

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

**THE FORMER YUGOSLAV REPUBLIC OF
MACEDONIA**

Skopje, the Former Yugoslav Republic of Macedonia

30 October – 7 November 2017

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



**Integrated
Regulatory
Review Service**

IRRS



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**REPORT OF THE
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INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
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THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA

Mission dates: 30 October – 7 November 2017
Regulatory body visited:
Location: Skopje, the Former Yugoslav Republic of Macedonia

Regulated facilities and activities in the mission scope:	<i>Radiation Sources in Industrial and Medical Facilities, Radioactive Waste Management, Decommissioning, Transport, Emergency</i>
Organized by:	<i>IAEA</i>

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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.

CONTENTS

EXECUTIVE SUMMARY	1
I. INTRODUCTION	3
II. OBJECTIVE AND SCOPE	4
III. BASIS FOR THE REVIEW	5
1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	7
1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY.....	7
1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY.....	8
1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE.....	9
1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS	10
1.5. COORDINATION OF AUTHORITIES WITH RESPONSIBILITIES FOR SAFETY WITHIN THE REGULATORY FRAMEWORK.....	10
1.6. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE EXISTING OR UNREGULATED RADIATION RISKS.....	10
1.7. PROVISIONS FOR THE MANAGEMENT OF RADIOACTIVE WASTE.....	11
1.8. COMPETENCE FOR SAFETY.....	13
1.9. PROVISION OF TECHNICAL SERVICES	15
1.10. SUMMARY.....	16
2. THE GLOBAL SAFETY REGIME	17
2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION	17
2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE.....	18
2.3. SUMMARY.....	18
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	19
3.1. ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND ALLOCATION OF RESOURCES.....	19
3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS	19
3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY	20
3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS.....	20
3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES.....	21
3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL	22
3.7. SAFETY RELATED RECORDS.....	22
3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES.....	23
3.9. SUMMARY.....	24
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	25
4.1. LEADERSHIP FOR SAFETY	25
4.2. MANAGEMENT FOR SAFETY	25
4.2.1. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM.....	25
4.3. THE MANAGEMENT SYSTEM	26
4.4. MANAGEMENT OF RESOURCES	27
4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES.....	28
4.6. CULTURE FOR SAFETY	28
4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT	29
4.8. SUMMARY.....	29
5. AUTHORIZATION	30
5.1. GENERIC ISSUES	30
5.2. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES.....	32
5.3. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES.....	32

5.4. AUTHORIZATION OF TRANSPORT	32
5.5. SUMMARY.....	33
6. REVIEW AND ASSESSMENT.....	34
6.1. GENERIC ISSUES.....	34
6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT.....	34
6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT....	34
6.1.3. BASES FOR REVIEW AND ASSESSMENT	34
6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT.....	35
6.2. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES	36
6.3. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES	36
6.4. REVIEW AND ASSESSMENT FOR TRANSPORT	36
6.5. SUMMARY.....	36
7. INSPECTION.....	37
7.1. GENERIC ISSUES.....	37
7.2. INSPECTION PROGRAMME	37
7.3. INSPECTION PROCESS AND PRACTICE.....	37
7.3.1 INSPECTORS	39
7.4. INSPECTION OF WASTE MANAGEMENT FACILITIES	39
7.5. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES	39
7.6. INSPECTION OF TRANSPORT	39
7.7. SUMMARY.....	40
8. ENFORCEMENT	41
8.1. ENFORCEMENT POLICY AND PROCESS	41
8.2. ENFORCEMENT IMPLEMENTATIONS.....	41
8.3. SUMMARY.....	41
9. REGULATIONS AND GUIDES.....	42
9.1. GENERIC ISSUES	42
9.2. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES	43
9.3. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES	43
9.4. REGULATIONS AND GUIDES FOR TRANSPORT	44
9.5. SUMMARY.....	45
10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS.....	46
10.1. AUTHORITY AND RESPONSIBILITIES FOR REGULATING ON-SITE EPR OF OPERATING ORGANIZATIONS.....	46
10.2. REGULATIONS AND GUIDES ON ON-SITE EPR OF OPERATING ORGANIZATIONS.....	47
10.3. VERIFYING THE ADEQUACY OF ON-SITE EPR OF OPERATING ORGANIZATIONS.....	48
10.4. ROLE OF REGULATORY BODY IN A NUCLEAR OR RADIOLOGICAL EMERGENCY	49
10.5. SUMMARY.....	52
11. ADDITIONAL AREAS	54
11.1. CONTROL OF MEDICAL EXPOSURES.....	54
11.2. OCCUPATIONAL RADIATION PROTECTION.....	58
11.3. CONTROL OF DISCHARGES AND MATERIALS FOR CLEARANCE. ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION	63
11.4. SUMMARY.....	65
12. INTERFACE WITH NUCLEAR SECURITY	67
12.1. LEGAL BASIS	67

12.2. REGULATORY OVERSIGHT ACTIVITIES.....	68
12.3. INTERFACE AMONG AUTHORITIES	68
12.4. SUMMARY.....	69
APPENDIX I – LIST OF PARTICIPANTS.....	73
INTERNATIONAL EXPERTS	73
APPENDIX II MISSION PROGRAMME	74
APPENDIX III SITE VISIT.....	76
APPENDIX IV– LIST OF COUNTERPARTS.....	77
APPENDIX V RECOMMENDATIONS (R), SUGGESTIONS (S) AND GOOD PRACTICES (GP).....	78
APPENDIX VI REFERENCE MATERIAL USED FOR REVIEW.....	83
APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW	85
APPENDIX VIII ORGANIZAIONAL CHART	87

EXECUTIVE SUMMARY

At the request of the Government of the Former Yugoslav Republic of Macedonia, an international team of senior radiation safety experts met with representatives of the Government and of the Radiation Safety Directorate (RSD) from 30 October to 7 November 2017 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the IRRS mission was to perform a peer review of the Former Yugoslav Republic of Macedonia national regulatory framework for radiation safety. The mission took place at the RSD Headquarters in Skopje. Meetings were organized with representatives of the Government, the Ministry of Finance, the Ministry of Health, the Ministry of Transport and Communications, the Crises Management Centre, the Transport Inspectorate and the Customs Administration.

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

The IRRS team consisted of 9 senior regulatory experts from 9 IAEA Member States, one observer, 2 IAEA staff members and one IAEA administrative assistant. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including authorization, review and assessment, inspection and enforcement processes, development and content of regulations and guides; emergency preparedness and response; control of medical exposures, occupational radiation protection, control of radioactive discharges and materials for clearance, environmental monitoring, transport, radioactive waste management and interface of safety with security.

The IRRS mission included two policy issues discussions on the “Financial independence of the regulatory body” and on the “Radioactive waste management: transparency and public acceptance”. The discussion revealed the need for RSD to take immediate actions to ensure that there is sufficient regulatory control of legacy sources and radioactive waste until the Government establishes and implements the national policy and strategy for the management of radioactive waste. Communication with all stakeholders, including the public, and awareness campaigns will help achieving the goal.

The mission included observations of regulatory activities and interviews and discussions with staff of RSD. Activities included visits to: Institute of Public Health, Institute of Pathophysiology and Nuclear Medicine, RZ Technicka Kontrola - Industrial Radiography, and Biotek Transport Company. The IRRS team members observed regulated activities and performance of inspection activities, including discussions with the licensee personnel and management.

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

The IRRS team observed that the RSD counterparts were committed to provide the regulatory oversight of all activities with radiation sources. The invitation of the IRRS mission demonstrates the Government’s and the RSD’s commitment to improve the national legal and regulatory framework for radiation safety.

The IRRS team noted that the regulatory body faces challenges, for example, in regulating disused radioactive sources until the national strategy for decommissioning and radioactive waste management is being established and implemented.

The IRRS team identified a good practice and made recommendations and suggestions that indicate where improvements are necessary or desirable to continue enhancing the effectiveness of regulatory functions in line with IAEA safety standards. The IRRS team recognized that some of its findings confirmed the actions identified by RSD as result of its self-assessment.

The good practice identified by the IRRS team concerns a web-based system (EXIM) commonly used by RSD and Customs for the authorization of import and export of radioactive materials that significantly enhances transparency of RSD and promotes the effective cooperation among the two authorities.

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

The mission provided recommendations and suggestions for improvements, including:

- The Government should:
 - revise and complete the national legal framework to ensure consistency with IAEA safety standards;
 - establish and implement a national policy and strategy for decommissioning and the management of radioactive waste;
 - provide RSD with sufficient resources to adequately implement its functions and responsibilities
- RSD should:
 - review and revise the regulatory framework to be consistent with IAEA safety standards;
 - ensure that there is sufficient regulatory control of legacy sources and radioactive waste;
 - establish and implement an integrated management system with formal processes that are based on specific policies, principles and criteria, and follows specified procedures;
 - establish and use guides that cover all its regulatory functions and all types of facilities and activities using radiation sources;
 - ensure that all radiation sources, including disused sources and radioactive waste, are appropriately authorized;
 - further promote cooperation and communication with interested parties;
 - ensure that safety measures and nuclear security measures are designed and implemented in an integrated manner.

The IRRS team findings are summarized in Appendix V.

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

I. INTRODUCTION

At the request of the Government of the Former Yugoslav Republic of Macedonia, an international team of senior safety experts met representatives of the Government, the Radiation Safety Directorate (RSD), the Ministry of Health, the Ministry of Finance, the Ministry of Transport and Communications, the Transport Inspectorate, the Crises Management Centre and the Customs Administration from 30 October to 7 November 2017 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the Former Yugoslav Republic of Macedonia's regulatory framework for radiation safety. The review mission was formally requested by the Government of the Former Yugoslav Republic of Macedonia in April 2015. A preparatory mission was conducted 7-8 June 2017 at RSD Headquarters in Skopje to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in the Former Yugoslav Republic of Macedonia and their related safety aspects and to agree the scope of the IRRS mission. It was agreed that all facilities and activities are included in the scope of the IRRS mission. The IRRS team consisted of 9 senior regulatory experts from 9 IAEA Member States, one observer, 2 IAEA staff members and one IAEA administrative assistant. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, control of medical exposure, public and environmental exposure control, transport of radioactive material, waste management and decommissioning; interface of safety with security.

In addition, policy issues were discussed, including: "Financial independence of the regulatory body" and "Radioactive waste management: transparency and public acceptance".

The RSD conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of the RSD 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 advance reference material, conduct of interviews with management and staff from RSD and direct observation of RSD regulatory activities at regulated facilities. Meetings with representatives of the Government, the Ministry of Finance, the Ministry of Health, the Ministry of Transport and Communications, the Transport Inspectorate, the Crises Management Centre and the Customs Administration were organized.

All through the mission the IRRS team received excellent support and cooperation from Radiation Safety Directorate.

II. OBJECTIVE AND SCOPE

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

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

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

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA TEAM

At the request of the Government of the Former Yugoslav Republic of Macedonia, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 7 to 8 June 2017. The preparatory meeting was carried out by the appointed team leader Mr Mika Markkanen, and the IRRS team coordinator Ms Vasiliki Kamenopoulou.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of RSD represented by Ms Biljana Georgievska Dimitrievski, RSD - Unit on legal and general affairs, international cooperation and EU integration, RSD 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;
- Transport of radioactive materials;
- Control of medical exposure;
- Occupational radiation protection;
- Public and Environmental exposure control;
- Waste management (policy and strategy, predisposal and disposal) and Decommissioning;
- Selected policy issues.

Ms Biljana Georgievska Dimitrievski made presentations on the national context, the current status of RSD and the self-assessment results to date.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in the Former Yugoslav Republic of Macedonia in October 2017.

The proposed composition of the IRRS Team was discussed and tentatively confirmed. Logistics including meetings and work places, counterparts identification, proposed site visits, lodging and transportation arrangements were also addressed.

The Former Yugoslav Republic of Macedonia Liaison Officer for IRRS mission was confirmed as Ms Biljana Georgievska Dimitrievski. RSD provided IAEA with the advance reference material (ARM) for the review at the mid of August 2017. In preparation for the mission, the IAEA team members reviewed the ARM 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, 29 October, 2017, directed by the IRRS team leader and the IRRS 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 IRRS 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, 30 October, 2017, with the participation of Ms Sandra Andovska, Cabinet Vice Prime Minister, Ms Jullijana Balevska, National Liaison Officer for IAEA as well as RSD senior management and staff. Opening remarks were made by Mr Svetislav Gjorgjevic, RSD Director, Mr Mika Markkenen, IRRS team leader and Ms Vasiliki Kamenopoulou, IRRS team coordinator. Ms Biljana Georgievska Dimitrievski gave an overview of the the Former Yugoslav Republic of Macedonia context, RSD activities and the action plan prepared as a result of the pre-mission self-assessment.

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

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

The IRRS exit meeting was held on Tuesday, 7 November, 2017. The opening remarks at the exit meeting were presented by Mr Svetislav Gjorgjevic, RSD Director and were followed by the presentation of the results of the mission by Mr Mika Markkenen, IRRS team leader. Closing remarks were made by 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 main piece of legislation governing radiation safety in the Former Yugoslav Republic of Macedonia is the “Law on Ionizing Radiation Protection and Safety”, which applies to any planned, existing or emergency exposure situation involving a risk from exposure to ionizing radiation with a view of long-term human health and environmental protection. The Law on Ionizing Radiation Protection and Safety establishes the Radiation Safety Directorate (RSD) as the single, independent regulatory body with clear powers and responsibilities to oversee radiation safety and nuclear security, and assigns clear responsibility for safety and security to regulated entities. The Government of the Former Yugoslav Republic of Macedonia has not yet established a comprehensive national policy and strategy for safety. Although some elements of the policy and strategy are embedded in the legal framework and the ratified international agreements, the IRRS team observed that not all of the requisites of a national policy and strategy for safety are addressed in the framework, in particular as they relate to effective leadership and safety culture. The IRRS team observed that it has been difficult to sustain effective leadership and management for safety within RSD since there have been changes of incumbents in the position of director of RSD over the last year. Furthermore, while the RSD has demonstrated a commitment for safety culture in practice, the elements of safety culture have not been documented in any high-level policy document. The IRRS team made a similar observation with respect to the need for documenting adequate mechanisms for considering social and economic developments, such as the national plans for facilities and activities in the medical sector. The needs for specialised staff in medical sector, including qualified experts, should be considered.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The legal framework does not contain all the requisite elements of a national policy and strategy for safety, and does not sufficiently reflect a graded approach.*

(1) **BASIS: GSR Part 1 (Rev.1) Requirement 1, para. 2.3 (f) and (g) state 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:

(f) Adequate mechanisms for taking account of social and economic developments;

(g) The promotion of leadership and management for safety, including safety culture.”

(2) **BASIS: GSR Part 1 (Rev.1) Requirement 1, para 2.4. states that** “The national policy and strategy for safety shall be implemented in accordance with a graded approach, depending on national circumstances, to ensure that the radiation risks associated with facilities and activities, including activities involving the use of radiation sources, receive appropriate attention by the government or by the regulatory body.”

R1 **Recommendation:** **The Government should review the legal framework to be consistent with the elements listed in GSR Part 1 (Rev.1), paragraph 2.3 regarding the national policy and strategy for safety in accordance with a graded approach.**

The national framework makes provision regarding human and financial resources for the RSD, and includes cost-recovery measures for services rendered by the RSD; with requirements for persons responsible for radiation practices to pay for the disposal of radioactive waste and clean up when they cease to conduct their authorized activities.

The RSD has authority to initiate research in ionizing radiation protection, radiation safety and nuclear security, aimed at improving the regulatory framework.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Government of the Former Yugoslav Republic of Macedonia has established a governmental, legal and regulatory framework for safety. The legislative basis for radiation safety is the Law on Ionizing Radiation Protection and Safety, enacted in 2002, and its subsequent amendments which refer to the main Euratom Directives, IAEA safety standards and the recommendations from the 2005 RaSSIA Mission. The legal framework is not fully in line with the latest IAEA safety standards.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>The legal framework is not fully in line with the IAEA safety standards, in particular GSR Part 1 (Rev.1), GSR Part 2, GSR Part 3, GSR Part 5 and GSR Part 7.</i>	
(1)	BASIS: GSR Part 1 (Rev.1) Requirement 2, para. 2.5 states that “ <i>The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety.</i> ”
R2	Recommendation: The Government should review and revise the legal framework to ensure compliance with the IAEA safety standards.

The legal framework makes provision in all relevant areas relating to radiation safety and applies to all types of facilities and activities in the country, providing clear allocation of responsibilities to the various stakeholders and authorized parties. The legislative framework assigns clear responsibility for safety to authorized parties responsible for the radiation facilities and activities. The legislation also establishes clear role, responsibilities and powers to the RSD as the single independent regulatory body exercising discretion to oversee radiation protection, accounting for nuclear materials and nuclear security, including the authority to make the relevant regulations. There are 26 regulations established by the RSD, specifying the principles, criteria and requirements for safety. RSD has published a guidance document on application for export, import and transit; additional guidance documents can be developed for other areas as needed.

Since there are no nuclear facilities in the country, the framework establishes safety requirements for facilities and activities using radiation sources in medical, educational and industrial settings. The various types of practices with ionizing radiation and related facilities are subject to regulatory control for radiation protection, by way of authorization and appropriate inspections, commensurate with the magnitude and likelihood of exposures resulting from the practice. In accordance with the Law on Ionizing Radiation Protection and Safety, legal person may begin a radiation practice only after obtaining a licence from the RSD and after being registered in the unique register of legal persons conducting such practices. The exemption and licensing process are prescribed in regulations issued by the RSD.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The Government of the Former Yugoslav Republic of Macedonia, through the Law on Ionizing Radiation Protection and Safety, has established and maintains the RSD as the single, independent state administrative body, responsible for regulatory oversight of ionizing radiation practices in the country. The RSD was established in 2002 by this law and became functional in 2005 by appointment of the first director. The RSD is headed by a director, who is appointed and dismissed by the Government of the Former Yugoslav Republic of Macedonia. The director is accountable for his/her work to the Government.

The government provides human and financial resources to RSD to properly exercise its functions and duties under the Law on Ionizing Radiation Protection and Safety. As provided for under the legislation, the RSD is functionally separate from any other body having interests or responsibilities that could unduly influence regulatory decision making, such as the promotion or utilization of nuclear energy and ionizing radiation in general. However, the budget of the RSD is established as a subprogram within the budget program of the Ministry of Health, therefore the RSD does not have full financial independence as there remain uncertainties regarding sufficiency of budget, potential conflict of interest between RSD and the Ministry of Health, and possible competing priorities between RSD and Ministry of Health in the assignment of resources.

During the meeting with the Ministry of Health, their representatives clearly expressed the position that the RSD is a fully independent regulatory body and although budget of the RSD is a subprogram of the Ministry of Health they have never influenced its budget. Similar message was received from meetings held with representatives of the Ministry of Finance. However, as long as the budget is under the control of the Ministry of Health, there is a possibility that the Ministry of Health could make some decision to influence financial independence of RSD. This issue is specifically important considering that the Ministry of Health is going to establish new medical facilities that are to be licensed by the RSD.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The budget of the RSD is established as a subprogram within the budget program of the Ministry of Health which is the major user of radiation sources in the country; therefore, the RSD does not have full financial independence.*

(1)	<p>BASIS: GSR Part 1 (Rev.1) Requirement 4, para. 2.8 (b) and (d) states that “<i>To be effectively independent from undue influences on its decision making, the regulatory body:</i></p> <p><i>(b) Shall have access to sufficient financial resources for the proper and timely discharge of its assigned responsibilities;</i></p> <p><i>(d) Shall be free from any pressures associated with political circumstances or economic conditions, or pressures from government departments, authorized parties or other organizations;”</i></p>
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S1	<p>Suggestion: The Government should consider revising its legislative framework to ensure effective independence of the RSD from the Ministry of Health with respect to the RSD financial budget.</p>
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The RSD has authority to liaise directly with regulatory bodies of other States and international organizations to promote cooperation and the exchange of regulatory related information and experience.

The RSD is effectively independent from undue influence in its decision making on safety matters, can make independent regulatory judgments and decisions and is able to give independent advice to government departments and governmental bodies on matters relating to the safety of facilities and

activities. It does not have responsibilities that might compromise or conflict with discharging its responsibility for regulating the radiation safety of facilities and activities. For example, technical services are clearly separated from regulatory functions of the RSD.

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

The Law on Ionizing Radiation Protection and Safety clearly assigns prime responsibility for safety to the persons or organizations (as legal entities) responsible for operating a facility or conducting an activity involving radiation sources, and require them to comply with regulatory requirements, as well as to demonstrate such compliance. They are therefore fully responsible for the protection of people and the environment, through the safe handling of equipment with radiation sources. Any modification of the conditions for practice may be made only based on a permission granted by the RSD and after their recording into the RSD register. The license may not be transferred to another legal person.

