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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

BOSNIA AND HERZEGOVINA

Sarajevo, Bosnia and Herzegovina

28 November to 7 December 2022

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

Integrated
Regulatory
Review Service

IRRS

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Regulatory
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REPORT OF THE
INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
TO
BOSNIA AND HERZEGOVINA

Mission dates:	28 November to 7 December 2022
Regulatory body visited:	State regulatory agency for radiation and nuclear safety (SARNS)
Location:	Sarajevo, Bosnia and Herzegovina
Regulated facilities, activities, and exposure situations in the mission scope:	Radiation Sources in Industrial and Medical Facilities, Radioactive Waste Management, Decommissioning, Transport of Radioactive Material, Emergency Preparedness and Response, Medical Exposure, Occupational Exposure, Public and Environmental Monitoring
Organized by:	IAEA

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

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EXECUTIVE SUMMARY

At the request of the Council of Ministers of Bosnia and Herzegovina, an international team of senior nuclear and radiation safety experts met with representatives of the State Regulatory Agency for Radiation and Nuclear Safety (SRARNS), from 28 November to 7 December 2022, to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the IRRS mission was to perform a peer review of Bosnia and Herzegovina´s national regulatory framework for nuclear, radiation, radioactive waste and transport safety. The review compared Bosnia and Herzegovina´s regulatory framework for safety against IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS team members and Bosnia and Herzegovina counterparts in areas covered by the IRRS.

The IRRS team consisted of 11 senior regulatory experts from 11 IAEA Member States and two IAEA staff members. The review covered the IRRS core modules 1 to 10, i.e. the responsibilities and functions of the government, the global safety regime, responsibilities and functions of the regulatory body, the management system of the regulatory body, the activities of the regulatory body including authorization, review and assessment, inspection and enforcement, regulations and guides, and emergency preparedness and response. Facilities, activities and exposure situations covered included radiation source applications, waste management facilities, decommissioning, transport, occupational exposure, medical exposure, and public and existing exposure situations.

At the request of SRARNS, the IRRS mission included a policy issue discussion on “Radioactive Waste Management” during which the members of the IRRS team and senior staff of SRARNS shared views and regulatory experiences.

The review mission included a series of interviews and discussions with key personnel at the SRARNS.

The IRRS team also observed an on-site inspection conducted by SRARNS at the Radiology Department of the University Clinical Center, Sarajevo. Site visits were performed at the Institute for Public Health Federation of Bosnia and Herzegovina – Waste storage facility in Rakovića and at the TLD Laboratory of the same Institute. A visit was performed at the Operational and Communication Centre of Bosnia and Herzegovina (BiH – 112), to discuss matters relevant to Emergency Preparedness and Response.

The IRRS team members reported very favourably on the professionalism of the SRARNS staff in the preparation and conduct of the inspection. During the site visits, open discussions took place with the management level and the Radiation Protection Officers (RPO) of the authorized parties.

In preparation for the IRRS mission, SRARNS conducted a self-assessment and prepared a preliminary action plan. The results of the self-assessment and supporting documentation were provided to the IRRS team as advance reference material for the mission. The IRRS team was positively impressed by the extensive preparation, expertise and dedication of SRARNS taking also into consideration the limited number of staff. The IRRS team was extended full cooperation in the regulatory, technical, and policy discussions with the management and staff of SRARNS, in a very open and transparent manner.

Throughout the mission, the administrative and logistical support, as well as the hospitality, were outstanding.

The IRRS team acknowledged good performances: (a) the detailed regulatory requirements defining the competencies of the qualified experts and (b) the possibility for pregnant occupationally exposed workers to choose different options for their work conditions in a non-discriminative manner.

The IRRS team report includes a number of recommendations and suggestions to improve the SRARNS regulatory system and the effectiveness of the regulatory functions in line with IAEA safety standards. The IRRS team recognizes that many of its findings confirm the actions for further improvement that were

identified in SRARNS´s self-assessment and that Recommendations and Suggestions addressed were already included in the action plan included in the ARM. The IRRS team concluded that the following issues are representative of those which, if addressed by the Government of Bosnia and Herzegovina and SRARNS, should further enhance the overall performance of the regulatory system.

The Council of Ministers should:

- revise and implement the policy for safety in line with IAEA safety standards;
- provide SRARNS with adequate human and financial resources to fulfil its' regulatory responsibilities and functions for safety;
- revise and implement the strategy for the radioactive waste management to ensure the effective management and control of radioactive waste in the country.

SRARNS should:

- apply a graded approach in its regulatory functions;
- further develop its management system;
- revise some of the regulations in the fields of radiation protection, radioactive waste management, transport activities and emergency preparedness and response and ensure the compliance with IAEA safety standards;
- develop additional guidance to facilitate the implementation of the regulatory provisions.

The IRRS Team believes that the recommendations and suggestions, if acted upon, will contribute to meeting these challenges and enhance nuclear and radiation safety in Bosnia and Herzegovina.

To conclude, in inviting the IAEA to conduct this IRRS mission and providing a transparent self-assessment, the Council of Ministers of Bosnia and Herzegovina and the Regulatory Body SRARNS, 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 Council of Ministers of Bosnia and Herzegovina, an international team of senior safety experts met representatives of the State Regulatory Agency for Radiation and Nuclear Safety (SRARNS) from 28 November to 7 December 2022 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the legal and regulatory framework for nuclear and radiation safety in Bosnia and Herzegovina. The review mission was formally requested by the Council of Ministers of Bosnia and Herzegovina in April 2018. A preparatory mission was conducted 9 to 10 March 2022 at SRARNS Headquarters in Sarajevo to discuss the purpose, objectives, and detailed preparations of the review in connection with regulated facilities and activities in Bosnia and Herzegovina and their related safety aspects and to agree the scope of the IRRS mission.

The IRRS team consisted of 11 senior regulatory experts from 11 IAEA Member States, one IAEA staff member and two IAEA administrative assistants. The IRRS team carried out the review in the following areas: responsibilities and functions of the Council of Ministers 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, a policy issue on radioactive waste management was discussed.

SRARNS conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of the self-assessment and supporting documentation were provided to the IRRS Team as advance reference material for the mission. During the mission the IRRS team performed a systematic review of all topics within the agreed scope through review of the Bosnia and Herzegovina advance reference material, conduct of interviews with management and staff from SRARNS and direct observation of the regulatory activities at regulated facilities.

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

II. OBJECTIVE AND SCOPE

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

The key objectives of this mission were to enhance the national governmental, legal 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 Council of Ministers) with a review of its regulatory technical and policy issues;

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

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

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

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

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

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

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

j) promoting the application of IAEA Safety Requirements; and

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

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IRRS TEAM

At the request of the Council of Ministers of Bosnia and Herzegovina, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 9 to 10 March 2022. The preparatory meeting was carried out by the at that time appointed Team Leader Ms Isabel Delgado Villanueva and the IRRS IAEA Team Coordinator Ms Vasiliki Kamenopoulou.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of SRARNS represented by Mr Emir Dizdarević SRARNS Deputy Director, 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:

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

Mr Emir Dizdarević made presentations on the national context, the current status of SRARNS 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 Bosnia and Herzegovina in November 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 SRARNS Liaison Officer for the IRRS mission was confirmed as Mr Emir Dizdarević.

SRARNS provided IAEA with the advance reference material (ARM) for the review at the end of September 2022. In preparation for the mission, the IAEA review team members reviewed the 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, 27 November 2022 in Sarajevo, directed by the newly appointed IRRS Team Leader Igor Sirc and the IRRS IAEA Team Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS programme. The understanding of the methodology for review was reinforced. The agenda for the mission was presented to the team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

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

The IRRS entrance meeting was held on Monday, 28 November 2022, with the participation of SRARNS senior management and staff. Opening remarks were made by Mr Marinko Zeljko, Director of SRARNS, Mr Zoran Tešanović and Mr Emir Dizdarević, Deputy Directors of SRARNS, Mr Samir Huseinbašić, Representative of the Ministry of Foreign Affairs and Mr Igor Sirc, IRRS Team Leader.

Mr Emir Dizdarević gave an overview of the Bosnia and Herzegovina legal and regulatory framework, facilities and activities in the country as well as the action plan prepared as a result of the pre-mission self-assessment.

During the IRRS mission, a review was conducted for all review areas within the agreed scope with the objective of providing the Council of Ministers and SRARNS with recommendations and suggestions for improvement and where appropriate, identifying good practices or good performances. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations regarding the governmental, legal, 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 Wednesday, 7 December 2022. The opening remarks at the exit meeting were presented by Mr Zoran Tešanović, Deputy Director of SRARNS and were followed by the presentation of the results of the mission by the IRRS Team Leader, Mr Igor Sirc. Closing remarks were made by Ms Vasiliki Kamenopoulou, IAEA Team Coordinator on behalf of Mr Peter Johnston, Director, Division of Radiation, Transport and Waste Safety, IAEA.

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

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

The Council of Ministers of Bosnia and Hercegovina (hereinafter the Council of Ministers) adopted the "Policy on the safety of ionizing radiation sources in Bosnia and Herzegovina" (hereinafter the Policy) in 2012 and thus expressed a high-level political commitment to radiation and nuclear safety. The Policy stipulates the main objectives and principles of the safety of ionizing radiation sources and contains five specific policies: radiation safety; nuclear safety; safe management of radioactive waste; safe transport of radioactive material; and security of radioactive and nuclear material.

For its implementation, the Policy sets the adoption of appropriate strategic and operational plans. The IRRS team was informed that such plans have not been adopted, but the State Regulatory Agency for Radiation and Nuclear Safety (hereinafter SRARNS) takes the Policy into account in the preparation of its annual working plan for the Council of Ministers and in the annual report on radiation safety in Bosnia and Hercegovina for the Parliament.

Although the Policy takes into account substantial part of the requirements of IAEA GSR Part 1 (Rev.1), reference for the following matters is missing:

- The need for human and financial resources of all stakeholders;
- The framework for research and development;
- The promotion of leadership and management for safety.

One of the objectives of the Policy is to establish a framework for regulatory activities of SRARNS as a state body having regulatory responsibilities inter alia in radiation safety, nuclear safety, safe management of radioactive waste, safe transport of radioactive material and the security of radioactive and nuclear material. In the area of safe management of radioactive waste, the Policy also assigned SRARNS the responsibility to resolve the issue of permanent disposal of radioactive waste.

The assignment of the responsibility to seek possible solutions, for disposal of radioactive waste to SRARNS may compromise or conflict with its regulatory activities. SRARNS has regulatory responsibilities of licensing and inspecting the operation of the central storage facility and of licencing disposal of radioactive waste, on the territory of Bosnia and Hercegovina.

The IRRS team was informed that the Policy is envisaged to be revised.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Policy on the safety of ionising radiation sources in Bosnia and Herzegovina does not include provisions relevant to the need for human and financial resources of all stakeholders, the framework for research and development and the promotion of leadership and management for safety. Also, in the Policy, the responsibility for finding solutions for the disposal of radioactive waste is given to the SRARNS, a responsibility that may compromise or conflict SRARNS effective independence and its regulatory activities in the same area.	
(1)	**BASIS: GSR Part 1 Requirement 1, para. 2.3 states that** *"National policy and strategy for safety shall express a long-term commitment to safety. The national policy shall be promulgated as a statement of the government's intent. The strategy shall set out the mechanisms for implementing the national policy. In the national policy and strategy, account shall be taken of the following:* *…*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	(d) The need and provision for human and financial resources; *(e) The provision and framework for research and development;* *…* *(g) The promotion of leadership and management for safety, including safety culture."*
(2)	**BASIS: GSR Part 1 Requirement 4, para. 2.9 states that** *"No responsibilities shall be assigned to the regulatory body that might compromise or conflict with its discharging of its responsibility for regulating the safety of facilities and activities."*
R1	**Recommendation: The Council of Ministers should revise the Policy for safety to be in line with IAEA GSR Part 1 (Rev.1) requirements.**

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

Bosnia and Herzegovina has established a legal framework for safety with the Law on Radiation and Nuclear Safety in Bosnia and Herzegovina (hereinafter the Law) in 2007. The aim of the Law is the protection of people and environment against ionising radiation and applies to all situations that include exposure or potential exposure to ionising radiation and covers all types of facilities and activities using radiation sources.

The Law provides for the establishment of SRARNS as a single authority, the regulatory body for nuclear and radiation safety and nuclear security, responsible for the regulatory control over all activities, facilities and exposure situations.

The Law empowers SRARNS to issue regulations and guides for the implementation of the legal provisions. It defines the enforcement instrument as penal provision and empowers SRARNS inspectors to carry out their inspection and initiate enforcement processes.

Based on the Law, SRARNS adopted a set of various regulations.

The regulatory framework sets out, *inter alia*, the following:

- The safety principles for protecting people and the environment from radiation risks, both now and in the future;
- The types of activities included within the scope of the safety framework;
- The types of authorization;
- The establishment of the regulatory body;
- Provisions for involvement of interested parties in decision making;
- Provisions for assigning legal responsibility for safety to the authorized parties;
- Provisions for review and assessment;
- The authority and responsibility of the regulatory body for preparing or issuing regulations and guides for their implementation;
- Provision for inspection of activities and enforcement of regulations;
- Provision for preparedness for, and response to, a nuclear or radiological emergency;
- The criteria for release from regulatory control;
- The specification of offences and the corresponding penalties;
- Provision for controls of the import and export of ionizing radiation sources and their tracking within the territory of Bosnia and Herzegovina.

The IRRS Team was informed, that SRARNS is systematically reviewing the regulatory framework to be in line with the IAEA safety standards.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

SRARNS was established by the Law in 2007 and became operational in 2008.

SRARNS performs tasks as set in the Law that include *inter alia:* defining the policy and the principles of safety; preparing and issuing regulations and guides; establishing and implementing procedures for notification, authorization, inspection and enforcement of regulatory requirements; inspecting the safety of radiation sources; issuing, amending, suspending, revoking, and imposing authorization requirements for import, export, production, acquisition, receipt, possession, storage, use, transit, transport, maintenance, recycling and disposal, as well as for any other activity related to radiation sources; issuing, amending, suspending or revoking authorizations granted to technical services; determining exclusions and exemptions; taking protective actions in radiological and nuclear emergencies; establishing and maintaining a national register of radiation sources and occupationally exposed workers; cooperating with other administrative bodies and other institutions and disseminating public information about the matters related to ionizing radiation; cooperating with other countries and relevant international organizations; taking measures for monitoring and discovering orphan sources; implementing the obligations assumed by Bosnia and Herzegovina under the international conventions and bilateral agreements related to radiation and nuclear safety and the application of safeguards for the purpose of non-proliferation of nuclear weapons.

Independence of SRARNS

SRARNS is established as an independent state administrative body, subordinated directly under the Council of Ministers and reporting only to the Council of Ministers. As such, it is functionally separate from any other body with interests or responsibilities that could unduly influence regulatory decision making, such as the promotion or utilization of nuclear energy or ionizing radiation in general.

SRARNS is effectively independent of undue influence in its decision making on radiation safety matters and can make independent regulatory decisions. However, the Appeals Committee of the Council of Ministers has powers to amend the decisions made by SRARNS. **Recommendation R7 in Section 3.2 addresses this issue.**

Resources of SRARNS

The IRRS team was informed that from an initial assessment in 2008 of competence requirements a complement of 34 employees is required. SRARNS currently has 18 employees including administrative staff.

The IRRS Team was informed that a prior agreement from the Council of Ministers is required for employing new staff in governmental institutions. In recent years SRARNS has not been allowed to employ new staff, or to replace retiring or leaving staff.

SRARNS' financial resources are provided through the annual state-level budget. SRARNS' estimation of needed resources is assessed by the Ministry of Finance which prepares a final proposal for the Council of Ministers. The IRRS Team was informed that the basis for a final proposal by the Ministry of Finance is based on the budget of the previous year.

Due to limited human and financial resources, SRARNS experiences difficulties in fulfilling its obligations in some areas such as inspection, authorization, preparation of regulations and emergency preparedness and response.

Taking into account the number of facilities and activities, the IRRS team considers that SRARNS does not have a sufficient number of competent staff to perform its functions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: SRARNS does not have sufficient financial and human resources to properly carry out its 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; …"*
R2	**Recommendation: The Council of Ministers should ensure sufficient financial and human resources for SRARNS to fulfil its responsibilities.**

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

The first IAEA fundamental principle on the prime responsibility for safety is detailed in the Law.

SRARNS is empowered to perform inspections and to act in case of violation of legislation and regulations. Carrying out an activity involving radiation or the use of radiation sources without an authorization is prohibited by the Law.

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

The Regulatory Body requirements do not relieve authorised parties from their prime responsibility for safety.

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

SRARNS is the regulatory body responsible for nuclear and radiation safety in Bosnia and Herzegovina. As SRARNS has been established as the only competent authority in the country performing regulatory functions in the field of ionizing radiation, possible omissions, undue duplication, or conflicting requirements imposed on various authorized parties are excluded.

In some areas, such as in emergency preparedness and response, in environmental radioactivity monitoring or in security matters, SRARNS efficiently cooperates with other relevant state authorities.

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

SRARNS is responsible for implementing a system to reduce risks from exposure to ionizing radiation and has set up a system for detecting and recovering orphan sources in the regulation of high-activity sealed sources and orphan sources. The regulation sets provisions for detection equipment in scrap metal yards and recycling facilities, cooperation between SRARNS and the customs authorities at the border crossing points, training of the workers, guides for handling orphan sources and on SRARNS campaigns to regain control over potential orphan sources.

Not all provisions for protective measures needed to reduce existing radiation risks are put in place. The IRRS team was informed that setting provisions to manage undue radiation risks associated with natural radionuclides is among the development priorities of SRARNS. **Recommendation R14 in Section 6.8 addresses this issue.**

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

The governmental policy and strategy on radioactive waste management was published in two separate documents - 'Policy on the safety of ionizing radiation sources in Bosnia and Herzegovina' (2012) and 'Strategy on Radioactive Waste Management in Bosnia and Herzegovina' (2014).

The objective of the 'Policy' is to establish an efficient and transparent radiation protection system ensuring the basis for protection of people and the environment from harmful effects of ionising radiation in accordance with international standards. The 'Policy' lists several specific policies, including the policy on the safe management of radioactive waste.

The 'Strategy' is dedicated to radioactive waste management only and defines objectives, requirements, and methods for their achievement through defining the roles and responsibilities of the subjects involved in generation, transport, processing, and storage of radioactive waste. The 'Strategy' uses radioactive waste classification in accordance with the IAEA GSG-1. The document contains several tables with the overview of institutions/organizations possessing radioactive sources, including radioactive lightning rods. However, it is not clear how many of these sources can be sent back to foreign suppliers or be recycled. Furthermore, the amount of radioactive waste (current and generated in the future), including radioactive waste from past activities, is not clearly quantified in the 'Strategy' despite of the fact, that the Regulations on radioactive waste management expect that the Agency will establish and maintain a separate register of radioactive waste within the National Register of Radiation Sources.

The 'Strategy' expects that a centralized approach to radioactive waste management will be implemented, which means the storage of radioactive waste in a single facility for the entire Bosnia and Herzegovina territory.

The development of the disposal facility is not explicitly considered in the 'Strategy' and the country strives to dispose its radioactive waste in a foreign disposal facility. The conditioned radioactive waste may not comply with the acceptance criteria for foreign or national disposal facility. Therefore, the interdependencies between the various steps in the management of radioactive waste cannot be considered in full scope, covering radioactive waste management options available.

