

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

Chisinau, Moldova

10 to 19 December 2018

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



Integrated
Regulatory
Review Service

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Mission dates:	<i>10 to 19 December 2018</i>
Regulatory body visited:	<i>National Agency for Regulation of Nuclear and Radiological Activities of the Republic of Moldova (NARNRA)</i>
Location:	<i>Chisinau, Moldova</i>
Regulated facilities and activities in the mission scope:	<i>Radioactive waste management facilities, radiation sources in industrial and medical facilities, emergency preparedness and response, decommissioning, occupational radiation protection, patient protection, discharges and material clearance</i>
Organized by:	<i>IAEA</i>

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IAEA-2018

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

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EXECUTIVE SUMMARY

At the request of the Government of the Republic of Moldova (Moldova), an international team of senior radiation safety experts met with representatives of the National Agency for Regulation of Nuclear and Radiological Activities (NARNRA), and the National Public Health Agency from 10 to 19 December 2018 to conduct an Integrated Regulatory Review Service (IRRS) mission. The mission took place at NARNRA. The purpose of the IRRS mission was to perform a peer review of Moldova's national regulatory framework for radiation safety.

The review compared Moldova's regulatory framework for safety against IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS review team members and the Moldovan counterparts in the areas covered by the IRRS.

The IRRS team consisted of 8 senior regulatory experts from 7 IAEA Member States, 1 IAEA staff member, and 1 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 discharges and material clearance.

The IRRS mission included a policy issue discussion on risk-informed inspections planning.

The mission included interviews and discussions with staff of NARNRA, visits to Oncological Institute and national radioactive waste management company "Special Facilities 5101, 5102" and observations of regulatory inspection activities, including discussions with the authorized parties' personnel and management. Additionally, a meeting was held with the State Secretary General of the Ministry of Agriculture, Regional Development and Environment who has responsibility for NARNRA, regarding the purpose of the mission and preliminary findings.

In preparation for the IRRS mission, NARNRA conducted a self-assessment and prepared a preliminary action plan to address areas that were identified for improvement. The results of the self-assessment and supporting documentation were provided to the IRRS 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 made the following general observations:

- NARNRA staff were committed to provide the regulatory control of all facilities and activities under their jurisdiction. The invitation of the IRRS mission demonstrates Moldova's commitment to improve the national legal and regulatory framework for radiation safety;
- NARNRA has made important progress to improve the radiation safety regulatory framework;
- The action plan for further developing the radiation safety regulatory framework clearly demonstrates NARNRA's commitment to enhancing the regulatory framework.

The IRRS team believes that Moldova faces several challenges, which include:

- Clearly defining and implementing the authorities, roles and responsibilities of

NARNRA and the National Public Health Agency;

- Comprehensive implementation of safety legislation for all facilities and activities using a graded approach;
- Enhancing NARNRA's regulatory program through formalization of regulatory policies, processes, and procedures;
- Strengthening NARNRA's independence to make safety decisions and provide appropriate regulatory control of activities that involve radiation safety;
- Ensuring sufficient resources, including qualified staff, are available for NARNRA to conduct all mission-critical activities.

The IRRS team 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 NARNRA as a result of its self-assessment.

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 Government should:

- Establish a regulatory framework to implement the Basic Safety Standards and a regulatory framework for decommissioning of facilities and safe management of radioactive waste;
- Revise or update national laws or decrees to clearly define and implement the authorities, roles and responsibilities of NARNRA and the National Public Health Agency;
- Revise and develop safety regulations to ensure compliance with IAEA safety standards;
- Strengthen NARNRA's authority to conduct independent unannounced inspections, when appropriate, in order to ensure safety;
- Ensure that NARNRA has sufficient resources, including qualified staff, to conduct all of its mission critical activities.

NARNRA should:

- Develop and implement a policy document that articulates Mission, Vision, Organizational Values, and behavioural expectations;
- Develop and implement regulatory policies, plans, and procedures to formalize review and assessment, authorization, enforcement, and emergency responses processes;
- Develop and implement an integrated management system that includes promotion and support of a strong safety culture in the organization;
- Develop and implement a Human Resources Plan, including a specific training program, to ensure a sufficient number of qualified staff are available to conduct its mission-critical activities.

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 Republic of Moldova, an international team of senior safety experts met representatives of the National Agency for Regulation of Nuclear and Radiological Activities of the Republic of Moldova (NARNRA) from 10 to 19 December 2018 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the Republic of Moldova's regulatory framework for radiation safety. The review mission was formally requested by the Government of the Republic of Moldova in January 2016. A preparatory mission was conducted on 17 to 18 May 2018 at NARNRA in Chisinau to agree on the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in the Republic of Moldova and their related safety aspects and to agree on the scope of the IRRS mission.

The IRRS team consisted of 8 senior regulatory experts from 7 IAEA Member States, 1 IAEA staff member and 1 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, discharges and material clearance, waste management and decommissioning.

In addition, one policy issue was discussed: Risk-informed Inspections Planning.

NARNRA conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of the self-assessment and supporting documentation were provided to the IRRS team as advance reference material for the mission. During the mission, the IRRS team performed a systematic review of all topics within the agreed scope through review of the Republic of Moldova's advance reference material, conduct of interviews with management and staff from NARNRA, and direct observation of regulatory activities at regulated facilities. The National Public Health Agency participated in the interviews. A meeting with Mr Iurie Ușurelu, General State Secretary, Ministry of Agriculture, Regional Development and Environment was also organized.

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

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review the Republic of Moldova's 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 Republic of Moldova, except transport. It is expected this IRRS mission will facilitate regulatory improvements in the Republic of Moldova and other Member States, utilising the knowledge gained and experiences shared between NARNRA counterparts and IRRS reviewers and the evaluation of the Republic of Moldova's regulatory framework for radiation safety.

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

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

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of the Republic of Moldova, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 17 to 18 May 2018. The preparatory meeting was carried out by the appointed Team Leader, Mr Daniel Collins, and IAEA Team Coordinator, Ms Olga Makarovska.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of NARNRA represented by Ion Apostol, Director, National Agency for Regulation of Nuclear and Radiological Activities and other senior management and staff. It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides

- Waste management facilities;
- Radiation sources facilities and activities;
- Decommissioning;
- Control of medical exposure;
- Occupational radiation protection;
- Discharges and material clearance;
- Selected policy issues.

