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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

SLOVENIA

Ljubljana, Slovenia

4 to 14 April 2022

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

IAEA Integrated Regulatory Review Service IRRS

REPUBLIC OF SLOVENIA
MINISTRY OF THE ENVIRONMENT AND SPATIAL PLANNING
SLOVENIAN NUCLEAR SAFETY ADMINISTRATION

REPUBLIC OF SLOVENIA
MINISTRY OF HEALTH
SLOVENIAN RADIATION PROTECTION ADMINISTRATION

Integrated
Regulatory
Review Service

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REPORT OF THE
INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
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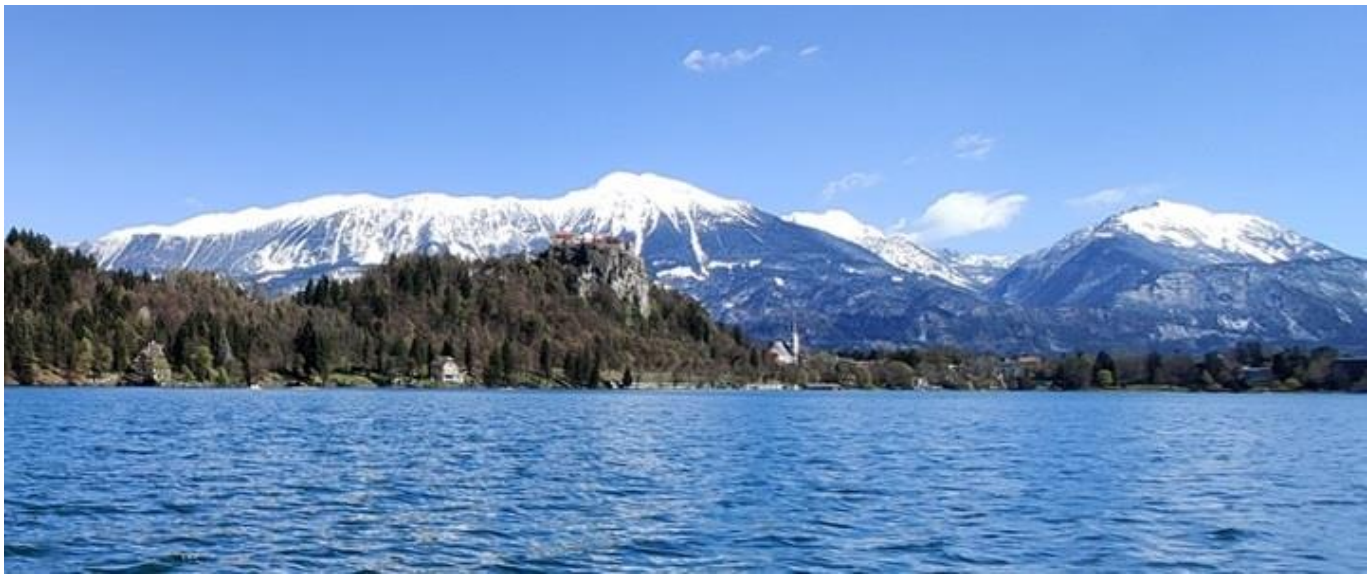

Integrated Regulatory Review Service

IAEA | IRRS

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

Mission dates:	*4 to 14 April 2022*
Regulatory body visited:	*Slovenian Nuclear Safety Administration (SNSA), Slovenian Radiation Protection Administration (SRPA)*
Location:	*SNSA headquarters, Ljubljana*
Regulated facilities, activities, and exposure situations in the mission scope:	*Nuclear power plants, research reactors, waste management facilities, uses of radiation sources in research and industry, transport, as well as medical, occupational and public exposure.*
Organized by:	*IAEA*

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SARDELLA Rosa	Deputy Team Leader (Switzerland)
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EGAN Michael	Reviewer (Sweden)
HUNT John	Reviewer (Brazil)
KLENOVIC Ivan	Reviewer (Slovakia)
MATTILA Aleksi	Reviewer (Finland)
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DANI Mario	IAEA Administrative Assistant

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 Slovenia, an international team of senior safety experts met representatives of the Slovenian Nuclear Safety Administration (SNSA) and Slovenian Radiation Protection Authority (SRPA) between 4 and 14 April 2022 to conduct an Integrated Regulatory Review Service (IRRS) mission. Meetings were organized with SNSA and SRPA representatives. The purpose of the peer review was to review the Slovenian governmental, legal and regulatory framework for nuclear and radiation safety. The mission was organized back-to-back with an ARTEMIS mission, scheduled from 22 to 30 May 2022.

The mission took place at the SNSA Headquarters in Ljubljana. The IRRS mission covered all civilian nuclear and radiation facilities and activities in Slovenia. The review compared the Slovenian regulatory framework for nuclear and radiation safety against International Atomic Energy Agency (IAEA) safety standards as an international benchmark for safety. The mission was also used to exchange information and experience between the IRRS team members and the Slovenian counterparts in the areas covered by the mission. The IRRS team consisted of fourteen senior regulatory experts from twelve IAEA Member States, two IAEA staff members, one IAEA administrative assistant and one observer from a Member State.

The IRRS team conducted a review of 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; regulation of nuclear power plants; the research reactor; radiation sources facilities and activities; occupational radiation protection, control of medical exposures, public exposure control, transport of radioactive material, waste management and decommissioning, and the interface between safety and nuclear security.

The IRRS mission included discussions on two policy issues: the implications of the COVID-19 pandemic on the correct functioning of the regulatory authorities and the regulatory challenges in the context of possible new build.

In preparation for the IRRS mission, Slovenia conducted a self-assessment of the governmental, the legal and regulatory framework for nuclear and radiation safety, and prepared a preliminary action plan to address the weaknesses that were identified. The results of the self-assessment and supporting documentation were provided to the IRRS team as advance reference material for the mission. During the mission, the IRRS team performed a systematic review of all topics presented in the advance reference material, conducted interviews and discussions with management and staff of SNSA and SRPA, as well as conducted meetings with the Minister of Environment and Spatial Planning and the Minister of Health. The IRRS team observed regulated activities and performance of inspection activities, including discussions with the licensee personnel and management during visits to Krško nuclear power plant (NPP), Jožef Stefan Institute, the Institute of Oncology Ljubljana and the central storage facility for institutional radioactive waste at Brinje. Throughout the mission, the IRRS review team was extended full cooperation in the regulatory, technical, and policy issues by all parties in a very open and transparent manner.

SNSA and SRPA are the regulatory authorities for oversight of nuclear and radiation safety of facilities and activities. Both SNSA and SRPA have developed regulations and guidance to carry out their regulatory responsibilities in compliance with IAEA safety standards and international best practices. The IRRS team recognized that SNSA and SRPA continue to update their regulatory requirements in line with demands on regulatory functions and encouraged SNSA and SRPA to further enhance the regulatory framework.

The IRRS report includes a number of recommendations and suggestions to improve the Slovenian regulatory system and the effectiveness of the regulatory functions in line with IAEA safety standards. The

IRRS team acknowledged that many of its findings confirm the actions for further improvement that were identified in SNSA's and SRPA's self-assessment.

The IRRS team noted strong commitment and dedication of both SNSA and SRPA staff. The regulatory scope is wide, which means the pressure on staff to fulfil their tasks in line with IAEA safety standards is considerable. In several areas, both SNSA and SRPA experience difficulty in fulfilling their obligations, despite what would seem to be best efforts of its staff. The impact of resource constraints on capability has been noted in previous IRRS missions' recommendations addressed to the Slovenian Government. The IRRS team therefore underlines once more the importance for the government to ensure that sufficient funding and human resources are provided to both SNSA and SRPA to enable them to fulfil their responsibilities.

The IRRS team concluded that the following issues are representative of those which, if addressed by the Government of Slovenia and the regulatory authorities, should further enhance the overall performance of the regulatory system.

In addition to the issue of providing sufficient resources, noted above, the Government should also:

- make appropriate provisions to ensure that the independence of SNSA and SRPA is sustained.
- further develop the regulatory framework and improve coordination and cooperation between all relevant competent authorities.

SNSA should:

- further develop guidance on format and content for some of the documents required to be submitted with the application for authorization.
- develop clearly specified and established procedures for amendment, renewal, suspension or revocation of the authorization.
- finalize the development of the specific training programme for inspectors to cover principles, concepts and technological aspects, as well as procedures for inspecting facilities and activities.

SRPA should:

- further develop their management system to be in line with IAEA safety standards and ensure it is applied, sustained and continuously improved.
- develop procedures for the licensing process.
- develop an enforcement policy and establish criteria for responding to non-compliance with regulatory requirements or conditions of authorization.

In recognition of an outstanding programme, the IRRS team identified a good practice in SNSA's activities related to emergency exercises with cyber security scenarios. Such scenarios are at the interface between safety and nuclear security and require heightened awareness as well as preparedness.

Furthermore, the IRRS team was made aware of several areas of good performance, as for example the SNSA's initiative at an early stage of the pandemic to develop written instructions addressed to licensees on how to participate in successful and effective remote inspections; SNSA's web portal for environmental monitoring with on-line dose rate monitoring results and nuclide specific results from environmental samples; as well as the National Protection Strategy for Nuclear and Radiological Emergencies, which was developed in line with IAEA's recent Emergency Preparedness and Response (EPR) Series publications.

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

The IRRS team findings are summarized in Appendix V.

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

I. INTRODUCTION

At the request of the Government of Slovenia, an international team of senior safety experts met representatives of the Slovenian Nuclear Safety Administration (SNSA) and Slovenian Radiation Protection Authority (SRPA) from 4 to 14 April 2022 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the Slovenian governmental, legal and regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Slovenia in January 2018. A preparatory mission was conducted 6-7 October 2021 at the SNSA Headquarters in Ljubljana to discuss the purpose, objectives, and detailed preparations of the review in connection with regulated facilities and activities in Slovenia and their related safety aspects and to agree on the scope of the IRRS mission.

This mission was organized back-to-back to an Integrated Review Service for Radioactive Waste and Spent Fuel, Decommissioning and Remediation (ARTEMIS) mission scheduled on 22 to 30 May 2022. To avoid unnecessary duplications between the IRRS and the ARTEMIS missions, the preparation and conduct of the IRRS mission were carried out in a coordinated manner with the ARTEMIS mission. 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 12 IAEA Member States, two IAEA staff members, one IAEA administrative assistant and one observer. Due to last minute cancellations of participation in the IRRS team caused by the pandemic, the responsibilities of IRRS Reviewers as owners of specific modules had to be redistributed compared to the standard assignment of modules, presented in Appendix X of the IRRS Guidelines. Thus, the IRRS team carried out the review of the entire scope of the mission 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. In addition, policy issues were discussed, including 'the implications of a pandemic situation and associated challenges for regulatory bodies' and 'challenges of the regulatory body in the context of possible new builds.'

SNSA and SRPA conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of the SNSA and SRPA self-assessment and supporting documentation were provided to the IRRS team as advance reference material for the mission. During the mission the IRRS team performed a systematic review of all topics within the agreed scope through review of the Slovenia advance reference material, conduct of interviews with management and staff from SNSA and SRPA and direct observation of SNSA and SRPA regulatory activities at regulated facilities. Meetings with the Ministry of Environment and Spatial Planning and the Ministry of Health were also organized.

All through the mission the IRRS team received excellent support and cooperation from SNSA and SRPA.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review the Slovenian 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 and exposure situations regulated in Slovenia. This IRRS mission is expected to facilitate regulatory improvements in Slovenia and other Member States, utilising the knowledge gained and experiences shared between SNSA and SRPA and the IRRS team and the evaluation of the Slovenian regulatory framework for nuclear 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 of IAEA safety standards;

l) providing feedback on the regulatory implications of pandemic situations.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IRRS TEAM

A preparatory meeting for the IRRS mission from 6 to 7 October 2021 was carried out by the appointed Team Leader, Mr Cantemir Ciurea-Ercau, Deputy Team Leader, Ms Rosa Sardella, and the IAEA representatives, Mr Geza Macsuga, Team Coordinator, and Mr Teodros Hailu, Deputy Team Coordinator.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of SNSA and SRPA represented by Mr Igor Sirc, Director of SNSA, and Damijan Škrk, Director of SRPA, and other senior management and staff. It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides:

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

Mr Igor Grlicarev made presentations on the national context, the current status of SNSA and SRPA 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 Slovenia in April 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 SNSA and SRPA Liaison Officers for the IRRS mission were confirmed as Mr Igor Grlicarev and Ms Nina Jug respectively.

SNSA and SRPA provided IAEA with the advance reference material (ARM) for the review in February 2022. In preparation for the mission, the IAEA review team members reviewed the Slovenia advance reference material and provided their initial impressions to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

The 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, 03 April 2022 in uHotel, directed by the IRRS Team Leader and the IAEA Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS programme. The understanding of the methodology for review was reinforced. The agenda for the mission was presented to the team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

The host Liaison Officers participated in 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, 04 April 2022, with the participation of the IRRS team and SNSA and SRPA senior management and staff. Opening remarks were made by Mr Igor Sirc, SNSA Director General, Mr Damijan Škrk, SRPA Director General, Mr Cantemir Ciurea-Ercau, IRRS Team Leader and Mr Geza Macsuga, IAEA Coordinator. Mr Igor Sirc gave an overview of the Slovenia context, SNSA and SRPA activities and the action plan prepared as a result of the pre-mission self-assessment.

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

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

The IRRS exit meeting was held on Thursday, 14 April 2022. The opening remarks at the exit meeting were presented by Mr Igor Sirc and were followed by the presentation of the results of the mission by the IRRS Team Leader Mr Cantemir Ciurea-Ercau. Closing remarks were made by Ms Anna Hajduk Bradford, IAEA, Director, Division of Nuclear Installation Safety.

An IAEA press release was issued.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

To determine the specific functions of the regulatory body and the allocation of responsibilities in the field of safety, the Republic of Slovenia has been maintaining separation and independence of the regulatory bodies responsible for the supervision of nuclear and radiation safety from those entities whose primary mission is to promote the use of nuclear energy or ionizing radiation sources.

SNSA reports to the Parliament once a year, within the special chapters of the Annual Report on Radiation Protection and Nuclear Safety in Slovenia.

The Resolution on Nuclear and Radiation Safety in the Republic of Slovenia (for the period 2013 – 2023) was adopted by the Parliament in 2013.

Through this Resolution, already examined during the IRRS follow up mission in 2014 and considered as a good practice, the government of Slovenia clearly establishes a national policy and strategy for safety and expresses a long-term commitment to safety.

This 10 years duration resolution is a formal statement of the Government that emphasizes inter alia:

- A long-term commitment to safety
- The respect of the 10 fundamental safety principles addressed in IAEA's SF-1
- Promotion of leadership for safety and safety culture

The resolution indicates that "With the reorganization of the state administration in 2012 the SNSA became a body within the newly created Ministry of Agriculture and the Environment." whereas its title is now Ministry of Environment and Spatial Planning.

The IRRS team was informed that the new Resolution on Nuclear and Radiation Safety in the Republic of Slovenia for the period from 2023 to 2033 is expected to be finalized in 2022 and will take into account this change.

The finalization of the future resolution could also be an opportunity for the Government of Slovenia and their respective Ministers to strengthen and sustain independence of SNSA and SRPA despite changes due to political reasons (see Recommendation R1).

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Republic of Slovenia has established a legal framework with the Act on Ionising Radiation Protection and Nuclear Safety (the Act).

The aim of the Act is to reduce the detrimental effects on human health to the lowest possible level due to radioactive contamination of the environment and due to ionising radiation resulting from the use of sources of ionising radiation.

This Act provides separate allocation of responsibilities for SNSA and for SRPA. The licences delivered respectively by SNSA and SRPA are listed in article 18 of the Act.

SNSA is in charge of issuing licenses in the field of activities in relation with industry and research while SRPA is in charge of issuing licenses in the field of medical and veterinary applications.

SNSA and SRPA prepare drafts of regulations and propose them to their relevant Ministers (Minister of Environment and Spatial Planning for SNSA and Minster of Health for SRPA) or to the Government (if a regulation covers areas of different authorities) in order to be adopted.

The Act defines the enforcement instrument as penal provision through a list provided in its article 179.

The Act also empowers SNSA and SRPA inspectors to carry out inspections and initiate enforcement processes.

The Act is regularly reviewed and updated. The last revisions took place in 2021.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

SNSA is a body created in 1987, currently under the Ministry of the Environment and Spatial Planning.

SNSA performs professional, administrative, supervisory and development tasks related to regulatory oversight in the areas of radiation and nuclear safety, radiation practices and the use of radiation sources (except in healthcare or veterinary medicine), protection of the environment against ionising radiation, physical protection of nuclear material and facilities, non-proliferation of nuclear weapons, and safeguards.

SNSA has 41 employees (civil servants), including administrative staff.

SRPA is a body created in 2003, currently under the Ministry of Health.

SRPA performs administrative, development and inspection tasks related to regulatory oversight in the areas of radiation practices and the use of ionising radiation sources in human and veterinary medicine and the protection of public against the harmful effects of ionising radiation.

SRPA has 6 employees (civil servants), including administrative staff.

Independence of SNSA

The IRRS team was informed that, a few months ago, some changes in the government led to the move of the position of ARAO, a licensee in charge of the operation of nuclear installations such as waste storage, from the Ministry of infrastructure to the Ministry of Environment and Spatial Planning.

The IRRS team considers that there could be a conflict of interest especially in the case of an appeal process launched by ARAO against a decision of SNSA.

The director of SNSA informed the IRRS team that the nuclear safety administration's independence has never been compromised by the Minister of Environment and Spatial Planning.

The IRRS team had an interview, conducted in English, with the Minister of Environment and Spatial Planning, Mr Andrej Vizjak.

During this interview the IRRS team asked the Minister if there could be a conflict of interest considering the fact that ARAO is under his responsibility.

The Minister of Environment and Spatial Planning declared that nothing could affect the independence of the SNSA.

Independence of SRPA

The IRRS team noted that SRPA reports to the Minister of Health who has other responsibilities in health sector using radiation applications and sources. This might potentially compromise the independence of SRPA.

The director of SRPA informed the IRRS team that the radiation protection administration's independence has never been compromised by the Minister of Health.

The IRRS team had also an interview, conducted in English, with the Minister of Health, Mr Janez Poklukar.

The IRRS team was informed that the risk of conflict of interest is considered low.

The Minister of Health declared that nothing could affect the independence of the SRPA.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Both, ARAO and SNSA, as regulatory body for ARAO, report to the Minister of Environment and Spatial Planning. This could compromise the independence of SNSA.* *SRPA reports to the Minister of Health, who has other responsibilities in the health sector that uses radiation applications and radioactive sources. This could compromise the independence of SRPA.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 4, para. 2.7 states that** *"An independent regulatory body will not be entirely separate from other governmental bodies. The government has the ultimate responsibility for involving those with legitimate and recognized interests in its decision making. However, the government shall ensure that the regulatory body is able to make decisions under its statutory obligation for the regulatory control of facilities and activities, and that it is able to perform its functions without undue pressure or constraint."*
R1	**Recommendation: The Government should make appropriate provisions to ensure the independence of SNSA and SRPA is sustained.**

Resources of SNSA

Due to limited resources, SNSA experiences difficulties in fulfilling its obligations in some areas such as emergency preparedness response and inspection activities.

Furthermore, the IRRS team was informed that a new build programme is under discussion. This project consists of the construction of a second unit on the Krško site. Although this project is not launched yet, the IRRS team considers that SNSA does not have sufficient numbers of competent staff to perform its functions.

Considering that recruitment and training of sufficient numbers of competent staff for specific activities such as licencing and safety assessment of new NPPs is a long term process, the Government should anticipate this demand.

Resources of SRPA

SRPA is composed of 6 persons, including its director. The IRRS team observed that, considering the number of facilities and activities under its regulatory control, it could be difficult for SRPA to address an increase of demands of authorizations and carry out the subsequent control activities.

SRPA also carries out other activities at the international level (see Section 2).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SNSA and SRPA don't have sufficient numbers of competent staff to properly carry out their responsibilities.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 4, para. 2.8 states that** *"To be effectively independent from undue influences on its decision making, the regulatory body:* *(a) Shall have sufficient authority and sufficient competent staff;* *(b) Shall have access to sufficient financial resources for the proper and timely discharge of its assigned responsibilities; …"*
(2)	**BASIS: GSR Part 7 Requirement 21 states that** *"The government shall ensure that overall organization for preparedness and response for a nuclear or radiological emergency is clearly specified and staffed with sufficient personnel who are qualified and are assessed for their fitness for their intended duties."*
R2	**Recommendation: The Government should ensure sufficient funding and human resources for both SNSA and SRPA to fulfil their responsibilities.**

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

The first principle of the safety fundamental principles from the IAEA's SF-1 document "The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks." is detailed in the Act, Article 4: "A provider of a radiation practice, including the operator of a radiation or nuclear facility, shall be responsible for radiation protection and radiation safety, the operator of a nuclear facility is responsible also for the nuclear safety. The operator of the facility may not transfer its liability to another person. The operator of the facility shall also be responsible for all activities of contract providers and sub-contractors whose activities could affect nuclear or radiation safety (the principle of prime responsibility)."

Practically SNSA and SRPA only control/inspect authorization holders. Nuclear activities carried out by outside organisations or workers such as subcontractors are inspected in the presence of the authorized party and the potential issues are addressed to the authorized party.

SNSA and SRPA are empowered to act in case of violation of legislation. Carrying out an activity involving radiation or the use of radiation sources without a licence or registration is prohibited by Article 10 of the Act.

Responsibility for safety covers all stages in the lifetime/duration of the facility/activity.

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

SNSA's and SRPA's responsibilities and competencies are defined in the Decree on Administrative Authorities within Ministries.

As explained in the section 1.2, the responsibilities and functions of SNSA and SRPA are legally specified in Article 18 of the Act.

Article 18 provides two separated lists of licenses to be delivered by SNSA and SRPA.

SNSA and SRPA cooperate during emergency response activities and joint inspections and share feedback experience.

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

The responsibility for implementing a system to reduce risks from exposure to ionizing radiation is shared among the different levels of government.

According to the Article 26 of the Act, SNSA, in cooperation with other national authorities, periodically organises searches for sources of unknown origin or from past activities or practices. These searches include purpose directed inspections, financial incentives for searching for such sources, public awareness campaigns about such sources, examination of archive records of administrative authorities and providers of radiation practices and sources.

SNSA regularly informs providers of activities for which it is likely that orphaned sources may arise (waste facilities and processing facilities for all kind of waste, companies dealing with waste, transport centres, etc.) about the probability of finding such sources, their potential risk and required protective measures.

Based on the Decree on the reduction of exposure due to natural radionuclides and past or existing activities or events (UV5) a special national program on reduction of exposure has been established. The program is financed from the state budget and is regularly reviewed in all industry sectors where the NORM can be expected.

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

The Resolution on the national programme for managing radioactive waste and spent fuel for the period from 2016 to 2025 (ReNPRRO16-25), was adopted by the Parliament in April 2016.

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. Furthermore, the draft revision to the national programme for managing radioactive waste and spent fuel (covering the period 2023 to 2032) is included in the scope of the ARTEMIS mission.

1.8. COMPETENCE FOR SAFETY

The commitment from the government to deliver the necessary provision for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities is stated in Article 174 of the Act.

These provisions support the following organization involved in nuclear activities:

- Person/organization responsible for a facility/activity
- Regulatory body and its support organizations
- Research and development centres

The IRRS team was informed that Slovenian educational institutions offer comprehensive study programmes. Graduates from these institutions can achieve high ranked positions in organizations in charge of nuclear safety, such as regulatory bodies, TSOs or industry.

SNSA and SRPA provide ongoing training for its staff to ensure they are competent and qualified for the work they perform in the regulation of safety. This is described in more detail in Sections 3, 4 and 7 below.

Each year SNSA and SRPA prepare an educational and training plan for their employees, in which special attention is given to newly employed colleagues.

1.9. PROVISION OF TECHNICAL SERVICES

Due to their limited resources, SNSA and SRPA need to be supported by technical services in the field of safety and radiation protection.

The Slovenian legislation has put in place independent controls performed by authorized organizations. These authorizations, defined in the Act and elaborated in more detail in the associated decrees and rules, cover different activities such as safety assessments, calibrations, measurements, analyses, etc.

Numbers of technical services such as TSOs and laboratories are accredited according to ISO/IEC 17 025 standards General requirements for the competence of testing and calibration laboratories. The organisation in charge of the accreditations is an Accreditation Board, an independent single state body and structured as a non-profit organisation.

These accreditations include requirements to these organizations in the field of technical competence for their staff.

The technical services in relation to safety, such as services for personal dosimetry or environmental monitoring, are essentially provided by two organizations: the laboratory of the Jožef Stefan Institute (IJS); and the laboratory of the Institute of Occupational Safety (ZVD).

Those laboratories are both accredited according to the ISO/IEC 17 025.

In addition to the direct provision of training resources, the state of Slovenia uses its influence on providing the professional support and development of nuclear profession of authorized organizations in the long run.

1.10. SUMMARY

The Government of Slovenia has a consistent regulatory framework for nuclear and radiation safety and a national policy and strategy for safety formalized by a resolution on Nuclear and Radiation Safety in the Republic of Slovenia for the period 2013–2023 and the Act on Ionising Radiation Protection and Nuclear Safety.

The attachment of SNSA and SRPA to Ministries that interested parties also depend on, might lead to conflict of interest in different circumstances.

The current activities and the potential construction of a new NPP present a significant challenge for SNSA regarding human and financial resources.

The following areas for improvement were identified:

- Maintaining the independence of SNSA and SRPA
- Ensuring sufficient funding and human resources

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

SNSA and SRPA contribute to the Slovenian effort to fulfil its respective international obligations and agreements, including international peer reviews, and promote international cooperation and assistance to enhance safety globally.

SNSA and SRPA are empowered by Article 5 of the Act to participate and represent Slovenia in international activities.

SNSA participates in a number of conventions, workshops, and meetings with international organizations. SNSA participates in activities organised by the following organizations and groups:

- International Atomic Energy Agency (IAEA),
- European Nuclear Safety Regulators Group (ENSREG), Working Party on Atomic Questions (ATO), Euratom consultative committees under the umbrella of the EU,
- Nuclear Energy Agency (NEA) of OECD,
- West European Nuclear Regulators Association (WENRA),
- International Nuclear Law Association (INLA),
- European Nuclear Security Regulators Association (ENSRA),
- Heads of European Radiological protection Competent Authorities (HERCA) – in Working Groups only.
- Nuclear Suppliers Group (NSG) and Zangger Committee,
- European Association of Competent Authorities for safe and sustainable transport of radioactive materials (EACA),
- NSCG – Nuclear Security Contact Group

The IRRS team was informed that the investment in international activities represents around 3 equivalent persons a year.

Because of its size, SRPA's contribution to participation is limited and focuses on IAEA, HERCA, OECD/NEA, European Commission Working Groups, and the European ALARA Network (EAN).

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

The operator of a nuclear facility shall implement programs for monitoring and analysis of operational experience in nuclear and radiation facilities.

Article 90 of the Act establishes that:

- the operator of a radiation or nuclear facility shall ensure that monitoring programmes on operating experience in radiation or nuclear facilities are carried out.
- the findings of the programmes referred to in the preceding paragraph shall be considered by the operator of a radiation and nuclear facility while assessing, verifying and improving radiation and nuclear safety.

Rules JV9 were amended to specify the event reporting threshold for NPP facilities.

The IRRS team was informed that, for other facilities, event reporting is a condition of the authorization.

2.3. SUMMARY

Both SNSA and SRPA contribute to the Slovenian effort to fulfil its respective international obligations, in the relevant international arrangements.

Despite their limited resources, SNSA and SRPA have a strong presence at international level and gain significant feedback experience from this to manage their own organisation.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

SNSA's organization reflects its tasks of overseeing nuclear safety and the safety of industrial radiation sources, and of inspection and emergency preparedness. Within SNSA, most resources are allocated to the division of Nuclear Safety and to the division of Radiation Safety and Materials, which indicates a graded approach in allocating resources. The resources are allocated based on the tasks of the different organizational units. For large oversight tasks, multi-disciplinary teams are formed.

SRPA performs different tasks related to the protection of public against harmful effects of ionizing radiation. SRPA's tasks are numerous. SRPA

- oversees the use of ionizing radiation in health care and in veterinary practices;
- inspects systematically working and living premises due to natural radiation sources;
- implements monitoring of foodstuffs and drinking water;
- evaluates and approves experts who carry out professional tasks related to ionizing radiation;
- carries out duties with the aim of raising public's awareness of radiation related questions.

However, the organization of SRPA is small, having only two departments (Radiation Protection Inspectorate and Administrative Procedure Department) and six employees (5 experts, 1 administrator). SRPA has received a permission from the Ministry of Health to employ one more expert during 2022. Resources are discussed further in section 3.3.

Making changes to the organizational structure needs approval from the respective Minister and from the Government. This is a procedure concerning all governmental offices and it applies to both SNSA and SRPA. However, the experience is that as long as the proposed change does not affect the number of staff, the approval is mainly a formality and does not prevent making changes to the organization when seen to be necessary.

Within SNSA, the decisions are issued by the director, or by a senior staff member, assigned by the director.

Within SRPA, the director makes all the decisions.

The decisions are based on the review and assessment performed by the regulatory body's own staff and by the technical support organizations.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

Within the governmental infrastructure, SNSA is under the Ministry of the Environment and Spatial Planning and reports to the Minister. The ministry has no role in promotion of nuclear energy, although recently the ministry became responsible for ARAO, the licensee for the final repository for low and intermediate level radioactive waste and the operator of a central interim storage for low and intermediate level radioactive waste.

SRPA is under the Ministry of Health, which is responsible for health sector using radiation. The organizational independence of SNSA and SRPA is discussed in Section 1.3.

The ministries are not involved in the daily activities or in the decision making of SRPA or SNSA. As SRPA's resources are limited, the Ministry of Health provides SRPA services in legal and administrative questions e.g. regarding procurement, but even then the related decisions are made independently by SRPA.

SNSA and SRPA are independent in their decision making and in the use of their budget.

