJD SR has evaluated the needs of human resources and competences for

fulfilment of its tasks including review and assessment. Maintaining a high professional level and professionalism of staff of the regulatory bodies has also helped by the application of the results of science and research.

ÚJD SR has adequate competence available to perform comparison calculations of safety analysis and various computer codes, and NPP models are also in place. However, if relevant expertise is not available in the regulatory body, then the services of technical support organizations are sought.

The ÚVZ SR has organised its existing resources and staff to undertake review and assessment to fulfil its regulatory obligations. The ÚVZ SR does not have an integrated management system which enables it to effectively organise and maintain its technical resources in the performance of its review and assessment function. This has been further impacted by staffing and resource constraints. The IRRS team was informed that access to specific regulatory tools for review and assessment (e.g., computer codes, experimental facilities) is limited due to funding issues. The ÚVZ SR does not use technical support organizations to support its decision making in responding to complex safety and protection matters on regular basis.

Regulatory body staff are provided internal training using more experienced staff and are placed in specific areas depending on their qualifications. There is limited training and internal procedures for review and assessment. Applicants and authorized parties are required to use the services of suitably qualified and authorized experts to undertake safety assessments. Except under specific circumstances, the regulatory body does not undertake verification of safety assessments prepared by experts commissioned by applicants or authorized parties. For certain complex and high-risk radiation source facilities, e.g., cyclotrons, ÚVZ SR uses internal expertise to support its verification of safety prior to decision making. Resource constraints have prevented ÚVZ SR from conducting independent verification of safety assessments internally or through securing external support.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *ÚVZ SR does not always carry out independent verification of safety assessments prepared by the authorised parties as part of its review and assessment for radiation facilities and activities.*

(1)

BASIS: GSR Part 4 Requirement 21, Para. 4.71 states that *“In addition, the regulatory body shall carry out a separate independent verification to satisfy itself that the safety assessment is acceptable and to determine whether it provides an adequate demonstration of whether the legal and regulatory requirements are being met. The verification by the regulatory body is not part of the operating organization’s process and it is not to be used or claimed by the operating organization as part of its independent verification”.*

R13

Recommendation: The ÚVZ SR should carry out independent verification of safety assessments prepared by authorised parties for radiation facilities and activities.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

Legal provisions governing the ÚJD SR review and assessment are laid down in the Atomic Act and Decrees covering almost every aspect of review and assessment. Principles for the ÚJD SR review and assessment are provided in the Quality Manual.

Legislative requirements for the scope and content of the Safety Analysis Report (SAR) and the Probabilistic Safety Assessment (PSA) are in line with the Atomic Act and set out in the Decree No. 58/2006 Coll.

The bases for review and assessment for radiation source activities and facilities in ÚVZ SR are prescribed under the Act on Radiation Protection. There is limited guidance provided by the regulatory body for safety assessment by the authorized parties or applicants other than the list of requirements prescribed under the Act which is specific for different types of facilities or activities. The Act allows external experts to be used by authorized parties or applicants to address safety criteria specified for each type of activity or facility.

There is a general consistency of safety assessment requirements with the IAEA Safety Standards. However, the use of prescriptive safety requirements for specific sources and facilities (as specified under enclosure 6 of the Act on

Radiation Protection) has the potential to limit the scope and rigour of review and assessment undertaken by the regulatory body.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

Review and assessment of relevant information to determine whether facilities and activities comply with regulatory requirements belong to the basic competencies of the ÚJD SR. The ÚJD SR requires technical and other documents to be submitted for the review and assessment to determine whether the nuclear installation or activity complies with relevant objectives, principles and associated criteria for safety or conditions in authorization.

The review and assessment performed by the ÚJD SR covers all aspects of the safety analyses including thermal-hydraulic aspects, neutron-physic aspects, stress-mechanic aspects, etc. During the review process, ÚJD SR guides are applied; where there are no ÚJD SR guides available then the IAEA guides are used as reference.

The IRRS team was informed by ÚVZ SR that they place high reliance on the qualified experts or the radiation protection officers to verify that safety assessments have been appropriately completed. Other than on an infrequent basis, the regulatory body does not undertake independent verification of information provided by applicants or authorised parties. However, inspections are carried out as part of review and assessment to verify some of the safety measures.

The Act on Radiation Protection has specified criteria for notification and authorisation by registration or licensing. Annex 6 of the Act has prescribed regulatory measures which are specific to the type of radiation source activity or facility.

Lack of ÚVZ SR resources has limited the ability for periodic review and assessment during the lifetime of the facility or activity by the regulatory body. Further, as there are no requirements for renewal of authorisations, a follow-up review and assessment of safety related features may not be conducted. There is a potential for significant changes or modifications including degradation of safety related aspects of the facility or activity remaining undetected. The IRRS team also noted that the safety conditions at the facility place high reliance on the inspection programme which is also impacted by the resource constraints of the regulatory body.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: ÚVZ SR does not have a mechanism to periodically review that the conditions for the authorization are valid for radiation facilities and activities.

(1)

BASIS: GSR Part 1 (Rev. 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”.

R14

Recommendation: The ÚVZ SR should implement mechanisms to periodically review the conditions of the authorisations for radiation facilities and activities.

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

ÚJD SR performs safety review and assessment for nuclear power plants during siting, design, construction, commissioning, modification and operation of NPPs. The regulatory requirements to be met at various stages of life of a nuclear installation are defined in the Atomic Act. Review and assessment of the NPPs is conducted by ÚVZ SR in the area of radiation protection.

In the process of review and assessment of a nuclear facility, the following major submissions are required by ÚJD SR as per requirements of the Atomic Act for various phases of authorization of nuclear power plants:

- Preliminary safety reports of NPPs under construction;
- Preoperational safety reports of NPPs;
- Periodic safety reviews of operating facilities;
- Safety analyses related to modifications to Structures, System and Components;
- Event investigation reports of NPPs;
- Operational topical reports (e.g., various reports from the pre-operational tests after completing the refuelling and maintenance outages);
- Updated final safety analysis reports, including new and up-dated deterministic and probabilistic safety analyses;
- Safety related design modifications of NPPs;
- Periodic reports from the operating plants;
- Commissioning plans;
- QA reports of the various tests of SSCs during the construction and commissioning process;
- Decommissioning plans etc.

The process of review and assessment at ÚJD SR is described in the procedure for assessment of documentation including modifications (S 310 029:20). This procedure gives details on documentation evaluation including the cooperation between various divisions of the regulatory body.

ÚJD SR also performs reviews of PSR submittals required after very ten years to fulfil the requirements of PSR as per requirements of the Decree No. 33/2012 Coll. The periodic safety reviews (PSR) play a central role in nuclear plant regulatory oversight. In this scheme, the lifetime extension of the plants does not require any specific arrangement and the significance of the PSR is for that reason extremely high. Ageing management aspects are basically taken care of within the framework of PSR. Apart from reviewing the PSR submissions, ÚJD SR arranges several inspections related to the topics covered in the PSR process.

The ÚJD SR guide BN 5/2019 provides requirements for deterministic safety analyses. ÚJD SR has a Division of Safety Analysis and Technical Support, which is staffed with highly experienced safety analysts. They carry out the safety analysis work annually to systematically re-calculate the deterministic and probabilistic safety analyses of the supervised plants.

ÚJD SR has also issued regulations for verification of selected employees` professional qualification and competence. For operational event investigation, ÚJD SR has developed a regulation (Decree No. 48/2006 Coll.) which lays down the basic contents of the event investigation reports to be submitted following the incident.

IRRS team observed that ÚJD SR has developed a procedure on event investigation of nuclear installations in the Slovak Republic and also prepared a procedure on activities of national coordinator in the system of event reporting in nuclear installation which is being utilized for reporting events to INES. However, during discussion, it was revealed that there is no documented process for review and evaluation of international events and its utilization during review and assessment.

ÚVZ SR does not have a procedure for the systematic review and evaluation of international events, and receiving and sharing information on lessons learnt. The IRRS team was informed that ÚVZ SR inspectors of NPPs do not have resources nor the authority to participate in European or international forums on sharing information concerning events and lessons learnt. This type of information should be considered in planning and conducting regulatory oversight activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Event investigation and reporting by ÚVZ SR and ÚJD SR do not include provision for the review and evaluation of international events and sharing of information on lessons learnt.*

(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*

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	<i>experience, including experience in other states and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities”.</i>
S6	Suggestion: ÚJD SR should consider revising the existing procedure and ÚVZ SR should consider developing a procedure on event investigation and reporting to include a provision for the systematic review and evaluation of international events and sharing of information on lessons learnt.

6.3. REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILITIES

Provisions for the safety assessment of spent nuclear fuel management facilities as well as requirements related to particular facility life-stages (e.g., siting, construction, operation, decommissioning) are provided in the Decree No. 30/2012 Coll., Decree No. 430/2011 Coll., Decree No. 33/2012 Coll. and Decree No. 431/2011 Coll.

These nuclear safety requirements provide details for handling of nuclear materials, handling and storage of spent nuclear fuel, scope and contents of documentation when treating spent nuclear fuel. These include criteria for the categorisation of classified equipment into safety classes and regulates the details on assessment of the scope, content and impacts of modifications, details on evaluation, documenting, feedback scope, the scope and content of probabilistic assessment of nuclear safety, and details on monitored indicators and nuclear safety parameters.

Decree No. 30/2012 Coll. provides requirements on limits and conditions of safe handling of spent nuclear fuel (Section 15) and safe storage (Section 16) of spent nuclear fuel including requirements on subcriticality and heat removal, deposition of spent nuclear fuel to the repository (section 18). Periodic safety review is done in accordance with the Decree No. 33/2012 Coll. that is used for all nuclear installations.

6.4. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

Provisions for the safety assessment of radioactive waste management facilities as well as requirements related to particular facility life-stages (e.g., siting, construction, operation, including closure and post-closure stages for disposal facilities) are provided in Decrees No. 30/2012 Coll. and No. 430/ 2011 Coll.

Those nuclear safety requirements provide details for the management of the radioactive waste, including its generation, classification, import and export, scope and contents of documentation, and associated facilities. Also, they include criteria for the categorisation of classified equipment into safety classes and regulates the scope of the assessment, content and impacts of modifications, evaluation, documentation, feedback, the scope and content of probabilistic nuclear safety assessment, and monitoring of indicators and nuclear safety parameters.

According to the Decree No. 30/2012 Coll. as amended, Sec. 10 safety analyses for a repository require a comprehensive assessment of risks related to the disposal of radioactive waste and proof of the functionality of the entire repository system considering its possible impact on humans and on the environment, and taking into account the natural evolution of the repository and the possibility of intrusion during institutional control after its closure. The scope of the safety analyses, the time interval assessed, input quantities and the selection of other parameters bounding the safety analyses, are to be proposed by the authorisation applicant or licensee, supported with appropriate justification.

Periodic safety review is done in accordance with the Decree No. 33/2012 Coll. that is used for all radioactive waste management facilities.

6.5. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

In the process of its review and assessment of radiation source facilities and activities, the ÚVZ SR considers the submission prepared by the applicant in accordance with the requirements of the Act on Radiation Protection and the Administration law 71. Regulatory requirements are graded according to whether the radiation source is subject to notification or authorisation by registration or licensing.

The Annex 6 of the Act has prescribed a list of considerations which are specific for the type of radiation source activity or facility e.g., unsealed sources for nuclear medicine, food irradiation or radiotherapy generators. The list of considerations includes description and justification of activity leading to irradiation, radiation protection programme, storage and security, measures for control of occupational exposure, accident plan, shielding and protective equipment, etc.

The safety assessment of the radiation source facility or activity is performed by a radiation protection officer, who may use an appropriately authorised qualified expert to support the preparation. Initial task of the review and assessment is to confirm the completeness of submissions. The IRRS team was advised that the review and assessment by the regulatory body typically does not extend beyond these checks. Independent safety verification checks, e.g., shielding calculations, or other safety assessments are not performed by the regulatory body due to lack of expertise and funding. There are no procedures for ensuring consistency and completeness of information for review and assessment. Discussions have also revealed that graded approach is not utilised in prioritising safety assessments during review assessments. A two-stage document verification process prior to final issue of the authorisation by the head of the regulatory body is undertaken.

However, in specific circumstances during the review and assessment of complex and high-risk radiation source facilities, e.g., cyclotron, ÚVZ SR has involved the use of expertise drawn from within the regulatory bodies to support its decision making. Resource constraints have prevented the regulatory bodies from securing expert external support for independent verification of safety.

6.6. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

Regulatory requirements on scope and content of submittals related to decommissioning (decommissioning strategy, plans, management and implementation, conduct, completion by reaching end state) are provided in the Decree No. 58/2006 Coll. It includes requirements on reference report on the decommissioning method, preliminary conceptual plan, conceptual plan, decommissioning stage plan, as well as decommissioning concept for the period following the decommissioning stage, to be permitted.

Pursuant to Section 5 (3) (b) and (c) of the Atomic Act, the licensee shall update a conceptual plan for the decommissioning of a nuclear installation from operation to reflect changes and consider provisions and periodicity of revision of National Strategy on spent nuclear fuel and radioactive waste management and decommissioning.

The final description of a decommissioned nuclear installation site and of all work performed during decommissioning shall demonstrate the achievement of the objectives of decommissioning and compliance with the requirements of the regulatory authorities.

A number of non-legally binding safety guides were issued to support assessment of safety of decommissioning that express good practice for implementation of requirements.

Detail guidelines for decommissioning are provided in BNS I.9.5/2017, BNS I.9.3/2017, BNS I.9.4/2017.

The IRRS team concluded that the development of comprehensive safety requirements for decommissioning of nuclear installations and its supplementing detail guides is **a good performance**. This helped to achieve implementation of decommissioning stage plan of Bohunice V-1 NPP timely and within the planned cost.

6.7. REVIEW AND ASSESSMENT FOR TRANSPORT

The review and assessment activities related to transport of radioactive material are described mainly in the Atomic Act and the ÚJD SR Decree of No. 57/2006 Coll. which provide details of the requirements for the transportation of radioactive materials for nuclear material and the Act on Radiation Protection for radioactive material. Review, assessment, and authorization of the transport of nuclear material including radioactive waste is performed by ÚJD SR, and for radioactive material (non-nuclear) by the MDV SR.

However, the scope of the ÚJD SR and MDV SR assessment activities related to package design authorizations and transport authorizations for nuclear radioactive material and radioactive material respectively, must ensure the requirements set out in the “Agreement concerning the International Carriage of Dangerous Goods by Road (“ADR”, which adopts all the requirements of SSR-6 (Rev.1), are met; EU directive 2008/68 inland transport of dangerous goods also applies.

Discussion with ÚJD SR revealed that a programme by the authorised facility to evaluate the ageing management of containers used to store spent nuclear fuel has been implemented. However, no examples of assessment of ageing mechanisms were provided for other packages designs containing nuclear radioactive material or radioactive material by ÚJD SR or MDV SR respectively, as required by SSR-6 (Rev. 1) with guidance provided by SSG-26 (Rev. 1).

The ÚJD SR Decree No. 430/2011 Coll. on nuclear safety requirements fresh fuel packages classified equipment class III. For classified equipment, ageing management is one of the requirements which must be fulfilled according to the ÚJD SR Decree No. 431/2011 Coll. on a quality management system. According to the Decree No. 431/2011 Coll., all classified equipment shall meet the requirements of this Decree, Annex No. 5, I. The quality plan for the first phase contains letter g) the requirements for ageing management of the classified equipment.

It is therefore recommended that ÚJD SR and MDV SR should ensure the assessment of the ageing management mechanisms be a part of the authorisation process for packaged nuclear radioactive material and packaged radioactive material.

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Observation: ÚJD SR and MDV SR do not perform assessment of ageing management for package designs other than spent fuel.

(1)	BASIS: SSR-6 (Rev. 1) states that “ <i>The design of the package shall take into account ageing mechanisms.</i> ”
(2)	BASIS: SSG-26 (Rev. 1) states that “ <i>613A.3. For packagings intended for repeated use, the effects of ageing mechanisms on the package should be evaluated during the design phase in the demonstration of compliance with the Transport Regulations. Based on this evaluation, an inspection and maintenance programme should be developed. The programme should be structured so that the assumptions (e.g., thickness of containment wall, leaktightness, neutron absorber effectiveness) used in the demonstration of compliance of the package are confirmed to be valid through the lifetime of the packaging. An example of a procedure to prepare an ageing management programme for Type B(U) packages is provided in Ref. [12].</i> ” <i>“613A.4. In the design of packages intended to be used for shipment after storage, consideration of ageing mechanisms is important due to the long period between loading and the end of shipment after storage, the conditions of storage (even though the Transport Regulations do not apply to the storage of the package), and the difficulties in the inspection (to detect ageing effects) and maintenance of packages loaded with radioactive material. Furthermore, factors such as new technical knowledge, changes of package design, new requirements in the Transport Regulations applicable to package design or new technology for the identification and assessment of ageing effects should be recognized”.</i>
R15	Recommendation: ÚJD SR and MDV SR should ensure the assessment of the ageing management mechanisms be part of the authorisation process for packaged nuclear radioactive material and packaged radioactive material.