The observation from the site visit at premises of the Public Health Institute of the Federation of Bosnia and Herzegovina, Centre of Radiation Protection is that there is a lack of coordination among governmental bodies involved in radioactive waste management, especially in the process of development of central radioactive waste storage facility. This issue is also evident from the 'Strategy', which also does not specify the responsibility for the development of this facility, nor contain clear milestones and key performance indicators for this task. This observation supports the conclusion, that there is no effective management and control of radioactive waste in Bosnia and Herzegovina.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: The arrangements for the implementation of national policy for radioactive waste management are not sufficient due to the lack of coordination among involved governmental bodies. At the same time the 'Strategy' does not clearly set up responsibility for the development of the central radioactive waste storage facility and milestones to reach the construction, commissioning and operation of this facility. There are also no provisions in the 'Strategy' for SRARNS to develop and maintain a detailed inventory of radioactive waste including disused sources, which cannot be recycled or returned to the country of origin, that could be used for the implementation of the national radioactive waste management policy and strategy.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Also, options such as the development of a national disposal facility or the identification of foreign disposal facility are not considered in detail in the 'Strategy'.	
(1)	**BASIS: GSR Part 5 Requirement 2 states that** *"To ensure the effective management and control of radioactive waste, the government shall ensure that a national policy and a strategy for radioactive waste management are established. The policy and strategy shall be appropriate for the nature and the amount of the radioactive waste in the State,…The national policy and strategy shall form the basis for decision making with respect to the management of radioactive waste."*
(2)	**BASIS: GSR Part 5 Paragraph 3.6 states that** *"The national strategy for radioactive waste management has to outline arrangements for ensuring the implementation of the national policy. It has to provide for the coordination of responsibilities. It has to be compatible with other related strategies such as strategies for nuclear safety and for radiation protection."*
(3)	**BASIS: SSG-45 Paragraph 3.18 states that** *"In order to facilitate the establishment of a national policy and strategy, the government should establish a national inventory of radioactive waste (both current waste and anticipated waste, including waste generated during the decommissioning and dismantling of facilities) and should update it at regular intervals."*
(4)	**BASIS: GSR Part 5 Requirement 2 para 3.5 states that** *"The national policy on radioactive waste management has to set out the preferred options for radioactive waste management. It has to reflect national priorities and available resources and has to be based on knowledge of the waste to be managed (e.g. knowledge of the inventory and of waste streams) now and in the future…."*
(5)	**BASIS: GSR Part 5 Requirement 6 states that** *"Interdependences among all steps in the predisposal management of radioactive waste, as well as the impact of the anticipated disposal option, shall be appropriately taken into account."*
(6)	**BASIS: GSR Part 1 Requirement 10, para. 2.30 states that** *"Radioactive waste generated in facilities and activities shall be managed in an integrated, systematic manner up to its disposal. The interdependences of the steps in the entire management process for radioactive waste, and likewise for spent fuel, shall be recognized"*
R3	**Recommendation: The Council of Ministers should ensure effective management and control of radioactive waste.**

1.8. COMPETENCE FOR SAFETY

The commitment from the Council of Ministers to deliver the necessary provisions for building and maintaining the competence of all parties with responsibilities in relation to the safety of facilities and activities is implicitly incorporated in the Policy outlining that particular attention is to be paid to improvement of knowledge and skills of all actors in the radiation protection system.

These provisions support the following parties with safety responsibilities:

- Authorized parties;
- Qualified experts;
- Technical services;

- SRARNS.

Mandatory training for persons responsible for radiation protection and persons working with radiation sources in different fields are prescribed in the Regulation on training in ionizing radiation protection. This regulation sets types and programs of training as well as provisions for refresher training.

SRARNS has developed and adopted the concept of qualified experts, which are certified legal or natural persons providing expertise in a specific field. Today there are around 25 qualified experts in the country. To regulate the activities of qualified experts SRARNS has established the 'Regulation on recognition of the qualified expert status', which defines the system of recognizing the status of qualified expert in radiation protection, in radioactive waste management or in the transport safety of radioactive material. This regulation specifies the duties of qualified experts, criteria and procedure for recognition of the expert status, the contents of the application form, the contents and layout of the certificate of recognition of the expert status and the syllabus of the required knowledge of the qualified expert. Further details on obligation of qualified experts are provided in regulations to specific areas of their duties. For instance, the regulation on radioactive waste management sets out requirements for employing a qualified expert in radioactive waste management.

The IRRS team considers the detailed regulatory requirements defining the competencies of the qualified experts as a good performance.

Regulation on technical services for ionizing radiation protection sets out necessary competence levels for persons employed in technical services. SRARNS provides training for its staff to ensure they are competent and qualified for the work they perform in the regulation of safety.

The IRRS team was informed that Bosnia and Herzegovina educational institutions offer different study programmes, but there is a general lack of interest for technical studies and for the area of radiation safety, which may represent a risk for the general level of competencies in the country in future.

1.9. PROVISION OF TECHNICAL SERVICES

The Law enables SRARNS to authorize technical services to provide services in the area of radiation protection. SRARNS adopted the "Regulation on technical services for ionizing radiation protection" that provides for the types of external technical services in this area. The Regulation sets provisions for twelve types of technical services, including radiation safety control, medical physics, radiation monitoring of the environment, medical surveillance of exposed workers, calibration of measuring instruments and training. Technical services are required to obtain an authorization from SRARNS. Authorization requirements, such as the required qualifications of personnel, equipment and premises, accreditation, as well as the content of the reports and certificates issued by technical services are set in the Regulation.

The IRRS team was informed that several laboratories in Bosnia and Herzegovina have appropriate equipment to analyse, and instrumentation to evaluate, different samples containing a wide range of radionuclides. However, a wider scope of capabilities to evaluate intakes of radioactive materials such as whole body counting is not accessible in Bosnia and Herzegovina, nor are arrangements put in place to ensure the provision of this service from an institution outside the country. When efforts on waste management are elaborated, the treatment of waste may result in internal exposures, thus it is needed that arrangements should be available to determine occupational exposures from intakes.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The capabilities in the country are limited to perform dosimetry in case of internal exposures.	
(1)	**BASIS: GSR Part 1 Requirement 13 states that** "*The government shall make provision, where necessary, for technical services in relation to safety, such as services for personal dosimetry, environmental monitoring and the calibration of equipment.*"
(2)	**BASIS: GSR Part 1 Requirement 13, para. 2.41 states that** "*Technical services do not necessarily have to be provided by the government. However, if no suitable commercial or non-governmental provider of the necessary technical services is available, the government may have to make provision for the availability of such services. The regulatory body shall authorize technical services that may have significance for safety, as appropriate.*"
R4	**Recommendation: The Council of Ministers should make provisions to ensure that internal dosimetry is made available to exposed workers.**

1.10. SUMMARY

In Bosnia and Herzegovina there is a Law on Radiation and Nuclear Safety. The Council of Ministers has set a national policy and strategy for safety. The regulatory framework for safety includes a set of regulations.

The Law establishes SRARNS as an independent regulatory body, subordinated directly under the Council of Ministers and performing administrative and professional operations in the field of ionizing radiation.

The Council of Ministers established a legal framework for radioactive waste management, however, there is no effective management and control of radioactive waste.

The IRRS team considers the detailed requirements for the qualified experts as a good performance.

The IRRS team found some areas for improvement related to the revision of the Policy and Strategy for Safety, the provision of sufficient financial and human resources for SRARNS, the effective management and control of radioactive waste and the provision of internal dosimetry services.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Bosnia and Herzegovina is a participant under the international global safety regime, and has signed, ratified and implemented the following international conventions:

- Convention on Nuclear Safety;
- Convention on the Physical Protection of Nuclear Materials (and its Amendment);
- Vienna Convention on Civil Liability for Nuclear Damage (and the Protocol);
- Convention on Assistance in Case of a Nuclear Accident or Radiological Emergency;
- Convention on Early Notification of a Nuclear Accident;
- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.

Regarding safeguards, Bosnia and Herzegovina has ratified the:

- Application of Safeguards in connection with the Treaty on Non-Proliferation of Nuclear Weapons;
- Agreement between Bosnia and Herzegovina and the IAEA for the Application of Safeguards in connection with the Treaty on the Non-Proliferation of Nuclear Weapons;
- Protocol Additional to the Agreement between Bosnia and Herzegovina and the IAEA for the Application of Safeguards in connection with the Treaty of Non-Proliferation of Nuclear Weapons.

IRRS team was informed that Bosnia and Herzegovina is in the process of acceding to the Joint Protocol Relating to the Application of the Vienna Convention and the Paris Convention.

Bosnia and Herzegovina has made political commitment to the Code of Conduct on the Safety and Security of Radioactive Sources. Furthermore, Bosnia and Herzegovina has notified the IAEA of its intention to act in accordance with the Guidance on the Import and Export of Radioactive Sources and has nominated a Point of Contact for the purpose of facilitating the export and/or import of radioactive sources. In addition, the country has made available the responses to the Importing and Exporting States Questionnaire and notified IAEA of its commitment to implement the Guidance on the Management of Disused Radioactive Sources.

Through SRARNS, Bosnia and Herzegovina fulfills its obligations resulting from the above international instruments and regularly submits national reports, and participates at the meetings.

Regarding IAEA Technical Cooperation Agreements, Bosnia and Herzegovina has ratified the Revised Supplementary Agreements concerning the Provision of Technical Assistance by the IAEA (RSA). Bosnia and Herzegovina actively participates in many IAEA Technical Cooperation regional projects and is the beneficiary of national projects.

Additionally, the IRRS team was informed that Bosnia and Herzegovina has signed memorandums of understanding (MoU) with several neighboring and other countries in the region. These MoUs are not intended to be considered as international agreements signed under the rules of the Vienna Convention on the Law of Treaties. They are agreements exclusively between the respective regulatory bodies. SRARNS has signed such MoUs with the regulatory bodies of Slovenia, North Macedonia, Montenegro, and Albania and they concern exchange of safety-related information, exchange of experience in the field of authorization and performing inspections and training of regulatory body staff. Furthermore, initial steps

have been taken to strengthen the cooperation of Bosnia and Herzegovina with the Republic of Croatia and the Republic of Serbia by signing MoUs.

SRARNS hosted an IAEA Emergency Preparedness Review Service (EPREV) in 2012, an Advisory Mission for Safety (AMRAS) in 2015 and an Occupational Radiation Protection Appraisal Service (ORPAS) in 2018.

Also, using the European Union (EU) Instrument for Pre-accession Assistance (IPA), several assessments of the regulatory infrastructure for radiation safety were performed.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

Bosnia and Herzegovina participates in the IAEA Incident and Trafficking Database (ITDB) system for reporting incidents within the scope of illicit trafficking and other unauthorized activities involving radioactive material.

As a party to the Assistance Convention and Convention on Early Notification, SRARNS uses the IAEA's Incident and Emergency Center's website (USIE) for secure exchange of emergency information and for requesting assistance, if needed.

The process for Bosnia and Herzegovina to become part of the European Community Urgent Radiological Information Exchange (ECURIE) system has been initiated.

SRARNS has put in place some arrangements for collecting and carrying out analysis to identify lessons learned from regulatory experience, including experience in other states.

SRARNS participates in a series of European and other international conferences, symposiums, workshops, and meetings. It also cooperates with persons who have extensive operating experience and works closely with the authorized parties and Technical Services to gain insight from their established operating experience feedback programs.

SRARNS uses authorization and inspection experience in a process of updating legislation and regulation. Lessons from experiences are also considered in the review of the management system of SRARNS.

SRARNS has no procedure for the systematic collection and analysis of operating and regulatory experiences and for the dissemination of lessons learned for their use by all stakeholders.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: SRARNS makes some efforts to collect and share operating and regulatory experiences, however this is not done on a systematic basis and there is no relevant procedure in this respect.	
(1)	**BASIS: GSR Part 1 Req. 15 state that** *"The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities."*
R5	**Recommendation: SRARNS should provide for collecting and analysing operating and regulatory experiences and for disseminating the lessons learned for their use by authorized parties, SRARNS itself and other relevant authorities.**

2.3. SUMMARY

SRARNS contributes to the Bosnia and Herzegovina efforts to fulfil its international obligations, in the relevant international arrangements. Bosnia and Herzegovina is a contracting party to relevant binding international conventions, treaties and other instruments related to radiation and nuclear safety.

The systematic analysis of operating and regulatory experience and dissemination of the lessons learned to all stakeholders has been identified as an area for further improvement.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

The State Regulatory Agency for Radiation and Nuclear Safety (SRARNS) is the regulatory body for radiation and nuclear safety in Bosnia and Herzegovina under the Law as an independent administrative organization that became operational in 2009.

The Law states that the headquarters office is in Sarajevo, while regional offices are established in Banja Luka (Republic of Srpska) and Mostar (Federation of Bosnia and Herzegovina). SRARNS has six organizational units: Administrative Division (for general, legal, human resources and financial services), Authorization Division (for registration and licensing activities, and approvals), Inspectorate (for inspection and enforcement; headed by assistant director as Head of Inspectorate), two regional offices in Mostar and Banja Luka, and the Office of the Director.

The Law provides details on the status, functions, and authority of SRARNS. SRARNS reports to the Council of Ministers and is funded from the state-level budget. The SRARNS Director submits on annual basis the budget proposal for the next year to the Council of Ministers based on the need to implement the regulatory program. In addition, SRARNS is obliged to submit to the Council of Ministers a yearly report on the lawful, complete, effective and professional exercise of the functions and powers of SRARNS. The IRRS Team was informed, that these yearly reports have not given rise to any reflections nor feedback by the Council of Ministers.

The required financial and human resources are currently not fully provided due to the restrictions in the state budgeting and employment. SRARNS organizational chart established in 2009 with assistance from the IAEA is planned for a total of 34 positions with only 18 positions filled. **Recommendation R2 in Section 1.3 addresses this issue.**

SRARNS is strongly challenged due to the restrictions in employment decided by the Government in 2011. According to the Management Manual the latest revision on the organizational structure of SRARNS goes back to 2016 and no changes of SRARNS organizational structure have been made accordingly.

Observations and recommendations related to the organizational structure of SRARNS are addressed below in section 3.3.

SRARNS has not fully built its main regulatory functions such as authorization, review and assessment, inspection, enforcement, and development of regulations and guides, on a basis of a graded approach commensurate with the radiation risks associated with facilities and activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: A graded approach is not fully implemented in the regulatory functions of SRARNS such as authorization, review and assessment, inspection, enforcement and development of regulations and guides.	
(1)	**BASIS: GSR Part 1 Requirement 16 states that** *"The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities.*
R6	**Recommendation: SRARNS should perform its functions effectively in a manner commensurate with the radiation risks associated with facilities and activities.**

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

The Law states the effective independence of SRARNS in the decision-making process "Under the Law and other regulations, the Agency shall independently perform regulatory control of the safety of radioactive sources, the safety of radioactive waste and transport safety." In addition, the Law states that SRARNS is established as an independent administrative organization.

However, in the Law on Administrative Procedures, 2002 it is stated that "If a second-instance authority finds that on the basis on the facts stablished in the completed procedure the (appealed) matter has to be resolved differently than it was resolved by the first-instance decision, it shall revoke the first-instance decision by its decision and resolve the matter by itself." This means that the Appeals Committee of the Council of Ministers has the power to change the regulatory decisions made by SRARNS.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Appeals Committee of the Council of Ministers can change the regulatory decisions made by SRARNS.	
(1)	**BASIS: GSR Part 1 Requirement 4 states that** *"The Government shall ensure that the regulatory body is effectively independent in its safety related decision making"*
R7	**Recommendation: The Council of Ministers should ensure that SRARNS is effectively independent in its safety related decision making.**

The IRRS team was informed that regulations prepared and issued by SRARNS involve in the drafting process individual professional consultants (experts) who are employed by technical services which are authorized by SRARNS. This practice creates a potential conflict of interest.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Regulations prepared and issued by SRARNS involve in the drafting process individual professional consultants (experts) who are employed by technical services which are authorized by SRARNS. This practice creates a potential conflict of interest.	
(1)	**BASIS: GSR Part 1 Requirement 17 states that** *"The regulatory body shall perform its functions in a manner that does not compromise its effective independence"*
(2)	**BASIS: GSR Part 1 Requirement 17, para. 4.9 states that "***To maintain its effective independence, the regulatory body shall ensure that, in its liaison with interested parties, it has a clear separation from organizations or bodies that have been assigned responsibilities for facilities or activities or for their promotion."*
(3)	**BASIS: GSR Part 1 Requirement 20 states that** *"The regulatory body shall obtain technical or other expert professional advice or services as necessary in support of its regulatory functions, but this shall not relieve the regulatory body of its assigned responsibilities."*
S1	**Suggestion: SRARNS should consider putting in place formal arrangements with technical services and other professional consultants in order to avoid conflicts of interest.**

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

The funding of SRARNS is anchored in the Law, and the amount is agreed on yearly basis with the Council of Ministers. However, as highlighted in Section 3.1, current financial and human resources are insufficient for SRARNS to meet all of its obligations due to state budget and employment restrictions. **Recommendation 2 in section 1.3 addresses this issue.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Required financial and human resources are not fully provided to SRARNS due to the restrictions in the state budgeting and employment. SRARNS organizational chart established in 2009 is planned for a total of 34 positions with only 18 positions filled.	
(1)	***BASIS: GSR Part 1 Requirement 18 states that*** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."*
(2)	***BASIS: GSR Part 1 Requirement 18, para. 4.11 states that*** *"The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions."*
(3)	**BASIS: GSR Part 1 Requirement 16 states that** *"The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities."*
R8	**Recommendation: SRARNS should develop and periodically revise a human resource plan based on an analysis of the competences and skills needed to perform its regulatory functions and revise its organizational structure accordingly.**

SRARNS has no procedures for training programmes when on-boarding new staff and no procedures for training and further developing the expertise of existing staff, an issue that does not ensure the stability of regulatory control. New staff members are given the opportunity to have courses in public administration. Education and training in specific technical areas are accomplished only when staff members are participating in international cooperation projects, typically in the auspices of IAEA. **Recommendation R11 in Section 4.5 addresses these issues.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

There is no requirement in the Law for SRARNS to have advisory committees; however, Article 11 in the Law gives SRARNS the power to establish ad hoc independent committees for the purpose of resolving professional issues within its authority. The IRRS team noted that advisory committees have not been established to date.

SRARNS often uses individual professional consultants and technical services according to the Law. **Suggestion S1 in Section 3.2,** related to potential conflicts of interest between SRARNS and professional consultants such as technical services, **addresses this issue.**

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

SRARNS communicates directly with authorized parties through several formal and informal mechanisms. SRARNS web page facilitates the communication with authorized parties and applicants.

Drafts of regulations and guides are communicated via “e-Consultations” web platform, or on SRARNS's official web page for suggestions and additional information from interested parties when changes in regulatory requirements are proposed.

Before COVID-19 pandemic, SRARNS held a series of round tables discussions where invited authorized parties discussed issues concerning regulatory authorizations and inspections. The IRRS team was informed that SRARNS is planning to organize such round table discussions again.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

SRARNS regulatory framework is based on specified policies and principles given in the Policy. Specifically, it is stated in the Policy “Part five – Policy Implementation” that SRARNS shall make independent objective and consistent regulatory decisions in order to ensure that the authorization holder fulfils its obligations under the Law and regulations.

The framework is generally ensuring consistency in the decision-making process of SRARNS and availability to build confidence among interested parties.

The Law, states that SRARNS has the authority to prepare and issue regulations and guides as a basis for its regulatory actions. In addition, SRARNS has the authority to propose legislative amendments to the Council of Ministers. However, no provisions are in place stating how and when it is appropriate to make changes in regulations and guides. **Recommendation R16 in Section 9.1 addresses this issue**.

The regulatory processes in Bosnia and Herzegovina are formal and transparent based on policies and principles and associated criteria. However, the related procedures for regulatory activities in the SRARNS management system are of very general character, not ensuring the stability and consistency of the regulatory control. Even if the Management System Manual is to be revised biennially, there are no provisions or procedures in place addressing the review of the procedures in the management system. **Recommendation R11 in Section 4.5. addresses this issue.**

3.7. SAFETY RELATED RECORDS

SRARNS has made provisions for establishing and maintaining main registers and inventories related to the safety of facilities and activities.