The foundation for independence of SNSA and SRPA is given in the legislation (State Administration Act and Resolution on Nuclear and Radiation Safety in the Republic of Slovenia) which determines both organizations as independent bodies within their respective Ministries. Legislation does not provide SNSA and SRPA any responsibilities or duties which would be in conflict with regulatory control.

According to the Act and Inspection Act, any inspector from SNSA and SRPA has the authority to stop an activity if there is an immediate danger to life or health or an immediate danger of damage to environment or property.

The technical competence of their staff and the possibility to use external independent expert organizations support the independence of SNSA and SRPA from the licensees in technical matters. However, SNSA has identified that it has limited expertise in deterministic and probabilistic safety analyses, and that certain areas of nuclear safety are not adequately covered by expertise. The lack of competent resources may compromise the effective independence of SNSA and SRPA. The resources are discussed further in the next section.

To avoid conflict of interest, SNSA and SRPA apply several measures. This is covered by legislation (e.g. Code of Conduct for Public Employees, Public Employees Act), and by the management systems of SNSA. The SNSA and the SRPA have Integrity Plans, in which a conflict of interest is discussed as a possible risk of loss of integrity. Once a year training sessions are given regarding conflict of interest and the obligations for each individual involved. Internal controls are used to check compliance with the rules. Each new employee has to sign a statement that he or she is aware and will follow principles regarding conflicts of interests.

Neither SNSA nor SRPA have any special arrangements when new employees are recruited from the authorized parties. Until now, such recruitment has never occurred. Items like code of conduct, integrity and risks of conflicts of interests are well covered in the training provided to all staff members.

SNSA does not have any resident inspectors inside operator's facilities.

The independence of the SNSA's external support organizations is required by "Rules on authorised radiation and nuclear safety experts (JV3)". In procurement, the Public Procurement Act is followed.

In the field of review and assessment, both SNSA and SRPA use safety assessments performed by authorized expert organizations. These assessments are ordered by the authorized parties and also paid by them directly to the authorized expert organization. The Act obliges the authorized parties to provide an independent safety assessment by an authorized expert organization for certain applications. However, the decisions taken by SNSA or SRPA are never solely based on the assessment by the expert organizations. In their decisions, SNSA and SRPA need to address how they consider the conclusions delivered by the authorized expert. SNSA and SRPA can also order additional assessments from other organization when necessary.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

The number of staff of both SNSA and SRPA is subject to the restrictions imposed by state policy. In both organizations staff shortages may affect performing properly their statutory obligations. For example, they have been forced to reduce the inspection frequency of less risk-significant facilities and to postpone the development of some support functions. In some technical areas, SNSA would have challenges to perform a full review and assessment itself and it relies largely on the assessments performed by technical support organizations. Furthermore, SRPA would need additional resources in the field of radon exposure to be able to continue its planned work in that area. Also, both organizations should have resources to build their competences regarding new technologies. For example, health care devices and practices that have not been used in Slovenia before may come into use in the near future. SRPA should be able to assess their safety. Slovenia is also considering constructing a new NPP. In that case, the staff of SNSA and SRPA would need

to be significantly increased, well in advance before the start of the actual project. Ensuring sufficient resources to SNSA and SRPA is discussed in section 1.3.

To improve the financial situation, SNSA provides expert services e.g. to countries embarking on nuclear energy programmes. The income can be used for hiring temporary staff. A challenge is to find projects that would provide enough income to compensate for the use of SNSA's own resources for the project and the expenses of the new expert(s).

SNSA and SRPA provide input, in the frame of a draft budget, to the governmental human resource plan. The plan is prepared annually, and it covers the next two years. The plan includes only the number of employees, not the competences.

Competences for different tasks are defined in the document "Internal Organization and Systematization of Jobs in the SNSA/SRPA." Annual interviews with each employee are used to identify any gaps in the competences, and the interview results are used to develop annual training plans. During interviews, the effectiveness of received training is evaluated.

In their self-assessments, both SNSA and SRPA identified a need to develop further their Systematic Approach to Training. In the development, SNSA has utilised good practices from other organizations, including those from outside the field of nuclear and radiation safety. Currently SNSA is creating an overall view of the different competence areas and their resource needs in order to have support of longer term human resource planning. Succession plans and knowledge transfer are developed further, too. SRPA also develops competence and knowledge management to support human resource management in the long term. However, the long-standing recruitment restrictions by the government tend to reduce the relevance of long-term planning.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

The Act provides provisions for two expert councils that advise both SNSA and SRPA, e.g. on preparation on regulations or on the annual work plans of SNSA and SRPA, or on other topics, if requested. The council members are nominated by the respective Ministers. A process for avoiding conflict of interest is defined in "Rules on the Specialist Council on Radiation and Nuclear Safety."

Both SNSA and SRPA give authorizations to expert organizations and individual experts. The authorization process is defined in regulations, e.g. "Rules on Authorized Radiation and Nuclear Safety Experts (JV3)", "Rules on Approving of Experts Performing Professional Tasks in the Field of Ionising Radiation (SV7)" and "Rules on Approving Radiation Protection Experts (SV7a)". The authorized experts provide services not only to SNSA and SRPA but also to the licensees. For example, SRPA authorizes dosimetry services, radiation protection experts and medical physics experts which provide services also to the users of radiation.

The authorisation is given for a maximum of five years. During that time, audits can be regularly performed. Typically, audits are not performed more than once during the five-year period. The areas where authorized experts would need to subcontract activities must be indicated in the application and are as such defined in SNSA's authorization. However, the authorized experts are not required to inform SNSA in advance if they subcontract activities or if they make changes among their staff or any other changes that could impact the conditions under which they received the authorization. The subcontracted activity and data of subcontractor is indicated in the final report submitted by the authorized expert. The experts are also required to provide an annual report of their activities and present in the report significant changes that could impact their authorization.

SNSA and SRPA may also receive services from other organizations, whether in Slovenia or from abroad. The procurement is undertaking according to the Public Procurement Act.

As discussed in section 3.2, SNSA and SRPA use safety assessments performed by the authorized expert organizations to support their decision-making process. Despite the use of support organizations, SNSA and SRPA are themselves responsible for the decisions they make as competent authorities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The authorised expert organizations are not required to inform SNSA and SRPA in advance if they subcontract activities or if there are changes to their staff or other changes that could impact their authorization.*	
(1)	**BASIS: GSG-12 para. I.20 states that** *"The provider of external expert support should make rigorous, demonstrable arrangements to maintain the required independence and should clearly indicate to the regulatory body any actual, potential or perceived conflicts of interest. Any changes in staff that might affect independence should be discussed with the regulatory body before they are made."*
S1	**Suggestion: The SNSA and the SRPA should consider requiring authorised expert organizations to inform SNSA and SRPA in advance of subcontracting activities or to changes to their staff.**

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

SNSA and SRPA have established both formal and informal communication channels with the authorised parties.

Inspection reports and other regulatory decisions are forms of official communication. The decisions include justification for the decision. The justification presents the legal bases of the decision as well as the arguments that lead to the conclusions.

SNSA has regular management level meetings with the licensee of the Krško NPP. Related to daily work, the staff communicates with the licensees by emails and by phone when needed.

SRPA has regular meetings with the management of the largest authorized parties and TSOs (Institute of Oncology Ljubljana, University Medical Center Ljubljana and Maribor, Jožef Stefan Institute and Institute of Occupational Safety). With other authorized parties, SRPA communicates for example through professional associations to exchange views and to share information of any new developments in the regulatory framework.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

Bases for regulatory control is defined in the legislation. The processes for issuing and renewing licences and the requirements that must be fulfilled to get the licence are defined. During the licensing process, the applicant has, through regular communication, the opportunity to ensure avoiding any misunderstandings.

The regulatory decisions must include justification for the decision. The justification presents the legal bases as well as an explanation of the decision. The explanation is given in an obligatory explanatory note that every decision must have. The explanatory note describes the arguments and reasoning for the conclusion.

A process is defined to change the regulatory requirements. Interested parties have the opportunity to comment on the drafts. Explanation and justification are given on whether a comment is taken into account. For changing the Act, a broad evaluation of the impacts of the change is done (environmental, social, financial impacts etc.).

Management systems play an important role in ensuring stability and consistency of regulatory control. The procedures within the management system help to ensure consistent performance of regulatory control. However, during the mission some improvements to enhance the consistency of regulatory control were identified.

3.7. SAFETY RELATED RECORDS

The Act provides requirements for the safety related records to be maintained and for the content of these records. In addition, SNSA and SRPA maintain records on their own initiative. The most important register and records are the following:

- register of radiation and nuclear facilities, low risk radiation facilities and closed disposal facilities (SNSA)
- register of radiation practices and register of radiation sources in industry and research (SNSA)
- register of radiation practices, register of radiation sources and register of radiation facilities in health and veterinary care (SRPA)
- radioactive waste and spent fuel generated in Slovenia (SNSA)
- records of nuclear materials (SNSA)
- records on personal doses of exposed workers (SRPA)
- medical records of exposed workers (SRPA)
- records related to the safety of facilities and activities and for information that might be necessary for shutdown and commissioning (SNSA)
- records of events (SNSA)
- radon measurement database (SRPA)
- register of medical physicists (SRPA)
- records of licensed personnel in nuclear facilities (SNSA)
- records of environmental measurements (SNSA)

Information delivered for the records is mainly collected from the authorized parties, and they are obliged to keep their own records (e.g. the operators are obliged by Article 9 of the Act to maintain records of radiation practices and to record, for facilities, information that is important for safety.)

SNSA and SRPA use the records to support their regulatory tasks (for example for following different trends).

Lack of resources has delayed some development tasks related to the accessibility of registers through SNSA's website.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

SNSA has a Public Communication Strategy, which is a part of the SNSA Management System documentation. The strategy highlights publicity and transparency. The strategy describes the responsibilities related to communication and the different ways of communication to be used. The IRRS team was informed that this approach has worked well in ensuring timely and effective communication with the interested parties. SNSA could benefit from evaluating the circumstances in which a specific communication plan is appropriate, taking account of significant projects.

SRPA does not have such a communication strategy or communication plan.

The interested parties are for example the general public, media, other authorities, local communities, people in the vicinity of facilities, non-governmental organizations and professional and other associations.

Both SNSA and SRPA communicate with the interested parties in several ways. For both, the website is an important communication channel. Social media is not used systematically in communication due to lack

of resources. On few occasions some information has been published through the Ministry of Health's social media channels (for example publication of building codes related to radon).

A public annual report is prepared jointly by SNSA, SRPA and several other organizations. It includes, among other things, information on inspection results. SNSA publishes couple of times a year "Radiation News" and "News from Nuclear Slovenia". In addition, both organizations publish news and information on their website.

For certain topics, consultation of the interested parties is required by legislation. Such topics are for example preparation of legislation, planning acts and environmental impact assessments. In such cases SNSA and SRPA invite the opinions. SNSA and SRPA are obliged to give feedback on the opinions and explain and justify actions taken or if some proposal was not taken into account. Website eDemokracija (e-Democracy) is used for the process.

Both SNSA and SRPA participate in local events when invited. In addition, both SNSA and SRPA answer questions from the media and individuals. Recently SRPA, together with other public health institutions, has been active in efforts to increase awareness of radon risks.

Several other governmental authorities have duties related to use of nuclear energy and radiation and are involved in implementation of the Act. The framework for cooperation and the responsibilities of the different governmental organizations is defined in legislation, such as in the State Administration Act. There are several formal and informal working groups and commissions for the cooperation of the different governmental organizations. Personal relationships and informal communication play an important role in the cooperation.

The obligation for an authorized party to inform the public about possible radiation risks associated with its facility or activity is determined in the Act. The operator of a nuclear or radiation facility must inform the public that could be affected during an emergency.

In case of incidents, SNSA informs the public, different authorities and organization mainly through its website and press releases. SNSA has an internal guideline about informing the public about incidents (ON 5.3.2 Informing the public during an emergency). INES events are reported also in the annual report.

The Republic of Slovenia has bilateral arrangements with all its neighbouring countries (Austria, Hungary, Croatia, Italy). The arrangements concern especially information exchange; both in the case of radiological emergency and otherwise in regular meetings and by other communication. SNSA has meetings annually with Croatia, Austria and Hungary (quadrilateral meetings Czech Republic-Slovakia-Hungary-Slovenia). With Italy the meetings are organized less regularly.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SRPA does not have a communication strategy or communication plan.*	
(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 (see Appendix I). This strategy should be integrated within the overall strategy of the regulatory body."*
(2)	**BASIS: GSG-6 para. 4.34 states that** *"For effective and efficient implementation of the communication and consultation process, a communication plan should be established (see Appendix II). This is a key tool for properly addressing a specific issue and for efficient use of the human and financial resources available for communication and consultation with interested parties."*
S2	**Suggestion: SRPA should consider developing a communication strategy and implementing it through a communication plan.**

3.9. POLICY DISCUSSION ON NEW BUILDS

In Slovenia, the company GEN has expressed interest in building a new NPP unit. However, no decisions have yet been made and no licence application has been submitted to SNSA. The reactor design is still an open question, too.

SNSA has recognized key points in its preparation for the potential licence application, for example the review and update of regulations, building the competence and resources of the regulatory body and utilizing international cooperation and experiences as support.

The IRRS team shared its views on the subject. Up-to-dateness of the regulations and regulatory processes is essential. In many countries, regulations and regulatory body's oversight processes have been optimized for operating units. Ensuring that they both cover the early stages of a facility's lifecycle is a precondition for a successful new build project. It was also noted that very strict national requirements, exceeding the international level, may cause challenges in licensing.

The benefits of cooperation with the regulatory body of the country of origin were emphasized, as well as cooperation with other countries licensing the same reactor design. International platforms exist for cooperation (e.g. MDEP, SMR Regulators' Forum). The cooperation is a good way to build competence both on the reactor technology but also on good regulatory practices.

Engaging in discussions with the potential licence applicant as early as possible may facilitate the licensing process to a significant extent. It is important to ensure the licensee understands the licensing process and the requirements and that they will, in turn, ensure the plant vendor shares the same understanding.

Finally, the importance of addressing questions like radioactive waste and spent fuel management as well as emergency planning zones at a sufficiently early stage was highlighted.

3.10. SUMMARY

Overall, the responsibilities and functions of the regulatory body comply with the IAEA safety standards.

However, the following areas for improvement were identified:

- requiring the authorized expert organizations to inform SNSA and SRPA in advance of subcontracting activities or to changes to their staff;
- development of communication strategies and plans.

4. MANAGEMENT OF THE REGULATORY BODY

The SNSA and the SRPA have developed separate management system documentation designed to be in line with GSR Part 2. Both the SNSA and the SRPA have management system manuals, organizational procedures, organizational instructions, and other associated management system documentation.

The management systems seek to ensure that the SNSA and the SRPA meet their respective mission statements through the attainment of goals.

In 2001 the SNSA management system was first developed, the current version is based on its Management Manual of SNSA and has gone through a series of revisions, the latest being version 13 and is dated March 2022. The SNSA held a certification of its management system according to the ISO 9001 Standard Quality Management Systems up to the year 2013.

The SRPA management system is structured on its Management System Manual that that was created in January 2022. The SRPA Management System Manual built upon the existing management documents including Mission, Vision, developmental priorities that were already in place at the SRPA. The SRPA identified in the ARM that its management system needed to be developed further.

The IRRS team observed that the SNSA has established a management system that adequately covers the requirements of GSR Part 2.

During interviews with all categories of staff in the SNSA it was evident to the IRRS team that staff are committed to their achieving the goals of the SNSA. The SNSA offers good opportunities to their employees that allows them to develop their skills in specific technical aspects and various aspects such as: safety assessments; human factors; development of regulations; emergency response activities and international cooperation.

The IRRS team noted that despite being a small regulatory body the SRPA had managed to compile documentation with a structure based on GSR Part 2. The IRRS team also observed that the SRPA management system documentation still needs refinement and development. The SRPA stated their intent to further develop their management system and that the Head of the Management System will be able to dedicate more time to this issue once extra staff join the SRPA.

Despite limited resources SNSA's and SRPA's leadership have managed to maintain within its organization a constructive workplace culture that has led to positive attitudes, beliefs, and behaviours of its employees. The good working atmosphere created by the leadership of the SNSA and SRPA, and the commitment of staff is considered by the IRRS team as an area of good performance.

4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

The SNSA and the SRPA operate independently from one another and have separate leaderships and management systems. There is no formal system of liaison between the SNSA and the SRPA but the IRRS team was informed that there was a good working relationship between the two regulatory bodies. The IRRS team was informed that areas of cooperation between both regulatory bodies includes preparation of legislation, emergency preparedness exercises, and preparation of the annual report.

The management systems of both the SNSA and the SRPA have their respective management system manuals and related management system documents. The management systems assign leadership roles with the Directors of both organisations with having the overall responsibility for their management systems.

Core, management and supporting processes at the SNSA and the SRPA are defined in their management manuals: each process has a process owner.

The SNSA management manual has a documented system of accountability of managerial staff. There is a structure of four divisions (Nuclear Safety, Radiation Safety and Materials, Radiation and Nuclear

Inspection, Emergency Preparedness) and two offices (Office of International affairs and Office of General affairs).

The SNSA Director appointed the Management System Manager who is, among others, responsible for coordination, maintenance, development, implementation, and continuous improvement of the management system.

The SRPA has two divisions under the Director: one for the inspectorate for radiation protection and one for administrative procedures. The Radiation Protection Inspectorate has its own manager.

The Director of SRPA appointed a Head of the Management System who is responsible for the coordination, maintenance, development, and implementation of the management system.

4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

The respective Directors of the SNSA and the SRPA have the overall responsibility for establishing, implementing, sustaining, and continuously improving the management system to ensure safety of their organisation.

Both the SNSA and the SRPA have established safety goals in their management system documentation that are consistent with their stated in their mission statements.

The SNSA management system is based on its high-level documentation which consists of mission, vision core values and policy statement.

Responsibilities and competences of the SNSA management and the SNSA employees are defined in the management manual of the SNSA and related management system documents.

The SNSA identified in their action plan the need to develop their management policy to stress the safety, security, safety culture and other elements in order to get an integrated management policy and to fulfil the SNSA mission and vision. The SNSA addressed this issue by including in its management system manual: a revision of its management policy to further stress the importance of safety, a safety culture policy and organizational procedure OP 1.52 Implementation of the SNSA Safety Culture Principles.

The SNSA employees are assigned as custodians of goals. The SNSA organisation assesses the achievement of these goals through the annual plan that is reviewed on a 4 month basis. At the management review the SNSA management together with the owners of the processes examine the fulfilment of the goals. At the end of the year, the Management System Manager prepares the final report of the realization of the annual plan.

The SRPA management system documentation is based on its high-level documentation which consists of mission, vision, core values, development priorities, annual work, and inspection plans.

The SRPA has an annual plan which contains a set of activities assigned to employees, and monitoring of progress of employees is performed on a 6 monthly basis.

The SRPA has not developed a safety policy document within its management system. This is not in line with GSR Part 2 which states that senior management is required to establish a safety policy.

The recommendation on the need to further develop the management system R3 in Section 4.3 addresses this issue.

4.3. THE MANAGEMENT SYSTEM

Article 93 of the Act has the provisions for management systems, Article 94 makes a requirement for the SNSA as the authority for nuclear safety but this article does not refer to the SRPA (authority for radiation protection).

The directors of the SNSA and the SRPA are responsible for establishing, implementing, sustaining, and continuously improving the management system to ensure safety.

The SNSA management system documentation has gone through several revisions. The management system documentation has the following levels:

Level 0 Mission, Vision, Values, Policy statements

Level 1 Management manual

Level 2 Organisational procedures

Level 3 Organisational instructions

Level 4 Records generated by management system

The SRPA management system documentation has only very recently been developed and has the following levels:

Level 1 Management System Manual which includes Mission, Vision, Core Values, Development priorities, annual work plan, annual inspection plan

Level 2 Organisational procedures

Level 3 Organisational instructions (not developed as yet)

Level 4 Records generated by management system

The SNSA action plan indicated the need to clarify in their management manual regarding arrangements for the resolution of conflicts arising in the decision making processes. Prior to the IRRS mission the SNSA addressed this issue by section 6.3.4 of their management manual entitled: "Conflicts of interest of the regulatory body's decision making" which included:

- The check for the possibility of conflicts of interests during the annual interviews, between the heads of sectors / services / departments together and the employees;
- The appropriate actions to take to address any cases of conflicts of interest that are detected;
- When implementing the processes, the SNSA ensures that conflicts of interest do not affect final decisions that could have a negative impact on security or safety;
- The SNSA must also ensure that operators of radiation and nuclear facilities and radiation practitioners identify the potential effects of physical protection measures on safety and vice versa, and that these effects are addressed in a way that does not jeopardize safety or security.

With regard to prevention of conflicts of interest the SRPA stated that they comply with the requirements of the Integrity and Prevention of Corruption Act and report to the Commission for the Prevention of Corruption. The SRPA does not have any internal procedures for identifying conflicts of interest within their management system, which is not in line with GSR Part 2. The recommendation on the need to further develop the management system in Section 4.3 addresses this issue.

The IRRS team was informed that the SNSA management system requirements are graded so as to deploy appropriate resources. The management system takes into account the significance and complexity of each activity and its results as well as the hazards and the potential impacts (risks) and consequences in case the action was not taken properly, or its results would have been inadequate.

The SRPA stated they are committed to a graded approach and this is reflected in section 6.2 of their management manual.

The SRPA identified in their action plan that some of the contents from the SRPA management system manual and related documents were incomplete. There are five operating procedures in place, some of the operating procedures incorporate some organisational instructions. The five operating procedures are:

OP 1 Licencing

OP 2 Inspections

OP 3 Tendering process

OP 4 Recognition of technical support organisations

OP 5 Administrative processes

The SRPA Management System Manual structure includes operational instructions, however none of these have been prepared.

The SRPA stated that they intend to develop more operational procedures and will consider restructuring the content of the different levels within their Management System Manual.

The SNSA has document control procedures in place and the SRPA stated that access to their management system documentation is granted through a shared folder on computer drive and in the SPIS documentation system, and that no unauthorised alternations to the documentation can be made.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The recently developed management system of the SRPA is incomplete in that several aspects are missing including documentation on: safety policy , resolution of conflicts arising, self-assessment of leadership for safety and of safety culture, independent assessments and self-assessments of the management system, certain organisational procedures, and organisational instructions.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 19 states that** *"The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement."*
(2)	**BASIS: GSR Part 2 Requirement 3 states that** *"Senior management shall be responsible for establishing, applying, sustaining and continuously improving a management system to ensure safety."*
(3)	**BASIS: GSR Part 2 Requirement 6 para 4.8 states that** *"The management system shall be developed, applied and continuously improved. It shall be aligned with the safety goals of the organisation."*
(4)	**BASIS: GSR Part 2 Requirement 10 states that** *"Processes and activities shall be developed and shall be effectively managed to achieve the organization's goals without compromising safety."*
(5)	**BASIS: GSG-12 paragraph 5.4 states that** *"The integrated management system of the regulatory body is required to clearly specify its organizational structure, resources and processes. A set of coherent processes and procedures should be used to help carry out the regulatory functions in an effective and efficient manner, with account taken of all internal and external requirements."*
R3	**Recommendation: The SRPA should further develop their management system to be in line with GSR Part 2 and ensure it is applied, sustained and continuously improved.**

4.4. MANAGEMENT OF RESOURCES

The SNSA and the SRPA directors are responsible for ensuring all necessary resources are available.

The SNSA assesses their current human resources competence on an annual basis by reviewing competencies and identification of training needs. SNSA succession planning is addressed by section 3.1 of their procedure OP 1.60 "Career development of the SNSA staff".

The IRRS team was informed that the SRPA seeks to ensure competence of employees through training and a system of mentoring. The need for individual employee education and training needs are identified during the annual review. The SRPA does not have a documented strategy to compensate for the departure of qualified staff built into the management system.

In view of the fact that the SRPA management system needs further development, the SRPA will need to allocate sufficient resources to achieve this.

4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

The SNSA's processes that lead towards the implementation of the SNSA mission are defined in the management system manual as well as in related organisational procedures.

The SNSA management system manual has defined 8 core processes with 1 management and 1 supporting process. Each process has one process owner except the process on Radiation and Nuclear Safety Control where one person is responsible for nuclear and one for radiation safety.

The SRPA management system manual has defined 7 core processes with 1 management and 1 supporting process. The Director is the process owner for the management process, supporting process and 6 of the core processes, the process owner for the regulatory oversight process owner is the Director of Inspection.

Both the SNSA and the SRPA have procedures in place with regard to making arrangements with vendors, contractors and suppliers.

4.6. CULTURE FOR SAFETY

The SNSA and the SRPA stated that they have a commitment to foster a strong safety culture.

The SNSA identified in their action plan the need to perform a self-assessment of their safety culture, which was completed prior to the IRRS mission. The SNSA performed the self-assessment and included safety culture as one of their values (number VIII) that states that they put safety first in all decisions and actions. The SNSA stated that they periodically carry out safety culture assessments, which are required by OP 1.52 "Principles of safety culture and their implementation".

The SRPA noted in their action plan that the self-assessment of leadership for safety and of safety culture is missing. The IRRS team was informed that this issue will be addressed by the Management System Manager. The fact that the SRPA does not perform self-assessment of leadership for safety and of safety culture is not in line with GSR Part 2, which requires that assessments of leadership for safety and of safety culture are regularly performed.

The recommendation on the need to further develop the management system in Section 4.3 addresses this issue.

4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

The SNSA internal audits of their management system are covered by OP 1.51 "Implementation of audits" this procedure has a system of assigned 7 internal auditors, each auditor will perform audits every year but not of their own section or process. Until 2019, the internal audits were conducted each year for each process. After the audit in 2019 it was decided that processes would be audited every two years except if the need for additional audit arises. Audits in 2020 were carried out virtually during the COVID-19 pandemic. In the period 2007 to 2013, the SNSA was subject to external audits as part of its certification under ISO 9001:2008. This activity ceased in 2014 due to lack of funding.

The SRPA noted in their action plan the need for internal review of the management system. The fact that the SRPA has not performed this review is not in line with GSR Part 2.

The recommendation on the need to further develop the management system in Section 4.3 addresses this issue.

4.8. SUMMARY

SNSA has developed a management system in line with GSR Part 2 which has been assessed, sustained and improved over the years.

The SRPA management system has been recently developed and there is a need to further develop it and set up appropriate systems to review it and to bring it in line with the requirements of GSR Part 2.

The following areas for improvement were identified:

- Development of the management system of SRPA to be in line with GSR Part 2 and ensure that it is applied, sustained and continuously improved.

5. AUTHORIZATION

5.1. GENERIC ISSUES

The general Administrative Procedure Act prescribes the procedure for all steps of the authorization process. The legal basis for authorization is the Ionising Radiation Protection and Nuclear Safety Act (the Act). The second level legislation (regulations) consists of decrees issued by the Government and rules issued by the minister. In accordance with the Act, prior to the granting of an authorization, the applicant shall be required to submit a detailed demonstration of the safety of the facility, activity, or practice. The graded approach is applied in different areas of administrative procedures in nuclear and radiation safety (graded approach principle, Art. 4, Paragraph 13 of the Act). The detailed content of the licenses (operating licence for a facility, licence for radiation activity, licence for use of radioactive source) is defined in Art. 137 of the Act. The Operational Conditions and Limits as well as other requirements that licensees should comply with are specified by SNSA or SRPA as the main part of the license (Art. 137 of the Act). Performing a radiation practice, use of sources, management of radioactive waste or spent fuel and operation of nuclear or radiation facilities without appropriate authorization are prohibited (Art. 10 of the Act).

Decision making by the regulatory authority is based on the compliance with the regulatory requirements set in the Act and subsidiary legislation (Decree UV1, Rules JV5, JV9, JV2/SV2, Rules SV5, Rules SV8, Rules SV8A and others). Both regulatory authorities have established internal procedures for review of applications, formulation of decisions and for entry of information into registries of radiation practices and of radiation sources. Short instructions and legal requirements together with application forms can be used by the applicant, were prepared by the SNSA and are published on the web site. For the common activities and sources in medicine and veterinary care the SRPA has prepared detailed instructions for applicants and published them on its website.

The legal basis for the authorization of nuclear power plants and research reactors is the Act. The second level legislation consists of so-called rules; the most important ones are the Rule JV5 on the radiation and nuclear safety factors and the Rule JV9 on safety assurance of radiation or nuclear facilities. Rule JV5 describes the documentation to be submitted, as well as the details of the licensing procedure, while Rule JV9 gives instruction as to which methodology should be used for the classification and notification of plant changes and for the periodic safety review of radiation and nuclear facilities. Complementary instructions are issued as practical guidance by the regulatory body, e.g. PS 1.01 The content and scope of periodic safety review of a radiation or nuclear facility and PS 1.02 Assessment of modifications in a nuclear or radiation facility.

One of the main licensing documents for authorization of the different stages of the lifetime of facilities is the Safety Analysis Report (Arts.101 and 110 of the Act and Arts. 42-45 of Rule JV5). The Safety Analysis Report is regularly reviewed and updated annually to reflect the latest status of the facility.

Licensing decisions of SNSA are issued in the form of written orders. According to the nuclear legislation, the authorized party has a right to appeal all written decisions of the regulatory body. The first instance of appeal is the Ministry of the Environment and Spatial Planning. Exemptions are clearly indicated in the Act and are related to decisions on significant safety issues (e.g. the decision of start of trial operation, decision to halt operation, decision on extraordinary periodic safety review, decision on proposed changes, which are significant for radiation or nuclear safety). For such exemptions the legal procedure is to challenge the decisions in front of an administrative court.

SNSA has developed guidance for documents to be submitted with the license application at different stages of the process. However, the IRRS team noted that guidance on the format and content of some documents to be submitted by the applicant in support of an application for an authorization of NPPs and research reactors are not developed/issued as per para 4.34 (Requirement 24 of GSR Part 1 (Rev. 1)). The IRRS

team was informed that guidance on the format and content of the documents is applicable both for nuclear power plants and research reactors.