Ms Angela Sidorencu gave presentations on the national context, the current status of the national regulatory infrastructure 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 Republic of Moldova in December 2018.

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

The Liaison Officer for the IRRS mission was confirmed as Ms Angela Sidorencu, Senior Specialist, Safeguards and Non-proliferation Division.

NARNRA provided IAEA with the advance reference material (ARM) for the review in October 2018. In preparation for the mission, the IAEA team members reviewed the Republic of Moldova's advance reference material and provided their initial impressions to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

The relevant IAEA safety standards 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, 9 December, 2018 in Chisinau, directed by the IRRS Team Leader and the IRRS IAEA Team Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and 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, 10 December, 2018, with the participation of NARNRA senior management and staff. Opening remarks were made by Mr Ion Apostol, Director, NARNRA, and Mr Daniel Collins, IRRS Team Leader. Mr Ion Apostol Director and Mr Ionel Balan Deputy Director NARNRA gave an overview of the Moldovan context, activities and the results of the pre-mission self-assessment.

During the IRRS mission, a review was conducted for all review areas within the agreed scope with the objective of providing the Republic of Moldova with recommendations and suggestions for improvement and where appropriate, identifying good practices. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations regarding the national legal, governmental and regulatory framework for safety. A policy issue was also discussed relating to Risk-informed inspections planning.

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

The IRRS exit meeting was held on Wednesday, 19 December, 2018. The presentation of the results of the mission by the IRRS Team Leader, Mr Daniel Collins, was followed by remarks by Ion Apostol. Closing remarks were made by Peter Johnston IAEA, Director, Division of Radiation, Transport and Waste Safety.

An IAEA press release was issued.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

The Republic of Moldova is a parliamentary representative democratic republic with a multi-party system. The country is governed by the “Separation and Cooperation of Powers”. The government, headed by the prime minister, exercises executive power while the legislative power is vested in the Parliament. The judiciary is independent of both the executive and the legislative powers.

The Constitution is the Supreme Law of the Republic of Moldova. All other laws in the country shall follow the Constitution and respectively any law or other legal act which contravenes the provisions of the Constitution shall have no legal force. Article 8 of the Constitution establishes the commitment of the Republic of Moldova to observe international treaties to which it is a party, and which have priority over the national laws.

Most elements of a national policy and strategy for safety are in place and documented in the national laws and regulations, and in particular Law No. 132 of 08.06.2012 on the Safe Conduct of Nuclear and Radiological Activities (hereinafter referred as the Law 132). The Law 132 was adopted by the Parliament and promulgated in the Official Gazette No. 229-233, art. No: 739 of 02.11.2012.

The Law 132 establishes the policy of the Republic of Moldova for conducting safe and secure nuclear and radiological activities, that are exclusively focused on peaceful purposes, and which are in conformity with the international obligations of the Republic of Moldova. The Law 132 (Article 2) establishes the fundamental safety objective as “protection of personnel, population, goods and the environment against the adverse impact of ionizing radiation, in accordance with international standards” and other objectives as: “non-proliferation of nuclear weapons”; “ensuring an adequate level of safety of all facilities and activities”; “prevention of unauthorized activities”; “prevention of illicit traffic”; etc.

Some of the fundamental safety principles, as stated in the IAEA Fundamental Safety Principles (SF-1), have been incorporated in Article 5 of the Law 132 “Basic regulatory principles”. According to this Article, the primary regulatory principles for nuclear and radiation safety cover, but are not limited to:

- Preventing the maximum permitted level of exposure to ionizing radiation from being exceeded;
- Reducing irradiation levels to a minimum;
- Justification of activities (or practices);
- Maintenance of nuclear and radiation safety;
- Physical protection of nuclear and radioactive materials;
- Responsibility of the holders of authorization.

The incorporation of the fundamental and other safety objectives in the Law 132, as well as the inclusion of some of the IAEA Fundamental Safety Principles, is an important step toward the establishment of a complete national policy and strategy for safety and is a demonstration of Moldova’s long-term commitment to safety.

However, the IRRS team identified that some of the fundamental safety principles and some prerequisites for the establishment of an effective legal and regulatory framework for safety are not completely addressed, namely:

- The need and provision for human and financial resources;
- The provision and framework for research and development;
- The promotion of leadership and management for safety, including safety culture;
- The implementation of the national policy and strategy for safety in accordance with a graded approach.

The IRRS team identified that further efforts are needed to raise the awareness of all parties on the contents and ways for the practical implementation of the national policy and strategy for safety. Such initiatives will assist the country in ensuring that radiation risks associated with facilities and activities receive the appropriate attention, according to their safety significance.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The national policy and strategy for safety, as defined by the national laws and regulations, does not take due account of all fundamental safety principles and of all its elements as required by GSR Part 1 (Rev 1). This is part of NARNRA’s Action Plan.	
(1)	<p>BASIS: GSR Part 1 (Rev 1) Requirement 1 para 2.3 states that <i>“In the national policy and strategy, account shall be taken of the following:</i></p> <p><i>(a) The fundamental safety objective and the fundamental safety principles established in the Fundamental Safety Principles;</i></p> <p>...</p> <p><i>(d) The need and provision for human and financial resources;</i></p> <p><i>(e) The provision and framework for research and development;</i></p> <p>...</p> <p><i>(g) The promotion of leadership and management for safety, including safety culture.”</i></p>
(2)	<p>BASIS: GSR Part 1 (Rev 1) Requirement 1 para 2.4 states that <i>“The national policy and strategy for safety shall be implemented in accordance with a graded approach...”</i></p>
R1	<p>Recommendation: The Government should ensure that the national policy and strategy for safety takes due account of:</p> <ul style="list-style-type: none"> • The promotion of leadership and management for safety; • The need and provision for human and financial resources; • The provision and framework for research and development. <p>The Government should ensure that the policy and strategy for safety is implemented in accordance with a graded approach.</p>

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Constitution is the Supreme Law and stays at the top of the hierarchically structured legislative pyramid. The Laws are adopted by the Parliament and published in the Official Journal (State Gazette). According to the Constitution, International Treaties being ratified by Republic of Moldova have precedence over national laws and regulations. The first tier of the legislative pyramid includes two types of laws, so called “Organic” and “Ordinary” laws. Organic laws stay higher in the hierarchy and define main country arrangements in the fulfilment

of the Constitution.