The Law and regulations assign SRARNS to keep records of individual doses from occupational exposure but a system for this purpose is not in place. The IRRS team was informed that SRARNS is participating in a pilot project relating to creating a version of RAIS+. In addition, SRARNS is developing a database for central dose register for occupationally exposed workers. These two databases will be compatible through a specific interface. The RAIS+ system should, when established, enable technical services to send dose readings electronically to SRARNS.

SRARNS is assigned by the Law to establish and maintain a national register of radiation sources. This is implemented through the RAIS system. SRARNS has established this register, however it does not update it on a systematic basis.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Law and regulations include provisions for SRARNS to establish and maintain a register of individual doses from occupational exposure. However, a system for this purpose is not in place. SRARNS has established and maintains a national register of radiation sources, however it does not update it on a systematic basis.	
(1)	**BASIS: GSR Part 1 Requirement 35, states that** *"The regulatory body shall make provision for establishing, maintaining and retrieving adequate records relating to the safety of facilities and activities."*
(2)	**BASIS: GSR Part 1 Requirement 35, para. 4.63 states that** *"The regulatory body shall make provision for establishing and maintaining the following main registers and inventories:* — *Registers of sealed radioactive sources and radiation generators;* — *Records of doses from occupational exposure;* — *Records relating to the safety of facilities and activities;* — *Records that might be necessary for the shutdown and decommissioning (or closure) of facilities;* — *Records of events, including non-routine releases of radioactive material to the environment;* — *Inventories of radioactive waste and of spent fuel."*
S2	**Suggestion: SRARNS should consider establishing a register for individual doses from occupational exposure and systematically maintaining the register of radiation sources.**

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

According to the Law, SRARNS cooperates with other administrative bodies and other institutions in matters within the scope of SRARNS' work and in addition determines appropriate methods for disseminating public information about matters relating to ionizing radiation.

SRARNS management ensures processes and plans for the interaction with the interested parties, however, no formal provisions for effective mechanisms of communication and meetings with interested parties are established.

SRARNS staff provide general information on administrative matters in the field of their work to the authorized parties, as well as to relevant interested parties.

Information on SRARNS's activities is sent to other administrative bodies and interested parties, and SRARNS informs the public on relevant decisions, as well as information on accidents and abnormal events via newspapers, radio, television, and the internet. SRARNS's information to the public reflects the radiation risks associated with facilities and activities in accordance with a graded approach.

Information related to SRARNS's participation in international projects, such as those involving the IAEA, is provided to interested parties in meetings, training courses, and other relevant fora. Such information is also disseminated to SRARNS's staff members. SRARNS communicates with interested parties, however no provisions for identifying relevant interested parties, as well as effective mechanisms of communication and consultations with interested parties and the public are established.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: SRARNS cooperates with other administrative bodies and other institutions in matters within its scope of work and in addition determines appropriate methods for disseminating public information about matters relating to ionizing radiation. However, no provisions for effective mechanisms of communication and meetings with interested parties, as well as with the public, are established.	
(1)	**BASIS: GSR Part 1 Requirement 36, states that** *"The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body."*
(2)	**BASIS: GSR Part 1 Requirement 36, para. 4.66 states that** *"The regulatory body shall establish, either directly or through authorized parties, provision for effective mechanisms of communication, and it shall hold meetings to inform interested parties and the public and for informing the decision-making process."*
R9	**Recommendation: SRARNS should establish provisions for effective mechanisms of communication and meetings with interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body.**

3.9. SUMMARY

Overall, the responsibilities and functions of SRARNS are in good compliance with IAEA safety standards. The IRRS found some areas for further improvement related to the implementation of the graded approach in the regulatory functions, the effective independence of SRARNS, the human resource plan, the national register for individual doses from occupational exposure and the communication and consultation with interested parties, including the public.

4. MANAGEMENT OF THE REGULATORY BODY

4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

Management of SRARNS demonstrates leadership and commitment for safety by defining the organization's mission, vision, values and goals within the management system. The Director supported by the two Deputy Directors promote safety values though regular interaction with staff and other interested parties. The values and goals are contained in the management system manual, strategic and annual plans of SRARNS and are available to staff through various means that include the website, intranet and the Office Workflow Information System (OWIS).

4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

The Director of SRARNS has responsibility for the development and continuous improvement of the management system and delegated specific responsibilities to the Director Assistant responsible for the management system who regularly reports on its performance and areas of suggested improvement during meetings of senior management. While the management system contains several elements promoting safety and a culture of safety, SRARNS has not developed its own safety policy to ensure that safety is the main priority in all its operations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Management at SRARNS has not established a safety policy for the organization within its management system	
(1)	**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."*
R10	**Recommendation: SRARNS should establish a safety policy in its management system**

4.3. THE MANAGEMENT SYSTEM

SRARNS has documented its management system into a manual that is available to its staff on the intranet and OWIS. It contains the values and goals of the organization, policies, process descriptions, procedures, and checklists. The organisational structure hierarchy, levels of authority and individual job descriptions have been developed.

The management system has integrated safety, quality, health, security, as well as human factor elements in line with IAEA GSR Part 2. Its development depicts a graded approach with priority given to core processes with an impact on safety. However, the IRRS team noted that the development of the management system is incomplete as some processes and procedures are outstanding while others are too generic and require further development for effective implementation and ensuring the stability and control of regulatory practices. **Recommendation R11 in Section 4.5 addresses this issue.**

4.4. MANAGEMENT OF RESOURCES

Management of SRARNS is responsible for planning and managing its resources and is accountable to the Council of Ministers. The shortage of staff has been addressed in Section 3.3. Furthermore, the Director Assistant responsible for the management system was due to retire by the end of 2022 and there will be no replacement until the hiring-freeze instruction is lifted. Similarly, funding for the operations of SRARNS is inadequate. **Recommendation 2 in Section 1.3 addresses this issue**.

Management of SRARNS has defined job descriptions that define the scope of work conducted by individuals and the general educational and experience requirements of employment. However, SRARNS has no defined process of assessing the evolving competence and training requirements in line with changes in the regulated practices and activities. **Recommendation R8 in Section 3.3 addresses this issue.**

4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

Several processes have been developed in the management system of SRARNS. These include the core processes of authorization and approvals, inspection and enforcement, issuing regulations and guides (instructions), as well as some management and support processes. The processes are accessible through OWIS with a defined process flow covering the various responsibilities required to ensure completion. The system ensures traceability and individual accountability in decision making. Process owners have been defined in the management system and they are responsible for monitoring the effectiveness of their processes and report to the Management System Representative (MSR), as well as suggest improvements. However, the process descriptions are not adequate to cover the full scope of work conducted by SRARNS, hence there is a need to continue with the process development and documentation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: SRARNS has developed and documented procedures to assist its staff on the implementation of some its processes and regulatory activities. However, gaps still exist, as some processes and procedures are missing or are inadequately addressed.	
(1)	**BASIS: GSR Part 1 Requirement 22 states that** "The regulatory body shall ensure that the regulatory control is stable and consistent.**"**
(2)	**BASIS: GSR Part 2 Requirement 10 states that** *"Processes and activities shall be effectively managed to achieve the organization's goals without compromising safety."*
(3)	**BASIS: GSR Part 2 Requirement 14 states that** *"Senior Management shall regularly commission assessments of leadership for safety and of safety culture in its own organization."*
R11	**Recommendation: SRARNS should ensure that all processes and procedures are documented to ensure stability and consistence of regulatory control and to enhance regulatory effectiveness and efficiency.**

4.6. CULTURE FOR SAFETY

The culture for safety at SRARNS is maintained by continued application of the management system, which guides all staff when making decisions. Management support is available to guide the implementation of processes and regular team meetings are held where staff provide feedback on their own performance. Management meetings chaired by the Director address any safety concerns raised by staff. The use of online

systems such as the intranet and OWIS guide staff in ensuring that appropriate decisions are made. The management system provides for staff to express themselves freely and encourage a questioning attitude.

4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

The management system manual of SRARNS contains provisions for regular reviews of the management system at various levels that include process owners and management during regular meetings, as well as mandatory annual reviews. The IRRS team noted that no evidence was available to prove that the regular reviews are performed. Furthermore, the management system requires independent assessment to ensure it is fit for purpose and identifies inadequacies for continuous improvements. The IRRS team noted that while SRARNS has not established internal audits of the management system and relied on the external audit mandated by the Council of Ministers, it has a bias on financial matters over other processes.

Similarly, SRARNS management has not commissioned independent assessments of the leadership for safety in the organisation and its culture for safety as provided in IAEA GSR Part 2. This assessment would be essential in addressing any deficiencies in leadership and its contribution to the safety culture of the organisation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Regular reviews and independent assessments of the management system to measure its continued effectiveness, as well as assessments for leadership and of safety culture in SRARNS have not been carried out.	
(1)	**BASIS: GSR Part 2 Requirement 13 states that** *"The effectiveness of the management system shall be measured, assessed and improved to enhance safety performance, including minimizing the occurrence of problems to safety."*
(2)	**BASIS: GSR Part 2 Requirement 13 para states that "***All processes shall be regularly evaluated for their effectiveness and for their ability to ensure safety."*
(3)	**BASIS: GSR Part 2 Requirement 13 para 6.6 states that "***Senior management shall conduct a review of the management system at planned intervals to confirm its suitability and effectiveness….."*
(4)	**BASIS: GSR Part 2 Requirement 14 states that** *"Senior Management shall regularly commission assessments of leadership for safety and of safety culture in its own organization."*
(5)	**BASIS: GSR Part 2 Requirement 14 states para 6.10 that "***Senior management shall ensure that an independent assessment of leadership for safety and of safety culture is conducted for enhancement of the organizational culture for safety…"*
R12	**Recommendation: SRANS should conduct independent assessments regularly to measure, assess and review its management system, leadership for safety and its safety culture in order to improve safety performance.**

4.8. SUMMARY

SRARNS has gone a long way in documenting its management system in line with the IAEA GSR Part 2 depicting strong management commitment and leadership for safety. Several processes have been developed and documented. Management is required to continue the development of the management system ensuring the integration of safety as well as conduct regular reviews and assessments for continued improvement.

5. AUTHORIZATION

5.1. GENERIC ISSUES

In Bosnia and Herzegovina, there are activities and facilities with radiation sources in medicine, industry, transport, and radioactive waste management. The authorization system reflects this situation and the needs of the country.

In accordance with the Law, SRARNS is empowered to establish and implement procedures for notification, approval, authorization, inspection, and the enforcement of regulatory requirements as well as for issuing, amending, suspending, renewing and revoking authorizations. The Law defines both general and specific requirements for the authorization process. Under this Law, a legal entity may not start performing a practice unless obtaining an authorization from SRARNS and prime responsibility for safety remains within the legal entity applying for the practice. Upon receipt of approval, the legal entity may proceed to apply for a registration or licence as advised by SRARNS (with the exception of transport activities). Authorizations are issued for a maximum period of 5 years. Currently the validity of licences is three years and five years for registrations with the exception of dental radiology where licences are issued for five years.

Additional details of authorization process are provided in a set of regulations implementing the Law.

In addition to authorizing practices with radiation sources, SRARNS is also empowered for defining practices exempted from regulatory control and authorizes technical services to support the authorized parties.

5.2. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

The Law defines the activities, to be authorized by SRARNS. Management of radioactive waste is not included in the list, only the so called “final disposal […] relating to sources of ionising radiation”. The authorizations performed by SRARNS consider only activities related to the management of radiation sources.

The different storage facilities, which are used for storage of radioactive waste are not authorised due to missing regulatory provisions for authorization of radioactive waste storage facilities and are not inspected by SRARNS. Nevertheless, all radioactive waste storages are monitored by SRARNS inspectors. **Recommendation R3 in Section 1.7 addresses this issue**.

Radioactive lightning rods were used in the past, but the use of such devices is no longer justified. There are several hundred of such sources present in the country, which are under limited regulatory control (only evidence of lightning rods is available) due to the lack of arrangements to manage radioactive waste. **Recommendation R3 in section 1.7 addresses this issue**.

In Bosnia and Herzegovina clearance of radioactive material from the regulatory control is a subject to authorization. The regulation on radioactive waste management contains some main criteria for clearance. These regulatory requirements allow all radioactive waste to be cleared, however, the IAEA safety standards specify that only exempted waste and very short-lived waste after storage for decay can be cleared. As in the case of exemption, clearance activity concentrations based on IAEA GSR Part 3 and the effective dose expected to be incurred by any member of the public due to the cleared material of 10 μSv in a year are applicable.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The legal framework considers all classes of radioactive waste to be subject of clearance procedure.	
(1)	**BASIS: RS-G-1.7, para 2.13 states that** *"Clearance is defined as the removal of radioactive materials or radioactive objects within authorized practices from any further regulatory control by the regulatory body."*
(2)	**BASIS: GSG 1, para 2.2 states that** *"… six classes of waste are derived and used as the basis for the classification scheme:* *(1) Exempt waste (EW): Waste that meets the criteria for clearance, exemption or exclusion from regulatory control for radiation protection purposes …* *(2) Very short lived waste (VSLW): Waste that can be stored for decay over a limited period of up to a few years and subsequently cleared from regulatory control according to arrangements approved by the regulatory body …."*
S3	**Suggestion: SRARNS should consider excluding radioactive waste from the clearance concept except exempt waste and very short-lived radioactive waste after storage for decay.**

5.3. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The Law states that authorization is issued by SRARNS to a legal entity that has applied for carrying out a practice involving radiation sources.

A legal entity must notify SRARNS of practices involving radiation sources that it intends to possess and use. SRARNS then decides if they will approve the practice to proceed to the next stage of either registration or licensing. This decision comes in the form of an approval (pre-authorisation). SRARNS issues a letter to the applicant and requests a safety assessment carried out by either a technical service or a qualified expert to be submitted to SRARNS in order for them to grant the approval. On receipt of a satisfactory safety assessment, SRARNS issues a letter of approval to the applicant authorising the legal entity to take possession of the radioactive source or X-ray device and invites the legal entity to apply for either a registration or licence for its use.

To support authorization (or approval) applications for possession and use of radiation sources, applicants have to submit the radiation safety assessment (general content defined in the Regulation on the radiation protection in occupational exposure and public exposure).

Regarding the possession and use of sealed radioactive sources, evidence is required in the application that there is an agreement with the supplier to take back the source at the end of its useful life.

In addition to the registration or license, the applicant is obliged to obtain for a radiation source an approval from SRARNS for possession, import, export, transit, transport and storage. The approval is issued for a duration from 6 to 12 months. For import or export of sources, the approval is issued after the licence and gives detailed technical information about the sources concerned by the forthcoming imports/exports occurring during its validity. This approval is checked by the customs at border crossings.

Concerning the overall authorization process, the regulatory framework does not clearly specify that an authorization may be reconsidered in the case of safety significant changes. There is no guidance for SRARNS staff or licensees, to ensure consistency, on what changes must be notified to SRARNS which

result in an amendment of the authorization. **Recommendations R11 and R16 in Sections 4.5 and 9.1 respectively address these issues.**

In the case of the cessation of a practice there are no provisions for issuing an authorization which should, if necessary, impose conditions for remediation or release the authorized party from its responsibilities in safety, once it has been demonstrated that the premises are no longer under regulatory control.

Also, SRARNS is encouraged to establish a guidance for authorized parties outlining when a notification for any change during the lifetime of the facility or the duration of an activity might lead to an amendment of the authorization or a request of a new authorization.

The regulations, take into account the graded approach in the overall authorization process, however in the case of medical facilities and activities authorization is granted only by licence, even for those involving low risk radiation sources (e.g. dental and diagnostic radiology). **Recommendation R6 in Section 3.1 addresses this issue.**

5.4. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

Decommissioning activities are not authorized, the safety of decommissioning activities is not reviewed and assessed, no inspections are performed, and no regulations and guides have been developed by SRARNS, except for the planned central radioactive waste storage facility.

5.5. AUTHORIZATION OF TRANSPORT

The Ministries of Interior and of Transport and Communications of Republic of Srpska, Ministry of Interior of Federation of Bosnia and Herzegovina, Government of the Brčko District of Bosnia and Herzegovina are the authorities overseeing the transport of dangerous goods by road.

SRARNS is the regulatory authority for class 7 radioactive materials.

The Bosnia and Herzegovina Directorate of Civil Aviation is the authority performing regulatory functions, overseeing and issuing licenses in the field of civil aviation with reference to the provisions of ICAO Technical Instructions.

Transport of radioactive material in Bosnia and Herzegovina is performed by road (special form radioactive material in Type B(U) packages for industrial use) and by air (Type A packages containing other than special form radioactive material for medical use).

Approximately, 20 shipments of Type B(U) packages and 3000 shipments of Type A packages are performed in a year.

Transport of radioactive material is regulated by the Regulation on the transport safety of radioactive material. This regulation, which is the only guidance available for transport operators was issued in 2012 and it is based on the IAEA TS-R-1 (2009) therefore, the IAEA SSR-6 (Rev.1) requirements are only partially applied. **The Recommendation R21 in Section 9.5 addresses this issue**. In particular, SRARNS doesn't:

- Issue the approvals provided in SSR-6 (Rev.1);
- Perform assessment of designs for transport packages.

SRARNS accepts approval certificates from other countries without validation. SRARNS is encouraged to establish a procedure for the validation of foreign certificates of package designs for all the packages that need a multilateral approval.

There are no companies manufacturing or performing maintenance of transport packages in Bosnia and Herzegovina. The maintenance of Type B(U) packages for industrial use is performed abroad by the

supplier during the source recharge, while technical services can perform monitoring on the functionality of the packages.

The transport of radioactive sources is defined as a practice. Article 3, point ff) of the Law on radiation and nuclear safety defines a radioactive source as anything that can give rise to exposure to radiation, including radioactive material and radiation generating equipment. Therefore, in the national framework the transport of radioactive sources is considered as transport of radioactive material.

For the transport of radioactive material, SRARNS issues licences to carriers, which have a validity of three years and are subject to renewal. The licence is issued to road transport carriers.

Transport by air of radioactive material is not subject to authorization.

The provisions for the authorization of transport are not in accordance with the graded approach because no classification or proper shipping name assignment is performed with regard to IAEA SSR-6 (Rev.1). For that reason, SRARNS is encouraged to include the indication of the UN numbers and the appropriate shipping name of radioactive materials the applicant is authorized to transport, when issuing a license. **Recommendation R6 in Section 3.1 addresses this issue.**

Transport approvals and notifications are applicable only to import or export of shipments and not for domestic ones. However, no registries gathering detailed information on shipments are available. For that reason, SRARNS is encouraged to establish and maintain a transport database or utilizing their existing RAIS database to register these shipments.

5.6. AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE

According to the Regulation on the radiation protection in occupational exposure and public exposure, special authorization is required for occupational exposures which may exceed the prescribed dose limit of 20 mSv effective dose. There were no applications for such authorizations so far. Pregnant and breastfeeding workers, students and apprentices are not authorized for any special exposure exceeding the dose limit.

It is not explicit in the regulatory framework that people under the age of 16 cannot be exposed to ionizing radiation.

Where appropriate, workplace monitoring, activity concentration and contamination measurements are required by the Regulation on the radiation protection in occupational exposure and public exposure.

Personal dosimetry is mandatory for category A and B workers. Category A workers are required to be monitored on a monthly basis, whereas Category B workers may be monitored less frequently, having a three-month long personal dosimetry monitoring period. This decision is made by SRARNS. Health surveillance is mandatory only for Category A workers, when they are employed, and once each year thereafter.

Regulation on the radiation protection in occupational exposure and public exposure requires that the authorized party provides training and information for workers, apprentices and students commensurate with the responsibility and risk of the individual. Education and training providers are recognized by SRARNS.

The authorization holder is required to ensure that pregnant workers are reporting their pregnancy in a timely manner. Pregnant workers may choose to keep working under the same employment conditions, while the authorization holder must ensure that until the end of pregnancy, the equivalent dose to the foetus does not exceed 1 mSv. Another possible choice for the pregnant worker is to request transfer to another work area where there will be less exposure to ionizing radiation or none at all. For any such decision made by the mother, no discriminative measure shall be imposed by the employer. This is considered a good performance.