The RSD has authority to perform inspections of facilities and activities, to verify compliance with regulatory requirements, and enforce the provisions of the Law and its associated regulations. On their part, authorised parties are required to comply with regulatory requirements, ensure the safe conduct of the inspection without any interruption in every part of the premises where the radiation practice is carried out and, at the request of the inspector, must submit correct and true data, information and other records, without any remuneration and without fettering with the inspector's authority.

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

The legal framework makes adequate provision for the effective conduct of RSD regulatory function, avoiding any omissions or undue duplication or conflicting requirements being placed on various parties. Also, the Government has provided for the effective coordination of the functions of the various authorities having other responsibilities within the regulatory framework, such as in emergency preparedness and response, and in environmental radioactivity monitoring. Among its duties and responsibilities, the RSD cooperates with other state administrative bodies and institutions on matters within its competence through Memoranda of Understanding (e.g., with the Ministry of Health, Ministry of Finance, Ministry of Interior, Ministry of Transport and Communications - through the National Coordination Centre for Border Management-, the Crises Management Centre and the Protection and Rescue Directorate).

The RSD participates in the National Commission for Integrated Border Management, by way of a Memorandum of Understanding with the Customs Administration, in the National Coordination Centre for Border Management and other organisations. The cooperation of all relevant institutions having roles and responsibilities in case of radiological emergency is established under the plan on the protection of the population in case of radiological emergency in the country (National Radiation Emergency Plan - NREP), promulgated by the Government in 2011.

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

Radiation risks associated with unregulated sources and contamination from past activities or events are dealt with under the provisions of the Law on Ionizing Radiation Protection and Safety, and its associated regulations, which prescribe safety requirements related to such situations.

A memorandum of understanding has been established between the RSD and the Customs Administration regarding the procedure and responsibilities of each organization in respect of import/export of radiation

sources and in respect of orphan sources. To decrease potential exposure to the general public from abandoned sources of radiation, where there is a high probability that a dangerous uncontrolled source be present, the dose rate of all objects/sites are measured in accordance with the Regulation on the categorization of threats. This is also the case where scrap metal might be introduced into the territory of the Former Yugoslav Republic of Macedonia. If such situations occur, the RSD undertakes supervision and monitoring of the radiation sources (including orphan sources) or of the natural radiation to reduce or prevent, and control exposure. The transport and storage of the radiation sources or any radioactive material, and/or resulting radioactive waste are managed by technical services (including any found orphan sources) as requested by the RSD. However, the IRRS team observed that most locations where disused legacy sources are stored are not licensed by the RSD for this purpose. This issue is addressed in more detail in Section 5.

The regulatory framework, through the NREP, designates the organizations to be responsible for making the necessary arrangements for the protection of workers, the public and the environment, and provides them with adequate resources. The plan describes in detail the category of threat, the possible consequences, the responsibilities, the measures to be taken, the national and international cooperation, etc.

1.7. PROVISIONS FOR THE MANAGEMENT OF RADIOACTIVE WASTE

There is no national policy and strategy for decommissioning of facilities and radioactive waste management in the Former Yugoslav Republic of Macedonia. A draft policy and strategy in this respect has been prepared by RSD, following an IAEA expert mission in 2014, which contains provisions regarding the policy statements (safety and security objectives, responsibility for radioactive management, national security infrastructure, long term management of radioactive waste, management of inventory).

The draft strategy for radioactive waste management includes provisions on waste inventory (waste accounting, classification of radioactive waste, characterization of radioactive waste, future development), waste management schemes (disused sealed radioactive sources, other radioactive waste, orphan sources), radioactive waste management infrastructure (status, requirements for infrastructure development, implementing the strategy) and action plan. The draft strategy does not include provisions for the management of radioactive waste arising from radiological emergencies.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *There is no national policy and strategy for decommissioning and radioactive waste management in the Former Yugoslav Republic of Macedonia. A policy and strategy are being developed but the drafts do not include provisions such as the management of radioactive waste arising from radiological emergencies.*

(1)	BASIS: GSR Part 1 (Rev.1) Requirement 10, para. 2.28 states that <i>“Decommissioning of facilities and the safe management and disposal of radioactive waste shall constitute essential elements of governmental policy and the corresponding strategy over the lifetime of facilities and the duration of activities.”</i>
(2)	BASIS: GSR Part 5 Requirement 2, states that <i>“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.”</i>
(3)	BASIS: GSR Part 7 Requirement 15 states that <i>“The government shall ensure that radioactive waste is managed safely and effectively in a nuclear or radiological</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>emergency...”</i>
(4)	BASIS: GSR Part 7 Requirement 15, para 5.84 states that <i>“The national policy and strategy for radioactive waste management shall apply for radioactive waste generated in a nuclear or radiological emergency.”</i>
R3	Recommendation: The Government should establish a national policy and strategy for decommissioning of facilities and the safe management and disposal of all types of radioactive waste.

Also, there are no provisions in the legal framework for the decommissioning of facilities, the management and disposal of radioactive waste, although the Law on Ionizing Radiation Protection and Safety, and its associated regulation contain provisions relating to the safe management of radioactive waste. Licensees must ensure that the activity and volume of any radioactive waste resulting from the sources for which the licence is issued are kept as low as reasonably achievable, and that waste is managed, i.e. collected, handled, stored, conditioned, transported and disposed of in accordance with the Law on Ionizing Radiation Protection and Safety and regulations. There is explicit provision in this law prohibiting the import of radioactive waste and/or nuclear waste on the territory of the Former Yugoslav Republic of Macedonia.

With respect to the establishment of a national storage or disposal facility, the Law on Ionizing Radiation Protection and Safety prescribes that disposal of disused ionizing radiation sources and the radioactive waste shall be placed on a location established by the Government of the Former Yugoslav Republic of Macedonia, upon the proposal of the RSD, following consultation with the Ministry of Environment and Physical Planning and the Ministry of Health. The costs for disposal of disused radiation sources and radioactive waste, as prescribed under the Law on Ionizing Radiation Protection and Safety, are to be assumed by the legal person that possesses the source or the waste.

Currently, radioactive waste that arise or have arisen from legacy activities, including disused sources and other radioactive material such as lightning rods and smoke detectors, and waste that may result from emergency situations, are stored in several facilities throughout the country. There is no national central storage facility for radioactive waste. Management of disused sources and radioactive lightning rods represent the most difficult challenge in this regard, as for example, there are more than 150 lightning rods still in their places of use all over the country because of the absence of a central storage facility for those materials. The implementation of a national strategy for radioactive waste management is expected to bring a solution to this issue, as the current draft of the policy and strategy considers that a centralized facility would ensure an appropriate storage location for all these sources. Although the regulatory body has been exercising regulatory control to ensure safety and security in both situations, additional measures are needed until the centralized predisposal waste management facility becomes available.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Although RSD has been exercising regulatory control to ensure safety and security for legacy sources and radioactive waste management, additional regulatory measures are needed for ensuring radiation safety until the national policy and strategy is implemented.*

(1)	BASIS: GSR Part 1 (Rev.1) Requirement 9 states that <i>“The government shall establish an</i>
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RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<i>effective system for protective actions to reduce undue radiation risks associated with unregulated sources.”</i>
(2)	BASIS: GSR Part 3 para. 5.2 states that <i>“The government shall ensure that, when an existing exposure situation is identified, responsibilities for protection and safety are assigned.”</i>
(3)	BASIS: GSR Part 3 para. 5.4 states that <i>“The regulatory body or other relevant authority assigned to establish a protection strategy for an existing exposure situation shall ensure that it specifies:</i> <i>(a) The objectives to be achieved by means of the protection strategy”</i>
R4	Recommendation: The RSD should ensure that there is sufficient regulatory control of legacy sources and radioactive waste until the national strategy for radioactive waste management is implemented.

There are no detailed provisions in legislative framework regarding the decommissioning of facilities and disposal of radioactive waste. Some general provisions on decommissioning appear in the Regulation on radioactive waste management, under which a decommissioning plan must be prepared for each radioactive waste storage facility, including financial provisions for decommissioning. Additional general provisions for decommissioning of facilities are also included in the Regulation on premises, equipment and devices for laboratory type I (maximum activity of radionuclides used is greater than 10000 times of exemption levels).

1.8. COMPETENCE FOR SAFETY

The Government, through the national framework, has made provision for building and maintaining the competence of the parties having responsibilities relating to the safety of radiation facilities and activities, including the management of competences of the parties having responsibilities for safety. The building of competence is required for all parties responsible for the safety of facilities and activities, including authorized parties, the regulatory body and organizations providing services or expert advice on matters relating to safety. In this respect, throughout this peer review it was noted that key specialties with significant role in radiation safety matters are not available in the country, consequently further actions are needed on behalf of the government towards building of competence through education and training for all parties involved in radiation safety, such as medical physicists and radiation protection specialists. The same applies for RSD. The IRRS team observed that there is no system for the formal recognition of qualified experts.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>Throughout this peer review it was noted that there are not sufficient governmental provisions for building competence for the parties having responsibilities in relation to safety, including RSD staff. Additionally, it was noted that there is no formal system in place for the recognition of qualified experts.</i>	
(1)	BASIS: GSR Part 3 Requirement 2, para. 2.21 states that <i>“The government shall ensure that requirements are established for:</i> <i>(a) Education, training, qualification and competence in protection and safety of all persons</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<p><i>engaged in activities relevant to protection and safety;</i></p> <p><i>(b) The formal recognition of qualified experts;</i></p> <p><i>(c) The competence of organizations that have responsibilities relating to protection and safety.”</i></p>
(2)	<p>BASIS: GSR Part 3 Requirement 11, states that <i>“The government shall make provisions for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities.”</i></p>
R5	<p>Recommendation: The Government should ensure that requirements are established within the legislation for building and maintaining competence through education and training for all parties having responsibilities for safety as well as for the formal recognition of qualified experts.</p>

The main provisions for qualification and training are established under the Law on Ionizing Radiation Protection and Safety, which also assigns to RSD the responsibility to ensure that proper training is provided to the persons in charge of radiation protection and persons working with radiation sources. The form, content and duration of this training is prescribed under the regulation. In addition, the director of the RSD is authorized to adopt regulations on the types of training and the content of the programme for training of radiation protection officers and the persons working with sources of ionizing radiation.

The RSD has defined the minimum level of qualification of persons who can work with radiation sources in the Regulation on qualifications and health condition. The regulation contains conditions that shall be fulfilled by the persons who can work with sealed radiation sources for such uses as diagnostic and therapeutic purposes, with X-rays in dentistry, with sealed radioactive sources, in the cyclotron for production of radionuclides to be used in PET.

Expert technical services, authorized under a licence issued by the RSD, must comply with regulatory requirements regarding qualified staff with appropriate secondary and higher education and work experience, trained for conducting and implementing measures on ionizing radiation protection, radiation safety and nuclear security.

Additional provisions contained in the Regulation on the limits of exposure, require people or workers who voluntarily participate in radiation emergencies to have training in the field of protection against ionizing radiation and are familiar with the risks. In accordance with the NREP, the institutions which have role in the system of preparedness and response to radiological emergency in the Former Yugoslav Republic of Macedonia shall provide training for the persons who have tasks or participate in the preparedness and response to radiological emergency. The training can be organized by institutions in the country or through cooperation with international organizations.

The IRRS team observed that the RSD does not have sufficient resources to fully perform all its duties and responsibilities under the Law, such as to participate in international activities and to cover the 24/7 operations during an emergency.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The RSD does not have sufficient resources to fully perform all its duties and responsibilities under the Law on Ionizing Radiation Protection and Safety, including participation in international activities and to discharge its responsibilities for prolonged 24/7 operations during a radiological emergency.*

(1)	BASIS: GSR Part 1 (Rev.1) Requirement 3 states that “The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities.”
(2)	BASIS: GSR Part 7 Requirement 25, para 6.10 states that “Appropriate numbers of suitably qualified personnel shall be available at all times (including during 24 hour a day operations) so that appropriate positions can be promptly staffed as necessary following the declaration and notification of a nuclear or radiological emergency. Appropriate numbers of suitably qualified personnel shall be available for the long term to staff the various positions necessary to take mitigatory actions, protective actions and other response actions.”
R6	Recommendation: The Government should provide the RSD with sufficient resources to adequately implement its functions and responsibilities.

1.9. PROVISION OF TECHNICAL SERVICES

The Government has made adequate provision for technical services in relation to safety. The Institute of Public Health (IPH) has been designated as technical service provider. The Institute has two organizational units related to radiation protection area: the Laboratory for ionizing radiation and the Laboratory for radioecology. IPH is adequately equipped to provide technical services and the technical/scientific staff has a high level of education and competence, with additional training and specialisation. The responsibilities of the IPH, as defined under the regulatory framework, include: monitoring the content of the radionuclides in water, air, soil and food; measuring the occupational exposure of persons working with radiation sources, as well as of the population; conducting continuous medical control and keeping records of occupationally exposed persons to ionising radiation; performing calibration on radiation protection measuring instruments; and, submitting reports to RSD on the promotion of radiation protection when using ionization radiation sources, as well as controlling them. The IPH actively participates in relevant international networks and in inter-comparison exercises to assess the analytical results and to maintain its ISO/IEC/17025 accreditation.

The IPH is not authorized by RSD as a technical service provider, as prescribed by the Law on Ionizing Radiation Protection and Safety and the relevant regulation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The Institute of Public Health is not authorized by the RSD to provide technical services to authorized parties.*

(1)	BASIS: GSR Part 1 (Rev.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
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RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

appropriate.”

R7

Recommendation: RSD should authorise all technical service providers in accordance with the Law on Ionizing Radiation Protection and Safety and relevant regulation.

In addition to the services provided by IPH, the RSD may request other expert institutions to provide expert services necessary for the implementation of the Law on Ionizing Radiation Protection and Safety, for example other expert services authorized by the Ministry of Environment and Physical Planning, the Ministry of Health, the Directorate and the Ministry of Agriculture, Forestry and Water Economy.

The regulation establishes detailed requirements for technical services, including requirements for education, qualification and training of the staff. The authorized expert technical service must keep records regarding the performed activities and submit to the RSD monthly reports by the 20th day of the month for the previous month, as well as annual report by 31st of March at the latest for the previous year. Authorized expert technical services are required to immediately inform the RSD in case of emergency or increased radioactivity above the allowed level.

The RSD supervises the work of the authorized expert technical services. The director of the RSD can withdraw the licence of the authorized expert technical service if it does not conduct the services for which it has been authorized in accordance with the provisions of the Law on Ionizing Radiation Protection and Safety or if it stops to fulfil the requirements stipulated in this law. The decision of the director of the RSD is final and administrative dispute may be initiated against it before a competent court.

1.10. SUMMARY

The Former Yugoslav Republic of Macedonia has established a national legal and regulatory framework for radiation safety, accounting for nuclear materials and nuclear security, to ensure adequate regulatory control of radiation facilities and activities, to protect people and the environment, both under normal circumstances and during emergencies. The framework makes general provision for the justification of practices, the limitation of risk and the optimization of protection for people and the environment through the application of key principles, such as exemptions, limitation of practices, operator accountability and regulatory requirements that are commensurate with risk. The responsibility for safety clearly rests with authorized parties, as prescribed under the legislation. There is no confusion or duplication of powers or responsibilities amongst the national institutions regarding radiation safety.

Needed improvements to the national framework are related to further alignment with IAEA safety standards regarding establishment and implementation of a national policy and strategy on safety and on radioactive waste management; financial independence of the RSD; management of legacy radioactive waste; authorization of technical service providers; and formal recognition of qualified experts.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

The Former Yugoslav Republic of Macedonia takes part in relevant international activities contributing to enhance safety globally and has made adequate provision to ensure that international obligations it has agreed to in this regard are properly fulfilled. The legislative framework in the relevant field is not in line with the latest IAEA safety standards (**Recommendation 2 in Section 1.2** has been made in this regard).

The Former Yugoslav Republic of Macedonia has ratified, signed or has accessed to international conventions, protocols, agreements and other instruments in the area of safety and security. As an ongoing commitment to improve its national regulatory framework, the country has accepted to be subject to peer reviews by having invited a RaSSIA Mission in 2005 and the present IRRS Mission.

The Former Yugoslav Republic of Macedonia has ratified the Convention on Nuclear Safety in 2008, and Joint Convention on the Safety of the Spent Fuel Management and on the Safety on the Radioactive Waste Management in 2009 and fulfils its obligations through the RSD by submitting national reports as required under these Conventions. The Former Yugoslav Republic of Macedonia is a party to the Convention on Early Notification in a Case of Nuclear Accident and to the Convention on Assistance in case of Nuclear Accident or Radiological Emergency. The Government of the Former Yugoslav Republic of Macedonia has made a political commitment to the Code of Conduct on the Safety and Security of Radioactive Sources and its supplementary Guidance on the Import and Export of Radioactive Sources and thus, endeavours to follow the guidance in the Code and its accompanying guidance.

Other relevant conventions or protocols ratified by the Former Yugoslav Republic of Macedonia on environmental impact assessment and on public participation issues are the Convention on Environmental Impact Assessment in a Transboundary Context (Espoo Convention), its associated Protocol (UNECE Kiev Protocol on Strategic Environmental Assessment to the Convention on Environmental Impact Assessment in a Transboundary Context), the Multilateral Agreement among the countries of South-Eastern Europe for implementation of the Convention on Environmental Impact Assessment in a Transboundary Context (Bucharest, 2008) and the UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention) and its Protocol on Pollutant Release and Transfer Registers (PRTRs).

The Former Yugoslav Republic of Macedonia is engaged in international and regional activities through various venues such as training activities, seminars, workshops and technical meetings, and participates in different IAEA projects. RSD has signed MoUs with relevant regulatory bodies from countries of the region (Bulgaria, Slovenia, Montenegro, Bosnia and Herzegovina, and Romania). It has also initiated the signing of MoUs with the regulatory bodies from Serbia, Albania and Kosovo. The legislation assigns to RSD the function of coordinating the State's actions in respect to international cooperation on safety. However, the IRRS team observed that the RSD does not have sufficient resources to participate in relevant international and regional activities, seminars, workshops and technical meetings on safety (**Recommendation 6** in Section 1.8 has been made in this regard).

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

The RSD has established arrangements for carrying out analysis to identify lessons learned from operating experience and regulatory experience in the field of ionizing radiation safety, 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. The RSD has signed MoUs with countries from the region for cooperation in related areas (radiation protection, radiation safety etc.). Specific arrangements for analysis of operating and dissemination of lessons learned are not explicitly defined but these could be included to any issue related to radiation protection, radiation safety and nuclear security among regulatory bodies.

The RSD continuously follows the updates of the international and European standards and implements them in the national legislation by preparing and issuing amendments. The practice, the experience and reports from the Unit on Inspection, as well as the implementation of the regulations during the licensing process provide important information for updating the regulations. During the process of review and revision of the regulations, issues and situations that are identified in the field of competence of the RSD are taken into account; this process is performed once per year as part of the process of RSD strategic planning. The update of the legislation considers lessons learned and experience from the operational and regulatory experience and feedback from other countries and organizations. The legislation in the Former Yugoslav Republic of Macedonia should be updated considering the latest international standards (**Recommendation 2** in Section 1.2 has been made in this regard).

The RSD participates in a series of European and other international conferences, symposia, workshops and meetings. It also cooperates with persons who have extensive operating experience and communicates with licensees and TSOs to share regulatory experience and gain insights from established operating experience feedback programmes by others. The lack of resources of the RSD to fully participate in these activities has been raised in Section 1.8, along with **Recommendation 6**.

2.3. SUMMARY

The Former Yugoslav Republic of Macedonia takes part in relevant international activities contributing to safety globally and has made adequate provision to ensure that these arrangements are properly fulfilled. The legislation in the Former Yugoslav Republic of Macedonia should be updated considering the latest international safety standards. There are adequate arrangements and resources in place for carrying out analysis to identify lessons learned from OPEX (OPERatingEXperience) and regulatory experience (assessment, licensing and compliance) from within the Former Yugoslav Republic of Macedonia and from other States, contributing to the improvement of the national regulatory framework. There are also arrangements for the dissemination of lessons learned and their use by authorized parties, the regulatory body and other relevant authorities. However, sufficient resources should be provided to RSD to adequately participate in international activities.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

The Law on employees in the public sector and the Law on administrative servants, apply to the RSD in respect of its functioning and in relation to its employees. The internal organization of the RSD and job descriptions are set out in the regulations prepared by the RSD and implemented after approval by the Ministry of Information Society and Administration. The Regulation on internal organisation prescribes the type and number of organisational units in the institution and their field of responsibilities. The Regulation on systematisation of the working places establishes for each working place the group, the category, the level of the working place, as well as the general, specific and description of the working places. The Regulation on internal organization of the Radiation Safety Directorate establishes 5 units within the organisational structure of RSD as follows: Unit on Human Resource Management; Unit on Financial Issues; Unit on Legal and General Affairs, International Cooperation and EU Integration; Unit on Licensing, Monitoring and Emergency and Unit on Inspection.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

The Law on Ionising Radiation Protection and Safety clearly establishes the RSD as an independent state administrative body with the capacity of legal entity for the purposes of this law. The RSD is effectively independent from undue influence in its decision making on safety matters, can make independent regulatory judgments and decisions and is able to give independent advice to government departments and governmental bodies on matters relating to the safety of facilities and activities and does not have responsibilities that might compromise or conflict with discharging its responsibility for regulating the safety of radiation facilities and activities. Under the legislation, technical services are clearly separated from regulatory functions of the RSD.