6.8. REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE

The Act on Radiation Protection requires that licence applications are compiled in cooperation with a radiation protection expert (RPE) or by a radiation protection officer (RPO). Only one private company (ÚRO – Ústav radiačnej ochrany, Radiation Protection Institute Ltd.) is recognised as an RPE. In the case when a licence application is submitted to the ÚVZ SR by an applicant who asked URO to compile this documentation, according to the Act on Radiation Protection, ÚVZ SR does not evaluate the appropriateness of the safety assessment. The Act on Radiation Protection does not require that the RPEs compile the documents for the authorisation. In the case when it is not done by an RPE, the evaluation of the documentation is performed by the ÚVZ SR or one of its regional branches, depending on the type of radiation source or facility and activity. When a licence application is submitted to the ÚVZ SR where the ÚVZ SR does not have the competence to confirm its appropriateness, then technical support organisations are asked to provide support for the authorisation procedure. **Recommendation R13 in Section 6.1.2. addresses this issue.**

Workers may access records of their occupational exposures when they quit their job or request this information from ÚVZ SR or their employer. Investigation levels are defined by the Act on Radiation Protection and when these are exceeded, the employer of the worker and the ÚVZ SR are notified. Events resulting in doses above the investigation levels must be investigated.

6.9. REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE

The Act on Radiation Protection defines the duties and responsibilities of the licensees (registrants and licensees), for facilities and activities which include medical exposures to ionising radiation. The licensee's duties include the assessment of aspects that are usually part of the safety assessment of facilities and practices in medical applications. The Act on Radiation Protection also requires that authorization applicants submit documents that provide proof of compliance with their duties, and it requires that the regulatory authority verify the compliance.

However, there are no provisions to require licensees to periodically perform safety reviews of their facilities for the duration of the authorization, or for the periodic review of the safety assessment by the regulatory body.

In particular, for authorization purposes there are provisions for the applicants to submit documentation on justification, and assessment of optimization of medical exposures in what concerns source calibration, dosimetry of patients, reference levels, and dose constraints. There are also provisions for authorization applicants to submit documents pertaining to assessment of quality assurance for medical exposures.

The IRRS team was informed that licensees in the area of medical exposures are required to periodically test the performance of the radiological equipment, by contracting a services provider. If the services providers identify any non-compliance with the regulatory framework requirements, they are obliged to inform the regulatory authority. However, no provisions were identified for the review and assessment of such non-compliances.

The regulatory framework includes provisions for the modifications of authorizations in the case of significant changes to the facility or to its operating or maintenance procedures, and in case of significant changes occurring on the site that could affect the safety of the corresponding facility or of activities.

6.10. REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE

Provisions to be implemented by authorized parties for the protection of members of the public are verified during the review of authorization application documentation, following the requirements established in the Act. Procedures for the review and assessment of documentation submitted by authorization applicants have not been implemented. **Recommendation R10 in Section 4.3. addresses this issue.**

6.11. SUMMARY

ÚJD SR has the necessary elements to ensure that review and assessment of activities it regulates are sound. Those reviews are carried out by qualified staff, and reviews are documented and retrievable. One area of improvement is to perform the assessment of ageing mechanisms for packaging nuclear radioactive material. Moreover, MDV SR does not currently include assessments of ageing mechanisms in package designs for radioactive material.

Further areas for improvement include development of procedure for review and evaluation of international events, mechanisms to periodically review the conditions of the authorisations by ÚVZ SR and refined implementation of application of the graded approach.

7. INSPECTION

7.1. GENERIC ISSUES

In the Slovak Republic, responsibility for inspections of facilities and activities is divided among several regulatory authorities. For nuclear facilities all these authorities are involved, with each being responsible for the regulatory oversight of their particular domain. The following are the primary regulatory authorities and corresponding Acts that empower each authority to monitor compliance with the legislative and regulatory requirements using inspections:

- ÚJD SR – Atomic Act
- ÚVZ SR and RÚVZs – Act on Radiation Protection
- MDV SR, MV SR, MO SR, SIS – Act on Radiation Protection
- NIP (IP Nitra) under the MPSVR SR – Act No. 125/2006 Coll.

The regulatory authorities are empowered under their respective legislation to enter and inspect facilities and activities without prior notification. The regulatory authorities may perform both planned and reactive inspections for nuclear activities and facilities using a graded approach and in different phases of the lifetime of a nuclear facility.

Given the number of regulatory authorities, this section focuses on generic issues, while further information on the conduct of inspections and their planning is provided in subsections 7.2-7.10. Inspection methods typically applied by the regulatory authorities include examination and evaluation of procedures, records and documentation, surveillance and interviewing of personnel, as well as the possibility to take samples and perform measurements. The results of inspections are typically rated according to their safety significance, documented in reports, and provided to the licensee.

The responsible authorities are guaranteed unrestricted access to facilities and activities under regulatory control, with and without prior notification. Joint inspections with multiple authorities are not typically conducted.

The IRRS team noted that due to limited coordination and cooperation between regulatory bodies, sharing inspection findings between the regulatory authorities is not formalised.

Inspection findings are not formally shared between ÚJD SR, ÚVZ SR, respective RÚVZs, MDV SR and NIP, as each has defined competencies in the relevant Acts. ÚJD SR does conduct daily meetings with all NPP site inspectors, as well as quarterly inspection meetings, to discuss inspections, findings, lessons learnt and other relevant topic areas to regulatory oversight. ÚVZ SR and MDV SR does not conduct formal inspector meetings to share information, but informally discusses inspections findings and lessons learnt.

Sharing of inspection findings supports information sharing and may provide useful information for consideration in inspection planning in relation to cross cutting areas between nuclear, radiation and transport safety, and environmental protection. The regulatory authorities should share inspection findings due to the potential for cross cutting findings and lessons learnt. The information would also directly support meeting requirements of IAEA International Safety Standards to ensure planning and conducting inspections takes into account similar findings and supports the application of the graded approach.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The regulatory authorities do not share finding of inspections within and across regulatory authorities to ensure cross-cutting issues and lessons learnt are effectively shared.*

(1)	BASIS: GSG-13, para. 3.288 states that <i>“Inspection findings should be discussed at regular meetings attended by groups of inspectors. It is also a good practice in many States to include those regulatory body staff involved in review and assessment activities or authorization activities in such meetings”.</i>
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S7	Suggestion: The regulatory authorities should consider sharing relevant inspection findings within and across regulatory authorities.
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The IRRS team also noted that unlike ÚJD SR, ÚVZ SR, respective RÚVZ and MDV SR do not have a comprehensive inspection programme. According to the IAEA International Safety Standards, regulatory authorities should establish an inspection programme which specifies the type, frequency and location of authorised parties to be inspected, taking into account the graded approach. Furthermore, ÚVZ SR and MDV SR do not have guidelines on preparing inspection check lists to ensure regulatory requirements are inspected in a consistent and coherent manner. This is important to ensure that inspectors are appropriately prepared and conduct a thorough inspection of facilities and activities.

Furthermore, ÚVZ SR, respective RÚVZ and MDV SR do not have guidance in their inspection procedures on how to ensure inspector objectivity and fairness. Guidance is important for inspectors about the importance of impartiality and the need to conduct themselves in a manner that inspires confidence in, and respect for, their competence and integrity. Although legislation has provisions concerning conflicts of interest and corruption, guidance and training on inspector objectivity is an important part of an Inspection Programme.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The ÚVZ SR and MDV SR do not have a comprehensive inspection programme.*

(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 29, para. 4.50 <i>“The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach”.</i>
(2)	BASIS: GSR Part 1 (Rev. 1) Requirement 29, para 4.52 states that <i>“Regulatory inspections shall cover all areas of responsibility of the regulatory body, and the regulatory body shall have the authority to carry out independent inspections. Provision shall be made for free access by regulatory inspectors to any facility or activity, at any time, within the constraints of ensuring operational safety at all times and other constraints associated with the potential for harmful consequences. These inspections may include, within reason, unannounced inspections. The manner, extent and frequency of inspections shall be in accordance with a graded approach”.</i>
R16	Recommendation: The ÚVZ SR and MDV SR should develop and implement a comprehensive risk-based inspection programme, taking into account the graded approach.

7.2. INSPECTION OF NUCLEAR POWER PLANTS

In the Slovak Republic, responsibility for regulatory oversight of nuclear power plants (NPPs) is administered primarily by three authorities. ÚJD SR is responsible for nuclear safety, ÚVZ SR is responsible for environmental and radiation protection, and NIP is responsible for occupational health and safety. The responsibilities of each authority are described in the Atomic Act, Act on Radiation Protection, and Act No. 125/2006 Coll., respectively.

ÚJD SR has established a comprehensive inspection and oversight programme to verify compliance with regulatory requirements and authorization conditions established for NPPs. At the time of the IRRS mission, there were two operating NPPs in the Slovak Republic: two units at the Bohunice site and two units at the Mochovce site. Additionally, two units are under construction at the Mochovce site, with one unit entering commissioning. Resident inspectors are present at both of the NPP sites, and conduct oversight activities of both operating units and units under construction and commissioning. The resident inspectors are supported by other experts from ÚJD SR to ensure all required competencies are available. In total there are 8 resident inspectors at NPP sites supported by dozens of inspectors from ÚJD SR office in Bratislava and Trnava. The planning, execution, reporting and follow up activities of inspections are guided by the ÚJD SR procedures for conducting inspections.

For NPPs, ÚJD SR, ÚVZ SR and NIP have established routine and non-routine inspections, which can be conducted on an announced or unannounced basis. The regulatory authorities also review scheduled licensee submissions on

performance indicators and other reports (e.g., events). Routine inspections by ÚJD SR are conducted by resident inspectors. Non-routine inspections are conducted when changes are made to safety significant systems, structures, components, and documentation as identified in the licence. Additionally, reactive inspections may be initiated following events or non-compliances by the licensee. Inspection results are documented in inspection reports. Areas requiring follow-up are identified for the licensee to provide clarification or take corrective action. Inspectors are provided with checklists to ensure inspection activities are conducted thoroughly and consistently. Inspectors of ÚJD SR and NIP follow a formal process for conducting inspections, while ÚVZ SR does not have inspection procedures.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>ÚVZ SR and MDV SR do not have internal guidance for inspectors on performing regulatory inspections.</i>	
(1)	BASIS: GSG-13, para. 3.262 (X) states that <i>“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. Each inspector should be given adequate training in following this guidance.”</i>
(2)	BASIS: GSG-13, para. 3.263 states that <i>“The guidance for inspectors should include the following:</i> <i>(a) Policies of the regulatory body regarding inspections.</i> <i>(b) The legal basis for regulatory inspection and the scope of the inspector’s authority.</i> <i>(c) The use of regulatory requirements, regulations, guides and standards.</i> <i>(d) The development of an inspection programme.</i> <i>(e) The implementation of the inspection programme, including:</i> <i>(i) Facilities (or areas of the facility) or activities to be subject to inspection;</i> <i>(ii) Method of inspection to be used;</i> <i>(iii) Methods for selection of inspection samples;</i> <i>(iv) Use of relevant technical information;</i> <i>(v) Use of inspection questionnaires;</i> <i>(vi) Follow-up on inspection findings.</i> <i>(f) Reporting requirements and practices for inspectors.</i> <i>(g) Standards of conduct of inspectors.</i> <i>(h) The enforcement policy, procedures and practices”.</i>
S8	Suggestion: <i>The ÚVZ SR and MDV SR should consider developing internal guidance for inspectors on performing regulatory inspections.</i>

An annual inspection plan is generated and approved annually for each NPP by the regulatory authorities. For ÚJD SR, the annual inspection plan is based on a three-year inspection plan. Flexibility is provided to the inspectors in the selection of individual tasks to be inspected using their professional judgement, results of previous inspections and the performance of the facility.

ÚVZ SR prepares annual inspection plans and carries out on-site inspections according to the plan for nuclear facilities. ÚVZ SR is also able to conduct additional inspections when required based on circumstances that may arise. ÚVZ SR does not have internal guidance or procedures on conducting inspections, but does conduct inspections in accordance with checklists. NIP establishes annual inspection plans and conducts inspections in accordance with internal guidance and procedures. NIP also responds, as appropriate, to occupational health and safety issues that arise on-site.

ÚJD SR can perform investigations or reactive inspections to ensure oversight following a serious event or exceedance of operational parameters. However, there are no provisions in the regulatory framework or internal guidance for the conduction of an independent investigation of a serious event by ÚVZ SR and MDV SR.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *ÚVZ SR and MDV SR do not always conduct independent investigations for serious events but does require licensees to conduct investigations.*

(1)	BASIS: GSG-13, para. 3.245 states that <i>“For a more serious event (or a potentially serious event), or when operational parameters (e.g., doses) exceed regulatory limits or are significantly elevated, an independent investigation should be conducted by the regulatory body and in some cases by other governmental bodies, in addition to the investigation to be conducted by the authorized party”</i> .
S9	Suggestion: The ÚVZ SR and MDV SR should consider conducting independent investigations for more serious events, or when operating parameters exceed regulatory limits or are significantly elevated.

Site visit to Mochovce NPP

The IRRS team observed a planned onsite inspection at Mochovce NPP in the area of operational limits. Specifically, the team observed the opening meeting between ÚJD SR and the licensee, in-field observations and data collection, and the closing meeting with the licensee. The ÚJD SR inspection team was led by one inspector of ÚJD SR from Trnava, with support from a second resident inspector. The inspection was performed using the approved checklist. The ÚJD SR inspection results were documented and discussed with licensee’s staff including previous areas for follow up and requests for clarification. In the opinion of the IRRS team, the ÚJD SR resident inspectors were professional, knowledgeable, and well prepared to conduct the inspection. The IRRS team also met the licensee, who identified that the relationship with ÚJD SR was of mutual respect, roles were clearly defined, and open conversations and consultation were conducted regularly. The licensee spoke of clarity in regulatory requirements and inspection practices, as well as possible enforcement for non-compliances.

7.3. INSPECTION OF FUEL CYCLE FACILITIES

Inspections in the area of spent nuclear fuel management are performed by staff of division of fuel cycle facilities as well as sites inspectors and following general inspection procedure on conducting inspections S 310 011:19. ÚJD SR inspectors have unlimited access to authorized facilities and activities (Atomic Act Section 31 part 11). During the inspections document reviews, interviews, walk downs, observation of activities methods are used. Reports are provided to management of ÚJD SR and licensee that was inspected. If deviation was indicated in the report, enforcement document (protocol) with deviation indication and justification as well as request to implement corrective measures during prescribed period is submitted to licensee. Specific internal inspection procedures for conducting inspections in areas of storage of fresh and spent fuel are in use (P 330 003:17).

Training of staff is provided in accordance with provisions of Atomic Act Sec. 31 for new employees as well as refresh training for other staff.

7.4. INSPECTION OF WASTE MANAGEMENT FACILITIES

Inspections in the area of radioactive waste management are performed by ÚJD SR staff of the Division of radioactive waste management and decommissioning as well as by ÚJD SR site inspectors dedicated to the area of radioactive waste management and decommissioning.

Inspection activities are carried out in accordance with the general inspection procedure on conducting inspections S 310 011:19. ÚJD SR inspectors have unlimited access to authorized facilities and activities. During the inspections document reviews, interviews, walk downs, and observation of activities are used. Inspection reports are provided to ÚJD SR management and the licensee that was inspected. If deviation was indicated in the report, enforcement document (protocol) that includes description of deviation and justification, as well as request to implement corrective measures during prescribed period shall be submitted to the licensee.

Training of ÚJD SR inspectors is provided in accordance with provisions of Atomic Act Sec. 31 for new employees as well as refresh training for other staff.

Also, specific inspection procedures for conducting inspections in areas of decommissioning, radioactive waste management and transport of radioactive waste are in use. Inspectors supervising radioactive waste management, decommissioning and transport of radioactive waste follow the specific inspection procedure – Control of nuclear safety at decommissioned nuclear power plants, during radioactive waste management and radioactive waste transport (P 340 002:19). The procedure applies to the area of supervision of radioactive waste management and radioactive waste transport and decommissioning of nuclear power plants. It covers inspection arrangements in generation, collection, sorting, handling of radioactive waste, processing and treatment, storage, disposal as well as transport of radioactive waste. Also covers aspects of decommissioning of nuclear installations.

For site inspectors, there is a draft internal procedure on conducting site inspections in area of decommissioning, radioactive waste management and transport of radioactive waste, which is expected to be valid from 15 September 2022. The procedure determines the rules for routine inspections performed by site inspectors supervising decommissioning activities, radioactive waste management activities and transport of radioactive waste.