SRPA has limited guidance for the applicants regarding the format and the content of the applications, that exists only for the most common practices (e.g. dental X-ray, conventional radiology, bone densitometry etc.). The guidance can be accessed on the SRPA website.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SNSA has not developed guidance on the format and content of some documents regarding authorization of NPPs and RRs. SRPA has not developed guidance on the format and content of some documents submitted by the applicant in support of an application for an authorization for the less common practices.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 24, para 4.34 states that** *"The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization. The applicant shall be required to submit or to make available to the regulatory body, in accordance with agreed timelines, all necessary safety related information as specified in advance or as requested in the authorization process."*
R4	**Recommendation: SNSA and SRPA should further develop guidance on the format and content for the documents to be submitted by the applicant in support of an application for an authorization for all facilities and activities.**

The IRRS team was informed that SRPA has procedures for authorization of some facilities and activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SRPA has not developed internal procedures for the authorisation of all facilities and activities.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 19 states that** *"The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement."*
(2)	**BASIS: GSR Part 2 Requirement 3 states that** *"Senior management shall be responsible for establishing, applying, sustaining and continuously improving a management system to ensure safety."*
(3)	**BASIS: GSR Part 1 Requirement 22 states that** *"The regulatory body shall ensure that regulatory control is stable and consistent."*
R5	**Recommendation: SRPA should develop procedures for the licensing process.**

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

In accordance with the Act, prior to the granting of an authorization, the applicant shall be required to submit a detailed demonstration of safety of the facility, activity or practice to obtain licence or approval. The graded approach is applied in different areas of administrative procedures in nuclear and radiation safety (graded approach principle, Art. 4, Paragraph 13 of the Nuclear Act).

The Act requires an authorization issued by the SNSA for the different stages of the lifetime of facilities: start of trial operation, operation and end of operation, beginning and end of decommissioning, and storage of fresh fuel on-site of a nuclear power plant or research reactor.

The IRRS team observed during interviews that procedures for issuing authorizations for each stage of the lifetime of an installation and for each type of installation are not well developed, and are necessary to ensure that all the required steps are taken prior to the granting of a license as recommended in para 2.13 of SSG-12. SNSA may consider the development of procedures for issuing authorizations for each stage of the lifetime of an installation and for each type of installation to ensure that all necessary steps are taken prior to granting a licence with consideration to the graded approach.

SNSA does not issue formal approval for resumption of operation of nuclear installations following refuelling outages, major maintenance activities, long term shutdown or other significant activities, but in practice performs inspection prior to resumption of operation. The inspector can prohibit the resumption of operation in case of insufficient demonstration of safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Before a nuclear installation is brought back into operation following a refuelling outage, major maintenance activities, long term shutdown or other significant activities, the organization responsible for the nuclear installation is not required to demonstrate and to ask for formal approval from SNSA that the nuclear installation will be able to continue to operate in compliance with the safety requirements. However, the future safe operation is checked by the inspector who can prohibit the resumption of operation in case of insufficient demonstration of safety.*	
(1)	**BASIS: SSG 12 para 3.64 states that** *"Before a nuclear installation is brought back into operation following a refuelling outage, major maintenance activities, long term shutdown or other significant activities, the person or organization responsible for the nuclear installation and its activities should demonstrate to the regulatory body that the nuclear installation will be able to continue to operate in compliance with the safety requirements. Resumption of operation may be subject to approval or agreement by the regulatory body, which should attach conditions, as appropriate."*
S3	**Suggestion: SNSA should consider requiring the organization responsible for the nuclear installation to demonstrate to SNSA that the nuclear installation will be able to continue to operate in compliance with the safety requirements before a nuclear installation is brought back into operation following a refuelling outage, major maintenance activities, long term shutdown or other significant activities.**

The IRRS team noted that the SNSA does not have clearly specified and established procedures for amendment, renewal, suspension or revocation of the authorization for both nuclear power plants and research reactors.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SNSA does not have clearly specified and established procedure for amendment, renewal, suspension or revocation of the authorization for the nuclear power plant and the research reactor.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 24 para 4.37 states that** *"Any subsequent amendment, renewal, suspension or revocation of the authorization for a facility or an activity shall be undertaken in accordance with a clearly specified and established procedure, and shall make provision for the timely submission of applications for the renewal or amendment of the authorization."*
R6	**Recommendation: SNSA should develop clearly specified and established procedure for amendment, renewal, suspension or revocation of the authorization for the nuclear power plant and the research reactor.**

5.3. AUTHORIZATION OF RESEARCH REACTORS

There is one operational research reactor in Slovenia. The Jožef Stefan Institute (JSI) operates a TRIGA Mark-II 250 kW reactor with the operating license issued in 1992 for modernization and pulse mode operation.

For the authorization of the research reactor, all the licensing phases were applied as defined for nuclear facilities. Also, the licensing submissions are the same both for the nuclear power plant and the research reactor with the application of the graded approach.

The principle of a graded approach for research reactors is considered at the level of the Rules in the regulatory framework.

5.4. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

With the exception of disposal facilities for NORM waste, all radioactive waste management facilities are classified according to Article 3 of the Act as nuclear facilities. The authorization process for radioactive waste management facilities, including both storage and disposal, follows the same underlying principles and staged approach as those for other nuclear facilities. The various steps in the authorization process under the Act relating to siting, construction, and operation, as well as the termination of operation, start and completion of decommissioning are therefore the same as for nuclear power plants and research reactors.

Application of a graded approach to authorisation includes, inter alia, the general expectation that the design of a nuclear facility should reflect the nature of the hazard that it represents (JV5 Article 3(9)) and that the safety analysis report that forms a central component of the basis for seeking authorization should focus the greatest attention to detail and comprehensiveness in relation to factors that are more important for safety. The IRRS team noted that regulatory processes surrounding the facility (including inspection – see Section 7.4) are properly applied to the nature of this facility and the hazard that it represents.

Questions of siting and choice of concept are not directly a component of the SNSA's authorization process, but are addressed in Slovenian legislation under the Spatial Planning Act and the Environmental Protection Act. According to Article 95 of the Act ZVISJV-1, the Ministry of Environment and Spatial Planning receives the opinion of SNSA on matters relating to nuclear safety in corresponding decisions under Environmental and Spatial Planning legislation. Moreover, the required content of the related Environmental Impact Assessment (EIA) on matters relating to nuclear and radiation safety is defined by SNSA. This means that, although authorization of siting (2009) and conceptual design (2021) for the Low and Intermediate Level Waste (LILW) facility at Vrbina was not formally the responsibility of SNSA, the various steps in the overall authorization process involved the regulatory body in a manner that the Review Team considers to be consistent with GSR Part 1 (Rev 1). In the context of waste disposal facilities, this also means that there is engagement of SNSA throughout the process of authorization in questions relating to the relevance and implications for safety of available options for a facility, consistent with IAEA safety standards.

Recent experience of the permitting processes under the different legislative instruments identified above, up to and including authorization of nuclear facility construction, is illustrated by the various stages leading up to the granting of a construction licence for the disposal facility for LILW (2022), as well as the spent fuel dry storage facility at Krško NPP (2020).

A condition that must be fulfilled before authorization to commence trial operation of a nuclear facility can be granted is confirmation that the facility has been constructed in accordance with the construction licence. Verification is undertaken in accordance with the provisions of the Building Act. The approval process under this Act requires the opinion of different authorities according to their specific areas of responsibility, where SNSA verifies (among other things) the construction of structures, systems and components with relevance to safety.

Specific attention is given in regulations to the definition of "trial operation" in relation to a disposal facility and what this implies for the scope of what will be authorized at this stage of the process when the facility is commissioned for receiving waste. The IRRS team noted that such authorization is consistent with the objectives of IAEA Safety Guidance for disposal since it is construed as a permit for emplacement of radioactive waste or spent fuel in the facility while retaining assurance that those wastes can be retrieved and that the facility's original state can be recovered (JV5 Article 26(4)).

5.5. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The legal basis for the authorization of radiation sources is the Act and associated regulations (Decree UV1, Rules JV2/SV2).

SNSA is responsible for authorisation of radiation practices in industry, research and education, while the SRPA is responsible for the area of medicine and veterinary care. Both regulators (SNSA and SRPA) are using the same basis for their authorisations processes.

It was observed by the IRRS team that some practices related to service providers such as transport of radioactive material listed in the Act (Art. 18) are determined based on the end user of the service. This could possibly lead to the situation when a licensee intending to carry out the practice with the radiation source will be required to apply for authorisation to both regulatory bodies SNSA and SRPA for the same practice if the end users of their services fall under regulation of both regulatory bodies. Such an approach could lead to the duplication of the authorisation process for the same practice following the same authorisation procedure. The IRRS team was informed that, in practice, for such cases, the SNSA and SRPA could meet and decide which regulatory body would be in charge of authorisation and inspection; however, any procedure for such solution is not foreseen neither in regulation or in another way (i.e. Memorandum of Understanding between SNSA and SRPA).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Service providers such as transporters of radioactive material could be authorised twice in case the end users fall under the regulation of different regulatory bodies.*	
(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."*
R7	**Recommendation: The Government should make arrangements to ensure that situations leading to the need for authorisation from both SNSA and SRPA for the same practice are avoided.**

There are about 300 facilities (about 420 X-ray machines and 720 sealed sources, about 1140 in total) for different radiation activities under the supervision of SNSA. SNSA has 6 personnel involved in the process of authorisation.

SRPA is responsible for about 750 facilities performing radiological procedures (7 nuclear medicine departments, 2 teletherapy departments (13 teletherapy units), 1.200 X-ray devices, etc.). Two persons are involved in the authorization of radiation sources facilities and activities and another 2 (inspectors) can assist them in case of an application involving a complex practice (e.g. radiotherapy, nuclear medicine, etc.).

SNSA issues one general license (or registration) for the practice and one license (or registration) for all the sources that are used in the practice. Later on, the license (or registration) can be amended following established procedures. The graded approach principle is applied since SNSA uses criteria established in UV1, Art. 16, which obliges a legal entity to apply for license or register its practice. The graded approach is also applied regarding the validity of the license. Typically, upon the first issue of a licence to carry out a radiation practice, this licence is valid for a maximum of 5 years and validity of the registration of radiation practice is valid for 10 years (general rule applicable for both SNSA and SRPA), but this can be adjusted regarding the risks that are involved in the practice. The licence or registration can be renewed based on the procedure equivalent to the first licensing or registration procedure.

All practices in medicine and veterinary care need to be licenced by SRPA, except for calibration sources with an activity not exceeding the activity indicated in Table 4 of the Annex of the Decree UV1 (only 4 and 5 category radioactive sources). Temporary licenses are issued for a short duration when there are some aspects of radiation protection that need to be addressed within the "grace period" of one year. In this way, every major practice in a facility (nuclear medicine, teletherapy, X-ray diagnostics, etc.) and every source used in this practice have separate licenses. The IRRS team was informed that the graded approach is

applied in establishing requirements in accordance with the associated risk of the practice or source; however, the validity of the authorization is similar for all sources and practices.

SNSA has an internal procedure ON 2.3.3. dedicated to the authorisation process. It covers basic steps on the review of applications, issuance or amendment of the authorisation, filling the associated registers, etc. The outcome of the authorisation process is communicated to the inspectors for later consideration. SNSA also has prepared guidance for the applicants regarding the format and the content of the application for various practices. It can be accessed on the SNSA website.

The issues regarding SRPA internal procedures and the format and the content of applications for SNSA and SRPA licensees has been detailed in section 5.1 (see recommendations R4 and R5).

The Act, Art.170 obliges SNSA and SRPA to keep the records of radiation practices, the register of radiation sources and the register of radiation facilities in dedicated public registers. In case more information is needed, the exchange of information between the regulatory authorities can be initiated through an official request. Information on radiation sources is also provided to other public institutions, e.g. the authority responsible for civil protection.

There are mechanisms in place (Act, Article 121) that allow the provider of the commercial public service of radioactive waste management to recover a radiation source, which is stored in the central storage facility for radioactive waste as radioactive waste, and return it to the licensee or supply it to a new licence holder for use in his radiation practice.

According to Article 91 of the Act, the user of a high-activity radioactive source must assure financial resources for the safe disposal of the radioactive source for situations where the user terminates its operation or becomes insolvent.

Article 126 of the Act establishes that for entry/exit from/to EU Member States and for import/export of nuclear and radioactive substances as well as for the transit of nuclear material and radiation sources with significant activity a licence from SNSA or SRPA is required. For Slovenia, the Council Regulation (Euratom) No. 1493/93 on Shipments of Radioactive Substances between Member States of EU applies directly. For import/export of radioactive source/substance (to non-EU countries) the Rules on the transboundary shipment of nuclear and radioactive substances (JV12) prescribes the content of the application for the licence in Article 4 of the Rules JV12.

5.6. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

As noted in Section 5.4, formal authorization is required in accordance with the Act ZVISJV-1 for the termination of operation, as well as for the start and the completion of decommissioning of a nuclear facility. Furthermore, before authorization can be obtained from the SNSA to commence decommissioning, a licence to remove the facility must be obtained from the Ministry of the Environmental and Spatial Planning under the Building Act. An Environmental Impact Assessment is required in relation to this process, and consent from SNSA is required as one of the regulatory authorities that contributes to evaluation of the decision.

The JV5 rules introduce further specific authorization provisions that relate to the final closure of a disposal facility, both in terms of the requirement to submit a programme for closure already as part of the application for an operating licence and the need for a specific consent in relation to final closure. The approval of a Safety Report for authorization of the closure of a disposal facility may be dependent on completing necessary remediation work and includes consideration of requirements on long-term control and maintenance.

The definition of decommissioning under Article 3(1.86) of the Act ZVISJV-1 (and thereby applied in principle to all types of nuclear facility) includes “the removal of radioactive waste and spent fuel from the facility”. In the case of a disposal facility, however, Article 32(3) of JV5 clarifies that a permit to commence

decommissioning relates only to those related processing and storage facilities that will be decommissioned, that is to say the above ground structures at the site of the facility.

The IRRS team was informed that the transfer of responsibility to ARAO as the public body carrying out long-term maintenance of control means that safety analysis and reporting relating to the final end state of a decommissioned site must also involve ARAO's formal consent to those aspects that affect the extent – in terms of spatial scope, complexity and time – for which the control and monitoring programme will be required.

5.7. AUTHORIZATION OF TRANSPORT

SNSA, as the Competent Authority for transport of radioactive material issues the necessary approval or validation certificates. Approvals also include "special arrangements" for the movement of orphan sources and re-validation of foreign designs of packages.

A licence from SNSA is a prerequisite for transport activities by a carrier. Obligations include a major part of the requirements from IAEA SSR-6, para 834.

A method of recognition of foreign approvals is in place, consistent with SSR-6 para 840. This is in line with Art. 7 (para 7) of "ZPNB" (Transport of Dangerous Goods Act).

In addition to SNSA, SRPA is also a competent authority for transport of radioactive materials. A licence is issued if this is required by international transport agreements (ADR and other international acts listed in ZPNB, Art. 3).

In the field of transport, SRPA is competent for:

the authorization of transport practices involving radioactive sources used in medicine and veterinary care according to the Act, art. 18. A licence is required for the transport of sources in IAEA Cat. 1 & 2. If a transport company already has a licence to transport Cat. 1 & 2 sources in its country of origin, it can be acknowledged, provided that it was issued on comparable conditions as stipulated in the Act.

- SRPA is not the competent authority for approval or validation certificates according to IAEA SSR-6 paras 832-839 and first paragraph of Article 7 of ZPNB.
- The primary legislation is the Act and the Transport of Dangerous Goods Act.

SNSA's role in the authorisation process is stipulated in both acts (ZPNB, Articles 7, 8 and 22 and in the Act in Article 18). Similarly, SRPA's role in the authorisation process is stipulated in ZPNB, Article 22 and in Act, Article 18). In addition to these, "transit" (an administrative procedure for crossing the Slovenian territory with radioactive sources) is also covered in the Rules JV12. Certain ("higher-risk") transits require a dedicated application, i.e. those, including transport of radioactive sources of Cat. 1 & 2. Relevant and prescribed transport-related documentation is assessed in the licensing process. The relevant details are set out in Article 4 of Rules JV12. All such transits (transports/carriages/shipments) must comply with all relevant ADR-related provisions.

Additionally, the competent authority for transport can register the serial numbers of transport packaging manufactured to an approved design, in accordance with IAEA SSR-6.

5.8. AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE

Legal requirements for occupational radiation protection

The three basic principles of occupational radiation protection: justification, optimization and dose limitation are included in the Act. The Act also describes special arrangements for protection and safety of female workers and for persons under 18.

The licensing process

Licensing is a two-step process involving the licensing of the radiation practice and the licensing of the radiation source. The licensee must provide a radiation protection assessment, as required by Act, art. 40. The radiation protection assessment is a safety assessment document that estimates the risk and doses and describes radiation protection measures for the practice. The content of the radiation protection assessment is prescribed in the legislation (SV5, Appendix I). A licensee must draw up a radiation protection assessment in cooperation with a recognised independent radiation protection expert (RPE).

All practices in medicine and veterinary care need to be licenced. The graded approach is applied in case of dental radiology using intraoral or panoramic X-ray units and in bone densitometry. For these two types of practice, generic radiation protection assessments were prepared instead of a specific assessment for each individual practice. In these two types of practices, the workers are not classified as exposed workers, but they are included in the individual monitoring programme.

Requirements and responsibilities for the protection of workers in planned and existing exposure situations

The radiation protection assessment contains the prior risk assessment as stated in GSR Part 3 Requirement 13. It also contains most but not all of the items of the radiation protection programme as stated in GSR Part 3 Requirement 24: Arrangements under the radiation protection programme, and as detailed in GSG-7 "Occupational radiation protection" para. 3.60.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The radiation protection assessment contains most but not all of the items required in GSG-7 for radiation protection programmes.*	
(1)	**BASIS: GSG -7, para. 3.60 states that** *"The radiation protection programme should document the following, with an appropriate level of detail:* *(a) The assignment of responsibilities for protection and safety for workers to different management levels, including corresponding organizational arrangements and, if applicable (e.g. in the case of itinerant workers), the allocation of the respective responsibilities between employers and the registrant or licensee;* *……* *(n) The requirements for the assurance of quality and process improvement."*
S4	**Suggestion: The SNSA and the SRPA should consider amending the Regulations so that the radiation protection assessment includes all the items in GSG-7 for radiation protection programmes.**

The Regulations specify the responsibilities of the RPO in SV8, article 7, and these include detailing the local rules and procedures, conducting on-the-job worker training, specifying PPEs, carrying out workplace monitoring and etc. The RPO should periodically review the radiation protection program to revise existing procedures, to create new procedures or to revise the individual and workplace monitoring programs.

The IRRS team was informed that the occupationally exposed workers that showed the highest annual effective doses are the guides in the tourist caves, where effective doses higher than 10 mSv per year have been seen. The air in the caves can contain relatively high levels of radon (Rn-222), and this can lead to a relevant intake of the decay products of radon. No forced ventilation systems can be installed due to the sensitive ecosystem, and the occupational exposure is limited by controlling the time each worker spends in the caves.

Individual dose assessments for the occupationally exposed workers in tourist caves are carried out and recorded in the national database, however individual monitoring is not performed for radon-in-air exposures of these workers. Workplace monitoring is made on a periodic basis with real-time radon concentration and radon daughters concentration measurements and with passive track detectors for

continuous radon concentration measurements. Passive radon dosimeters are placed in representative work areas to integrate the variable radon-in-air concentrations though the year.

5.9. AUTHORIZATION ISSUES FOR MEDICAL EXPOSURE

The Ministry of Health through SRPA is responsible for regulatory control of medical exposures according to Art. 16 of Decree on Bodies Affiliated to Ministries. All activities in medicine need to be authorized. The authorization process is prescribed in the Act and consists of two types of authorization: an authorization to use a radiation source and an authorization for the activity.

According to the Act, Art. 40, the applicant must provide a radiation protection assessment carried out by an authorised Radiation Protection Expert (RPE) in order to be granted an authorization of the activity. Holding an authorization for the activity is a requirement for the applicant to acquire an authorization to use a radiation source. A Programme of Radiological Procedures for each individual radiation source is the main document required as a precondition for issuing an authorization to use a radiation source. The Programme of Radiological Procedures must address the responsibilities for radiation protection of the patients and describe the quality assurance and quality control programme, including all optimisation aspects of the medical exposure.

The IRRS team was informed that the period of validity of an authorization is 5 years for every type of activity related to medical exposure. While the graded approach is applied in terms of the authorisation conditions it is not being applied in terms of the duration of an authorisation.

The Act and the Rules SV3 establish the responsibilities and requirements for specialization, training and competence in radiation protection of all medical and paramedical personnel. Furthermore, it is required as part of the content of the Programme of Radiological Procedures that a list is prepared of all medical and paramedical personnel who will assume responsibilities. The regulations do not specify the minimum number of medical and paramedical personnel needed for a specific facility and activity.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no requirements stipulating how many medical personnel and paramedical personnel are sufficient for each kind of facilities and activities.*	
(1)	**BASIS: GSR Part 3 Requirement 36, para. 3.154 (c) states that** *"Registrants and licensees shall ensure that:* *c) Sufficient medical personnel and paramedical personnel are available as specified by the health authority;"*
R8	**Recommendation: The Government should revise the regulation to specify the number of medical and paramedical personnel that needs to be available for a specific facility and activity.**

5.10. AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE

In their self-assessment, SNSA identified that requirements on the contents of the product labels and on instructions to be provided with consumer products could be amended to explicitly require that all the information items required in GSR Part 3 are stated in the labels and in the instructions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Art. 6.1.5 of the Decree UV1 on consumer product labels does not require the label to state that the consumer product contains radioactive substances and to identify the radionuclides and their activities;* *does not require the label to state that the provision of the consumer product to the public has been authorized by the regulatory body; does not require the label to provide information on required or recommended options for recycling or disposal.* *Art. 6.1.5 of the Decree UV1 on the requirements for the instructions to be provided with the consumer product do not include requirement to provide information on servicing and repair; do not include requirement to provide information on the radionuclides and their activities at a specified date; do not include requirement to provide information on dose rates in normal operation and during servicing and repair.*	
(1)	**BASIS: GSR Part 3 Requirement 33, para. 3.142 states that** *"Providers of consumer products shall ensure that:* *(a) Where practicable, a legible label is firmly affixed to a visible surface of each consumer product that:* *(i) States that the consumer product contains radioactive substances and identifies the radionuclides and their activities;* *(ii) States that the provision of the consumer product to the public has been authorized by the regulatory body;* *(iii) Provides information on required or recommended options for recycling or disposal."*
(2)	**BASIS: GSR Part 3 Requirement 33, Para. 3.143 states that** *"Providers of consumer products shall provide clear and appropriate information and instructions with each consumer product on:* *…* *(b) Servicing and repair;* *(c) The radionuclides and their activities at a specified date;* *(d) Dose rates in normal operation and during servicing and repair;* *…"*
S5	**Suggestion: SNSA should consider amending their regulatory documents on information to be contained in the product labels and on the instructions to be provided with consumer products, to include all items listed in GSR Part 3.**

Requirements placed on the producer of consumer products towards retailers are not in line with the requirements of GSR Part 3. The IRRS team was informed that the requirement to provide information on storage to a reseller has been considered in the past practices for consumer product licences.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no requirement for providers of consumer products to provide information on safety and instructions on transport and storage to a reseller.*	
(1)	**BASIS: GSR Part 3 Requirement 33, para. 3.144 states that** *"Providers of consumer products shall provide the consumer product retailers with appropriate information on safety and instructions on their transport and storage."*
R9	**Recommendation: SNSA should establish requirements for providers of consumer products to provide retailers with appropriate information on safety and instructions on transport and storage.**

The safety goals of the independent verification of environmental monitoring of radioactivity conducted by SNSA are not explicitly stated. Defining the safety goals would enable SNSA to verify that the extent of the independent monitoring program is appropriately established.

SNSA does not require the sampling of aquatic plants in the environmental monitoring program of Krško NPP. Fish samples collected as part of the monitoring program typically contain only few radionuclides at very low concentrations and are possibly not optimally suited for monitoring of gamma emitting nuclides

in the aquatic environment for the purpose of verification of source monitoring. Rules JV10 foresees inclusion of bioindicators if the presence of radionuclides in the environment is too low to be measurable in the usual samples.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Aquatic plants are not included in the environmental monitoring program of Krško NPP. Collected fish samples contain only few radionuclides at very low concentrations.*	
(1)	**BASIS: RS-G-1.8 para. 6.7 states that** *"the constituents monitored and the frequencies of sampling and measurement are summarized in Table 3. This should be considered a framework; the specific programme should be set up in consideration of the radionuclides involved, site specific considerations and the levels of discharges."*
(2)	**BASIS: RS-G-1.8 para. 6.13 states that** *"the environmental media that should be considered in emergency monitoring and the recommended frequency and location of sampling or measurement are summarized in Table 4. It should be regarded as a framework; the specific monitoring programme should be set up in consideration of the radionuclides involved, site specific considerations and the levels of the releases."*
(3)	**BASIS: RS-G-1.8 tables 3 and 4 include** *"seaweed as an aquatic indicator monitored during normal discharges and in emergencies."*
S6	**Suggestion: The SNSA should consider investigating if aquatic plants as indicators should be added to the environmental monitoring program of Krško NPP for the verification of source monitoring, taking into consideration involved radionuclides, details of the site and the levels of discharges.**

5.11. SUMMARY

The authorization process in Slovenia covers all nuclear and radiation facilities and activities. A multistage licensing process is followed for nuclear installations.

The authorization process for occupational exposure is well established in Slovenia. There are some minor gaps in the Slovenian requirements for radiation protection programmes with respect to GSG-7. The highest occupational exposures come from existing exposures due to radon. It was noted that SNSA should consider setting safety goals for the independent verification of environmental monitoring of radioactivity. Additionally, the competent authority for transport can register serial numbers of transport packaging manufactured to an approved design, in accordance with IAEA SSR-6. The areas for improvement identified by the IRRS team include;

- Development of guidance on format and content for some of the documents required to be submitted with the application for authorization.
- Formal requirement to the operator for demonstration to SNSA that the nuclear installation will be able to continue to operate in compliance with the safety requirements before a nuclear installation is brought back into operation following a refuelling outage, major maintenance activities, long term shutdown or other significant activities.
- Clearly specified and established procedures for amendment, renewal, suspension or revocation of the authorization.
- Defining requirements for the development and submission of the commissioning programme as part of the licensing application.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

In accordance with provisions of the Act, SNSA or SRPA are empowered to request from the licensees, or from the applicants for a license, all the documentation needed for the regulatory decision-making process on safety related matters. The general Administrative Procedure Act prescribes the regulatory body reviews and assessments of relevant information and determine how the authorization is undertaken. Both regulatory bodies have established a process for review and assessment, in accordance with the graded approach, that covers all regulated facilities and activities and all the aspects relevant to safety. The graded approach principle is addressed in the Act, Article 4. When considering nuclear and radiation safety, issuing of licences, inspections and other administrative matters must be examined according to their safety significance and possible exposure due to the carrying out of a radiation practice in a way that the major issues are given more attention than the less important. Internal procedures and guides are available for staff. Review and assessment for facilities is partially undertaken through an independent review and assessment made by authorized Technical Support Organisations (TSOs).

At least every 10 years a periodic safety review is undertaken to determine the overall compliance of licensees with relevant safety objectives, criteria and principles. In line with the Rule JV9, Article 46, the contents, scope and methodology of a Periodic Safety Review (PSR) for nuclear facilities are graded and adjusted to the type of the facility and to the importance of different areas for radiation or nuclear safety.

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

SNSA conducts its own review and assessment. Furthermore, it also evaluates both the safety assessments conducted by the licensees and the independent safety assessments performed by authorized expert organizations, as well as other safety relevant information.

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

The Nuclear Safety Division (NSD) of the SNSA is in-charge of performing the regulatory review and assessment function for nuclear facilities. It consists of two units (the Operational Safety Section and the Analysis and Licensing Section) and it has a total of eleven positions, all currently filled. The inspectors in the Radiation and Nuclear Safety Inspection Division also participate in safety reviews, in cooperation with NSD.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

In accordance with provisions of the Act, SNSA is empowered to request from the licensees, or from the applicants for a license, all the documentation needed for the regulatory decision making process on safety related matters.

The general regulatory review and assessment principles and the regulatory process implemented by SNSA are established in the regulations (Rules JV5 and JV9) and described in the SNSA Management Manual and in an internal procedure ON 2.1.4 (Guide for conducting review and assessment).

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

For major reviews, such as those performed by SNSA on the occasion of the periodic safety reviews, interdisciplinary teams are established. These teams include experienced staff from the technical divisions and units to ensure the necessary expertise to cover all the areas of review. Most of the experts responsible for the assessment of the safety related documentation also participate in the teams that perform the inspections. The assessments and inspections performed as part of the major reviews mentioned above are supplementary to the assessment and inspection activities deployed by each division on a regular basis. In

some specific cases, assistance from external specialists is required to supplement the assessment needs of SNSA.

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

The current number of staff is generally sufficient to cover the activities for the routine regulatory reviews. However, in case of more demanding activities such as major modifications, regulatory oversight during NPP outages SNSA decisions are mostly based on independent expert opinion contracted by the licensee as per provisions of the law.

SNSA staff involved in review and assessment of nuclear facilities has limited expertise in deterministic safety analyses. It was generally sufficient for ensuring that all major areas of review and assessment are properly addressed, provided that independent safety analyses are performed by technical support organizations. However, SNSA needs independent expert opinions by the TSO in reviewing nuclear safety issues related to the safety upgrade program of the Krško NPP as well as the application for long-term operation, PSRs, etc.

It is required to perform review and assessment of information associated with the authorization through all phases of the lifetime of the nuclear power plant. In the Act, and more specifically in regulations (the Rule JV5, section III Granting of consents and permits), the requirements regarding the content of applications for approval of individual phases of the lifetime of facilities are established.

The Safety Analysis Report is regularly reviewed and updated to reflect modifications to the nuclear power plant, and to consider all new knowledge and facts, including the information related to the characteristics of the site and the site environment, as well as the changes based on new regulatory requirements. The update shall also consider the operator's own experience, new regulatory requirements, new standards or new ways of utilizing them, and development of science and technology in a timely manner after the new information is available and applicable.