RSD staff is competent and remains focused on performing their functions in relation to safety. The RSD has the authority to intervene about any facilities or activities that present significant radiation risks, irrespective of the possible costs to the authorized party.

There is a clear allocation of decision-making to the RSD and relevant decisions are prepared through the organizational scheme of the RSD, preventing the probability of occurrence of direct or indirect interest in facilities or activities under regulatory control. The regulatory decisions of the RSD in implementing the existing legislation (e.g. granting authorizations to facilities or activities with radiation sources) are taken by the director of the RSD. For simplicity purposes, in accordance with the national legislation, the director of the RSD has the right to delegate regulatory decisions to other staff within the RSD.

However, the RSD director does not have authority to delegate financial decisions to other staff within RSD. This might present a potential impediment to the effectiveness or efficiency of the RSD to carry out its functions and responsibilities.

The effective independence of the staff of the RSD is regulated in accordance with the general Law on conflict of interest prescribing in detail the procedure for resolving the conflict of interests. The staff of the

RSD have no direct or indirect interest in facilities and activities beyond the interest necessary for regulatory purposes.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

The RSD employs qualified staff with the essential knowledge, skills and abilities to perform the necessary regulatory functions. Currently the total number of the RSD staff is 14 (director plus 13 employees), of which 6 are administrative and support staff. This might present an issue with respect to the capacity of the RSD to effectively perform its regulatory functions. Furthermore, with the most recent changes in the organisational structure of the RSD, there have been drastic changes and abolition of sectors and working places within the RSD with the objective of harmonisation with the national legislation relevant to all public institutions. In accordance with the provisions of the Law on employees in the public sector the RSD should have 30% more servants on the number of currently employed. The number of qualified staff and the sufficiency of financial resources for the proper discharge of its assigned responsibilities is an ongoing challenge, and there is always space for enhancing the capabilities and capacity of the RSD (**Recommendation 5** in Section 1.8 has been made in this regard). The IRRS team observed that the RSD does not have sufficient staff to fully perform all its responsibilities and functions under the Law on Ionizing Radiation Protection and Safety, including the participation in international activities and the prolonged 24/7 operations during an emergency (**Recommendation 6** in Section 1.8 has been made in this regard).

To ensure systematic approach in coordination, planning and implementation of the continuous professional development programme of the staff, the RSD prepares the Annual programme for training of the administrative servants in the RSD. All RSD staff are required to participate in a continuous professional development programme. The training of RSD personnel is governed under the Law on administrative servants. According to the provisions of this Law, the RSD each year prepares an annual training program for its staff which contains the foreseen training (general and specialized) for the next year. Regulatory aspects are considered in the preparation of the training plan for the employees in the RSD.

The procedure of recruitment of new staff in the RSD is prescribed in detail in the Law on administrative servants. The Law explains in detail the required steps for recruitment of new staff in the state institution, the planning of new employments - preparation of annual plan for recruitment by the RSD, the public announcement, etc. Further details and explanation of the procedure for employments is established in detail in the Decree for conducting the procedure for employment of administrative servants, that is promulgated by the Government.

The Law on administrative servants also prescribes the conditions which shall be fulfilled by the candidate applying for working position in RSD. There are general conditions which are established under this Law and shall be fulfilled for each post in the public institutions, as well as specific conditions for the working position and for the institution itself regarding the necessary qualifications, working experience, and competences.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

The Law on Ionizing Radiation Protection and Safety provides for the establishment of the Radiation Safety Commission as an advisory body to the RSD regarding issues relevant to radiation protection, radiation safety and nuclear security. The Commission is composed of around 20 representatives from

ministries and other relevant organisations as established by the RSD director, but it is currently not functional.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: <i>The Law on Ionizing Radiation Protection and Safety provides for the establishment of an advisory body, the Radiation Safety Commission, which is composed of around 20 representatives from ministries and relevant institutions as established by the RSD director. However, the Commission is not functional.</i></p>	
(1)	<p>BASIS: GSR Part 2 Requirement 5, para. 4.6 states that “Senior management shall identify interested parties for their organization and shall define an appropriate strategy for interaction with them.”</p>
(2)	<p>BASIS: GSR Part 1 (Rev.1) Requirement 20 states that “The regulatory body shall obtain technical advice or services as necessary in support of its regulatory functions...”</p>
S2	<p>Suggestion: The RSD should consider making the Radiation Safety Commission functional.</p>

The IPH, according to the Law on Ionizing Radiation Protection and Safety, has been designated as the TSO of the RSD. There appears to be some lack of cooperation and communication between the RSD and the IPH (**Suggestion 3** in Section 3.8 has been made in this regard).

In accordance with the provisions of the Law on Ionizing Radiation Protection and Safety and the Law on organisation and work of state institutions, the RSD, acting in the frame of its responsibilities in accordance with the Constitution, the legislation and the ratified international agreements, is solely responsible for the implementation of the legislation and regulation. The RSD can request only advice or assistance from external parties.

The RSD may request and authorize other expert institutions to provide expert services necessary for the implementation of the Law on Ionizing Radiation Protection and Safety.

The effective independence of all the employees of the RSD is regulated under the general Law on conflict of interest. The Law prescribes that civil servants in the course of their duties shall not take into account any personal, family, religious, political and ethical interests and influences. The Law prescribes in detail the procedure for resolving conflicts of interest.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

The RSD has established formal and informal mechanisms of communication with authorized parties on safety related issues. According to the Law on free access to the information of public interest, any interested party may request information from the RSD on an informal basis. Free access to public information retained by the government and its institutions is available to all legal and physical persons, as well as foreign legal and physical persons in accordance with legislative provisions. The RSD can also organize information sessions and informal meetings with interested parties and members of the public, as needed, to provide regulatory information or clarification of regulatory requirements. In this way, the RSD maintains open communication with the authorized parties and is transparent about the basis and justification for its decisions or licenses.

The RSD follows transparent procedures and requires from all legal persons to submit completed applications accompanied by the required documentation. The conditions and documentation required for a license are available to the legal persons by publishing the regulations on the RSD website. Every decision made by the RSD inspectors is supported by the legal basis used for the decision, along with an explanation of the decision, the reason(s) why the decision was made, and instructions for legal remedy. A decision made by the RSD inspector can only be challenged outside the RSD, through a competent commission. However, there are no guidance documents describing this process.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

The RSD is responsible to ensure that regulatory control is stable and consistent by implementing the same procedures and rules for all its decisions. However, the IRRS team observed that procedures were lacking in many areas, for example relating to authorisation and inspection (**Recommendation 15** in Section 7.3 and **Recommendation 9** in Section 4.3 are made in this regard).

Since staff members of RSD are administrative servants, they must follow the provisions of the Law on administrative servants and additionally the Code for administrative servants in performing their duties. The Code contains detailed provisions governing the behaviour of staff in their work to maintain confidence of clients. The process of Preparation of legislation and regulation is identified as one of the core processes in the RSD management system. The procedure for this core process defines the manner for carrying out the process of preparation and issuance of regulations, and establishes uniform process and form for their preparation and revision. The procedure provides for efficient and organized preparation of regulations in the field of radiation safety and nuclear security.

When preparing a regulation, the RSD takes into consideration best international practices. A draft of the regulation is posted on the RSD website for public comments and for comments by interested institutions, among which the Ministry of Finance, the Secretariat for European Affairs and the Secretariat for Legislation. The draft regulation is finalized after the consultation period, taking into account the comments received, and submitted for publication in the Official Gazette of the Former Yugoslav Republic of Macedonia. Review and revision of the published regulations are conducted on an as-needed basis.

3.7. SAFETY RELATED RECORDS

The RSD has made provisions for establishing, maintaining and retrieving adequate records relating to the safety of facilities and activities. There is a procedure under the management system of the RSD (Control of records) defining how records are kept and controlled, including responsibilities, archiving, protection, the timeframe for keeping records etc. As required under the Law on Ionizing Radiation Protection and Safety, RSD maintains the national registry of radiation sources, as well as the register of nuclear material. The registers are updated upon receipt of information and data provided in the licensing and inspection procedure. However, the IRRS team observed that the RSD does not maintain records of doses from occupational exposure. **Recommendation 30** in Section 11.2 has been made in this regard, whereas the management of safety records is further discussed in Section 4.

As part of the licensing process, legal persons are required to establish a system for effective information regarding the conditions and events of interest for the protection and safety. There are provisions in the regulations which refer to the obligation of the authorized party to maintain all records related to the use of radiation sources, other radioactive material and devices.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

The RSD has established some means of informing and consulting interested parties and the public about radiation risks associated with facilities and activities and about the processes and decisions of the regulatory body. However, the IRRS team observed that communication between the RSD and authorized parties could be improved. As part of the measures for improvement and in order to promote effective communication between the RSD and authorized parties, RSD is planning information sessions with authorized parties, starting in February 2018.

The RSD has established some means of cooperation with other governmental authorities and institutions on matters within its competence. Information to the public and authorised parties regarding radiation safety and nuclear security, intervention situations and regulatory processes is provided through the RSD web site. RSD maintains cooperation with national competent authorities through MoUs. However, the IRRS team observed that there appears to be some lack of cooperation and communication between the RSD and the Institute of Public Health, one of the major interested parties in matters of radiation safety.

Furthermore, any interested party may request information from the RSD on free access to information of public interest. In accordance with the national legislation, the public shall be consulted in the process of preparation of the legislation and regulation through announcement of the content and the timeframe for issuance of the regulations, organization of public consultations and obtaining opinion by the interested parties. As requested, the RSD also conducts additional informal communication activities with the public, including the community around the site of an authorized facility, and other stakeholders.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: <i>There appears to be some lack of cooperation and communication between the RSD and the Institute of Public Health, one of the major interested parties in matters of radiation safety. Information to the public and licensees regarding radiation safety and security related aspects, intervention situations and regulatory processes is provided through the RSD web site.</i></p>	
(1)	<p>BASIS: GSR Part 1 (Rev.1) Requirement 36 states that <i>“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.”</i></p>
(2)	<p>BASIS: GSR Part 2 Requirement 5, para. 4.6 states that <i>“Senior management shall identify interested parties for their organization and shall define an appropriate strategy for interaction with them.”</i></p>
(3)	<p>BASIS: GSR Part 1 (Rev.1) Requirement 36, para. 4.66 (a) states that <i>“The regulatory body shall establish, either directly or through authorized parties, provision for effective mechanisms of communication, and it shall hold meetings to inform interested parties and the public and for informing the decision-making process. This communication shall include constructive liaison such as:</i></p> <p><i>(a) Communication with interested parties and the public on regulatory judgements and decisions;”</i></p>
S3	<p>Suggestion: The RSD should consider taking appropriate measures to improve the cooperation and communication with all interested parties.</p>

Licences issued by the RSD contain conditions requiring the authorized party to make the licence visible in their premises. The RSD, as part of its public information activities and consultation, has set up appropriate means of informing interested parties, including the public and the mass media about the radiation risks associated with facilities and activities, the requirements for protection of people and the environment, and the processes of the regulatory body. The information concerning the public about the radiation safety and security related aspects of regulated practices, intervention situations and the regulatory process can be found on the RSD website.

3.9. SUMMARY

The RSD structures its organisation and manages its resources to discharge its responsibilities and functions effectively, in an open and transparent manner, commensurate with the radiation risks associated with facilities and activities, and in a manner that does not compromise its effective independence. The RSD employs qualified and competent staff; however, some improvements are needed in resource capacity for the RSD to adequately fulfil all its regulatory functions and duties. The RSD obtains technical and other expert professional advice or services as necessary in support of its regulatory functions, but this does not relieve the RSD of its assigned responsibilities. The RSD has established formal and informal mechanisms of communication with the public, the media and authorized parties on radiation risks associated with facilities and activities. Improvements are needed with respect to communication and cooperation between the RSD and interested parties, and communication between the RSD and authorized parties.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

The RSD is in the process of establishing a management system and preparing the relevant documentation; thus, the management system is not yet implemented and the relevant documentation including the management system manual is still in draft. In this section when the management system manual is mentioned the draft version is meant.

4.1. LEADERSHIP FOR SAFETY

The mission, vision and the values of the RSD which are reflected in the management system are already established through its strategic plan since 2008 and approved by the director. The RSD has not developed its policies, except the quality policy that is included in the manual, mostly in order to fulfil the requirements for certification purposes according to ISO 9001:2015 standard.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The RSD has not established a safety policy in line with the IAEA safety standards.*

(1)	BASIS: GSR Part 2, Requirement 2 states that <i>“Managers shall demonstrate leadership for safety and commitment to safety.”</i>
(2)	BASIS: GSR Part 2, Requirement 2 para 3.2 states that <i>“Managers at all levels in the organization, taking into account their duties, shall ensure that their leadership includes: (a) Setting goals for safety that are consistent with the organization’s policy for safety, actively seeking information on safety performance within their area of responsibility and demonstrating commitment to improving safety performance; (b) Development of individual and institutional values and expectations for safety throughout the organization by means of their decisions, statements and actions; (c) Ensuring that their actions serve to encourage the reporting of safety related problems, to develop questioning and learning attitudes, and to correct acts or conditions that are adverse to safety.”</i>
(3)	BASIS: GSR Part 2, Requirement 3, para 4.2 states that <i>“Senior management shall be responsible for establishing safety policy.”</i>
R8	Recommendation: The RSD should define its safety policy in the management system.

4.2. MANAGEMENT FOR SAFETY

4.2.1. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

The management system of the RSD integrates elements related to safety, health, environmental, security, quality, human and organizational factors as well as societal and economic elements.

The RSD senior management developed the Medium term strategic plan for 2018 – 2020 which defines the goals, plans, objectives and the tasks required for fulfillment of the objectives. The strategic plan is

reviewed by the RSD and updated annually. The consistency of the goals, plans and objectives with the organization's safety policy cannot be assessed as the safety policy is not established yet.

The RSD senior management has identified in the draft management system manual the external and internal interested parties, as well as the key interested parties. An appropriate strategy for interaction with the interested parties and processes and plans resulting from this strategy are not established yet.

The RSD has planned to finish the process of its accreditation and its certification according to ISO 9001:2015 which is obligatory by the national legislation.

4.3. THE MANAGEMENT SYSTEM

The RSD has not established an integrated management system that is aligned with its safety goals and contributes to their achievement. The director of the RSD has appointed the quality manager, has nominated process owners and has established working group with responsibilities for the development of the integrated management system within RSD.

The management system manual contains the list of the processes applied in the RSD, including the core processes, management processes and supporting processes. RSD has already prepared draft versions of the management system manual and its procedures.

Many of the management system elements are already in place and have documented processes, however there are processes which are not developed and documented in procedures, inter alia interaction with interested parties, organizational changes, maintaining of documentation of safety records, review and assessment.

Procedures used by the RSD to discharge its responsibilities are included in regulatory documents. These elements are only referred but not integrated into the management system.

Within the management system manual and the associated procedures, the need for safety to be considered is not explicitly mentioned in relation to decision making.

The RSD has not made arrangements in the management system for the resolution of conflicts arising in decision making processes.

Any organizational changes at the RSD must be based on the Law on administrative servants. RSD has prepared a draft document for procedures related to human resources.

RSD has not made any provision in the management system to identify any changes (including organizational changes and the cumulative effect of minor changes) that could have significant implications for safety and to ensure that they are appropriately analyzed.

The IRRS team noted that there are no arrangements established in the management system for any independent review to be made before decisions significant to safety are made.

A graded approach is not fully reflected in the management system, since criteria (e.g. safety significance and complexity of the facility or activity or the hazards and magnitude of the risks associated safety) used to grade the development and the application of the management system are not documented.

The documentation available for this review does not include the policy statements of the organization on values and behavioral expectations.

The RSD has identified two kinds of records: records which are outputs of the RSD processes and records of the management system established to provide evidence that the management system is in accordance with requirements.

The control of the records is prescribed in the draft procedure for control of records in the RSD. The Law on archiving and the Decrees of the Government in the field of archiving define the way of identification, storage, retrieval, retention, and the period of storage and disposition of records. Owners of the processes from which individual records derive, are responsible for ensuring that records remain legible, readily identifiable, complete and retrievable.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The RSD has not established and implemented an integrated management system in the organization.*

(1)	BASIS: GSR Part 1 (Rev.1) Requirement 19 states that <i>“The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement.”</i>
(2)	BASIS: GSR Part 2 Requirement 19 states that <i>“Senior management shall be responsible for establishing, applying, sustaining and continuously improving a management system to ensure safety.”</i>
R9	Recommendation: The RSD should complete its program for establishing and implementing an integrated management system in accordance with the IAEA Safety Standards GSR Part 2.

4.4. MANAGEMENT OF RESOURCES

The RSD has developed an electronic library where all acquired literature and other materials are stored in an electronic version.

RSD ensures training of the employees to perform their tasks effectively and efficiently. Training programmes are planned in accordance with the post requirements. The training of employees is defined at annual interviews and is included in the RSD relevant annual plans.

Competence of employees is also ensured by proper assignment of duties and continuous training for acquiring new knowledge, while they transmit their experience to other RSD staff.

The records of the education, training, skills and experience are kept at the Personnel Service of the RSD. The most recent changes in the organizational structure of the RSD, due to the harmonization with the national legislation related to all public institutions, decreased the number of RSD positions, however those were the vacant positions, so the total number of employees is unchanged.

The IRRS team noted that there is insufficient number of qualified and competent staff with in RSD, inter alia for review and assessment, emergency preparedness and response. **Recommendation 5** and **Recommendation 6** in Section 1.8 are made in this regard.

4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

The processes in the RSD are defined in the management system manual. There are 5 established core processes (preparation of legislation and regulation; licensing; inspection and enforcement; monitoring and emergency preparedness and response and international cooperation) and 3 management processes (establishing maintaining and improving the integrated management system, resources; mission, vision, quality policy; measurement, assessment and improvement). In addition, there are supporting processes (document control; internal audit; training and competencies; IT support; records control; corrective and preventive measures; public procurement and financial issues).

Processes for the implementation of RSD functions are carried out according to the type, size, complexity and importance of the project within the hierarchical management system.

The scope of process owner responsibilities is defined in two documents: the director's resolution which contains the general responsibilities, while the details of the content of the procedures are defined in the document of Preparing standard operational procedure. Both documents are in draft version and not in force yet.

The IRRS team noted that although the management system consists of several processes and procedures, RSD should consider finding out which processes are not defined and documented in the management system yet.

The RSD has developed "process cards" for each drafted process with the relevant information fostering to be carried out under controlled conditions. Among other information in the process card are listed the other processes that interact with the process, but these interactions are not specified and elaborated yet.

The procurement process, including information relating to procurement, supplier selection and verification of purchased products are conducted in accordance with legislation relevant to governmental bodies. Details are described in Public procurement act, relevant regulations and reference of guidance. These documents are available on the web page of the Bureau for Public Procurements. The RSD has developed the process for the public procurement, which is among the drafted procedures.

Recommendation 9 in Section 4.3 that concerns the establishment and implementation of the integrated management system covers the issue of the management of processes and activities.

4.6. CULTURE FOR SAFETY

Since RSD has not yet established an integrated management system, tools for fostering a strong culture for safety are not used.

In the draft management system manual, the RSD prescribes the methods that intend to use in order to ensure a high level of safety culture.

Recommendation 9 in Section 4.3 regarding the establishment and implementation of the integrated management system covers the issue of the culture for safety.

4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

Considering that the RSD has not yet established and implemented an integrated management system, the effectiveness of the management system has not been measured, assessed and improved.

According to the draft manual, procedures of measurement, analysis and improvement are enforced to:

- assure and maintain the alignment of the work and services with the legislation,
- requirements and specific requirements described in the processes; indicators are defined in the “RSD Strategic Plan”,
- implement corrective actions if needs of customers and other stakeholders cannot be met using RSD processes and if internal procedures and/or legislation cannot be implemented,
- determine process quality,
- continuously improve the efficiency and effectiveness of the management system.

In the RSD draft management system manual, the objectives of measuring effectiveness and indicators for measuring effectiveness are defined.

Recommendation 9 in Section 4.3 made in regard of the establishment and implementation of the integrated management system covers the issue of measurement, assessment and improvement.

4.8. SUMMARY

The RSD is in the process of establishing a management system and preparing the relevant documentation. The draft management system is aligned with RSD safety goals; however, it does not include its safety policy. Many elements of the management system are already in place, however further development of processes and procedures is needed. The RSD should complete its programme for establishing and implementing an integrated management system in accordance with the requirements of the IAEA Safety Standards GSR Part 2.