The second tier in the legislative pyramid includes decrees, ordinances, and regulations at different levels. These are:

- Government decrees and ordinances;¹
- Regulations of the central public administration authorities;
- Regulations of autonomous public authorities;
- Regulatory acts of the authorities of autonomous territorial entities with a special legal status;
- Regulations of local public authorities.

These normative acts become binding to everyone in the country after promulgation in the State Gazette. So, Ministers and central public administration authorities are vested with the power to issue binding legislative acts, which should undergo the same coordination procedure as described by the Law #100 of 22.12.2017 on Normative Acts (Law 100). All regulations need to be assessed (juridical expertise) by the Ministry of Justice legislation office and, after that, they are published in the State Gazette.

The main Law in the area of radiation safety is the Law 132. This Law 132, in combination with the implementing regulations, establishes the regulatory body, specifies the types of regulated facilities and activities, empowers the regulatory body for development and promulgation of regulatory requirements, requires authorization for the operation of facilities and for the conduct of activities, provides for the inspection of facilities and activities, and for the enforcement of regulations, etc. The Law 132 empowers the National Agency for Regulation of Nuclear and Radiological Activities (NARNRA) to develop proposals and drafts for policies, strategies and laws, regulations and guides and propose amendment of already existing ones. The Law 132 articulates the areas where specific requirements are necessary to complete the legal and regulatory framework. According to Article 7 of the Law 132 these are:

- normative acts by NARNRA, that are approved by the Government according to the established procedure, for regulating: safety and security of facilities and physical protection of nuclear materials and radioactive sources; radioprotection qualification requirements of personnel; management of radioactive waste and spent nuclear fuel; and transport of nuclear and radioactive materials;
- other normative acts that are elaborated and approved by decisions of NARNRA according to provisions of the legislation for: regulating nuclear and radiation safety and security (such as regulations, instructions, guides, technical regulations), and for the execution and enforcement of laws;
- normative acts issued by other public authorities empowered by law, with the countersigning of NARNRA, that establish values of the radiological factors for products subject to irradiation with impact on the health of the personnel, population and on the environment.

Several regulations have been issued that further developed the requirements of the Law 132, as described in Section 9.

The IRRS team was informed that the Regulation on the national Basic Safety Standards (“FRPN-2000”) is not legally binding. Further discussion challenged that initial statement and provided some evidences that the Regulation is still in force. Irrespective of the above-mentioned unclear status of the national Basic Safety Standards, there is no doubt that the existing legal and regulatory framework is incomplete with respect to IAEA safety standards’ requirements related

¹ The term governmental decisions refer to governmental decrees, ordinances or decisions

to the safety of facilities and activities. The IRRS team concluded that this is a significant gap in the national legislation and the Government, working with NARNRA, should urgently establish the missing requirements.

Additionally, NARNRA drafted and coordinated with all relevant institutions a regulation that includes the requirements on education, training, qualification and competence in protection and safety of all individuals and organizations engaged in radiation activities relevant to protection and safety. However, that regulation has not been finalized and issued. Such a Regulation is required by the Law 132 and is vital for the authorization of facilities and activities. Lack of such requirements puts the applicants in a condition that they are not able to demonstrate the professional qualification of their personnel, which is one of the leading authorization preconditions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: The legal status of “FRPN-2000” (national Basic Safety Standards) regulation is not clear and requirements are not in full compliance with GSR Part 3. A regulation on qualification of persons engaged in activities relevant to protection and safety has been in draft form for the last few years without being issued. This is part of NARNRA’s Action Plan.</p>	
(1)	<p>BASIS: GSR Part 1 (Rev 1) 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></p>
(2)	<p>BASIS: GSR Part 3 para 2.21 states that <i>“The government shall ensure that requirements are established for:</i></p> <p><i>(a) Education, training, qualification and competence in protection and safety of all persons 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>
R2	<p>Recommendation: The Government should, working with NARNRA and as a matter of urgency, establish national Basic Safety Standards and legal requirements on education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety; on the formal recognition of qualified experts; and on competence of organizations that have responsibilities relating to protection and safety.</p>

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

Law 132 establishes NARNRA as the regulatory body for facilities and activities posing radiation risk. The Law 132 assigns to NARNRA the main functions and responsibilities to:

- develop and implement the national policy on protection and safety and adopt measures for the effective regulation of nuclear and radiological activities;
- monitor the implementation and enforce compliance with the international treaties and national legislation in this field;
- prepare and promote legislative and other normative acts;

- register or authorize nuclear or radiological activities, based on safety assessment where appropriate;
- carry out the state supervision of nuclear and radiological facilities and activities;
- impose enforcement measures;
- issue or recognize certificates of approval for installations with ionizing radiation sources;
- certify or recognize nuclear and radiological experts;
- manage the National Register of ionizing radiation sources and authorized physical and legal entities;
- provide free assistance on detection of orphan radioactive sources;
- recognize technical support organizations, national and international experts, certifying personnel training institutions;
- coordinate and monitor the implementation of international technical assistance projects;
- sign bilateral or multilateral agreements with similar authorities in third countries;
- draft and submit the national reports under international treaties;
- participate as an integral part in the national response system in cases of nuclear or radiological urgencies;
- cooperation with other regulatory bodies.

NARNRA is a legal entity under the public law and has its own treasury accounts. It is an independent agency within the system of the Ministry of Agriculture, Regional Development and Environment (MARDE). The Government has established NARNRA to be independent in its safety related decision-making and functionally separated from entities having responsibilities or interest that could unduly influence its decision making.