Development and use of comprehensive internal procedures for inspections in areas of decommissioning, radioactive waste management and transportation, improve the effectiveness of inspections performed by ÚJD SR. The IRRS team commends the establishment of such internal procedures as **a good performance** and encourages ÚJD SR to maintain and expand on such measures.

7.5. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The regulatory body is empowered to inspect radiation source facilities and activities. The IRRS team was informed that 2 171 inspections were undertaken in 2020, COVID-19 public health emergency interrupted the regulatory body's inspection programme in 2021 and 2022.

The ÚVZ SR and the RÚVZ SR have 25 inspectors. The Ministry of Transport of the SR has 3 inspectors. Regulatory body officers are appointed as inspectors as part of their employment conditions. Inspectors conduct inspections on the basis of their assigned role and expertise within the regulatory body. For example, nuclear power plants are inspected by nuclear physicists or nuclear chemists, and medical facilities by medical physicists. Powers of inspectors are provided for under paragraphs 155 and 156 of the Act on Radiation Protection.

Announced and planned inspections are typically conducted. However, unannounced and reactive inspections are conducted in response to known or suspected breaches. Inspections may be partial or full scope depending upon the circumstances leading to the inspection. Inspection checklists are also available for consistently conducting inspection for radiation source facilities and activities.

On completion of inspections, the inspectors of ÚVZ SR provide a signed report to the authorised party, which is countersigned by the representative of the facility. The inspector may take actions as described in detail in Module 8. The inspection report's contents are set on an ad-hoc basis, leading to inconsistencies. As the IRRS team reviewed the sample inspection report from the site visit to BIONT (see section 7.8), it found that the report contains the review of patient dose records. The IRRS team learned that an electronic system is in development to help with the management of inspections. Currently the findings, feedback and experience from inspections are not disseminated amongst ÚVZ SR inspectors to share findings and lessons learnt. The IAEA International Safety Standards specify that sharing of inspection findings amongst inspectors has the ability to enhance the effectiveness of the regulatory body's inspection programme. **Suggestion S7 in Section 7.1. addresses this issue.**

The ÚVZ SR has a list of inspections which are developed by the respective inspectors for inspection of sources and facilities. The regulatory body however does not have a planned and comprehensive inspection programme which specify the types (full or partial; announced and unannounced) of regulatory inspections including the frequency, locations and programmes to be inspected, taking into account the risk of facilities and activities. The inspection programme may be used to develop annual plans on the basis of available number of inspectors including addressing any gaps in inspection resources.

7.6. INSPECTION OF DECOMMISSIONING ACTIVITIES

Inspections of decommissioning activities are performed applying common internal ÚJD SR procedure and specific procedure on inspections in the areas of decommissioning, radioactive waste management and transport. Details are provided in **Section 7.4**.

7.7. INSPECTION OF TRANSPORT

ÚJD SR has documented the processes in relation to inspections, inspection programme, and inspection check list and records, for the inspection of all authorised parties for the transport of nuclear radioactive material. MDV SR has informally documented the process for inspections which reflects discussions between MDV SR and ÚJD SR, however, the development of formal documented processes concerning inspection programmes, inspection procedures, are not yet in place. MDV SR implemented check lists for transport inspection based on the Technical Guide “Compliance Inspections by the European Competent Authorities on the Transport of Radioactive Material” and there is a system for keeping the records and reports from the inspection.

The ÚJD SR and MDV SR inspection programmes are risk-based and incorporate the appropriate regulatory measures to be inspected. There are fifty (50) authorised parties in the Slovak Republic of which twenty to thirty (20-30) authorized parties are inspected annually by MDV SR. ÚJD SR conducts inspections for each transport of nuclear radioactive material.

There are several authorities with regulatory oversight responsibilities of the authorised parties and facilities involved in the scope of transport as defined in IAEA International Safety Standards (SSR-6 (Rev. 1)). Coordination of the regulatory functions when several authorities have responsibilities for safety within the regulatory framework for safety is critical and requires effective coordination of their regulatory functions.

It is further considered appropriate to evaluate and benchmark the effectiveness of collaboration, thereby providing a basis to develop a continuous improvement process for the collaboration between the respective regulatory bodies responsible for safety.

In addition, consideration should also be given to developing formal interface agreements between the Ministries and Authorities involved, to formalise and emphasise the importance of the collaboration process. **Recommendation R4 in Section 1.5 addresses this issue.**

7.8. INSPECTION OF OCCUPATIONAL EXPOSURE

Inspectors of ÚVZ SR and RÚVZs perform their inspections according to the Act on Radiation Protection. Their education and training include passing a training course on radiation protection and on the job training, however there is no training programme in place. An inspection must take place before an authorisation is granted to a facility.

Site visit to BIONT

The IRRS team was invited to observe an inspection carried out at a site operating a cyclotron to produce radioactive isotopes. The visit by ÚVZ SR to carry out an inspection was due as a reactive inspection, as the facility commissioned a new hot cell for the processing of the radioisotopes produced. The ÚVZ SR inspector did not have an instrument to measure dose rate or contamination, the inspection was limited to the review of the documentation and visual inspection. After finishing daily production, the inspector and the licensee visited the cyclotron. The inspector and the licensee then visited the quality control laboratory and the area where transportation of the radiopharmaceuticals is prepared. The inspection of the documentation included the production reports of the cyclotron, the inventory of new type A packages to be used for transportation and a report was compiled by the inspector based on these. No non-compliances were identified by ÚVZ SR the inspectors.

The licensee remarked that the Act on Radiation Protection is quite complex, and it is confusing sometimes how one may conform its requirements.

7.9. INSPECTION OF MEDICAL EXPOSURE

ÚVZ SR is responsible for inspections in the area of the medical exposures. However, it is the RÚVZs that conduct the inspections of facilities and activities authorized for medical exposures. This includes inspecting the releases of radioactive substances, as well as contaminated objects resulting from activities involving medical exposures.

The ÚVZ SR and the RÚVZ SR do not have a common policy for planning and conducting inspections of facilities and activities involving medical exposure. The RÚVZ SR are also required to conduct an initial inspection of the facilities and activities that include medical exposures prior to issuing the authorizations. There are no approved procedures, methods or techniques of inspection. Therefore, the content of the check lists used by inspectors depend on their training, and personal experiences, and can differ significantly, particularly between inspectors from different regional radiation protection authorities.

Inspections are not planned by applying a graded approach, instead the inspections are primarily reactive to changes in the conditions of the authorizations already issued. Therefore, if such changes are not reported to the ÚVZ SR by either the licensee or by the providers of service in radiation protection, inspections are not planned at these facilities. Further, inspections by ÚVZ SR does not adequately consider authorized parties management systems for safety nor does it assess the competence of staff involved in medical exposures.

The regulatory framework does not include provisions for ÚVZ SR to ensure that the scope of inspections include all aspects mentioned in IAEA Safety Standards, such as structures, systems, components and materials important to safety; management systems; operational activities and procedures; records of operational activities and results of monitoring; liaison with contractors and other service providers; competence of staff; and safety culture. The ÚVZ SR inspection programme should cover all aspects of the IAEA Safety Standards using a graded approach.

The regulatory framework for radiation protection also lacks provisions for inspecting causes and consequences of unintended or accidental medical exposures. Additionally, ÚVZ SR does not inspect if the lessons learned from significant events are included in the emergency plan for the medical facilities and activities.

Recommendation R16 in Section 7.1 addresses these issues.

7.10. INSPECTION OF PUBLIC EXPOSURE

During the interviews with representatives of ÚVZ SR, the IRRS team was informed that there are no specific inspection procedures for practices leading to public exposures. ÚVZ SR does not have any processes to ensure requirements established in the authorization specific for public protection are adequately verified. **Recommendation R10 in Section 4.3. addresses this issue.**

7.11. SUMMARY

The IRRS team observed that the regulatory authorities conduct inspections for facilities and activities in the Slovak Republic.

ÚVZ SR should further develop their inspection programme and supporting processes and internal guidance, as well as ensure areas identified in IAEA requirements and guidance in the area of medical exposure are included.

ÚVZ SR and MDV SR should develop internal guidance on the conduct of inspections and consider objectivity in inspection programme.

All regulatory authorities responsible for conducting inspections should share inspection findings given the potential for cross cutting findings that may impact the planning and scope of inspections by each regulatory authority.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

Enforcement actions are clearly identified and defined within applicable legislation. The Atomic Act provides the ÚJD SR with legislative authority to take enforcement action against the licensee. The Act provides provisions for ÚJD SR to modify or terminate an issued permission or authorization, enforce economic sanctions, and prescribe the period of time for a licensee to correct non-compliance. ÚJD SR has a Procedure on Enforcement Actions that specifies how ÚJD SR can take enforcement actions. ÚJD SR also has a related enforcement procedure and an administrative process. However, ÚJD SR, ÚVZ SR and MDV SR have not established a comprehensive and overarching enforcement policy covering the whole range of enforcement actions. The regulatory authorities deal with non-compliances under the threshold of the sanction regime verbally, with a written note or with imposing additional regulatory requirements as a means of enforcement. The procedure on inspection includes some provisions for non-compliances under the threshold of the sanction regime, such as who is in charge to take enforcement decisions, but there are no documented specific criteria for determining the appropriate enforcement response.

According to the Act on Radiation Protection, ÚVZ SR and RÚVZs and MDV SR while carrying out its duties during an inspection, has the right to enforce the requirements of the Act. This action must be commensurate with the risk which may arise from the given facility or activity. The Act on Radiation Protection also describes what non-conformances could arise and in response to these, sanctions may be imposed on the authorised parties. Enforcement actions include demands for revision of the documentation and arrangements for protection, repeal of the licence, suspension of the activities, confiscation of radiation sources and a range of fines. Safety culture is not addressed when enforcement actions are taken. All reports by the inspectors are provided to the authorised parties in writing. However, since there are no training programmes, guides and policies set for enforcement there may be an inconsistency on how non-compliances are addressed.

NIP has established and implemented an enforcement policy within the legal framework. The Inspection Act defines the basic procedures and amounts of penalties for non-compliance with the basic rules in the field of occupational safety and health.

The authorized party has the right to appeal sanctions issued by ÚJD SR, ÚVZ SR, RÚVZs, MDV SR and NIP.

The MDV SR also follows an informal procedure concerning enforcement. This is related to the issue that MDV SR should take action to ensure a management system that includes the responsibilities, duties, documented procedures of the Radiation Protection Department for the regulatory oversight of the transport of radioactive material, and the prescribed interfaces between other regulatory authorities. **Recommendation R4 in Section 1.5 addresses this issue.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The legal framework provides a sanction regime and ÚJD SR and ÚVZ SR have established elements of an enforcement policy. However, ÚJD SR and ÚVZ SR have not explicitly established a comprehensive enforcement policy for responding to all types of non-compliances according to a graded approach.*

(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 30 states that “ <i>The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization</i> ”.
(2)	BASIS: GSR Part 1 (Rev. 1) para. 4.55 states that “ <i>Enforcement actions by the regulatory body may include recorded verbal notification, written notification, imposition of additional regulatory requirements and conditions, written warnings, penalties and, ultimately, revocation of the authorization. Regulatory enforcement may also entail prosecution, especially in cases where the authorized party does not cooperate satisfactorily in the remediation or resolution of the non-compliance</i> ”.
R17	Recommendation: The Regulatory Body should establish and implement an enforcement policy covering the whole range of possible enforcement actions.

8.2. ENFORCEMENT IMPLEMENTATIONS

The majority of enforcement actions of ÚJD SR, ÚVZ SR, RÚVZs and NIP consist of verbal notifications, written notifications and the imposition of additional regulatory requirements. The regulatory authorities apply the sanction regimes only in case of severe violations, resistance, or non-compliance with the corrective actions by the authorized party. Sanctions imposed by ÚJD SR and ÚVZ SR are made public through their websites.

The regulatory authorities can impose penalties on the licensee or on individual workers.

Although the competencies are clearly defined for ÚJD SR, ÚVZ SR, RÚVZs and NIP, there are cross cutting areas that may impact the work associated with each regulatory body. In order to ensure that cross cutting areas are not missed, information on relevant enforcement actions taken by each authority should be shared. The IRRS team noted that provisions for cooperation and sharing information are provided in the Act on Control in the State Administration as amended (Act No. 10/1996 Coll.). However, ÚJD SR, ÚVZ SR, RÚVZs and NIP do not have a procedure to implement the provisions in this Act. A procedure to share information on enforcement actions will strengthen the cooperation between regulatory bodies, enable discussions on legal challenges associated with enforcement, and provide a mechanism for regulatory authorities to take relevant enforcement actions into consideration regarding inspection and enforcement activities.

ÚJD SR has identified the need for a formal written warning addressed to the licensee before further legal enforcement proceedings. The IRRS team agrees with this.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *ÚJD SR, ÚVZ SR and NIP do not have procedures to share information among regulatory authorities on enforcement actions taken.*

(1)	BASIS: GSG-13, para 3.314 states that “Procedures should stipulate which other governmental bodies, if any, should be informed in the event of enforcement actions being taken”.
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S10	Suggestion: The ÚJD SR, ÚVZ SR and NIP should consider developing and implementing a procedure to inform each authority of relevant enforcement actions being taken.
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8.3. SUMMARY

The legal framework provides enforcement powers to the regulatory authorities. There is a sanction regime with a graded approach in place, however ÚJD SR and ÚVZ SR lack a comprehensive enforcement policy covering the whole range of possible enforcement actions from verbal notification to revocation of the authorization. In addition, procedures to share information on enforcement actions between the regulatory authorities are missing.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

The Slovak legislative and regulatory framework for nuclear and radiation safety includes the Constitution of the Slovak Republic, Acts, Ordinances, Decrees, Measures and Associated Guidelines. The Acts, Ordinances, Decrees and Measures outline the regulatory requirements, and the Associated Guidelines outline detailed supporting information that enables compliance with the regulatory requirements.

The Atomic Act and the Act on Radiation Protection govern the regulation of civilian uses of nuclear facilities, nuclear materials, and sources of ionizing radiation. The Atomic Act establishes principles and requirements for ensuring nuclear safety and security, and licensing nuclear facilities and activities. The Act on Radiation Protection establishes the basic principles and requirements for the radiation safety of activities, installations, events and situations that might involve ionizing radiation hazards.

The Atomic Act defines the role of ÚJD SR in the regulatory process and authorizes ÚJD SR to issue Decrees and guidelines. ÚJD SR develops Decrees and guidelines in accordance with the Atomic Act. The decrees cover, among other topics, requirements for Provision of Physical Protection (ÚJD SR Decree No. 51/2006 Coll.), Emergency Planning for the event of an incident or accident (ÚJD SR Decree No. 55/2006 Coll.), Nuclear Safety Requirements (ÚJD SR Decree No. 430/2011 Coll.), Quality Management System (ÚJD SR Decree No. 431/2011 Coll.), Reporting Operational Events (ÚJD SR Decree No. 48/2006 Coll.) and Requirements for the handling of nuclear materials, radioactive waste and spent nuclear fuel (ÚJD SR Decree No. 30/2012 Coll.).

The issuance of regulations and guides is governed by the ÚJD SR Procedure on preparation, approval of decrees (S 230 025:21) and the Procedure on the issuance of safety guides of ÚJD SR (S 230 016:20). ÚJD SR Procedure on transposition of international standards (S 210 032:21) ensures the relevant international standards including IAEA safety standards are taken into account in this process. In addition, the procedures ensure that international experience and research findings are considered and used to benchmark materials to draft, review and/or revise regulatory requirements and guides, which may take into account the graded approach. The result is a 3-year plan that is revised on an annual basis for the development of regulations and safety guides.

The ÚJD SR has published a total 35 safety guides and has placed them on their website. These guides are non-binding and aim to provide a consistent approach in compliance with the regulations. The ÚJD SR procedure on the issuance of safety guides includes forming a peer group of experts from outside the ÚJD SR (licensees, research groups, universities, etc.) to review and comment on the draft guide. This group will meet several times to discuss the draft guidance with the aim of reaching consensus on the specific wording of the guide. The process requires that comments received will be documented and addressed. The final guide is provided to the ÚJD SR chairperson for final approval. The IRRS team considers it **a good performance** that a draft guide is reviewed by a peer group of experts for commenting and revision before finalisation.

Participation of other government agencies, relevant stakeholders and the public in reviewing and developing regulations is ensured by publishing a notice about the proposed regulation and providing the opportunity to comment on the regulation through a public website, in accordance to Act No. 400/2015 Coll. on the drafting of legislation. This process is not unique to ÚJD SR but applies to all binding legislation issued by the Government of the Slovak Republic.

The Act on Radiation Protection defines the role of ÚVZ SR in the regulatory process and authorizes MZ SR to issue regulations and ÚVZ SR to issue guides. For the issuance of regulations, participation of stakeholders and the public is ensured by the general process mentioned above, but it does not include provisions to take account of international standards, feedback of relevant experience, technological advances, research and development, relevant operational lessons learned and institutional knowledge. This relates to the issue that ÚVZ SR is lacking an integrated management system, which is addressed in **Recommendation R10 in Section 4.3**.