Risks that are not related to radiation are not covered in the regulatory framework and have been identified in SNSA's action plan. The IRRS team was informed that this requirement has been included in draft Rules JV9. SNSA further informed that this requirement will be applicable both for the nuclear power plant and the research reactor.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Not all non-radiological risks that may arise in the operation of facilities or the conduct of activities are covered in the current regulatory framework.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 26 para 4.47 states that** *"Risks that are not related to radiation may arise in the operation of facilities or the conduct of activities, and these risks shall also be taken into account in the decision making process of the regulatory body."*
R10	**Recommendation: SNSA should conclude the revision of JV9 and ensure implementation of the requirement related to non-radiological risks.**

During the review of the reference material, it was observed that requirement 11 of GSR Part 4 regarding human factors engineering and human-machine interface is not covered in the regulatory framework. The IRRS team was informed that this requirement will be applicable both for nuclear power plant and research reactor.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Requirements related to human factors engineering and human-machine interface is not addressed in the regulatory framework.*	
(1)	**BASIS: GSR part 4 Requirement 11 states that** *"Human interactions with the facility or activity shall be addressed in the safety assessment, and it shall be determined whether the procedures and safety measures that are provided for all normal operational activities, in particular those that are necessary for implementation of the operational limits and conditions, and those that are required for responding to anticipated operational occurrences and to accident conditions, ensure an adequate level of safety."*
(2)	**BASIS: GSG-13 para 3.15 states that** *"The safety objectives and regulatory requirements should include the following, as appropriate: … (f) Criteria relating to human factors and the human–machine interface."*
R11	**Recommendation: The SNSA should develop requirements related to human factors engineering and human-machine interface.**

6.3. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS

In general, the review and assessment for research reactors (RRs) is performed according to the same processes as for NPPs and employs the same bases for review and assessment. The graded approach is applied considering the criteria for grading.

PSA for assessment of modifications, analysis of events, and review of the PSR is not utilized in case of the research reactor due to relaxation in Rules JV 9 for submission of PSA.

The design requirements vary for nuclear power plants and research reactors as defined in the Rules JV5 for NPP (Annex 1) and for RR (Annex 2). The design requirements for RR include also experimental devices and different modes of operation and RR utilization.

In the case of the research reactor, the scope and contents of the second PSR are based on IAEA SRS-99.

6.4. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

Recent and ongoing review and assessment activities conducted by SNSA for waste management facilities in Slovenia encompass authorization for the construction of the spent fuel dry storage facility at Krško NPP, authorization for the construction of the LILW disposal facility, and ongoing activities relating to the authorisation of closure of the Boršt disposal site at the former uranium mine Žirovski Vrh. In addition, the first Periodic Safety Review of the central storage facility for institutional waste was conducted some years ago, which led to a renewal of the operating licence for a further 10 years in 2018. SNSA has an internal procedure (ON 2.1.4) that provides general guidance on performing review and assessment (see Section 6.1.3), in order to harmonize its internal processes and to support implementation of a graded approach. A separate internal procedure (OP 2.2) is used to guide the review and assessment of periodic safety reports.

A general aspect of the review process as applied in Slovenia (see 6.1) is that the safety report developed by the licensee must be conducted in accordance with Article 101(1) of the Act ZVISJV-1. Among other things, this means that a safety report that is to be reviewed and assessed by SNSA as part of the authorization process must first be reviewed by a formally approved independent expert. Such a process does not exclude the possibility for the SNSA to appoint separate specialist experts for specific technical areas to support its own review and assessment process. Assessment activities that underpin the identification of remedial actions to be undertaken by RŽV d.o.o. at the Boršt disposal site are subject to specific arrangements involving advice from an Expert Project Council. The corresponding safety report for closure of the site remains to be finalised, depending on the receipt of a positive opinion from an authorised expert.

SNSA has developed an internal guide (ON 2.1.8) to support its review and assessment of the safety report submitted in support of ARAO's licence application for construction of the LILW repository. The review guide was finalised in 2017 and draws extensively on regulatory guidance for safety reporting published by the SNSA in 2012 (see Section 9.4). The guide also provides, inter alia, information on the organisation of the project team for the review, the criteria to be addressed in assessing safety, the process for submitting technical comments and requests for additional information regarding the content of the safety report, and key reference documents and standards to be used in undertaking the review. A tracking system relating to the resolution of identified technical issues was used in support of the review project. The IRRS team considers the approach taken by SNSA to be consistent with principles for review and assessment outlined in SSG-5 Requirement 2, paragraph 3.10, as well as under GSR Part 1 (Rev 1) Requirement 25, paragraphs 4.41 – 4.43 and 4.45. Risks not related to radiation (GSR Part 1 (Rev 1), paragraph 4.47) are considered as an intrinsic element in the development of waste acceptance criteria for the disposal facility and were therefore implicitly taken into account in the assessment process.

A related aspect of review and assessment that concerns the initial stages in development of new facilities is the consultation process that is linked to the conduct of environmental impact assessment in the context of spatial planning and the Environmental Protection Act. Such consultation procedures are not formally under the control of the SNSA, but the content of the environmental report (e.g. in the case of the LILW disposal facility) is prepared according to guidelines prepared by the SNSA.

6.5. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

SNSA reviews and assesses whether the information provided in the application documentation determines whether the facilities and activities comply with regulatory requirements and the conditions specified in the authorization. The review and assessment is carried out according to SNSA internal procedures ON 2.1.4 "Guide on performing review and assessment" and ON 2.3.3. "Guide on issuing licenses in a field of radiation safety and maintenance of official records". The Act, Art. 40, obliges an applicant to ensure that the radiation protection assessment is prepared and amended to the application. Prior to the application, the radiation protection assessment shall be reviewed by an independent RPE. In the case of licence renewal, the same authorisation process shall be followed. IRRS team was informed that SNSA in case of issues organizes hearings, if needed, visits the facility for demonstration and make sure that information provided in documentation supporting application corresponds with real situation. Such practice is also applied in SRPA.

In case of a more complex facility, SNSA may use recognized TSOs to review and assess the technical information provided by the applicants.

During their lifetime radiation sources shall be periodically technically checked in prescribed intervals by a recognized TSO. The written report on technical checks is sent to the authorized person and to regulatory authority (SNSA or SRPA).

The general procedure on review and assessment process established by the Act also applies to SRPA. Initial review and assessment of facilities and activities with radiation sources is performed by SRPA staff during the authorization procedure.

SRPA requires that a Quality Control (QC) report of the radiation generators used in medical and veterinary facilities be submitted annually for most practices. The report is normally prepared on behalf of the licensee by a Qualified Expert/TSO and the technical status of the machine is given a grade. If the QC report of a radiation generator is graded differently from A, SRPA requires that any issues identified during the QC assessment be corrected in a certain time period. There is no additional review and assessment required for facilities with A grades.

The IRRS team was informed that although the TSO/qualified expert provides paid services to the licensee for preparing a safety assessment report, in rare cases, the TSO has also been involved with SRPA projects such as on establishing DRLs, and also on a study conducted for the safety of dental practices in order to apply a graded approach.

6.6. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

SNSA does not have any specific procedures or processes relating to the review and assessment of safety reports and related information prior to authorization of decommissioning activities. However, the IRRS team was informed that no applications for regulatory authorization to start, or to complete, decommissioning of nuclear facilities are expected in the near future. Nevertheless, because of the regulatory requirement that decommissioning plans should be incorporated into safety reporting at every stage in the development and operation of a facility (see Section 9.6), there is a need to take such plans into account in the SNSA's review and assessment of safety reports relating to earlier stages of authorization.

The regulation JV5 requires that decommissioning programmes for operational facilities are reviewed and, where necessary, updated at least every ten years as an element of Periodic Safety Review. Updates to the decommissioning programme for the Krško NPP are prepared more frequently (every five years) on the basis of agreement between the Republic of Slovenia and the Republic of Croatia; this process is intended to facilitate the regular review of financial provisions for decommissioning and waste disposal. Article 121(1) of the Act ZVISJV-1 requires in turn that the decommissioning strategies for individual facilities are consistent with the National Programme for Radioactive Waste and Spent Nuclear Fuel Management, which means that assessment of such consistency is an integral part of SNSA's review activity.

As noted above, SNSA has a general procedure (ON 2.1.4) for the conduct of review and assessment, which is applied the review and assessment of decommissioning strategies and plans. SNSA's human resources for review and assessment of decommissioning programmes are primarily assured in the frame of the Division of Radiation Safety and Materials. As with the review and assessment of waste management facilities, more demanding projects are led through the establishment of special project groups, involving the cooperation of experts from different areas and divisions.

6.7. REVIEW AND ASSESSMENT FOR TRANSPORT

The competent authority for transport (SNSA), performs review and assessment of relevant information for determining whether the applicant for authorization or the authorized party complies with applicable regulatory requirements.

The authorization process takes into account the "graded approach" as well as the QA/Management system of SNSA. SNSA covers all aspects and matters which should be cited in the authorisation. The applicant (customer) also has to comply with all national/international requirements which are directly applicable. The criteria for regulatory review and assessment are derived from the requirements stipulated in the legislation and regulations.

The SNSA as the competent authority for transport can follow the manufacture and testing of different package models (e.g. IP-2, Type A, etc.) and the management system of the manufacturer can be examined and the regulator may participate during the tests.

In addition to SNSA, SRPA is a competent authority for transport of radioactive materials used in medicine and veterinary care. In practice, the majority of decisions issued in the field of transport in recent years were the official acknowledgement that the licence to transport, issued in other EU member states was equivalent to the licence issued according to the Act. In the process, SRPA verifies the content of the foreign licence and decides, if the radiation protection principles were considered and if the licence was issued in comparable conditions as stipulated in the Act.

The bases and general criteria for review and assessment, granting of consents and permits, and requirements regarding the content of applications are set out in Articles 3-9 in Rule JV2SV2. Practical guidelines / instructions are available for the applicant and internally for the inspectors who review the relevant documentation.

Applications follow the suite, based upon the General Administrative Procedure Act, the Ionising Radiation Protection and Nuclear Safety Act and the Transport of Dangerous Goods Act. The simplest reviews may take less than a month while more complex reviews (when the application is not complete or a special expertise by TSO(s) is used) could require several months.

SNSA continues to review and assess, as necessary, relevant information associated with transport approvals during the validity period of the transport authorization. Carrying out a radiation practice or "special arrangements" are also considered and reviewed as necessary. SNSA, within its QA/Management System has a dedicated procedure for review and assessment (ON 2.1.4, An Instruction for Performing Reviews and Assessments.

The review and assessment can occur before the licence expires and may also occur if there are any significant changes in the legislation or the source's held or the user needs to change the practices or provide information to the regulator, which entails another administrative procedure.

The approaches for any regulatory review and assessment are consistent with and derived from the requirements stipulated in the national legislation, regulations and in the conditions attached to the authorizations. An appeal mechanism is also in place.

6.8. REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE

The main document provided by the licensee for review is the "Radiation protection assessment" This document is assessed by the relevant Regulatory Authority. The "Radiation protection assessment" includes:

- design criteria and design features relating to the exposure and potential exposure of workers in all operational states and in accident conditions;
- design criteria and design features of the appropriate systems and programmes for monitoring of workers for occupational exposure in all operational states and in accident conditions.

The first license is issued for a period of maximum 5 years. After that, a licensee has to apply for renewal. The license renewal procedure is equivalent to the first licensing procedure. The requirement for a renewed license is a reviewed radiation protection assessment.

A review of the radiation protection assessment must be performed in the case of:

- any changes in radiation practice that can significantly affect the radiation protection conditions
- on a request from a competent inspector
- immediately after each emergency
- after completing works activities to remedy the consequences of an emergency.

The review and assessment are performed following the Administrative Act that establishes the review procedure and timelines. SRPA also periodically reviews the individual and workplace monitoring programs, results and records, and control of occupational exposures in planned exposure situations in accordance with the requirements of the Regulations.

SRPA authorizes the service providers for individual monitoring and calibration services. These services are accredited in the ISO 17025 standard. Two TSOs are also authorized to perform workplace monitoring.

The two TSOs are accredited in the ISO 17025 standard. Dose constraints and other optimization processes are also kept under review.

6.9. REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE

There are provisions in the Act and Rule SV3 related to review and assessment during the authorization process as well as during the lifetime of the activity regarding medical exposure.

A Programme of Radiological Procedure contains the requirements related to justification, optimization, quality assurance programme and learning from incidents. A copy of the Programme of Radiological Procedure must be provided by the licensee to SRPA as a condition to issuing the first authorization and must be reviewed as a condition for renewal of the authorization. Annex 1 of the Rule SV3 specifies the content, scope and format of this Programme of Radiological Procedure.

6.10. REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE

In the self-assessment, SNSA identified that, in the assessment of radiation protection, the requirement to consider good practices in the operation of a similar sources, the requirement to consider possible future authorized practices and the requirement to consider views of interested parties are missing.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *In the assessment of radiation protection for the implementation of radiation activities in industry, research or education requirements for taking into account good practices in the operation of a similar sources, possible future authorized practices and the views of interested parties is missing.*	
(1)	**BASIS: GSR Part 3 Requirement 29, para. 3.120 states that** *"the government or the regulatory body shall establish or approve constraints on dose and constraints on risk to be used in the optimization of protection and safety for members of the public. When establishing or approving constraints in respect of a source within a practice, the government or the regulatory body shall take into account, as appropriate:* *…* *(b) Good practice in the operation of similar sources;* *(c) Dose contributions from other authorized practices or from possible future authorized practices, estimated at the design and planning stage, so that the total dose to members of the public is not expected to exceed the dose limit at any time after the start of operation of the source;* *(d) The views of interested parties."*
S7	**Suggestion: SNSA should consider including in their internal procedure for safety assessment a requirement for considering good practices in the operation of similar sources, doses from possible future authorized practices, and the views of interested parties in assessing public exposure.**

The IRRS team considers SNSA's web portal showing environmental monitoring data to be an area of good performance that could be copied and developed by others. The portal has an easy-to-use map interface and both on-line dose rate monitoring results and nuclide specific results from environmental samples that can be accessed, with several years of historical monitoring data available.

SRPA has done coordinated work with other authorities on updating the building code to include enforcement on indoor radon levels, but further coordinated actions with other organizations relevant for the reduction of indoor radon seem to be missing from the plan. Such actions could further enhance the reduction of indoor radon in Slovenia. Example of a coordinated action would be an information campaign planned and conducted jointly with organizations in the construction business, aimed at promoting radon safe construction practices.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: SRPA has done coordinated work with other authorities on updating the building code to include enforcement on indoor radon levels. However, the Radon action plan UV4 does not include coordinated actions of relevant parties other than SRPA, such as organizations involved in the construction business.	
(1)	**BASIS: GSR Part 3 Requirement 50, para. 5.20 states that** *"Where activity concentrations of radon that are of concern for public health are identified on the basis of the information gathered as required in para. 5.19(a), the government shall ensure that an action plan is established comprising coordinated actions to reduce activity concentrations of radon in existing buildings and in future buildings,…"*
S8	**Suggestion: SRPA should consider investigating what coordinated actions involving relevant parties, such as organizations involved in the construction business, would promote the reduction of indoor radon in Slovenia.**

SRPA has produced guidelines for mitigation of radon in public buildings. Preparing additional information material specific to structural aspects of small or private houses could further support indoor radon mitigation efforts.

In their self-assessment, SNSA recognized the need to finish a study on construction materials and use the results to establish a strategy for systematic monitoring of construction materials. The study has been recently completed and it shows that public exposure from building materials typically sold in Slovenia does not significantly contribute to the dose to the public.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SNSA has conducted a study on natural radionuclides in building materials, but has not yet incorporated those results into the strategy for building materials monitoring.*	
(1)	**BASIS: GSR Part 3 Requirement 51, para. 5.22 states that** *"the regulatory body or other relevant authority shall establish specific reference levels for exposure due to radionuclides in commodities such as construction materials, food and feed, and in drinking water, each of which shall typically be expressed as, or be based on, an annual effective dose to the representative person that generally does not exceed a value of about 1 mSv."*
(2)	**BASIS: SSG-32, para. 4.14 states that** *"the national authority should use the data generated in surveys of the levels of radionuclides of natural origin in building materials to identify those radionuclides that may make a significant contribution to exposure to gamma radiation indoors. Where there are only limited data available on levels of radionuclides in building materials, the national authority should make arrangements for a survey to be carried out, and/or it should require manufacturers of building materials and suppliers of imported building materials to provide it with such data."*
S9	**Suggestion: SNSA should consider utilizing the results from the building material study when drafting a strategy for monitoring of building materials.**

6.11. SUMMARY

In the occupational radiation protection and medical exposure area, the licensee's documentation required for review and assessment is well defined, as is the review and assessment process. Periodic reviews are foreseen every five years. A related aspect of review and assessment that concerns the initial stages in development of new facilities is the consultation process that is linked to the conduct of environmental impact assessment in the context of spatial planning and the Environmental Protection Act. Such consultation procedures are not formally under the control of SNSA, but the content of the environmental report is prepared according to guidelines prepared by SNSA. The approaches for any regulatory review and assessment are consistent with and derived from the requirements stipulated in the national legislation,

regulations and in the conditions attached to the authorizations. An appeal mechanism is also in place. In accordance with provisions of the Act, SNSA and SRPA are empowered to request from the licensees, or from the applicants for a license, all the documentation needed for the regulatory decision-making process on safety related matters. SNSA has a well-defined review and assessment processes and procedures. In addition, arrangements for independent review and assessment of operating experience, the oversight of the operating experience feedback and periodic safety review of NPPs and RRs are in place.

Some areas for improvement were identified by the IRRS team, including risks that are not related to radiation and human factors engineering to be addressed in the regulatory framework for nuclear installations.

7. INSPECTION

7.1. GENERIC ISSUES

In SNSA, the inspection unit consists of six inspectors including a chief inspector with four inspectors for nuclear facilities and two inspectors for other sources and facilities. The inspection staff can be supplemented by specialists from other divisions such as the Division for Nuclear Safety. SNSA carries out approximately 140 inspections per year.

For SNSA, the inspection process is based on the Inspection Programme. This document requires the development of an annual inspection plan. The annual plan for Radiation and Nuclear Safety Inspection addresses administrative requirements, inspection of Krško NPP, inspection of the research reactor, inspection of ARAO, inspection of the Žirovski Vrh mine and inspection of radiation practices and sources.

The IRRS team was informed that the Annual Inspection Plan is based on three-year baseline plan and further developed in a collaborative process which includes other divisions, input from operating experience, recommendations from outage reports (when applicable) and follow-up activities from inspection reports, etc.

The Act establishes provisions about SNSA and SRPA inspectors' powers. e. g. issuing decisions, ordering measures for radiation protection and measures for radiation and nuclear safety and stopping carrying out a radiation practice or the use of a radiation source. In addition, the Act addresses powers of the inspectors related to withdrawal of a license, procedures for suspending the operation of a facility and access to the records related to nuclear materials and records relevant to security and personal information

When SNSA's Annual Inspection Plan is prepared, the potential magnitude and nature of the hazard associated with the facility or activity is considered and the frequency of inspections and the areas to be inspected are established in accordance with the graded approach.

SRPA has two dedicated inspectors who conduct about 200 inspections per year. Approximately 40 to 50 inspections are performed on-site, the rest via written requests to provide proof of compliance with the regulatory requirements. SRPA has developed an annual inspection programme. During planned inspections, the time of the last inspection and the performance history of the facility are taken into consideration.

SNSA and SRPA informed the IRRS team that there is a general training program for all inspectors. A specific training program of SNSA and SRPA inspectors is however not available. The IRRS team was informed that SNSA's specific training program for SNSA inspectors is under development.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The specific training program for inspectors is under development to cover principles, concepts and technological aspects, as well as the procedures for inspecting facilities and activities.*	
(1)	**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. This process shall include the development of a specific training program on the basis of an analysis of the necessary competence and skills. The training program 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."*
R12	**Recommendation: SNSA should finalize the development of the specific training programme for inspectors to cover principles, concepts and technological aspects, as well as the procedures for inspecting facilities and activities.**

Liaison with other inspection authorities is exercised on a regular basis. In particular, joint inspections are implemented when inspecting fire protection, physical security and emergency preparedness. SNSA and SRPA periodically perform joint inspections. This approach is based on the Act. In addition, according to the Inspection Act, the Inspection Council is established as a permanent inter-ministerial working body to co-ordinate the joint implementation of inspection duties of different inspection services. All aspects of GSR Part 1 para 4.53 are also included in the Annual Inspection Plan.

7.2. INSPECTION OF NUCLEAR POWER PLANTS

Four inspectors, including a chief inspector, are dedicated to inspections of the Krško NPP and are involved in the planning, preparation, and conduct of the Krško NPP inspections. All have a high level of knowledge and experience, which enables them to assess the interactions of the activities associated with different technical disciplines relevant to NPP operation.

SNSA’s inspection program includes scheduled inspections and unannounced inspections. The majority of inspections are scheduled. The frequency of inspections, the areas to be inspected, and the scope of the inspection are set in accordance with the graded approach. At present, ten inspection procedures exist: Inspection Program as an umbrella procedure and specific ones which currently cover preparation and conduct of inspections, the inspection of outages at the Krško NPP, emergency response, cyber security, minor offences, enforcement, classification of inspection findings, transport and some specific inspection topics at the Krško NPP.

Most planned inspections are announced to the operator, but two or three unannounced inspections per year are performed as well. When necessary, a reactive inspection is performed, typically immediately after an unplanned shutdown or abnormal event in order to verify the status of the safety systems, deviations, performed actions and causes for the event, as well as to obtain fast and unfiltered information for SNSA’s own event analysis. Some reactive inspections are also performed with a preventative focus, following relevant foreign operational experience, new requirements from international standards, etc.

To provide in-depth, detailed and comprehensive inspections of all operational areas at the NPP, experts from the SNSA's Nuclear Safety Division are often included in the inspection teams. These "subject matter experts" (SMEs) provide support, in their areas of expertise, to the inspectors during the thematic inspections. Furthermore, during the NPP's refuelling outages, the inspectors draw on support not only from SMEs within the SNSA, but also from authorized technical support organizations (TSOs) who perform an in-depth oversight of the outage activities according to their area of expertise. The support of a TSO can also be requested for other complex inspections (not only during the outage), but this support is seldom used.

Whereas inspections are performed in accordance with the annual inspection plan, as determined by the overall inspection programme comprising all aspects of NPP operation, the focus is always on aspects important for safety and on areas that have been identified as having lower performance. Information on the safety importance of the inspected area, probabilistic data, past operational performance, foreign operational experience feedback, etc. are all used as inputs in developing the annual inspection plan.

SNSA has identified some additional inspection procedures for nuclear power plants that need to be developed. These are included in the action plan. Some of these procedures are:

i. System walk down inspection
ii. Main control room
iii. Refuelling including transport of fresh fuel
iv. Management system inspection
v. Ageing management

vi. Fire protection,

vii. Training

viii. Surveillance of mobile equipment

ix. Unannounced inspection

x. Reactive inspections

xi. Safety culture and human organizational factors

The IRRS team was informed that SNSA also has a plan to develop inspection procedures for research reactors.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SNSA has identified some additional inspection procedures that need to be developed for inspection of nuclear power plants. SNSA has planned to develop inspection procedures for research reactors.*	
(1)	**BASIS: GSG 13 para 3.221 (i) states that** *"The Specific responsibilities of the regulatory body with respect to inspection should include the following: Developing procedures and directives as necessary for the effective conduct and administration of the inspection program."*
S10	**Suggestion: SNSA should consider developing and finalizing the identified inspection procedures for effective inspections of NPPs in the relevant areas. The SNSA should consider developing inspection procedures for RRs.**

SNSA has developed an inspection program (OP 3.3) both for NPPs and RRs, which also requires conduction of follow-up inspections, when needed, especially to verify implementation of required corrective actions. However, the detailed circumstances under which it is appropriate to carry out further (follow-up) inspections has not been covered in the programme.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Circumstances under which it is appropriate to carry out further inspections have not been covered in the inspection programme*	
(1)	**BASIS: GSG 13 para 3.315 states that** *"Regulatory procedures should state the circumstances under which it is appropriate to carry out further inspections to check whether the authorized party has responded to regulatory enforcement measures. The purpose of such inspections should be to confirm that the authorized party has complied with the enforcement measures within the periods of time specified. This aspect may be confirmed during review of the inspection procedures."*
S11	**Suggestion: SNSA should consider revising the inspection programme to include circumstances under which it is appropriate to carry out further inspections.**

SNSA has informed that there is not normally a resident inspector at the nuclear power plant, owing to the relatively short distances involved. Inspections are, however, carried out on a weekly basis with a typical duration of one day. Routine inspections such as walk downs or unannounced inspections can be performed by a single inspector, whereas the composition of the inspection team for complex and thematic inspections requires more members in order to cover different disciplines. One or two comprehensive (complex) inspections are performed per year with a duration of up to one week. SNSA deploys a resident inspector during outages for strict regulatory oversight; the inspector is also accompanied by additional expert support during this activity, as noted above.

In accordance with the General Administrative Procedure Act and the Inspection Act, the inspector prepares the Inspection Report which is signed by the inspector and the representative of the NPP at the end of inspection.

All inspection findings are documented in the report, together with corrective actions required by the inspector and implementation deadlines. If a non-compliance or violation of legislation is recorded in the Inspection Report, the enforcement actions are taken later, according to processes described in the Minor Offences Act, Inspection Act, the Act and inspection procedure ON 3.2 Enforcement Process.

Detailed investigation of the root cause of non-compliances, including additional inspections, is carried out by SNSA on an as-required basis. Implementation of required corrective actions is strictly followed up, based on the assessment of reports submitted by the NPP, or by performing follow-up inspections. The inspection database within the InfoURSJV supports tracking of the implementation of corrective actions.

Inspection findings are used not only to improve the safety and operation of the NPP, but also to support planning or improving SNSA's own activities. This is done by regular assessment of inspection reports within the inspection division and subsequent discussion of important findings during periodical SNSA management meetings. The Process of Supervision and Analysis of the Krško NPP Refuelling Outage (inspection procedure ON 3.1.2) as well as implementation of Classification of Inspection Findings (inspection procedure ON 3.1.9) are in place to support determination of the SNSA's action plan. Some typical actions mentioned in discussion during the course of the mission are: improvement of regulations, performance of additional analyses, identifying issues to be addressed within the 10-year PSR, and identification of topics for discussion at the NPP/SNSA management meetings.

The IRRS team joined SNSA inspectors on a site visit of an inspection at the NPP. The IRRS team observed inspectors performing a follow-up inspection. In the entrance meeting, the inspectors explained the purpose and scope of the inspection. They reviewed the relevant documents and asked questions during the interview for clarification. SNSA inspectors followed the applicable inspection procedure in a professional way. At the end of the inspection, an inspection report was prepared by inspectors and handed over to the representative of nuclear power plant for review before signing. At the end of the inspection, two copies of the inspection report were signed, one for each party.

The IRRS team also conducted a meeting with plant management to discuss the relationship between SNSA and the licensee of Krško NPP. They informed the IRRS team that SNSA inspectors are competent, professional, respectful and well prepared for inspections. The relation between SNSA and plant management is good and based on mutual respect.

7.3. INSPECTION OF RESEARCH REACTORS

Inspections of the only research reactor in Slovenia, namely TRIGA Mark II at the JSI, are performed according to the Annual Inspection Plan. These are typically one-day inspections based on interviews, walk downs and documentation checks. The areas to be inspected include, among other things, operational monitoring of radioactivity, operation and the performance of corrective actions (as part of the follow-up from previous inspections).

The frequency of inspection is defined according to SNSA's operational procedure OP 3.3 (Inspection Program). This specifies that at least three annual inspections will be conducted, and that additional inspections of specific areas shall be conducted every two or every three years.

During the interview with SNSA staff, they informed that separate inspection procedures are to be developed for the research reactor as noted in S10, to complement those developed for the Krško nuclear power plant.

7.4. INSPECTION OF WASTE MANAGEMENT FACILITIES

According to the SNSA's inspection programme, one inspection (occasionally two) is conducted every year at the central storage facility for institutional radioactive waste (CSRW), operated by ARAO. Apart from the waste storage building and waste manipulation building at the Krško NPP, which are covered by the

inspection programme for the nuclear power plant, the CSRW is the only operational waste management facility in the country.

During the course of the mission, the IRRS team observed a planned inspection at CSRW. There are no facility-specific inspection procedures for the CSRW, but the IRRS team noted evidence of the use of a checklist for the issues to be addressed. This had been converted by the lead inspector to a draft inspection report on which annotations were made by hand during the course of the inspection. The majority of the current inspection team at SNSA has many years' experience, and it has been recognised that there is a need to develop more formal facility-specific procedures and training in the light of the current age distribution of its inspectors.

ARAO receives notification of the time and scope of each planned inspection approximately two weeks in advance, in order to ensure the availability of the facility manager and relevant support staff. The facility manager and Radiological Protection Officers present during the inspection are all ARAO staff based in Ljubljana.

Following the entrance meeting, with initial checks on the status of general documentation and certificates, the areas addressed during the inspection included:

- arrangements for secure storage of calibration sources used by ARAO for radiation monitors used at the facility;
- radiation monitoring and environmental control arrangements (ventilation, humidity control, etc.) within the storage building;
- environmental monitoring and sampling in the vicinity of storage building, including the production of the annual monitoring report;
- register control for wastes consigned to CSRW;
- equipment and documentation relating to the vehicle used to collect sources from waste producers, including certification of the transport container required for higher active sources; and
- Follow-up of previous observations (e.g. repair of cracks in the floor of the facility).

The inspector made a short summary of preliminary observations halfway through the inspection. The closing meeting covered all observations and findings, and a deadline was agreed for the submission of follow-up information. The updated inspection report, which was used in draft form as a practical guide, is first sent for fact checking after it has been finalised by the inspector, and then formally agreed and signed.

The IRRS team observed a systematic and professionally conducted inspection that was at the same time not overly formal. The two experienced inspectors worked as a team, with clear delineation of their roles. ARAO's overall experience of inspections at CSRW is that communication is good, that expectations regarding requirements and follow-up are clearly expressed, and that the SNSA is supportive when ARAO needs help in managing issues that arise with waste consignors.