Requirements are in place in the Regulation on the radiation protection in occupational exposure and public exposure in order to identify and impose control measures for existing exposure situations. The reference level for occupational exposure in existing exposure situations due to radon and its progenies is set to be 1000 Bq/m^3 average annual activity concentration. Identification of activities which should be under control as an existing exposure situation is not addressed in the regulations. **Recommendation R14 (second part) in section 6.8 addresses this issue.**

5.7. AUTHORIZATION ISSUES FOR MEDICAL EXPOSURE

Regulation on the medical exposure control, provides for the radiation protection of individuals in relation to medical exposure, laying down the responsibilities and obligations of the licensees and registrants including the elements of the quality assurance program. In the regulation there are requirements for the specialization of health professionals with responsibilities for medical exposure, the delegation of the clinical responsibility of health professionals regarding individual medical exposures for ensuring protection and safety during diagnostic and therapeutic radiological procedures. Provisions are also included for the information of the patient about potential risks before the conduct of high dose procedures in radiology (such as interventional radiology and CT), patient consent in nuclear medicine practices and provision of instructions and request of consent of the radiotherapy patients, about the treatment and related risks.

Requirements for justification and optimization of medical exposures are provided in the regulations. The involvement of the referrer and practitioner in the justification process of medical exposure for individual patient is required. Requirements for the justification of the medical exposure of volunteers as part of a programme of biomedical research are also included in the regulations.

The use of relevant national or international referral guidelines for the justification of the medical exposure of an individual patient in a radiological procedure is not provided in the regulatory framework. **Recommendation R25 in Section 9.7 addresses this issue**.

The requirement for generic justification of new procedures involving medical exposure and for the revision of existing types of procedures when necessary is provided in regulations, however the responsibility and the involvement of the health authority in conjunction with appropriate professional bodies is not included.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: In the regulations, there are provisions for the generic justification of new procedures involving medical exposure before their adoption and for the revision of existing types of procedures whenever required. However, the regulation does not specify which authority has the responsibility for the justification.	
(1)	**BASIS: GSR Part 3 Requirement 37, para. 3.156 states that** *"Generic justification of a radiological procedure shall be carried out by the health authority in conjunction with appropriate professional bodies, and shall be reviewed from time to time, with account taken of advances in knowledge and technological developments.*
R13	**Recommendation: The Council of Ministers should make provisions for clear assignment of responsibilities for justification of new procedures involving medical exposure before their adoption and for revising the existing types of procedures whenever new important evidence on their efficiency or consequences has appeared.**

Provisions for the national Diagnostic Reference Levels (DRLs) are included in the regulations, and values for radiographic and fluoroscopic procedures, mammography, dental and CT examinations and for some cardiology interventional procedures are proposed. The IRRS team was informed that these values were adopted from international publications, however they are not used by SRARNS, because they are not considered representative for the country.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Regulations for medical exposure include values for DRLs. However, as these values are considered as not representative for the local circumstances they are not used in practice and SRARNS is in the process of defining the national values of DRLs.	
(1)	**BASIS: GSR Part 3 Requirement 34, para. 3.148, states that** *"The government shall ensure, as part of the responsibilities specified in para. 2.15, that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a set of diagnostic reference levels is established for medical exposures incurred in medical imaging, including image guided interventional procedures. In setting such diagnostic reference levels, account shall be taken of the need for adequate image quality, to enable the requirements of para. 3.169 to be fulfilled. Such diagnostic reference levels shall be based, as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstances."*
S4	**Suggestion: SRARNS should consider continuing the development of the national DRLs and the implementation of their use for the optimization of medical exposures.**

The regulations contain provisions for dose constraints for carers and comforters, dose constraints for volunteers participating in biomedical and medical research programs, criteria for the release of patients after radionuclide therapy and optimization of exposure to pregnant and breast-feeding patients.

The requirement for periodic radiological review for specific medical practices of radiotherapy, nuclear medicine and radiology is provided in regulations. However, the IRRS team was informed that radiological reviews are not conducted in the country. SRARNS is encouraged to develop and issue the guidance for authorized users on the conduct of radiological reviews.

The regulation on medical exposure provides for taking necessary measures to minimize the likelihood of unintended or accidental medical exposures. In addition, the Regulation on radiological emergency in practices involving radioactive sources, provides for radiological events requesting the authorised party to notify SRARNS and to determine the criteria for notification/reporting unintended and accidental patient exposures for diagnostic/interventional radiology, nuclear medicine and radiotherapy.

5.8. AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE

The main safety objective delineated in the Law and highlighted in the Policy for safety is to protect the population and the environment from the harmful effects of ionizing radiation. In this respect, SRARNS has established and implemented a system for the regulatory control, through authorization, of all activities and facilities that may result in public exposure.

The overall requirements and related criteria for the authorization of facilities and activities are specified in the Regulation on the notification and authorization of practices involving radiation sources. The IRRS team was informed that in line with this regulation, the applicant for an authorization is required to submit to SRARNS, among others, a safety report including the results of the assessment of all pathways of public

exposure and, if pertinent, the related environmental impact. Nevertheless, the regulation does not explicitly require the applicant to submit specific information on the provisions related to the control of the public exposure when applying for the approval to possess or the licence/registration to possess and use radiation sources.

The discharge of radioactive effluents is authorized by SRARNS. The IRRS team was informed that the applicant for such an authorization shall characterize the effluents and conduct an impact assessment to verify that the regulatory constraints are not exceeded. Nevertheless, the authorization granted does not specify the applicable limits and conditions. **Suggestion S5 in Section 6.8 addresses this issue.**

A similar authorization system applies for the approval of the clearance of solid radioactive materials. The IRRS team was informed that the applicant submits sufficient evidence to SRARNS that provisions are in place to ensure that radioactive material is cleared only when the corresponding activity concentrations are below the established generic clearance levels. A specific approval is required when activity concentrations are exceeding the generic clearance levels. In this case, the submitted safety assessment confirms that the related constraints are met.

5.9. SUMMARY

The law and regulations include provisions for the authorization of radiation sources facilities and activities. This legal and regulatory framework is developed and implemented and to a certain extent includes consideration of a graded approach. It is, in general, in line with IAEA safety standards.

However, areas for improvement in the authorization process were identified and include the development of a guidance for authorised parties, the exclusion of radioactive waste from clearance concept, the provisions for clear assignment of responsibilities for justification of medical practices and the need for further development and implementation of national DRLs.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

The review and assessment process are conducted by the staff of the Authorization Division of SRARNS to determine the compliance of the applicant, or the authorized party, with the relevant regulatory requirements.

Review and assessment are performed during the approval and authorization process or when there is a modification of the authorization. SRARNS inspectors are also performing review and assessment of the radiation safety, quality control and health surveillance reports sent by the authorized technical services at specified intervals during the lifetime of a facility or activity. According to the regulations, the applicant is required to submit a radiation safety assessment for the facility in which a radiation source will be used and stored prior to granting the approval for possession and another one before the authorization for possession and use is issued.

The information to be submitted by the applicant to support the application for authorization is provided in the relevant regulations. The documentation subject to review and assessment is mainly the radiation safety assessment and the radiation protection program, along with a report and certification from the authorized technical services confirming the compliance of the ionizing radiation sources and premises with the radiation protection requirements. If some non-compliances are identified by the technical service, they are generally addressed by the applicant before the documentation is finalized.

SRARNS has drafted Standard Operating Procedures for authorization. These procedures include checklists also used for the purposes of review and assessment. However, a formal procedure and associated checklists have not been developed for the consistent review and assessment of the documentation submitted to SRARNS. **Recommendation R11 in section 4.5 addresses this issue.**

The regulations do not explicitly address the scope and level of detail of the safety assessment carried out at a particular stage for any facility or activity in accordance with a graded approach. **Recommendation R6 in section 3.1 addresses this issue.** Since there is no detailed procedure to support the process of review and assessment, it is not ensured that the safety assessment is carried out in a consistent manner. **Recommendation R11 in section 4.5 addresses this issue.**

Furthermore, as there is no clear requirement for the applicant defining the need to apply for a new authorization, the update of the safety assessment might not be reviewed and evaluated by SRARNS in a systematic manner. In the same way, feedback of operating experience, in particular in case of occurrence of radiological events, is not always taken into account for the update of the safety assessment. **Recommendation R5 in section 2.2**. **addresses this issue.**

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

For some cases such as the authorization of technical services, the review and assessment is performed by an internal SRARNS committee. The inspectors or the Administrative Division (for general, legal, human resources and financial services) may also be involved. Moreover, according to the regulations, SRARNS may establish an ad hoc independent committee to resolve professional matters from within its authority and may use individual professional consultants to ensure compliance with regulatory requirements.
The number of SRARNS staff required for review and assessment is much less than the numbers specified in the organizational chart due to the restrictions in the state budget and employment. The IRRS team was informed that due to these restrictions and the need for further training to enhance competence of the staff, as new practices arise, there are possible shortfalls in performing the review and assessment function. **Recommendation R2 in section 1.3 and Recommendation R8 in section 3.3 address these issues.**

When specialized competence is not available in SRARNS, authorized technical services or experts (local or from other countries) might be used by SRARNS to provide an independent professional opinion in radiation protection.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

The regulations provide that prior to granting an approval for the possession of a radiation source, the applicant is required to submit a radiation safety assessment for the facility in which the radiation source will be used and stored. In addition, another safety assessment must be submitted by the applicant to SRARNS before granting an authorization for possession and use of this source. The scope and level of detail of the safety assessment carried out at a particular stage for any facility or activity is not explicitly addressed in the regulations. The update of the safety assessment is required in the cases of significant changes of carrying out the practice or when the results of personal dosimetry or monitoring of the workplace significantly deviate from the anticipated ones.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

The Authorization Division of SRARNS verifies the completeness of the documents and information submitted by the applicant to support the application for authorization. If the documentation is not complete, a letter is sent to the applicant requiring additional documentation, whereas in case of findings related to non-compliance with the regulations, SRARNS issues a procedural decision for implementing corrective measures. The conduct of an inspection following the review and assessment is not a requirement for granting an authorization. However, in some cases an inspection may be performed. SRARNS has not developed a procedure for reviewing the elements and quality of the safety assessment submitted by the applicant. **Recommendation R11 in Section 4.5**. **addresses this issue.**

6.2. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

The IRRS team was informed, that there are two "central temporary" storage facilities (one in Rakovića serving the Federation of Bosnia and Hercegovina and one in Čajevac in Republika Srpska), six "interim" storage facilities at companies that used radioactive sources (some of them are bankrupt) and several small "storage facilities" with maximum four pieces of category 5 sources. None of the operational storage facilities have been authorized and their safety has not been assessed. This observation supports the conclusion that there is no effective management and control of radioactive waste in the country. **Recommendation R3 in Section 1.7**. **addresses this issue.**

However, during the site visit at the Public Health Institute of the Federation of Bosnia and Herzegovina, Center of Radiation Protection, a safety case for operational centralised radioactive waste storage facility at Rakovića has been presented to the IRRS team members. The safety case has been delivered to SRARNS in 2019 together with the authorization application of Rakovića storage facility and amended in 2020 and 2021. The authorization process is not finished yet. The IRRS Team encourages SRARNS to review and assess the safety of radioactive waste storage facilities in the country.

6.3. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

During the approval process and when amendments are made to existing authorizations the same documentation is requested to be submitted by the applicant as during the initial application process and these are reviewed and assessed by SRARNS staff. There is currently no graded approach applied to the function of review and assessment. **Recommendation R6 in Section 3.1**. **addresses this issue.**

6.4. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

Decommissioning activities are not authorized, the safety of decommissioning activities is not reviewed and assessed, no inspections are performed, and no regulations and guides have been developed by SRARNS, except for planned central radioactive waste storage facility.

6.5. REVIEW AND ASSESSMENT FOR TRANSPORT

SRARNS reviews and assesses the documents submitted by the applicants using standard operating procedures for review and assessment that is general and not in accordance with graded approach. Furthermore, the checklist used for the review and assessment is general, and not in accordance with graded approach; for example, provisions for the review and assessment for packages, shipments, special arrangements and special form of radioactive material are not taken into account. For that reason, SRARNS is encouraged to consider establishing specified procedures for the review and assessment of the safety assessment submitted by the applicants prior to granting licences for the transport of radioactive material, for the import and export of radioactive material and approvals for every shipment. The issue of the graded approach is addressed in **Recommendation R6 in Section 3.1**.

The staff of the Authorization Division have experience and skills, however SRARNS is encouraged to consider providing the staff specific training for review and assessment in accordance with SSR-6 (Rev.1).

6.6. REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE

When applying for an authorization, the applicant must appoint a radiation protection officer and all occupationally exposed workers must be under a personal dosimetry programme. Records of occupational health surveillance reports are required to be submitted to SRARNS, along with the proof of professional qualification for workers. Additional requirements are addressed for the radiation source to be used for different activities. These include acceptance tests, radiation protection program, copy of the contract on maintenance of the equipment with relevant service for radiation sources in radiotherapy and plan for the safety of radiation sources. Workplace monitoring is carried out by a technical service, making an estimate for the expected effective dose from a given source. There are no practices requiring the use of respiratory protective equipment in planned exposure situations. The conformance to the above requirements is reviewed by SRARNS at the time of granting an authorization and at the time of inspections. Periodic reviews of controlled and supervised areas are required to be performed by the authorized parties.

Occupational health surveillance of category A workers are required annually and at the time they start to work. The technical services, authorized for the health assessment of exposed workers, shall receive the records of personal dosimetry, thus these are reviewed by the health professionals.

Records of occupational exposures are sent to SRARNS for review and are also reviewed during the on-site inspections through the registry kept by the authorized parties, as it was observed during the site visit to the Sarajevo University Clinical Center. Individual monitoring results are not included in the national dose register. **Suggestion S2 in Section 3.7**. **addresses this issue.**

Individual monitoring results in excess of the dose limits are required to be investigated by the authorized parties, however there are no procedures in place on how SRARNS takes further actions in case of an overexposure. **Recommendation R11 in Section 4.5**. **addresses this issue.**

6.7. REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE

Regulation on medical exposure requires the establishment of a quality assurance (QA) program for the medical facilities that is required to be submitted to SRARNS during the authorization process for review

and assessment. Justification and optimization procedures are part of the QA program for radiology facilities. In the case of diagnostic nuclear medicine facilities, procedures related to the implementation of individual justification are not part of this program. Assessment of typical doses submitted by the applicants to SRARNS is not performed due to the issue of not having available values for national DRLs. **Suggestion S4 in Section 5.7**. **addresses this issue.**

The general procedures and checklists used by SRARNS for review and assessment do not incorporate the assessment of justification and optimization processes and this can lead to possible shortfalls in the implementation of review and assessment. For this reason, SRARNS is encouraged to incorporate in their procedures and checklists relevant areas for reviewing justification and optimization of medical exposure.

6.8. REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE

SRARNS reviews authorization applications to identify any potential impact on the environment due to e.g. planned discharges or proposed clearance of radioactive materials.

Requirements for the development and implementation of an environmental monitoring program, when it is required, are not explicitly included in the regulations. There are facilities where some provisions for monitoring the radioactive discharges are in place.

The submitted requests for authorization renewal are not accompanied by explicit evidence of the implemented safety measures for controlling the public exposure including a performance evaluation of the license's conditions. Nevertheless, the IRRS team was informed that such evidence is requested on a case by case basis and reviewed by SRARNS prior to granting the license renewal.

The licensees are required to submit reports to SRARNS periodically about discharges of radioactive materials. As part of the oversight activities, SRARNS reviews data on effluents submitted by the licensees. However, SRARNS has not fully implemented provisions to:

- Specify applicable license conditions and limits for discharges;
- Implement an independent monitoring programme;
- Maintain records of discharges, and results of the monitoring programmes and assessment of public exposure;
- Publish or make available the results from source and environmental monitoring programmes and the assessment of public exposure.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The authorized parties are required to submit reports to SRARNS periodically about discharges of radioactive materials. However, SRARNS has not developed and implemented a procedure to specify discharge conditions and maintain records of discharges, results of monitoring programmes and results of assessments of public exposure. Moreover, SRARNS has not developed and implemented an independent monitoring programme.	
(1)	**BASIS: GSR Part 3 Requirement 29, para. 3.123 states that "***The regulatory body shall establish or approve operational limits and conditions relating to public exposure, including authorized limits for discharges. These operational limits and conditions:…"*
(2)	**BASIS: GSR Part 3 Requirement 32, para. 3.135 states that** *"The regulatory body shall be responsible, as appropriate, for:* *(a) Review and approval of monitoring programmes of registrants and licensees, which shall be sufficient….*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	(c) Making provision for an independent monitoring programme. *(d) Assessment of the total public exposure due to authorized sources and practices in the State on the basis of monitoring data provided…* *(e) Making provision for maintaining records of discharges, results of monitoring programmes and results of assessments of public exposure.* *(f) Verification of compliance of an authorized practice with the requirements of these Standards for the control of public exposure."*
(3)	**BASIS: GSR Part 3 Requirement 32, para. 3.136 states that** *"The regulatory body shall publish or shall make available on request, as appropriate, results from source monitoring and environmental monitoring programmes and assessments of doses from public exposure."*
S5	**Suggestion: SRARNS should consider improving the implementation of the oversight provisions to control radioactive discharges in line with GSR Part 3.**

SRARNS has initiated actions to control natural sources of exposures, such as preliminary measurements of indoor radon. However, the regulatory framework does not specify the exposure scenarios to be considered as existing exposure situations. Moreover, SRARNS has not identified existing exposure situations that may be of concern from the radiation safety point of view.

SRARNS has drafted a regulation for the control of activities involving NORM. The drafted regulation includes notification and authorization requirements based on a graded approach and will specify reference levels to facilitate the implementation of the protection strategy. The IRRS team encourages SRARNS to finalise and issue this regulation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: SRARNS has initiated actions to control natural sources of exposures, such as preliminary measurements of indoor radon, and to draft a regulation for related oversight activities involving NORM. However, the regulatory framework does not specify the exposures scenarios that shall be considered as existing exposure situations. Moreover, SRARNS has not developed appropriate provisions: - to ensure that existing exposure situations that have been identified are evaluated to determine which exposures, including radon indoors, are of concern from the radiation protection point of view; - for the management of identified exposure scenarios.	
(1)	**BASIS: GSR Part 3 Requirement 47 states that** *"The government shall ensure that existing exposure situations that have been identified are evaluated to determine which occupational exposures and public exposures are of concern from the point of view of radiation protection"*
(2)	**BASIS: GSR Part 3 Requirement 47, para. 5.3 states that** *"The government shall include in the legal and regulatory framework for protection and safety (see Section 2) provision for the management of existing exposure situations. The government, in the legal and regulatory framework, as appropriate:*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	(b) Shall specify the general principles underlying the protection strategies developed to reduce exposure when remedial actions and protective actions have been determined to be justified; *(c) Shall assign responsibilities for the establishment and implementation of protection strategies to the regulatory body and to other relevant authorities and, as appropriate, to registrants, licensees and other parties involved in the implementation of remedial actions and protective actions;* *(d) Shall provide for the involvement of interested parties in decisions regarding the development and implementation of protection strategies, as appropriate".*
(3)	**BASIS: GSR Part 3 Requirement 47, para. 5.5 states that** *"The regulatory body or other relevant authority shall implement the protection strategy, including:* *(a) Arranging for evaluation of the available remedial actions and protective actions for achieving the objectives, and for evaluation of the efficiency of the actions planned and implemented;* *(b) Ensuring that information is available to individuals subject to exposure on potential health risks and on the means available for reducing their exposures and the associated risks."*
(4)	**BASIS: GSR Part 5 Requirement 50 states that** *"The government shall provide information on levels of radon indoors and the associated health risks and, if appropriate, shall establish and implement an action plan for controlling public exposure due to radon indoors."*
R14	**Recommendation: SRARNS should develop and implement provisions to ensure:** - **that existing exposure situations that have been identified are evaluated to determine which public exposures, including radon indoors, are of concern from the radiation protection point of view.** - **the appropriate management of public exposures of concern from the radiation protection point of view.**

6.9. SUMMARY

Review and assessment are performed by SRARNS to determine compliance of the applicant or the authorized party with relevant regulatory requirements during the approval and authorization process, or when there is a need for a modification of the authorization. SRARNS inspectors are also performing review and assessment of the radiation safety, quality control and health surveillance reports given by the authorized technical services during the authorization process. The scope and level of detail of the safety assessment carried out at any stage for any facility or activity is not explicitly addressed in the regulations and SRARNS has not developed a detailed procedure to support the conduct of review and assessment in a consistent way.