In addition, ÚVZ SR currently does not develop nor issue guidance to support applicants and licensees in complying with the relevant regulations. In case of questions from licensees or other relevant parties, ÚVZ SR and MDV SR employees communicate additional information through informal means to stakeholders or stakeholder groups and might post such information on their website. However, these activities depend on choices and actions of individual employees and no formal guidance is issued.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Currently, ÚVZ SR have not developed and issued guides to support applicants and licensees in complying to the relevant regulations.*

(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 32 states that <i>“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”.</i>
(2)	BASIS: GSG 13 para 3.18 states that <i>“Irrespective of the degree to which the government or regulatory body has developed prescriptive regulations, the regulatory body should give consideration to supplementing its regulations with supporting guides of a non-mandatory nature on how to comply with regulations, where appropriate”.</i>
R18	Recommendation: ÚVZ SR should establish or adopt guidance to support applicants and licensees in complying to the relevant regulations.

It is the authorised party’s responsibility to ensure that their duties, as defined in the Act for Radiation Protection, are performed. However, the licensee can delegate certain tasks pertaining the radiation protection of its facilities and activities to specialised health professionals, who are trained and certified to perform their duties and responsibilities. An example of this kind of delegation are the duties and responsibilities of the RPO. However, there are no provisions in the regulatory framework for radiation protection to assure that the delegation of responsibilities by a principal party is documented.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *There are no provisions in the regulatory framework for radiation protection to assure that the delegation of responsibilities by a principal party is documented.*

(1)	BASIS: GSR Part 3 Requirement 9, para 3.15 states that <i>“Registrants and licensees ... (b) shall ensure that any delegation of responsibilities by principal party is documented”.</i>
R19	Recommendation: The Government should ensure that the regulatory framework for radiation protection includes provisions to assure that the delegation of responsibilities by registrants and licensees is documented.

Overall, ÚJD SR has a well-established regulatory framework that enables the effective regulatory oversight of nuclear facilities in the Slovak Republic. For the oversight of radiation protection by ÚVZ SR regulatory guides are lacking.

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

The Nuclear Power Plants (NPPs) are regulated in accordance with the Atomic Act, the Act on Radiation Protection and associated regulations and guides. ÚJD SR has established and maintains a comprehensive set of Decrees and Safety Guides covering nuclear safety, which currently includes 12 Decrees and 35 Safety Guides. Together with the Atomic Act, these Decrees and Safety Guides form a comprehensive set covering all relevant key areas in both design and operation, such as fundamental safety functions, application of defence in depth, nuclear power plant states, design basis, postulated initiating events and design extension conditions, reliability, operational limits and conditions, reporting of events, personnel qualification and training, accident management, operating procedures, modification, maintenance, testing, surveillance and inspection, and monitoring and control of activities performed by vendors, contractors and suppliers.

ÚJD SR Decrees and Safety Guides are routinely revised in accordance with the processes mentioned in **Section 9.1.**

9.3. REGULATIONS AND GUIDES FOR FUEL CYCLE FACILITIES

As spent nuclear fuel handling and storage facilities are considered as nuclear installations all requirements and guidelines on safety are applied. The following regulations are provided on regulations for fuel cycle facilities:

- Decree of the Nuclear Regulatory Authority of the Slovak Republic No. 30/2012 Coll. as amended by Decree No. 101/2016 Coll. laying down details of requirements for managing the nuclear materials, radioactive waste and spent nuclear fuel;
- Decree of the Nuclear Regulatory Authority of the Slovak Republic No. 430/ 2011 Coll. as amended by Decree No. 103/2016 Coll. on nuclear safety requirements;
- Decree of the Nuclear Regulatory Authority of the Slovak Republic No. 33/2012 Coll. as amended by Decree No. 106/2016 Coll. and Decree No. 71/2019 Coll. on the regular, comprehensive and systematic assessment of the nuclear safety of nuclear installations;
- Decree of the Nuclear Regulatory Authority of the Slovak Republic No. 431/2011 Coll. as amended by Decree No. 104/2016 Coll. on a Quality Management System;
- Decree of the Nuclear Regulatory Authority of the Slovak Republic No. 58/2006 Coll. as amended by Decree No. 31/2012 Coll. and Decree No. 102/2016 Coll. Laying Down Details on the Scope, Contents, and Manner of Maintaining Documentation of Nuclear Installations Necessary for Individual Decisions.

The Decree on nuclear safety requirements for nuclear installations (No. 430/ 2011 Coll., as amended) shall be used at the several stages, including siting, design, construction, commissioning, operation and decommissioning. The nuclear safety requirements for nuclear installations also include criteria for the categorisation of classified equipment into safety classes. The Decrees also regulate the assessment of the scope, content and impacts of modifications, details on evaluation, documenting, feedback scope, the scope and content of probabilistic assessment of nuclear safety, details on monitored indicators, criticality control, maintenance, periodic testing and inspection, operational limits and conditions, operating procedures, organisational structure, and staff.

The Decree No. 30/2012 Coll., as amended contains requirements on nuclear materials and radioactive waste management and for handling and storage of spent nuclear fuel.

The Decree No. 33/2012 Coll., as amended governs the intervals and scope of the performance of regular, comprehensive, and systematic assessment of the nuclear safety of the nuclear installations.

The Decree No. 431/2011 Coll., as amended contains requirements for the scope, content, hierarchy, structure and review of the quality management system of the applicant for an authorisation and the licensee, as well as requirements for the scope, content, hierarchy and structure of its documentation, details of requirements for nuclear installation quality assurance, details of requirements for classified equipment quality assurance of and details on the scope of their approval.

The Decree No. 58/2006 Coll., as amended contains requirements on the scope, contents, and methods for maintaining documentation provided for authorisation set forth in Sec. 5 of the Atomic Act.

9.4. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

In accordance with provisions of Sec. 6 part 1 of the Act on the National Nuclear Fund No. 308/2008 Coll., the Board of Governors of the Fund is required to develop and update the proposal of the National Policy for management of the spent nuclear fuel and radioactive waste and the National Programme, in cooperation with consent or licensees issued by the Authority pursuant to special provisions of Atomic Act. The National Programme shall comprise, among others, the inventory of the spent nuclear fuel and radioactive waste and estimations for future quantities including those generated during decommissioning. This Programme also must include the concepts, plans, technical solutions for the management of the spent nuclear fuel and radioactive waste from generation to disposal thereof, and assessment of costs for implementation and its underlying basis. Considerations for public information sharing

(including the process for public engagement in decision-making process) must also be included for the management of spent nuclear fuel and radioactive waste and in addressing the end stage use of nuclear material in the Slovak Republic. ÚJD SR reviews and issues opinions on the Policy and National Programme. ÚJD SR also reviews this report on the fulfilment of the National Programme pursuant to Atomic Act sec. 4 para 2e, points 6, 7 and 8.

Basic requirements on predisposal management are provided in Sec. 21 of the Atomic Act and details are given in Decree No. 30/2012 Coll., as amended. Provisions on interdependencies at each stage of the process during managing and/or handling the radioactive waste [Sec. 2 (1)] are identified. Determination of the physical properties of radioactive wastes are required. This Programme requires that a radioactive waste storage facility is designed and operated so that during the planned storage period radioactive waste is protected from degradation due to changes in physical and chemical forms – whether as a result of negative climatic or meteorological conditions and other external conditions. The Decree requires that storage safety is primarily ensured through passive safety elements, that stored radioactive waste can be easily and safely handled and withdrawn, and that the properties of conditioned radioactive that determine its disposal do not change (Sec. 9 (2)).

Sec. 12 of Decree No. 30/2012 Coll. requires limits and conditions for safe operation of radioactive waste management facilities to be based on safety analyses, and to include information on quantities characterizing the conditions with which nuclear safety and radiation protection is ensured during the management of radioactive waste, and the manner and frequency of their measurement and assessment. It contains requirements for procedures, frequency, type and scope of radioactive waste checks to be performed to demonstrate compliance with limits and conditions for waste acceptance criteria and measures for management of radioactive waste that does not meet the waste acceptance criteria. It requires safe storage operating limits and conditions to include conditions of acceptability of radioactive waste for storage, which must also meet the requirements for management of stored radioactive waste. Safe repository operating limits and conditions are also required to include conditions of acceptability of waste package forms for the repository, particularly the type of waste package form and its structural stability, leachability, thermal and radiation effects, possibility of a critical condition or microbial degradation occurring, gas formation, content of corrosive, explosive and self-igniting substances, flammable materials, free liquids and complexing or chelating agents, surface contamination, dose rate, dimensions, weight, and labelling of the packaged form of radioactive waste.

Sec. 7 of Decree No. 57/2006 Coll. stipulates that if radioactive waste packages include dual purpose storage and transport of the cask, the design, manufacturing, and safety case is also subject of approval of package design for transportation.

In accordance with Decree No. 430/2011 Coll. on nuclear safety, the safety of the repository shall be ensured throughout its design lifetime, preferentially through passive characteristics so that the necessity of active actions is minimised after the repository closure. The repository design shall include a definition of structural barriers, supplementing the natural features of the area, and together preventing or slowing the potential release of radioactive substances from stored radioactivity into the environment over the long term. Provisions of the isolation of radioactive waste from the environment relies on a multi-barrier protective system whose safety features are based on various physical or chemical processes that prevent or slow the potential release of radioactive substances into the environment. The Decree also includes characteristics of the site that exclude its use for the siting of nuclear installations.

In accordance with the provisions of Sec. 22 of the Atomic Act, closure of a repository shall mean the administrative and technical activities after completion of the placement of radioactive waste or spent nuclear fuel in the repository, including the final construction or other works necessary to bring the repository into a long-term safe condition. Institutional control shall mean a set of activities that ensures control of access to the repository and control and maintenance of functionality of its barriers after closure of the repository at the time specified in the safety documentation. Authorisation for repository closure and for the institutional controls shall be issued by the Authority upon submitting a written application of the licensee for operation of a repository, supported by the documentation referred to in Annex 1 point E of the same Act. The licensee shall implement measures to ensure, that after the repository closure, records are maintained, institutional control of the repository is provided for, and remedial action is taken, if necessary, in the case of unplanned release of radioactive substances. Details on content of submittals for authorisation of repository closure and for the institutional controls are provided in Decree No. 58/2006 Coll. as amended.

9.5. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The legal framework for radiation protection in the Slovak Republic is based on the Act on Radiation Protection and a series of underlying Decrees issued by the MZ SR. It contains the fundamental principles of radiation protection concerning justification, optimisation and dose limitations. The Act on Radiation Protection defines the roles of ÚVZ SR and RÚVZ SR in the regulatory process for radiation sources and activities.

Overall, the regulatory framework for radiation protection enables the regulatory oversight of radiation protection as the Act on Radiation Protection is very detailed and covers the relevant aspects of radiation protection, however, guidance is lacking. **Recommendation R18 in Section 9.1 addresses this issue.**

9.6. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

The Act on the National Nuclear Fund No. 308/2018 Coll Sec. 6(6) requires the National Programme proposed by the Board of Governors to include a planning of activities related to the final stage of the peaceful use of nuclear energy (end point of decommissioning) and to include the activities related to the decommissioning of nuclear installations. It shall provide an assessment of the costs for the National Programme implementation and its underlying basis and prerequisites for that assessment, taking time perspective into account, the financial scheme of the National Programme implementation.

According to provisions of Decree No. 58/2006, the final description of a decommissioned nuclear installation site and of all work performed in decommissioning shall contain demonstration of achievement of the objectives of decommissioning and compliance with the requirements of supervisory authorities, assessment of decommissioning by comparing the envisaged and actual data of radiological status, a list of installations, premises and lands released for restricted use, a description of all work performed during decommissioning. Collective effective and equivalent dose data received by the occupational permit holders staff during their work are required to be documented and shall include potential doses to the public during decommissioning if restrictions of site use are envisaged.

9.7. REGULATIONS AND GUIDES FOR TRANSPORT

In the Slovak Republic, ÚJD SR and MDV SR operate under the Atomic Act and the Act on Radiation Protection respectively. Discussions with both Authorities revealed that the requirements are contained the Acts. However, as detailed in Section 6.7., the scope of the ÚJD SR and MDV SR regulatory oversight activities relating to the transport of nuclear radioactive material and radioactive material respectively, must ensure the authorizations both authorities issue, comply with the scope and requirements of the “Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)” which adopts all the requirements of SSR-6 (Rev. 1); Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods also applies.

During discussions with ÚJD SR and MDV SR, the IRRS team was informed that this gap in the Act on Radiation Protection did not provide regulatory authority to MDV SR to grant authorization for Type B and Type C packages containing radioactive material. The IRRS team was advised that this gap has been recognised and a revised Act is currently passing through the legal process for enactment. **Recommendation R12 in Section 5.7. addresses this issue.**

9.8. REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE

The Act on Radiation Protection stipulates that workers must be categorised and their exposures shall be adequately monitored by a competent organisation, recognised by the ÚVZ SR. Nuclear facilities have their own recognised service providers for dose assessment. The Act on Radiation Protection is very detailed and covers almost all aspects of occupational exposures, however, guidance is lacking. **Recommendation R18 in Section 9.1 addresses this issue.**

The Act on Radiation Protection requires that authorised parties employ radiation protection officers (RPO), who received relevant training according to their tasks, and are recognised by the ÚVZ through an assessment procedure by written and oral examinations. RPOs provide training to other workers, but the scope and extent of these trainings is inconsistent and may not include information on risks to pregnant and breastfeeding workers. The IRRS team learned that a modification of the Act on Radiation Protection is already drafted to address this issue.

The Act on Radiation Protection also defines a class of workers as “person with direct responsibilities” who participates in planning of work resulting in exposures, informs workers on protective measures, oversees the activities with radiation sources, and participates in the investigation of incidents and accidents. The cooperation between employers and licensees is required by the Act on Radiation Protection, and incidents and issues having potential safety implications must be reported to the employer.

Related to existing exposure situations, the ÚVZ SR prepared the National Radon Action Plan, a strategic document outlining the arrangements to identify, measure and implement corrective actions to reduce exposure to radon. There are natural caves in the country, where circumstances give rise to occupational exposure of the tourist guides employed there. These activities are not authorised (only notified) by the ÚVZ SR, although the effective doses could be as high as 20 mSv per year. Necessary requirements for planned exposure situations are applied and inspected at these workplaces. **Recommendation R5 in Section 1.6. addresses this issue.**

Dose limits are laid down in the Act on Radiation Protection. The dose limits are in line with the requirements of the IAEA (GSR Part 3, Section III). When a worker is exposed to more than 20 mSv effective dose in a given year, a health assessment must be carried out by a recognised occupational health service. The worker may continue to work if the health assessment still confirms the fitness of the worker. The Central Dosimetry Registry operated by the ÚVZ SR summarises the radiation dose received by workers.

The Act on Safety and Health Protection at Work (124/2006) describes in detail what factors, medical examinations and health assessment should be provided by occupational health services to radiation workers.

Several benefits are in place for workers exposed to higher risks according to Act No. 311/2001 Coll. Labour Code. These include extra holidays, a voucher to use services of recreational facilities at a discounted price, and reducing the work hours per week to 36 hours for occupationally exposed workers. However, these benefits do not relieve in any way the licensees from their responsibilities or from the requirement that they must provide appropriate protection to the workers. This was confirmed during the site visit.

9.9. REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE

The Act on Radiation Protection defines the general requirements for radiation protection in medical applications of ionising radiation, while Decree MZ SR No. 101/2018 Coll defines the contents of required documents and the necessary measures to comply with the requirements from the Act. However, ÚVZ SR has not developed or issued any guidance for the application of the principles of radiation protection for medical exposure situations for applicants or licensees, nor has ÚVZ SR established or adopted guidance for protection and safety. **Recommendation R18 in Section 9.1 addresses this issue.**

There are provisions in the regulatory framework that require specific education, training and competence from health professionals responsible for protection, safety and authorization of medical exposure. In addition, the regulatory framework contains provisions for ÚVZ SR to establish diagnostic reference levels, and for dose constraints for carers and voluntaries in biomedical research programmes, and for the design of shielding. The regulatory framework also contains information regarding the criteria for the release of patients after radionuclide therapy, and measures to minimize the likelihood of unintended and accidental exposures, including the information given by the licensee about the benefits and risks to patients and carers, and to the public in the cases of radionuclide therapy.