5. AUTHORIZATION

5.1. GENERIC ISSUES

The Law on Radiation Protection and Safety specifies that the RSD is responsible for licensing and control of ionizing radiation sources, including issuing and withdrawing licenses for practices with radiation sources. A legal entity may start a practice only after obtaining a license from the RSD and after being registered in the unique register of legal entities conducting a practice with ionizing radiation sources. The authorization is required for all facilities and activities which are not exempted by the law.

The Law on Radiation Protection and Safety contains provisions for notification and licensing. A graded approach is implemented only partly through the different duration of a license depending on the risks associated with the practice and the content of the Radiation protection programme and security plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>The regulatory framework does not contain efficient provision for full implementation of a graded approach in the authorization process.</i>	
(1)	BASIS: GSR Part 1 (Rev.1) Requirement 2, para. 2.5. states that <i>“The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following ...”</i> <i>(3) The type of authorization that is required for the operation of facilities and for the conduct of activities, in accordance with a graded approach”.</i>
(2)	BASIS: GSR Part 1 (Rev.1) Requirement 24, para. 4.33 states that <i>“Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach.”</i>
(3)	BASIS: GSR Part 3 Requirement 3, para. 2.31 states that <i>“The regulatory body shall adopt a graded approach to the implementation of the system of protection and safety, such that the application of regulatory requirements is commensurate with the radiation risks associated with the exposure situation.”</i>
R10	Recommendation: The RSD should make provisions for efficient and effective implementation of a graded approach in the authorization process.

Licensing is carried out by two persons of the RSD Unit on licensing monitoring and emergency preparedness. The IAEA RAIS system is used for managing licensing data, in addition to hardcopies of documents. The transition from a paper based system to fully operational electronic databases is not completed yet. The management of safety records e.g. registers and inventories, and other documentation of the RSD is not fully in line with requirements concerning implementation of integrated management system as prescribed in the IAEA safety standards. The need to implement an integrated management system is addressed in **Recommendation 9** in Section 4.3.

The applicants are required to submit documentation demonstrating that safety and security measures are in place, in support of their license applications. The form of the applications and content of the documents

to be submitted for an authorization is well defined in the legislation and in regulations. However, there is no additional guidance on the content of the documents to be submitted by the applicant for a particular facility or activity, except for import, export and transit.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>The form and the content of the documents of the applications for requesting an authorization is defined in the legislation and regulations, however no guidance on the content of the documents to be submitted by the applicant, except for import, export and transit, is available.</i>	
(1)	BASIS: GSR Part 1 (Rev.1) Requirement 24, para. 4.34 states that <i>“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.”</i>
R11	Recommendation: The RSD should issue guidance on the format and content of application for an authorization.

There are approximately 120 applications for licenses each year. The maximum validity of a license is 5 years. Where applicable, the RSD issues a decision when the activity is no longer carried out.

During a visit to the Customs Administration, IRRS team observed the use of an electronic system (EXIM) to control all types of foreign-trade operations including issuing licenses. The system is used by 16 different authorities in the country having a 24h access to the Customs Administration database. The RDS manages and issues approximately 50 licenses for import, export and transit of radiation sources using this system. The system also enables the applicants to monitor the status of their application. The EXIM system demonstrates effective cooperation among regulatory authorities, as well as, transparency of RSD.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>The authorization of import and export of radioactive sources is conducted by efficient coordination of regulatory authorities using the electronic system EXIM which enables transparency regarding the process of application for authorization.</i>	
(1)	BASIS: GSR Part 1 (Rev.1) Requirement 7 states that <i>“Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties.”</i>
(2)	BASIS: GSR Part 1 (Rev.1) Requirement 22, para 4.28 states that <i>“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.”</i>
GP1	Good Practice: The Customs and RSD have established and use a web-based system (EXIM) for authorization of import and export that significantly enhances transparency of RSD and the effective cooperation among the authorities.

5.2. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

There are no facilities devoted to radioactive waste management in the Former Yugoslav Republic of Macedonia. The management of radioactive waste is conducted by operators where waste is generated. As most of radioactive wastes are short lived, their management relies on interim storage for decay, control, clearance and ultimately release as common waste. The IRRS team observed that clearance levels published in the Regulations on the radioactive waste management are not in line with the IAEA safety standards. This issue is addressed in **Recommendation 33** in Section 11.3.

There is no national policy for radioactive waste management in the Former Yugoslav Republic of Macedonia. The IRRS team was informed of examples of disused sources and other radioactive waste which are located at the premises of their original user or in some temporary storage which are not under the full regime of regulatory control (see **Recommendation 12** in section 5.3). For example, there are disused sources from legacy activities such as lightning rods and smoke detectors, or contaminated scrap metal resulting from an accidental melting of a radioactive source. The issue of establishing a national policy for radioactive waste management is addressed in **Recommendation 3** in Section 1.7.

5.3. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

Radiation sources are not produced in the Former Yugoslav Republic of Macedonia, except for some short-lived radionuclides to be used in medical applications such as positron emission tomography (PET). All sealed sources are imported and an agreement from the supplier to take back the source at the end of its useful life must be in place prior to issuing a license for importing a new sealed radioactive source.

Authorization of radiation sources facilities and activities and the import, export and transit of radiation sources, as well as, issues related to the national register of sources is described in section 5.1.

The IRRS Team observed that the IPH is using a Category 3 source at its Secondary Standards Dosimetry Laboratory which is not licensed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Not all practices which are carried out are authorized.*

(1)

BASIS: GSR Part 1 (Rev.1), Requirement 23 states that “*Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process.*”

R12

Recommendation: The RSD should authorize all those facilities and activities that are not explicitly exempted or approved by means of a notification process.

5.4. AUTHORIZATION OF TRANSPORT

The Law on Radiation Protection and Safety establishes the RSD as the competent authority for granting authorization (design or shipment approval) for the transport of radioactive material. A license for “transport” is required for the transport, import or export of radioactive material. The licence is the basis for supervision of the operations. Procedures for application for and issuing of licenses are laid down in the Regulation on the manner of transporting radioactive material.

Approval for packages, special form radioactive material and low dispersible radioactive material is specified in the legal and regulatory framework (with reference to international modal regulations), but no detailed procedure or application form has been defined. This issue is addressed in **Recommendation 11**.

The Former Yugoslav Republic of Macedonia does not perform package design approval, because all the packages used in the country are foreign packages which were approved by the country of origin in accordance with the dangerous goods regulations (ADR, RID, ICAO-Technical Instructions and IMDG-Code). There are no procedures specified for package design approval, testing and manufacturing. Also, the requirements for transport under special arrangement, for approval of calculated A_1/A_2 values and for documentation of compliance of packages not requiring competent approval, are set out in the legal and regulatory framework only by reference to international modal regulations. No fissile materials are transported in the Former Yugoslav Republic of Macedonia.

In addition, the Law on the transport of dangerous goods, requires a license for road-drivers concerning the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) and a certificate for the "Safety Advisor". These provisions are valid for all the 9 classes of dangerous goods and therefore are issued by the Ministry of Transport and Communications and not by the RSD that has only class 7 related responsibilities.

5.5. SUMMARY

The Law on Radiation Protection and Safety assigns the responsibility to the RSD to license facilities and activities with radiation sources. Authorization of facilities and activities is performed through licensing. Applicants are required to submit documentation to the RSD that includes among others, radiation protection programme, radiation emergencies plan and a programme for quality assurance and safety control. Licenses are issued for periods up to five years, depending upon the activities carried out and risks involved.

Regarding the transport of radioactive material, the authorization processes followed by the RSD are generally in accordance with IAEA safety standards.

The legal framework does not fully provide for a graded approach for authorization, and the RSD only partly implements a graded approach. The RSD has not issued guidance on the form and content of application for authorization that can be used by the applicants, except for import, export and transit. The IRRS team also observed that not all practices are authorized.

The IRRS team acknowledged the web-based system (EXIM) used by Customs Administration and the RSD for the authorization of import and export, which significantly enhances the effective cooperation among the authorities and the transparency of RSD.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

The Law on Radiation Protection and Safety includes provisions related to review and assessment, mostly as part of the authorization process. An applicant for a license is required to submit documentation to the RSD including a Radiation protection programme, a Radiation emergency plan and a Programme for quality assurance and safety control. These documents are produced by the applicant without the mandatory involvement of external advice such as advice from qualified experts. The issue of recognition of qualified experts is addressed in **Recommendation 5** in Section 1.8. RSD reviews and assesses the information to determine whether the facilities and activities comply with the regulatory requirements. A graded approach for review and assessment is only implicitly built into the process. Based on the outcome of the review and assessment, the RSD might authorize the operation of a facility or the conduct of an activity and might set conditions in the license. The findings of the review and assessment are documented and reflected in regulatory decisions.

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

Usually the review and assessment of the documentation submitted by the applicant is conducted by one person within the RSD, however more staff can be involved in cases of complex facilities and activities, e.g. use of a cyclotron, radiotherapy, nuclear medicine. Review and assessment is performed by the RSD staff without having standard procedures in place. This issue is addressed in **Recommendation 13** in section 6.1.3.

The IRRS team noted that the competence and the number of RSD staff assigned to perform review and assessment is limited for a broad scope of different types of practices (**Recommendation 5 and Recommendation 6** in Section 1.8 are made in this regard).

During the review and assessment process, the RSD does not seek technical or other expert professional advice or services in support of its regulatory functions. Qualified experts are not formally recognised. **Recommendation 5** in Section 1.8 is made in these regards.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

The review and assessment is based mainly on the criteria set directly in the legislation and regulations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The procedure to assess the safety assessment as a part of the reviewing of the application for authorization is not well established.*

(1)

BASIS: GSR Part 1 (Rev.1), Requirement 24, para. 4.33 states that “Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures.”

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(2)	BASIS: GSR Part 1 (Rev.1), Requirement 22 states that <i>“The regulatory body shall ensure that regulatory control is stable and consistent.”</i>
R13	Recommendation: The RSD should establish and implement procedures for reviewing and assessing the submitted safety assessment.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

A preauthorization visit can be conducted by RSD as part of the review and assessment of the application for license. The findings need to be appropriately addressed by the applicant prior to issuing a license. A preauthorisation visit is also conducted before renewing a license.

The legislation does not foresee periodic review and assessment by the licensee. Therefore, the authorized parties do not perform comprehensive periodic safety reviews of facilities, nor does the RSD periodically assess the radiation risks associated with operation throughout the lifetime of the facility or for the duration of the activity, considering any modification of a practice, source or premises.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The authorized parties do not perform periodic comprehensive safety reviews of facilities. The review and assessment performed by the RSD is taking place during authorisation and renewal of authorisation but not between.*

(1)	BASIS: GSR Part 1 (Rev.1), Requirement 26, para. 4.39A states that <i>“The regulatory body shall ensure, adopting a graded approach, that authorized parties routinely evaluate operating experience and periodically perform comprehensive safety reviews of facilities, such as periodic safety reviews for nuclear power plants. These comprehensive safety reviews are submitted to the regulatory body for assessment or are made available to the regulatory body. The regulatory body shall ensure that any reasonably practicable safety improvements identified in the reviews are implemented in a timely manner.”</i>
(2)	BASIS: GSR Part 1 (Rev.1), Requirement 26, para. 4.43 states that <i>“The regulatory body shall assess the radiation risks associated with normal operation, anticipated operational occurrences and accidents, including possible events with a very low probability of occurrence, prior to operation of the facility or conduct of the activity, and periodically throughout the lifetime of the facility or the duration of the activity, to determine whether radiation risks are as low as reasonably achievable.”</i>
(3)	BASIS: GSR Part 1 (Rev.1), Requirement 26, para. 4.46 states that <i>“...This integrated safety assessment shall be repeated periodically, with account taken of the radiation risks associated with the facility or activity, in accordance with a graded approach.”</i>
R14	Recommendation: The RSD should request the authorised parties to submit a periodic safety assessment. The RSD should assess the radiation risks periodically taking into account also modification of a facility or activity.

6.2. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

There are no authorised facilities dedicated to the storage of radioactive waste in the Former Yugoslav Republic of Macedonia.

6.3. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

Information presented in paragraph 6.1 above essentially covers the review and assessment for radiation sources facilities and activities, and is thus not repeated in this paragraph.

6.4. REVIEW AND ASSESSMENT FOR TRANSPORT

At present, the RSD does not assess package designs or materials for an approval under the dangerous goods regulations, since there are no packages designed or shipped in the Former Yugoslav Republic of Macedonia that would require competent authority approval according to the regulations. Only foreign design packages are used in the country, which are approved by the country of origin.

The RSD is responsible for checking dose rate and performing assessments relating to transport. For complex assessments, the RSD can contract external experts or technical support organizations that are independent of the applicant.

6.5. SUMMARY

Legislation includes provisions related to review and assessment mostly within the authorization process. An applicant for a license is required to submit documentation to the RSD; review of the submitted safety assessment is conducted by RSD staff. A pre-authorization visit can be conducted by RSD which supports its decisions related to review and assessment. No external advice or support is used for review and assessment.

Procedures to review the safety assessment, as a part of reviewing the application for authorization, are not established. In addition, the authorized parties do not perform periodic safety reviews of facilities, in accordance with a graded approach. The RSD does not periodically assess the radiation risks associated with operation throughout the lifetime of the facility or for the duration of the activity.

7. INSPECTION

7.1. GENERIC ISSUES

The Law on Ionizing Radiation Protection and Safety empowers the RSD inspectors to conduct inspections of facilities and activities to verify that authorized parties are in compliance with safety requirements and the conditions specified in the authorization. The inspection process covers all facilities and activities including inspection of transport. The process of inspection follows the Law on Radiation Protection and Safety, the Law on inspection, the rules on general administrative procedures and other relevant laws such as the Law for transport and the Criminal Code.

7.2. INSPECTION PROGRAMME

The RSD is preparing an annual inspection program which is regularly updated. The annual program is based on a graded approach only partly, e.g. in the frequency of inspections which is related to risks associated with a practice. In general, inspections are announced. During the inspection, the RSD inspectors may obtain technical or other expert professional advice or services in support of their regulatory functions.

Joint inspections are performed with the Customs Administration when there is a suspicion at the border that cargo is related to illicit trafficking of radioactive material. The IRRS team was informed that joint inspections might be performed with other relevant institutions. Typically, the RSD conducts around 300 inspections per year.

7.3. INSPECTION PROCESS AND PRACTICE

The RSD prepared the Guidelines on inspection in 2007 but it was never updated since then. Procedures or check lists related to inspection are not issued (**Recommendation 15** is made in this regard).

During the inspections, the inspectors are conducting interviews, checking documentation and records and perform visual inspection. The RSD is equipped with measurement instruments; however, measurements are not routinely performed during the inspections, as the RSD does not have a process related to the use of the measurement instruments. As a rule, the inspection report is prepared on the site at the end of the inspection and is signed by the licensee and the inspector. In more complex cases the report is further elaborated at the RSD office and sent to the licensee. The inspection reports are archived in the RSD documentation system. Reactive inspections are exercised if necessary.

The IRRS team observed the performance of the following inspections:

Industrial Facility

The IRRS team observed an inspection conducted by the RSD at a company practicing industrial radiography using gamma projectors with Ir-192 sources and X-ray devices. The company also conducts transport of radioactive materials.

The inspection started with an entrance meeting with the deputy director and representative of the company who was present during the whole visit of the facility replacing Radiation Protection Officer (RPO). The inspection included the checking of documents and records related to the issued licenses for

industrial radiography and for transport required by RSD. The discussion included radiation protection programme and procedures. The inspector proceeded to visual inspections of the vehicle used for the transport of radioactive material and of the equipment used as well as of the storage place of radioactive sources. The inspector used an electronic dosimeter. The inspector prepared the reports at the facility and presented the findings at the exit meeting. Both reports of the inspection, i.e. on industrial radiography and on transport, were signed by the representative of the company and by the inspector.

The IRRS team noted that no procedures or check lists were used by the inspector (**Recommendation 15 in Section 7.3** is made in this regard). The IRRS team also noted that the licensee stores in the storage visited numerous disused sources without a license for this activity (**Recommendation 12** in Section 5 is made in this regard).

In addition, during the visit it was verified that emergency preparedness and response arrangements are not a priority for the licensee. The licensee was not capable of presenting the internal emergency plan for inspection. It was also stated by the licensee that no emergency preparedness and response exercise has been conducted. The licensee had no knowledge of the NREP, and no articulation with the off-site first responders was established (firefighters, emergency medical personnel, law-enforcement forces, etc.). **Recommendation 23** in section 10.4 addresses this issue.

During the discussion of the IRRS team with the representatives of the licensee, it came out that there is an open relationship between the RSD inspectors and the licensee. The IRRS team noted that stronger involvement of the authorized parties when preparing legislation would be beneficial. **Suggestion 3** in section 3.8 is made in this regard.

Nuclear Medicine Facility

The IRRS team observed an inspection conducted by the RSD at a nuclear medicine service center, with an authorization to operate with Mo-99/Tc-99 generators, I-131 and Co-57. The inspection started with an entrance meeting with the representative of the Institute, where the inspector discussed radiation protection programme, procedures, staffing & training, medical and occupational exposures and environmental monitoring. The inspector then proceeded to visit the different rooms at the location, including two radioactive waste storages. No workplace measurements were performed by the inspector who used TLD and electronic dosimeter, but this last one was used as a monitor for workplace measurement in the waste storage room. The inspector did not elaborate the report at the facility, which was supposed to be written at the RSD office, and there was no exit meeting. Even if the inspector had a kind of check list, no notes were taken on it; no guidelines were used by the inspector. **Recommendation 15** is made in this regard. There seemed to be an open relationship between the RSD inspector and the licensee.

The IRRS team considers that the inspections were not performed in a fully consistent manner, due to the lack of detailed procedures and check lists for performing inspections.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The RSD carries out inspections of facilities and activities to verify that the authorized party is in compliance with safety requirements and the conditions specified in the authorization and legislation. However, there are no established procedures followed by the regulatory body for inspecting facilities and activities; in particular, check lists for performing inspections do not exist.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	BASIS: GSR Part 1 (Rev.1), Requirement 26 states that <i>“The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system.”</i>
(2)	BASIS: GS-G-1.5, para 3. 61 states that <i>“3.61. To ensure that all operators are inspected to a common standard and that the level of safety is consistent, the regulatory body should establish procedures for its inspectors. Appropriate subjects for the inspection procedures could include:...</i> <i>(c) The implementation of the inspection programme, including persons to be interviewed, documents to be reviewed, measurements to be made, equipment to be used, and the use of checklists and technical information;”</i>
(3)	BASIS: GS-G-1.3 para. 4.15 states that <i>“Preparations should be made by the individual or team [...] who will be conducting the inspection. Furthermore, it may be useful to establish a special plan for the inspection and to compile a questionnaire and a list of the documents to be reviewed with the operator. [...]Appropriate subjects for guidance and instructions for inspectors could include [...]relevant technical information and questionnaires</i>
R15	Recommendation: The RSD should establish and implement standardized procedures for inspections, including check lists, for all facilities and activities.

7.3.1 INSPECTORS

Presently, three inspectors are employed by the RSD, (2 seniors, 1 junior). They are also involved in the 24/7 on duty service provided by the RSD to assure prompt emergency response in case of an accident or incident. The authority of inspectors is provided in the Law on Ionizing Radiation Protection and Safety, the Law on inspection supervision and other laws. There are no provisions for training the inspectors for new types of facilities and activities. Training is provided only through ad-hoc mechanisms of international support. There is a lack of competent inspectors. **Recommendation 5** and **Recommendation 6** in section 1.8 regarding the resources and the competence as well as **Recommendation 9** in section 4.3 regarding the establishment and implementation of an integrated management system cover the above issues.

7.4. INSPECTION OF WASTE MANAGEMENT FACILITIES

There are no authorised facilities dedicated to the storage of radioactive waste in the Former Yugoslav Republic of Macedonia.

7.5. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The inspection practice of the RSD and the two RSD inspections observed by IRRS team are described in subchapters 7.2 and 7.3.

7.6. INSPECTION OF TRANSPORT

Inspections of carriers transporting radioactive material is done by inspectors from RSD depending on the information obtained from the licensing process. Inspections are based on internal procedures. Inspections cover all important areas like condition of vehicles and packages, marking, labelling and placarding, compliance with radiation protection and training requirements for workers, status of emergency response

arrangements, written instructions, radiation protection programme and security measures. Inspections are conducted in accordance with a graded approach. Both, planned and unplanned inspections are performed. Inspections also include measurements of dose rates and contamination at the vehicles and the packages. The results of the inspections are reported to the licensees. RSD records inspection reports and non-compliances.