Even though there are provisions to assess and authorize radioactive discharges, SRARNS could enhance oversight actions in this field. Preliminary surveys were carried out to characterize natural sources of exposure, especially radon in dwellings. Nevertheless, provisions to define, assess and control the existing exposure situations still need to be developed.

7. INSPECTION

7.1. GENERIC ISSUES

The *Law* empowers SRARNS to conduct inspections which concern *"all persons possessing radiation sources or carrying out a practice involving radiation sources"* as well as the authorized technical services. The regulation also provides the inspectors of SRARNS access to the areas and to the documentation deemed necessary to perform their tasks.

SRARNS conducts inspections of facilities and activities with radiation sources including transport and control of technical services, as planned in its annual inspection work plan (defining the number of inspections for each particular area, *e.g.*, dental radiology, radiotherapy). Annual inspection work plan is approved by SRARNS Director and is a part of SRARNS Working Programme that is submitted and approved by the Council of Ministers. On this basis, quarterly work plans specifying the authorized parties to be inspected, are scheduled for each inspector. A graded approach is partially addressed, as only the inspection frequency is depending on the practice carried out. **Recommendation R6 in Section 3.1 addresses this issue.** SRARNS is encouraged to optimize the inputs of facilities operating experience in the establishment of the inspection programme.

SRARNS Inspectorate Division is in charge of the inspection function; three inspectors (one in the headquarters of the agency and two in the regional divisions) carry out the yearly planned inspections (about 200 inspections – initial and follow-up). The IRRS team was informed that human resources are not fully provided due to the restrictions in the state budget and employment. **Recommendation R2 in Section 1.3. addresses this issue.** In addition, the IRRS team acknowledges the number of yearly inspections carried out.

This plan also includes "administrative" inspections in reviewing the periodic reports provided by technical services or those related to the implementation of corrective actions. According to the Regulation, inspections can be planned, reactive or follow-up inspections (to check the implementation of imposed corrective actions required by a procedural decision). In terms of the Regulation on radiological emergency events in practices involving radioactive sources, SRARNS inspectors shall also perform reactive inspections after the receipt of a radiological event notification. The IRRS team was informed that unannounced inspections are rarely performed, in particular in medical facilities, and only carried out in case of suspected non-compliances.

SRARNS has documented its inspection process. Inspections are announced 7 days in advance. Conclusions of inspections are presented in writing at the end of the inspection using a form, the content of which is defined. The record is signed by both parties. If non-compliances are identified, the corrective actions are required to be addressed in a fixed timeframe by the authorized party through a procedural decision issued by the inspector, at the latest 30 days after the inspection. After the information on corrective actions is received and verified during a follow-up inspection (on-site or "administrative", depending on the kind of initial findings), the inspector issues a second report to record whether the corrective actions have been taken; the report is sent to the authorized party. All inspection records are uploaded in OWIS. Nevertheless, there is no tracking system of corrective actions prescribed and related deadlines.

In case of significant non-compliances, the Law empowers SRARNS to fine the authorized party, to suspend or to revoke its authorization (Cf. section 8).

7.2. INSPECTION OF WASTE MANAGEMENT FACILITIES

The IRRS team has been informed, that radioactive waste storage facilities are not inspected. Nevertheless, all radioactive waste storages are monitored by SRARNS inspectors. The access to one storage facility is not possible due to a physical barrier at the entrance (welded door).

7.3. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

Prior to on-site inspections, SRARNS inspectors review all relevant documents submitted by the authorized party (safety assessments, technical services reports, notifications) as well as the reports of previous inspections and get feedback by the Authorization Division.

As support to conduct the inspection, the inspectors use a general checklist together with a secondary checklist according to the practice inspected (*e.g.* radiology, nuclear medicine, NDT radiography). The IRRS team was informed that, whenever the inspection concerns a practice involving high-activity sealed sources, the fulfilment of the security requirements is also controlled.

7.4. INSPECTION OF DECOMMISSIONING ACTIVITIES

Decommissioning activities are not authorized, the safety of decommissioning activities is not reviewed and assessed, no inspections are performed, and no regulations and guides have been developed by SRARNS, except for planned central radioactive waste storage facility.

7.5. INSPECTION OF TRANSPORT

The competent authorities overseeing the transport of radioactive material in Bosnia and Herzegovina are SRARNS, Customs and the Ministry of Security (State level) and Ministry of the Interior (Entity level). Inspections can be performed in coordination with these authorities, and in particular, SRARNS has signed a formal agreement with the Customs and with the Ministry of Security. Given that there are no clear provisions defining the procedures for random inspections of packages, SRARNS is encouraged to improve the above formal agreements with the Customs and with the Ministry of Security to complete the procedures for Customs to follow when verifying shipments and packages.

SRARNS inspectors are not trained for performing inspections of transport activities, therefore SRARNS is encouraged to consider providing its staff with specific training in accordance with the SSR-6 (Rev.1). **Recommendation R8 in Section 3.3 addresses this issue.**

For road transport activities SRARNS inspectors have unlimited access to authorized facilities and activities and have the authority to perform inspections to consignors, carriers and consignees, but they are not authorized to stop the vehicles on the road without the support of the police. For air transport activities SRARNS actions are limited to inspections on shipment within national airports.

The inspection process for transport includes documents review, interviews, direct verification of equipment and marking, labelling and placarding provisions, as measurements for the verification of transport indexes.

There is a limited number of procedures for performing inspections in transport, which do not cover all aspects. SRARNS is encouraged to complete the set of procedures for performing inspections in transport and in particular, the ones regarding the inspections of packaging. **Recommendation R11 in Section 4.5 addresses this issue.**

7.6. INSPECTION OF OCCUPATIONAL EXPOSURE

The scope of inspections depends on the practice carried out as described in section 7.1. Nevertheless, for each inspection conducted in industrial or medical facilities, items of the check-list contents for occupational exposure include workers' personal dosimetry, health surveillance for category A workers, training, content of radiation protection programme, classification, and signs of supervised and controlled areas, in addition to workplace monitoring results.

7.7. INSPECTION OF MEDICAL EXPOSURE

In the annual inspection plan the highest priority is given to radiotherapy facilities, followed by nuclear medicine facilities and radiology services performing high dose radiology procedures (interventional and CT). Medium priority is given to conventional radiology and lowest to dental and densitometry facilities.

The areas of inspections are mostly concentrated in controlling compliance with regulations related to radiation protection of exposed workers, quality control procedures, training requirements for the staff involved in medical facilities and to equipment specifications. The optimization and justification of medical exposure are not yet addressed in the checklists for medical practices. However, the IRRS team was informed that the inspectors of SRARNS have recently started to incorporate these issues in their inspections. SRARNS is encouraged to include optimization and justification of medical exposure procedures within their inspection check-lists.

7.8. INSPECTION OF PUBLIC EXPOSURE

SRARNS inspection program includes activities that involve public exposure. The IRRS team was informed that the inspections cover, among others, the measures taken to restrict the external exposure of the public, the provisions for discharges of radioactive materials, the performance of monitoring programmes, and the implementation of reference and action levels.

However, SRARNS inspection checklists do not include specific items and relevant evaluation criteria supporting its oversight tasks, *e.g.* the verification of the status and performance of the authorized parties regarding the control of the public exposure as stated in the radiation protection program. **Recommendation R11 in Section 4.5 addresses this issue.**

7.9. SITE VISITS

Site visit at the Sarajevo University Clinical Center

IRRS team members observed an inspection at the radiology department in the Sarajevo University Clinical Center. At the start of the inspection SRARNS inspectors outlined to the licensee representatives (RPO and medical physicist) the purpose and scope of the inspection, its format, the areas of focus to be reviewed and the areas to be visited.

SRARNS inspectors reviewed specific details of the hospitals licence, licensee personnel details including RPO, senior management and medical physics staffing. They reviewed also the database of exposed workers, they selected a CT, a mammography and a radiography unit from the licence and reviewed records on quality control and workplace monitoring (radiological surveillance monitoring) for these three units. Access to the radiation protection manual for all relevant staff, as well as training were also discussed and patient doses from CT examinations in the hospital's dose monitoring system were compared with the national DRLs for the 5 previous months.

Inspectors visited the rooms where the X-ray units were located and checked the daily QC test results, display of annual quality control test certification, signage for controlled and supervised areas and if the identifiers present on the X-ray machines corresponded to the licence details.

At the end, inspectors performed an exit meeting and gave verbal summary of findings to licensee representatives.

The IRRS Team members consider that the inspectors carried out their duties with proficiency.

Site visit at the Public Health Institute of the Federation of Bosnia and Herzegovina

1. The IRRS team visited the laboratory providing several technical services, such as personal dosimetry and environmental monitoring. The laboratory is accredited according to ISO 17025 standard and has capabilities to characterize the presence of different radionuclides in samples. The laboratory cannot evaluate biological samples. One case of a sealed Cs-137 source contaminating a larger area was discussed, where there were no capabilities in place to deal with decontamination and waste management. Due to lack of such capacities, help from abroad was sought and internal monitoring of workers, including whole body counting, was done abroad as well. As in the foreseeable future Bosnia and Herzegovina will deal with the issue of radioactive waste management, thus arrangements for internal monitoring should be put in place. **Recommendations R3 in Section 1.7 and R4 1.9 respectively address these issues.**

2. During the site visit at the waste storage facility in Rakovića the IRRS team members were informed that there is only very limited progress for the site selection of planned central radioactive waste storage facility. The site selection lasts for more than 10 years. The Commission on the Site Selection for the Central Radioactive Waste Storage Facility was established by SRARNS comprising of representatives from ministries (health, environment and interior), SRARNS, civil protection authority, etc. Ministry of Defense, which owns some facilities, that may serve, after modification, as radioactive waste storage facility is not involved in the work of the Commission. In this way the implementation of the national policy for radioactive waste management is jeopardized. At the same time, the 'Strategy' does not clearly set up responsibility for the development of the central radioactive waste storage facility and milestones to reach the construction, commissioning and operation of this facility. During the site visit the IRRS team was informed, that one of two temporary radioactive waste storage facilities in Rakovića does not accept any radioactive waste for storage from Federation of Bosnia and Herzegovina and is not authorized yet. The application for facility authorization is at SRARNS since 2019, including safety case, which has been presented to the IRRS team (waste acceptance criteria, monitoring system and Systems Structures and Components, decommissioning plan, safety assessment, etc.). IRRS team members visited the facility itself. Despite of some technical and safety issues, such as use of flammable materials or limited physical protection system, the facility is in an acceptable condition and provides for basic safety functions during storage of radioactive waste. The members of the IRRS team were informed in the Public Health Institute of the Federation of Bosnia and Herzegovina, that the number of radioactive waste storage facilities increases annually as identified orphan sources are kept at the sites or premises, where they were found. In this way, the number of radioactive waste stores is increasing. This fact is in line with the observation, that there is no effective management and control of radioactive waste in Bosnia and Herzegovina. **Recommendations R3 in Section 1.7 addresses this issue.**

7.10. SUMMARY

SRARNS has established a set of internal procedures on inspections, including an inspection program and check lists depending on the practice involving radiation sources. The process is performed in a comprehensive and documented manner from the beginning to the closure of the inspection and feedback is shared with the authorized party.

Areas of improvement were identified and include the application of a graded approach in preparing the yearly inspection program, the development of internal procedures to support the staff, in particular in transport, justification and optimization of medical procedures, public exposure and waste management.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

The Law and the regulations provide the requirements for SRARNS inspectors to impose enforcement measures and to define the enforcement powers of the inspectors.

Enforcement actions by SRARNS, include procedural decisions, imposing corrective measures and fines. In the event of immediate danger to human life, health and environment, the inspectors may verbally request to stop a given activity or issue a procedural decision imposing temporary measures. SRARNS has the authority to amend, suspend or revoke an authorization.

The Law on Administrative Procedures describes the process of appealing against a regulatory decision.

SRARNS has not established a policy, specific to enforcement to respond to non-compliances of the authorized parties' practices and to the regulatory requirements or to conditions specified in their authorization. SRARNS has not established criteria for the imposition of corrective actions according to the significance for safety of the non-compliances and has not developed a guidance for the consistent implementation of the enforcement process by the inspectors according to a graded approach.

Due to the lack of a comprehensive enforcement policy and guidance on enforcement, there are no formal mechanisms in place to provide feedback to authorization, review and assessment and inspections processes, however the inspectors disseminate this information among themselves.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: SRARNS has not established an enforcement policy.	
(1)	**BASIS: GSR Part 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."*
R15	**Recommendation: SRARNS should establish an enforcement policy.**

8.2. ENFORCEMENT IMPLEMENTATIONS

The enforcement implementation by SRARNS is described in sections 7.1 and 8.1. Due to the lack of policy documents and guides, or procedures on enforcement, most of the decisions issued to implement corrective measures by the authorized party, are up to the interpretation of the inspector and may lead to inconsistencies. **Recommendations R15 and R17 in sections 8.1 and 9.1. respectively address this issue.**

Furthermore, regarding transport, no specific guidance material is available on how the non-compliances identified during SRARNS regulatory inspections should be corrected. SRARNS is encouraged to develop guidance on how the regulatory requirements are to be fulfilled for various transport activities.

Finally, as training for inspectors, specific to enforcement is not in place, SRARNS is encouraged to provide such training.

8.3. SUMMARY

The Law and the regulations provide the requirements for SRARNS inspectors to impose enforcement measures and define their enforcement powers. SRARNS inspectors have the authority to amend, suspend

or revoke an authorization. The Law on Administrative Procedures describes the process of appealing against a regulatory decision.

Areas of improvement have been identified including the establishment and implementation of an enforcement policy and the provision or training on enforcement to SRARNS inspectors. The development of guidance on how the regulatory requirements for transport activities are to be fulfilled is also addressed.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

According to the Law SRARNS is empowered to define the policy in the field of radiation and nuclear safety and consequently to prepare and issue the regulation and guides related to the principles set up in the Policy on the safety of ionizing radiation sources in Bosnia and Herzegovina.

The Law gives the power to the SRARNS director to issue regulations, guides, and other legal documents in the field of nuclear and radiation safety. The regulations issued by SRARNS are binding and the guides are non-binding documents.

An annual work program containing a plan of regulatory activities for the following year is sent by SRARNS to be adopted by the Council of Ministers. Part of this plan includes details on regulations to be drafted or updated and subsequently adopted. When updating existing regulations or drafting new regulations, the Director of SRARNS establishes a committee responsible for drafting these regulations. The committee comprises of 1-2 lawyers from SRARNS, SRARNS staff members from authorization division and senior management. The Director of SRARNS can issue a decision to include external professionals in the committee when required. When the regulations concerning radiation safety are to be drafted, a radiation safety expert should be on the committee. Committee usually comprises of 5-7 members and the chair of the committee can be from SRARNS or can be an external person. This mechanism for drafting and issuing regulations does not apply to the development of guides.

SRARNS considers IAEA safety standards and EURATOM Directives as the basis for updating its regulations. It has implemented a mechanism of consultation with interested parties including the public. After a regulation is drafted it is uploaded on the web application e-Consultation and on SRARNS website for three weeks and also sent to other interested parties as part of the consultation process. The comments and suggestions received are either accepted or rejected by the committee and the reasons for this are published. When SRARNS adopts a regulation, it is published in the Official Gazette of Bosnia and Herzegovina and enters into force on the eighth day after the date of publication.

The procedures for drafting, issuing and amending regulations is not documented. There is no procedure in place or documented for drafting, issuing or amending guides.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: SRARNS considers IAEA safety standards and EURATOM Directives as basis for updating its regulations and has implemented a mechanism of consultation with interested parties including the public, the process of establishing or amending regulations. However, this process is not clearly documented, and no such mechanism is in place or documented for establishing or amending guides.	
(1)	**BASIS: GSR Part 1 Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained."*
(2)	**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 learned and*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	institutional knowledge can be valuable and shall be used as appropriate in revising the regulations and guides."
(3)	**BASIS: GSR Part 3 Requirement 3 para. 2.30 states that** *"The regulatory body shall establish a regulatory system for protection and safety that includes:* *[…]* *(f) Provision of information to, and consultation with, parties affected by its decisions and, as appropriate, the public and other interested parties."*
R16	**Recommendation: SRARNS should document its mechanism for establishing and amending regulations and extend it to guidance development.**

SRARNS has also issued a set of guides for licensees, registrants and other interested parties outlining how to comply with regulatory requirements. More details on guides issued by SRARNS is described in Section 9.3 below. Guidance on the extent of content of a safety assessment, criteria for justified practices and the licensing and registration processes is not developed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: SRARNS has established a set of legally non-binding guides that specify some regulatory provisions covering radiation protection aspects. Nevertheless, for some areas, guidance or procedures for authorized parties are missing, e.g. extent of the content of a safety assessment, criteria for justified practices, details on the content of the documents (according to the practice carried out and the different stages in its lifetime) submitted by an applicant for an approval or an authorization.	
(1)	**BASIS: GSR Part 1 Requirement 24 para. 4.34 states that "***The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization. The applicant shall be required to submit or to make available to the regulatory body, in accordance with agreed timelines, all necessary safety related information as specified in advance or as requested in the authorization process."*
R17	**Recommendation: SRARNS should establish additional guidance to assist the authorized parties in implementing the regulations.**

The regulatory framework for radiation sources safety includes inter alia:

- regulation on the notification and authorization of practices involving ionizing radiation sources;
- regulation on requirements for the transfer and use of sources of ionizing radiation;
- regulation on the radiation protection in occupational exposure and public exposure;
- regulation on technical services for ionizing radiation protection;
- regulation on inspection monitoring in the field of radiation and nuclear safety;
- regulation on the control of high-activity sealed radioactive sources and orphan sources;
- regulation on keeping records of legal persons performing activities with sources of ionizing radiation;

- regulation on the security of nuclear material and radioactive sources;
- regulation on radiological emergency events in practices involving radioactive sources.

In the regulations there are no provisions for the use of radiation for human imaging for purposes other than medical practices.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no regulatory provisions for the use of ionizing radiation for human imaging for purposes other than medical practices.	
(1)	**BASIS: GSR Part 3 Requirement 18 states that** *"The government shall ensure that the use of ionizing radiation for human imaging for purposes other than medical diagnosis, medical treatment or biomedical research is subject to the system of protection and safety."*
R18	**Recommendation: SRARNS should revise the regulations to ensure that the use of ionizing radiation for human imaging for purposes other than medical diagnosis, medical treatment or biomedical research is subject to the system of protection and safety.**

9.2. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

The Law identifies the responsibility of the regulatory body (establishment of legal requirements and independently performance of regulatory control) and the duties of the authorized parties (liability for the safe management of radioactive waste generated from a practice involving radioactive sources).

A specific Regulation on Radioactive Waste Management provides additional requirements. It also defines mandatory measures and responsibilities in radioactive waste management, details of the management system, general obligations of the radioactive waste generator and storage facility operator, details on classification and characterisation of radioactive waste, requirements on radioactive waste management steps, and record keeping requirements.