The Act on Radiation Protection and the Decree MZ SR No. 101/2018 Coll. require justification of medical exposures to be shared by the specialised medical referrer and the medical practitioner responsible for the exposure. The requirements for the methodology for justification that should be followed are included in Act 578/2004, and Act 576/2004. The regulatory framework for radiation protection also includes provisions for special measures regarding the medical exposure of pregnant and breast-feeding patients. However, it was identified that the Act on Radiation

Protection does not contain provisions for the independent verification of calibration of radiation therapy units prior to clinical use, nor does the Decree MZ SR No. 101_2018 Coll.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>The regulatory framework does not have provisions for independent verification of calibration of radiation therapy units prior to clinical use.</i>	
(1)	BASIS: GSR Part 3 Requirement 38, para. 3.167 (c) states that “3.167. <i>In accordance with para. 3.154(d) and (e), the medical physicist shall ensure that:</i> <i>(c) Calibrations of radiation therapy units are subject to independent verification prior to clinical use</i> ”;
R20	Recommendation: The Government should ensure that the regulatory framework includes provisions for independent verification of calibration of radiation therapy units prior to clinical use.

There is a lack of trained medical physicists in all specializations of medical applications of ionising radiation, but particularly in the field of radiology. Acceptance and commissioning of radiological medical equipment is done by the authorised party’s RPO or by external experts from the providers of services in the area of radiation protection. Dose assessments resulting from medical exposures to patients, carers and members of the public are usually made by RPOs. However, the regulatory framework for radiation protection lacks provisions to assure that acceptance and commissioning tests of the equipment prior to its clinical use on patients are done by, or under the supervision of, a medical physicist.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>There are no provisions in the regulatory framework for radiation protection to assure that acceptance and commissioning tests of the equipment prior to its clinical use on patients are done by, or under the supervision of, a medical physicist.</i>	
(1)	BASIS: GSR Part 3 Requirement 36, para. 3.154 (d) (e) states that “ <i>Registrants and licensees shall ensure that:</i> <i>(d) For therapeutic radiological procedures, the requirements of these Standards for calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, as specified in paras 3.167, 3.168(c), 3.170 and 3.171, are fulfilled by or under the supervision of a medical physicist;</i> <i>(e) For diagnostic radiological procedures and image guided interventional procedures, the requirements of these Standards for medical imaging, calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, as specified in paras 3.167, 3.168(a) and (b), 3.169, 3.170 and 3.171, are fulfilled by or under the oversight of or with the documented advice of a medical physicist, whose degree of involvement is determined by the complexity of the radiological procedures and the associated radiation risks</i> ”;
(2)	GSR Part 3 Requirement 38, para. 3.171 (a)(i) states that “ <i>Registrants and licensees shall ensure that programmes of quality assurance for medical exposure include, as appropriate to the medical radiation facility:</i> <i>(a) Measurements of the physical parameters of medical radiological equipment made by, or under the supervision of, a medical physicist:</i> <i>(i) At the time of acceptance and commissioning of the equipment prior to its clinical use on patients</i> ”.
R21	Recommendation: The Government should ensure that the regulatory framework includes provisions for acceptance and commissioning tests of the equipment prior to its clinical use on

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

patients are done by, or under the supervision of, a medical physicist.

9.10. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE

Act 24/2006 of the Ministry of the Environment establishes provisions to ensure the protection of the public outside the national territory due to releases in the country and for the exchange of information and consultations, as appropriate, with authorities from neighbouring countries.

Act on Radiation Protection (Act 87/2018) includes criteria for the classification of areas in facility premises and establishes provisions for the protection of visitors to these areas. Provisions related to control of discharges and monitoring with public protection purposes are referred to in Section 5.10.

Provisions for the control of consumer products in compliance with GSR Part 3 have been also incorporated in the Act. Reference levels have been established for drinking water and building materials. Decisions on the use of other commodities are taken on a case-by-case basis, but no specific criteria have been developed. Regarding the control of the exposure of the public to radon, the Act 87/2018 establishes a radon concentration reference level of 300 Bq m⁻³ for dwellings and public buildings.

9.11. SUMMARY

The legal and regulatory framework of the Slovak Republic provides a comprehensive and robust foundation for the regulatory oversight of nuclear facilities. ÚJD SR implements and maintains a comprehensive set of guidelines that demonstrate a high level of quality in regulation for all nuclear facilities and activities.

The IRRS team observed that ÚJD SR is fully committed to regularly updating its Regulatory Guides. ÚJD SR actively participates in information sharing fora, collects and systematically explores national and international experience, and ensures that information regarding ÚJD's regulatory requirements is widely available.

The regulatory framework in the field of radiation protection provides a sound foundation for the regulatory oversight of radiation protection on the requirements level.

The IRRS team identified deficiencies including lack of guidance in the field of radiation protection and gaps in the regulations for medical exposure.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

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

The Slovak Republic has established a statutory framework at the national level to prepare for and manage the consequences of radiological emergencies. There are several governmental bodies involved in these processes and roles and responsibilities are key during an emergency:

- ÚJD SR national competent authority and contact point under the Convention on Early Notification of a Nuclear Accident and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency and for the European Commission.
- ÚVZ SR, contact point for WHO determines reference levels for optimization of exposure in an emergency situation or in case of persistent exposure in an existing exposure situation and determines the conditions for the transition from an emergency to an existing exposure situation.
- MV SR serves as the main civil protection authority, as a contact point of the Emergency Response Coordination Centre of the European Union and of neighbouring States and as a national warning point for the IAEA.
- MDV SR includes responsibilities during incidents and emergencies during transport of radioactive material and approves the emergency transport plan containing protective measures during an incident or emergency.

The main laws, legislative acts, conventions, and bilateral agreements which discuss various aspects of radiation emergency preparedness and response (EPR) include:

- Act No. 171/1993 Coll. on Police Corps
- Act No. 42/1994 Coll. on Public Civil Protection, as amended
- Act No. 315/2001 Coll. on firefighters and rescue corps and others
- Act No. 575/2001 Coll. on Organisation of Governmental Activities and of Central State Administration, as amended
- Act No. 387/2002 on state crisis management in crisis situations during peace time
- Act No. 129/2002 Coll. on the Integrated Rescue System
- Act No 541/2004 Coll. on Peaceful Uses of Nuclear Energy (Atomic Act)
- Act No. 128/2015, § 9, on Prevention of Severe Industrial Accidents
- Decree of the ÚJD SR No. 55/2006 Coll. laying down details in emergency planning for the event of an emergency, as amended
- Act No. 87/2018 Coll. on Radiation Protection (PHA Regulations)
- Decree of the MZ SR No. 96/2018 Coll. on Radiation Monitoring Network
- Council Decision 87/600/Euratom of 14 December 1987 on Community arrangements for the early exchange of information in the event of a radiological emergency
- Act of the NC SR No. 129/2002 Coll. on the Integrated Rescue System as amended
- MoH Decree of the MZ SR No. 99/2018 Coll. on ensuring radiation protection
- Convention on Nuclear Safety (Article 16, Emergency Preparedness)
- Convention on Early Notification of a Nuclear Accident (Notification No. 327/2001 Coll.)
- Convention on Assistance in case of a Nuclear Accident or Radiological Emergency
- Bilateral agreements with other countries (Hungary, Austria, Czech Republic, Poland, Ukraine, Romania, Russian Federation, Slovenia, Germany, Bulgaria) and agreements on cooperation with USA, France, and Canada.

Authorities and fields of competence among the different governmental regulatory bodies are assigned by the Act No. 575/2001 Coll. on Organization of Governmental Activities and of Central State Administration. The level of decision making is dependent on the territory that is affected by the emergency. In case the emergency exceeds the territory of one region, MV SR's Central Crisis Headquarters (CCH) is responsible for coordination of activities and for orders issued during an emergency. As stated above, MV SR serves as the contact point for the Emergency Response Coordination Centre with the European Union and neighbouring states and as a national warning point for the IAEA. CCH provides advice to the Government of the Slovak Republic that makes decisions. The MV SR serves

as the secretariat of the CCH, in which the Chair of ÚJD SR, chief public health officer of the Slovak Republic and the minister of health are sitting as members.

ÚJD SR has primary responsibilities for nuclear safety and emergency preparedness and planning, ÚVZ SR has responsibilities in radiation protection, including incidents and emergencies involving radiation sources and facilities, and MDV SR has responsibilities during incidents and emergencies during transport of radioactive material. In addition to the review of the nuclear power plant's (NPP's) EPR plan for on-site emergencies, which is authorized by ÚJD SR, ÚVZ SR is required to review monitoring plans for emergency situations and the plans for the health measures of the licensees. ÚVZ SR is also the headquarters of the national radiation monitoring network and manages its activity during normal and emergency situations. During a nuclear installation emergency, the primary responsibility lies with ÚJD SR and ÚVZ SR, for analysing consequences of emergencies at nuclear installations and for recommendation of urgent protective actions in accordance with the responsibilities given by the Atomic Act and Act on Radiation Protection. ÚVZ SR recommends protective actions and other response actions, such as decontamination to the civil protection organizations with the aim to protect the public and workers according to the Act on Radiation Protection.

The 2015 IRRS follow-up mission report stated that a new national emergency plan (called the Population Protection Plan) was planned to enter into force on August 1, 2015, together with Amendment of the Law of Civil Protection (42/1994). Because the 2015 IRRS follow-up mission team believed that the national emergency plan was nearly complete, it removed this as an open recommendation for the Slovak Republic. However, despite nearing issuance of a national emergency plan in 2015 and its associated legislation, only the legislation [Amendment of the Law of Civil Protection (42/1994)] was entered into force on August 1, 2015. This 2015 Amendment gave responsibility to the MV SR to issue a national emergency plan that included a specific subsection for radiation protection that would have specified the roles and responsibilities of the various governmental agencies during a nuclear or radiological emergency for the Slovak Republic. In addition, Act 387/2002 establishes the Integrated Crisis Management System (ICMS) for all emergencies. The ICMS includes all governmental organizations, county, and local authorities with responsibilities in emergency situations, and is the responsibility of the MV SR. The national emergency plan for nuclear or radiological emergencies is a part of ICMS and includes the coordination of tasks and duties at national level, according to the current legislative framework.

It remains uncertain when the MV SR can complete its statutory functions to complete and issue the national emergency plan. The IRRS team noted that there is a working group comprised of staff from each agency that is drafting a new NER, but there is no timeline for completion. MV SR expressed a desire to complete it before the next OECD/NEA INEX 6 emergency preparedness exercise – planned for October 2023. Apart from the Acts listed in this section, there are no specific formal coordination mechanisms between the regulatory authorities. Such a statutory plan is needed to ensure effective and efficient cooperation amongst governmental agencies and operators during a nuclear or radiological emergency, especially those potential nuclear or radiological emergencies that could affect the territory of the Slovak Republic.

Despite the lack of a national emergency plan, Section 29 (2) of the Competence Act empowers the ÚJD SR to have jurisdiction over nuclear safety of nuclear installations, including EPR. ÚJD SR has responsibility for: approving the on-site emergency plans and emergency planning zones (EPZs) of facilities; inspecting the adequacy of emergency arrangements (including training and exercises) at nuclear installations, enforcement, and civil penalties, as appropriate if a licensee has failed to comply with the regulations. Specifics regarding associated fines and civil penalties can be found in Sections 32 and 34 of the Atomic Act.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The Government does not have a national emergency plan to prepare for and respond to radiological or nuclear emergencies.*

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| (1) | BASIS: GSR Part 7, Requirement 23 states that: <i>“The government shall ensure that plans and procedures necessary for effective response to a nuclear or radiological emergency are established”.</i> |
| (2) | BASIS: GSR Part 1 (Rev. 1) Requirement 8, para. 2.21 states that: <i>“In addition to assigning the responsibilities of authorized parties, the government shall establish a nationwide system, including</i> |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>emergency arrangements, to protect the public in a nuclear or radiological emergency declared as a consequence of an incident within or outside the territories and jurisdiction of the State”.</i>
(3)	BASIS: GSR Part 7, Requirement 2, para. 4.5, states: “ <i>The government shall make adequate preparations to anticipate, prepare for, respond to and recover from a nuclear or radiological emergency at the operating organization, local, regional and national levels, and also, as appropriate, at the international level. These preparations shall include adopting legislation and establishing regulations for effectively governing the preparedness and response for a nuclear or radiological emergency at all levels”.</i>
R22	Recommendation: The Government should ensure that MV SR develop and implement and regularly exercises a national emergency plan to prepare for and respond to radiological or nuclear emergencies.

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

The framework of emergency arrangements of licensee is based on Atomic Act, as well as the following laws:

- § 16 (1e) of Act No. 42/1994 on Civil Protection of People
- § 9 of Act No. 128/2015 on Prevention of Severe Industrial Accidents

The basic regulatory principles and requirements for EPR arrangements of the operating organizations are stipulated in the Atomic Act, Section 28, which requires the operating organization to submit the on-site emergency plan to ÚJD SR for approval, and then periodically re-submit it for approval every five years to keep it up to date. If there are modifications made to the nuclear installation or to their emergency response organizational structure, operators are required to submit their on-site emergency plan for reassessment or approval within a period of less than five years. Standards used by ÚJD SR for evaluation of these EPR arrangements include the Atomic Act and IAEA GSR Part 7, paragraphs 4.1, 4.13, and 4.14. Decree No. 55/2006 provides emergency planning requirements for the operator in the event of an incident or emergency.

The ÚJD SR on-site requirements and EPR guidelines are comprehensive in addressing requirements for the licensee. When a licensee requests a change to its EPR plan, they need review and approval of their modifications from the MZP SR, MV SR, and ÚVZ SR from each of their respective areas of expertise. ÚVZ SR reviews and issues a binding statement for the licensee acknowledging approval of the EPR Plan for on-site response. These statements are then sent to ÚJD SR who will authorize the on-site EPR plan. ÚJD SR has targeted 30 days for its regulatory review, however, this could be extended to 60 days, if needed.

The ÚJD SR, along with other authorities (ÚVZ SR, MV SR) are involved in conducting EPR exercises. Large scale emergency exercises are required by the operator before the start of operations and every 3 years thereafter to examine the interface between on-site and off-site response. ÚJD SR stated that while there have been no exercises to test the interface between a technology-based event response and security-based event response, they have observed security-based exercises at NPPs. On-site EPR exercises are required for all nuclear installations including NPPs that are decommissioned, and those exercises are conducted annually. For these operational NPP exercises, observation by other Ministries, such as MV SR, MO SR, MZP SR, NIP, local municipalities hospital staff, firefighters, and other policy makers is typical.

When ÚVZ SR performs their EPR assessments at NPP exercises, they may or may not accompany ÚJD SR during these exercises, but if they do accompany ÚJD SR, they do not issue a separate inspection report. Separately, Act No. 87/2018 on Radiation Protection (ÚVZ SR regulations) Annex VI, Part 5 Section C discusses the requirements of the emergency plans for radiation sources and facilities. ÚVZ SR also does not separately analyse or independently evaluate the risk-based (graded approach) appropriateness of the EPR programme for various sources and facilities. When asked how often these facilities’ EPR programmes are inspected, ÚVZ SR stated that inspections are only conducted once at issuance of the licence and that there are no inspection plans developed, nor periodic (follow-up) inspections conducted. In addition, there are no requirements for the licensees of radiation sources or facilities for periodic reviews and testing of their EPR programmes. ÚVZ SR stated that they do not have formal documented

processes concerning inspection programmes, or inspection procedures. ÚVZ SR stated that their inspection plans and frequency of inspections are determined by the individual inspector.

Lastly, within the Slovak Republic, any applicant requesting authorization for transport of fresh and spent nuclear fuel, nuclear materials, or radioactive waste must also develop emergency transport plan (ETPs) for preventive and protective measures in case of an emergency during the transport. Once ÚJD SR and other authorities have assessed these ETPs, these plans are approved by the Minister of Transport. Transport certificate holders must conduct exercises annually (including a full-scale exercise every 3 years) to exercise various modes of transport to account for the extent and type of risk associated with each mode of transport (rail, air, truck, etc).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: ÚVZ SR does not have any requirements for periodic review and testing of EPR programmes for radiation facilities and activities.

(1)	BASIS: GSR Part 7, Requirement 25, para. 6.30 states: “Exercise programmes shall be developed and implemented to ensure that all specified functions required to be performed for emergency response, all organizational interfaces for facilities in category I, II or III, and the national level programmes for category IV or V are tested at suitable intervals. ... The exercises shall be systematically evaluated (see para. 4.10(h)) and some exercises shall be evaluated by the regulatory body. Programmes shall be subject to review and revision in the light of experience gained”.
(2)	BASIS: GSR Part 7, Requirement 25, para. 6.33 states: “The conduct of exercises shall be evaluated against pre-established objectives of emergency response to demonstrate that identification, notification, activation and response actions can be performed effectively to achieve the goals of emergency response (see para. 3.2)”.
R23	Recommendation: ÚVZ SR should develop requirements for periodic review and testing of EPR programmes for radiation facilities and activities.