According to Law 132, Article 10, NARNRA is funded from the state budget as well as from other sources according to the legislation in force. Its budget is part of the budget of the MARDE. NARNRA prepares the budget request and submits it to MARDE, which submits it to the Government. Following discussions with the Ministry of Finance, the budget is approved by the Government and included in the annual budget of the MARDE. The budget includes mostly funds for salaries and covering of operational cost. The budget does not allocate any funds for some of the main and support regulatory functions, i.e. implementation of international obligations under the conventions; drafting regulatory requirements; training and retraining of regulatory staff; contracting external review and assessment; international cooperation; drafting internal procedures; etc. The IRRS team was informed that, in case of an urgent need, the MARDE could provide some additional funds to NARNRA on a request, but this could not be done now due to financial restrictions.

For the last five years the allocated budget remained stable with small variations of the total amount. The budget has increased approximately 1% per year while the number of sources and activities in the country is continuously increasing and additional responsibilities are assigned to NARNRA, e.g. safeguards, conventions, Code of Conduct on the Safety and Security of Radioactive Sources and its supplementary Guidance implementation, recovery of orphan sources, etc. Finally, due to current budget restrictions, some regulatory functions are not fully or effectively implemented, as for example: development of regulatory requirements; establishment of a management system; education of regulatory staff; and sharing of international operating and regulatory experience; etc.

Additionally, the number of qualified and competent staff dedicated to licensing, inspection, review and assessment and development of requirements appears to be insufficient and not

commensurate with the nature and the number of regulated facilities and activities. For example, for the oversight of more than 500 facilities and activities, NARNRA has four inspector positions, two of which are vacant. The IRRS team was informed that there are no candidates for these positions, because of the high responsibilities of the job in front of the public and at the same time salaries that are not competitive in comparison to the private sector. The IRRS team noted that NARNRA staff are dedicated and committed to their work. Many of them frequently remain to work overtime in order to compensate for the understaffing.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Some of NARNRA’s main regulatory activities do not receive the appropriate and timely attention, because of staff shortage and overload. Additionally, the NARNRA budget does not provide funds for some of its legal duties (i.e. preparation of regulations, fulfilment of obligations under conventions, training of staff, etc.).	
(1)	BASIS: GSR Part 1 (Rev 1) Requirement 3 states that <i>“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.”</i>
(2)	BASIS: GSR Part 1 (Rev 1) Requirement 18 states that <i>“The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities.”</i>
(3)	BASIS: GSR Part 1 (Rev 1) Requirement 4 para 2.8 states that <i>“To be effectively independent from undue influences on its decision making, the regulatory body:</i> <i>(a) Shall have sufficient authority and sufficient competent staff;</i> <i>(b) Shall have access to sufficient financial resources for the proper and timely discharge of its assigned responsibilities; ...”</i>
R3	Recommendation: The Government should ensure that NARNRA is provided with sufficient human and financial resources to effectively perform its functions and to discharge its responsibilities.

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

Law 132, Article 5 sets out the basic regulatory principles. One of these principles is “Responsibility of the holders of authorization”. The IRRS team was informed that the legislative system will not allow the use of terms such as “Prime” or “Ultimate” responsibility. Hence, the Law 132 contains no specific text on the prime responsibility of authorized persons.

In its self-assessment, NARNRA identified that the prime responsibility for safety is explicitly addressed through Article 50 of the Law 132. Nevertheless, there are other provisions that transpose the principle of prime responsibility for safety, such as: Article 43. “Responsibility for radioactive waste management is vested with the waste generator and, after handing over, the specialized institution - the holder of authorization for the management of radioactive waste”.

The Law 132, through several related articles specifies that the authorized person's responsibility for safety is valid throughout the lifetime of facilities and activities; that this responsibility cannot be delegated; and that no authorization issued by NARNRA may be transferred to third parties, directly or indirectly, without NARNRA's prior approval.

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

The Law 132 specifies the allocation of responsibilities amongst the governmental authorities involved in the process of state control over nuclear and radiation safety. The regulatory control and authorization of nuclear and radiation facilities and activities is vested to NARNRA. The Government has made an attempt to explicitly specify the responsibilities for safety within the regulatory framework of authorities concerned in the Law 132. Article 13 lists the authorities with responsibilities in the field of nuclear and radiological activities. These are:

- the central public administration authority in the field of health care;
- administrative authority in the field of civil protection and exceptional situations;
- the central public administration authority in the field of the environment;
- the central public administration authority in the agro-industrial field;
- the administrative authority of customs control;
- the administrative border control authority;
- research or promotion organizations for nuclear or radiation technologies.

Further down, Articles 14 to 18 specify the list of responsibilities and power of each of these authorities. In fulfilment of the arrangements established by the Law 132, NARNRA has established Memorandums of understanding with most national competent authorities to assure effective cooperation, namely the General Inspectorate for Emergency Situations; the Custom Service; the General Inspectorate of Border Police and State Hydrometeorological Service. A Memorandum of Understanding has also been prepared between NARNRA and the Ministry of Health, Labour and Social Protection (MoH). This agreement remains in draft as both authorities could not agree on clear division of their functions and responsibilities.

The IRRS team discussed this issue with both organizations and identified that there are major differences in the understanding of the provisions of the Law 132, and in particular Article 14, where the responsibilities of the MoH are established. It was identified that both authorities fulfil similar tasks in the area of radiation safety. While NARNRA is issuing radiological authorizations, MoH, through its National Public Health Agency (NPHA) is issuing sanitary authorizations. Both authorizations allow the applicant to perform radiological activities. Furthermore, these authorizations look almost the same and include the same elements, e.g. type of the source, site location, staff availability, etc. Additionally, both organizations (NARNRA and NPHA) perform inspections of the authorized facilities. This leads not only to duplication of inspections, but also to additional burden on the authorized entities. For the duration of the mission, the IRRS team could not clearly identify the separation of responsibilities between the two authorities.

One more issue of concern to the IRRS team was the fact that MoH operates the government hospitals and clinics and at the same time it (through NPHA) inspects and issues the sanitary authorizations for these facilities. The IRRS team was informed, but could not verify, that there is no conflict of interest. Furthermore, there are no, or only limited number of, specific procedures and guidance to provide impartiality and unified approach to both governmental and private facilities. Additionally, NPHA provides services to the authorized persons in the areas of

individual and working places monitoring and after that inspects these facilities for compliance with the requirements.