Areas for improvement identified cover:

- development of a safety case for siting, design, construction, commissioning, operation, shutdown and decommissioning of all predisposal radioactive waste management facilities, not only storage facilities;
- passive means of storage facilities;
- maintenance of predisposal radioactive waste management facilities;
- approval of emergency preparedness and response plans by the regulatory body;
- development, in the design stage, an initial plan for the decommissioning of the predisposal radioactive waste management facility;
- priority of safety arrangements over the system of accounting for and control of nuclear material.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: Regulations on radioactive waste predisposal are in place. However, the following areas are either not fully or partially addressed:

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
- development of a safety case for siting, design, construction, commissioning, operation, shutdown and decommissioning of all predisposal radioactive waste management facilities, not only storage facilities; - passive means of storage facilities; - maintenance of predisposal radioactive waste management facilities; - approval of emergency preparedness and response plans by the regulatory body; - development, in the design stage, an initial plan for the decommissioning of the predisposal radioactive waste management facility; - priority of safety arrangements over the system of accounting for and control of nuclear material.	
(1)	**BASIS: GSR Part 5 Requirement 4 states that** *"The operator shall carry out safety assessments and shall develop a safety case, and shall ensure that the necessary activities for siting, design, construction, commissioning, operation, shutdown and decommissioning are carried out in compliance with legal and regulatory requirements."*
(2)	**BASIS: GSR Part 5 Requirement 11 states that** *"Waste shall be stored in such a manner that it can be inspected, monitored, retrieved and preserved in a condition suitable for its subsequent management. Due account shall be taken of the expected period of storage, and, to the extent possible, passive safety features shall be applied. For long term storage in particular, measures shall be taken to prevent degradation of the waste containment."*
(3)	**BASIS: GSR Part 5 Requirement 7, para 3.24 states that** *"To ensure the safety of predisposal radioactive waste management facilities and the fulfilment of waste acceptance criteria, management systems are to be applied to the siting, design, construction, operation, maintenance, shutdown and decommissioning of such facilities and to all aspects of processing, handling and storage of waste."*
(4)	**BASIS: GSR Part 5 Requirement 19 states that** *"Emergency preparedness and response plans, if developed by the operator, are subject to the approval of the regulatory body."*
(5)	**BASIS: GSR Part 5 Requirement 26 states that** *"The operator shall develop, in the design stage, an initial plan for the shutdown and decommissioning of the predisposal radioactive waste management facility…"*
(6)	**BASIS: GSR Part 5 Requirement 21 states that** *"For facilities subject to agreements on nuclear material accounting, in the design and operation of predisposal radioactive waste management facilities the system of accounting for and control of nuclear material shall be implemented in such a way as not to compromise the safety of the facility."*
R19	**Recommendation: SRARNS should establish and implement requirements on radioactive waste predisposal facilities in compliance with IAEA GSR Part 5.**

The regulation on radioactive waste management defines general requirements on the properties of radioactive waste package and measurable indicators of the package quality. The acceptance criteria for radioactive waste specify the characteristics of packaged and non-packaged radioactive waste and as a minimum they define the maximum radioactive content, permitted mass and dimensions of packages.

These criteria have to be approved by SRARNS. The content of a safety case provided in Annex 2 of the Regulation does not explicitly specify criteria for accepting radioactive waste package and unpacked radioactive waste for processing, storage and, in the future, for disposal. Therefore, it is not clear where and how the specifications of the radioactive waste packages and unpacked radioactive waste are derived.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Regulation on radioactive waste management identifies the basic requirements on radioactive waste package and unpacked radioactive waste properties. It is expected that these properties will be a part of waste acceptance criteria developed by the operator of the storage facility and approved by SRARNS. However, it is not clear where and how are these properties derived.	
(1)	**BASIS: GSG 3 para. 4.80 states that** *"The safety case should be used to assist in the establishment of licence conditions and other controls and requirements on the facility or activity."*
(2)	**BASIS: GSG 3 para. 4.84 states that** *"Waste acceptance criteria for the facility may be established both for individual waste packages and for the facility as a whole."*
(3)	**BASIS: SSG 23 para. 4.72 states that** *"The safety case should be used to assist in the establishment of limits, controls and conditions to be applied to all work and activities that have an influence on the safety of the facility and to be applied to the waste that will be disposed of in the facility."*
(4)	**BASIS: SSG 23 para. 4.73 states that** *"Limits and conditions of particular importance for disposal facilities are the total waste inventory acceptable and/or the acceptable concentration levels for specific radionuclides in the waste. These should be defined and/or justified on the basis of the safety assessment. Waste acceptance criteria should be established both for individual packages and for the entire facility by considering the analysis of various scenarios…"*
S6	**Suggestion: SRARNS should consider further elaborating the regulations to include the safety case as the main source of specific criteria and the indicators for accepting radioactive waste packages and unpacked radioactive waste for processing, storage and, in the future, for disposal.**

9.3. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

SRARNS has issued a number of regulations and guides to outline the requirements for radiation sources. However, there are also some areas where guidance for authorized parties is missing and would assist authorized parties in complying with regulatory requirements. SRARNS has also issued a number of guides to assist licensees and registrants to implement the requirements of the regulations. In particular:

- Guide for the development of a radiation protection program in radiodiagnostics;
- Guide for the development of a radiation protection program in dental clinics;
- Guide for radiation protection of occupationally exposed pregnant and breastfeeding workers;
- Guide for the classification of controlled and supervised areas and the categorization of occupationally exposed workers, apprentices, high school and university students;
- Guide for the radiation protection of pregnant and breastfeeding workers in medical exposure;

- Guide for the content of training of radiation protection officers in ionizing radiation protection;
- Guide on the use of personal dosimeters.

Recommendation R17 in section 9.1 addresses this issue.

9.4. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

There are no regulations on decommissioning of medical, industrial and research facilities, including radioactive waste storage facilities in operation. Regulation on radioactive waste management is the only regulation that contains selected requirements on the decommissioning of a planned centralised storage facility.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Despite the fact that there are several operating medical and industrial facilities using radiation sources, there is no regulation on decommissioning of these facilities. The regulation on radioactive waste management is the only regulation that contains selected requirements on the decommissioning for a planned centralised storage facility.	
(1)	**BASIS: GSR Part 6 Requirement 2 states that** *"A graded approach shall be applied in all aspects of decommissioning in determining the scope and level of detail for any particular facility, consistent with the magnitude of the possible radiation risks arising from the decommissioning."*
(2)	**BASIS: GSR Part 6 Requirement 5 states that** *"The regulatory body shall regulate all aspects of decommissioning throughout all stages of the facility's lifetime, from initial planning for decommissioning during the siting and design of the facility, to the completion of decommissioning actions and the termination of authorization for decommissioning. The regulatory body shall establish the safety requirements for decommissioning, including requirements for management of the resulting radioactive waste, and shall adopt associated regulations and guides. The regulatory body shall also take actions to ensure that the regulatory requirements are met."*
R20	**Recommendation: SRARNS should develop, in accordance with the IAEA GSR Part 6, regulations for decommissioning – including funding provisions for medical, industrial and research facilities using radiation sources in Bosnia and Herzegovina.**

9.5. REGULATIONS AND GUIDES FOR TRANSPORT

The Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) has entered in to force and has been ratified by succession in 1993. It has been adopted as the basis for regulation of the carriage of dangerous goods by road within the territories of Bosnia and Herzegovina.

The transport of radioactive material in Bosnia and Herzegovina is regulated by Regulation on the transport safety of radioactive material which is the only guidance available for transport operators and was issued in 2012 and is based on the IAEA TS-R-1 (2009).

Misalignments between the Regulation on the transport safety of radioactive material and IAEA SSR-6 (Rev. 1) are noted in the usage of terms (of instance, the recurring term "Radiation level" should be replaced with the term "Dose rate"). In addition, items such as the:

- introduction of a new group for the classification of Surface Contaminated Objects and all consequent changes to related paragraphs;

- introduction of new radionuclides in Table 2 of IAEA SSR-6 (Rev.1);
- introduction of the concept of ageing mechanism for packages that is to be used for shipment after storage and consequent considerations to ageing mechanisms in the safety analysis and within operating and maintenance instructions;
- modifications in the transitional arrangements regarding package designs meeting the provisions of previous editions of the transport regulations;
- deletion of leaking test requirement for LSA-III

are not taken into account in the Regulation on the transport safety of radioactive material.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Regulation on the transport safety of radioactive material is not in line with SSR-6 (Rev. 1)	
(1)	**BASIS: SSR-6 (Rev. 1), para. 307 states that** *"The competent authority shall assure compliance with these Regulations"***.**
(2)	**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 judgements, decisions and actions are based".*
R21	**Recommendation: SRARNS should revise the Regulation on the transport safety of radioactive material, to align it with the IAEA SSR-6 (Rev 1) and provide guidelines for its implementation.**

As mentioned above, SRARNS has not issued additional guidance for transport of radioactive material for users and applicants to meet the requirements as described in IAEA SSR-6 (Rev 1) and advised in:

- Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (2018 Edition) - IAEA Safety Standards Series No. SSG-26 (Rev. 1);
- Preparedness and Response for a Nuclear or Radiological Emergency Involving the Transport of Radioactive Material - IAEA Safety Standards Series No. SSG-65;
- Radiation Protection Programmes for the Transport of Radioactive Material - IAEA Safety Standards Series No. TS-G-1.3;
- The Management System for the Safe Transport of Radioactive Material - IAEA Safety Standards Series No. TS-G-1.4.

Recommendation R17 in section 9.1 addresses this issue.

9.6. REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE

According to the Regulation on radiation protection of outside workers who are engaged in work which could involve a source not under the control of their employer are not fully in line with requirements of the IAEA safety standards. Provisions for the compliance of workers are not present at all in any other regulations, thus there are no requirements listing the duties of the workers and, nor it is addressed in their training.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The obligations of workers are not present in the regulatory framework, nor it is a requirement to be part of the workers' training.	
(1)	**BASIS: GSR Part 3 Requirement 22, para. 3.83 states that** *"Workers shall fulfil their obligations and carry out their duties for protection and safety."*
R22	**Recommendation: SRARNS should revise the regulations to ensure that compliance, along with workers' obligations are present and required to be communicated to the workers.**

According to the Regulation on the radiation protection in occupational exposure and public exposure, occupationally exposed workers' medical surveillance and the assessment of occupational exposures should be done by the appropriate authorized technical services. Such technical services are also mandated to keep records of the individual exposures related to their activities, beside the authorized party.

Airline operators whose aircrew may receive more than 1 mSv effective dose per year from cosmic radiation shall seek an authorized technical service to assess the exposure of their aircrew and furthermore request information for them. The IRRS team was informed that there are no airline operators registered in Bosnia and Herzegovina.

The Regulation on the national register of individuals exposed to ionizing radiation addresses provisions for SRARNS record keeping of results from individual monitoring in an electronic system, but this is not implemented. **Recommendation S2 in Section 3.7 addresses this issue.**

The Regulation on the radiation protection in occupational exposure and public exposure states that the registration level, or the equivalent of a recording level for personal dosimetry is 0.08 mSv per month, while the Regulation on the national register of individuals exposed to ionizing radiation states that recording level for personal dose equivalent is 0.1 mSv per month. These requirements are contradictory.

Regulations state that "unusually high doses" shall be immediately reported to SRARNS, however neither this regulation, nor guides clarify the term "unusually high". Consequently, this requirement is ambiguous.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The regulations contain contradictory requirements for the recording levels for personal dosimetry and inconsistent requirements for the investigation of individual monitoring results.	
(1)	**BASIS: GSR Part 1 Requirement 2, para. 4.28 states that** "*There shall be consistency in the decision-making process of the regulatory body and in the regulatory requirements themselves, to build confidence among interested parties.*"
R23	**Recommendation: SRARNS should revise the regulations related to occupational exposures in order to make them consistent.**

Dose limits are in line with IAEA GSR Part 3 Schedule III. Dose constraints are required to be used, according to the Regulation on the radiation protection in occupational exposure and public exposure. This regulation explicitly states that the dose constraint shall be 2 mSv in a year for occupational exposures.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: An exact numerical value of 2 mSv effective dose per year is set in the regulations as a dose constraint for every practice regarding occupational exposures. Contrary, dose constraint serves as a tool for optimization of occupational exposures.	
(1)	**BASIS: GSR Part 3 Requirement 21, para. 3.77 states that** "*Employers, registrants and licensees:* *(b) Shall establish and use, as appropriate, constraints as part of optimization of protection and safety."*
R24	**Recommendation: SRARNS should make provisions to ensure that appropriate dose constraints are determined by the employers, registrants and licensees in order to optimize the protection of workers.**

The regulatory framework does not require authorized parties to have provisions to restrict access to controlled areas by administrative or physical measures for every facility. Limitation of access to controlled areas by physical means, for example where high activity sealed sources are in use, is only required because of security reasons.

During the site visit to the Sarajevo University Clinical Center, it was confirmed that arrangements are checked for the control of occupational exposures. Within the national administrative framework there are arrangements for some benefits for occupationally exposed workers. These provisions are not considered as benefits to occupationally exposed workers in exchange of providing radiation protection measures and these benefits do not relieve in any way the authorized parties from their responsibilities towards ensuring radiation protection of the occupationally exposed workers.

9.7. REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE

Regulations on radiation protection in medical exposure, provide for the specialization of health professionals with responsibilities for medical exposure, and for the delegation of the clinical responsibility of health professionals regarding individual medical exposures for ensuring protection and safety during diagnostic and therapeutic radiological procedures. Health professionals must obtain a working license from the appropriate society that requires continuous education and competence in the field of their expertise.

Regulations on training, determine a standardized way and content of training, testing, and improving knowledge about radiation protection through a single curriculum of theoretical and practical training in radiation protection and applies to the persons whose duties require specific competences in radiation protection, including RPO, exposed workers in medical practices, and the medical doctors who refer to radiological examination.

Justification of medical exposure, of new practices and individual justification, are addressed in regulations, however it is not specified which authority has the responsibility for the justification of new procedures involving medical exposure before their adoption and for the revision of existing types of procedures whenever required. **Recommendation R13 in section 5.7 addresses this issue.** Moreover, there are no regulatory provisions for the use of national or international referral guidelines for the justification of the medical exposure of an individual patient in radiological procedures.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no regulatory provisions for the use of national or international referral guidelines for the justification of the medical exposure of an individual patient in radiological procedures.	
(1)	**BASIS: GSR Part 3 Requirement 37, para. 3.158 states that** *"Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure."*
R25	**Recommendation: SRARNS should make regulatory provisions regarding the use of national or international referral guidelines for the justification of the medical exposure of an individual patient in a radiological procedure.**

Within the Regulation there are provisions for informing the patients on matters regarding the potential risks before the conduct of high dose procedures in radiology and nuclear medicine. Patients are informed about the treatment and related risks for radiotherapy practices and their consent is requested before undergoing treatment.

Optimization of medical exposure is also addressed in regulations specifically, provisions are included for the establishment and use of DRLs, for dose constraints for carers and comforters as well as for volunteers participating in biomedical and medical research programs. Criteria for the release of patients after radionuclide therapy and optimization of exposure to pregnant and breast-feeding patients are also addressed.

Regulations provide for taking necessary measures to minimize the likelihood of unintended or accidental medical exposures. In addition, Regulation on radiological emergency in practices involving radioactive sources, provides for radiological events requesting the authorized party to notify SRARNS and determines the criteria for notification/reporting unintended and accidental patient exposures for diagnostic/interventional radiology, nuclear medicine and radiotherapy.

9.8. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE

The main obligations of relevant parties concerning public exposure are established in the Law. Requirements for optimization are established and dose limits for public exposure that are in line with GSR Part 3 are established and implemented. Further requirements addressing the control of the public exposure are included in regulations. A generic dose constraint of 0.3 mSv for public exposure is established, pointing out that a lower value could be used by the authorized parties for optimization purposes.

Nevertheless, the IRRS team noticed that the established requirements for the responsibilities of relevant authorized parties, the control of discharges of radioactive materials, and the development and implementation of environmental monitoring programmes are not in line with the IAEA safety standards. Moreover, the regulatory framework does not include requirements for the authorization to provide consumer products to the public.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: The regulatory framework requires licensees and registrants to implement provisions for the control of the public exposure. However, there are no regulatory requirements for the authorization to provide consumer products to the public. In addition, the requirements related to (a) detailed responsibilities of authorized parties, including those related to control of visitors, external and

contamination in areas accessible to the public; (b) discharge of radioactive materials; and (c) monitoring programmes are not in line with GSR Part 3.	
(1)	**BASIS: GSR Part 3 Requirement 11 states that** *"The government or the regulatory body shall establish and enforce requirements for the optimization of protection and safety, and registrants and licensees shall ensure that protection and safety is optimized".*
(2)	**BASIS: GSR Part 3 Requirement 30, para. 3.126 states that** *"Registrants and licensees, in cooperation with suppliers, in applying the principle of optimization of protection and safety in the design, planning, operation and decommissioning of a source (or for closure and the post-closure period for waste disposal facilities), shall take into account: …"*
(3)	**BASIS: GSR Part 5 Requirement 30, para 3.127 states that** *"Registrants and licensees, for sources under their responsibility, shall establish, implement and maintain:* *…* *(e) Programmes for appropriate training of personnel … as well as periodic retraining as required, to ensure the necessary level of competence.* *(f) Provision for appropriate monitoring equipment, monitoring programmes and methods for assessing public exposure."*
(4)	**BASIS: GSR Part 5 Requirement 30, para 3.128 states that** *"Registrants and licensees, in cooperation with employers where appropriate:* *(a) Shall apply the relevant requirements of these Standards in respect of public exposure for visitors to a controlled area or a supervised area;* *…* *(c) Shall provide adequate information and instructions to visitors before they enter a controlled area or a supervised area…. "*
(5)	**BASIS: GSR Part 5 Requirement 30, para 3.130 states that** *"Registrants and licensees shall ensure, as appropriate, that:* *(a) Specific provisions for confinement are established ….;* *(b) Measures for protection and safety are implemented for restricting public exposure due to contamination in areas within a facility that are accessible to members of the public."*
(6)	**BASIS: GSR Part 5 Requirement 31, para 3.134 states that** *"Registrants and licensees shall review and modify their discharge control measures, as appropriate and in agreement with the regulatory body, taking into account:* *(a) Operating experience;* *(b) Any changes in exposure pathways or in the characteristics of the representative person that could affect the assessment of doses due to the discharges"*
(7)	**BASIS: GSR Part 5 Requirement 32, para 3.137 states that** *"Registrants and licensees shall, as appropriate:* *(a)Establish and implement monitoring programmes … These programmes shall include monitoring of the following, as appropriate:* *…;* *(iii) Radioactivity in the environment.* *(iv) Other parameters important for the assessment of public exposure.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	… *(f) Establish and maintain a capability to conduct monitoring in an emergency* *…* *(g) Verify the adequacy of the assumptions ….* *(h) Publish or make available on request, as appropriate, results from source monitoring ….”*
(8)	**BASIS: GSR Part 5 Requirement 33, states that** *“Providers of consumer products shall ensure that consumer products are not made available to the public unless their use by members of the public has been justified, and either their use has been exempted or their provision to the public has been authorized”*
R26	**Recommendation: SRARNS should establish regulatory requirements for the authorization to provide consumer products to the public.**
S7	**Suggestion: SRARNS should consider amending the regulations referring to the:** **- responsibilities of authorized parties regarding public exposure;** **- discharge of radioactive materials;** **- monitoring programmes** **to be in line with the IAEA safety standards.**

Regulation on the concentration limits for radionuclides in food, feed, medicines, items of general use, building materials and other goods placed on the market defines specific limits to restrict the commercialization of such commodities. An annual effective dose to the representative person between 0.1 to 1mSv is used to define the corresponding limits. Therefore, the derived concentration limits are considered conservative. Furthermore, no reference levels to facilitate the optimized control of exposures due to radionuclides in commodities have been established.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Specific concentration limits for radionuclides in commodities to control their commercialization and the public exposure have been established. Nevertheless, reference levels for the optimization of public exposure due to radionuclides in commodities are not defined.	
(1)	**BASIS: GSR Part 3 Requirement 51 states that** *“The regulatory body or other relevant authority shall establish reference levels for exposure due to radionuclides in commodities.”*
S8	**Suggestion: SRARNS should consider establishing reference levels for the optimization of exposures due to radionuclides in commodities.**

9.9. POLICY ISSUE

Radioactive Waste Management

Background:

Bosnia and Herzegovina is a small non-nuclear country. The uses of radiation sources are limited to sealed radioactive sources of all five categories, unsealed sources, and radiation generators in medical and industrial facilities.