ÚJD SR performs inspections on various aspects of the operating organization’s EPR programme that are included in its pre-prepared inspection plans that are established and prepared on a yearly basis. ÚJD SR stated that they have specific details in the legislation and internal procedures that serve as guidance for their annually planned EPR inspection programme and that written procedures for determining a graded approach for these inspections are not needed. Once the pre-prepared inspection plans are finalized, the inspection procedures recommend sending a notification to the operators two weeks in advance of the inspection. As an open and transparent **good performance**, the EPR inspection plan schedule is also posted on the ÚJD SR public website for awareness.

The IRRS team also observed that ÚVZ SR lacks a documented process to be used and followed during each EPR inspection (at NPPs or at other radioactive material licensee facilities) that would describe the inspection process criteria, from the decision to initiate an inspection (reactive or routine), through to the follow-up stage, which would include criteria for a graded approach based on the risk posed by the radiation facilities and sources. No graded approach guidance exists in the legislation, nor have written inspection instructions been developed. ÚVZ SR does not meet the requirements of GSR Part 1 for developing and implementing an inspection programme and the conduct of inspections. Specifically, the inspection programme shall also be carried out in accordance with GSR Part 1 to ensure the manner, extent and frequency of inspections is in accordance with the graded approach. **Recommendation R16 in Section 7.1. addresses this issue.**

Although UVZ SR stated that its legislation and regulations have specific details that serve as guidance for the development of its annually planned EPR inspection programme, written procedures for determining a graded approach for these inspections have not been developed. Having a documented procedure for its programme of inspection will specify the types of regulatory inspections and stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach. Such a documented process would assist the

staff in preparing for such activities, enable the management system to set out best practices, and effectively transform their inspection programme to be risk informed. **Recommendation R10 in Section 4.3. addresses these issues.**

Although ÚJD SR on-site requirements and EPR guidelines are comprehensive in addressing requirements for the licensees, there are no criteria developed by the government for the termination of the emergency or transition to the recovery phase. Such guidance would provide information to operators and licensees, when and under what conditions assistance from off-site emergency services may be needed to be activated and provided to the site.

Separately, while ÚVZ SR determines reference levels for optimization of exposure in an emergency situation or in case of persistent exposure, in an existing exposure situation, they have not developed criteria for the off-site termination of the emergency, transition to an existing exposure situation, or transition to the recovery phase which are typically included in the national emergency plan. **Recommendation R22 in Section 10.1. addresses this issue.**

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

Within the Atomic Act, Decree No. 55/2006 describes the requirements and associated emergency planning and response criteria for the NPP operator or licensee in the event of nuclear or radiological emergency occurs. The NPP operator's on-site emergency plan requires its emergency response organization activities to have several elements, including: planning and preparation of organizational EPR activities; protection of personnel; material and technical measures to successfully manage crisis and emergency situations according to the classified event; technical information input to State authorities and the public; preservation of records on received doses; and monitoring of the radiological situation, including prognostication of the event as it unfolds. In addition, in accordance with the Convention on Nuclear Safety, Slovak Republic, as a contracting party, has ensured that there are on-site and off-site emergency plans that are routinely tested for nuclear installations by ÚJD SR and cover the activities to be carried out in the event of an emergency (See **Section 10.2.**).

The NPP operators are responsible for determining the emergency class based on legislation (from Decree 55/2006): General emergency, Site Area emergency, and Alert. Although these three emergency classes differ slightly from the five specified in IAEA GSR Part 7, para. 5.14 (General emergency, Site Area emergency, Facility emergency, Alert and Other nuclear or radiological emergency), they do include emergencies of all these types. To facilitate a correlation between the classes of transmitted events to the IAEA's Unified System for Information Exchange in Incidents and Emergencies (USIE) system, ÚJD SR has developed a written procedure in its emergency response centre (ERC) that links the ÚJD SR designation of an emergency class to that of the IAEA's GSR Part 7.

A national emergency preparedness structure has been set up to manage events at nuclear installations. This structure is divided into three levels:

1. The **first (licensee) level** consists of an emergency response organization of operators of nuclear installations whose main function is to manage and respond to the emergency and limit the consequences for personnel, equipment, and the environment (called an Alert). Authorities at the national level (MV SR, ÚJD SR, and ÚVZ SR) provide information on the state of facilities and possible impacts on the environment.
2. The **second (municipality and regional) level** is made up of staff of the local government, whose territory falls into the emergency planning zone (off-site emergencies), where life, health or property may be at risk, and where measures to protect the population are planned. The second level is initiated in case the NPP operator is unable to prevent the impact on the population and the environment by its own forces and means.
3. The **third (national) level**, at the SR government level, is initiated if the nuclear emergency affects more than one region or if the district office in the emergency planning zone (EPZ) is unable to protect the population and the environment with its own staff (off-site emergencies). The Minister MV SR serves as the Chairman of the Central Crisis Staff (CCS). During these off-site emergencies, the CCS cooperates with its specialized support units: the ÚJD SR ERC, the ÚVZ SR Radiation Monitoring Network, and Central Monitoring and Control Centre of the MV SR.

By law, NPP operators are required to notify authorities immediately when their emergency plan thresholds are reached or exceeded. A system for early warning and public information dissemination in the EPZs around nuclear installations are in place for each level. For the first level, the NPP operator is required to have a warning and notification system through an autonomous network of electronic sirens. For the second level, sirens and additional

verbal communication (radio, TV) including electronic announcement notification (voice, text messages and e-mail messages) are used for effective and prompt notification of potential emergency situations. It serves as an early warning system for all employees and individuals in the premises of the nuclear installations, as well as notification to authorities and organizations involved in external emergency planning. For the third level, a warning goes out to any residents that could potentially be affected by such an event within the EPZ of NPP Bohunice (21 km) or NPP Mochovce (20 km). These early notification systems operate continuously and are interconnected with the nationwide system and can be activated and used also locally for other emergencies, such as in the case of a flood. Regular tests of these early warning notification systems are carried out once a month for designated areas near the EPZ of the NPPs. In addition, the ÚJD SR staff routinely verify the capabilities of the NPP operator for communication during inspections and exercises.

Competent state authorities and municipalities (authorized by the District) have developed off-site emergency plans for the public's protection. The NPP emergency plans of four regions are sent to MV SR for approval, and to ÚJD SR and ÚVZ SR for review from their perspectives. MV SR has not established any EPR arrangements with other regions outside these areas.

10.4. ROLES OF THE REGULATORY BODY IN A NUCLEAR OR RADIOLOGICAL EMERGENCY

The Slovak Republic uses an integrated all-hazards approach for emergency response at the national level. The Central Monitoring and Control Centre (CMCC) was set up to monitor, control, evaluate and support activities of continuous operative management of state administration within the MV SR in the field of Integrated Rescue System, civil protection, and crisis management.

ÚJD SR is the responsible regulatory authority for nuclear safety and security oversight and responds to events involving authorized facilities, as well as events during transport of radioactive material, when nuclear safety and public health could be affected. ÚJD SR has not been given any responsibility in response to an emergency such that it will compromise or conflict its primary responsibility as a regulator. In the event of an NPP emergency, the CMCC receives supporting documentation and draft protective measures based on technical recommendations from the ERC staff in cooperation with ÚVZ SR and submits them to the CCS. ÚJD SR serves as the 24/7 contact point for IAEA, the European Commission, neighbouring countries and state parties. The CMCC also provides 24/7 operation of the national contact point for receiving and transmitting alert messages, information messages and messages requesting assistance from the coordination centres of the Integrated Rescue System, including the national contact points of the neighbouring and state parties.

While the sole responsibility for meeting the Slovak safety requirements resides with the licensee, ÚJD SR relies on its ERC technical staff when responding to events, to provide support to governmental and regional organizations, and also to the ÚJD SR Chairman during nuclear or radiological emergencies. During some exercises, the ÚJD SR Chairman is physically at the MV SR CCH, also with their counterparts from ÚVZ SR and the MV SR (who serves as the Chair of the CCH). ÚJD SR's ERC is a well-defined emergency organization and centre. In the event of a nuclear emergency at an NPP or during transport of nuclear material, the ERC operates as a technical support organization for the CCH. ÚJD SR is also responsible for the investigation of the causes and consequences of selected emergencies at a nuclear installation or during the transport of radioactive materials.

In the event of a nuclear or radiation emergency, which is defined as an accident pursuant to Section 27 of Act No. 541/2004 (Atomic Act), the ÚVZ SR representative(s) at the ERC, together with members of the ÚJD SR staff, can view the NPP's active data and processes from the plant to analyse the condition of safety systems. In the event of an NPP emergency (or during exercises), the ERC staff uses various software packages (RTARC, JRODOS, and ESPRO) to conduct independent accident assessment and prognosis activities regarding accident progression for decision makers. ERC staff also receive on-line technological and radiological data from the nuclear installation operator, which is combined with on-line (electronic) meteorological data from the Slovak Hydrometeorological Institute (SHMU), to inform their recommendations for protective measures. Detailed flow charts and procedures exist within the ERC for EPR events and for sharing with ÚVZ SR, MV SR, and CCH. Most recently, in 2021, ÚVZ SR was able to obtain new prognostic software for estimating doses during a radiological or nuclear event that included evaluation of foodstuffs and water. During emergency exercises, the ERC emergency staff also includes 1-2 technical experts from ÚVZ SR who evaluate the calculated radiological impacts to inform their recommendation

for radiation protective actions, ERC emergency staff can work in four shifts so as to ensure continuity during actual events that may exceed 8 hours.

Since 2013, a new electronic system for information management was implemented by ÚJD SR, and it is used by all expert groups of the ERC. In 2018, this platform moved to a web-based system because of restrictions of the earlier systems. The new system allows for greater flexibility of information transfer between ERC teams and could potentially be used for future intra-governmental use. Background information, manuals and procedures are also available in a paper form as a redundant system.

Four teams (reactor safety, radiation protection, media and logistics) work together at the ERC to obtain and evaluate event information and to assess the event's potential impact on nuclear safety and public health. The ERC is able to preserve, document and protect, to the extent practicable, data and information important for an analysis of the emergency and emergency response. ERC staff exercises are conducted four times annually to use and revise the ERC procedures, as necessary.

Members of ÚJD SR emergency response staff are required to undergo annual training and exercising. In addition, ERC emergency procedures are reviewed and updated as needed, or in case of major lessons learned or discrepancies that arise, after each drill or exercise. This training allows staff to practise transmitting urgent notifications on event data to IAEA via its USIE and as well as the European Community's Urgent Radiological Information Exchange (ECURIE) system for early notification system in the event of radiological or nuclear emergencies.

It is notable that during the COVID pandemic, all trainings of the emergency response staff of ÚJD SR were completed according to schedule, albeit in smaller groups. All ÚJD SR licensees were still required to do EPR exercises during the COVID pandemic, with appropriate health restrictions that included limiting the number of staff in classroom training and not "sheltering in place."

In addition to the conduct of EPR seminars with licensees and peers, ÚJD SR, in coordination with other relevant governmental bodies, developed a special procedure in 2018 called "Joint Guidelines for Ensuring the Activities of the Contact Points." Per section 4, paragraph 1(f) of the Atomic Act, ÚJD SR serves as the liaison point during nuclear or radiological emergencies. Because of a lack of a national emergency plan, ÚJD SR pursued the need to document these arrangements and facilitated signatures by all senior management from relevant governmental bodies that have emergency response functions, including ÚJD SR, MV SR, ÚVZ SR, MZ SR, the Ministry of Transport and Construction, the MO SR, the Ministry of Finance, the MZP SR, the Ministry of Foreign and European Affairs, the Slovak Information Service and SHMU. This procedure specifically references IAEA GSR Part 7 regarding events of transnational significance and serves as a timely reminder of the need for cooperative efforts amongst various agencies during exercises and emergencies.

During national emergency response events, this procedure highlights the requirement for specific government bodies to immediately provide their relevant information to ÚJD SR in order for them to effectively provide complex relevant information mainly to the Ministry of Interior. This information is also used to promptly inform the public, European Commission, IAEA, and countries with bilateral agreements on any nuclear or radiological event.

Due to the lack of a national emergency plan, ÚJD SR demonstrated leadership by developing a signed cooperative agreement amongst all the relevant government bodies that have key emergency response functions during a nuclear or radiological emergency. The IRRS team recognized this as **good performance**.

In 2021, ÚJD SR staff also conducted a special training session for its media (public affairs) group to simulate and exercise the ÚJD SR media roles in responding to potential questions from the public and social media during a postulated NPP accident. From a governmental perspective, ÚJD SR staff and management at the ERC have shown a leadership role in effective communication and sharing of knowledge management in the EPR area that only serves to strengthen its programme.

10.5. SUMMARY

The Slovak Republic has established a statutory framework for EPR at the national level to effectively regulate its licensed operators and prepare for the potential consequences of nuclear and radiological emergencies.

The IRRS team observed that some of the requirements for EPR are not in compliance with the requirements of GSR Parts 1 and 7, mainly:

- The Government does not have a national emergency plan to prepare for and respond to radiological or nuclear emergencies.
- ÚVZ SR lacks a documented process to be used and followed during each EPR inspection that would describe the inspection process criterion that would include criteria for a graded approach.
- ÚVZ does not have any requirements for licensees of radiation sources or facilities to conduct periodic reviews and testing of their respective EPR programmes.
- There are no regulatory criteria developed by the Government for the termination of off-site emergency response activities, including recovery and transition to recovery.

The IRRS team noted the **good performance** of ÚJD SR by demonstrating leadership in facilitating and documenting the various government agency roles and responsibilities during a nuclear emergency in a signed special procedure to serve as a reminder of the need for cooperative efforts amongst various agencies during a nuclear or radiological emergency.

APPENDIX I – LIST OF PARTICIPANTS

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GROUP PHOTO



APPENDIX II – MISSION PROGRAMME

Time	SAT 03 Sep	SUN 04 Sep	MON 05 Sep	TUE 06 Sep	WED 07 Sep	THU 08 Sep	FRI 09 Sep	SAT 10 Sep	SUN 11 Sep		
8:00 – 9:00				Team meeting Discussion w/Counterpart	Team meeting Discussion w/Counterpart	Team meeting Discussion w/Counterpart	Team meeting Discussion w/Counterpart	Team meeting Discussion w/Counterpart			
9:00-12:00	Arrival of Team Members		Entrance Meeting	Interviews and Visits	Interviews TL, Meets DGs	Interviews and Visits DTC writes introductory parts	TM write Report TL and DTL review introductory part Draft text to TL	<ul style="list-style-type: none"> Discussing and improving Draft Report Cross-Reading TL, DTL, TC and DTC read everything 	Free day, Social Tour		
12:00-13:00			Lunch with Host	Standing lunch							
13:00-14:00					Interviews and Visits	Interviews	Interviews	DTC writes introductory parts	Policy Discussions		
14:00-15:00					Interviews (individual or in groups)	Interviews and Visits	Interviews	Follow-up Interviews	DTC writes introductory parts	Secretariat edits the report Preliminary Draft Report Ready Cross-reading by TM	Finalisation of the Draft Report
15:00-16:00			IRRS Initial Team Meeting <ul style="list-style-type: none"> Welcome 5 minutes/TM self-intro Refresher training Meet host liaison officer Mission logistics Discussion of first impressions Closing 								
16:00-17:00							Written preliminary findings delivered				Reading, cross-reading of the draft report if needed
17:00-18:00					Daily Team Meeting	Daily Team Meeting	Daily Team Meeting: Discussion of findings	Daily Team Meeting	Daily Team Meeting		
18:00-20:00				Team Dinner	Dinner	Dinner	Dinner	Dinner	Dinner	Dinner	
20:00-24:00					Writing of the report	Writing of the report	Daily Team Meeting: Discussion of findings	Writing of the report	TM Read Draft	Secretariat edits the report	

	MON 12 Sep	TUE 13 Sep	WED 14 Sep	THU 15 Sep	FRI 16 Sep	
8:00 – 9:00	Team meeting Discussion w/Counterpart	Team meeting Discussion w/Counterpart	Team meeting Discussion w/Counterpart	Team meeting Discussion w/Counterpart	Submission of the Preliminary Report	
9:00-10:00	Discussion of Recommendations, Suggestions and Good Practises with counterparts by module	Cross-Reading of the Report TL, DTL, TC and DTC read everything Finalisation	Common read through and finalisation of the Report by the Team	Host reads Draft Report	Team discusses the Mission and provides IAEA with feedback	Exit Meeting Press Conference Publication of Press Release
10:00-12:00			Submission of the Draft to the Host			
12:00-13:00	Standing lunch	Standing lunch	Lunch	Standing Lunch	Lunch	
13:00-15:00	Individual discussions of Recommendations, Suggestions and Good Practises with counterparts	Discussion of the Report by the Team	TC, DTC prepare Executive Summary and exit presentation	Host reads Draft Report TL finalises Executive Summary and Exit Presentation TC Drafts the Press Release	Written comments provided by the Host	Departure of the IRRS Team
15:00-17:00					Team meeting to discuss and resolve Host comments	
17:00-18:00	Daily Team Meeting	Discussion of Executive Summary and delivery to the Host	Briefing of the Senior IAEA Manager. Finalisation of the press release and of the Preliminary Report			
18:00-20:00	Dinner	Dinner	Dinner	Farewell Dinner		
20:00-21:00	Secretariat updates Report	Secretariat finalises Report	Free	Free		
21:00-24:00				Free		