Finally, NARNRA and NPHA need to have close cooperation in the development of legal and regulatory requirements in the area of radiation protection and safety. This is of utmost importance for the proper transposition of the Basic Safety Standards (IAEA GSR Part 3) and Republic of Moldova’s policy for the harmonization with EU legislation in the field (Council Directive 2013/59/Euratom of 5 December 2013).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no clear allocation of responsibilities between NARNRA and the Ministry of Health, Labour and Social Protection. This leads to legal requirements not being discussed and agreed; and undue duplication of authorization and inspection activities.	
(1)	BASIS: GSR Part 1 (Rev 1) Requirement 2 states that <i>“The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated.”</i>
(2)	BASIS: GSR Part 1 (Rev 1) Requirement 2 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>
R4	Recommendation: The Government should ensure that clear allocation of responsibilities and formal coordination arrangements are established between NARNRA and the Ministry of Health, Labour and Social Protection.

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

Law 132, Article 11, para. 4 specifies that NARNRA is responsible for “providing free assistance on detection of orphan radioactive sources”. The Law 132 also provides definition of the term “Orphan radioactive source”. Some specific arrangements on the recovery of orphan radioactive sources are included in the 2017-2026 National Strategy on Radioactive Waste Management (NSRAWM). According to the strategy, the General Inspectorate for Emergency Situations (GIES) is responsible for the recovery of orphan radioactive sources and for their safe storage at the GIES operated storage facility. The Action Plan to the strategy defines that the funding of recovery of orphan radioactive sources is ensured by the Reserve Fund of the Government or from national or international grants.

For contaminated sites, NARNRA is responsible for consultations, measurement and assessment of the contamination, while GIES is responsible for the remediation of contaminated sites.

The IRRS team concluded that many activities are being implemented in the country to reduce unregulated risks. However, there is no governmental system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural or artificial origin) and contamination from past activities. Future actions are needed in analyses and identification of contamination from past activities or events; formal designation of organizations to be responsible for making necessary arrangements for the protection of workers, the public and the environment; clear allocation of responsibilities; establishing coordination arrangements; and

specifying regulatory requirements and criteria; development and implementation of protective actions, etc.

Additionally, coordination between NARNRA and GIES in recovery of orphan radioactive sources and protective actions in the cases of areas contaminated by residual radioactive material needs to be formalized.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: A number of initiatives are being implemented in the area of identification and recovery of orphan sources. However, an effective system for protective actions to reduce other undue radiation risks (of natural or artificial origin) has not been established. This is part of NARNRA’s Action Plan.	
(1)	BASIS: GSR Part 1 (Rev 1) Requirement 9 states that <i>“The government shall establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural or artificial origin) and contamination from past activities or events, consistent with the principles of justification and optimization.”</i>
R5	Recommendation: The Government should establish and implement an effective system for identifying and reducing unregulated radiation risks.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The coordination between NARNRA and General Inspectorate for Emergency Situations regarding recovery of orphan radioactive sources and protective actions in the cases of areas contaminated by residual radioactive material has not been formalized.	
(1)	BASIS: GSR Part 1 (Rev 1) Requirement 7 para 2.18 states that <i>“Where several authorities have responsibilities for safety within the regulatory framework for safety, the responsibilities and functions of each authority shall be clearly specified in the relevant legislation. The government shall ensure that there is appropriate coordination of and liaison between the various authorities...”</i>
S1	Suggestion: The Government should consider formalizing the existing arrangements regarding recovery of orphan radioactive sources and protective actions in case of contamination of areas by residual radioactive material.

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

Radioactive wastes in the country originate mainly from the use of radioactive sources in medical applications, research, education and industry. There is no spent fuel in the Republic of Moldova. Disused radioactive sources are stored under the regulatory control of NARNRA in the user’s premises until transported to the Radioactive Waste Disposal Facility (RWDF) situated in the municipal Chisinau. RWDF is a central facility for long-term storage of radioactive waste that

serves the whole country. The RWDF was built in 1961 and used for storage of disused sealed radioactive sources.

Law 132, Art. 49 requires that authorized persons should develop a decommissioning programme and submit it to NARNRA for approval. It also requires authorized persons to ensure sufficient funds for decommissioning. The NSRAWM contains some provisions on decommissioning of radioactive waste management facilities. Additionally, Regulation No. 388 on the Radioactive Waste Management contains some requirements for decommissioning of radioactive waste storage facilities (Chapters XIV and XVI). Legislation does not include requirements for the development by authorized persons of final decommissioning plans. Establishment of a decommissioning strategy is not required either.

Radioactive waste disposal is not completely covered by the legislation in force. Law 132 requires the preparation of a radioactive waste disposal plan, which is not further explored in the regulations. A term “Institutional control” is defined by Regulation 388. However, the Regulation does not contain specific requirements related to the institutional control of disposal facilities after their closure. **Related Recommendation R24 is provided in Section 9.2.**

The 2017-2026 NSRAWM was approved by Parliament in 2017. The NSRAWM describes the current situation and pays major attention to underground storages (Special Facilities 5101, 5102), which presently are not in full conformity with the regulatory requirements. The NSRAWM is accompanied by an action plan that includes measures on decommissioning of the underground storages; repackaging of the waste; decontamination; remediation; and management of the generated radioactive waste. It is planned that these measures be completed by 2026. Estimated cost for that is 2.9 million Euro, which is to be provided by the state budget and donors’ contributions.

The NSRAWM defines disposal as the end point for radioactive waste management and identifies borehole facility or geological structure as disposal options. Progress reports on NSRAWM implementation are sent to the Strategy Monitoring Group (consisting of representatives of NARNRA, GIES and authorized persons in the field of RAW management). Once approved, progress reports are submitted to the Government.

1.8. COMPETENCE FOR SAFETY

The IRRS team was informed that the Government understands the importance of the availability of sufficient number of competent and qualified experts (physicists, engineers, scientists) for the safety of its radiation facilities. However, the Republic of Moldova does not have an overall national policy and strategy for education and training in radiation, transport and waste safety. Higher education is ensured through the national universities, where students attend most of the courses related to radiation disciplines. As in many other small countries the graduates from these specialties are limited in number.

The country identified a gap in the needed and available experts in radiation safety and may benefit from a detailed assessment of: existing and planned radiation facilities and activities; expertise available; and future needs to support the safe operation of these facilities. In addition, in the areas where the Republic of Moldova has no or limited internal capabilities for providing education and training, it effectively relies on assistance from IAEA.