Through the years disused radioactive sources have been accumulated in the country and they constitute the biggest part of radioactive sources present in the country.

Problem:

Bosnia and Herzegovina need to safely manage the existing disused radioactive sources in the country and find long-term solutions for their storage and disposal.

Discussion:

The IRRS team met SRARNS staff and a representative of the Public Health Institute of the Federation of Bosnia and Herzegovina to discuss matters on radioactive waste management in Bosnia and Herzegovina. No representatives of governmental bodies (Ministries, Council of Ministers, …) participated at the meeting.

The discussion was moderated by the Team Leader. SRARNS introduced the topic and the list of the topics to be dealt with in the discussion.

All team members contributed to the discussion and shared the experience and practice in their own countries.

The IRRS team emphasised during the discussion on the site selection process for central radioactive waste storage facility, that there is an urgent need for commitment of governmental bodies to develop this facility. SRARNS, as independent regulatory body, cannot lead these activities. The IRRS team supports the initiative of SRARNS to establish a committee for the site selection process but expresses serious concerns on the implementation of the committee's outcomes.

The IRRS team proposed that one Minister from the Council of Ministers is nominated as responsible for the safe management of radioactive waste in Bosnia and Herzegovina. Then the Minister can communicate with other members of the Council on this matter, e.g. on the use of former military installations for radioactive waste management. As the current practice in Bosnia and Herzegovina is to keep identified orphan sources in public domain, the IRRS team considers the establishment of an effective management and control of radioactive waste to have the highest priority for safety and security.

The members of the IRRS team shared their experience from the development of radioactive waste management facilities. In both nuclear and non-nuclear countries represented in the IRRS team, appointed high-level governmental officials undertake the leading and overall responsibility. Only as a temporary solution, in one country represented by a member of IRRS team, the regulatory body develops and operates radioactive waste management facility.

The option to dispose radioactive waste in a facility of another country, incl. disposal in a regional disposal facility is considered as unrealistic by the IRRS team, with the exception of the recycling/re-use option.

Regional solutions for disposal of radioactive waste are considered at least since 1980's without any concrete outcome. As an option, the national radioactive waste management strategy could strive to develop a disposal facility instead of central storage facility. This option would provide for a safe and sustainable solution of radioactive waste management in the country without undue burden to future generations.

The IRRS team also advised SRARNS to keep open several options, and to take advantage of assistance provided by IAEA or EC mechanisms and projects on the subject.

9.10. SUMMARY

SRARNS has issued legally binding regulations setting out basic criteria for regulatory compliance which have implemented IAEA safety standards (and transposed European Directives). SRARNS has established a process for the drafting and issuing of regulations which includes a consultation process with interested parties. SRARNS should document its mechanism for establishing and amending regulations and extend this to guidance development.

Within the regulations, areas for alignment with the provisions of IAEA safety standards include: transport regulations (alignment with SSR-6 (Rev.1); responsibilities of authorized parties regarding public exposure, discharge of radioactive materials, and monitoring programmes; dose constraints values for occupationally exposed workers; workers' obligations; use of national or international referral guidelines for the justification of the medical exposure; authorization to provide consumer products to the public. Some inconsistencies with regards to occupational exposure need to be addressed.

Finally, SRARNS would benefit from establishing additional guides to assist the authorized parties in implementing the regulations.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

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

The Law and the National Action Plan for emergency cases of public protection against ionising radiation in the event of an emergency, a nuclear accident or occurrence of nuclear damage assign the responsibility for the on-site Emergency Preparedness and Response (EPR) to the authorized party. SRARNS applies a graded approach in regulating the EPR arrangements based on source categorization.

Applicants for licenses for practices with radioactive sources are required to submit a detailed radiation protection programme. These programmes incorporate conditions for issuing authorization for practices with radiation sources in accordance with the Regulation on Notification and Authorization of Practices with Sources of Ionizing Radiation. The content of the programme is defined by the Regulation on Requirements for the Transfer and Use of Sources of Ionising Radiation. An integral part of the radiation protection programme is the emergency plan. However, Regulation on Radiological Emergency Events in Practices Involving Radioactive Sources require to develop a plan for emergency events that could occur in the practice involving radioactive sources. Additionally, the producers of radioactive waste and the operator are also obligated to prepare an emergency plan.

The IRRS team was informed that SRARNS reviews and assesses these plans in the process of granting authorizations for practices involving radioactive sources, but the regulations do not specify that SRARNS approves the plans of operating organizations.

Scrap metal yards and recycling plants are not obliged to submit an action plan to the regulatory body for review and approval for the detection of an orphan source. However, control and awareness for scrap metal yards and recycling plants has been established in the country.

SRARNS has issued the Guide for authorized parties and first responders to be used in emergencies involving orphan sources and other radioactive material in scrap metal.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The regulations related to the EPR system for radiological and nuclear emergencies are not harmonized and do not include provisions that SRARNS approves emergency plans of a facility or for an activity in Emergency Preparedness Categories III and IV.	
(1)	**BASIS: GSR Part 7 Requirement 1, para 4.5. states that** *"The government shall make adequate preparations to anticipate, prepare for, respond to and recover from a nuclear or radiological emergency at the operating organization, local, regional and national levels, and also, as appropriate, at the international level. These preparations shall include adopting legislation and establishing regulations for effectively governing the preparedness and response for a nuclear or radiological emergency at all levels. "*
(2)	**BASIS: GSR Part 7 Requirement 1, 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. 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)."*
(3)	**BASIS: GSR Part 7 Requirement 23, para 6.19. states that** *"The operating organization of*

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	a facility or for an activity in category I, II, III or IV shall prepare an emergency plan. This emergency plan shall be coordinated with those of all other bodies that have responsibilities in a nuclear or radiological emergency, including public authorities, and shall be submitted to the regulatory body for approval."
S9	**Suggestion: SRARNS should consider revising the regulations to avoid multiplication of the obligations of license applicants, to achieve harmonization of provisions regarding EPR arrangements and to define provisions for approval of emergency plans of operating organizations.**

The Law empowers SRARNS to prepare a National Action Plan and submit it to the Council of Ministers for approval.

The National Action Plan covers radiological emergencies that could occur in Bosnia and Herzegovina, as well as emergencies in other countries with the potential to cause significant consequences in the country. The National Action Plan defines roles and responsibilities for preparedness and response for a nuclear or radiological emergency that are clearly allocated among operating organizations, the regulatory body and the response organizations. SRARNS is responsible for coordinating the implementation of the Plan. After the National Action Plan is approved and implemented, it is necessary to perform a gap analysis and periodically review the document. This would reveal weak points, i.e. the functional and infrastructural elements which are not adequately covered or are not covered at all. All stakeholders, participating in the National Action Plan should perform an assessment to verify if they can meet the requirements of the Plan, and to produce a list of what is still needed in terms of functional and infrastructural requirements. Through this procedure the institutions' emergency response plans shall be harmonized with the National Action Plan. The exercise analysis will also assess the concept of operations which was used to develop the National Action Plan. SRARNS is responsible for coordinating the implementation of the Plan. However, SRARNS does not have all the information about the implementation of the National Action Plan in operating organizations and other organizations participating in EPR. Quality management programme of operating organizations, as part of the overall emergency management system, is not established.

The regulatory framework does not provide the operating organizations to develop and implement a quality management programme.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The regulatory framework does not provide the operating organizations to develop and implement a quality management programme.	
(1)	**BASIS: GSR Part 7 Requirement 26, para 6.34 states that** *"The operating organization, as part of its management system, and response organizations, as part of their emergency management system, shall establish a programme to ensure the availability and reliability of all supplies, equipment, communication systems and facilities, plans, procedures and other arrangements necessary to perform functions in a nuclear or radiological emergency as specified in Section 5. The programme shall include arrangements for inventories, resupply, tests and calibrations, to ensure that these are continuously available and are functional for use in a nuclear or radiological emergency."*
(2)	**BASIS: GSR Part 7 Requirement 26, para 6.36 states that** *"Arrangements shall be made to maintain, review and update emergency plans, procedures and other arrangements and to incorporate lessons from research, operating experience (such as in the response to*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	emergencies) and emergency exercises."
R27	**Recommendation: SRARNS should revise regulations to include the quality management programme as integral part of the emergency plan of operating organization.**

A National Action Plan is revised and updated as needed in relation to the realisation of the plan in the field of protection against ionizing radiation in accordance with international conventions. The current version addresses different scenarios as part of an assessment of existing threats that must be taken into account in the dimensioning and planning of EPR for all relevant stakeholders. The scenarios contain the description of the nature of the threats as well as the possible consequences. Nevertheless, the country lacks a comprehensive hazard assessment in line with the IAEA GSR Part 7 (e.g. description of Emergency Preparedness Category (EPC) IV and V).

In addition to the hazard assessment, off-site emergency planning distances regarding the Nuclear Power Plants (NPP) Krško and Paks need to be identified in advance during the preparedness stage. This is to ensure that effective protective actions and other response actions can be promptly implemented to protect the public that can be impacted by the hazard. For a justified and optimized response, hazards should be identified and potential consequences of a nuclear emergency beyond the borders of the country should be assessed to provide basis for establishing arrangements for preparedness and response for a nuclear emergency.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The EPR arrangements lack a comprehensive hazard assessment for a nuclear emergency for facilities classified in the EPC I or II located in another State. Off-site emergency distances regarding the NPP Krško and NPP Paks are not identified in advance during the preparedness stage.	
(1)	**BASIS: GSR Part 7 Requirement 4 states that** *"The government shall ensure that a hazard assessment is performed to provide a basis for a graded approach in preparedness and response for a nuclear or radiological emergency."*
(2)	**BASIS: GSR Part 7 Requirement 4, para 4.18 states that** *"Hazards shall be identified and potential consequences of an emergency shall be assessed to provide a basis for establishing arrangements for preparedness and response for a nuclear or radiological emergency. These arrangements shall be commensurate with the hazards identified and the potential consequences of an emergency."*
(3)	**BASIS: GSR Part 7 Requirement 9, para 5.38 states that** *"For facilities in category I or II, arrangements shall be made for effectively making decisions on and taking urgent protective actions, early protective actions and other response actions off the site in order to achieve the goals of emergency response, on the basis of a graded approach and in accordance with the protection strategy."*
R28	**Recommendation: The Council of Ministers should ensure that a comprehensive hazard assessment is performed and arrangements are made for nuclear emergencies in line with GSR Part 7.**

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

The preparedness for radiological and nuclear emergencies only concerns facilities or activities classified in EPC III, IV and V, as per IAEA categorization. No facilities of EPC I and II exist in the country.

SRARNS does not require the coordination and integration of on-site emergency arrangements with off-site emergency response organizations (such as police, firefighting services, medical services, protection and rescue organization etc.). SRARNS does not require that operating organizations who deal with dangerous sources inform the local and regional governments on their plan for emergency events. The IRRS team was informed that the off-site response organizations are not aware of the EPR on-site arrangements.

The IRRS Team was informed that off-site emergency services are available to support the on-site emergency response as required in IAEA GSR Part 7. However, this off-site support has not been formally arranged among operators and responders to ensure its availability and reliability when needed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Off-site emergency services are available to support the on-site emergency response. However, this off-site support has not been formally arranged among operators and support providers to ensure its availability and reliability when needed.	
(1)	**BASIS: GSR Part 7 Requirement 22, 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 .The arrangements shall be clearly documented and the documentation shall be made available to all relevant parties. Arrangements shall be put in place to ensure effective working relationships among these organizations, both at the preparedness stage and in an emergency."*
R29	**Recommendation: SRARNS should require that operators establish formal arrangements or protocols with off-site emergency services providing the operator with assistance and support during the on-site emergency response.**

The Law, together with the Regulation on the Radiation Protection in Occupational Exposure and Public Exposure defines the legal basis for the protection of "workers, who take part in interventions". The Regulation on the Radiation Protection in Occupational Exposure and Public Exposure establishes dose limits and reference levels for occupational exposures in emergency exposure situations. It defines dose limits for interventions, which are emergency workers' turn-back dose levels for different circumstances. These values are in compliance with IAEA GSG-2.

There is no definition for "Helpers" and no arrangements are in place for the protection of helpers in a nuclear or radiological emergency. Even if no definition was found for "Emergency Workers", the IRRS team was informed that "Emergency Workers", responding in an emergency are formally considered as exposed workers pursuant to the Regulation on the Radiation Protection in Occupational Exposure and Public Exposure.

No criteria are established for the transition from an emergency exposure situation to an existing exposure situation, or to a planned exposure situation, or for the termination of an on-site or off-site emergency.

With the Regulation on the Radiation Protection in Occupational Exposure and Public Exposure, the generic criteria for protective actions and other response actions from the IAEA GSG-2 were transposed into legislation as well as suggested radius of the safety perimeters in a radiological emergency from the IAEA GS-G 2.1.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Some of the requirements for EPR are not in compliance with the GSR Part 7, such as the protection of helpers in nuclear or radiological emergency and the arrangements for the definition of criteria for the termination of an emergency.	
(1)	**BASIS: GSR Part 7 Requirement 11 states that** *"The government shall ensure that arrangements are in place to protect emergency workers and to protect helpers in a nuclear or radiological emergency."*
(2)	**BASIS: GSR Part 7 Requirement 18 states that** *"The government shall ensure that arrangements are in place and are implemented for the termination of a nuclear or radiological emergency, with account taken of the need for the resumption of social and economic activity."*
R30	**Recommendation: SRARNS should ensure that the regulatory framework for EPR is in line with IAEA GSR Part 7.**

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

According to the Regulation on Radiological Emergency Events in Practices Involving Radioactive Sources, the authorized party should keep the arrangements for EPR up to date. The authorized parties should provide training of their employees for emergency situations and conduct periodic exercises on emergency response on-site and off-site. The IRRS team encourages SRARNS to establish an exercise programme including comprehensive process for sharing lessons learned from on-site training drills and exercises conducted by the authorized parties.

SRARNS has the authority to evaluate and supervise the operator's emergency arrangements and to carry out inspections over the implementation of the Law and subordinate regulations in this regard. However, the IRRS team was informed that SRARNS is not performing this type of inspections.

SRARNS may conduct an on-site check to verify the validity of the submitted documentation before issuing the license. The IRRS team encourages SRARNS to improve the inspection procedures related to operator's emergency arrangements including the evaluation of their exercises. The Regulation on inspections in the field of radiation and nuclear safety does not contain clear requirements to validate EPR arrangements of operating organizations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: According to the Law, SRARNS has the responsibility to regulate on-site emergency arrangements of operators. However, SRARNS does not perform inspections in EPR, does not participate and evaluate any of their exercises.	
(1)	**BASIS: GSR Part Requirement 25, para 6.30 states that** *"Exercise programmes shall be developed and implemented to ensure that all specified functions required to be performed for emergency response, all organizational interfaces for facilities in category I, II or III, and the national level programmes for category IV or V are tested at suitable intervals. These programmes shall include the participation in some exercises of, as appropriate and feasible, all the organizations concerned, people who are potentially affected, and representatives of news media. The exercises shall be systematically evaluated (see para. 4.10(h)) and some exercises shall be evaluated by the regulatory body. Programmes shall be subject to review and revision in the light of experience gained (see paras 6.36 and 6.38)."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSR Part 1 Requirement 27, states that** *"The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization."*
R31	**Recommendation: SRARNS should implement regulatory provisions regarding EPR and perform inspection, enforcement and evaluation of operator's emergency exercises.**

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

Bosnia and Herzegovina is a Party to the IAEA "Convention on Early Notification of a Nuclear Accident", and "Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency". SRARNS is the Competent Authority for Emergencies Abroad and the Competent Authority for Domestic Emergencies for these conventions and assumes the role of the INES National Officer.

Roles and responsibilities for preparedness and response to a nuclear or radiological emergency are clearly allocated among stakeholders. In order to fulfil its role in EPR, SRARNS has established a radiation emergency team within its organizational structure. The team performs the tasks arising from the National Action Plan under the jurisdiction of SRARNS.

SRARNS has issued plan and procedures to ensure an adequate response of its personnel in case of an emergency (SRARNS Emergency Plan, SRARNS Procedures for notification and activating, SRARNS Procedures for Response, SRARNS Emergency Response Handbook, and SRARNS Maintaining Emergency Preparedness).

Pursuant to the "Framework Law on the Protection and Rescue of People and Property from Natural or Other Disasters in Bosnia and Herzegovina" of 15 May 2008, the Council of Ministers establishes the Coordination Body of the country for Protection and Rescue of People and Property from Natural or Other Disasters in Bosnia and Herzegovina. If the Coordinating Body has not been activated then coordination is carried out by SRARNS in accordance with the National Action Plan, depending on the EPC.

Bosnia and Herzegovina has established bilateral agreements and memoranda of understanding related to EPR with several countries, namely: Montenegro, Slovenia, North Macedonia and Albania. In 2011, the Protocol on communication between regulatory bodies of Bosnia and Herzegovina and Croatia in case of illicit trafficking was signed.

The IRRS team was informed of insufficient human resources for the discharges of the competences in EPR of SRARNS. **Recommendation R2 in Section 1.3. addresses this issue.**

10.5. SITE VISIT

Operational and Communication Centre of Bosnia and Herzegovina – 112

The Ministry of Security of Bosnia and Herzegovina comprises of the Civil Protection Sector, which has four units (international cooperation, strategic planning and countermeasures, organization and training, operational-communications centre – 112). It is expected that this sector will cooperate in national emergency planning and support the Coordination Body at the state level.

The main role of the Operational and Communication Centre – 112 is to collect and exchange information on a daily basis with the stakeholders in protection and rescue system, implement and coordinate the response to all types of hazards. It acts as an internal communication hub, as well as a link to international institutions in the area of protection and rescue. The National Warning Point role in a nuclear or radiological

emergency is assigned to the Operational and Communication Centre – 112. This centre houses a room for the Coordination Body of Bosnia and Herzegovina.

One of the primary tasks of the Operational and Communication Centre of Bosnia and Herzegovina – 112 is to improve the operational readiness and coordination with the operational centres at the lower levels of the organization. This centre does not receive calls from citizens except at the explicit request of the entities and/or Brcko District.

10.6. SUMMARY

Bosnia and Herzegovina has put in place an operational EPR capability for radiological and nuclear emergencies and has established bilateral and multilateral exchange with the neighbouring countries.

Within the regulation, some EPR provisions are not in compliance with IAEA GSR Part 7, mainly in the areas of SRARNS provisions for approving emergency plans of operating organizations; a comprehensive process for sharing, evaluating and implementing lessons taken by the on-site exercises; a quality management programme for EPR of operating organization; a definition of emergency workers and helpers and criteria for protection of helpers in an emergency; criteria for the termination of an emergency; and a comprehensive hazard assessment for nuclear emergencies.

11. REGULATORY IMPLICATIONS OF PANDEMIC SITUATIONS

During the period of COVID-19 pandemic, SRARNS used the additional option of work from home. SRARNS IT department had developed a secured environment that enabled any three staff members to be remotely connected to SRARNS's server. As such, the staff had the same access to the SRARNS server as being in the office. Other correspondence and document management were functional through an on-duty staff member in the office. Most of the documents were received as scanned at SRARNS' official mail info@darns.gov.

Authorization: During this period SRARNS covered the function of authorization as usual. Approvals for export, import, and transport were issued upon request of authorization holders, however, the number of requests was smaller than before the pandemic. The validation of authorizations was extended for a period of one year.

Inspections: No restrictions were imposed on carrying out on-site inspections, even on medical facilities. Nevertheless, the inspectors had also the flexibility to perform "administrative" inspections in reviewing the documents requested from the authorized parties (which were previously informed). The option of on-line inspections was not used by SRARNS. The inspectors kept contact with RPOs in the institutions with the most significant radiation risk (clinical centers). In 2020 and 2021 not all planned on-site inspections were performed, especially in the medical facilities. SRARNS took actions to visit and assess locations where lightning rods are in place.