7.5. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The inspections conducted by SNSA and SRPA are managed and conducted according to the general procedures established in the Inspection Act, which cover details related to inspection of premises, documents and managing interviews as well as using the powers granted by the Act. Some responsibilities of the SNSA inspectors are referred to in The Building Act.

In SNSA, 2 inspectors are dedicated to inspection of radiation sources facilities and activities. About 140 inspections are conducted each year.

The inspection programme prepared by SNSA covers all facilities and activities. The OP 3.3 Inspection Program addresses the steps in preparation of such programme. SNSA has prepared an Annual Inspection Plan; however, the IRRS team was informed that inspections are not fully conducted in accordance with the approved inspection programme due to the lack of human resources. Therefore, priority has been given to high-risk facilities and facilities that have indications of possible non-compliances. As a result, SNSA does not fully implement its defined frequency of inspections.

Inspectors have a legal power to perform programmed inspections and reactive inspections, both announced and unannounced. In practice, mostly programmed announced inspections, and where needed reactive inspections, are being performed. The criteria for drawing up the Annual Inspection Plan are largely based on the IAEA categorisation of radioactive sources and regulatory experience of SNSA. Also, the feedback from authorization teams is taken into consideration. The frequency of inspections is established in accordance with the graded approach.

SRPA has developed and implemented an inspection programme, however, it does not include the frequency of inspections for all facilities and activities. A fixed number of facilities from every group of practices is used instead. During planned inspections, the time of the last inspection and the performance history of the facility are taken into consideration. If a facility has been inspected recently but some issues of non-compliance have been identified, priority is given in the annual inspection plan for the inspection of this facility.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SRPA's inspection programme does not define the frequency of inspections for all facilities and activities. SNSA does not fully implement their approved inspection programme.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 29, para. 4.50 states that** *"The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach"*
(2)	**BASIS: GSG-13 para. 3.281 states that** *"Inspections should be conducted in accordance with an approved inspection programme, plan, guidelines, procedures and checklists. (…)."*
R13	**Recommendation: SRPA should revise its inspection programme to include the frequency of inspection for each facility and activity. SNSA and SRPA should fully implement their approved inspection programme for radiation sources facilities and activities.**

SRPA performs mostly announced inspections. Unannounced inspections are performed only when it is expected that an announced inspection would not provide the required information. SRPA has occasionally conducted an unannounced inspection. The majority of on-site inspections are planned. Detailed inspection guides are not established, but inspection "templates" are available for the most common types of inspections (e.g. inspection of dental practices, veterinary practices, general radiography services).

SNSA uses the general internal procedure OP 3.1 Preparation and conduction of inspection, which covers the preparation and implementation of the inspection of radiation sources facilities and activities.

The IRRS team was informed that standardised checklists are not currently used by SNSA during inspections, however some draft checklists are being prepared.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SNSA and SRPA have developed some checklists and templates for conducting inspections to ensure consistency of regulatory control. However, some facilities and activities using radiation sources are inspected without standardised checklists.*	
(1)	**BASIS: GSG 13 para 3.281 states that** *"Inspections should be conducted in accordance with an approved inspection programme, plan, guidelines, procedures and checklists. (…)."*
(2)	**BASIS: GSG 13 para 3.225 states that** *"The regulatory inspection programme should be comprehensive and consistent with the overall regulatory strategy. The inspection programme should be thorough enough to ensure that the regulatory objectives and requirements are being met, thereby providing the regulatory body with a confidence that the authorized party is effectively maintaining the safety of the facility or activity. The inspection programme should also be developed so that the regulatory body can determine whether the authorized party conducts activities in accordance with previously established procedures, and has an effective self-assessment process capable of prompt identification and correction of actual and potential problems."*
S12	**Suggestion: SNSA and SRPA should consider further developing standardized inspection checklists to ensure consistency in regulatory inspections of all radiation sources facilities and activities.**

According to the Inspection Act, the inspectors are obliged to prepare an inspection report. The authorized party also receives a copy of the inspection report. The inspection report summarizes the performance of the authorized person, indicates non-compliances and, where necessary, establishes corrective actions. SRPA inspectors have developed report templates to record the findings of each inspection.

The results of the inspection are recorded in accordance with the document management system of SRPA. A copy of the report goes to an electronic data base and all paper documents are saved in inspection archives. Non-compliances are put in written inspection ruling which also includes the time limit for resolving the issue. For follow-up purposes, reports with a ruling specify the date of the deadline for addressing the non-compliance. Inspection findings may also initiate additional processes. In some cases, a detailed investigation is initiated to reveal the root causes of non-compliances.

The reactive inspections are most often triggered by information that indicates non-compliances with regulatory requirements or conditions specified in the authorization. In most cases, the inspection starts with a written request for information or a proof of compliance and are only followed-up by an on-site inspection when necessary.

The IRRS team was informed that SRPA does not perform any independent confirmatory tests and measurements using its own equipment during inspections.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The *SRPA does not perform any independent confirmatory tests and measurements during inspections.*	
(1)	**BASIS: GSG 13 para 3.268 states that** *"The inspection procedures of the regulatory body should incorporate and use a variety of methods, as follows:* *(…)* *(d) Confirmatory tests and measurements."*
(2)	**BASIS: GSG 13 para 3.277 states that** *"The regulatory body should have the authority and resources [4] to be able to carry out confirmatory tests and measurements as necessary, at fixed points or in places of special interest, as applicable, using its own equipment. (…)."*
S13	**Suggestion: The SRPA should consider ensuring independent verification of tests and measurements in its inspections.**

SNSA and SRPA staff involved in inspections are senior inspectors with decades of experiences in their field of expertise. All the inspectors have also benefitted from participating in IAEA activities and projects.

The IRRS team members observed an inspection by SNSA inspector at the Jožef Stefan Institute, F-2, Department of Low and medium energy physics, at the Microanalytical Center (MIC). The MIC is licensed for the use of a 2 MeV tandetron ion accelerator. The tandetron ion accelerator allows research with accelerated ion beams to be conducted.

The inspection planning started at the SNSA premises with checking of the documentations, radiation surveillance equipment and personal dosimetry. Inspection in the facility involved a brief introduction, interviews and document review and a walk around the facility checking the safety status of the facility. A briefing on the inspection findings was made at the end of the inspection. During the inspection, the inspector made measurements of radiation dose rate together with the Radiation Protection Expert of the facility using the facility's measuring equipment. However, although the inspector had prepared in advance a list of questions for the areas to be inspected that guided the inspection, a standardized inspection checklist was not used.

The management of the facility informed that inspections at the institute are quite frequent. Additionally, although there are several mechanisms for information exchange and consultation, such as asking for comments on drafted regulations and guides, the licensee stated that it would be a benefit if direct engagement with the regulatory body were practised, such as meetings when relevant regulations and guides are developed.

7.6. INSPECTION OF DECOMMISSIONING ACTIVITIES

Preparations for the approved final closure of the Boršt disposal facility for mill tailings at the former uranium mine Žirovski Vrh are currently (and for the foreseeable future) the only authorised decommissioning activities in Slovenia. Inspections of ongoing activities undertaken by RŽV d.o.o. to stabilise the site are carried out on by the SNSA on an annual basis. In addition, the SNSA undertakes annual inspections of monitoring and control activities by ARAO as the responsible operator for the nearby, now-closed, Jazbec disposal facility for mine tailings. The IRRS team did not have an opportunity to observe such inspections, but notes that inspections are currently typically led by experienced personnel, with the support of technical specialists where required. The SNSA recognises the need to develop more formal facility-specific procedures and training in the light of the current age distribution of its inspectors.

7.7. INSPECTION OF TRANSPORT

The competent authority for transport of radioactive material carries out inspections of facilities and activities related to transport of radioactive materials to verify compliance with regulatory requirements and the conditions specified in SNSA's approvals / authorization – in accordance with a graded approach.

The inspections of transport activities are addressed in the Article 52 of the Transport of Dangerous Goods Act. Article 4 (Principle of independence) in the Inspection Act requires the independence of the inspectors in performing their inspection duties, within the framework of their powers. The frequency of inspections and the areas and programmes to be inspected are set in accordance with a graded approach.

The SNSA has established a process (operational procedure OP 3.3 Inspection Program) and has implemented a documented inspection programme plan, including guidelines and procedures. The SNSA organizational instructions ON 3.1.7 Inspections of Transport of Radioactive and Nuclear Materials assist inspectors in their training as well as conducting inspections. IAEA guidance documents are also used for reference. The IAEA e-learning modules on transport of radioactive material are also available to enhance the inspectors training programme. One inspector is currently undertaking this training programme.

Regulatory transport related inspections cover areas, including:

- nuclear fuel transports, which are planned well in advance;
- reviews of the management system of the package manufacturer to ensure that all the requirements have been correctly implemented (note: there are no producers of type B packages in Slovenia; reviews of management system for other packages are normally done through audits);
- facilities engaged in manufacturing are audited, including sub-contractors;
- an auditing programme based on EACA (European Association of Competent Authorities) documentation to verify that the transport organization's management system is implemented and followed correctly;
- audits to verify the management system arrangements of the suppliers and carriers;
- unannounced or planned inspections of handling and stowage of packages by consignors and carriers;
- periodic (announced and unannounced) inspection of the users' activities including determination as to whether consignors and carriers are performing relevant duties
- unannounced or planned inspection of the activities important to safety, particularly where approval is not required (note: approval, i.e. "licence for transporting radioactive material – carrying out a radiation practice" is required only for Cat. 1 and 2 sources);
- random or planned inspection of packages of foreign origin while in transit (note: transits of radioactive sources are carried out);
- transits of high consequence radioactive material (IAEA Category 1 or 2) or non-medical radioactive sources are occasional; all such shipments can be randomly stopped and checked by police, and certain transits of high consequence radioactive material are escorted by police;
- inspection of test facilities (normally before tests), witnessing of tests (note: this review/check can be normally carried out through occasional audits by the SNSA);
- inspection of maintenance and servicing arrangements and operations, including lifetime records;
- inspection of records for package designs where it is not required that a competent authority for transport issue a certificate of approval.

The SNSA's inspections concentrate on road transport of radioactive material (loading, unloading) but may also include other modes of transport. However, unannounced inspections in the area of transport of radioactive material are infrequent. The inspection frequency for industrial radiography is annually and for users and transport of nuclear moisture density gauges is typically every 3 years.

After the SNSA's inspections, users / carriers are provided with a summary of the results of the inspection, including any non-compliances noted. Appropriate follow up takes place by SNSA.

The regulatory inspection process takes into account the baseline of requirements of para. 4.49 to 4.52 of GSR Part 1 (Rev. 1).

The SRPA also performs inspections of carriers and shipments, which are usually carried out for hospitals' needs (i.e. before their nuclear medicine departments receive radioactive materials, mainly unsealed sources for diagnostics or therapy).

7.8. INSPECTION OF OCCUPATIONAL EXPOSURE

Both SNSA and SRPA carry out inspections in the area of occupational radiation protection. The inspections of both regulatory authorities are carried out following the Inspection Act. The inspectors receive formal training and are examined at the end of the training course. An annual inspection plan is established including the inspection frequency expected for each type of installation.

The SRPA inspectors do not usually make workplace monitoring measurements during inspections to independently confirm the licensee's measurement results. The licensee is required by SRPA or SNSA to contract a TSO that offers workplace monitoring services accredited in the ISO 17025 standard. The TSO performs a routine workplace monitoring survey in a period that depends on the risk potential of the source, every 6 months or annually. This survey is also carried out in the NPP. The results are provided to the licensee and to the respective regulatory authority.

Workplace monitoring, however, recognizes four types of monitoring: routine, confirmatory, special and task-related. The last three are not covered by the TSO. In a nuclear medicine clinic with radionuclides with short half-lives, routine workplace monitoring every six months usually does not give very conclusive results. In a NPP, daily and continuous workplace monitoring measurements are made.

The IRRS team therefore considers it necessary that, during inspections, importance be given to ensuring the licensee has adequate, correctly specified and calibrated equipment and that the RPO has sufficient training to carry out a workplace monitoring programme as established in the radiation protection assessment and in SV8. The inspector should also perform workplace monitoring measurements to independently verify the workplace conditions.

The IRRS team accompanied an inspection conducted by SRPA to the department of radiotherapy of the Institute of Oncology Ljubljana, covering the areas of medical and occupational radiation protection. The inspection was conducted in a professional manner by one SRPA inspector. As established in the inspection procedure, the inspection started with an entrance meeting attended by the Radiation Protection Officer, Medical Physics Experts, Radiation Oncologists and Radiation Therapy Technologists. On the return of the inspector, the inspection on medical radiation protection briefly went over the justification – referral – treatment procedure and then focused on commissioning and quality assurance of the recently installed radiation generator and incident report system. In the occupational exposure area, the review of dose and training records and interview with the RPO were the primary means used to collect evidence. The inspection ended with an exit discussion summarizing the main findings followed by the signing by all parties and issuance of the inspection report. A quick walk-around of the linear accelerators and surrounding controlled areas was also performed. The IRRS team discussed with the licensee, in the absence of the inspectors, about the interactions and relationship between the licensee and SRPA. The licensee confirmed a good working relationship, and that the SRPA inspector always showed a knowledgeable and professional attitude during the inspection process.

7.9. INSPECTION OF MEDICAL EXPOSURE

The inspections of medical facilities are carried out by only two senior inspectors of SRPA. The radiation protection inspection programme for activities of medical facilities is based on the general guideline for inspection planning which also addresses how to set the annual inspection plan.

The IRRS team was informed that each inspection is conducted by one inspector only, who is empowered by the regulations to issue the inspection report at the end of inspection.

The IRRS team noted a lack of resources available to carry out inspections of medical exposure with appropriate frequency.

The primary means used for inspections are the review and assessment of records and interviews.

The IRRS team was informed that the inspectors do not perform any measurements during an inspection as only an authorized Radiation Protection Expert is considered to have appropriate expertise to perform these. This is addressed in section 7.5 radiation sources.

The inspection plan follows a graded approach based on the risk associated with the source used, therefore high priority is given to radiotherapy facilities and such facilities are inspected every year.

The IRRS team was informed that unannounced inspections are not generally included in the inspection programme for medical exposures because this kind of inspection can interfere with the clinical work and in some cases the relevant staff might not be available. However, the IRRS team was informed that the Inspection Act empowers the inspectors to decide themselves how to plan the inspections based on the general inspection programme and the type of inspection is defined previously the inspection is performed. The decision on an announced or unannounced inspection is made during the preparation for the inspection.

7.10. INSPECTION OF PUBLIC EXPOSURE

Registrants and licensees required to conduct an environmental radioactivity monitoring program are inspected on a regular basis. The inspections cover authorization of discharges, radioactive waste management and environmental monitoring programs. Inspections are conducted according to an annual inspection plan with the possibility to conduct additional inspections, for example, triggered by events potentially affecting public exposure. The Inspection Act forms the legal basis.

Following a discussion with a representative of Krško NPP, the IRRS team understood that the inspections conducted by the SNSA on public exposure contribute to the continuous improvement of safety. The IRRS team was informed that changes in the operating environment are taken into account by the NPP and lead to an assessment of potential changes in public exposure. An example of such assessment is the procurement, testing and verification of dispersion modelling software for discharges to the Sava river. The simulation package is being used to model the dispersion of effluents in the river following the completion of new dam structures a few years ago. It was noted that the current arrangements on reporting and information exchange between the SNSA and the licensee are good and both sides have a good and timely picture of the radiological situation relevant for public exposure in the environment of the plant. The IRRS team took a note of the high level of professionalism, extensive experience, and dedication of the Krško NPP representative.

For facilities or activities involving sources, public exposure including optimisation of radiation protection is inspected as a part of general inspections. The arrangements for visitors are a part of such inspections.

Inspections related to disused smoke detectors with radioactive sources are conducted by SNSA to verify proper waste management practices.

Public buildings with high radon concentrations are inspected by the SRPA (in 2020, the SRPA conducted 8 in-depth inspections). Measurement results and possible actions to mitigate high radon levels are discussed between the stakeholder and the SRPA.

7.11. SUMMARY

In general, the inspection process meets the requirements of IAEA safety standards. The current focus, which is also reflected in the action plan, is to increase the number of defined inspection procedures to ensure a more coherent approach and facilitate the work of inspectors.

Some areas of improvement were also identified such as improvement of SNSA processes for SNSA’s inspection program and practices. These include, for example, development of a specific training program, and the development and revision of inspection procedures. The IRRS team also identified a need for SRPA to develop a programme covering the necessary frequency of inspections and to further develop checklists for inspection.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

SNSA has developed and issued the internal procedure OP 3.2 Enforcement Process, which is a consolidated policy and procedure document. The enforcement procedure is in line with the Inspection Act, Minor Offences Act and Criminal Code. The SNSA's strategy and practice is implemented based upon the procedure for enforcement. Staff of SNSA have not been trained in the enforcement procedure, which was issued in 2021. SRPA uses the general Inspection Law for taking enforcement actions and has not established an enforcement policy and criteria for taking enforcement actions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SRPA uses the general Inspection Law for taking enforcement actions and has not established an enforcement policy and criteria for taking enforcement actions.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 30 states that** *"The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization".*
(2)	**BASIS: GSR Part 1 (Rev. 1) Requirement 31 para. 4.58 states that** *"The regulatory body shall establish criteria for corrective actions, including enforcing the cessation of activities or the shutting down of a facility where necessary".*
R14	**Recommendation: SRPA should develop an enforcement policy and establish criteria for responding to non-compliance with regulatory requirements or conditions of authorization.**

According to the Inspection Act an inspector shall apply a graded approach when dealing with non-compliance. The inspectors may apply several types of enforcement action, while prosecution is led by prosecutors. In particular, when only minor non-compliances are noted during an inspection an oral warning might be given during an inspection followed by a written warning, which is recorded in the inspection report. In the Slovenian legal system when the inspector does not identify any non-compliance, this fact should be stated in writing, and the inspection process and the relevant file are closed. The SNSA procedure of enforcement further specifies the application of graded approach.

According to the Inspection Act, an inspector has several tools at his/her disposal, all prescribed by the Inspection Act: written warning, admonitions, decision, withdrawal of a licence, fine and indictment. The inspector is authorized according to the Inspection Act for inspection and separately for enforcement by state administration, after taking the relevant exam. In the event of deviation from, or non-compliance with the regulatory conditions and requirements, SNSA and SRPA take enforcement actions. Enforcement procedures have been established describing how the SNSA reacts in cases of non-compliance. The enforcement instruments available enable a graded approach to non-compliances or deviations. They range from a financial penalty, through an administrative order, which gives the inspector the potential to stop activities or shut down a facility, to revocation of the licence. The Act contains specific requirements related to withdrawal of a licence, the procedure for suspending the operation of a facility and other actions taken by SNSA and SRPA inspectors. In the enforcement strategy, the responsibility for compliance and thereby for safety is primarily on the licensee. The personal responsibility of the management of licensee is also taken into account. Fines are defined in the Act, the Transport of Dangerous Goods Act and in the Act on Liability for Nuclear Damage as well as in the Inspection Act.

In addition to written warnings, an inspector must also apply the provisions of the general Minor Offences Act. Minor offences are divided into two main categories. For the majority of offences, the inspector issues a fine (financial penalty) directly, while for the second category of offences, the inspector may propose initiation of prosecution. The same applies when an inspector discovers serious unlawful activities, omissions or negligence, which the Criminal Code qualifies as a criminal offence report. In cases that may

lead to criminal proceedings, the SNSA collects all information and sends it to the public prosecutor for further investigation. The ultimate decision to prosecute rests with the public prosecutor and is separate from the SNSA.

The SNSA developed an electronic database to support the follow-up of the enforcement actions. The database records all enforcement actions of the last 20 years, which gives the inspector the possibility to prepare for inspection and to follow the status of enforcement actions. The database also contains deadlines for the elimination of non-compliances, so that tracking the implementation of necessary corrective actions is ensured. The SRPA inspectors similarly use an established system to follow-up the implementation of corrective actions. In both SNSA's and SRPA's inspection process, the licensee is obliged to send written confirmation that corrective actions have been implemented. The assessment and confirmation of effectiveness of the implementation shall be recorded at the time of closure of the individual enforcement action. A further follow-up inspection is then proposed by the inspector as required. The licensee is notified of the closure of the enforcement action by an administrative letter.

The enforcement procedure includes the consideration of safety culture aspects and licensee's responsibility for safety in the enforcement. The check list in the procedure covers safety cultural aspects in several ways.

The system of administrative law provides the licensee with the possibility to appeal a decision and ultimately challenge enforcement actions in court. The form and manner of an appeal are described in every enforcement decision.

The enforcement action is based mainly on the inspection experience. If an issue arises in connection with an authorization or from the review and assessment process, an inspection will still be performed to gain the proper information. The leaders of the different departments share information on recent enforcement activity at the weekly management meeting.

In some cases, other authorities may be involved, for example with regard to fire or labour safety issues. These governmental bodies may need to be informed about SNSA enforcement actions. Exchange of information on enforcement actions is not fully formalised, and is not addressed in the enforcement-related procedure.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Other governmental bodies may need to be informed about SNSA enforcement actions. Exchange of information on enforcement actions is not fully formalised, and is not addressed in the enforcement related procedure.*	
(1)	**BASIS: GSG-13 para. 3.46 states that** *"Guides should also indicate which other governmental organizations, if any, are to be informed in the event of enforcement actions."*
(2)	**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."*
S14	**Suggestion: SNSA should consider improving its enforcement procedure to indicate when other governmental organizations are to be informed of its formal enforcement actions.**

8.2. ENFORCEMENT IMPLEMENTATIONS

SNSA and SRPA use several types of enforcement action, which reflect the application of a graded approach. In practice, the SNSA inspectors mostly issue written warnings, while admonitions and other enforcement tools were used only a few times during the last decade. In the case of SRPA inspectors, the most commonly used tool when non-compliances are identified is a written decision that specifies the non-compliances that need to be addressed and the time limit for their elimination. SRPA inspectors have the authority to take enforcement actions on site if they find that safety is compromised, such as formally sealing a radiation generator to prevent use until the non-compliance is addressed. The seal is removed only

by SRPA inspectors. Inspectors also provide a ruling when there are issues of non-compliance that need to be fixed with a certain time limit.

SNSA does not automatically make enforcement decisions public. If asked for this information, it will be granted according to the Public Information Access Act, while taking into account the principles of GDPR (EU Data Protection Directive). SNSA and SRPA provide a detailed summary of enforcement actions in their annual reports.

According to the Inspection Act the inspectors participated in a central state training and exam. This training is a general training for all inspectors in certain areas. However, SNSA staff have not been trained in the enforcement procedure, which was issued in 2021.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Staff of SNSA have not been trained in SNSA's enforcement procedure, which was issued in 2021.*	
(1)	**BASIS: GSG-13 para. 3.312 states that** *"The regulatory body should adopt clear administrative procedures governing the taking of enforcement actions, which should be documented in internal guidance. All inspectors and other staff of the regulatory body should be trained in, and knowledgeable about, the procedures."*
(2)	**BASIS: GSR Part 2 para. 4.23 states that** *"Senior management shall ensure that competence requirements for individuals at all levels are specified and shall ensure that training is conducted, or other actions are taken, to achieve and to sustain the required levels of competence. An evaluation shall be conducted of the effectiveness of the training and of the actions taken."*
S15	**Suggestion: SNSA should consider training their staff on SNSA's enforcement procedure.**

8.3. SUMMARY

The SNSA has established and implemented a well-balanced enforcement process by using a wide range of enforcement activities. However, the staff of SNSA have not been trained in the enforcement procedure and the information flow on enforcement actions between the governmental bodies is not formalized.

SRPA uses the general Inspection Law for taking enforcement actions and has not established an enforcement policy and criteria for taking enforcement actions.

The SNSA and SRPA provide information on their enforcement actions in the annual summary report, which are publicly available on SNSA website.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

Slovenia has a regulatory framework consisting of a set of legally binding regulations and non-binding documents. The regulations are structured at different levels and the basic legal framework governing nuclear activities is contained in the Ionizing Radiation Protection and Nuclear Safety Act. In accordance with the Constitution of the Republic of Slovenia, primary legislation (Acts) are adopted by the National Assembly. Decrees are adopted by the Government to enforce Acts, while rules are issued by ministers. The State Administration Act defines that administrative bodies such as SNSA and SRPA should draft regulations and other acts and prepare other materials for the Government. Regulations prepared by SNSA and SRPA are adopted through the Minister for Environment and Spatial Planning and the Minister for Health respectively, either alone or where necessary in agreement with other competent ministers if the content of the regulations also applies to their area of interest. SNSA and SRPA are empowered to publish, jointly or individually, non-binding instructions, recommendations or practical guidelines relating to nuclear safety and radiation protection on a website or in another appropriate manner. SNSA issues so called Practical Guidance (e.g. Regulatory Guides), which are not obligatory and are published on SNSA's website.

SNSA has two internal procedures OP 4.1 on Preparation and monitoring of regulations and OP 4.2 on Preparation of practical guidelines for SNSA. The first of these defines the procedure for the development of legislation (acts, decrees, rules), including all interfaces with the Ministry of Environment and Spatial Planning, other parts of the governmental administration and other stakeholders. The procedure identifies methods for monitoring implementation and modifying legislation, which include formal provision for systematic periodical screening of legislation that may be a trigger for initiating changes in the legislation. For most legislation, a review every 2 years is established. Changing or expanding any part of legislation may also take place at the initiative of SNSA's technical departments, based on national or international experiences.

SRPA does not have internal procedures for the development of regulations and guidelines. This shortcoming is addressed in the Recommendation 3 in Module 4. No formal provisions exist for systematic, periodic screening of legislation that may be a trigger for initiating change/modification in the legislation. A formal procedure exists for the whole governmental administration in case of transposition of European law.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SRPA does not have formal provisions for the systematic periodical screening of national regulations. The initiative to change or expand any part of legislation is based on the screening of international standards and internal or external experiences.*	
(1)	**BASIS: GSR Part 1 Requirement 33 states that** *"Review of regulations and guides Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained."*
(2)	**BASIS: GSG-13 para 3.63 states that** *"The process used by the regulatory body to establish regulations and guides should include the following steps: Determining the need for the regulations or guide. This need may arise from the regulatory body's activities and from the inventory of facilities and activities in the State. Alternatively, the need may be identified as a result of a request or enquiry by an authorized party, or an applicant for a new facility or activity. Additionally, the need for regulations may arise as a result of national debates or to meet international obligations."*
S16	**Suggestion: SRPA should consider implementing a process for systematic periodic review of regulatory safety requirements against relevant international safety standards and technical standards and of relevant experience gained.**

A process for establishing or adopting, promoting and amending regulations and guides is in place. These processes include consultation with the public and interested parties. According to the Resolution on Legislative Regulation and the Rules of Procedure of the Government of the Republic of Slovenia, the regulatory authority responsible for preparing the draft must invite interested parties and the public to comment and share their opinions during a period of at least 30 days from the publication on the website eDemokracija. The regulatory authority proposing the legislation must inform stakeholders and the public of essential proposals or opinions that have not been considered, explaining the reasons within 15 days of adopting the regulation or submitting the draft regulation for further consideration. A governmental inter-department consultation is also performed. Consultation with most relevant stakeholders starts before the formal consultation process. Draft regulations are also published on the website of SNSA. The authority is required to publish on the internet its reasoned opinion, and to state the reasons for taking or not taking comments into account in drafting the regulation.

SNSA and SRPA do not have a consolidated long-term plan on development of regulations and guidance but, in accordance with national practice, the Government is informed in advance of their annual regulation development plan. Acts, decrees, rules and guidance are made available on the SNSA's website. SNSA publishes the correlation tables with European and international standards on their website and the IRRS team noted this as an area of good performance with respect to transparency.

Graded approach is defined as one of the main principles in Slovenian legislation especially in the Radiation Protection and Nuclear Safety Act, which obliges SNSA and SRPA in dealing with nuclear and radiation safety matters to take into consideration the importance for safety and potential exposure due to radiation practice, devoting more attention to matters of greater importance.

In the process of reviewing regulations and guides, SNSA also considers relevant international safety standards, technical standards and relevant experience gained.

Periodic verification of the safety of the facilities is performed through the process of a periodic safety review, which is required by the Act. The PSR process is defined more in detail in the JV9 Rules. The scope and content of a PSR for NPP is defined in Annex 9 of JV9, while for the RR these contents are applied with a graded approach.

Regarding the promotion of regulations and guides, the SNSA publishes on its website a news and issues newsletter with radiation protection topics entitled "Radiation News", with the aim of informing interested parties and the public. The interested public and interested parties can subscribe to receive the SNSA's newsletter. Lectures and symposia are sometimes organized. In addition to obligatory consultation, SRPA promotes new provisions in the legislation through its website. Representatives of SRPA take active part in professional forums and working groups. These include preparation working groups for legislative acts, involvement at forums for medical professionals (radiation protection of patients, dosimetry of response units, breast cancer screening, etc.) and involvement at public forums with a radon agenda.

The IRRS team was informed that Slovenia is considering building a new nuclear power plant, and that Slovenia has fully transposed the WENRA safety objective for new reactors as well at the Nuclear Safety Directive. Nevertheless, new reactors are expected to achieve higher levels of safety than existing ones, meaning that in some safety areas, fulfilment of the requirements defined for existing reactors may not be sufficient. If new applications for power reactors are anticipated, SNSA should consider further development of its regulations to ensure the consistent regulation of facilities. Furthermore, the licensing process for new plants is very complex and the related requirements are distributed across different legal documents; providing consolidated guidance to the prospective licensee could therefore be useful. No systematic review of the legislative system of Slovenia has yet been performed taking into account the aspects of new build project needs.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Slovenia is considering to build a new nuclear plant. No systematic review on the legislative system has been performed that takes into account needs of the new build project.*	
(1)	**BASIS: GSR Part 1 Requirement 34, para. 4.61 states that** *"The government or the regulatory body shall establish, within the legal framework, processes for establishing or adopting, promoting and amending regulations and guides. These processes shall involve consultation with interested parties in the development of the regulations and guides, with account taken of internationally agreed standards and the feedback of relevant experience. Moreover, technological advances, research and development work, relevant operational lessons and institutional knowledge can be valuable and shall be used as appropriate in revising the regulations and guides."*
(2)	**BASIS: GSG-13 para. 3.5 states that** *"When regulations are not established directly by the regulatory body mechanisms established within the legal and governmental framework should ensure that such regulations are developed and issued in a timely manner. The regulatory body should advise the government on the need for regulations on matters affecting safety to be established or adopted"*
S17	**Suggestion: SNSA should consider making a strategic plan to review and develop Regulations and Guides in relation to the new build project.**

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

Slovenia has a comprehensive set of safety requirements for nuclear power plants which are divided into two Rules JV5 and JV9 ("preoperational" phases JV5 and "operational phases" JV9). Other related regulatory requirements are included in Rules JV3, JV4, JV7 and JV10.