APPENDIX III – SITE VISITS

- Mochovce Nuclear Power Plant (NPP)
- Cyclotron Centre of the Slovak Republic in Bratislava (BIONT)

APPENDIX IV – LIST OF COUNTERPARTS

	IRRS EXPERTS	Lead Counterpart	Support Staff
1.	LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES		
	QAYYUM Muhammad	TURNER Mikuláš	POSPÍŠIL Martin DRÁBOVÁ Veronika AUXTOVÁ Ludmila JURINA Vladimír
2.	GLOBAL NUCLEAR SAFETY REGIME		
	QAYYUM Muhammad	KARELOVÁ Marcela	TURNER Mikuláš
3.	RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY		
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4.	MANAGEMENT SYSTEM OF THE REGULATORY BODY		
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6.	REVIEW AND ASSESSMENT		
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	IRRS EXPERTS	Lead Counterpart	Support Staff
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	IRRS EXPERTS	Lead Counterpart	Support Staff
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10.	EMERGENCY PREPAREDNESS AND RESPONSE		
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APPENDIX V – RECOMMENDATIONS (R), SUGGESTIONS (S) AND GOOD PRACTICES (GP)

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES	S1	Suggestion: The Government should consider reviewing and updating the national policy “Policies, principles and strategies for further development of nuclear safety” to ensure it is fully consistent with the safety principles of SF-1.
	R1	Recommendation: The Government should ensure that ÚVZ SR and respective RÚVZs, are effectively independent from the organizational entities that are under its regulatory control in the field of radiation protection.
	R2	Recommendation: The Government should ensure that ÚVZ SR, respective RÚVZs and MDV SR are effectively resourced to fulfil their regulatory responsibilities.
	R3	Recommendation: The Government should amend the Act on Radiation Protection to clearly assign the prime responsibility for safety to the authorised party.
	R4	Recommendation: The Government should establish a means for effective coordination and cooperation between the different regulatory authorities, which may include the development of formal agreements, to ensure consistency in the regulatory requirements and avoid any omissions, undue duplication, and conflicting requirements, being placed on authorized parties.
	S2	Suggestion: The Government should consider implementing a comprehensive programme to identify all possible existing exposure situations considered significant from a public protection aspect.
	R5	Recommendation: The Government should ensure that strategies and measures against radon exposures, as laid down in the National Action Radon Plan, are implemented.
2. THE GLOBAL SAFETY REGIME	R6	Recommendation: The Government should express the political commitment to the supplementary guidance on Import and Export of Radioactive sources and Guidance on the Management of Disused radioactive sources.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	S3	Suggestion: The regulatory body should consider ensuring that the performance of the regulatory functions is commensurate with the magnitude of the radiation risks arising from facilities and activities. The graded approach takes into account any exposures to radiation, in normal operation, anticipated operational occurrences and accident conditions, as well as the possibility of events with a very low probability of occurrence.
	R7	Recommendation: The ÚVZ SR, RÚVZs and MDV SR should develop and implement a human resources plan to have an adequate number of appropriately qualified and competent staff to effectively perform their regulatory functions.
	R8	Recommendation: ÚVZ SR, RÚVZ SR and MDV SR should ensure that the existing staff training programme includes the necessary knowledge, skills and abilities in radiation safety to perform the regulatory functions.
	R9	Recommendation: ÚVZ SR and respective RÚVZs should develop and implement a process for knowledge management that will ensure that knowledge relevant for the activities of the regulatory body is acquired and retained.
	S4	Suggestion: ÚVZ SR should consider preparing a public communication strategy, specifically tailored to the activities of the radiation protection department, taking into account interfaces with other authorities.
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	R10	Recommendation: The ÚVZ SR and MDV SR should establish, implement, and continuously improve an integrated management system with processes and procedures to cover the core regulatory functions in line with IAEA safety requirements.
	R11	Recommendation: ÚVZ SR and MDV SR should implement a systematic approach to foster a strong safety culture.
5. AUTHORIZATION	S5	Suggestion: ÚVZ SR should consider developing application forms for authorization of facilities and activities.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R12	Recommendation: The proposed revision of the Act on Radiation Protection, which is currently going through due process for enactment, should include the requirement for MDV SR to assess and issue authorizations relating to Type B and Type C package designs for the transport of radioactive material.
6. REVIEW AND ASSESSMENT	R13	Recommendation: The ÚVZ SR should carry out independent verification of safety assessments prepared by authorised parties for radiation facilities and activities.
	R14	Recommendation: The ÚVZ SR should implement mechanisms to periodically review the conditions of the authorisations for radiation facilities and activities.
	S6	Suggestion: ÚJD SR should consider revising the existing procedure and ÚVZ SR should consider developing a procedure on event investigation and reporting to include a provision for the systematic review and evaluation of international events and sharing of information on lessons learnt.
	R15	Recommendation: ÚJD SR and MDV SR should ensure the assessment of the ageing management mechanisms be part of the authorisation process for packaged nuclear radioactive material and packaged radioactive material.
7. INSPECTION	S7	Suggestion: The regulatory authorities should consider sharing relevant inspection findings within and across regulatory authorities.
	R16	Recommendation: The ÚVZ SR and MDV SR should develop and implement a comprehensive risk-based inspection programme, taking into account the graded approach.
	S8	Suggestion: The ÚVZ SR and MDV SR should consider developing internal guidance for inspectors on performing regulatory inspections.
	S9	Suggestion: The ÚVZ SR and MDV SR should consider conducting independent investigations for more serious events, or when operating parameters exceed regulatory limits or are significantly elevated.
8. ENFORCEMENT	R17	Recommendation: The Regulatory Body should establish and implement an enforcement policy covering the whole range of possible enforcement actions.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	S10	Suggestion: The ÚJD SR, ÚVZ SR and NIP should consider developing and implementing a procedure to inform each authority of relevant enforcement actions being taken.
9. REGULATIONS AND GUIDES	R18	Recommendation: ÚVZ SR should establish or adopt guidance to support applicants and licensees in complying to the relevant regulations.
	R19	Recommendation: The Government should ensure that the regulatory framework for radiation protection includes provisions to assure that the delegation of responsibilities by registrants and licensees is documented.
	R20	Recommendation: The Government should ensure that the regulatory framework includes provisions for independent verification of calibration of radiation therapy units prior to clinical use.
	R21	Recommendation: The Government should ensure that the regulatory framework includes provisions for acceptance and commissioning tests of the equipment prior to its clinical use on patients are done by, or under the supervision of, a medical physicist.
10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS	R22	Recommendation: The Government should ensure that MV SR develop and implement and regularly exercises a National Emergency Plan (NEP) to prepare for and respond to radiological or nuclear emergencies.
	R23	Recommendation: ÚVZ SR should develop requirements for periodic review and testing of EPR programmes for radiation facilities and activities.

APPENDIX VI – COUNTERPART’S REFERENCE MATERIAL USED FOR THE REVIEW

I.	<u>IRRS Slovak Republic SARIS Self-Assessment Report</u>
II.	<u>IRRS Slovak Republic ARM Summary Report</u>
III.	<u>IRRS Slovak Republic Initial Action Plan</u>
1.	Act of NC SR No. 71/1967 on administrative procedure (Administrative Procedure Code) as amended
2.	Act of the NC SR No. 50/1976 Coll. on Land use Planning and Building Regulations (Building Act) as amended
3.	Act of the NC SR No. 372/1990 Coll. on Offences
4.	Constitution of the Slovak Republic (460/1992 Coll.)
5.	Act of the NC SR No. 171/1993 Coll. on the Police Force as amended
6.	Act of the NC SR No. 42/1994 Coll. on Civil Protection as amended
7.	Act No. 10/1996 Coll. on Control in the State Administration as amended
8.	Act No. 211/2000 Coll. on Freedom of Information
9.	Act No. 311/2001 Coll. Labour Code as amended
10.	Act No. 315/2001 Coll. on the Fire and Rescue Service as amended
11.	Act No. 575/2001 Coll. on Organization of Governmental Activities and of Central State Administration Organisations as amended
12.	Act No. 129/2002 Coll. on Integrated Rescue System as amended
13.	Act No. 395/2002 Coll. on Archives and Registries and on the Supplements to Some Acts as amended
14.	Act No. 387/2002 Coll. on the Management of State in Crisis Situations Other than Time of War and State of War as amended
15.	Constitutional Act No. 357/2004 Coll. on the Protection of Public Interest in the Performance of Functions by Public Holders as amended
16.	Act No. 205/2004 Coll. on collection, storage and dissemination of environmental information
17.	Act No. 523/2004 Coll. on Budget Rules of the Public Service and of Change and Amendment of Some Acts as amended
18.	Act No. 541/2004 Coll. on the peaceful use of nuclear energy (the Atomic Act) and on amendments and supplements to some acts as amended – as last amended by Act No. 363/2021 Coll.
19.	Act No. 576/2004 Coll. on Healthcare as amended
20.	Act No. 578/2004 Coll. on Healthcare Providers, Health Workers and Professional Organizations in the health and on amendments and supplements to some acts as amended
21.	Act No. 300/2005 Coll. Criminal Code as amended
22.	Act No. 24/2006 Coll. on environmental impacts assessment and on alternations and amendments to certain acts as amended
23.	Act No. 124/2006 Coll. on safety and health protection at work and on amendments and supplements to certain acts as amended
24.	Act No. 125/2006 Coll. on Labour Inspection and on amendment to Act No. 82/2005 Coll. on Illegal Work and Illegal Employment as amended
25.	Act No. 569/2007 Coll. on geological works (Geological Act) as amended
26.	Act No. 131/2010 Coll. Funeral Act as amended
27.	Act No. 54/2015 Coll. on Civil Liability for Nuclear Damage and on its Financial Coverage and on changes and amendments to certain laws
28.	Act No. 79/2015 Coll. on waste as amended
29.	Act No. 400/2015 Coll. on the drafting of legislation and on the Collection of Laws of the Slovak Republic as amended
30.	Act No. 55/2017 Coll. on <i>Civil Service</i> and on amendment and supplements to some acts as amended
31.	Act No. 87/2018 Coll. on radiation protection and on amendments and supplements to some acts as amended

32.	Act No. 308/2018 Coll. on National Nuclear Fund and on amendment to Act No. 541/2004 Coll. on the peaceful use of nuclear energy (the Atomic Act) and on amendments and supplements to some acts as amended by Act no. 221/2019 Coll.
33.	Decree of the Nuclear Regulatory Authority of the Slovak Republic No. 48/2006 Coll. as amended by Decree No. 32/2012 Coll. Laying Down Details on the Manner of Reporting Operational Events and Events in Transportation and Details of Ascertaining Causes Thereof
34.	Decree of the Nuclear Regulatory Authority of the Slovak Republic No. 51/2006 Coll. Laying Down Details of Requirements for Provisions of Physical Protection
35.	Decree of the Nuclear Regulatory Authority of the Slovak Republic No. 52/2006 Coll. as amended by decree No. 34/2012 Coll. and Decree No. 410/2019 Coll. on professional competence
36.	Decree of the Nuclear Regulatory Authority of the Slovak Republic No. 54/2006 Coll. on Record Keeping and Checking of Nuclear Materials and on Notification of Selected Activities
37.	Decree of the Nuclear Regulatory Authority of the Slovak Republic No. 55/2006 Coll. as amended by Decree No. 35/2012 Coll. and Decree No.9/2018 Coll. Laying down details in emergency planning for the event of an incident or an accident
38.	Decree of the Nuclear Regulatory Authority of the Slovak Republic No. 57/2006 Coll. as amended by Decree No. 105/2016 Coll. laying down details of the requirements for the transportation of radioactive materials
39.	Decree of the Nuclear Regulatory Authority of the Slovak Republic No. 58/2006 Coll. as amended by Decree No. 31/2012 Coll. and Decree No. 102/2016 Coll. Laying Down Details on the Scope, Contents, and Manner of Maintaining Documentation of Nuclear Installations Necessary for Individual Decisions
40.	Decree of the Nuclear Regulatory Authority of the Slovak Republic No. 430/2011 Coll. as amended by Decree No. 103/2016 Coll. on nuclear safety requirements
41.	Decree of the Nuclear Regulatory Authority of the Slovak Republic No. 431/2011 Coll. on a quality management system as amended by Decree No. 104/2016 Coll.
42.	Decree of the Nuclear Regulatory Authority of the Slovak Republic No. 30/2012 Coll. as amended by Decree No. 101/2016 Coll. laying down details of requirements for the handling of nuclear materials, radioactive waste and spent nuclear fuel
43.	Decree of the Nuclear Regulatory Authority of the Slovak Republic No. 33/2012 Coll. as amended by Decree No. 106/2016 Coll. and Decree No. 71/2019 Coll. on the regular, comprehensive and systematic evaluation of the nuclear safety of nuclear installations
44.	Decree of the Nuclear Regulatory Authority of the Slovak Republic No. 112/2020 Coll. laying down the special materials and equipment falling under the supervision of the Nuclear Regulatory Authority of the Slovak Republic
45.	Decree of the Government of the Slovak Republic No. 400/2019 Coll. on the code of ethics of public officials
46.	Decree of the Ministry of Interior of the Slovak Republic No. 388/2006 Coll. on details for ensuring technical and operational conditions of the civil protection information system
47.	Decree of Ministry of Health of the Slovak Republic No. 321/2005 Coll. on the scope of practice in certain medical professions
48.	Decree of the Ministry of Health of the Slovak Republic No. 96/2018 Coll. Laying down details on the activities of the radiation monitoring network
49.	Decree of the Ministry of Health of the Slovak Republic No. 98/2018 Coll. laying down details on the limitation of exposure of workers and the general public to sources of ionizing radiation
50.	Decree of the Ministry of Health of the Slovak Republic No. 99/2018 Coll. on ensuring radiation protection
51.	Decree of the Ministry of Health of the Slovak Republic No. 100/2018 Coll. on the restriction of exposure of the population from drinking water, natural mineral water and spring water
52.	Decree of the Ministry of Health of the Slovak Republic No. 101/2018 Coll. laying down details on the provision of radiation protection in the course of medical exposure.
53.	Governmental Ordinance No. 296/2010 on professional competences of healthcare workers, way of further education of healthcare workers, system of specialization and system of certified practices

54.	Legislative Rules of the Government
55.	ÚJD SR Safety Guide BNS I.4.5/2018 Requirements for the safety of nuclear installations in relation to natural hazards
56.	ÚJD SR Safety Guide BN 5/2019 Requirements for deterministic safety analyses of NPPs with VVER-440/V213 (6th edition – revised and supplemented)
57.	ÚJD SR Safety Guide BN 1/2020 Comprehensive periodic safety review of nuclear safety (3rd edition – revised and supplemented)
58.	Report of the Slovak Republic compiled in terms of Article 14 par. 1 Council Directive 2011/70/EURATOM, August 2021
59.	Report of the Slovak Republic compiled in terms of Article 9.1 Council Directive 2009/71/EURATOM, July 2020
60.	National Report of the Slovak Republic compiled in terms of the Convention on Nuclear Safety, May 2019
61.	National Report of the Slovak Republic compiled in terms of the Joint Convention on the safety of spent fuel management and on the safety of radwaste management, August 2020
62.	National Policy and National Programme for handling of spent nuclear fuel and radioactive wastes in SR
63.	National Assessment Report of the Slovak Republic for the Purposes of Topical Peer Review on “Ageing Management” under the Nuclear Safety Directive 2014/87/EURATOM, December 2017
64.	Policy, Principles and Strategy for Further Development of Nuclear Safety, Government Resolution No. 256/2014, May 28, 2014
65.	National Action Plan of the Slovak Republic – TPR Ageing Management, Update 2019
66.	National Action Plan of the Slovak Republic, December 2019
67.	Occupational Safety and Health Protection Strategy in the Slovak Republic for the Period of 2021 – 2027 and the Programme of Its Implementation for the Period of 2021 – 2023
68.	Occupational Safety and Health Protection Strategy in the Slovak Republic until 2020 and the Programme of Its Implementation for the Period of 2013 – 2015 with Prospects until 2020
69.	Report on the state of labour protection and on the activities of state administration bodies in the field of labour inspection for the year 2020
70.	ÚJD SR Annual Report 2020
71.	ÚJD SR Annual Report 2021
72.	ÚJD SR Statute
73.	ÚJD SR Organizational Structure 1.5.2019 Annex 1
74.	Quality Manual S 500 006:21
75.	ÚJD SR Quality Policy (Annex I. to Quality Manual)
76.	ÚJD SR Organizational Rules P 400 001:19
77.	Procedure laying down the details on the training of the ÚJD SR staff S 401 009:20
78.	Inspection procedure – Control of the nuclear safety at the nuclear installations under decommissioning, by the radioactive waste management, import of radioactive waste and the realisation of the transports of the radioactive waste P 340 002:19
79.	Staff regulation on Inspector’s exam SP 401 003:19
80.	Procedure on Inspection activities of ÚJD SR S 310 011:19
81.	Procedure on preparation and internal process for the approval of decrees of ÚJD SR S 230 025:21
82.	Procedure for assessment of documentation S 310 029:20
83.	Risk Management Procedure S 240 021:20
84.	Procedure on Issuance of Decision pursuant to the Atomic Act, Building Act and the Administrative Procedure Code S 320 014:20
85.	Inspection procedure Control of storage of fresh and spent nuclear fuel P 330 003:17
86.	Procedure on registration S 130 014:19
87.	Procedure on transposition of international standards S 210 032:21
88.	Procedure on management of non-conformities and corrective actions S 240 004:17