The Law 132 sets the fundamental requirement for ensuring the competence of any person who is carrying out activities in radiological facilities and requires that they should receive adequate training on safety measures to be controlled in the conduct of such activities. It introduces the term “Radioprotection officer” that corresponds to the “radiation protection officer” (RPO) as defined by the IAEA safety standards, as well as the term “certified expert”.

Article 11 of the Law 132 specifies NARNRA's responsibilities in the area of education and training:

- perform education and training of all persons, whose duties in the field require specific competence in the field of radiation protection;
- certification or recognition of radiological experts, with the release of the Level III exercise permission;
- knowledge assessment, release or recognition of Level I, Level II exercises, issued by entities recognized by NARNRA, personnel working in the radiological field and radiation protection officers;
- recognition of technical support organizations, national and international experts, certifying personnel training institutions, by including them in the register and by publishing them on NARNRA's website.

To obtain a radiological authorization the applicant needs to employ only persons holding an exercise permission valid for these activities. This permit may be issued by NARNRA or by other competent institutions being recognized by it. The permit is issued based on completed specific training in the field and fulfilment of qualification and training requirements. However, such requirements have not been published yet, which results in applicants not knowing how and what to do, and NARNRA not being able to verify their competence (lack of requirements or criteria). **Related Recommendation R2 is provided in Section 1.2.**

1.9. PROVISION OF TECHNICAL SERVICES

Technical services are available in the Republic of Moldova. Article 11 of the Law 132 provides the basis for NARNRA authorization of professional technical services.

The IRRS team was informed that the National Public Health Agency and two private organizations are authorized by NARNRA for quality control measurements (including calibration). NARNRA has authorized the National Public Health Agency to provide personnel dosimetry and work place monitoring service in the Republic of Moldova. Further actions to strengthen the conditions of this authorization would support ensuring the timely provision of dosimetry results to NARNRA, particularly during accidents and incidents. **Related Recommendation R13 is provided in Section 5.1.**

1.10. SUMMARY

The Republic of Moldova has established the basis for the legal and regulatory framework for safety. The Law 132 and its implementing regulations establish some of the prerequisites for an effective regulatory framework. To further align its legislation with the international standards, the Government needs to complement the framework for safety in the areas as indicated in this Section. Priority should be given to the transposition of the requirements of GSR Part 3 and the adoption of the already developed requirements on education, training, qualification and competence in protection and safety. The Government also needs to establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural or artificial origin).

The Government needs to ensure that NARNRA is provided with sufficient financial and human resources with the needed competencies to support the regulatory control of safety of facilities and activities in the country. The lack of sufficient financial and human resources results in some regulatory functions not being fully implemented, i.e. reduced scope of inspection programmes, delays in authorization; regulatory requirements not being developed; as well as insufficient education and training of regulatory staff.

Further efforts are needed in the coordination with relevant Government authorities. Special attention should be paid to the clear allocation of responsibilities and formal coordination arrangements between NARNRA and the Ministry of Health, Labour and Social Protection (NPHA). This should provide for elimination of duplication in authorizations and inspections, as well as joining efforts for the establishment of a complete legal and regulatory framework.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

The Republic of Moldova is committed to fulfil its international obligations and develop its legal framework in a manner commensurate with the internationally accepted principles and standards. The Constitution gives priority of international conventions and agreements in the field of human rights ratified by the country over the national legislation.

The Republic of Moldova has ratified the international instruments related to nuclear safety and radiation protection:

- Convention on Early Notification of a Nuclear Accident;
- Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency;
- Convention on Nuclear Safety;
- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (Joint Convention);
- Vienna Convention on Civil Liability for Nuclear Damage and protocol amending it.

Since the ratification of the Convention on Nuclear Safety (1998) and the Joint Convention (2011), the Republic of Moldova had prepared and submitted its national reports and participated in the process of asking and answering related questions. However, the only participation of the Republic of Moldova in the review meetings was in 2018, under the Joint Convention. In such a way, the Republic of Moldova is not completely fulfilling its obligations under the conventions and could not benefit from the peer-review process that is the central feature of this mechanism.

The Republic of Moldova has made a political commitment to work toward the principles of the Code of Conduct on the Safety and Security of Radioactive Sources, as well as to the Guidance on Import and Export of Radioactive Sources. The IRRS team was advised that the Republic of Moldova has not yet made a political commitment to the supplementary Guidance on the Management of Disused Radioactive Sources (endorsed by the IAEA General Conference in September 2017), but that such a commitment will also be done soon.

With regard to international cooperation, NARNA duties, as defined in Article 12 of the Law 132, include the fulfilment of commitments which the Republic of Moldova has to assume in accordance with international conventions including the drafting and transmission of the national reports to the international bodies in accordance with the international treaties to which the Republic of Moldova is a party, as well as coordination of technical cooperation with the IAEA and national contact point with the IAEA under the international nuclear and radiation treaties.

NARNRA has established Memorandums of Understanding with neighbouring countries, namely Romania and Ukraine for cooperation in related areas (radiation protection, radiation safety, training etc). The IRRS team understanding is that establishing agreements with all nearby countries in the region, including the states that have nuclear power plants (such as Bulgaria) will further support regional cooperation and exchange of regulatory experience.

The Republic of Moldova uses the IAEA safety standards as the basis for developing its national

safety requirements, but due to budgetary restrictions the participation of country experts in Safety Standards Committees and the working groups on development and revision of IAEA standards is quite limited.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: The Republic of Moldova is a party to the safety related Conventions. However, its participation in the Convention review meetings has been limited. This is part of NARNRA’s Action Plan.</p>	
(1)	<p>BASIS: GSR Part 1 (Rev 1) Requirement 14 states that <i>“The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation to enhance safety globally.”</i></p>
R6	<p>Recommendation: The Government should fulfil international obligations by participation in relevant review meetings.</p>

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

NARNRA is actively using the regulatory experience of other States to identify useful information and to disseminate the lessons learned to other related country authorities. Information received is processed and, if applicable, used as a learning tool to strengthen the safety in the country. Similarly, NARNRA reports such information internationally through interactions with other regulatory authorities in the region (seminars, document sharing, international projects, etc.).