The main regulations cover all aspects of regulatory supervision of nuclear power plants (e.g. fundamental safety functions, application of defence in depth, plant states, design basis, design extension conditions, postulated initiating events, personal qualification and training, monitoring of safety performance, accident management, operating procedures, modification, maintenance, testing, surveillance, operating limits and conditions). The provisions for the licensing of nuclear power plants during the different phases in their life cycle are defined in the Act and the Rules JV5. These include siting, design, construction, trial operation, operation, termination of operation, commencement of decommissioning, and completion of decommissioning and release from regulatory control. Additional requirements related to the siting and construction licence are given in the Act on Environmental Protection, the Act on Spatial Planning and the Building Act.

The Rules JV5 present in more detail requirements for design bases, issuing of consents and permits, safety documentation, safety and quality management of nuclear power plants. The Rules JV9 set requirements for operation including use of operational experience, event analysis and reporting, aging management, maintenance, testing and inspection, management of modifications, use of probabilistic safety analysis, periodic safety review (PSR), emergency preparedness, emergency operating procedures and severe accident management guidelines. Other related regulatory requirements for nuclear power plants are also addressed in other rules such as JV3, JV4, JV5, JV7, and JV10.

Additionally, SNSA has developed several Practical Guidelines to provide more details on specific regulatory requirements and associated criteria.

The IRRS team was informed that in 2021, additional requirements were prepared as amendments to the existing Rules JV5 and JV9. Both amended regulations are in the legislative procedure and are expected to be issued in 2022.

The IRRS team was further informed that revisions of Rules JV5 current being considered encompass requirements for the development of a commissioning programme. These are defined and described as the pre-operation test program within new Annex 9. The IRRS team was also informed that the stage where

submission of pre-operational test program with application for authorization is required will be added in the Rules JV5 for both nuclear power plants and research reactors.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Commissioning program for nuclear installations is not currently required by JV 5 to be submitted by the licensee in support of licence application.*	
(1)	**BASIS: SSG 12 para 2.5 states that** *"Licences and authorizations, should be granted or denied in accordance with the national legal and governmental framework and should cover all stages of the lifetime of the nuclear installation, namely, site evaluation, design, construction, commissioning, operation, decommissioning and subsequent release of the site from regulatory control."*
(2)	**BASIS: SSG 12 para 3.44 states that** *"The licensee or applicant should establish and justify plans and programs for commissioning the nuclear installations. The regulatory body should conduct reviews, assessments and inspections to determine whether:* *a) the commissioning test program is complete and contains asset of well defined operational limits, test acceptance criteria, conditions and procedures; the commissioning tests can be safely conducted as proposed by the licensee or applicant and their justification is appropriate."*
(3)	**BASIS: SSG 28 para 2.31 states that** *"The scope and content of the assessments, reviews and inspections conducted by the regulatory body in connection with the commissioning programme differ from State to State. In some States, the regulatory body approves the commissioning programme and establishes the hold points for inspections, reviews and assessments of the testing results in accordance with the acceptance criteria. An agreement (in some States, formal approval) should be obtained before advancing beyond these hold points. The commissioning stages are typical hold points at which the reviews and assessments of the results of commissioning stages are performed before proceeding to the next stage."*
S18	**Suggestion: SNSA should consider defining the requirements in JV5 for the development and submission of the commissioning programme as part of the licensing applications.**

9.3. REGULATIONS AND GUIDES FOR RESEARCH REACTORS

The regulations and guides that are applicable in general for radiation and nuclear facilities are applicable also for research reactors with consideration of graded approach. The Rules JV4, JV5, JV7, JV10 and JV9 cover all of above listed areas of regulatory supervision of research reactors. The provisions for the licensing of research reactors during the different phases in their life cycle are defined in the Act and the Rules JV5 and include siting, design, construction trial operation, operation termination of operation, commencement of decommissioning, and completion of decommissioning and release from regulatory control. Additional requirements on the siting and construction licence are given in the Act on Environmental Protection, the Act on Spatial Planning and the Building Act.

The Rules JV5 present requirements for design and authorization of research reactors in more detail. Annex 2 to the Rules JV5 contains the specific design requirements for a research reactor. The Rules JV5 also contain requirements for safety management of research reactors. Annex 5 to JV9 defines the format of the annual report on research reactor operation. Other regulations that apply to research reactors are Rules JV4 on qualification of research reactor staff, Rules JV7 for radioactive waste and spent fuel management as well as Rules JV10 for radioactivity monitoring.

The IRRS team was informed that comparison of existing regulations against the IAEA safety standards, as part of the self-assessment prior to the IRRS mission, revealed some gaps. In 2021, additional requirements based on these gaps were prepared as supplements to the Rules JV5 and JV9. Both amended regulations are in the legislative procedure and are expected to be issued in 2022.

9.4. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

The safety of waste management facilities is regulated by the Act ZVISJV-1 and by the regulations JV5, JV7 and JV9. The JV5 and JV9 regulations are more general in nature for all nuclear facilities, although certain special provisions relating to waste management – in particular waste disposal – are noted. JV7 summarises general provisions that are specifically directed towards waste and spent fuel management, for example in respect of the requirement for facility-specific waste management (or spent fuel) management plans, processing, packaging and acceptance criteria for storage or disposal.

Among the provisions of the Act ZVISJV-1 is a specific requirement (Article 121(1)) on all waste producers (which is also relevant to waste storage arrangements at the Krško NPP and the central storage facility for institutional waste) to ensure that the provisions of the national programme of radioactive waste and spent fuel are applied. This involves, inter alia, a requirement on producers to consider interdependencies among different steps the management through the safety analysis report and operating licences. These provisions are translated into regulatory requirements via Article 6(1) of the JV7 regulations.

The IRRS team was informed that SNSA has identified the need for a new regulatory guide relating to the contents of applications for different stages in the development of a waste repository. Such information can be helpful even at the current stage in the repository development programme in order to guide ARAO on the scope of issues to be addressed within continuing programme development that are relevant to future authorization stages.

When guidance is needed to support the implementation of regulations for specific types of facility, the provisions of the Act and supporting regulations are supplemented by separate regulatory guides. For example, the SNSA developed and issued specific guidelines on the format and content of safety documentation to be submitted in the context of authorisation of the LILW facility – Regulatory Guide 1.03 (Contents of the safety report for the LILW repository). These guidelines were subsequently used by ARAO in developing the safety analysis in support of its application to the Environment Agency in 2017 for authorisation under the Environmental Protection Act, as well as for its application for a construction licence in accordance with the Act ZVISJV-1 and JV5 regulations.

General considerations relating to the design basis for different types of radioactive waste management facility, as a precondition for authorization, are identified in Article 20 of JV5 and specified in Annexes 3, 4 and 5 thereto. These include, inter alia, standards for radiological protection that must be satisfied by a disposal facility, and demonstrated in the safety analysis report, not only during operation but also after closure (JV5 Article 46(1)2). During the course of self-assessment prior to the IRRS mission, the SNSA identified a need for additional radiological protection criteria relating to near surface disposal to ensure consistency with the objectives of SSR-5 paragraph 2.15, which (among other things) identifies criteria relevant to an assessment of the consequences of human intrusion.

The IRRS team was informed that a corresponding amendment to JV5 Annex 5 has already been proposed and is awaiting adoption by the Minister and implementation. The IRRS team considers it important to examine the implications of applying such criteria for the way in which guidance to ARAO is formulated regarding the evaluation of human intrusion scenarios in the safety report for LILW disposal. Such guidance is necessary in order to ensure that application of the new radiological protection criteria for intrusion scenarios, and assessing their implications for the definition of waste acceptance criteria prior to the authorisation of trial operation, are undertaken in an appropriate manner taking account of the facility design.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The radiological criteria defined in the current version Annex 5 to the JV5 regulations do not include criteria related to scenarios for human intrusion.*	
(1)	**BASIS: SSR-5 Requirement 20 para. 5.1 states that** *"Waste acceptance requirements and criteria for a given disposal facility have to ensure […] the fulfilment of the safety functions for the waste form and waste packaging with regard to safety in the long term. Examples of possible parameters for waste acceptance criteria include […] the characteristics and performance of the packages […] such as the radionuclide content or activity limits."*
(2)	**BASIS: SSR-5 Requirement 20 para. 5.11 states that** *"For near surface disposal facilities, the waste acceptance criteria will limit any consequences of human intrusion to within the specified [radiological protection] criteria, even if control over the site is lost."*
R15	**Recommendation: The SNSA should ensure that planned changes to criteria defined in JV5 regulations are reflected in timely guidance to ARAO for addressing human intrusion scenarios ahead of the next update of the safety analysis for the LILW disposal facility.**

The regulatory guide 1.03 on the contents of the safety report for low and intermediate radioactive waste disposal was published in 2012. The guide is considered by ARAO to have been indispensable to them in preparing their safety reporting ahead of submitting applications for an environmental licence and construction licence for the Vrbina disposal facility. Developments in regulatory requirements over the last 10 years, such as amendments to JV5 (including, but not limited to, those identified above with respect to radiological protection criteria for human intrusion), are recognised and understood by both the SNSA and ARAO. The IRRS team considers that it would be appropriate at some stage to update and re-issue the guide to reflect the current status of regulations, while also taking the opportunity to reflect the experiences of both parties with its application.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The regulatory guide 1.03 for the content of the safety report for low and intermediate radioactive waste disposal was published in 2012. Developments in regulatory requirements as well as experiences with review and assessment over recent years have not yet been considered for an update of the guide ahead of the next stage in authorisation of the Vrbina disposal facility.*	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 33 states that** *"Waste acceptance requirements and criteria for a given disposal facility have to ensure […] the fulfilment of the safety functions for the waste form and waste packaging with regard to safety in the long term. Examples of possible parameters for waste acceptance criteria include […] the characteristics and performance of the packages […] such as the radionuclide content or activity limits."*
S19	**Suggestion: SNSA should consider reviewing regulatory guide 1.03 to reflect changes in regulations since its publication and to take into account the experience of ARAO and the SNSA with its application.**

Given the importance of Regulatory Guide 1.03 to ARAO in developing a safety report and its value to the SNSA in conducting regulatory assessment and review, the IRRS team considers the potential value of developing a similar guide for geological disposal.

According to the Resolution on the National Programme for Managing Radioactive Waste and Spent Nuclear Fuel, as well as the decommissioning programme for the Krško NPP, the implementation strategy for long-term management of spent nuclear fuel and HLW is not expected to deliver a geological repository for several decades. Assumptions regarding the programme for geological disposal, and different strategic scenarios for implementation, represent an essential foundation for estimating the programme costs and thereby decisions taken today that are related to financing of the decommissioning and waste management fund. Although ARAO is able to draw on international experience and perspectives in order to develop such

cost estimates, this is done in the absence of a national regulatory perspective on what is required to deliver confidence in geological disposal within Slovenia.

The IRRS team considers that it might be appropriate for SNSA to consider developing regulatory input to discussions surrounding the necessary scope of a hypothetical future geological disposal programme in Slovenia (e.g. site investigation and characterisation, concept development, R&D etc.). The IRRS team further considers that participation of the SNSA in a wider discourse surrounding safety requirements and contributing factors to delivering safe geological disposal of spent fuel and HLW would contribute to transparency in programme evaluation and in the factors underpinning estimates of programme costs.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *A preferred implementation strategy for geological disposal of spent fuel and HLW remains to be determined by Slovenia and Croatia, but an understanding of the scope and potential cost implications of alternative solutions is nevertheless required. Guidance on expectations regarding safety objectives in order to inform the potential scope of such a programme (site investigation, concept development, R&D etc.) and contribute to transparency in programme evaluation is thus lacking.*	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 32 states that** *"The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgments, decisions and actions are based."*
(2)	**BASIS: SSR-5 Requirement 32 para 3.19 states that** *"Ensuring safety, both in the operational stage and after closure, is the overriding concern at each decision point [in the process of development and operation of a disposal facility]. If more than one option is capable of providing the required level of safety, then other factors also have to be considered. These factors could include public acceptability, cost, site ownership, existing infrastructure and transport routes."*
(3)	**BASIS: SSR-5 Requirement 2 para 3.9 states that** *"The regulatory body has to engage in dialogue with waste producers, the operators of the disposal facility and interested parties to ensure that the regulatory requirements are appropriate and practicable."*
S20	**Suggestion: The SNSA should consider defining regulatory expectations regarding the scope of a potential programme for safe geological disposal of spent fuel and HLW in Slovenia.**

9.5. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The responsibilities of SNSA and SRPA regarding regulation and supervision of safety and control of radiation sources are established in Article 18 of the Act.

Requirements for radiation sources applications are provided in the Act and in its subsidiary legislation. The main regulations regarding radiation sources are covered in:

- Decree UV1 (establishes criteria and classification of radiation sources define exemption, clearance, classification of facility, duration of license for radiation sources);
- Rules JV2/SV2 (establishes the content for different applications, requirements for use of sources, security measures, record keeping, registers and technical check of sources);
- Rules SV3 (establishes requirements on use of radiation sources in medicine).

Article 10 of Regulation JV2/SV2 defines the obligations of a legal entity when it no longer uses the radiation source.

According to the Regulations, the user of the radioactive source is obliged, within three months of ceasing use of the source, to hand it over to a provider of the mandatory public utility service for the management of radioactive waste, or to another holder of a licence to carry out a radiation activity, or to return the radiation source to the producer or supplier. In case of X-ray devices, the user is obliged, within six months

of ceasing use of the device, to hand over the device to an authorised expert organisation for the management of hazardous waste, or to another physical or legal person, to return it to the producer or supplier, or to notify the competent administrative authority of the intention to keep the X-ray device as a reserve.

There are provisions in the Act about control over orphan sources. Article 26 of the Act establishes obligations for competent authorities to periodically organise searches for orphan sources or for sources from past activities. The IRRS team was informed that such campaigns were performed by SNSA from 2004 to 2010 and managed to regain control over more than 1000 sources. The strategy for orphan sources is to transfer them to the waste management facility at the responsibility of the state in case the user is not known.

Decree UV11 establishes requirements for large metal scrap yards, major metal scrap recycling installations, significant nodal transit points, major post centres, operators of the municipal waste management, operators of waste electrical and electronic equipment processing. In addition, the Regulation JV10 stipulates conditions for these organizations to obtain SNSA's authorisation to carry out measurements of radioactivity of shipments.

Chapter V (Articles 41 to 45) of Regulation JV2/SV2 determines the requirements for the security of radiation sources.

Regulations and guides are regularly reviewed and updated so as to be in line with EU regulations and IAEA recommendations.

All regulations and guides are published in the Official Gazette of Republic of Slovenia, are available for public and can be accessed via the SNSA and SRPA websites.

9.6. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

A decommissioning programme is required in the JV5 regulations as part of the material submitted in support of authorization of different stages in the development of all nuclear facilities, starting from the application for consent to construction. Application of a graded approach in the authorization process means that the depth of detail in the definition of the facility decommissioning programme is expected to begin at an outline level and progressively be developed in more detail throughout the facility's planning, construction and operational lifetime.

A key consideration in the JV5 regulations with respect to the decommissioning programmes for individual facilities is that the programme must be consistent with the currently applicable Resolution on the National Programme for Managing Radioactive Waste and Spent Nuclear Fuel. The proposed revision to the National Programme, to run during the period 2023-2032, indicates that only direct dismantling (i.e. within a relatively short period after authorized cessation of operations) may be considered as a decommissioning strategy. Compliance with the national programme (e.g. in terms of efforts to minimise the volumes of radioactive waste that need to be disposed) is a key element of the information provided in support of a request to start, or to complete decommissioning, as well as being subject to inspection during the actual decommissioning.

As noted in Section 5.6, authorization under the Building Act to remove a nuclear facility must be obtained before a licence from the SNSA to commence decommissioning may be sought. The content of an application for consent from the SNSA to a decision to remove the facility is defined in JV5 Article 31. A subsequent application to commence decommissioning, as well as to complete decommissioning, according to the provisions of the Act ZVISJV-1, must be accompanied by information defined in the JV5 regulations.

The IRRS team assesses these provisions to be consistent at an overall level with the goals of GSR Part 6, Requirement 5, concerning the regulation of all aspects of decommissioning throughout all stages of a nuclear facility's lifetime and the establishment of related safety requirements. As noted previously,

however (Section 6.6), it is not expected that there will be any application in the near future to start, or to complete, the decommissioning of nuclear facilities.

According to information provided during the mission, an amendment to Article 33(1) of JV5 Annex 5 has been proposed and is awaiting adoption by the Minister and implementation. The amendment reflects the fact that complete, unrestricted clearance of buildings or areas may not be achievable at reasonable financial cost or without harm to the local environment. Such questions reflect the possibility, at the final stage of decommissioning, that the licensee may be faced with a decision between excavating and removing very low-level waste from a site, in order to dispose of it (most likely to landfill) at another location. The amendment therefore requires a description of the monitoring and surveillance regimes to be implemented in the event that buildings and structures are released from regulatory control with restrictions on future site use. In such circumstances, the amended article also requires a description of financial provisions made for assuring control and surveillance of the site.

9.7. REGULATIONS AND GUIDES FOR TRANSPORT

The regulatory body has established or adopted regulations and guides to specify the principal requirements and associated criteria for safety, upon which its regulatory judgements, decisions and actions are based.

The Slovenian legal system in the area of transport of radioactive or nuclear material consists of two parts – the general one that applies to all transport of dangerous goods containing requirements for each individual consignment (transport) and specific ones that apply only to radioactive and nuclear material containing requirements for the radiation related practice of transporting radioactive or nuclear material.

International organisations have issued a number of modal regulations for road, rail, sea and air transport. These are directly mentioned and applicable in Slovenia. Article 3 of the Transport of Dangerous Goods Act (“ZPNB”) references ADR, COTIF/RID, IMDG and ICAO. These modal regulations have a strong foundation in the IAEA SSR-6 requirements.

Article 38 from “ZPNB” stipulates the supervisory role of the Police regarding road transports (shipments, carriage) of dangerous goods, including radioactive material.

Authorisation of transport-related radiation practices (involving radioactive sources) is stipulated in the Ionising Radiation Protection and Nuclear Safety Act (the Act), Article 18. A licence is required to perform the transport of radioactive sources of Cat. 1 & 2.

Transit (the administrative procedure of crossing the Slovenian territory with radioactive sources) is also covered in another regulation, namely the Rules JV12. Certain transits require a dedicated application for authorization. These include, as above, those transporting radioactive sources of Cat. 1 & 2. Transport-related documentation is also assessed in the licensing process. This is set out in Article 4 of the cited rules. All transits (transports) must comply with all ADR-related provisions, regardless of the categorisation.

Requirements on the reporting of incidents/accident (“transport-related events”) are included in the Rules JV2/SV2, Article 22 – loss of radioactive sources or emergencies, including transport related accidents. ADR (in 1.8.3.6 and 1.8.5, generally also in 5.4.3.4 – instructions in writing) also sets out the requirements for reporting and notifications.

SNSA and SRPA do not issue specific guides on transport of radioactive material. However, they refer to the IAEA Safety Guides, which provide explanations and guidance for established requirements in SSR-6 to facilitate harmonized implementation. They also refer to any relevant documents or guidance prepared by the EACA or Mediterranean Transport Networks.

Additionally, several initiatives and outreach activities, have taken place, e. g. through a dedicated newsletter “Radiation News” (periodic leaflet, “Sevalne novice” in Slovene), annual meetings of transport-

related national stakeholders and occasional seminars / webinars for subjects, involved in transport of radioactive material in Slovenia.

9.8. REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE

The Slovenian Legal requirements and Regulations in the area of occupational radiation protection are based on national requirements and on the EU Council Directive 2013/59/EURATOM, 2013. The Council Directive establishes basic safety standards for protection against the dangers arising from exposure to ionising radiation.

The main legislation is the Act that establishes the principles of justification, optimization and limitation.

As the CD 2013/59 follows very closely the IAEA GSR Part 3, the Act and the accompanying Regulations are in conformity with GSR Part 3 in the area of occupational radiation protection.

These regulations require justification, optimization and establish dose limits, require the monitoring and recording of operational exposure, and also the compliance by workers and cooperation between employers and authorised persons. The radiation protection programme in Slovenia is called the Radiation protection assessment.

The Regulations also cover the assessment of occupational exposure and workers' health surveillance, information, instruction and training for protection and safety, exposure at working places due to existing exposure situation (remediation of areas with residual radioactive material, radon in workplaces, air and space crew) and the protection of female and under-age workers.

The Regulations do not mention the possibility of the licensee to offer benefits as substitutes for measures for protection and safety. In the past, certain benefit (earlier retirement for example) was a possibility, however the benefits did not substitute for the need to follow the legal requirements.

The Regulations are quite detailed, and for this reason the Regulators have not considered it necessary to publish guidance documents in the area of occupational radiation protection.

9.9. REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE

The Slovenian regulatory framework for medical exposure control is based mainly in the Act and in the Rules SV3.

The responsibilities and tasks of practitioners, radiation technologists, medical physicists and referring physicians are clearly established in the Act. The Act has specific requirements for practitioners who take responsibility for medical exposures and hold the ultimate responsibility for its justification.

The content, scope and format of the programme of radiological procedures requested to grant an authorization to use a radiation source is addressed in the Annex 1 of the Rules SV3.

According to the Act diagnostic reference levels (DRLs) are established by SRPA based on the results of the systematic review of data on patient exposure and published on the SRPA website. Typical doses for standard procedures are established for each X-ray unit at least every 5 years and a comparison of the typical local doses with the DRLs is a part of Programmes of radiological procedures.

The SV3 require the licensee to establish and implement dose constraints for the carers and comforters and for individuals participating in biomedical and medical research, those dose constraints must be included in the radiation protection assessment and approved by the SRPA in the licensing process.

The criteria and guidelines for the release of patients who have undergone therapeutic radiological procedures are established in SV3.

The Act and the Rules SV3 require the optimization of medical exposure and that the practitioner, the recognised medical physics expert and the person carrying out the radiological procedure are together

responsible to optimize the dose. The programme of radiological procedures must contain a list of radiological procedures that the license holder intends to perform and the assessment of the doses for standard diagnostic radiological procedures.

The calibration of dosimeters used to calibrate all types of sources must be in place as part of the optimization of the medical exposures. The Rules SV3 require that equipment for conducting calibrations of irradiation devices is calibrated. However, there are no regulatory requirements for calibration of measuring equipment used for calibration of sources used in brachytherapy or nuclear medicine.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are requirements in the Rules SV3 Art.28 regarding calibration of measuring equipment for conducting calibrations of irradiation devices. However, there are no clear requirements for calibration of measuring equipment used for calibration of brachytherapy and nuclear medicine sources.*	
(1)	**BASIS: GSR Part 3 Requirement 38, para. 3.167 (d) states that** *"In accordance with para. 3.154(d) and (e), the medical physicist shall ensure that:* *(d) Calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standards dosimetry laboratory."*
(2)	**BASIS: SSG 46 para. 4.200 states that** *"In the nuclear medicine facility, instruments used for dosimetry of patients, such as activity meters (dose calibrators), should also be calibrated at appropriate intervals using calibrated reference sources that cover the energy range used in clinical practice. After the initial calibration, the intervals for periodic calibrations might differ, depending on the availability at the facility of radioactive sources for calibration. A period of not more than two years is recommended."*
(3)	**BASIS: SSG 46 para. 4.201 states that** *"Paragraph 3.167(d) of GSR Part 3 [3] requires that the calibration of dosimetry instrumentation be traceable to a standards dosimetry laboratory. Ideally, this would be the national standards dosimetry laboratory (primary or secondary) in the State concerned, with access either directly or through a duly accredited calibration facility. However, it may be necessary for dosimetry instruments to be sent to another State or region if there is no national standards dosimetry laboratory in the State or region where the instruments are used."*
(4)	**BASIS: SSG 46 para. 5.208 (a) and (b) states that** *"… For radiation therapy, all external beam medical radiological equipment and brachytherapy sources used in the radiation therapy facility should be calibrated, as follows:* *(a) Medical radiological equipment for external beam radiotherapy should be calibrated in terms of radiation quality or energy and either absorbed dose or absorbed dose rate at a predefined distance under specified conditions; the recommended quantity is absorbed dose to water [316, 336]. The calibrations should be performed for at least the clinically used energies and qualities.* *(b) Sealed sources used for brachytherapy should be calibrated in terms of reference air kerma rate in air or an equivalent quantity as recommended by the ICRU, at a specified distance, for a specified date [316]."*
(5)	**BASIS: SSG 46 para. 5.216 states that** *"… To ensure the calibration is maintained, the calibrated dosimeter should be checked for consistency periodically in the facility against a reference check source."*
R16	**Recommendation: SRPA should require in the regulation the calibration of measuring equipment used for calibration of brachytherapy and nuclear medicine sources.**

The Act and Rules SV3 establish that the licensee must provide all reasonable measures for reducing the probability and the magnitude of unintended and accidental medical exposure and additionally implementing a system for monitoring actual or potential unintended and accidental medical exposure, including an analysis of such events. The Act establishes that only important unintentional exposures must be reported to the SRPA and that this must be done immediately and then investigated. However, there is

no regulation or guide that defines what kind of unintended or accidental medical exposures needs to be investigated.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *A requirement regarding the promptly investigation of important unintentional exposures is established in the Act Art. 81 (4). However, it is not determined what are considered as important unintentional exposures.*	
(1)	**BASIS: GSR Part 3 Requirement 41, para. 3.180 states that** *"Registrants and licensees shall promptly investigate any of the following unintended or accidental medical exposures:* *(a) Any medical treatment delivered to the wrong individual or to the wrong tissue or organ of the patient, or using the wrong radiopharmaceutical, or with an activity, a dose or dose fractionation differing substantially from (over or under) the values prescribed by the radiological medical practitioner, or that could lead to unduly severe secondary effects;* *(b) Any diagnostic radiological procedure or image guided interventional procedure in which the wrong individual or the wrong tissue or organ of the patient is subject to exposure;* *(c) Any exposure for diagnostic purposes that is substantially greater than was intended;* *(d) Any exposure arising from an image guided interventional procedure that is substantially greater than was intended;* *(e) Any inadvertent exposure of the embryo or fetus in the course of performing a radiological procedure;* *(f) Any failure of medical radiological equipment, failure of software or system failure, or accident, error, mishap or other unusual occurrence with the potential for subjecting the patient to a medical exposure that is substantially different from what was intended."*
R17	**Recommendation: The Minister of Health or SRPA should define what kind of unintended or accidental medical exposures need to be investigated.**

According to the Act, the findings of an investigation of an unintended or accidental medical exposure must be informed to SRPA within six months. However, there is no regulation or guide that defines if this information must be written or the content of this information.

The IRRS team was informed that SRPA recognizes that there are gaps related to the requirements for the management of unintended or accidental medical exposures and the issue is included in its action plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is a requirement establishing that the licensees must report to SRPA about the investigation findings of unintentional or accidental medical exposures in the Act Art. 81 (5). However, it is not established how it must be reported neither what it must be addressed in this report.*	
(1)	**BASIS: GSR Part 3 Requirement 41, para. 3.181 states that** *"Registrants and licensees shall, with regard to any unintended or accidental medical exposures investigated as required in para. 3.180:* *(a) Calculate or estimate the doses received and the dose distribution within the patient;* *(b) Indicate the corrective actions required to prevent the recurrence of such an unintended or accidental medical exposure;* *(c) Implement all the corrective actions that are under their own responsibility;* *(d) Produce and keep, as soon as possible after the investigation or as otherwise required by the regulatory body, a written record that states the cause of the unintended or accidental medical exposure and includes the information specified in (a)–(c) above, as relevant, and any other information as required by the regulatory body; and for significant unintended or accidental medical exposures or as otherwise required by the regulatory body, submit this written record, as soon as possible, to the regulatory body, and to the relevant health authority if appropriate."*
(2)	**BASIS: SSG 46 para. 3.267 states that** *"Paragraph 3.181 of GSR Part 3 [3] establishes requirements for the reporting (in writing) of significant events to the regulatory body and, if appropriate, to the*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	relevant health authority. The regulatory body may specify its own requirements for the reporting of events by registrants and licensees. It is difficult to quantify the term 'significant': specification of a numerical trigger value immediately creates an artificial distinction between values immediately below that value (and hence would not be reported) and those just above the value (which would be reported). However, the attributes of significant events can be elaborated, and events with one or more of these attributes should be reported to the regulatory body and the health authority. Such attributes would include the occurrence of, or the potential for, serious unintended or unexpected health effects due to radiation exposure, the likelihood of a similar event occurring in other radiology facilities, a large number of patients having been affected, and gross misconduct or negligence by the responsible health professionals. As stated in para. 3.266, one of the roles of the regulatory body for such a reported event is to disseminate information on the event and any lessons identified to all potentially affected parties, typically other radiology facilities and relevant professional bodies, but also in some cases manufacturers, suppliers and maintenance companies."
(3)	**BASIS: SSG 46 para. 4.257 states that** *"… one of the roles of the regulatory body for such a reported event is to disseminate information on the event and any lessons identified to all potentially affected parties, typically other nuclear medicine facilities and relevant professional bodies, but also in some cases manufacturers, suppliers and maintenance companies."*
(4)	**BASIS: SSG 46 para. 5.275 states that** *"… one of the roles of the regulatory body for such a reported event is to disseminate information on the event and any lessons identified to all potentially affected parties, typically other radiation therapy facilities and relevant professional bodies, but also in some cases manufacturers, suppliers and maintenance companies."*
R18	**Recommendation: The Minister of Health or SRPA should establish a requirement for submission of a written report about the investigation of an unintended and accidental medical exposure and define its content.**

9.10. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE

Slovenia has developed the necessary regulation and guidance required for the implementation of authorisation, review and assessment and enforcement requirements in the area of public exposure due to planned, emergency and existing exposure situations. The regulation and guidance cover public dose requirements related to radioactive sources, discharges, contamination and remediation, radon assessment in dwellings and public places, assessment of the dose to the public, etc.