89.	Procedure on the assessment of the nuclear safety of operating nuclear installations with nuclear reactor in SR S 310 010:14
90.	Procedure on Enforcement Activities S 320 003:17
91.	Procedure on the issuance of safety guides of ÚJD SR S 230 016:20
92.	Procedure on Education of employees S 401 009:20
93.	Procedure on Free Access to Information S 130 026:19
94.	Procedure on Issuance of Decision pursuant to the Atomic Act, Building Act and the Administrative Procedure Code S 320 043:22
95.	Procedure on knowledge management S 310 028:19
96.	ÚJD SR Inspection plan for year 2022 PP 310 002:22
97.	ÚJD SR Preliminary three-year inspection plan for years 2022-2024 PP 310 003:22
98.	Plan on issuance of safety guides of UJD SR in years 2021-2023 PP 230 006:21
99.	ÚJD SR Public Communication Strategy up to 2023
100.	ÚJD SR Strategy of Knowledge Management for the 2018-2020
101.	ÚJD SR Strategy of Knowledge Management for the 2022-2024
102.	KP-ÚVZSR / 01 Process and organizational model
103.	KP-ÚVZSR / 02 Top level
104.	KP-ÚVZSR / 03 Organizational structure of ÚVZ SR
105.	KP-ÚVZSR / 04 Organizational structure – departments / departments involved in activities
106.	KP-ÚVZSR / 06 Reporting, reporting and record keeping
107.	KP-ÚVZSR / 07 Divisions participating in state supervision activities
108.	KP-ÚVZSR / 08 Performance of state supervision activities
109.	KP-ÚVZSR / 09 Divisions involved in legislative activities
110.	KP-ÚVZSR / 10 Creation of concepts
111.	KP-ÚVZSR / 11 Divisions involved in the creation of concepts
112.	KP-ÚVZSR / 12 Methodological activity
113.	KP-ÚVZSR / 13 Providing methodological guidelines
114.	KP-ÚVZSR / 14 Control of compliance with methodological instructions of ÚVZ SR
115.	KP-ÚVZSR / 15 Professional advice, providing consultations
116.	KP-ÚVZSR / 16 Issuance of certificates
117.	KP-ÚVZSR / 17 Discussion in the Government of the Slovak Republic and the National Council of the Slovak Republic
118.	KP-ÚVZSR / 18 Issuance of statements
119.	KP-ÚVZSR / 19 Decisions of ÚVZ SR
120.	VD-01 Quality Manual
121.	VD-02 Quality Policy
122.	VD-03 Quality Objectives
123.	KP-OOZPŽ-02 Quality Management
124.	RP-03-1 Human Resources Management. Education
125.	RP-03-2 Human Resources Management. Recruitment of new employees
126.	RP-04 Records Management
127.	RP-05 Internal Audits
128.	F-RP-03-1/1 Annual Training Plan
129.	F-RP-03-1/2 Internal Training of employees
130.	F-RP-03-1/3 Certification of the participation at educational activity
131.	F-RP-03-1/4 Assessment of training
132.	F-RP-03-2/1 Job description
133.	F-RP-03-2/2 Training plan for a probationary employee in the performance of work in the public interest
134.	F-RP-03-2/3 Employee training on devices
135.	F-RP-03-2/4 Description of the activities of the civil service position
136.	F-RP-05/1 Annual Internal Audit Programme

137.	F-RP-05/2 Internal Audit Plan
138.	F-RP-05/3 Internal Audit Questionnaire
139.	F-RP-05/4 Internal Audit Report
140.	F-RP-05/5 Auditors' evaluation
141.	RP-06 Emergency Preparedness
142.	RP-07 Non-compliance management, corrective and preventive action
143.	F-RP-07/1 Non-compliance record
144.	SLP-06 Staff Regulations
145.	IP Nitra Organizational Rules, Internal norm No. 2/2020
146.	NIP Organizational Rules, Basic organizational norm No. 1-1/21
147.	Annex No. 1 to the IN No. 001/2021
148.	Labour Inspection System Training Concept
149.	Internal Norm No. 007/2019 on registration order
150.	Disclosure of information according to § 3 par. 6 of Act no. 71/1967 Coll. on administrative proceedings, as amended, on the initiation, implementation and termination of administrative proceedings in matters that are the subject of public interest conducted at ÚJD SR – administrative proceedings number 1649/2021
151.	IAEA DISPONET 2021 Technical Meeting Minutes
152.	Extraction from the Records from the inspection No. 520/2020
153.	Final Opinion no. 1065 / 2013-3.4 / hp issued by the Ministry of the Environment of the Slovak Republic pursuant to Act no. 24/2006 Coll. on Environmental Impact Assessment and on Amendments to Certain Acts, as amended – Expansion of the Republic Repository for Radioactive Waste in Mochovce for the Storage of Low-Level Waste and Construction of a Repository for Very Low-Level Waste
154.	LLW storage facility (construction of the third double row) – binding opinion
155.	Content of the documentation required to grant Authorization for Transport of Radioactive Material
156.	Country Programme Framework IAEA – SR 2022-2027
157.	MDV SR Application Form for Transport of Radioactive Materials

APPENDIX VII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1.	INTERNATIONAL ATOMIC ENERGY AGENCY - Fundamental Safety Principles, No SF-1, IAEA, Vienna (2006)
2.	INTERNATIONAL ATOMIC ENERGY AGENCY - Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements Part 1, No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016)
3.	INTERNATIONAL ATOMIC ENERGY AGENCY – Leadership and Management for Safety, General Safety Requirements Part 2, No. GSR Part 2, IAEA, Vienna (2016)
4.	INTERNATIONAL ATOMIC ENERGY AGENCY - Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, No. GSR Part 3, IAEA, Vienna (2014).
5.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety assessment for facilities and activities, General Safety Requirements Part 4, No. GSR Part 4 (Rev. 1), IAEA, Vienna (2016)
6.	INTERNATIONAL ATOMIC ENERGY AGENCY - Predisposal Management of Radioactive Waste, General Safety Requirement Series Part 5, No. GSR Part 5, IAEA, Vienna (2009)
7.	INTERNATIONAL ATOMIC ENERGY AGENCY - Decommissioning of Facilities, General Safety Requirement Series No. GSR Part 6, IAEA, Vienna (2014)
8.	INTERNATIONAL ATOMIC ENERGY AGENCY - Preparedness and Response for Nuclear or Radiological Emergency, General Safety Requirement Series No. GSR Part 7, IAEA, Vienna (2015)
9.	INTERNATIONAL ATOMIC ENERGY AGENCY - Site Evaluation for Nuclear Installations, Specific Safety Requirement Series No. SSR-1, IAEA, Vienna (2003)
10.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Nuclear Power Plants: Design, Specific Safety Requirements Series No. SSR-2/1 (Rev. 1), IAEA, Vienna (2016)
11.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Nuclear Power Plants: Commissioning and Operation, Specific Safety Requirements Series No. SSR-2/2 (Rev. 1), IAEA, Vienna (2016)
12.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Research Reactors, Specific Safety Requirements Series No. SSR-3, IAEA, Vienna (2016)
13.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Nuclear Fuel Cycle Facilities, Specific Safety Requirements Series No. SSR-4, IAEA, Vienna (2017)
14.	INTERNATIONAL ATOMIC ENERGY AGENCY - Disposal of Radioactive Waste, Specific Safety Requirements Series No. SSR-5, IAEA, Vienna (2011)
15.	INTERNATIONAL ATOMIC ENERGY AGENCY – Regulations for the Safe Transport of Radioactive Material, Specific Safety Requirements Series No. SSR-6, IAEA, Vienna (2012)
16.	INTERNATIONAL ATOMIC ENERGY AGENCY - Regulations for the Safe Transport of Radioactive Material, 2018 Edition, Specific Safety Requirements Series No. SSR-6 (Rev. 1), IAEA, Vienna (2018)
17.	INTERNATIONAL ATOMIC ENERGY AGENCY - Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)
18.	INTERNATIONAL ATOMIC ENERGY AGENCY - Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency, Safety Guide Series No GSG-2, IAEA, Vienna (2012)
19.	INTERNATIONAL ATOMIC ENERGY AGENCY - Communication and Consultation with Interested Parties by the Regulatory Body, General Safety Guide Series No. GSG-6, IAEA, Vienna (2017).
20.	INTERNATIONAL ATOMIC ENERGY AGENCY - Occupational Radiation Protection, Safety Guide Series No. GSG-7 , IAEA, Vienna (2018)
21.	INTERNATIONAL ATOMIC ENERGY AGENCY - Regulatory Control of Radioactive Discharges to the Environment, Safety Guide Series No GSG-9, IAEA, Vienna (2018)

22.	INTERNATIONAL ATOMIC ENERGY AGENCY - Organization, Management and Staffing of the Regulatory Body for Safety, General Safety Guide Series No. GSG-12, IAEA, Vienna (2018).
23.	INTERNATIONAL ATOMIC ENERGY AGENCY - Functions and Processes of the Regulatory Body for Safety, General Safety Guide Series No. GSG-13, IAEA, Vienna (2018).
24.	INTERNATIONAL ATOMIC ENERGY AGENCY - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)
25.	INTERNATIONAL ATOMIC ENERGY AGENCY - The Management System for the Disposal of Radioactive Waste, Safety Guide Series No GS-G-3.4, IAEA, Vienna (2008)
26.	INTERNATIONAL ATOMIC ENERGY AGENCY - Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna (2011)
27.	INTERNATIONAL ATOMIC ENERGY AGENCY - A System for the Feedback of Experience from Events in Nuclear Installations, Safety Guide Series No. NS-G-2.11, IAEA, Vienna (2006)
28.	INTERNATIONAL ATOMIC ENERGY AGENCY - Modifications to Nuclear Power Plants, Safety Guide Series No NS-G-2.3, IAEA, Vienna (2001)
29.	INTERNATIONAL ATOMIC ENERGY AGENCY - Recruitment, Qualification and Training of Personnel for Nuclear Power Plants, Safety Guide Series No NS-G-2.8, IAEA, Vienna (2002)
30.	INTERNATIONAL ATOMIC ENERGY AGENCY - Environmental and Source Monitoring for Purposes of Radiation Protection, Safety Guide Series No. RS-G-1.8, IAEA, Vienna (2005)
31.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Radiation Generators and Sealed Radioactive Sources, Safety Guide Series No. RS-G-1.10, IAEA, Vienna (2008)
32.	INTERNATIONAL ATOMIC ENERGY AGENCY - Borehole Disposal Facilities for Radioactive Waste, Safety Guide Series No SSG-1, IAEA, Vienna (2009)
33.	INTERNATIONAL ATOMIC ENERGY AGENCY - Deterministic Safety Analysis for Nuclear Power Plants, Specific Safety Guides Series No. SSG-2, IAEA, Vienna (2010)
34.	INTERNATIONAL ATOMIC ENERGY AGENCY - Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-3, IAEA, Vienna (2010)
35.	INTERNATIONAL ATOMIC ENERGY AGENCY - Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-4, IAEA, Vienna (2010)
36.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Conversion Facilities and Uranium Enrichment Facilities, Specific Safety Guide Series No. SSG-5, IAEA, Vienna (2010)
37.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Uranium Fuel Fabrication Facilities Specific Safety Guide Series No. SSG-6, IAEA, Vienna (2010)
38.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Uranium and Plutonium Mixed Oxide Fuel Fabrication Facilities, Specific Safety Guide Series No. SSG-7, IAEA, Vienna (2010)
39.	INTERNATIONAL ATOMIC ENERGY AGENCY - Licensing Process for Nuclear Installations, Specific Safety Guide Series No. SSG-12, IAEA, Vienna (2010)
40.	INTERNATIONAL ATOMIC ENERGY AGENCY - Geological Disposal Facilities for Radioactive Waste Specific Safety Guide Series No. SSG-14, IAEA, Vienna (2011)
41.	INTERNATIONAL ATOMIC ENERGY AGENCY - Storage of Spent Nuclear Fuel, Safety Guide Series No SSG-15 (Rev. 1), IAEA, Vienna (2020)
42.	INTERNATIONAL ATOMIC ENERGY AGENCY - Periodic Safety Review for Nuclear Power Plants, Safety Guide Series No SSG-25, IAEA, Vienna (2013)
43.	INTERNATIONAL ATOMIC ENERGY AGENCY - Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material, Specific Safety Guide No SSG-26, IAEA, Vienna, (2014)
44.	INTERNATIONAL ATOMIC ENERGY AGENCY - Commissioning for Nuclear Power Plants, Safety Guide Series No. SSG-28, IAEA, Vienna (2014)

45.	INTERNATIONAL ATOMIC ENERGY AGENCY - Predisposal Management of Radioactive Waste from Nuclear Power Plants and Research Reactors, Safety Guide Series No SSG-40, IAEA, Vienna (2016)
46.	INTERNATIONAL ATOMIC ENERGY AGENCY - Predisposal Management of Radioactive Waste from Nuclear Fuel Cycle Facilities, Safety Guide Series No SSG-41, IAEA, Vienna (2016)
47.	INTERNATIONAL ATOMIC ENERGY AGENCY - Management of Waste from the Use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education, Safety Guide Series No SSG-45, IAEA, Vienna (2019)
48.	INTERNATIONAL ATOMIC ENERGY AGENCY - Radiation Protection and Safety in Medical Uses of Ionizing Radiation, Safety Guide Series No SSG-46, IAEA, Vienna (2018)
49.	INTERNATIONAL ATOMIC ENERGY AGENCY - Decommissioning of Nuclear Power Plants, Research Reactors and Other Nuclear Fuel Cycle Facilities, Safety Guide Series No SSG-47, IAEA, Vienna (2018)
50.	INTERNATIONAL ATOMIC ENERGY AGENCY – Ageing Management and Development of a Programme for Long Term Operation of Nuclear Power Plants, Safety Guide Series No SSG-48, IAEA, Vienna (2018)
51.	INTERNATIONAL ATOMIC ENERGY AGENCY –Decommissioning of Medical, Industrial and Research Facilities, Safety Guide Series No SSG-49, IAEA, Vienna (2019)
52.	INTERNATIONAL ATOMIC ENERGY AGENCY – Operating Experience Feedback for Nuclear Installations, Safety Guide Series No SSG-50, IAEA, Vienna (2019)
53.	INTERNATIONAL ATOMIC ENERGY AGENCY - Accident Management Programmes for Nuclear Power Plants, Safety Guide Series No SSG-54, IAEA, Vienna (2019)
54.	INTERNATIONAL ATOMIC ENERGY AGENCY - Planning and Preparing for Emergency Response to Transport Accidents Involving Radioactive Material, Safety Guide No TS-G-1.2 (2002)
55.	INTERNATIONAL ATOMIC ENERGY AGENCY - Radiation Protection Programmes for the Transport of Radioactive Material, Safety Guide No TS-G-1.3, IAEA, Vienna, (2007)
56.	INTERNATIONAL ATOMIC ENERGY AGENCY - The Management System for the Safe Transport of Radioactive Material Safety Guide No TS-G-1.4, IAEA, Vienna, (2008)
57.	INTERNATIONAL ATOMIC ENERGY AGENCY - Compliance Assurance for the Safe Transport of Radioactive Material, Safety Guide No TS-G-1.5, IAEA, Vienna, (2009)
58.	INTERNATIONAL ATOMIC ENERGY AGENCY - Schedules of Provisions of the IAEA Regulations for the Safe Transport of Radioactive Material (2009 Edition), Safety Guide No TS-G-1.6 (Rev.1), IAEA, Vienna, (2014)
59.	INTERNATIONAL ATOMIC ENERGY AGENCY - Storage of Radioactive Waste, Safety Guide Series No WS-G-6.1, IAEA, Vienna (2006)
60.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No.WS-G-5.2, IAEA, Vienna (2009)
61.	INTERNATIONAL ATOMIC ENERGY AGENCY - Storage of Radioactive Waste, Safety Guide Series No. WS-G-6.1, IAEA, Vienna (2006)