7.7. SUMMARY

The RSD Unit on inspection is delegated to perform regulatory inspections. Annual program, partly based on a graded approach, is regularly prepared covering all facilities and activities including transport. An inspection is normally conducted by one inspector, except in cases where inspection is related to orphan sources or illicit trafficking, where a joint inspection with the Customs Administration is performed. Even if there are provisions for both announced and unannounced inspections, mostly announced inspections are performed. The inspection findings are documented in a report. Inspection findings and licensee follow up actions are tracked. RSD should establish and implement standardized procedures for inspections including check lists for all facilities and activities, allowing the inspections to be performed in a consistent and systematic manner.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

The legislation provides sufficient tools to be used for enforcement which are exercised by the RSD, including prohibition of carrying out a practice, including transport. The legislation also provides for appealing a decision taken by an inspector. The RSD inspectors track corrective actions related to inspections using a database enabling efficient tracking of authorized parties as well as RSD activities. The RSD provides legal support to the RSD inspectors during the enforcement processes.

The IRRS team noted that there is no formal enforcement policy dealing with non-compliances identified by the RSD inspectors.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *RSD has not established a formal enforcement policy for responding to non-compliance by authorized parties.*

(1)	BASIS: GSR Part 1 (Rev.1), Requirement 30 states that <i>“The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization.”</i>
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R16	Recommendation: The RSD should establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties.
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8.2. ENFORCEMENT IMPLEMENTATIONS

The RSD undertakes enforcement actions however not in a systematic manner, since there is no formal enforcement policy.

8.3. SUMMARY

The Law on Ionizing Radiation Protection and Safety and the Law on Inspection Supervision, provide sufficient tools to be used for enforcement actions that are exercised by the RSD. There is an appeal mechanism under which a person can challenge a decision taken by an inspector, as provided for under the Law on Ionizing Radiation Protection and Safety. The RSD provides legal support to the inspectors within the enforcement process. The RSD does not have a formal enforcement policy dealing with non-compliances identified during an inspection.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

The authority to the RSD for preparing and issuing regulations and guides is given by the Law on Ionizing Radiation Protection and Safety and it is one of the main regulatory activities of the RSD. The RSD has prepared and issued numerous (26) prescriptive regulations.

Except one, there are no other guides to provide detailed guidance to the licensees on how to comply with the safety requirements. Namely, only the Guidance on the format and content of documents to be submitted by the applicant for a license for import/export/transit has been issued.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>The RSD has not established guides (with the exception of a guidance on import/ export/ transit) to assist licensees in implementing the safety requirements.</i>	
(1)	BASIS: GSR Part 1 (Rev.1) Requirement 32, states that <i>“The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.”</i>
(2)	BASIS: GSR Part 1 (Rev.1) Requirement 33, states that <i>“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.”</i>
(3)	BASIS: GSR Part 1 (Rev.1) Requirement 34, para. 4.62 states that <i>“The regulations and guides shall provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization. They shall also establish the criteria to be used for assessing compliance. The regulations and guides shall be kept consistent and comprehensive, and shall provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach.”</i>
R17	Recommendation: The RSD should establish or adopt guides, which should be regularly revised and reviewed, to support its regulatory control.

The RSD has prepared an analysis of the present legislation to identify gaps in relation to the Euratom Directives regarding nuclear and radiation safety. Changes related to the 2013/51/ Euratom, 2013/59/ Euratom, 2009/71/ Euratom, 2011/70/ Euratom, 2006/117/ Euratom are envisaged. The incorporation of lessons learned is taken into account when drafting or amending regulations. Regulations are drafted by the working group established by the RSD with representatives of stakeholders. The RSD publishes the drafts of the regulations on its web page for comments of the interested parties and communicates the drafts for comments to the relevant national institutions with given timeframe for providing comments. The laws and regulations are published on RSD web site.

The RSD is envisaging other means to receive feedback from the stakeholders in due time, for example round table discussions with stakeholders.

9.2. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

Within the regulatory framework, the Regulation on the manner of managing, collecting, handling, conditioning, transporting and disposing of radioactive waste, establishes general requirements addressing key processes on the management of radioactive waste. The radioactive waste classification and the requirements for management activities (e.g. collection, characterization, segregation, entering storage, control over the discharges, records and reports) are in accordance with the relevant IAEA safety standards. These regulatory requirements fully support current waste management activities at the waste generating facilities which are limited to collect, storage and release the waste generated after the clearance and/or discharge levels are achieved.

Currently, there are no radioactive waste management facilities in the Former Yugoslav Republic of Macedonia. Nevertheless, the draft on the national policy and strategy for radioactive waste management includes the establishment of a centralized facility for predisposal management. There are many requirements on predisposal facilities covered in the national regulatory framework (e.g. description on premises, devices, equipment, qualified staff and all the stages on radioactive waste management, safety assessment, environmental impact assessment, and safety and security provisions). However, it seems necessary to develop a dedicated regulation, which would address the requirements for predisposal facilities as described in IAEA safety standards GSR Part 5.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Specific requirements related to the siting, design, construction, commissioning, operation and shutdown of predisposal facilities are not included in the regulations.*

(1)	BASIS: GSR Part 5, Requirement 2 states that <i>“The regulatory body shall establish the requirements for the development of radioactive waste management facilities and activities and shall set out procedures for meeting the requirements for the various stages of the licensing process.</i>
(2)	BASIS: GSR Part 5, para. 3.8 states that <i>“To facilitate compliance with regulatory requirements, the regulatory body has to do the following:</i> <ul style="list-style-type: none"> – <i>Provide necessary guidance on the interpretation of national standards and regulatory requirements that takes into consideration the complexity of the operations and the magnitude of the hazards associated with the facility and operations;”</i>
R18	Recommendation: The RSD should complete the regulatory framework for predisposal waste management facilities and set out the procedures for meeting the requirements of the IAEA Safety Standards GSR Part 5.

9.3. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The RSD has developed numerous regulations applicable to radiation sources, such as the Regulation on the criteria and measures on radiation protection for performing practice with X-ray devices, accelerators and other devices that generate ionizing radiation. Although there are numerous regulations, some safety

requirements for some practices are missing, e.g. industrial radiography with radioactive sources and use of brachytherapy sources. The large number of regulations issued and the lack of guidance don't reflect the implementation of a graded approach. This subject is already addressed in **Recommendation 10** in section 5.1 and **Recommendation 17** in section 9.1.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>The regulations, although they are numerous, do not cover all safety aspects of some specific facilities and activities, e.g. industrial radiography with radioactive sources.</i>	
(1)	BASIS: GSR Part 1 (Rev.1) Requirement 32, states that <i>“The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.”</i>
(2)	BASIS: GSR Part 1 (Rev.1) Requirement 33, states that <i>“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.”</i>
(3)	BASIS: GSR Part 1 (Rev.1) Requirement 34, para. 4.62 states that <i>“The regulations and guides shall provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization. They shall also establish the criteria to be used for assessing compliance. The regulations and guides shall be kept consistent and comprehensive, and shall provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach.”</i>
R19	Recommendation: The RSD should review the regulations to ensure that all safety aspects are covered.

9.4. REGULATIONS AND GUIDES FOR TRANSPORT

In the case of national and international shipments of radioactive material, the Former Yugoslav Republic of Macedonia applies the regulations set out under the international agreements for road, rail, sea and air transport that the Former Yugoslav Republic of Macedonia has signed, namely:

- the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR),
- the Regulation concerning the International Carriage of Dangerous Goods by Rail (RID),
- the International Maritime Code for Dangerous Goods (IMDG Code) and
- the International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air.

This ensures that the regulations for safety of transport of radioactive material in the Former Yugoslav Republic of Macedonia for all modes comply with the IAEA Regulations for the Safe Transport of Radioactive Material, SSR-6.

The national regulations and the responsibilities are laid down in the Law on the transport of dangerous goods and in the Law on Ionizing Radiation Protection and Safety.

The special provisions for the transport of radioactive material are summarized in the Regulation on the manner of transporting radioactive and nuclear material. The last version of this Regulation is December 2010 and is based on the 2009 Edition of the IAEA Transport Regulation SSR-6.

The RSD co-operates with other national organizations involved in the transport of dangerous goods, including the Ministry of Transport and Communications, the Ministry of Interior, the Border Police and the Customs Administration.

The RSD is also involved in international cooperation projects, especially with countries from the region. Nevertheless, the RSD would benefit from a more intensive and coordinated involvement in activities of the IAEA Transport Safety Standards Committee (TRANSSC) for optimizing exchange of information and improving uniformity of the application of the IAEA transport regulations in all member states. This issue is addressed in sections 1.8 and 2.1.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>The regulations for the transport of radioactive materials are not in line with the IAEA Transport Regulations SSR-6</i>	
(1)	BASIS: GSR Part 1 (Rev.1) Requirement 33 states that <i>“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.”</i>
R20	Recommendation: The RSD should update the regulations for the transport of radioactive materials to be consistent with the IAEA Transport Regulations SSR-6.

9.5. SUMMARY

The RSD has the authority under the Law on Ionizing Radiation Protection and Safety to draft and publish regulations. The radiation protection legislation needs to be updated in accordance with the IAEA safety standards. The RSD is drafting legislation for the transposition of Euratom Directives. The incorporation of lessons learned is considered when drafting regulations.

The RSD did not issue any guides except one for import/export/transit, to provide detail guidance to the licensees on how to comply with the safety requirement. The RSD did not update the transport regulations to bring them in line with the latest edition of the IAEA Transport Regulations SSR-6. The regulations, although they are numerous, do not cover all safety aspects related to specific practices, e.g. industrial radiography with radioactive sources. The complete regulations and guides related to predisposal waste management facilities are also not set.

The RSD publishes the Law on Ionizing Radiation Protection and Safety and its associated regulations on its website. The RSD is envisaging other means to receive feedback from the stakeholders.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

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

The functions of the national authorities with responsibilities in a radiological emergency are described in the National Radiation Emergency Plan (NREP). The NREP was adopted by the Government and published in the Official Gazette No.84/2011 of the Former Yugoslav Republic of Macedonia.

The RSD, has authority for undertaking measures in a case of a radiation emergency, for establishing interventions levels and for preparing a plan for protection of the public in case of radiation emergency in the Former Yugoslav Republic of Macedonia (the NREP).

The Crises Management Centre (CMC) is a governmental body, which has the role to coordinate all national institutions in the country in all kind of emergencies when a crisis is proclaimed by the Government.

In the NREP are defined the stakeholders having roles in the preparedness and response to a radiological emergency, such as: the CMC, which is the 24/7 coordination body and point of contact for any emergency; the Protection and Rescue Directorate which is responsible for the response for natural and other disasters; several other ministries (Interior, Health, Agriculture Watery, Forestry and Physical Planning, etc.); technical support organizations; local authorities; academic and other non-governmental organizations. The available national infrastructure for responding to other types of emergency is used for radiological emergencies.

The National Coordinative Body for Prevention, Risk Mitigation and Protection against Chemical, Biological, Radiation and Nuclear Weapons and Materials (National CBRN Commission) was established in 2012 by the Government of the Former Yugoslav Republic of Macedonia for strategic support, with several participating institutions, including the RSD.

The RSD has the authority to regulate emergency preparedness and response arrangements of the licensees during the licensing process, whereas the licensee must apply for license, which includes a radiation protection program. The Internal Emergency Plan (IEP) for preparedness and response is part of this program. Additionally, it is required that the licensee informs the RSD immediately about any emergency and has in place a system to respond to an on-site emergency.

The NREP and other relevant documents are based on previous IAEA safety standards, mainly Preparedness and Response for a Nuclear or Radiological Emergency (GS-R-2), 2002 and EPR-Method 2003. The current version of the NREP was published in the end of 2011.

The NREP and the legal and the regulatory framework should be aligned with the current IAEA's safety standards on Emergency Preparedness and Response, GSR Part 7. **Recommendation 2** in section 1.2 and **Recommendation 25** in section 10.4 are made in this regard.

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

It is legally defined that it is the obligation of the licensee to first respond to an emergency on-site and to take measures to mitigate the consequences. In the event of a more complex emergency, the initial mitigatory actions can be taken within the existing national emergency response framework and, if needed, the IAEA Convention on Assistance may be invoked.

According to the Law on Ionizing Radiation Protection and Safety the licensee should state in the IEP the persons responsible for the implementation and updating of this plan. Nevertheless, in the existing legislation, there are no definition and no criteria to designate workers as “emergency workers” or “helpers” in advance of a radiological emergency, even if a legal basis for the protection of emergency workers exists. **Recommendation 25** in section 10.4 addresses this issue.

The Regulation on the limits of exposure in a radiological emergency includes provisions related to the dose limits to be applied for the emergency workers. There are no provisions for training programme for emergency workers.

In case of an emergency, dose assessment is done first by the licensee, later with the collaboration of IPH and the RSD.

For EPC III, in case of an emergency that may need evacuation on-site to protect the public (visitors or staff) present in the premises of the facility, the licensee is responsible to organize and conduct the evacuation.

In case of an intervention, the levels used for undertaking urgent protective actions are the ones prescribed in the Regulation on the limits of exposure.

In case of loss, theft or unauthorized use of a radiation source and in an incidence or accident related to radiation facilities or activities, the licensee is required to notify the RSD in less than an hour.

According to the hazard assessment there are only facilities or activities giving rise to Emergency Preparedness Categories (EPC) III, IV and V. The regulatory requirements for the licensee regarding emergency classification EPC III, classify the emergency as a “Facility Emergency” or as an “Alert”, but sets no clear criteria to perform this classification. The legislation does not address clear criteria for declaration of an emergency.

The NREP includes arrangements for initial assessment of the situation, but no criteria for transition from an emergency exposure situation to an existing exposure situation nor criteria for the termination of an emergency are defined.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *No clear criteria for declaration, prompt classification and termination of an emergency exist in the legislation or in the National Radiation Emergency Plan.*

(1)

BASIS: *GSR Part 7 Requirement 7, para 5.14 states that “The operating organization of a facility or activity in category I, II, III or IV shall make arrangements for promptly classifying, on the basis of the hazard assessment, a nuclear or radiological emergency warranting protective actions and other response actions to protect workers, emergency*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>workers, members of the public and, as relevant, patients and helpers in an emergency, in accordance with the protection strategy.”</i>
(2)	BASIS: GSR Part 7 Requirement 18 states that <i>“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.</i>
R 21	Recommendation: The Government should ensure that clear criteria are established for the declaration, prompt classification and termination of an emergency.

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

There are regulatory requirements regarding plans and procedures for licensees. One of the main obligations of a licensee is to prepare an IEP and to test it. There are obligations for the periodic update and review, nevertheless there is a lack to define a frequency for testing the plan and clear criteria for revising it. In this respect, the RSD should include in the regulations, provisions for the review and update of the internal emergency plans for radiation activities or facilities. **Recommendation 25** in this section covers this issue.

The requirements for logistical support on EPR are described in the Regulation on radiation protection program. The licensee must describe the internal plans for prevention and response to radiological emergencies, including the available equipment and human resources.

The NREP includes provisions to the licensees for training their employees for emergency situations. Also, the NREP includes provisions for periodic tests and exercises (once per year on different scenarios) and a full scope exercise every three years. Nevertheless, it was observed a lack of an established framework for evaluation methodology and feedback process for training, drills and exercises. **Recommendation 25** in this section covers this issue.

The Regulation on radiation protection program includes requirements for quality assurance. Although these requirements are designed for the general activity of the licensee, they also apply for emergency plans and the review of the plans and procedures. During renewal of the license, the applicant is obliged to submit to the RSD an updated radiation protection program including the emergency plan as well.

Depending on the situation, different procedures are established, based on a graded approach, to conduct the recovery operations. In the recovery operations, other stakeholders are also involved such as owner/user of the source (licensee), Police, Technical Support Organization, Protection and Rescue Directorate, Ministry of Defence, Ministry of Health.

The RSD has full authority for the regulation of licensees with respect to emergency preparedness and response.

The RSD verifies the compliance of the on-site emergency arrangements of operating organizations against the regulatory requirements before commencing the operation of the facility and afterwards during the lifetime of the facility.

The RSD staff with assigned ERP activities has a suitable technical expertise but doesn't seem to be in sufficient number to discharge the RSD competencies for prolonged 24/7 operations during an emergency. **Recommendation 6** in section 1.8 addresses this issue.

The legislation contains requirements for the emergency plan, radiation protection competences, notification and training of the staff.

The meeting of these requirements is verified by RSD inspectors that have the authority to inspect the emergency procedures of the licensees. The RSD has the obligation to perform inspection when an emergency has occurred (investigation, enforcement measures etc...).

10.4. ROLE OF REGULATORY BODY IN A NUCLEAR OR RADIOLOGICAL EMERGENCY

The RSD has a role in the emergency preparedness and response. It may vary from active on-site participation to decision support to the CMC.

The Former Yugoslav Republic of Macedonia is a Party to the IAEA Conventions on Early Notification and Assistance; the CMC is the National Contact Point and the RSD is the National Competent Authority for emergencies within the country or abroad.

The Steering Committee of the Government is the decision-making body (ministry level) in a crisis. The Assessment Group of the Government is a high-level body (director level) for analysing and proposing decision to the Steering Committee. The RSD director doesn't participate in the Assessment Group of the Government; he is requested when needed (in case of radiation emergency or potential radiation emergency).

The Headquarter within the CMC is an operative body composed of representatives of different institutions having role in emergency (depending of emergency) in which RSD has representatives. The Headquarter proposes measures and solutions to the Steering Committee and forwarded to the Government as decision maker. The Headquarter, as operative body implements decisions made by the Government.

The coordination of all national stakeholders is established by the NREP, covering EPC III to V, and including some possible scenarios and response to each of them.

The RSD has facilities for regular work that are also used in case of emergency, and has available appropriate instruments for measuring radiation (alpha, beta, gamma, x-ray and neutron), instruments for identification of radionuclides, equipment for sampling, personal protective equipment, and means of communication, procedures, established communication and MoUs with all relevant national institutions having a role in radiological emergencies.

The RSD has not established annual training program on emergency preparedness and response, drills or exercises, but each year the RSD staff participate in exercises and drills organized by the IAEA (USIE), Euratom (ECURIE), Crises Management Centre, Protection and Rescue Directorate, Ministry of Defence, and also under regional programs.

The RSD is in the process of establishing a management system; relevant documentation has been prepared or is under preparation, in which the verification of effectiveness of RSD arrangements regarding the emergency preparedness and response will be included.

The RSD is responsible for defining the criteria for agricultural countermeasures, ingestion and longer-term protective actions in the NREP. The NREP also defines the procedure to guide the coordination of relevant activities.

In the Former Yugoslav Republic of Macedonia exist well-organized systems of control of radioactive material in scrap metal at the State border and at the facilities. In addition, for importing scrap metal in the country, a certificate of non-radioactivity provided by an authorized technical service in the country, is needed.

The NREP assigns responsibilities to the RSD in mitigating some of the non-radiological consequences of the emergency and response.

The Former Yugoslav Republic of Macedonia lacks a national policy on management of any radiological waste resulting from an emergency. **Recommendation 3** in section 1.7 addresses this issue.

The management of the medical response is detailed in the NREP. Whenever decontamination of injured persons is needed, the Ministry of Health designates a hospital for decontamination and treatment. Nevertheless, the NREP does not pre-designate, one or more hospitals, with the adequate training and equipment to perform the task.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>Neither the legislation nor the National Emergency and Response Plan establish predesignated medical facilities for initial medical treatment.</i>	
(1)	BASIS: GSR Part 7 Requirement 12, para 5.65 states that “ <i>For facilities in categories I, II and III, arrangements shall be made to manage an adequate number of any individuals with contamination or of any individuals who have been overexposed to radiation, including arrangements for first aid, the estimation of doses, medical transport and initial medical treatment in predesignated medical facilities.</i> ”
R22	Recommendation: The Government should ensure that medical facilities are predesignated for initial medical treatment in case of radiological emergencies.

The Ministry of Health is mandated to follow the health conditions of persons exposed to ionizing radiation to determine possible health effects due to exposure or contamination. No formal procedures and systematic arrangements are in place for general practitioners and medical emergency staff to make them aware of the symptoms of radiation exposure in patients. **Recommendation 25** covers this issue.

The NREP defines responsibilities for the institutions designated for the off-site emergency response and how they should coordinate with the on-site response. The arrangements for emergency preparedness and response could benefit of an ample disclose of the non-classified sections of the NREP to the licensees and to the relevant bodies having responsibilities in emergency response, first responders included.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>The internal emergency plans of a facility or for an activity of EPC III and IV are not known by the local first responders, impairing the coordination between all bodies that have responsibilities in a radiological emergency</i>	

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	BASIS: GSR Part 7 Requirement 23, para 6.19 states that <i>“The operating organization of 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.”</i>
R23	Recommendation: The RSD should establish arrangements for the licensee to coordinate with local first responders the implementation of internal emergency plans.