According to Article 12, para 1 (f) empowers NARNRA to require authorized persons to submit reports, information and notifications. This provision allows NARNRA to impose reporting requirements to authorized persons as an authorization condition, which possibility is not used.

The IRRS team identified that there are no legal or regulatory requirements for reporting events, and respectively no criteria for reporting. As a result, NARNRA is not receiving event reports. It is also not reviewing and learning from internationally published events. NARNRA will significantly benefit from the establishment of an Operating Experience Program, which collects and utilizes the national and international operating experience.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: No requirements or criteria have been established for reporting of safety related events. Additionally, there is no system for analysis to identify lessons learned or for dissemination of such information in the country or internationally.</p>	
(1)	<p>BASIS: GSR Part 1 (Rev 1) Requirement 15 states that <i>“The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities.”</i></p>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

R7	Recommendation: The Government should establish requirements and criteria for reporting of operating events by authorized persons. NARNRA should establish a system for analysing events and disseminating the lessons learned within the country and internationally.
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2.3. SUMMARY

The Republic of Moldova has ratified all of the international instruments related to nuclear and radiation safety. This commitment was not completely fulfilled as participation in the review meeting under the Convention on Nuclear Safety and the Joint Convention was very limited.

There are no legal or regulatory requirements or criteria for reporting of safety related events. A system for analyzing events and disseminating the lessons learned within the country and internationally needs to be established.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

Establishment of NARNRA is described in Section 1.3.

According to Article 10 of Law 132, the structure of NARNRA is approved by the government. The government adopted Decision #458 for approval of the Regulation on the organization and functioning of the NARNRA. (Decision 458). The IRRS team reviewed the structure and resources allocated to NARNRA to assess its ability to perform its regulatory functions and statutory obligations, both nationally and internationally.

The Director of NARNRA is appointed by the Minister of Agriculture, Regional Development and Environment, and is an ex officio Chief State Inspector in the field of nuclear and radiological activities. The Deputy Director is also appointed by the Minister on the recommendation of the Director of NARNRA including as the Deputy Chief State Inspector. To fulfil tasks and functions of NARNRA, the Director has the right to issue internal procedures for effective functioning of NARNRA.

Decision 458 prescribes that there are 18 management and staff positions within NARNRA, and describes the organizational structure, which details seven functional groups in the NARNRA:

1. Department of authorization, safeguard, nuclear and radiation safety which include:
 - a) The Authorizations and Evaluation Service, responsible for granting authorization for nuclear and radiation activities and supporting work program;
 - b) Radioactive Waste Management Service;
 - c) Safeguards, Accounting of Nuclear and Radioactive Materials Service, responsible for physical inventory of nuclear materials;
2. State Control and Surveillance Section, responsible for performing planned and unannounced inspections of nuclear and radiation facilities and associated enforcement actions;
3. National Register of Ionizing Radiation Sources and authorized persons;
4. Legal Service and Human Resources, responsible for legal advice and human resources;
5. Accounting (Finance) and Planning Unit, responsible for support of operations of the NARNRA.

Currently, NARNRA employs 13 people, including the director. NARNRA's organizational chart and allocation of staff are in the Appendix VIII of this report. Resources are allocated proportionally to each organizational unit of NARNRA, as prepared and recommended by the Head of NARNRA.

As discussed in Section 1.3, NARNRA is funded from the state budget as well as from other sources according to the legislation in force. NARNRA develops a budget plan for the upcoming year after evaluating the implementation of previous year's plans and current needs. NARNRA prepares and submits its budget to the MARDE.

The IRRS team noted that NARNRA does not have adequate staffing to effectively perform all of its regulatory functions. Additionally, the NARNRA budget does not provide resources for preparation of regulations, fulfilment of obligations under conventions, training of staff, etc.

Related recommendation R3 for the Government to provide NARNRA with additional resources in order to perform its functions effectively is provided in Section 1.3. Additionally, the IRRS team believes that NARNRA can optimize certain processes and strengthen cooperation between its organizational units (authorization and inspection) to more effectively use its staff resources.

The IRRS team observed that only NARNRA’s technical experts are involved in development and drafting of regulations and guides, and legal support to all of NARNRA’s regulatory functions is insufficient.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: NARNRA has the major challenge to develop the comprehensive legal and regulatory requirements on radiation safety. Only technical experts are involved in these activities and legal support is absent or insufficient.	
(1)	BASIS: GSG-12 para 4.27 states that <i>“The regulatory body should have access to expert legal advice. The objective of legal support is to provide the regulatory body with legal advice on international obligations, the national legal framework and legislation, and development of rules, regulations and guides for the implementation of the regulatory body’s functions.”</i>
(2)	BASIS: GSG-12 para 4.28 states that <i>“Activities typically requiring professional legal support include the following:</i> <ul style="list-style-type: none"> • <i>The development of basic legislation;</i> • <i>The development of regulations and review for compatibility with other relevant laws and regulations;</i> • <i>Assisting in the development of the internal administrative procedures of the regulatory body;</i> • <i>Providing legal advice in the authorization process;</i> • <i>Providing legal advice on proposed enforcement actions;</i> • <i>Representing the regulatory body in the event of enforcement activities involving formal legal processes;</i> • <i>Assisting regulatory body staff in responding to requests for public information.”</i>
S2	Suggestion: The Ministry of Agriculture, Regional Development and Environment should consider strengthening legal support to NARNRA in developing and promulgating legal and regulatory requirements and internal procedures, as well as providing legal advice in the authorization and enforcement processes.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

As discussed in Section 1, Law 132 and Decision 458 establish the regulatory body as effectively independent within the MARDE. Article 9 (special provisions) of Law 132, clearly separates NARNRA from users and organizations promoting uses of radiation promotional functions.