Emergency Preparedness and Response: SRARNS participated in virtual meetings and events on EPR, such as workshops, trainings, USIE and ECURIE exercises organized by the IAEA and European Commission.

Trainings and Meetings: The staff attended and participated in regional and other workshops, training courses, and meetings, whenever possible through on-line connection. The projects in which SRARNS participates (E.G. EC/ DG DEVCO projects) were implemented to the possible extend using the option of virtual meetings. The technical services didn't provide the planned training and SRARNS alleviated the training requirements and at the same time extended the validity of certifications.

SRARNS issued a decision (04-02-2-232/21, on 11-02-2021) to alleviate requirements for training of workers and did not consider the training certificates during inspections.

Overall, SRARNS believes that the radiation safety protection in Bosnia and Herzegovina was not affected during the pandemic. The country's international obligations entrusted to SRARNS (conventions and agreements) were implemented as required.

APPENDIX I – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS:		
SIRC Igor	Slovenian Nuclear Safety Administration, Slovenia	Igor.Sirc@gov.si
ALVANO Paolo	National Inspectorate for Nuclear Safety and Radiation Protection (ISIN), Italy	paolo.alvano@isinucleare.it
CHIPURU Justice	Radiation Protection Authority of Zimbabwe, Zimbabwe	jchipuru@rpaz.co.zw
CUNNINGHHAM Noeleen	Environmental Protection Agency, Office of Radiological Protection, Ireland	n.cunningham@epa.ie
DELRUE Andrée	Autorité de Sûreté Nucléaire (ASN), France	andree.delrue@asn.fr
ELEK Richard	Hungarian Atomic Energy Authority (HAEA), Hungary	richard.elek@gmail.com
KALATHAKI Maria	Greek Atomic Energy Commission (EEAE), Greece	maria.kalathaki@eeae.gr
LIETAVA Peter	State Office for Nuclear Safety, Czech Republic	peter.lietava@sujb.cz
ØHLENSCHLÆGER Mette	Danish Health Authority, Radiation Protection, Denmark	moe@sis.dk
POPOVIC Stela	Civil Protection Directorate, Department for radiological and nuclear emergency, Croatia	spopovic5@mup.hr
PRENDES Miguel	Nuclear and Radiological Regulatory Commission (NRRC), Saudi Arabia	mprendes64@gmail.com
IAEA STAFF		
KAMENOPOULOU Vasiliki	IAEA Team Coordinator	v.kamenopoulou@iaea.org
BISHOP LASOVSKA Martina	Administrative Assistant	m.bishop-lasovska@iaea.org
LIAISON OFFICER		
Dizdarević Emir	State Regulatory Agency for Radiation and Nuclear Safety (SRARNS)	emir.dizdarevic@darns.gov.ba

GROUP PHOTO


BOSNA I HERCEGOVINA
БОСНА И ХЕРЦЕГОВИНА
BOSNIA AND HERZEGOVINA

APPENDIX II – MISSION PROGRAMME

IRRS MISSION TO BOSNIA&HERZEGOVINA
27 November to 07 December 2022
MISSION PROGRAMME

Sunday 27 November 2022		
IRRS Initial Team Meeting		
13:30 - 18:00	Opening remarks by the IRRS Team Leader Introduction by IAEA Coordinator Self-introduction of all attendees IRRS Process (IAEA) Report writing (IAEA) Schedule (TL, IAEA) Administrative arrangements (host country Liaison Officer, IAEA): Detailed Mission Programme First impression from IRRS team members arising from the Advance Reference Material (all team members): Presentations and preliminary findings	Venue: Hotel Holiday Sarajevo Participants: IRRS team + Liaison Officer (LO)
19:30 – 21:00	IRRS team dinner	IRRS team, LO
Monday 28 November 2022		
IRRS Entrance Meeting		
09:30 – 11:30	09:30 Arrival, registration, 9:45 Welcoming Address – (*officials from the host country*) 10:15 IRRS Team Leader – Expectations for the Mission and introduction of the IRRS team 10:30 IRRS team members' and Counterparts' self-presentation 10:45 Host Institution presentation – Regulatory Overview, SARIS results (strengths, challenges, action plan) (SRARNS) 12:00 Group Photo	Venue: Parliamentary Assembly of B&H Participants: High level government official, Regulatory Body management and staff, officials from relevant organizations, IRRS team, LO
12:00 -13:00	Lunch	

13:00 - 17:00	Interviews and discussions with counterparts (parallel discussions)	Venue: SRARNS offices (per Module) Counterparts and IRRS team
17:00 - 18:00	Daily IRRS team meeting (Reporting on interviews; preliminary findings)	Venue: SRARNS Participants: IRRS team + LO
	Writing the report	Hotel
Tuesday 29 November 2022		
Daily Discussions / Interviews		
09:00 - 12:00	Interviews and discussions with counterparts (parallel discussions) and/or Site visits	Venue: SRARNS offices (per Module) Counterparts and IRRS team
09:00 – 16:00	Site-visits	(With SRARNS Inspectors) Medical facility: Clinical Hospital Sarajevo Ministry of Security of Bosnia and Herzegovina Operational and Communication center BH 112
12:00 - 13:00	Lunch	
13:00–17:00	Interviews and discussions with counterparts (parallel discussions) and/or site visits	Venue: SRARNS offices (per Module) Counterparts and IRRS team
17:00 - 18:00	Daily IRRS team meeting (quick briefing on interviews and/or site visits, draft of preliminary findings)	Venue: SRARNS Participants: IRRS team + LO
	Writing the report	Hotel

Wednesday 30 November 2022		
Daily Discussions / Interviews		
09:00 - 16:00	Interviews and discussions with counterparts (parallel discussions) and/or site visits	Venue: SRARNS offices (per Module) Counterparts and IRRS team
	Site-visits	(With SRARNS Inspectors) *Waste management facility: RAW storage facility Rakovica* *Dosimetry laboratory* *Public Health Institute of FB&H*
12:00 - 13:00	Lunch	
17:00-18:00 extend as needed	Daily IRRS team meeting (quick briefing on interviews and/or site visits, draft of preliminary findings)	Venue: SRARNS Participants: IRRS team + LO
	Draft of preliminary findings - finalization	Hotel
Thursday 01 December 2022		
Daily Discussions / Interviews		
09:00 - 10:30	Follow-up Interviews and discussions with counterparts, if necessary (parallel discussions) Individual discussion with counterparts on the preliminary findings	Venue: SRARNS Participants: IRRS team and Counterpart
10:30 – 12:00	IRRS Team finalize recommendations, suggestions and good practices	Venue: SRARNS Participants: IRRS team + LO
12:00 - 13:00	Lunch	
13:00 – 17:00	Report writing	Venue: SRARNS Participants: IRRS team

17:00 - 18:00 extend as needed	Daily IRRS Team Meeting (Quick review any difficulties regarding the report)	Venue: SRARNS Participants: IRRS team + the LO
	Finalization of first draft of the report (without compilation)	Hotel
Friday 02 December 2022		
Report reviewing and discussions		
09:00 - 12:00	Cross reading	Venue: SRARNS Participants: IRRS team
12:00	Draft report individual contributions after cross reading to administrative assistant – Compilation	
12:00 - 13:00	Lunch	
13:00 - 15:00	Policy Discussion	Venue: SRARNS Participants: IRRS team + the LO
15:00 – 18:00	Individual review of the full report	Venue: SRARNS Participants: IRRS team + the LO
	Individual review of the full report	Hotel
Saturday 03 December 2022		
Report finalization		
09:00 - 18:00	Finalization of the draft report by the entire IRRS Team	Venue : Hotel Participants: IRRS team
20:00 – 22:00	IRRS Team Lead and IAEA Coordinator edit draft report	Venue : Hotel Participants: IRRS team
	Draft Report submitted to counterparts	
Sunday 04 December 2022		
IRRS Team cultural event and rest day		Visit Mostar
Monday 05 December 2022		
Report commenting and finalization		
09:00 - 12:00	IRRS TL and TC draft the Executive Summary, the Press Release and the TL Presentation	Venue: Hotel

		Participants: TL and TC
12:00 - 13:00	Lunch	
13:00 - 15:00	Host finalises the review of the draft report and submit written comments to the IRRS Team	
15:00 -	IRRS Team reviews Host's comments and finalizes draft report.	Venue: Hotel Participants: IRRS team
	IRRS Team Lead and IAEA Coordinator finalize draft report editing	Venue: Hotel Participants: TL and TC
Tuesday 06 December 2022		
Report finalization		
09:00 - 12:00	Team meeting for report finalization based on discussions with the Hosts	Venue: SRARNS Participants: IRRS team and Host counterparts
12:00 - 13:00	Lunch	
13:00 - 16:00	Team meeting for report finalization based on discussions with the Hosts IRRS Team Lead and IAEA Coordinator finalize draft report editing	Venue: SRARNS Participants: IRRS team and Host counterparts
16:00	Submission of the Final Draft Report to the Hosts	
16:00 - 17:00	Press release finalization	Venue: SRARNS IRRS Team Leader and IAEA Coordinator
19:00 – 21:00	Farewell dinner	Venue: TBD Participants: IRRS team and Counterparts
Wednesday 07 December 2022		
IRRS Exit meeting		
9:30 - 12:00	IRRS Exit meeting	Venue: Premise of Parliamentary Assembly of B&H Participants: Government Officials
	Main findings of the IRRS mission (Team Leader)	
	Remarks by the Host Institution in response to the mission findings. (APA+IGAMAOT)	

	IAEA Official: Closing	(TBC), Management and staff, the IRRS team + the Liaison Officer

APPENDIX III – SITE VISITS

1. Site visit at the Sarajevo University Clinical Center

2. Site visit at Public Health Institute of the Federation of Bosnia and Herzegovina

3. Operational and Communication Centre of Bosnia and Herzegovina – 112

APPENDIX IV – LIST OF COUNTERPARTS

	IRRS EXPERTS	Lead Counterpart
1.	**LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES**	
	Igor Sirc	Marinko Zeljko Sanjin Pandžić
2.	**GLOBAL NUCLEAR SAFETY REGIME**	
	Igor Sirc	Marinko Zeljko Sanjin Pandžić
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**	
	Mette Øhlenschlæger	Marinko Zeljko Sanjin Pandžić Zoran Tešanović Nermin Halepović Selma Maksumić
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**	
	Justice Chipuru	Zoran Tešanović Nermin Halepović Selma Maksumić
5.	**AUTHORIZATION**	
	Peter Lietava Noeleen Cunningham Andrée Delrue Paolo Alvano Richard Elek Maria Kalathaki Miguel Prendes	Emir Dizdarević Irma Ćoralić Maida Isović Samir Lubenović Velibor Čuković
6.	**REVIEW AND ASSESSMENT**	
	Peter Lietava	Emir Dizdarević

	IRRS EXPERTS	Lead Counterpart
	Noeleen Cunningham Andrée Delrue Paolo Alvano Richard Elek Maria Kalathaki Miguel Prendes	Irma Ćoralić Maida Isović Samir Lubenović Velibor Čuković
7.	**INSPECTION**	
	Peter Lietava Noeleen Cunningham Andrée Delrue Paolo Alvano Richard Elek Maria Kalathaki Miguel Prendes	Emir Dizdarević Irma Ćoralić Maida Isović Samir Lubenović Velibor Čuković
8.	**ENFORCEMENT**	
	Peter Lietava Noeleen Cunningham Andrée Delrue Paolo Alvano Richard Elek Maria Kalathaki Miguel Prendes	Emir Dizdarević Irma Ćoralić Maida Isović Samir Lubenović Velibor Čuković
9.	**REGULATIONS AND GUIDES**	
	Peter Lietava Noeleen Cunningham Andrée Delrue Paolo Alvano Richard Elek Maria Kalathaki Miguel Prendes	Emir Dizdarević Irma Ćoralić Maida Isović Samir Lubenović Velibor Čuković

	IRRS EXPERTS	Lead Counterpart
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**	
	Stela Popovic	Velibor Čuković

APPENDIX V – RECOMMENDATIONS (R), SUGGESTIONS (S) AND GOOD PRACTICES (GP)

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES	**R1**	The Council of Ministers should revise the Policy for safety to be in line with IAEA GSR Part 1 (Rev.1) requirements.
	R2	The Council of Ministers should ensure sufficient financial and human resources for SRARNS to fulfil its responsibilities.
	R3	The Council of Ministers should ensure effective management and control of radioactive waste.
	R4	The Council of Ministers should make provisions to ensure that internal dosimetry is made available to exposed workers.
2. THE GLOBAL SAFETY REGIME	**R5**	SRARNS should provide for collecting and analysing operating and regulatory experiences and for disseminating the lessons learned for their use by authorized parties, SRARNS itself and other relevant authorities.
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	**R6**	SRARNS should perform its functions effectively in a manner commensurate with the radiation risks associated with facilities and activities.
	R7	The Council of Ministers should ensure that SRARNS is effectively independent in its safety related decision making.
	S1	SRARNS should consider putting in place formal arrangements with technical services and other professional consultants in order to avoid conflicts of interest.
	R8	SRARNS should develop and periodically revise a human resource plan based on an analysis of the competences and skills needed to perform its regulatory functions and revise its organizational structure accordingly.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	S2	SRARNS should consider establishing a register for individual doses from occupational exposure and systematically maintaining the register of radiation sources.
	R9	SRARNS should establish provisions for effective mechanisms of communication and meetings with interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body.
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	**R10**	SRARNS should establish a safety policy in its management system.
	R11	SRARNS should ensure that all processes and procedures are documented to ensure stability and consistence of regulatory control and to enhance regulatory effectiveness and efficiency.
	R12	SRANS should conduct independent assessments regularly to measure, assess and review its management system, leadership for safety and its safety culture in order to improve safety performance.
5. AUTHORIZATION	**S3**	SRARNS should consider excluding radioactive waste from the clearance concept except exempt waste and very short-lived radioactive waste after storage for decay.
	R13	The Council of Ministers should make provisions for clear assignment of responsibilities for justification of new procedures involving medical exposure before their adoption and for revising the existing types of procedures whenever new important evidence on their efficiency or consequences has appeared.
	S4	SRARNS should consider continuing the development of the national DRLs and the implementation of their use for the optimization of medical exposures.
6. REVIEW AND ASSESSMENT	**S5**	SRARNS should consider improving the implementation of the oversight provisions to control radioactive discharges in line with GSR Part 3.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R14	SRARNS should develop and implement provisions to ensure: - that existing exposure situations that have been identified are evaluated to determine which public exposures, including radon indoors, are of concern from the radiation protection point of view. the appropriate management of public exposures of concern from the radiation protection point of view.
7. INSPECTION		
8. ENFORCEMENT	**R15**	SRARNS should establish an enforcement policy.
9. REGULATIONS AND GUIDES	**R16**	SRARNS should document its mechanism for establishing and amending regulations and extend it to guidance development.
	R17	SRARNS should establish additional guidance to assist the authorized parties in implementing the regulations.
	R18	SRARNS should revise the regulations to ensure that the use of ionizing radiation for human imaging for purposes other than medical diagnosis, medical treatment or biomedical research is subject to the system of protection and safety.
	R19	SRARNS should establish and implement requirements on radioactive waste predisposal facilities in compliance with IAEA GSR Part 5.
	S6	SRARNS should consider further elaborating the regulations to include the safety case as the main source of specific criteria and the indicators for accepting radioactive waste packages and unpacked radioactive waste for processing, storage and, in the future, for disposal.
	R20	SRARNS should develop, in accordance with the IAEA GSR Part 6, regulations for decommissioning – including funding provisions for medical, industrial and research facilities using radiation sources in Bosnia and Herzegovina.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R21	SRARNS should revise the Regulation on the transport safety of radioactive material, to align it with the IAEA SSR-6 (Rev 1) and provide guidelines for its implementation.
	R22	SRARNS should revise the regulations to ensure that compliance, along with workers' obligations are present and required to be communicated to the workers.
	R23	SRARNS should revise the regulations related to occupational exposures in order to make them consistent.
	R24	SRARNS should make provisions to ensure that appropriate dose constraints are determined by the employers, registrants and licensees in order to optimize the protection of workers.
	R25	SRARNS should make regulatory provisions regarding the use of national or international referral guidelines for the justification of the medical exposure of an individual patient in a radiological procedure.
	R26	SRARNS should establish regulatory requirements for the authorization to provide consumer products to the public.
	S7	SRARNS should consider amending the regulations referring to the: - responsibilities of authorized parties regarding public exposure; - discharge of radioactive materials; - monitoring programmes to be in line with the IAEA safety standards.
	S8	SRARNS should consider establishing reference levels for the optimization of exposures due to radionuclides in commodities.
10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS	**S9**	SRARNS should consider revising the regulations to avoid multiplication of the obligations of license applicants, to achieve harmonization of provisions regarding EPR arrangements and to define provisions for approval of emergency plans of operating organizations.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R27	SRARNS should revise regulations to include the quality management programme as integral part of the emergency plan of operating organization.
	R28	The Council of Ministers should ensure that a comprehensive hazard assessment is performed and arrangements are made for nuclear emergencies in line with GSR Part 7.
	R29	SRARNS should require that operators establish formal arrangements or protocols with off-site emergency services providing the operator with assistance and support during the on-site emergency response.
	R30	SRARNS should ensure that the regulatory framework for EPR is in line with IAEA GSR Part 7.
	R31	SRARNS should implement regulatory provisions regarding EPR and perform inspection, enforcement and evaluation of operator's emergency exercises.

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

1	NS_Law (Act_on_Radiation_and_Nuclear_Safety)
2	Nucl_dam_Law (Law on liability for nuclear damage)
3	Safety_Policy (Policy on the safety of ionizing radiation sources in Bosnia and Herzegovina)
4	RAW_Strategy (Strategy of radioactive waste management in Bosnia and Herzegovina)
5	Emergency_Plan (National action plan for emergency cases)
6	RAW_Reg (Regulation on Radioactive Waste Management)
7	Transport_Reg (Regulation on the transport safety of radioactive material)
8	HASS_Reg (Regulation on the control of high activity sealed radioactive sources and orphan sources)
9	Thr_cat_Reg (Regulation on the categorization of radiation threats)
10	Oc_Pub_Reg (Regulation on the radiation protection in occupational exposure and public exposure)
11	Med_Reg (Regulation on the ionizing radiation protection in medical exposure)
12	Med_Surv_Reg (Regulation on the medical surveillance of occupationally exposed workers)
13	Rad_mon_Reg (Regulation on the monitoring of radioactivity in the environment)
14	Rad_food_Reg (Regulation on the concentration limits for radionuclides)
15	QE_Reg (Regulation on recognition of the qualified expert status)
16	Notif_Reg (Regulation on the notification and authorization of practices involving ionizing radiation sources)
17	Training_Reg (Regulation on the training in ionizing radiation protection)
18	Rad_Prot_Serv_Reg (Regulation on the radiation protection and medical physics service)
19	Security_Reg (Regulation on the security of nuclear material and radioactive sources)
20	TSO_Reg (Regulation for technical services for ionizing radiation protection)
21	Transf_Use_Reg (Regulation on requirements for the transfer and use of sources of ionising radiation) - Copy
22	Insp_Reg (Regulation on inspection monitoring in the field of radiation and nuclear safety)
23	RPO_Reg (Regulation on radiation protection officer)
24	Outs_work_Reg (Regulation on radiation protection of outside workers)
25	Emerg_Event_Reg (Regulation on radiological emergency events in practices involving radioactive sources)
26	Regist_Reg (Regulation on the national register of individuals exposed to ionizing radiation)

27	Regulation on keeping records of legal persons performing activities with sources of ionizing radiation
28	Reg on the conditions and manner of sealing business premises and funds for the work of the subject of supervision
29	Manag_Manual (Management manual of the State Regulatory Agency for Radiation and Nuclear Safety)
30	Draft Reg on NORM_final

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