The Former Yugoslav Republic of Macedonia does not have EPC I and II and no emergency planning zones have been outlined; however, based on the hazard assessment of transboundary emergency, the NREP should consider, for emergency preparedness category V, “planning distances” for ingestion and commodities (ICPD) for the closest nuclear power plant, in line with GSR Part 7. Action levels for restriction of the consumption of drinking water and food are defined in the NREP.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The hazard assessment of transboundary emergency foresees emergencies of emergency preparedness category V, however no emergency planning distances are established for coordinating the response, taking protection actions and other response actions and for providing mutual support.*

(1)	BASIS: GSR Part 7 Requirement 6, para 5.39 states that <i>“Within the emergency planning zones and emergency planning distances, arrangements shall be made for taking appropriate protective actions and other response actions effectively, as necessary, promptly upon the notification of a nuclear or radiological emergency. ...The arrangements shall be coordinated with all jurisdictions (including, to the extent practicable, jurisdictions beyond national borders, where relevant) within any emergency planning zone or distance.”</i>
R24	Recommendation: The RSD should ensure the proper implementation of emergency planning distances for emergency response category V.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The existing requirements for emergency preparedness and response are not consistent with the requirements of IAEA safety standards GSR Part 7; some issues could be single out like the pre-designation of the emergency workers, the review and update of the internal emergency plans, the establishment framework for exercises and the medical response.*

(1)	BASIS: GSR Part 1 (Rev.1) Requirement 33 states that <i>“Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained.”</i>
(2)	BASIS: GSR Part 7 Requirement 11, para 5.49 states that <i>“Arrangements shall be made to ensure that emergency workers are, to the extent practicable, designated in advance and are fit for the intended duty. These arrangements shall include health surveillance for emergency workers for the purpose of assessing their initial fitness and continuing fitness for</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>their intended duties.”</i>
(3)	BASIS: GSR Part 7 Requirement 23, para 6.18 states that “(e) <i>Emergency plans and procedures are periodically reviewed and updated...</i>
(4)	BASIS: GSR Part 7 Requirement 26, para 6.36 states that “ <i>Arrangements shall be made to maintain, review and update emergency plans...</i> ”
(5)	BASIS: GSR Part 7 Requirement 25 states that “ <i>The government shall ensure that personnel relevant for emergency response shall take part in regular training, drills and exercises to ensure that they are able to perform their assigned response functions effectively in a nuclear or radiological emergency.</i> ”
(6)	BASIS: GSR Part 7 Requirement 25, para 6.30 states that “ <i>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 and some exercises shall be evaluated by the regulatory body. Programmes shall be subject to review and revision in the light of experience gained.</i> ”
(7)	BASIS: GSR Part 7 Requirement 25, para 6.31 states that “ <i>The personnel responsible for critical response functions shall participate in drills and exercises on a regular basis so as to ensure their ability to take their actions effectively.</i> ”
(8)	BASIS: GSR Part 7 Requirement 25, para 6.33 states that “ <i>The conduct of exercises shall be evaluated against pre-established objectives of emergency response to demonstrate that identification, notification, activation and response actions can be performed effectively to achieve the goals of emergency response.</i> ”
(9)	BASIS: GSR Part 7 Requirement 12, para 5.63 states that “ <i>Arrangements shall be made for medical personnel, both general practitioners and emergency medical staff, to be made aware of the clinical symptoms of radiation exposure, and of the appropriate notification procedures and other emergency response actions to be taken if a nuclear or radiological emergency arises or is suspected.</i> ”
R25	Recommendation: The RSD should revise the regulations on emergency preparedness and response to ensure compliance with the IAEA Safety Standards GSR Part 7.

10.5. SUMMARY

The Former Yugoslav Republic of Macedonia is a country with facilities and activities belonging to IAEA Emergency Preparedness Categories III, IV and V.

The National Radiation Emergency Plan does not fully specify emergency preparedness categories in line with GSR Part 7 which is the current basis for implementation the graded approach on EPR. Nevertheless, the existing legislation and hazard assessments provide a good basis for implementing the IAEA requirements to achieve a harmonized graded approach in establishing arrangements for preparedness and response to radiological emergencies.

There are no provisions for managing any radiological waste resulting from an emergency. A comprehensive and efficient system to control scrap metal is established.

The RSD takes the leading role and responsibilities in the response to a radiological emergency; RSD is an advisor to the Government to responding in an emergency and the national competent authority under the Early Notification and Assistance Conventions of the IAEA.

The RSD regulates the emergency preparedness and response arrangements of the licensees; according to the licensing requirements an internal emergency plan should be included within the radiation protection program.

The RSD needs to further develop comprehensive emergency arrangements (plans, procedures, emergency management organization, staffing plan, training and exercise programmes, etc.) to comply with IAEA safety standards in emergency preparedness and response.

11. ADDITIONAL AREAS

11.1. CONTROL OF MEDICAL EXPOSURES

The Law on Ionizing Radiation Protection and Safety provides the statutory basis for control of medical exposure. There are general provisions regarding the radiation protection principles and more specific provisions for the justification of medical exposure compared to available alternative techniques - risk and benefit, need of medical prescription, responsibility of doctors for patient protection, availability of medical and paramedical staff, quality program under supervision of a medical physicist and personnel training.

The RSD has issued several regulations to complete the regulatory framework of the radiation protection in medical practices by establishing requirements related to quality control and diagnostic reference levels (DRL), quality criteria, training, plan of medical exposure and quality assurance, health professionals' qualification and dose constraints for medical exposure.

General principles of radiation protection applied to medical exposures including justification, optimization and DRL are included in the regulation.

In the country, there are 3 nuclear medicine departments (2 of them performing also therapy), 3 PET/CT units, 1 cyclotron facility for radioisotope production, 139 radiology and 269 X-rays dental equipment. For radiotherapy, there are 4 linear accelerators, 1 brachytherapy unit and one X-ray treatment unit.

A radiation protection program including the plan on medical exposure and the quality assurance programme is requested to be submitted by applicants during the license process, which is assessed and approved by the RSD.

Medical Physicists

According to the national classification of professions, the profession of medical physicist is recognised in the Former Yugoslav Republic of Macedonia since 2011. Currently, there are two education courses: the Faculty of Natural Sciences and Mathematics provides a one year M.Sc. course in medical physics for physicists and Medical Faculty provides 3 years clinical specialisation in "nuclear medical physics". There are no regulatory requirements related to criteria or curricula for the education and training of medical physicists on radiation protection in medical area. There are no requirements for the duties and responsibilities of medical physicists.

Currently, there are about 20 medical physicists in the country, employed in nuclear medicine facilities, cyclotron facility for radioisotope production and radiotherapy units as well as in technical service providers. There are no medical physicists in radiology facilities (conventional and CT) or in units providing image guided procedures. Moreover, the ongoing projects of installing new radiotherapy accelerators will increase the need for medical physicists in the country.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *The regulation does not define the qualifications, education, continuous training, duties and responsibilities for the medical physicists. There is insufficient number of medical physicists*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

available in the country.

(1)	BASIS: GSR Part 3 Requirement 2, para. 2.21 states that: <i>“The government shall ensure that requirements are established for:(a) Education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety; (b) The formal recognition of qualified experts; (c) The competence of organizations that have responsibilities relating to protection and safety.”</i>
(2)	BASIS: GSR Part 3 Requirement 3, para. 2.32 states that: <i>“The regulatory body shall ensure the application of the requirements for education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety.”</i>
(3)	BASIS: GSR Part 3 Requirement 34, para. 3.147 states that: <i>“The government, in accordance with paras 2.13–2.28, shall ensure with regard to medical exposures that, as a result of consultation between the health authority, relevant professional bodies and the regulatory body, the relevant parties identified in paras 2.40 and 2.41 are authorized to assume their roles and responsibilities, and shall ensure that they are notified of their duties in relation to protection and safety for individuals undergoing medical exposures.”</i>
(4)	BASIS: GSR Part 3 Requirement 36, para. 3.154 (c) states that: <i>“Registrants and licensees shall ensure that sufficient medical personnel and paramedical personnel are available as specified by the health authority”</i>
R26	Recommendation: The Government should make provisions in the legal framework for qualification, training, duties and responsibilities for medical physicists and ensure sufficient number of qualified medical physicists.

Training of medical staff

The health professionals’ qualifications and the list of the medical staff are reviewed by RSD during the licensing process. Requirements for training in the appropriate medical area are provided in the regulation except for brachytherapy. There are no provisions in the regulation for the continuous training on radiation protection of patients. There are no provisions for the recognition of the institutions that provide training on patients’ radiation protection.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *There are no provisions in the regulation about the continuous training or the frequency of updating, neither about the institutions which could provide training concerning radiation protection of patients.*

(1)	BASIS: GSR Part 3 Requirement 2, para. 2.21 states that: <i>“The government shall ensure that requirements are established for:(a) Education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety; ...”</i>
(2)	BASIS: RS-G.1.5 para. 2.70 states that: <i>“Changes that occur in equipment, instrumentation, practice, monitoring methods, recommendations and regulations make it essential that all the individuals involved in the use of ionizing radiation sources receive not just initial but also continuing education and training.”</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

S4	Suggestion: The Government should consider making provisions in the legal framework to ensure the continuous training of medical and paramedical staff in their appropriate area.
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Diagnostic Reference Levels

DRL for medical imaging are specified in regulation. RSD should be informed in case that measured doses in the diagnostics procedures exceed the national DRL. Within the medical facilities there are no procedures or appropriate infrastructure or availability of medical physicists to collect the patient exposure parameters and to compare their average patient doses to the national DRL. Provisions regarding the image guided procedures are not included in the regulations. This issue is covered in **Recommendation 27**.

Justification

Justification principle is addressed in the Law on Ionizing Radiation Protection and Safety. The regulations however do not clearly provide criteria for a practitioner to refuse an examination or to advise for another than the prescribed one. The consultation between the prescriber and the radiological practitioner in case of pregnant or breast-feeding women or children is not addressed in the regulations. This issue is included in **Recommendation 27**.

Calibration

The IPH and the EKOTEH provide quality control tests for conventional radiology and CT. Additionally, the IPH operate a laboratory for calibration of radiation measuring devices. There are no authorised providers of technical services for quality control in nuclear medicine, radiotherapy or brachytherapy. There is no possibility to calibrate radiotherapy equipment in the country, consequently there is no possibility for an independent verification prior to the clinical use for linear accelerators (3 new facilities in project). This issue is addressed in **Recommendation 27**.

Pregnant women and breast-feeding women

There is no requirement for signs to be placed to request female patients who are to undergo a radiological procedure to notify if they are (or might be) pregnant or breast feeding (at nuclear medicine departments). Nevertheless, the RSD provides the facilities with posters (for notification in case of pregnancy). This issue is addressed in **Recommendation 27**.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Not all requirements of the IAEA GSR Part 3 relating to medical exposure are addressed in the regulatory framework, including those related to diagnostic reference levels for image guided procedures, justification, calibration, and arrangements for female patients.*

(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,
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RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>including image guided interventional procedures.”</i>
(2)	BASIS: GSR Part 3 Requirement 37, para. 3.157 states that: <i>“The justification of medical exposure for an individual patient shall be carried out by means of consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, with account taken, in particular for patients who are pregnant or breast-feeding or paediatric”</i>
(3)	BASIS: GSR Part 3 Requirement 38, para. 3.167 states that: <i>“In accordance with para. 3.154(d) and (e), the medical physicist shall ensure that:</i> <i>(c) Calibrations of radiation therapy units are subject to independent verification prior to clinical use;</i>
(4)	BASIS: GSR Part 3 Requirement 39, para 3.175 states that: <i>“Registrants and licensees shall ensure that signs in appropriate languages are placed in public places, waiting rooms for patients, cubicles and other appropriate places, and that other means of communication are also used as appropriate, to request female patients who are to undergo a radiological procedure to notify the radiological medical practitioner, medical radiation technologist or other personnel in the event that:</i> <i>(a) She is or she might be pregnant;</i> <i>(b) She is breast-feeding and the scheduled radiological procedure includes the administration of a radiopharmaceutical.”</i>
R27	Recommendation: The RSD should revise the legal and regulatory framework to bring it in line with the IAEA Safety Standards GSR Part 3 for strengthening the medical exposure control and should ensure their full implementation.

Dosimetry of patients/Optimization

According to the regulations, patient’s dosimetry must be performed and recorded. In accordance with the Law on Ionizing Radiation Protection and Safety, dosimetry should be carried out under supervision of a medical physicist. This is implemented in nuclear medicine, radiotherapy and brachytherapy procedures; however, patients’ dosimetry is not carried out for radiological procedures as there are no medical physicists involved in this medical field.

The medical procedures should be conducted under reviewing of a process of optimization which has not been yet implemented as there are no sufficient resources of these professionals in the country. This issue is covered in **Recommendation 27**.

Reviews and records

The quality assurance programme required by regulation shall contain the description of the programme of periodic review and updating of the radiation protection programme and working procedures. The existing provisions are in line with the IAEA GSR Part 3 requirement but the implementation must be improved by increasing the involvement of medical physicists, in particular in radiological and image guided procedures.

Unintended and accidental medical exposures

There are provisions in the regulation through the NREP that the licensee should conduct investigation in case of an accidental medical exposure and notify RSD. The IRRS team was informed that RSD rarely receives notification of medical incidents. There is no available information to licensees (regulation or guides) specifying when an investigation regarding an unintended medical exposure should be conducted and which information should be included in the relevant report.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>There is no information available for licensees (regulations or guides) specifying when investigation should be conducted regarding unintended medical exposure, neither the expecting content of the report they should provide.</i>	
(1)	BASIS: GSR Part 3 Requirement 41, para 3.180 states that: “Registrants and licensees shall promptly investigate any of the following unintended or accidental medical exposures:...”
(2)	BASIS: GSR Part 3 Requirement 41, para 3.181 states that: “Registrants and licensees shall, with regard to any unintended or accidental medical exposures investigate as required in para. 3.180...”
S5	Suggestion: The RSD should consider specifying criteria for the licensees to initiate and conduct an investigation following an unintended medical exposure.

11.2. OCCUPATIONAL RADIATION PROTECTION

The Law on Ionising Radiation Protection and Radiation Safety lays down the basis for preventing and limiting the health hazards and other detrimental effects of radiation. The Law also establishes the RSD as the regulatory body responsible for the control of occupational exposure and assigns to it a range of tasks and responsibilities.

Additionally to the provisions concerning occupational exposure given in the Law on Ionizing Radiation Protection and Safety, the RSD has adopted many regulations specifying requirements for the occupational exposure control. Thus, the regulatory framework has considered most of the IAEA requirements on occupational exposure control such as:

- Compliance with the principles of justification, optimisation and limitation,
- Operational radiation protection of exposed workers (risk assessment),
- Classification of exposed workers (including apprentices and students),
- Measures for restriction of exposure (monitoring equipment, personal protective equipment, designation of controlled and supervised areas, information and training),
- Workplace and individual monitoring and records,
- Medical surveillance of exposed workers during all their exposed period and health records,
- Dose limits for different classes of persons including emergency workers,
- Existing exposure situations for workers,
- Workers’ responsibilities in their own protection from ionising radiation.

Although the regulation of workers’ protection against radiation exposure is voluminous, given the limited use of radiation sources (main practices are in the medical field), there are some shortfalls, vagueness and points needing up-dating.

Responsibility of employers to occupational exposure and cooperation between employers and licensees

The Law on Ionizing Radiation Protection and Safety places responsibility only on the legal entity operating a facility or conducting an activity with radiation sources; employers are not mentioned in the Law.

There is no legal or regulatory requirement assuring radiation protection for workers not employed by the licensees. The IRRS team was informed that allocation of responsibilities between licensees and employers in this case are stated in the contract between the relevant parties and this contract is reviewed by RSD during the licensing process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>The legal framework does not address the responsibilities of the employers in the case where the licensee is different from the employer.</i>	
(1)	BASIS: GSR Part 3 Requirement 19 para. 3.69 states that <i>“The government or the regulatory body shall establish the responsibilities of employers, registrants and licensees with regard to application of the requirements for occupational exposure in planned exposure situations.”</i>
(2)	BASIS: GSR Part 3 Requirement 23 para. 3.85 states that <i>“If workers are engaged in work that involves or that could involve a source that is not under the control of their employer, the registrant or licensee responsible for the source and the employer shall cooperate to the extent necessary for compliance by both parties with the requirements of these Standards.”</i>
(3)	BASIS: GSR Part 3 Requirement 25 para. 3.109 states that <i>“If one or more workers are to be engaged in work in which they are or could be exposed to radiation from a source that is not under the control of their employer, the registrant or licensee responsible for the source shall, as a precondition for the engagement of such workers, make with the employer any special arrangements for workers’ health surveillance that are needed to comply with the rules established by the regulatory body or other relevant authority.”</i>
R28	Recommendation: The Government should ensure that the responsibilities of employers and licensees and their cooperation are included in the legislation on radiation protection.

Training of workers & Radiation Protection Officer

According to the Law on Ionizing Radiation Protection and Safety, the RSD is responsible to ensure that training for the persons in charge of radiation protection is available. IRRS team was informed that RSD provided the last training for RPO four years ago and that now the Centre for Permanent Education (PERZA) performs this training. Regulation defines the same content for training of RPO as for training of workers using sources, while RPO should assure training for workers according to the same regulation. Regulation does not include provisions for the systematic retraining of workers.

The responsibilities of RPO are not defined in the regulation; the licensees specify RPO responsibilities within the radiation protection programmes.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *There are no provisions in the regulation ensuring periodic retraining for workers subject to occupational exposure, neither for RPO.*

(1)	BASIS: GSR Part 3 Requirement 2, para. 2.21 states that “The government shall ensure that requirements are established for: (a) Education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety; (b) The formal recognition of qualified experts; (c) The competence of organizations that have responsibilities relating to protection and safety.”
(2)	BASIS: GSR Part 3 Requirement 3, para. 2.32 states that “The regulatory body shall ensure the application of the requirements for education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety.”
(3)	BASIS: GSR Part 3 Requirement 21 para. 3.76 (h) states that “Employers, registrants and licensees shall ensure, for all workers engaged in activities in which they are or could be subject to occupational exposure, that suitable and adequate human resources and appropriate training in protection and safety are provided, as well as periodic retraining as required to ensure the necessary level of competence.”
R29	Recommendation: The Government should make provisions in the legal framework to ensure the retraining of workers engaged in activities in which they are or could be exposed to radiation.

Registry of occupational exposure doses

The Law on Ionizing Radiation Protection and Safety attributes to the RSD the responsibility for maintaining the national register of occupationally exposed workers; the IPH and other technical services are responsible for the keeping of records of occupational exposed workers to ionising radiation monitored by them and for submitting reports to RSD. The RSD has issued a regulation which states that the national register of the occupational exposed workers shall contain information of the doses received. The IRRS team observed a lack of cooperation between the involved entities so that RSD has no information about the doses received by workers, except in cases of exceeding the established dose limits.

The IPH is a technical service provider for workplace and individual occupational exposure monitoring. Based on the Law on Ionizing Radiation Protection and Safety, the RSD has authorised two other technical service providers: EKOTEH for workplace monitoring and individual occupational exposure monitoring and STEWART INSPECT for workplace monitoring. These service providers submit reports of the individual monitoring results to the licensees and to RSD only in case of exceeding the investigation levels established by the RSD.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Information of occupational exposure is not recorded in a centralised manner but maintained by several organisations including RSD.*

(1)	BASIS: GSR Part1. Requirement 35, para. 4.63 states that “The regulatory body shall make provision for establishing and maintaining the following main registers and inventories: ... Records of doses from occupational exposure;”
R30	Recommendation: The Government should make provisions to ensure that the registry of doses from occupational exposure is established and complete.

Dose limits

The dose limits set down in articles 8 and 10 of the Regulation on limit of exposure to ionising radiation and the conditions of exposure in particular cases and emergencies for the lens of the eye are derived from previous IAEA BSS115 and are not in accordance with GSR Part 3. This issue is addressed in **Recommendation 31** in this section.

Monitoring of workplaces

The regulation defines that workplace monitoring should be performed by technical services at least once per year; additional measurements can be carried out by licensees as defined in their own radiation protection programme. There is no requirement stating that the frequency of workplace monitoring should be commensurate to the risk generated by the ionising radiation source in accordance with a graded approach. This issue is addressed in **Recommendation 31** in this section.

Dose constraints are defined for aircrew members and the responsibility in this respect is assigned to employees.

Records of individual occupational exposure

The legislative and regulatory framework does not include requirement related to the duration of keeping records of occupational exposure for each worker. This issue is addressed in **Recommendation 31** in this section.

Pregnant and breast-feeding women

The Law on Ionizing Radiation Protection and Safety prohibits pregnant women from working with radiation sources; the same happens for breast-feeding women if there is a risk of contamination. This is not in line with GSR Part 3 requirement which states that the pregnant or breast-feeding worker shall not be excluded from work.

The radiation protection programme established by the licensee should contain procedures for the information of pregnant women (notification of pregnancy and conditions to protect the embryo or foetus); there are no similar provisions for breast-feeding women.