Requirements on public exposure are set in the ZVISJV-1 Act. The Act has requirements for assessment of public exposure, justification of practices and for dose limitation through limits, constraints, and reference levels. Public exposure requirements related to existing situations, responsibility for the evaluation and reporting of doses received by the population, and for safety assessments and reports that set the requirements for the evaluation of the public exposure as part of the licensing process are given in the Act. The Act sets responsibilities for monitoring of the environment for facilities that discharge radioactive substances and for practices with a possibility for public exposure.

The Act regulates consumer products and gives obligations to develop limits for radioactive contamination of commodities. Additional regulation for consumer products is defined in the UV1 Decree. The basis for remediation of contaminated areas is set in the Act. Additional guidance on remediation is given in recently published Procedures for Decontamination.

Discharges that can result in public exposure are further regulated in Decree UV1, Rules SV5, Rules JV5, and Rules JV7. Monitoring of radioactivity for the purpose of evaluation public exposure is dealt with in detail within the Rules JV10. JV10 establishes responsibilities for monitoring in the environment, as well as for operational and emergency monitoring. Reporting requirements are also set in said Rules.

Provisions regarding radon exposure indoors are defined in the Act and in Decree UV4, which also functions as the national radon mitigation plan. SRPA has prepared guidelines for public building on mitigation and reduction of radon. The new building code addresses enforcement of indoor radon levels. SRPA provides also public information material on the health risks of radon.

9.11. SUMMARY

In summary, there is good compliance with IAEA Safety Standards across all areas covered under Module 9. Some areas for improvement with respect to specific regulations (namely Rules JV5 and JV9 in the area of nuclear and radiation facilities, as well as Rules SV3, Rules SV5) were identified by the Regulatory Body during the course of the self-assessment process.

Identified areas of improvement and enhancement include: a program to revise and update regulations and guides on NPPs to address new build; opportunities for SNSA to contribute through guidance to a wider collective understanding on specific issues relevant to safety reporting for geological disposal of spent fuel; and requirements for how the licensee must manage and report incidents in the context of medical uses of ionising radiation.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

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

The SNSA and the SRPA have the authority to regulate on-site emergency preparedness and response within their scopes of responsibility in line with the Decree on Bodies within Ministries. SNSA is responsible for regulating on-site EPR of nuclear and radiation safety, radiation practices and the use of radiation sources, with the exception of medical and veterinary applications, while the SRPA is responsible for regulating on-site EPR of radiation practices and the use of ionizing radiation sources in human and veterinary medicine.

The requirement for having an emergency response plan or equivalent instruction is contained in the Act and is complied with during the licensing process. The required contents of such plans and instructions are stipulated in the Rules on the Safety Assurance of Radiation and Nuclear Facilities (Rules JV9).

The requirement for regular exercises of operating organizations is provided for in the Act, while the intervals to conduct them follow the graded approach according to the Rules on Exercises in the Field of Protection Against Natural and Other Disasters (Rules on Exercises). According to the Rules on Exercises, the management of the exercise is obliged to prepare an exercise evaluation. Additionally, most exercises are independently evaluated by the SNSA for compliance with the emergency plans of the operating organization and for the purpose of identifying any room for improvement.

General provisions for harmonization of the operator's emergency plan with its internal documentation and other plans of the radiation or nuclear facility, as well as with the National Emergency Response Plan for Nuclear and Radiological Accidents (National Emergency Response Plan) are stipulated in the Rules JV9.

Hazard assessment in Slovenia is conducted according to the Act on the Protection against Natural and Other Disasters (Civil Protection Act) and is prepared in cooperation between SNSA and submitted to the Administration for Civil Protection and Disaster Relief (ACPDR) for adoption. A hazard assessment is conducted whenever a need is identified or at least once in every five years.

SNSA, SRPA and ACPDR each have their own inspection plans, but they follow the same Act on Inspections. Within the Act on Inspections and also in the Act there are the necessary provisions for coordination between different regulatory bodies and possible conduct of joint inspections.

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

The IRRS team noted that the Rules JV9 do not apply for instructions to emergency response within the medical applications sector regulated by SRPA. In their case the instruction for emergency response is reviewed by a Radiation Protection Expert contracted by the licensee who afterwards submits it to SRPA for approval during the licensing process. Although general rules for emergency response apply and the use of the Radiation Protection Expert is a recognized concept, without clearly defined contents, the judgement of adequacy of the submitted instruction for emergency response is subject to the opinion of the reviewing SRPA officer.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *For medical radiation practices regulated by SRPA, the required content of instructions for emergency response is not stipulated in the legislative and regulatory framework.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 24 para. 4.34 states that** *"The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization. The applicant shall be required to submit or to make available to the regulatory body, in accordance with agreed timelines, all necessary safety related information as specified in advance or as requested in the authorization process."*
(2)	**BASIS: GSR Part 7 Requirement 2 para. 4.12 states that** *"The regulatory body is required to 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 [7]. These regulations and guides shall include principles, requirements and associated criteria for emergency preparedness and response for the operating organization (see also paras 1.12 and 4.5)."*
R19	**Recommendation: SRPA should formally define the content of the instructions for emergency response for medical radiation practices.**

The Rules JV9 give full authority to the operating organizations to promptly take necessary actions on the site to mitigate the consequences of an emergency, even if the actions could result in off-site consequences. In line with Rules JV9, the operating organizations shall have notification arrangements for prior notification to the regulatory body on the timing of controlled release of radioactive material into the environment.

According to the Rules JV9, the operating organizations need to review and, as appropriate, to revise their emergency arrangements prior to any changes in the facility or activity and during this process they shall also take into account lessons learned from exercises, training, and accidents.

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

According to Rules JV9, it is required that the licence holder's emergency response plan addresses arrangements with off-site response organizations obliged to provide on-site support. These arrangements are verified when the emergency response plans are submitted to the regulatory body during the licensing process and the regulatory body also receives all subsequent revisions of the operating organization's emergency response plan. The SNSA is authorized to inspect implementation of those arrangements during drills and exercises or during regular inspections, during which the operating organization has to give evidence that the off-site organizations have adequate plans, procedures, as well as human and other resources to meet the potential needs to mitigate emergency on-site.

For the Krško NPP, an on-site emergency exercise is held twice a year, while a larger-scale national exercise is held every five years. The SNSA, with the support of external experts from SRPA and the Jožef Stefan Institute, regularly participates in the above-mentioned activities, which include the National Civil Protection Commander (minimum every five years). According to the Rules on Exercises, exercises in emergency management are systematically evaluated. The experience gained in the exercises are applied in the review and updating of the emergency plan of the facility.

Based on the Rules on Exercises, a graded approach is applied to radiation and nuclear facilities by setting the frequency of exercises according to the characteristics and the hazards associated with the facility.

For radiation or nuclear facilities, the emergency plan of a facility is harmonized with the operator's internal documentation and other plans of the facility (e.g. physical protection plans, fire safety plans etc.). This connection between the plans is formally defined in Rules JV9 and the implementation is the subject of inspections.

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

Assignment of responsibilities for protective and response actions

The assignment and division of responsibilities are laid down in the State Administration Act and the Decree on Bodies within Ministries. There are no responsibilities assigned to the regulatory body to advise the operator during a response to an emergency in order not to interfere with the mitigatory actions that are the responsibility of the operator.

The leading regulatory authority for preparedness and response for all hazards on the national level is the ACPDR, while the other two regulatory authorities, which regulate nuclear and radiation safety are the SNSA and SRPA. The SNSA and the SRPA regulate on-site emergency preparedness and response; however, they are also tasked with other roles in national response, which are laid down in the National Emergency Response Plan itself. These include advising the ACPDR on the protective actions to be taken off-site, assessing the evolution of the emergency, facilitating communication between stakeholders, communication with the public, coordination of emergency radiation monitoring etc. These roles are mainly carried out by the SNSA Emergency Response Team (ERT), which is composed of SNSA employees and external experts from SRPA and Jožef Stefan Institute.

The IRRS team noted that the staffing requirement of ERT for a general emergency (21 staff) represents nearly half of SNSA's staff. In this context, any additional reduction in manpower would jeopardize SNSA's capability to perform its duties in the event of an emergency. Additionally, the foreseen mode of operation alternating two shifts of staff (12-hour shifts) is considered suboptimal and might prove inadequate during a long-lasting accident (see recommendation R2).

Noting that the mentioned lack of human resources is a long-standing issue in Slovenia, the IRRS team encourages SNSA, in order to fulfil its responsibilities according to the legal framework, to conduct an in-depth analysis on optimization of the ERT work during long-lasting accidents while taking into consideration the currently available human resources.

Training, qualification, drills and exercises

The general requirement for training all response personnel is stipulated in the Rules on Education and Training in the area of Protection against Natural and Other Disasters with more detailed provisions laid down in the Decree on the Organization, Equipment and Training of First Responders.

To ensure a high level of competence, the SNSA conducts several types of trainings, drills and exercises for their own personnel and the external experts which are a part of their ERT. These include basic training for all members of the team, dedicated training conducted in order for the ERT members to be able to efficiently perform their assigned function in the ERT, and international trainings in relevant international training courses, organized by different organizations. In addition, SNSA conducts exercises on internal, national and international levels. In summary, every member of the ERT undergoes several trainings per year (approx. 25 hours of training per year).

ACPDR has established a dedicated training centre, which provides training programs for civil protection emergency response staff and the staff of civil protection headquarters. The general requirements for this training are in the Civil Protection Act with further details in the Rules on Education and Training in the area of Protection Against Natural and Other Disasters.

Harmonization and coordination

ACPDR inspects the compliance of local, regional and national emergency plans with the provisions for harmonization. Additionally, the Inter-Ministerial Commission for the Monitoring of the Implementation of the National Emergency Response Plan is able to make decisions and provide guidance for all levels when required.

To support the responsibilities of the ERT, SNSA has elaborated detailed procedures for all the aspects needed to be covered in an emergency. These procedures are continuously being improved based on changes of national or international legislation, changes of other subsidiary documentation, equipment and also on the feedback from the ERT and the outcomes of exercises. The ERT has at its disposal the necessary communication tools and a full range of analytical tools to assess the situation and to support the decision making process. To provide for robustness and resilience of these tools and equipment, SNSA uses redundancy and backup alternatives.

To plan, coordinate, monitor and evaluate the implementation of the National Emergency Response Plan, the Government has appointed an Inter-Ministerial Committee, which, inter alia, also participates in the preparation of exercise plans, training programs and in exercises.

The Government of Slovenia has adopted a Protection Strategy for Nuclear and Radiological Emergencies, which was elaborated as a single document in line with the recent IAEA's EPR Series publication and relevant national legal documents and procedures. It has been adopted as a high level document as the principal and long-term strategy to ensure the preparedness of the Republic of Slovenia for nuclear and radiological accidents. The National Emergency Response Plan and other relevant plans and procedures are currently being revised in order to be aligned with the Protection Strategy. The IRRS team recognizes this as a good performance.

10.5. SUMMARY

The legislative framework of Slovenia establishes an adequate regulatory system with clearly assigned roles and responsibilities to support the emergency preparedness and response for radiological and nuclear emergencies.

It is also notable that Slovenia shows strong commitment to continuous improvement of EPR, which is visible in its performance in the EPREV mission and in the adoption of the Protection Strategy for Nuclear and Radiological Emergencies.

The IRRS team encourages the Government of Slovenia to improve the status of human resources allocated for SNSA so that emergency response to a nuclear or radiological emergency would not be compromised.

An additional area for improvement identified by the IRRS team is to clearly define regulatory requirements related to the content of those instructions for emergency response, which are required to be submitted by operating organizations within the medical sector.

11. INTERFACE WITH NUCLEAR SECURITY

11.1. LEGAL BASIS

The Slovenian government has established the legal framework for oversight and enforcement of nuclear security. This includes a state system of accounting for, and control of, nuclear material. The Act is the main legal document establishing roles and responsibilities with regard to physical protection and safeguards of nuclear material and facilities as well as of radiation sources activities and facilities. In the Act, the interface among the concerned authorities is defined and the basic arrangements are set out for the interface. For nuclear facilities, the security requirements are implemented in the physical protection plan as a separate annex to the safety analysis report, thus constituting the basic document for managing the interface and ensuring that conflicting requirements from the safety or security perspective are identified and properly addressed.

For non-nuclear sites, a graded approach is applied, as Slovenia endorsed the IAEA Code of Conduct on the safety and security of radioactive sources, and a physical protection plan and protective measures are required for category 1 and for category 2 to 3 sources respectively.

For transport, Slovenia has incorporated ADR and COTIF in the national legislation.

Slovenia is a party to the Convention on the Physical Protection of Nuclear Material (CPPNM) and its Amendment (aCPPNM), and to all relevant non-proliferation and nuclear weapons ban treaties (e.g. Treaty Banning Nuclear Weapon Tests in the Atmosphere, Comprehensive Nuclear Test Ban Treaty). Slovenia concluded safeguards agreement and additional protocol with the IAEA and entrusted implementation of safeguards to Euratom inspectors as stipulated by the Euratom Treaty.

The interface of safety with nuclear security is addressed in the legal framework. Rules JV5 explicitly states that physical protection measures of nuclear and radiation safety shall be designed and implemented in a coordinated and integrated manner, that decisions and actions related to them shall ensure that physical protection measures do not adversely affect nuclear or radiation safety, or that nuclear or radiation safety measures do not adversely affect physical protection.

11.2. REGULATORY OVERSIGHT ACTIVITIES

The Act assigns responsibilities for the interface to SNSA and SRPA as the regulatory bodies for nuclear and radiation safety in their respective domains, and to the Ministry of the Interior which in three units (Inspectorate, Police, Physical Protection Planning) is responsible for physical protection for nuclear facilities. The Ministry of Interior in particular performs the threat assessment on the basis of various inputs and disseminates the results as appropriate.

Authorization activities at the interface are concentrated around the physical protection plan of the nuclear facility as part of the safety analysis report. Any modification of the physical protection plan is authorized in two steps: SNSA reviews the plan submitted by the licensee to assess that the physical protection measures described are conducive to safety or at least do not have a negative impact on safety. The licensee submits the consent issued by SNSA with the physical protection plan to the Ministry of Interior for the second step of formal approval.

As stated in the Act each authority lays down their own inspection plan. SNSA is informed in advance when the Ministry's Inspectorate unit intends to perform a physical protection inspection at a nuclear facility (usually once a year for the NPP and once every 2-3 years for the other nuclear facilities) so that SNSA's experts may join in the inspection. SNSA receives the inspection report and may so take note of the enforcement actions adopted by the Ministry's Inspectorate unit. Input from SNSA related to interface areas that need to be inspected may be accepted, but the number of inspections is limited.

With respect to cybersecurity, SNSA is putting its expertise at disposal under the umbrella of the Government Information Security Office, acting as liaison for the many national CERTs and the nuclear industry as well as the Slovenian civil protection authorities and international EPR partners. In the field of emergency preparedness SNSA has in fact taken a leading role conducting regular emergency drills with cyber inputs. Furthermore, SNSA has organized a major emergency exercise (postponed to 2022 due to the pandemic) with a cybersecurity scenario at a nuclear facility in order to drill the emergency response staff at the national level (regulators, civil protection authorities, CERTs, nuclear operators and industry), but also testing the international response network. The scenario for the KiVA2022 exercise makes use of real-life hardware and software simulations to be realistic and raise awareness of the responding staff to the technical, organisational and human factors involved in a cyberattack. Experts from several countries (e.g. US, UAE, Germany, Romania, Canada) have confirmed their presence to observe and learn from the unique exercise KiVA2022.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SNSA has trained and developed its competences in the field of cybersecurity at the interface between safety and nuclear security making available internationally recognized experts. In particular SNSA has engaged all national partners for emergency exercises with cyber scenarios as a mean to raise awareness towards cybersecurity and train the network of collaborating EPR organisations to respond to such events. The IRRS team was informed that the IAEA is following such exercises in Slovenia in order to leverage those experiences for a planned IAEA TECDOC based on the Slovenian exercise series KiVA.*	
(1)	**BASIS: GSR Part 1 (Rev 1) para. 2.40 states that** *"Safety measures and nuclear security measures shall be designed and implemented in an integrated manner so that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security."*
(2)	**BASIS: GSR Part 7 para. 4.10 states that** *"The government shall establish a national coordinating mechanism to be functional at the preparedness stage, consistent with its emergency management system, with the following functions: …* *(c) To coordinate and ensure consistency between the emergency arrangements of the various response organizations, operating organizations and the regulatory body at local, regional and national levels under the all-hazards approach, including those arrangements for response to relevant nuclear security events, and, as appropriate, those arrangements of other States and of international organizations;"*
(3)	**BASIS: GSR Part 7 para. 6.12 states that** *"Arrangements shall be developed, as appropriate, for the coordination of emergency preparedness and response and of protocols for operational interfaces between operating organizations and authorities at the local, regional and national levels, including those organizations and authorities responsible for the response to conventional emergencies and to nuclear security events."*
GP1	**Good Practice: SNSA's activities with regards to organising and conducting emergency exercises (KiVA series) based on realistically simulated cyberattacks leading to a safety and nuclear security event were found remarkable for effective training and management of the interface between safety and nuclear security.**

SNSA's experts have established a detailed inspection programme on cybersecurity at nuclear facilities. They have trained SNSA inspectors according to their new internal guidance on "Conducting Cybersecurity Inspections at Nuclear Facilities" and implementation of the programme is well underway.

SNSA has recently introduced in its practical guideline for periodic safety reviews an additional safety factor related to the safety-security interface thus asking the licensee to provide input on, for example, training of security personnel, physical protection as performance indicator, contingency planning, but also security culture, event analysis and cybersecurity. This goes beyond what is expected in the international safety standards and is commended as an area of good performance. The IRRS team was informed that the first such PSR has been submitted by the Krško NPP and is under review.

SNSA is the competent authority for safeguards thus ensuring within its own organisation the correct functioning of the interface between nuclear safety and the State system of accounting for, and control of, nuclear material.

For category 1 sources, physical protection measures are implemented in accordance with the regulations governing the physical protection of nuclear facilities, nuclear and radioactive materials and the transport of nuclear materials, the regulatory activities would then evolve around a physical protection plan and the above coordination between SNSA and the Ministry of Interior would apply. The IRRS team was informed that there are no category 1 sources in Slovenia.

For sources of category 2 and 3 the Rules JV2/SV2 apply, so that source protection combines safety and security and is under the oversight of SNSA/SRPA. Art.43 of JV2/SV2 requires that the security measures are carried out in such a way not to compromise radiation protection and response in case of an emergency. Protective measures are to be described in a special chapter of the radiation protection assessment which is assessed by the regulator during licensing of the radiation source activity or facility (for other regulatory activities related to sources please refer to the previous chapters of the present report).

11.3. INTERFACE AMONG AUTHORITIES

The Act establishes the Commission for physical protection of nuclear facilities and nuclear and radioactive substances as the overarching official coordination group on physical protection led by the Ministry of Interior. The competent authorities and the operators of the Slovenian nuclear facilities are represented in the Commission (except SRPA). The Commission meets regularly twice a year and is tasked with giving opinions and suggestions in the preparation of regulations in the field of physical protection, giving opinions on the threat assessment as prepared by the police, monitoring and coordinating the performance of physical protective measures, and giving recommendations to improve physical protective measures. Opinions and recommendations of the Commissions are reported in the minutes of its meetings. Due to the high-level work of the Commission, the collaboration of the competent authorities at the interface between safety and nuclear security is done operationally on the basis of more personal contacts among those involved and in informal working groups. Thus, setting of priorities and planning of regulatory activities at the interface between safety and nuclear security are not always done in a coordinated manner. A structured cooperation beyond the work of the Commission is missing and the IRRS team was informed that in one case it happened in the past that the Ministry of the Interior approved changes to the physical protection plan of a nuclear facility after the SNSA consent without first consulting with SNSA.

SRPA is not currently a member of the Commission and is therefore not participating in their exchange of experience or keeping abreast of new developments in the field of physical protection through that channel. SRPA is instead participating in two informal exchange groups on illicit trafficking and safe and secure transport.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The daily collaboration among the authorities at the safety-security interface is done on a case by case basis sometimes at the initiative of single individuals. Furthermore, SRPA is not a member of the Commission for physical protection of nuclear facilities and nuclear and radioactive substances as defined in the Act.*	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 12 states that** *"The government shall ensure that, within the governmental and legal framework, adequate infrastructural arrangements are established for interfaces of safety with arrangements for nuclear security and with the State system of accounting for, and control of, nuclear material.""*
(2)	**BASIS: GSR Part 1 (Rev 1) para. 2.40 states that** *"Safety measures and nuclear security measures shall be designed and implemented in an integrated manner so that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R20	**Recommendation: The Government should improve the coordination among the different regulatory bodies and ministerial units at the interface between safety and nuclear security in order to ensure that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security.**
S21	**Suggestion: The Government should consider fully integrating the SRPA in the official collaborative arrangements related to the interfaces between safety and nuclear security.**

11.4. SUMMARY

The Slovenian government has established the legal framework for oversight and enforcement at the interface between safety and nuclear security defining roles and responsibilities of the competent authorities. However, liaison between all relevant competent authorities responsible for nuclear and radiation safety on one hand and nuclear security on the other could be further enhanced to improve coordination and cooperation.

Including aspects of the nuclear safety/security interface as a safety factor in the periodic safety reviews of nuclear facilities is recognized as an area of good performance for SNSA.

Cyberattacks may lead to accidents at the interface between safety and nuclear security and require a major coordination in the response at the national and international level. SNSA's activities related to emergency exercises (KiVA series) with cyber scenarios are outstanding and commended as a good practice.

12. REGULATORY IMPLICATIONS OF PANDEMIC SITUATIONS

As agreed by Slovenia, the scope of the mission covered the national regulatory implications of the COVID-19 pandemic with a focus on business continuity to maintain delivery of statutory duties and responsibilities for safety. This section presents relevant feedback and main conclusions drawn by the IRRS team from the discussions and evaluations made in the course of the mission, with the objective to identify ways to strengthen governmental, legal and regulatory frameworks for safety.

12.1 GOVERNMENTAL AND LEGAL FRAMEWORK FOR SAFETY

The first challenge for a regulatory body, in case of a pandemic situation, is for it to adapt quickly to ensure an adequate level of control of licensees in charge of nuclear facilities and activities is maintained.

A good communication toward the public and the licensees appears to be an important step. This was put in place rapidly in Slovenia through SNSA and SRPA's websites.

The establishment of high-level task forces at SNSA and SRPA made it possible to quickly identify the legal instruments necessary to maintain the legality of operations.

The objective of these task forces was to maintain effective control over operators, the NPP in particular, who continue to produce electricity, and on the other hand not to unnecessarily burden hospitals particularly impacted by COVID-19.

As a result, in Slovenia as in many other countries, the parliament and Government issued the necessary legal instruments to make possible the extension of duration of authorizations even if all the necessary related activities were not totally achieved.

The high level of knowledge and responsibilities of SNSA's and SRPA's staff made possible a rapid adaptation to the pandemic situation.

Remote inspections were carried out with the same legal level as physical inspections on sites.

12.2 REGULATORY FRAMEWORK

The regulatory framework was impacted by the pandemic but remained fully functional. The legislation and existing infrastructure (for example the computer-based document management systems) enabled the transition to teleworking. All involved organizations were able to continue carrying out their duties and new ways of communication were quickly established.

The main impacts were establishing remote work, virtual meetings, and the increased workload of some governmental organizations due to new duties related to management of the pandemic.

The transition to remote working was smooth in general. All employees of SNSA and SRPA were able to work remotely. In the beginning, the Ministry of Public Administration provided help for example in arranging remote meetings. Digital signing of documents was not available in the beginning but was implemented in a few months. Remote communication with the authorized parties and other interested parties functioned without any major problems.

Only a small number, the so called on-duty team, of SNSA and SRPA staff worked at the office during the pandemic. The members of the on-duty team were rotated on a weekly basis.

No specific contingency plans were drafted. Remote working and following the general anti-pandemic measures were enough to ensure a sufficient working force throughout the pandemic. However, the situation made very visible the limited resources of SRPA, as it has only two inspectors. Both SNSA and SRPA experienced some unavailability of inspectors for on-site work due to them belonging to a risk group and due to infections and quarantines.

The Government introduced budget changes to ensure sufficient funds for management of the pandemic. SRPA's budget was not cut, but SNSA's budget was reduced in 2020, and it had to cancel for example some planned training activities.

12.3 REGULATORY FUNCTIONS

Considerations relating to maintaining the resilience of regulatory functions under pandemic situations can be divided into three main thematic areas:

- the ability to adjust the conduct of regulatory functions to remote ways of interaction between staff as well as with licensees and their activities;
- the importance of knowledge transfer and the extent to which this may be restricted by a lack of physical interaction; and
- the implications of the pandemic for staffing levels, both within the regulatory body itself and in terms of critical services and infrastructure provided by others.

There is substantial common experience in all these areas, where the reflections presented in the ARM Summary Report for Slovenia are broadly similar to those of the members of the IRRS team.

The IRRS team was informed that SNSA staff transferred to remote working as soon as the pandemic was declared. Each employee had remote electronic access to documentation from home. A method for e-signature of documents was adopted and only essential on-site inspections were undertaken. A general experience is that regulatory body staff responded well and with commitment to the need for remote working. Although there are inevitable limitations with such working arrangements, the positive aspects of this experience were such that re-adjustment to office working has raised questions about a "new normal" in which teleworking for at least a fraction of time, becomes a standard feature for some staff, at least to the extent that such improvements in work-life balance can be made without detriment to regulatory functions.

After the declaration of the pandemic, the SNSA and SRPA immediately provided on their websites all relevant information regarding their operation and the operation of nuclear facilities. Both required that applicants for authorization communicate via e-mail or telephone. In-person communication was only undertaken in exceptional cases by appointment.

The IRRS team consider that the SNSA's initiative at an early stage of the pandemic to develop written instructions addressed to licensees on how to participate in successful and effective remote inspections is an area of good performance that could be copied and developed by others. At a later stage, the SNSA also worked closely with the Ministry of Health in joint physical inspections to assess the effectiveness of licensees' actions for health protection as well as their implications for safe continued operation. Reactive inspections were performed as usual by SNSA's inspectors.

Following countrywide rules on pandemic measures, the time limits for the performance of procedural actions of the parties were put on hold and the validity of administrative acts (e.g. authorizations) that expired during the implementation of measures under this rules was automatically extended. SRPA was also more flexible in terms of requirements on licensees regarding the time intervals for training and health surveillance.

Remote methods of surveillance and inspection contributed to maintaining necessary oversight, but whether or not this led to a detriment in quality compared with physical inspections is not something that appears to have been successfully measured yet. Some changes in prioritisation were made, according to a graded approach modified by awareness of potential impacts on licensees' own activities (e.g. so as not to put undue burden on healthcare services at the time of a health emergency), in order to maintain the focus of attention on higher hazards. There have not been any reported cases of activities or facilities working

without proper authorization during the pandemic, although some delays arose in the transport of radioactive material across internal EU borders.

Good communication with government and other regulatory authorities is recognised as an important element in providing assurance to licensees and other stakeholders regarding the consistency of the regulatory body's actions with wider protective measures at a time of anxiety and uncertainty. Feedback obtained from licensees during inspections that were observed during the IRRS mission suggests that both SRPA and SNSA were successful in maintaining accessibility and providing advice on matters of compliance in strained situations, such as when suppliers to the licensee were not able to provide an effective service. Some meetings with stakeholders were, however, delayed and/or held virtually.

12.4 EMERGENCY PREPAREDNESS AND RESPONSE

It can be concluded that during the COVID-19 pandemic the emergency system for nuclear or radiological emergencies in Slovenia had to be adapted to the new circumstances. Several exercises were postponed and training was implemented remotely, via video conferences. In the later stages of the pandemic exercises and training were carried out with adjustments to comply with the pandemic restrictions, e.g. number of exercising staff has been reduced, which was remedied by conducting additional exercises to facilitate exercising of all members of ERT.

The SNSA conducted an analysis on the possibility of remote access of ERT members to its information systems, services, applications, and programs. The result showed that currently, due to technical limitations (some systems cannot be accessed remotely on the account of cybersecurity rules) and the fact that remote communication is much slower than personal communication, working remotely, the ERT would almost certainly not be able to meet the time objectives for its tasks. This led to the conclusion that in the event of a nuclear or radiological emergency in Slovenia or abroad with a potential impact on the territory of Slovenia, the ERT should be at least partially activated even in exceptional circumstances, and if necessary, in full scale to perform its work in the Emergency Response Centre. For small-scale emergencies, where the work is limited only to informing the public and relevant organizations and not to the time-critical proposal of protective actions, it was suggested that the team should work remotely in accordance with applicable procedures.

12.5 OVERVIEW AND MAIN CONCLUSIONS OF THE POLICY DISCUSSION

During the policy issue discussions, the host and members from the IRRS team were able to share their experiences from their home states.

All regulatory bodies set up systems to manage the pandemic with the transition to remote working methods implemented quite smoothly.

During the pandemic there was a need for "Business Continuity" of both the regulatory bodies and licensees.

A challenge faced by regulatory bodies in many countries was that of maintaining inspection functions, while also adjusting working practices to minimise risks of contagion and protecting the health of the staff. In this respect, an important consideration is the balance between respect for the measures necessarily taken by licence holders to protect their own staff, particularly those with key safety roles, and the requirement for the regulatory body to have access.

Personal relationships are clearly an important part of team working as well as in knowledge management, where understanding is shared, both formally and informally.