These issues are addressed in **Recommendation 31**.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *Not all requirements of the IAEA GSR Part 3 relating to occupational exposure are addressed in the regulatory framework including those related to limits for the lens of eye, frequency of workplace monitoring, duration for keeping the records of occupational exposure and pregnant and breast-feeding women.*

(1)	BASIS: <i>GSR Part 3 Requirement 19 para. 3.71 states that “The government or the regulatory body shall establish and the regulatory body shall enforce compliance with the dose limits specified in Schedule III for occupational exposures and public exposures in planned exposure situations.”</i>
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RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(2)	<p>BASIS: GSR Part 3 Requirement 24 para. 3.97 states that <i>“The type and frequency of workplace monitoring:</i></p> <p><i>(a) Shall be sufficient to enable: (i) Evaluation of the radiological conditions in all workplaces; (ii) Assessment of exposures in controlled areas and supervised areas; (iii) Review of the classification of controlled areas and supervised areas.”</i></p>
(3)	<p>BASIS: GSR Part 3 Requirement 25 para. 3.104 states that <i>“Records of occupational exposure for each worker shall be maintained during and after the worker’s working life, at least until the former worker attains or would have attained the age of 75 years, and for not less than 30 years after cessation of the work in which the worker was subject to occupational exposure.”</i></p>
(4)	<p>BASIS: GSR Part 3 Requirement 28, para. 3.113 states that: <i>“Employers, in cooperation with registrants and licensees, shall provide female workers who are liable to enter controlled areas or supervised areas or who may undertake emergency duties with appropriate information on:</i></p> <p><i>(a) The risk to the embryo or foetus due to exposure of a pregnant woman;</i></p> <p><i>(b) The importance for a female worker of notifying her employer as soon as possible if she suspects that she is pregnant or if she is breast-feeding;</i></p> <p><i>(c) The risk of health effects for a breastfed infant due to ingestion of radioactive substances.”</i></p>
(5)	<p>BASIS: GSR Part 3 Requirement 28, para. 3.114 states that <i>“Notification of the employer by a female worker if she suspects that she is pregnant or if she is breast-feeding shall not be considered a reason to exclude the female worker from work....”</i></p>
R31	<p>Recommendation: The RSD should revise the current legal and regulatory framework to bring it in line with IAEA Safety Standards GSR Part 3 for strengthening the occupational exposure control and should ensure their full implementation.</p>

Workers’ health surveillance

The IRRS team was informed that occupational health services do not have access to information about the dose received by workers.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<p>Observation: <i>There is no provision for occupational health services with workers’ occupational exposure records.</i></p>
(1)	<p>BASIS: GSR Part 3 Requirement 25 para. 3.106 (b) states that <i>“Employers, registrants and licensees shall provide the supervisor of the programme for workers’ health surveillance, the regulatory body and the relevant employer with access to workers’ records of occupational exposure”</i></p>
S6	<p>Suggestion: The Government should consider making a provision so that employers and licensees provide occupational health services with information about the doses received by workers.</p>

11.3. CONTROL OF DISCHARGES AND MATERIALS FOR CLEARANCE ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION

Control of discharges and material for clearance

In the Former Yugoslav Republic of Macedonia, the only facilities releasing radioactive material into the environment are three nuclear medicine departments, two of them delivering therapeutic treatments, which deal with unsealed radioactive sources containing short and very short-lived radionuclides (I-131, Tc-99m, etc.).

General requirements for controlling discharges of radioactive substances into the environment are included in the Law on Ionizing Radiation Protection and Safety, while more specific details are given in regulations issued by the RSD. The Law on Ionizing Radiation Protection and Safety provides that any planned discharge must be preceded by a regulatory authorization.

The Regulation on the discharge limits of radioactive materials into environment, the manner of monitoring, maintaining records and reporting addresses the requirements for the control of discharges, used as a basis for the authorization process. According to this regulation, licensees shall support the relevant application by an appropriate discharge characterization and if needed by a safety assessment. In addition to the source monitoring arrangements, the operator shall keep appropriate records on the type of radionuclides discharged, activity involved, routes used and any relevant data regarding the discharges.

The regulation on the discharge limits establishes generic maximum permitted levels for unconditional discharges. These numerical values, defined for all types of waste, were calculated using 10 µSv as an annual dose constraint for the representative person. The regulation considers that these unconditional limits could be exceeded. However, it does not include specific requirements for the authorization process, needed either in such cases or where changes have happened in the exposure scenario used when establishing the initial discharge authorization.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>The regulation for controlling radioactive discharges does not address the authorization process required when either the discharges are exceeding the unconditional limits or changes have happened in the exposure scenario used when establishing the discharge authorization.</i>	
(1)	BASIS: GSR Part 3 para. 3.134 states that. <i>“Registrants and licensees shall review and modify their discharge control measures, as appropriate and in agreement with the regulatory body, taking into account:; (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.”</i>
(2)	BASIS: GSR Part 3 para. 3.123 states that. <i>“The regulatory body shall establish or approve operational limits and conditions relating to public exposure, including authorized limits for discharge...”</i>
R32	Recommendation: The RSD should establish authorization processes and requirements for situations where discharges exceed unconditional limits or where the exposure scenario used in the discharge authorization has changed.

The definition of “clearance” as a concept is included in the Law on Ionizing Radiation Protection and Safety, nevertheless no specific responsibility and/or requirements related to clearance are further

established. The regulation on waste management includes several general requirements on clearance and provides numerical values which could be considered as unconditional clearance levels. The values of activity concentration were selected based on the EC Guidance on General Clearance Levels for Practices (RP 122 Part I), specifically those derived from scenarios. In most cases selected unconditional clearance levels are more restrictive than those set out in IAEA RS-G 1.7, however this is not always valid for all radionuclides. For ensuring full compliance with the IAEA GSR Part 3, clearance levels provided in the regulations should be updated. Furthermore, the regulation does not address either the clearance of materials containing several types of radionuclide, or the type of materials to which the levels apply.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: <i>The provisions for clearance as included in the Law on Ionizing Radiation Protection and Safety and the regulation on radioactive waste management are not consistent with IAEA GSR Part 3.</i>	
(1)	BASIS: GSR Part 3 para. 3.12 states that <i>“The regulatory body shall approve which sources, including materials and objects, within notified or authorized practices may be cleared from regulatory control, using as the basis for such approval the criteria for clearance specified in Schedule I or any clearance levels specified by the regulatory body on the basis of these criteria. By means of this approval, the regulatory body shall ensure that sources that have been cleared from regulatory control do not again become subject to the requirements for notification, registration or licensing unless it so specifies”</i>
R33	Recommendation: The Government should revise and update the Law on Ionizing Radiation Protection and Safety and RSD should update regulation on predisposal management to ensure that provisions for clearance are fully in line with IAEA Safety Standards GSR Part 3.

Environmental monitoring for public radiation protection.

Requirements for the environmental monitoring for public radiation protection are included in the regulatory document dealing with the control of radioactive discharges (O.G. No.162/2009). As this regulation considers that no releases should be made unless they are below the unconditional discharge levels, the licensees are only required to implement source monitoring measures. The general content and other relevant requirements, such as provisions for recording and reporting of the monitoring results, are also established. As mentioned above, unconditional discharge levels could be exceeded; however, for these cases there is no clear instruction whether or not an environmental monitoring programme should be implemented. Provisions for such situations that may require specific monitoring for public protection purposes and the extent of the monitoring are not included in the regulation.

The IRRS team noticed that the regulation does not formally require the operator to submit the monitoring programme for review and approval by the RSD prior to its implementation. It was also observed that there are no requirements covering other operator’s responsibilities such as those related to the verification of the adequacy of the assumptions made for the assessment of public exposure and the establishment of a capability to conduct monitoring in emergency events.

The RSD is conducting at a regular basis an assessment of the monitoring data provided by the operators.

A nationwide monitoring network with the objectives of providing a warning of unusual or unforeseen event taking place beyond the national borders and, where appropriate, to trigger a special environmental

monitoring programme, is carried out in the country by the IPH. Periodical reports are evaluated by the RSD. The results of the monitoring are published at the public web site managed by the IPH.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: <i>The current provisions for operator responsibilities regarding source monitoring and environmental monitoring don't include provisions for the submission of the monitoring programme prior to its implementation, the verification of the adequacy of the assumptions made and the establishment of a capability to conduct monitoring in emergency events.</i></p>	
(1)	<p>BASIS: GSR Part 3 para. 3.135 states that <i>“The regulatory body shall be responsible, as appropriate, for: (a) Review and approval of monitoring programmes of registrants and licensees,”</i></p>
(2)	<p>BASIS: GSR Part 3 para. 3.137 states that <i>“Registrants and licensees shall, as appropriate: (f) Establish and maintain a capability to conduct monitoring in an emergency in the event of unexpected increases in radiation levels or in concentrations of radionuclides in the environment due to an accident or other unusual event attributed to the authorized source or facility. (g) Verify the adequacy of the assumptions made for the assessment of public exposure and the assessment for radiological environmental impacts...”</i></p>
R34	<p>Recommendation: The RSD should make additional provisions in the regulations regarding the monitoring for public protection to ensure compliance with relevant requirements in IAEA Safety Standards GSR Part 3.</p>

Existing exposure situations

The regulatory framework includes provisions for the management of existing exposure situations. In the case of natural radioactivity there are regulations establishing reference levels for indoor radon concentrations and radon in water. The reference levels for radionuclides in commodities are prescribed in the “Regulation on the limits of radionuclides in foodstuffs, water, air, soil, products and raw materials, and consumer products” and “Regulation on the maximum levels of radionuclides in metals, building materials, fertilizers, ashes from power stations and waste materials from mines and smelters”. Selected reference values are based on dose criteria that are in compliance with IAEA GSR Part 3.

The IPH has carried out an extensive research project to measure the radon concentration in houses (starting date 01.12.2008). The results so far obtained do not suggest the existence of significant radon exposure scenarios. However, additional measurements are needed and this project should be completed.

Regarding remediation activities, in the Former Yugoslav Republic of Macedonia, no areas or facilities have been identified as contaminated with residual radioactive material. General regulatory requirements established in the Law on Ionizing Radiation Protection and Safety and in the regulation, are considered as applicable for the remediation activities. In addition to that, the draft National Policy and Strategy for Radioactive Waste Management includes provisions in this respect (see **Recommendation 3** in section 1.7 in this respect).

11.4. SUMMARY

The existing regulation for medical exposure must be revised to be in line with IAEA GSR Part 3 requirements. In particular, the qualification, duties and responsibilities of medical physicists should be

defined in accordance with international best practice; provisions should be included in the regulation to ensure a sufficient number of these professionals are available in the country.

The regulation of workers' protection against radiation exposure is in compliance with most of IAEA GSR Part 3 requirements. Nevertheless, some improvements including those related to limits for the lens of eye, frequency of workplace monitoring, duration for keeping the records of occupational exposure and pregnant and breast-feeding women are needed. The regulation places the duty of workers' radiation protection on the licensee and not at all on the employer. There is no allocation of responsibilities between the different relevant parties in case of outside workers who may be affected by their work in a radiological area. Provisions regarding systematic retraining of occupational exposed workers and RPOs and provisions regarding the registry of occupational exposure doses are missing.

Provisions for ensuring the control of the public exposure are included in the legislative and regulatory framework. The regulation covering the management of radioactive waste addresses requirements on discharges. Unconditional discharge levels based on a value of $10\mu\text{Sv}$ as an annual dose constraint for the representative person are included. There is a lack of provisions for the authorization of discharges exceeding these unconditional levels. Criteria established in regulations for release of material from regulatory control through clearance are not in full compliance with criteria of IAEA GSR Part 3. The current provisions for operator responsibilities regarding source monitoring and environmental monitoring are not complete. A nationwide monitoring network with the objectives of providing a warning of unusual or unforeseen event is established in the country and operated by the IPH. A comprehensive programme is in place to assess the public exposure due to any source of radiation. Reference levels for radionuclides in commodities and other products are defined.

12. INTERFACE WITH NUCLEAR SECURITY

12.1. LEGAL BASIS

The Law No 135/2007 amended the Law on Ionising Radiation Protection and Radiation Safety No. 48/2002 to include, among other amendments, provisions on nuclear security and accounting and control of nuclear material. In addition, security during transport is regulated through the Law of Transport of Dangerous Goods which includes some provisions for security measures during transport such as escorting. RSD is the competent authority under both laws.

The Law on Ionizing Radiation Protection and Safety addresses safety, nuclear security and accounting and control of nuclear material in an integrated manner. The most important nuclear security specific requirement is that there must be measures in place to ensure radiation safety and nuclear security of radiation sources from damaging, stealing, illegal behaviour and transfer, lost or disappearing. The Law defines demonstration of complying with this requirement is a precondition for obtaining a license.

Nuclear security requirements have been established, in an integrated manner with radiation safety requirements, in the Regulation on the premises, devices and the equipment, as well as, the persons who may work with sources of ionising radiation. This Regulation establishes provisions on security objectives and measures for Category I – 3 sealed sources based on the IAEA Implementing Guide No 11 Security of Radioactivity Sources. Categorisation of radioactive sources is also applied to unsealed sources in a manner prescribed in Regulation on categorisation of sources and, therefore, the security objectives and measures are applicable also to unsealed radioactive sources.

As described above, the legislative and regulatory framework addresses radiation safety and nuclear security comprehensively in an integrated manner. However, there is no specific provision requiring that safety measures and nuclear security measures shall be designed and implemented in an integrated manner so that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *There is no specific provision requiring that safety measures and nuclear security measures shall be designed and implemented in an integrated manner so that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security.*

(1)

BASIS: **GSR Part 1 (Rev.1) Requirement 12, para. 2.40 states that** *“The Safety measures and nuclear security measures shall be designed and implemented in an integrated manner so that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security.*

S7

Suggestion: **The government should consider making appropriate provisions to ensure that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security.**

12.2. REGULATORY OVERSIGHT ACTIVITIES

The IRRS team was shown examples of safety and security being addressed in the regulatory processes in an integrated manner. These included radiation safety programmes and emergency plans submitted in support of an application for a license. These documents prescribed, in addition to safety aspects, the applied security measures. The IRRS team was provided examples of inspections and inspection findings which cover both safety and security aspects and of noncompliance being enforced irrespectively whether it safety or security related.

However, the regulatory processes, including those for authorization, review and assessment, inspection, and enforcement, have not been formally prescribed yet in any document while the management system is still under development. The IRRS team was informed that these processes will be prescribed in a manner ensuring that safety and nuclear security aspects are addressed in an integrated manner. Further, the IRRS team was informed that same will apply to other RSD processes such the use of operational experience and inspection findings to improve the regulatory programme. **Recommendation 9** in section 4 addresses the need for RSD to establish and implement an integrated management system.

RSD regulatory staff have participated to dedicated training courses on nuclear security which have been provided by the United States Department of Energy, European Commission and the IAEA. However, there are no formal mechanisms in place to ensure continuous training of the RSD staff regarding security of radioactive sources.

12.3. INTERFACE AMONG AUTHORITIES

The key authorities having responsibilities for nuclear security are:

- RSD: security measures at licensee's premises;
- Customs: detection of illicit trafficking;
- Border Police: securing a vehicle if unexpected radiation is detected;
- Ministry of Interior: providing escorting for conveyances of radioactive sources.

The roles and duties among these authorities are clarified in a MoU for Border Control.

In addition, according to the NREP, the local police can be involved in the response to all types of incidences, including those being security related.

The RSD is a member of the National Coordination Centre for Border Management. The Centre exchanges information among all institutions having responsibilities for border control or import/export of goods for performing risk assessments for targeting controls. Other members of the Centre are the Ministry of Interior, Ministry of Transport, Ministry of Defence, Ministry of Health, Customs Admiration and Food and Veterinary Directorate.

The IRRS team did not identify co-operation arrangements between RSD and other authorities such as the Ministry of Interior to evaluate and accommodate, when necessary, the security objectives and measures prescribed in the Regulation to the prevailing circumstances. **Suggestion 3** in Section 3.8 addresses the need to improve the cooperation and communication with all interested parties.

Security related incidences such as a dirty bomb or loss of a radioactive source are considered within the NREP.

The RSD has established formal relationships with several regulatory authorities in the countries of region with both safety and security related issues including those related to illicit trafficking.

12.4. SUMMARY

Safety and nuclear security are addressed in the legal and regulatory framework in an integrated manner. The provisions are in compliance with the IAEA requirements, however a specific provision stating that the integrated approach should be designed and implemented in a manner that nuclear security measures do not compromise safety, and safety measures do not compromise nuclear security should be introduced.

The need for RSD to establish and implement an integrated management system was stressed, even if in practice safety and nuclear security related matters are treated in an integrated manner.

No co-operation arrangements have been identified between RSD and other authorities such as the Ministry of Interior, to evaluate and accommodate, when necessary, the security objectives and measures to the prevailing circumstances.

Policy Issue - Financial independence of the Regulatory Body

The policy issue related to the financial independence of the Regulatory Body was introduced by Ms Biljana Georgievska Dimirtievski, who gave a short overview regarding the independence of a regulatory body for radiation safety as it is recognized in the Convention on Nuclear Safety and the IAEA General Safety Requirements on governmental, legal and regulatory framework for safety. The independence of a regulatory body from the promoters of nuclear technology is needed to ensure that regulatory judgments can be made and enforced without pressure from interests that may conflict with safety. Additionally, the credibility of the regulatory body in the eyes of the general public depends in large upon whether the regulatory body is regarded as being independent from the organizations it regulates, as well as, independent from government agencies or industry groups that promote nuclear technologies.

Effective regulatory independence could be considered in relation to the three main aspects: political, legislative and financial. The position of the RSD is that full independence in relation to political and legislative aspects is established, while the financial independency of the RSD currently is not fully ensured.

The financial resources of the RSD are provided through the annual budget of the Former Yugoslav Republic of Macedonia. General process is that RSD prepares a budget proposal on annual basis by the RSD according to its needs and according to strategic goals based on a three-year planning. The RSD proposes the budget to the Ministry of Finance through the Ministry of Health, as it is established as subprogram within the budget program of the Ministry of Health.

The IRRS team offered views based on experiences in their respective countries. Financial independency of a regulatory body is ensured if adequate staffing and financial resources to discharge assigned responsibilities are provided. It is recognized that a regulatory body cannot be independent in all respects from the rest of government, as it must function within a national system of laws and budget constraints, like all other governmental organizations.

Although the RSD is subject to the same financial controls as the rest of government, it is clearly underlined that their budget should not be subject to review and approval by government agencies responsible for the use and promotion of nuclear technologies, such as the Ministry of Health. This issue is specifically important considering that the Ministry of Health is going to establish new medical facilities that are to be licensed by the RSD.

To improve current situation, one of the possible options is to shift the RSD budget as a subprogram of another Ministry without responsibility for promoting nuclear technologies. This option was also mentioned during the meeting with the Ministry of Finance.

The view of the IRRS team was that the RSD should find the best compromise solution, in close collaboration with the Ministry of Health. The existing good cooperation between the RSD and the Ministry of Health should also be taken into consideration and on the other side to be aware of the advantage that the Ministry of Health well understands the role and responsibility of the RSD.

Policy Issue - Radioactive waste management: transparency and public acceptance

A brief presentation was made by Mr. Trifce Sandev regarding the current situation in radioactive waste management and disused sources and about the intention to establish a systematic approach to solving the problem. This approach includes openness and transparency as one of the key principles. There is no national storage facility for radioactive waste management in the country yet and the national policy and strategy for radioactive waste management is still in draft.

It is important to mention that the Nuclear Safety Directive (2009/71/Euratom) establishes legally binding obligations on the EU Member States in relation to information to the public.

The RSD faces many challenges in the quest to be open and transparent with the public for the issue of the radioactive waste management. A challenge is the need to strike the right balance between openness and security and commercial-related considerations, whilst still accommodating the public's desire to be well informed.

This issue has been on the agenda for a long time. There was effort to build the storage facility in 2002, but it was stopped because public was against of building the facility. In 2008 another location was selected, but there was not involvement of public and the requirements of international standards were not fulfilled.

The IRRS team offered views based on experiences in their respective countries. Different methods are used to enhance wider engagement with stakeholders, specifically including the general public in order to benefit from the increased transparency for resolving the issue for establishing a storage facility.

It was emphasised that proactive approach is needed and significant benefits can be gained from the early engagement of the regulatory bodies and the potential host communities before any regulatory decision is made, as openness and transparency provides the opportunity to obtain a broader basis for decisions.

It was advised that the RSD in its national policy and strategy should provide many scenarios and different solutions for Radioactive Waste management. The IRRS team members felt that the RSD should initiate an assessment of human and financial resources, the amount of waste currently in the country and their future projections.