It was felt there is a need to take stock of the situation and to analyses the lessons learnt. It was evident that there are some positives and negatives from the new working practices that were introduced as a consequence of the pandemic as indicated below:

Negatives:

- Negative affect on knowledge management within the organisation.
- Challenge in new recruits getting the necessary training and experiences.
- Reduction in interaction in international meetings, especially at the start of the pandemic.
- Reduced number of physical inspections especially for medical and nuclear facilities.
- Delays or postponements have taken place with respect to authorization and re-authorization processes, which has led to a backlog of issues to be addressed after the return to more traditional ways of carrying out regulatory functions. However, a general experience, shared by several participants in the policy discussion, is that the overall impact on the numbers of inspections conducted was not, in retrospect, particularly great.
- Teleworking can cause tension among employees if there is unequal distribution of work activities.

Positives

- Can promote better work-life balance for employees.
- Staff can be just as productive or even more so when working from home.
- Training and seminars can be conducted efficiently by remote communications tools.
- The increased familiarity with, and use of, IT tools for remote meetings may also provide lasting benefits, not least in terms of reducing the need for long journeys (domestically and internationally).

Now that states have adapted to working in a pandemic it is advisable to review their actions and see what lessons can be learned for the future in pandemic and non-pandemic situations. It appears that the careful use of remote working can be beneficial for work-life balance. A challenge for the future is therefore to learn from experience regarding what is effective while at the same time ensuring that formal and informal elements of knowledge transfer do not suffer. Such a lesson is equally important for the licensees.

APPENDIX I – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS:		
CIUREA-ERCAU Cantemir	National Commission for Nuclear Activities Control	cantemir.ciurea@cncan.ro
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JUG Nina	Slovenian Radiation Protection Administration (SRPA)	nina.jug@gov.si

GROUP PHOTO


PALAČA D·S·U
STATISTIČNI URAD
REPUBLIKE SLOVENIJE
UPRAVA REPUBLIKE SLOVENIJE
ZA JEDRSKO VARNOST

APPENDIX II – MISSION PROGRAMME

Schedule of the initial IRRS mission to Slovenia		
Time	**Date**	**Location and participants**
	Week 0, Sunday, 3 April 2022	
	IRRS Initial Team Meeting	
14:00 - 18:00	• Opening remarks by the IRRS Team Leader. • Introduction by IAEA. • Self-introduction of all attendees. • Refresher presentations - Overview of the IRRS process. - Conduct of the mission. - Regulatory implications of the pandemic. • Mission schedule. • Administrative arrangements (Host Country Liaison Officers, IAEA): premises, transportation, site visits, meals, detailed mission programme. • First impression from IRRS Team members arising from the ARM (summary by all team members). • Groups preparation for interviews.	Venue: IRRS Room (Hotel) Participants: • IRRS Team. • LOs.
18:00 - 20:00	Dinner	
	Week 1, Monday, 4 April 2022	
	IRRS Entrance Meeting	
09:00 - 12:00	09:00 Host Country welcoming address. 09:10 Expectations for the mission (IRRS Team Leader). IRRS Team members' self-introduction. Slovenian Counterparts' self-introduction. 09:40 Host Country presentation on regulatory overview, SARIS results (strengths, challenges, action plan). 10:15 Programme of the IRRS mission (IAEA Coordinator) 10:30 Group photo, coffee break 11:00 Reviewers' preparation at SNSA premises	Venue: DSU Conference Room Participants: • Governmental official. • RB management and counterparts. • Officials from relevant organizations. • IRRS Team. • LOs.
12:00 - 13:00	Lunch	Hosted by SNSA/SRPA

Schedule of the initial IRRS mission to Slovenia		
Time	**Date**	**Location and participants**
	Daily interviews and discussions	
13:00 - 16:30	Parallel interviews and discussions with counterparts for all modules and preparation of preliminary findings (recommendations, suggestions and good practices).	Venue: SNSA and SRPA premises Participants: • IRRS Team. • Counterparts.
17:00 - 18:00	Daily IRRS Team meeting	Venue: IRRS Room (Hotel) Participants: • IRRS Team. • LOs.
18:00 - 20:00	Dinner	
20:00 - 24:00	Report writing	IRRS Team
Week 1, Tuesday, 5 April 2022		
	Daily interviews and discussions	
09:00 - 16:30	Parallel interviews and discussions with counterparts for all modules and preparation of preliminary findings (recommendations, suggestions and good practices).	Venue: SNSA and SRPA premises Participants: • IRRS Team. • Counterparts.
10:00-11:00	Visit to the Minister of the Ministry of the Environment and Spatial Planning.	Venue: premises of Ministry of the Environment and Spatial Planning Participants: • IRRS TL, TC, Reviewers of Modules 1, 2 and 3.
12:00 - 13:00	Lunch	
17:00 - 18:00	Daily IRRS Team meeting	Venue: IRRS Room (Hotel) Participants: • IRRS Team. • LOs.
18:00 - 20:00	Dinner	
20:00 - 24:00	Report writing	IRRS Team

Schedule of the initial IRRS mission to Slovenia		
Time	**Date**	**Location and participants**
	Week 1, Wednesday, 6 April 2022	
	Daily interviews and discussions	
07:30 - 09:00	Travel to sites: • Krško NPP	Participants: • Reviewer of Modules 7-8 for NPP and RR and Reviewer of public exposure.
	• Central Radwaste Storage Facility	• Reviewer for waste management facilities.
	• Linear Accelerator at Jožef Stefan Institute – Tandetron	• Reviewer for sources.
	• Institute of Oncology	• Reviewers for Occupational Radiation Protection and medical exposure.
09:00 - 15:00	Site visits	Sites
09:00 - 15:30	Parallel interviews and discussions with counterparts for all modules and preparation of preliminary findings (recommendations, suggestions and good practices).	Venue: SNSA and SRPA premises Participants: • IRRS Team. • Counterparts.
12:00 - 13:00	Lunch	
13:00-14:00	Visit to Minister of Health.	Venue: premises of Ministry of Health Participants: • IRRS TL, TC, Reviewers of Modules 1, 2 and 3.
15:30 - 16:30	Preliminary findings delivery and compilation	IRRS Team
17:00 - 18:00	• Briefing from the site visits. • Daily IRRS Team meeting: discussion of findings.	Venue: IRRS Room (Hotel) Participants: • IRRS Team. • LOs.
18:00 - 20:00	Dinner	
20:00 - 24:00	Report writing	IRRS Team

Schedule of the initial IRRS mission to Slovenia		
Time	**Date**	**Location and participants**
Week 1, Thursday, 7 April 2022		
	Daily interviews and discussions	
09:00 - 12:00	Parallel interviews and discussions with counterparts for all modules and preparation of preliminary findings (recommendations, suggestions and good practices).	Venue: SNSA and SRPA premises Participants: • IRRS Team. • Counterparts.
12:00 - 13:00	Lunch	
13:00 - 16:30	• Report preparation. • TC/DTC write introductory parts.	Venue: IRRS Room (Hotel) Participants: IRRS Team.
17:00 - 18:00	Daily IRRS Team meeting: discuss observations, bases, recommendations, suggestions, and good practices.	Venue: IRRS Room (Hotel) Participants: • IRRS Team. • LOs.
18:00 - 20:00	Dinner	
20:00 - 24:00	Report writing	IRRS Team
Week 1, Friday, 8 April 2022		
	Report writing	
09:00 - 12:00	• IRRS team writes the report. • TL and DTL review introductory part. • Draft text is submitted by Reviewers to IAEA Administrative Assistant for compiling the report before cross reading.	Venue: IRRS Room (Hotel) Participants: • IRRS Team.
12:00 – 13:00	Lunch	
13:00 - 15:00	Policy issue discussion.	Venue: SNSA Large Conference Room Participants: • IRRS Reviewers. • Counterparts.

Schedule of the initial IRRS mission to Slovenia		
Time	**Date**	**Location and participants**
15:00 – 17:00	Preliminary draft report ready and cross reading	Venue: IRRS Room (Hotel) or individually in the Hotel Participants: IRRS Team.
17:00 - 18:00	Daily IRRS Team meeting: report preparation, finalize bases, recommendations, suggestions and good practices.	Venue: IRRS Room (Hotel) Participants: • IRRS Team. • LOs.
18:00 - 20:00	Dinner	
20:00 - 24:00	• Daily IRRS Team meeting continued: discussion of findings. • Report writing.	Venue: IRRS Room (Hotel) Participants: IRRS Team.
Week 1, Saturday, 9 April 2022		
	Report writing	
09:00 - 18:00	09:00 IRRS Team members draft the report and finalize recommendations, suggestions and good practices. 11:00 Draft report cross reading. 14:00 Finalization of the report by the entire IRRS Team.	Venue: IRRS Room (Hotel) Participants: IRRS Team.
20:00 - 24:00	IRRS Team Lead edits draft report	
Week 1, Sunday, 10 April 2022		
	IRRS Team rest day + cultural events	
Week 2, Monday, 11 April 2022		
	Review and discussions on the IRRS report sections	
09:00 -10:00	Discussion of recommendations, suggestions and good practices with counterparts by module	Venue: SNSA premises Participants: • IRRS Reviewers. • Counterparts.
10:00 - 12:00	• Parallel individual review and discussions of the report sections. • Report writing.	Venue: IRRS Room (SNSA) Participants: IRRS Team.

Schedule of the initial IRRS mission to Slovenia		
Time	**Date**	**Location and participants**
12:00 - 13:00	Lunch	
13:00 - 18:00	Preliminary draft IRRS report is finalised by the IRRS Team.	Venue: IRRS Room (Hotel) Participants: IRRS Team.
18:00 - 20:00	Dinner	
20:00 - 24:00	IRRS Team Lead finalises the preliminary draft IRRS report editing and submits to the Host Institution.	Venue: IRRS Room (Hotel) Participants: IRRS Team Lead
Week 2, Tuesday, 12 April 2022		
	Daily Discussions	
09:00 - 18:00	• Host Institution organises the review of the draft by all national counterparts and start review. • Host Institution finalises the review of the preliminary draft report and submit written comments to the IRRS Team.	Host
18:00	Written comments submitted by the Host to the IRRS Team.	Host
09:00 - 18:00	IRRS Team Lead drafts the executive summary, prepare exit presentation and initiate drafting of the press release.	Venue: IRRS Room (Hotel) Participants: IRRS Team Lead
Week 2, Wednesday, 13 April 2022		
	Daily Discussions	
09:00 - 12:00	IRRS Team reviews Hosts' comments and prepares for discussion with Hosts and addressing their comments.	Venue: IRRS Room (SNSA) Participants: IRRS Team.
12:00 - 13:00	Lunch	
13:00 -16:00	Plenary discussions with Hosts on addressing host comments	Venue: DSU Conference Room (or SNSA Large Conference Room) Participants: • IRRS Reviewers. • Counterparts.
16:00 - 18:00	• IRRS Team meeting for report finalization based on discussions with the Hosts. • IRRS Team Lead final editing of the draft report. • Submission of the Final Draft Report to the Hosts.	Venue: IRRS Room (SNSA) Participants: IRRS Team
18:00 - 20:00	Dinner	

Schedule of the initial IRRS mission to Slovenia		
Time	**Date**	**Location and participants**
20:00 - 21:00	• Briefing of the IAEA official. • Press release finalization.	Venue: IRRS Room (Hotel) Participants: • IRRS Team Lead. • IAEA official. • IAEA Press-Officer.
Week 2, Thursday, 14 April 2022		
	IRRS Exit Meeting	
09:00 - 11:00	• Remarks by IAEA Official. • Team Leader presentation on the main findings of the IRRS mission. • Remarks by the Host Institution in response to the mission findings. • Closing by IAEA Official.	Venue: Hotel Conference Room Participants: • Governmental official. • RB management and counterparts. • Officials from relevant organizations. • IRRS Team. • LOs.
11:00	Publishing of press release	IAEA

APPENDIX III – SITE VISITS

Week 1, Tuesday, 5 April 2022		
09:00-12:00	Site Visit to the Central Interim RW Storage (SNSA Inspector, IRRS Reviewer)	
10:00-11:00	Visit to the Minister (Ministry of the Environment and Spatial Planning), TL, TC, Reviewers of Modules 1, 2 and 3.	
Week 1, Wednesday, 6 April 2022		
07:30 – 16:00	• Krško NPP	Participants: • Reviewer of Modules 7-8 for NPP and RR • SNSA Inspectors
09:00-12:00	• Linear Accelerator at Jožef Stefan Institute – Tandetron	• Reviewer for sources • SNSA Inspector.
09:00-12:00	• Institute of Oncology	• Reviewers for Occupational Radiation Protection and medical exposure. • SRPA Inspector
13:00-14:00	Visit to Minister of Health	TL, TC, Reviewers of Modules 1, 2 and 3.

APPENDIX IV – LIST OF COUNTERPARTS

	IRRS EXPERTS	Lead Counterpart	Support Staff
1.	**RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**		
	Olivier Allain	Igor Sirc, Damijan Škrk	Aleš Škraban
2.	**THE GLOBAL SAFETY REGIME**		
	Olivier Allain	Igor Grlicarev	Jure Škodlar
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**		
	Minna Tuomainen	Aleš Škraban, Damijan Škrk, Igor Sirc	Matjaž Podjavoršek,
4.	**MANAGEMENT OF THE REGULATORY BODY**		
	Paul Brejza	Damijan Škrk, Darja Slokan Dušič,	Selma Fijuljanin, Vesna Logar Zorn
5.	**AUTHORIZATION**		
	John Hunt, Mohammad Qayyum, Michael Egan, Jarlath Duffy, Flavia Teixeira, Aleksi Mattila	Nina Jug, Igor Osojnik, Andreja Peršič, Damijan Škrk, Polona Tavčar	Michel Cindro, Janez Češarek, Tatjana Frelih-Kovačič, Tomaž Nemec, Zoran Petrovič, Jure Škodlar, Dejan Žontar
6.	**REVIEW AND ASSESSMENT**		
	John Hunt, Mohammad Qayyum, Michael Egan, Jarlath Duffy, Flavia Teixeira, Aleksi Mattila, Vaidas Statkus	Nina Jug, Igor Osojnik, Andreja Peršič, Damijan Škrk, Polona Tavčar	Michel Cindro, Janez Češarek, Tatjana Frelih-Kovačič, Tomaž Nemec, Zoran Petrovič, Jure Škodlar, Dejan Žontar
7.	**INSPECTION**		
	John Hunt, Mohammad Qayyum, Michael Egan, Jarlath Duffy, Flavia Teixeira, Aleksi Mattila, Vaidas Statkus	Matjaž Podjavoršek, Dejan Žontar	Helena Janžekovič, Zoran Petrovič,

	IRRS EXPERTS	Lead Counterpart	Support Staff
8.	**ENFORCEMENT**		
	Eszter Retfalvi	Matjaž Podjavoršek, Dejan Žontar	Helena Janžekovič
9.	**REGULATIONS AND GUIDES**		
	John Hunt, Mohammad Qayyum, Michael Egan, Jarlath Duffy, Flavia Teixeira, Aleksi Mattila, Vaidas Statkus	Nina Jug, Igor Osojnik, Aleš Škraban, Damijan Škrk, Polona Tavčar	Michel Cindro, Janez Češarek, Tatjana Frelih-Kovačič, Tomaž Nemec, Zoran Petrovič, Jure Škodlar, Djordje Vojnovič, Dejan Žontar
10.	**10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS**		
	Ivan Klenovic	Metka Tomažič, Nina Jug	Saša Kuhar
11.	**INTERFACE WITH NUCLEAR SECURITY**		
	Rosa Sardella	Samo Tomažič, Janez Češarek	
12.	**REGULATORY IMPLICATIONS OF PANDEMIC SITUATIONS**		
	Olivier Allain, Minna Tuomainen, Michael Egan, Ivan Klenovic, Paul Brejza	Igor Sirc	Aleš Škraban, Igor Osojnik, Andreja Peršič, Matjaž Podjavoršek, Metka Tomažič

APPENDIX V – RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

AREA	R: Recommendations S: Suggestions GP: Good Practices	Recommendations, Suggestions or Good Practices
1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	**R1**	The Government should make appropriate provisions to ensure the independence of SNSA and SRPA is sustained.
	R2	The Government should ensure sufficient funding and human resources for both SNSA and SRPA to fulfil their responsibilities.
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	**S1**	The SNSA and the SRPA should consider requiring authorised expert organizations to inform SNSA and SRPA in advance of subcontracting activities or to changes to their staff.
	S2	SRPA should consider developing a communication strategy and implementing it through a communication plan.
4. MANAGEMENT OF THE REGULATORY BODY	**R3**	The SRPA should further develop their management system to be in line with GSR Part 2 and ensure it is applied, sustained and continuously improved.
5. AUTHORIZATION	**R4**	SNSA and SRPA should further develop guidance on the format and content for the documents to be submitted by the applicant in support of an application for an authorization for all facilities and activities.
	R5	SRPA should develop procedures for the licensing process.
	S3	SNSA should consider requiring the organization responsible for the nuclear installation to demonstrate to SNSA that the nuclear installation will be able to continue to operate in compliance with the safety requirements before a nuclear installation is brought back into operation following a refuelling outage, major maintenance activities, long term shutdown or other significant activities.
	R6	SNSA should develop clearly specified and established procedure for amendment, renewal, suspension or revocation of the authorization for the nuclear power plant and the research reactor.

AREA	R: Recommendations S: Suggestions GP: Good Practices	Recommendations, Suggestions or Good Practices
	R7	The Government should make arrangements to ensure that situations leading to the need for authorisation from both SNSA and SRPA for the same practice are avoided.
	S4	The SNSA and the SRPA should consider amending the Regulations so that the radiation protection assessment includes all the items in GSG-7 for radiation protection programmes.
	R8	The Government should revise the regulation to specify the number of medical and paramedical personnel that needs to be available for a specific facility and activity.
	S5	SNSA should consider amending their regulatory documents on information to be contained in the product labels and on the instructions to be provided with consumer products, to include all items listed in GSR Part 3.
	R9	SNSA should establish requirements for providers of consumer products to provide retailers with appropriate information on safety and instructions on transport and storage.
	S6	The SNSA should consider investigating if aquatic plants as indicators should be added to the environmental monitoring program of Krško NPP for the verification of source monitoring, taking into consideration involved radionuclides, details of the site and the levels of discharges.
6. REVIEW AND ASSESSMENT	**R10**	SNSA should conclude the revision of JV9 and ensure implementation of the requirement related to non-radiological risks.
	R11	The SNSA should develop requirements related to human factors engineering and human-machine interface.

AREA	R: Recommendations S: Suggestions GP: Good Practices	Recommendations, Suggestions or Good Practices
	S7	SNSA should consider including in their internal procedure for safety assessment a requirement for considering good practices in the operation of similar sources, doses from possible future authorized practices, and the views of interested parties in assessing public exposure.
	S8	SRPA should consider investigating what coordinated actions involving relevant parties, such as organizations involved in the construction business, would promote the reduction of indoor radon in Slovenia.
	S9	SNSA should consider utilizing the results from the building material study when drafting a strategy for monitoring of building materials.
7. INSPECTION	**R12**	SNSA should finalize the development of the specific training programme for inspectors to cover principles, concepts and technological aspects, as well as the procedures for inspecting facilities and activities.
	S10	SNSA should consider developing and finalizing the identified inspection procedures for effective inspections of NPPs in the relevant areas. The SNSA should consider developing inspection procedures for RRs.
	S11	SNSA should consider revising the inspection programme to include circumstances under which it is appropriate to carry out further inspections.
	R13	SRPA should revise its inspection programme to include the frequency of inspection for each facility and activity. SNSA and SRPA should fully implement their approved inspection programme for radiation sources facilities and activities.
	S12	SNSA and SRPA should consider further developing standardized inspection checklists to ensure consistency in regulatory inspections of all radiation sources facilities and activities.

AREA	R: Recommendations S: Suggestions GP: Good Practices	Recommendations, Suggestions or Good Practices
	S13	The SRPA should consider ensuring independent verification of tests and measurements in its inspections.
8. ENFORCEMENT	**R14**	SRPA should develop an enforcement policy and establish criteria for responding to non-compliance with regulatory requirements or conditions of authorization.
	S14	SNSA should consider improving its enforcement procedure to indicate when other governmental organizations are to be informed of its formal enforcement actions.
	S15	SNSA should consider training their staff on SNSA's enforcement procedure.
9. REGULATIONS AND GUIDES	**S16**	SRPA should consider implementing a process for systematic periodic review of regulatory safety requirements against relevant international safety standards and technical standards and of relevant experience gained.
	S17	SNSA should consider making a strategic plan to review and develop Regulations and Guides in relation to the new build project.
	S18	SNSA should consider defining the requirements in JV5 for the development and submission of the commissioning programme as part of the licensing applications.
	R15	The SNSA should ensure that planned changes to criteria defined in JV5 regulations are reflected in timely guidance to ARAO for addressing human intrusion scenarios ahead of the next update of the safety analysis for the LILW disposal facility.
	S19	SNSA should consider reviewing regulatory guide 1.03 to reflect changes in regulations since its publication and to take into account the experience of ARAO and the SNSA with its application.

AREA	R: Recommendations S: Suggestions GP: Good Practices	Recommendations, Suggestions or Good Practices
	S20	The SNSA should consider defining regulatory expectations regarding the scope of a potential programme for safe geological disposal of spent fuel and HLW in Slovenia.
	R16	SRPA should require in the regulation the calibration of measuring equipment used for calibration of brachytherapy and nuclear medicine sources.
	R17	The Minister of Health or SRPA should define what kind of unintended or accidental medical exposures need to be investigated.
	R18	The Minister of Health or SRPA should establish a requirement for submission of a written report about the investigation of an unintended and accidental medical exposure and define its content.
10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS	**R19**	SRPA should formally define the content of the instructions for emergency response for medical radiation practices.
11. INTERFACE WITH NUCLEAR SECURITY	**GP1**	SNSA's activities with regards to organising and conducting emergency exercises (KiVA series) based on realistically simulated cyberattacks leading to a safety and nuclear security event were found remarkable for effective training and management of the interface between safety and nuclear security.
	R20	The Government should improve the coordination among the different regulatory bodies and ministerial units at the interface between safety and nuclear security in order to ensure that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security.
	S21	The Government should consider fully integrating the SRPA in the official collaborative arrangements related to the interfaces between safety and nuclear security.

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

A. National legal frame

A.1 Resolutions and Acts

- Resolution on Nuclear and Radiation Safety in the Republic of Slovenia - for the period 2013-2023
- Resolution on the National Programme for Managing Radioactive Waste and Spent Nuclear Fuel
- 2016-2025
- Act on Protection against Ionizing Radiation and Nuclear Safety

A.2 Governmental decrees and ministerial regulations

- Decree on radiation activities - UV1
- Decree on dose limit, reference levels and radioactive contamination - UV2
- Decree on the areas of limited use of space due to a nuclear facility and the conditions of facility
- construction in these areas - UV3
- Decree on national radon programme - UV4
- Decree on the reduction of exposure due to natural radionuclides and existing exposure situations –
- UV5
- Decree on safeguarding of nuclear materials - UV6
- Decree on the criteria for determining the compensation rate due to the restricted use of areas and
- intervention measures in nuclear facility areas - UV8
- Decree on checking of the radioactivity of consignments that could contain the orphan sources -
- UV11
- Decree on the implementation of Council Regulations (EC) and Commission Regulations (EC) on the
- radioactive contamination of foodstuffs and feedstuffs
- Decree on the implementation of Council Regulations (EC) and Commission Regulations (EC) on the
- radioactive contamination of foodstuffs and feedstuffs
- Decree on the method, subject of and conditions for performing a compulsory public utility service
- of long-term surveillance and maintenance of landfill of mining and hydrometallurgical tailings
- resulting from extraction of and exploiting of nuclear mineral raw materials
- Rules on the specialist council on radiation and nuclear safety - JV1
- Rules on the use of radiation sources and on activities involving radiation - JV/SV2
- Rules on authorised experts on radiation and nuclear safety - JV3
- Rules on providing qualification for workers in radiation and nuclear facilities – JV4
- Rules on radiation and nuclear safety factors - JV5

- Rules on radioactive waste and spent fuel management - JV7
- Rules on operational safety of radiation and nuclear facilities - JV9
- Rules on the monitoring of radioactivity - JV10
- Rules on transboundary shipments of radioactive waste and spent fuel - JV11
- Rules on the transboundary shipment of nuclear and radioactive substances - JV12
- Rules on functioning of the Expert Council for the issues of ionizing radiation protection, radiological
- activities, and the use of radiation sources in human and veterinary medicine - SV1
- Rules on the criteria for using ionising radiation sources for medical purposes and for the deliberate
- exposure of individuals for non-medical purposes - SV3
- Rules on special radiation protection requirements and the method of dose assessment - SV5
- Rules on health surveillance of exposed workers - SV6
- Rules on approving of experts performing professional tasks in the field of ionising radiation - SV7
- Rules on authorising ionising radiation protection experts - SV7A
- Rules on the obligations of persons performing radiation practices and holders of ionizing radiation
- sources - SV8
- Rules on radiation protection measures in controlled and monitored areas - SV8A
- Rules on the use of potassium iodide - SV9
- Rules on implementation of national screening programmes for the early detection of precancerous
- changes and cancer
- Rules on monitoring radioactivity in drinking water
- Rules on physical protection of nuclear facilities, nuclear and radioactive materials and transport of
- nuclear materials
- Rule on program for initial professional training and on program for periodic professional training of
- security staff, when performing works in the area of physical protection of nuclear facility and
- nuclear and radioactive material
- Rules on the equipment for inspectors carrying out inspection on physical protection of nuclear and
- radioactive materials and facilities

A.3 Other legislation

Third Party Nuclear Liability

- Act on Liability for Nuclear Damage
- Decree on determining the persons to whom the insurance of liability for nuclear damage is not
- mandatory

Decommissioning of the Nuclear Power Plant Krško

- Act on the Fund for Financing Decommissioning of the Krško NPP and Disposal of Radioactive Waste
- from the Krško NPP
- Instruction on the method of charging and payment to the Fund for Financing Decommissioning of the
- Krško Nuclear Power Plant Krško and Disposal of Radioactive Waste from the Krško NPP

Radioactive Waste

- Act on Cessation of Exploration of the Uranium Mine
- Act on Mining
- Decree on the transformation of the public company for the closure of uranium mine Rudnik
- Žirovski vrh, javno podjetje za zapiranje rudnika urana p.o., into Rudnik Žirovski vrh, javno podjetje za
- zapiranje rudnika urana d.o.o.
- Decree determining the area and of the compensatory amount due to the limited use of the
- environment in the area of Rudnik urana Žirovski vrh
- Decree on Establishment of a Public Agency for Radwaste Management
- Decree on the method and subject of and conditions for performing a public utility service of

radioactive waste management

- Price list of public service of radioactive waste management
- Civil Protection and Disaster Relief
- Act on Protection against Natural and Other Disasters
- Decree on the content and elaboration of protection and rescue plans

Administrative

- State Administration Act
- Inspection Act
- Act on General Administrative Procedure
- Act on Administrative Fees
- Decree on Administrative Authorities within Ministries

Energy

- Energy Act
- Decree on the Transformation of the NEK p.o. into the Public Company Krško NPP, d.o.o.

Environment

- Act on Environmental Protection
- Act on Spatial Planning,

- Building Act
- Decree on environmental encroachments that require environmental impact
- Decree on the method of drafting and on the content of the report on the effects of planned activities
- affecting the environment

General

- Penal Code
- Criminal Procedure Act
- Act on Minor Offences
- Maritime Code
- Act on Transport of Dangerous Goods
- Act on Export of Dual Use Goods
- Order on application of measuring units other than those accepted for use in the Nuclear Power Plant
- Krško
- Decree on procedures for issuing authorisations and certificates and on competence of the
- Commission for the Control of Exports of Dual-Use Items

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)

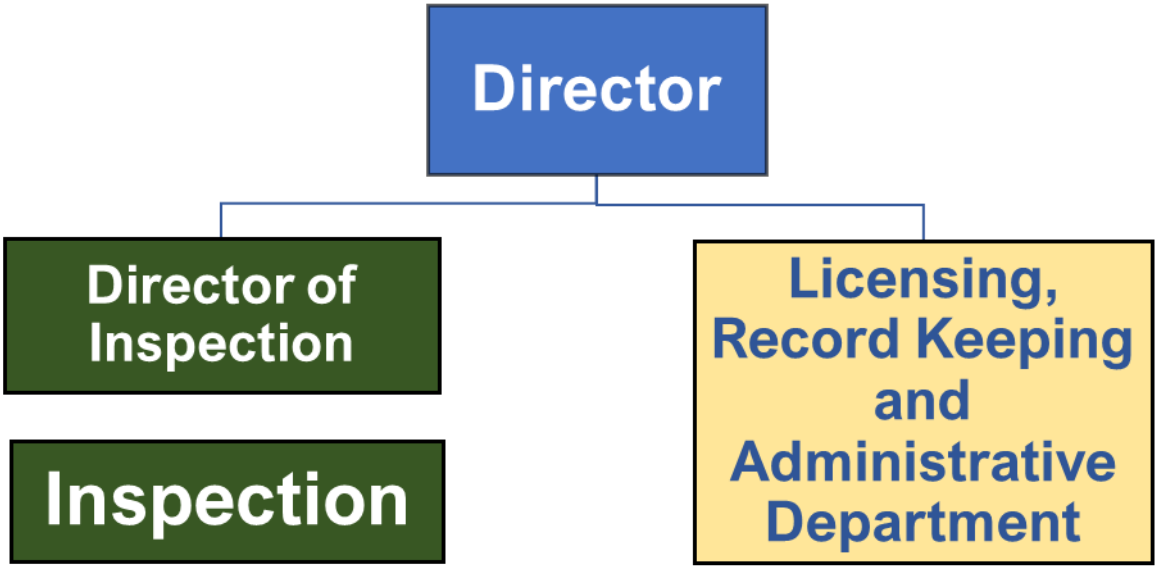
19.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Communication and Consultation with Interested Parties by the Regulatory Body, General Safety Guide Series No. GSG-6, IAEA, Vienna (2017).
20.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Occupational Radiation Protection, Safety Guide Series No. GSG-7 , IAEA, 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)

APPENDIX VIII – ORGANIZATIONAL CHART

SRPA



SNSA