The IRRS team members shared lessons learned including establishment of direct dialog with the association of citizens that play important role in environmental protection. An additional important point which was strongly advised is the use of communication experts in public communication, as discussion with public required simple plain language, without technical details. In some countries, the organization of specific information sharing sessions for the public is a regular practice. In a specific country, where a waste management facility has been established a center for visitors could provide means to communicate with the public. Also, the preparation of information suitable for the public and its distribution in newspapers and bulletins was proposed as an efficient method applied in many countries.

The IRRS team felt that communication to the public should emphasize the fact that radiation waste is originating from practices which are utmost beneficial to the health and wellbeing of people and thus the whole society and, therefore, the state must find a solution for management of such waste in accordance with international standard and recognized good practices.

In some countries government provide financial compensation to local communities that accept to host storage facility. In the case of the Former Yugoslav Republic of Macedonia this option is not feasible considering the small amount of waste and its non-commercial nature.

APPENDIX I – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS		
MARKKANEN Mika	Radiation and Nuclear Safety Authority (STUK)	Mika.Markkanen@stuk.fi
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APPENDIX II MISSION PROGRAMME

IRRS MISSION PROGRAMME	
Sunday, 29 October 2017	
IRRS Initial IRRS Team Meeting	
13:30 - 17:30	Opening remarks by the IRRS Team Leader (TL) Introduction by IAEA TC (TC) Self-introduction of all attendees IRRS Process (TC) Report writing (TC) Schedule (TL, TC) First impression from experts arising from the Advanced Reference Material (ARM) (All Experts) Administrative arrangements (Liaison Officer, TC) Detailed Mission Programme (Liaison Officer)
18:00	Team Dinner
Monday, 30 October 2017	
IRRS Entrance Meeting	
09:00 – 12:00	09:00 Arrival, registration, 09:15 Welcome Address 09:30 The IRRS programme (TC) 10:00 Expectations for the Mission (TC) and introduction of the IRRS Team 10:30 Coffee 11:00 Regulatory Overview, SARIS results (strength, challenges, action plan) (RSD) 11:45 Questions
12:00 – 13:30	Lunch
13:30 – 17:00	Interviews and discussions with counterparts (parallel discussions)
17:00 - 18:30	Daily IRRS Team meeting
Tuesday, 31 October 2017	
Daily Discussions / Interviews	
09:00 – 17:00	Interviews and discussions with counterparts (parallel discussions) and Visits
12:00 – 13:30	Lunch
17:00 – 18:30	Daily IRRS Team meeting – Discussion of preliminary findings
Wednesday, 1st November 2017	
Daily Discussions / Interviews	
09:00 – 17:00	Follow-up interviews and discussions with counterparts for all modules
08:30 – 13:30	Visits
12:00 – 13:30	Lunch
13:30 – 17:00	Report preparation
17:00 – 18:30	Daily IRRS Team meeting – Discussion on the written findings (Rs, Ss, GPs)
Thursday, 2 November 2017	
Daily Discussions / Interviews	
09:00 – 12:00	Follow-up interviews and discussions with counterparts (parallel discussions) and

IRRS MISSION PROGRAMME	
	Visits (if needed)
13:30 – 16:00	Policy issues discussion
16:00 – 18:30	Daily IRRS Team Meeting: Finalise Rs, Ss, GPs
Friday, 3 November 2017	
09:30 – 18:30	Report preparation, report cross reading
Saturday, 4 November 2017	
Daily Discussions/ Interviews (if needed)	
09:00 – 12:30	Draft the report based on cross reading remarks
12:30 – 14:00	Lunch
14:00 -	Finalizing draft and send it to RSD
	TL and TC: Prepare Executive summary
Sunday, 5 November 2017	
Daily Discussions	
	RSD review the draft
	TL and TC: Finalise Executive summary and prepare exit meeting presentations
	Team Free day, Social programme
Monday, 6 November 2017	
Daily Discussions	
08:00 – 11:00	RSD submit comments
11:00 – 15:00	Report finalization by the team
	TL: finalise exit meeting presentation
	Farewell Dinner
Tuesday, 7 November 2017	
09:00 – 11:00	IRRS Exit meeting
	Opening remarks by IAEA Official
	Submission of the Final Draft to RSD
	Presentation of the main findings of the IRRS mission (TL)
	Closing Remarks by RSD and response to the Mission findings.
	Press Conference

APPENDIX III SITE VISIT

The mission took place at the RSD Headquarters in Skopje.

Meetings were organized with representatives of:

- the Government (cabinet of the Prime Minister and cabinet of the Vice-prime Minister),
- the Ministry of Finance,
- the Ministry of Health,
- the Ministry of Transport and Communications,
- the Crises Management Centre,
- the Transport Inspectorate and
- the Customs Administration.

Visits were organised to:

- Institute of Public Health,
- Institute of Pathophysiology and Nuclear Medicine,
- RZ Technicka Kontrola - Industrial Radiography, and
- Biotek Transport Company.

APPENDIX IV– LIST OF COUNTERPARTS

Leading counterpart	Title
Biljana Georgievska Dimitrievski	IRRS Liaison Officer
Kabir Asani	Quality Manager
Sanija Zulfikjari	Junior Inspector
Gordana Nikolova	Inspector
Goran Trajkov	Inspector
Goran Angelovski	Monitoring and Emergency
Trifce Sandev	Licensing
Emilija Petrova	Licensing

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

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1.	RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	R1	The Government should review the legal framework to be consistent with the elements listed in GSR Part 1 (Rev.1), paragraph 2.3 regarding the national policy and strategy for safety in accordance with a graded approach.
		R2	The Government should review and revise the legal framework to ensure compliance with the IAEA safety standards.
		S1	The Government should consider revising its legislative framework to ensure effective independence of the RSD from the Ministry of Health with respect to the RSD financial budget
		R3	The Government should establish a national policy and strategy for decommissioning of facilities and the safe management and disposal of radioactive waste.
		R4	The RSD should ensure that there is sufficient regulatory control of legacy sources and radioactive waste until the national strategy for radioactive waste management is implemented.
		R5	The Government should ensure that requirements are established within the legislation for building and maintaining competence through education and training for all parties having responsibilities for safety as well as for the formal recognition of qualified experts.
		R6	The Government should provide the RSD with sufficient resources to adequately implement its functions and responsibilities.
		R7	The RSD should authorise all technical service providers in accordance with the Law on Ionizing Radiation Protection and Safety and relevant regulation.
2.	GLOBAL SAFETY REGIME		

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
3.	RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	S2	The RSD should consider making the Radiation Safety Commission functional.
		S3	The RSD should consider taking appropriate measures to improve the cooperation and communication with all interested parties.
4.	MANAGEMENT SYSTEM OF THE REGULATORY BODY	R8	The RSD should define its safety policy in the management system.
		R9	The RSD should complete its program for establishing and implementing an integrated management system in accordance with the IAEA Safety Standards GSR Part 2.
5.	AUTHORIZATION	R10	The RSD should make provisions for efficient and effective implementation of a graded approach in the authorization process.
		R11	The RSD should issue guidance on the format and content of application for an authorization.
		GP1	The Customs and RSD have established and use a web-based system (EXIM) for authorization of import and export that significantly enhances transparency of RSD and the effective cooperation among the authorities.
		R12	The RSD should authorize all those facilities and activities that are not explicitly exempted or approved by means of a notification process.
6.	REVIEW AND ASSESSMENT	R13	The RSD should establish and implement procedures for reviewing and assessing the submitted safety assessment.
		R14	The RSD should request the authorised parties to submit a periodic safety assessment. The RSD should assess the radiation risks periodically taking into account also modification of a facility or activity.
7.	INSPECTION	R15	The RSD should establish and implement standardized procedures for inspections, including check lists, for all facilities and activities.
8.	ENFORCEMENT	R16	The RSD should establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
9.	REGULATION AND GUIDES	R17	The RSD should establish or adopt guides, which should be regularly revised and reviewed, to support its regulatory control.
		R18	The RSD should complete the regulatory framework for predisposal waste management facilities and set out the procedures for meeting the requirements of the IAEA Safety Standards GSR Part 5.
		R19	The RSD should review the regulations to ensure that all safety aspects are covered.
		R20	The RSD should update the regulations for the transport of radioactive materials to be consistent with the IAEA Transport Regulations SSR-6.
10.	EMERGENCY PREPAREDNESS AND RESPONSE	R21	The Government should ensure that clear criteria are established for the declaration, prompt classification and termination of an emergency.
		R22	The Government should ensure that medical facilities are predesignated for initial medical treatment in case of radiological emergencies.
		R23	The RSD should establish arrangements for the licensee to coordinate with local first responders the implementation of internal emergency plans.
		R24	The RSD should ensure the proper implementation of emergency planning distances for emergency response category V.
		R25	The RSD should revise the regulations on emergency preparedness and response to ensure compliance with the IAEA Safety Standards GSR Part 7.
11.1	CONTROL OF MEDICAL EXPOSURES	R26	The Government should make provisions in the legal framework for qualification, training, duties and responsibilities for medical physicists and ensure sufficient number of qualified medical physicists.
		S4	The Government should consider making provisions in the legal framework to ensure the continuous training of medical and paramedical staff in their appropriate area.
		R27	The RSD should revise the legal and regulatory framework to bring it in line with the IAEA Safety Standards GSR Part 3 for

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			strengthening the medical exposure control and should ensure their full implementation.
		S5	The RSD should consider specifying criteria for the licensees to initiate and conduct an investigation following an unintended medical exposure.
11.2	OCCUPATIONAL RADIATION PROTECTION	R28	The Government should ensure that the responsibilities of employers and licensees and their cooperation are included in the legislation on radiation protection.
		R29	The Government should make provisions in the legal framework to ensure the retraining of workers engaged in activities in which they are or could be exposed to radiation.
		R30	The Government should make provisions to ensure that the registry of doses from occupational exposure is established and complete.
		R31	The RSD should revise the current legal and regulatory framework to bring it in line with the IAEA Safety Standards GSR Part 3 for strengthening the occupational exposure control and should ensure their full implementation.
		S6	The Government should consider making a provision so that employers and licensees provide occupational health services with information about the doses received by workers.
11.3	CONTROL OF RADIOACTIVE DISCHARGES AND MATERIAL FOR CLEARANCE, ENVIRONMENTAL MONITORING ASSOCIATED WITH AUTHORIZED	R32	The RSD should establish authorization processes and requirements for situations where discharges exceed unconditional limits or where the exposure scenario used in the discharge authorization has changed.
		R33	The Government should revise and update the Law and RSD should update regulation on predisposal management to ensure that provisions for clearance are fully in line with IAEA Safety Standards GSR Part 3.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	PRACTICES FOR PUBLIC RADIATION PROTECTION PURPOSES CONTROL OF CHRONIC EXPOSURES	R34	The RSD should make additional provisions in the regulations regarding the monitoring for public protection to ensure compliance with relevant requirements in IAEA Safety Standards GSR Part 3.
12	INTERFACE WITH NUCLEAR SECURITY	S7	The Government should consider making appropriate provisions to ensure that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security.

APPENDIX VI REFERENCE MATERIAL USED FOR REVIEW

1. Law on Ionizing Radiation Protection and Safety (“Official Gazette of the Republic of Macedonia” No.48/2002 with amendments);
2. Law on Transport of Dangerous Goods (“Official Gazette of the Republic of Macedonia” No.92/2007 with amendments);
3. Law on Administrative Servants (“Official Gazette of the Republic of Macedonia” No.27/2014 with amendments);
4. Law on General Administrative Procedure (“Official Gazette of the Republic of Macedonia” No.124/2015);
5. Law on Organization and Work of State Institutions (“Official Gazette of the Republic of Macedonia” No.58/2000 with amendments);
6. Law on Inspection (“Official Gazette of the Republic of Macedonia” No.50/2010 with amendments);
7. Law on Budgets (“Official Gazette of the Republic of Macedonia” No.64/2005 with amendments);
8. Law on Free Access on Public Information (“Official Gazette of the Republic of Macedonia” No.13/2006 with amendments);
9. Plan on Protection of the Public in Case of Radiation Emergency in the Republic of Macedonia (“Official Gazette of the Republic of Macedonia” No. 84/2011)
10. Regulation on the form and content of ID card of the radiation safety inspector (“Official Gazette of the Republic of Macedonia” No. 132/2006);
11. Regulation on the form and the content of the template of application for license, the form and the content of the license, as well as the procedure for issuing of the license (“Official Gazette of the Republic of Macedonia” No.157/2009);
12. Regulation on the content of the Radiation Protection Program, Emergency Plan and Quality Assurance Program and Safety Control Program (“Official Gazette of the Republic of Macedonia” No.157/2009);
13. Regulation on the criteria for exemption of an ionizing radiation source and exclusion of a defined source from regulatory control (“Official Gazette of the Republic of Macedonia” No.162/2009);
14. Regulation on the categorization of the ionizing radiation sources, as well as the categorization of the radioactive and nuclear material (“Official Gazette of the Republic of Macedonia” No.162/2009);
15. Regulation on the categorization of radiation and nuclear threats (“Official Gazette of the Republic of Macedonia” No.162/2009);
16. Regulation on the discharge limits of radioactive materials into environment, the manner of monitoring, maintaining records and reporting (“Official Gazette of the Republic of Macedonia” No.162/2009);
17. Regulation on the types of training and content of the training programme of the radiation protection officers (RPO) and occupationally exposed persons (“Official Gazette of the Republic of Macedonia” No.162/2009, 84/2012);
18. Regulation on the limits of radionuclides in foodstuffs, water, air, soil, products and raw materials, and consumer products (“Official Gazette of the Republic of Macedonia” No.163/2009, 58/2011, 74/2011, 84/2012);
19. Regulation on the form and the content of the template of the notification of the ionizing radiation sources, as well as the procedure of the notification of radiation protection source (“Official Gazette of the Republic of Macedonia” No.16/2010);

20. Regulation on the health conditions for work with ionizing radiation sources as well as the measures, the content of and the manner for health surveillance of the persons working with ionizing radiation sources (“Official Gazette of the Republic of Macedonia” No.28/2010);
21. Regulation on the means and measurement of occupational exposure, keeping records and submitting reports (“Official Gazette of the Republic of Macedonia” No.29/2010);
22. Regulation on limits of radiation exposure and conditions for exposure in special circumstances and in emergency (“Official Gazette of the Republic of Macedonia” No.29/2010);
23. Regulation on the maximum permitted quantities of radionuclides in metals, building materials, fertilizers, ash from the thermo power plants and the residues from mines and melting industry, (“Official Gazette of the Republic of Macedonia” No.98/2010);
24. Regulation on the manner and the measurement of the public exposure, maintaining records and reporting (“Official Gazette of the Republic of Macedonia” No.126/2010);
25. Regulation on the manner and the time frame for the testing of the ionizing radiation sources, patients exposure measurement during diagnostic and therapeutic procedures, maintaining records and reporting (“Official Gazette of the Republic of Macedonia” No.126/2010);
26. Regulation on the criteria for the facilities, equipment and staff in the authorized technical services and the legal persons for decontamination, as well as the form and content of the application for license and the form and the content of the license (“Official Gazette of the Republic of Macedonia” No.130/2010);
27. Regulation on the criteria and measures on radiation protection for performing practice with X-ray devices, accelerators and other devices that generate ionizing radiation (“Official Gazette of the Republic of Macedonia” No.130/2010);
28. Regulation on the criteria for the application of the ionizing radiation sources in the medicine, the veterinary medicine, the pharmacy and the dentistry radiation (“Official Gazette of the Republic of Macedonia” No.130/2010, 64/2011);
29. Regulation on the manner of managing, collecting, handling, conditioning, transporting and disposing of radioactive waste (“Official Gazette of the Republic of Macedonia” No.130/2010);
30. Regulation on the manner of the transport or radioactive and nuclear material (“Official Gazette of the Republic of Macedonia” No. 160/2010);
31. Regulation on qualification and health conditions of person who may work with ionizing radiation sources (“Official Gazette of the Republic of Macedonia” No.160/2011);
32. Regulation on the template and content of application of non-issuing a decision for license (“Official Gazette of the Republic of Macedonia” No.142/2011);
33. Regulation on the premises, devices and equipment and persons who may work with ionizing radiation sources (“Official Gazette of the Republic of Macedonia” No.78/2012);
34. Regulation on the criteria and measures on radiation protection during performing practice with ionizing radiation sources (“Official Gazette of the Republic of Macedonia” No.125/2014);
35. Regulation on the licensing fees (“Official Gazette of the Republic of Macedonia” No.180/2016);
36. Guidance on the form and the content of the application for import, export and transit

APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1. No. SF-1 - Fundamental Safety Principles
2. INTERNATIONAL ATOMIC ENERGY AGENCY - Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements Part 1(Rev 1), IAEA Safety Standards Series No GSR Part 1 (Rev.1) (Rev. 1), IAEA, Vienna (2016)
3. INTERNATIONAL ATOMIC ENERGY AGENCY- Leadership and Management for Safety, General Safety Requirements, Part 2, IAEA Safety Standards Series 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, IAEA Safety Standards Series No GSR Part 3, IAEA, Vienna (2014)
5. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety Assessment for Facilities and Activities, General Safety Requirements Part 4, IAEA Safety Standards Series No. GSR Part 4 (Rev 1), IAEA, Vienna (2016)
6. INTERNATIONAL ATOMIC ENERGY AGENCY – Predisposal Management of Radioactive Waste General Safety Requirements Part 5, IAEA Safety Standards Series No. GSR Part 5, IAEA, Vienna (2009)
7. INTERNATIONAL ATOMIC ENERGY AGENCY – Decommissioning of Facilities General Safety Requirements Part 6, IAEA Safety Standards Series No. GSR Part 6, IAEA, Vienna (2014)
8. INTERNATIONAL ATOMIC ENERGY AGENCY – Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Requirement Part 7, IAEA Safety Standards Series No. GSR Part 7, IAEA, Vienna (2015)
9. INTERNATIONAL ATOMIC ENERGY AGENCY - Regulations for the Safe Transport of Radioactive Material, Specific Safety Requirements 6, IAEA Safety Standards Series No. SSR 6, IAEA, Vienna (2012).
10. INTERNATIONAL ATOMIC ENERGY AGENCY - Organization and Staffing of the Regulatory Body for Nuclear Facilities, Safety Guide Series, IAEA Safety Standards Series No. GS-G-1.1, IAEA, Vienna (2002)
11. INTERNATIONAL ATOMIC ENERGY AGENCY - Review and Assessment of Nuclear Facilities by the Regulatory Body, Safety Guide Series, IAEA Safety Standards Series No. GS-G-1.2, IAEA, Vienna (2002)
12. INTERNATIONAL ATOMIC ENERGY AGENCY - Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, Safety Guide Series, IAEA Safety Standards Series No. GS-G-1.3, IAEA, Vienna (2002)
13. INTERNATIONAL ATOMIC ENERGY AGENCY - Documentation for Use in Regulatory Nuclear Facilities, Safety Guide Series, IAEA Safety Standards Series No. GS-G-1.4, IAEA, Vienna (2002)
14. INTERNATIONAL ATOMIC ENERGY AGENCY- - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series, IAEA Safety Standards Series No. GS-G-2.1, IAEA, Vienna (2007)
15. INTERNATIONAL ATOMIC ENERGY AGENCY – Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series, IAEA Safety Standards Series No. GSG-2, IAEA, Vienna (2011)

16. INTERNATIONAL ATOMIC ENERGY AGENCY– Assessment of Occupational Exposure Due to Intake of Radionuclides, Safety Guide Series, IAEA Safety Standards Series No. RS-G-1.2, IAEA, Vienna (1999)
17. INTERNATIONAL ATOMIC ENERGY AGENCY - Assessment of Occupational Exposure Due to External Sources of Radiation, Safety Guide Series, IAEA Safety Standards Series No. RS-G-1.3, IAEA, Vienna (1999)
18. INTERNATIONAL ATOMIC ENERGY AGENCY - Building Competence in Radiation Protection and the Safe Use of Radiation Sources, Safety Guide Series, IAEA Safety Standards Series No. RS-G-1.4, IAEA, Vienna (2001)
19. INTERNATIONAL ATOMIC ENERGY AGENCY – Classification of Radioactive Waste, General Safety Guide, IAEA Safety Standards Series No. GSG-1, IAEA, Vienna (2009)
20. INTERNATIONAL ATOMIC ENERGY AGENCY – Regulatory Control of Radioactive Discharge to the Environment, Safety Guide Series, IAEA Safety Standards Series No. WS-G-2.3, IAEA, Vienna (2000)
21. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series, IAEA Safety Standards Series No. WS-G.5.2, IAEA, Vienna (2009)
22. INTERNATIONAL ATOMIC ENERGY AGENCY – Establishing the Safety Infrastructure for a Nuclear Power Programme, Specific Safety Guide, IAEA Safety Standards Series No SSG-16, IAEA, Vienna (2011)
23. INTERNATIONAL ATOMIC ENERGY AGENCY - Disposal of Radioactive Waste, Specific Safety Requirements 5, IAEA Safety Standards Series No. SSR 5, IAEA, Vienna (2011)

APPENDIX VIII ORGANIZAIONAL CHART