Administrative and regulatory measures for ensuring independence in the decision-making process are also covered in other legislation, such as Law #158 on Governmental Function and Status of Public Servants (Law 158) and Law #16 on Conflict of Interest (Law 16). The IRRS team was informed that NARNRA does not have any policy provisions regarding the employment of staff from licensees. In the case that a significant risk regarding conflict of interest within NARNRA arises, the matter is referred to the Intelligence Service and Centre of Integrity of Republic of Moldova

The IRRS team therefore concluded that NARNRA, as a regulatory body, performs its functions in a manner that does not compromise its effective independence in fulfilling its regulatory obligations.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

The IAEA safety standards require that the regulatory body shall have sufficient and competent staff to perform its functions and to discharge its responsibilities. As discussed in Section 3.1, the number of staff positions according to Decision 458 for the approval of the Regulation on organization and functioning of the NARNRA is 18. However, NARNRA currently has only 13 employees. NARNRA has undertaken an analysis of competence requirements.

The IRRS team was informed that an assessment of the necessary staff was carried out in the past and was the basis for adoption of Decision 458. In the self-assessment NARNRA identified that the regulatory body lacks sufficient and competent staff.

A comprehensive Human Resources plan of NARNRA, with a detailed description of each position and position requirements, recruitment, rotation of staff and departure of staff, does not exist. Procedures are only available for recruitment of staff. NARNRA used Governmental Decision #201 on Human Resources, which implements Law 158 for detailed description of each position.

Additionally, there is no systematic training programme to assist the development and maintenance of staff competence. This issue has been recognized in the self-assessment. NARNRA uses only training available for regulatory bodies and workshops organized by IAEA and other partner States (training programmes for inspections in Bucharest and Iasi). The IRRS team could not find evidence of a systematic training programme but notes that NARNRA also identified this issue in the self-assessment.

Based on the information received from NARNRA and described in more detail in Sections 1.3 and 3.1 of this report, there is a lack of qualified staff resources. Given the scope of activities undertaken in Moldova, NARNRA does not have sufficient competence to effectively discharge its regulatory duties. As discussed in Section 3.1, the IRRS team believes that NARNRA may optimize certain processes to reduce burden on the available staff. **Related Recommendations R14, R15 and Suggestion S5 are provided in Section 5.1.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: NARNRA has conducted an analysis of the necessary competence and skills for its staff. However, a comprehensive Human Resources Plan has not been established. Additionally, there is no systematic training programme to ensure the development and maintenance of staff competence. This issue has been recognized in the self-assessment.

(1)	BASIS: GSR Part 1 (Rev 1) Requirement 18 para 4.11 states that <i>“A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions.”</i>
(2)	BASIS: GSR Part 1 (Rev 1) Requirement 18 para 4.13 states that <i>“A process shall be established to develop and maintain the necessary competence and skill of staff of the regulatory body. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills.”</i>
R8	Recommendation: NARNRA should develop and implement a human resources plan. NARNRA should also establish a specific training programme, which is based on analysis of the necessary competence and skills.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

The legislative framework for radiation safety does not provide a legal basis for establishment of an advisory body for NARNRA in relation to its responsibilities and authority. Such a body may execute an advisory role on a permanent basis within the scope prescribed by the legislation in advance or on an ad-hoc basis.

Currently, NARNRA has no dedicated support organization or advisory body. The NARNRA budget does not provide for contracting expertise from outside the country (country expertise is very limited). The only source of technical advice is the IAEA and bilateral arrangements with other foreign regulatory bodies. As a result, NARNRA has no, or very limited, access to external technical or other expert professional advice. There is only one Technical Support Organization (TSO) with a specific field of expertise. The Centre for Scientific Technical Development Centre” INOTEH” provides NARNRA support for:

- development of the normative acts
- implementation of international technical assistance programs;
- human resources development;
- organization of conferences, courses and seminars;
- searching of radioactive orphan sources.

The government should ensure that NARNRA can obtain technical or other expert professional advice or services as necessary in support of its regulatory functions, but this shall not relieve NARNRA of its assigned responsibilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: NARNRA has no dedicated support organization or advisory body and the

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
allocated budget does not provide for contracting expertise from outside. Resulting, NARNRA has no or very limited access to external technical or other expert professional advice.	
(1)	BASIS: GSR Part 1 (Rev 1) Requirement 20 states that <i>“The regulatory body shall obtain technical or other expert professional advice or services as necessary in support of its regulatory functions, but this shall not relieve the regulatory body of its assigned responsibilities.”</i>
R9	Recommendation: The Government, should ensure that NARNRA is provided with access to technical or other expert professional advice, as necessary.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

NARNRA has established formal and informal mechanisms of communication with authorized parties. However, NARNRA has not established regular meetings with authorized parties, to discuss matters of mutual interest.

During the authorization process, the formal mechanism of communication between NARNRA and licensees on safety related issues is in accordance with the procedures prescribed in the Law 100. Information about the regulatory process conditions and documentation required for authorization are available on the website www.anranr.gov.md NARNRA staff communicate with applicants in the event of missing or insufficient information. Following a review of applications, NARNRA may, as appropriate, perform visits on to the site (pre-authorization verification) to confirm the documents. If the result of the evaluation process is positive, NARNRA issues the authorization.

According to Law 132, (Article 11 h¹) NARNRA is also responsible for establishing an appropriate system for informing, educating and training of everyone in the field of radiation protection. The IRRS team was informed that NARNRA periodically (once or twice per year) organizes training courses for licensees.

Communication between the regulatory body and authorized parties, during preparation of legislation, is described in Section 9 of this report. **Related Suggestion S4 on interaction strategy is provided in Section 4.2.**

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

NARNRA’s regulatory activities and decision making in the authorization process are based on an annual plan of activities approved by Minister of Agriculture, Regional Development and Environment.

Authorizations are issued according to established criteria in Law 132 and Government Decision #727 of 09.08.2014 on approving the Regulation on the authorization of nuclear and radiological activities (Decision 727) and are available for review by authorized parties and applicants. NARNRA does not have procedures for the implementation of the core processes such as authorization, enforcement, etc. However, NARNRA prevents subjectivity in decision-making by an individual member of staff through a three-level evaluation process. In the opinion of the IRRS team, the lack of such procedures and guides, could influence the consistency in the

application of regulatory controls by NARNRA. **Related Recommendation R22 is provided in Section 9.1.**

The process for developing and modifying regulatory requirements is discussed further in Section 9. The formal process to be used when preparing new regulatory requirements, or changing existing ones is prescribed in the Law 100. For this purpose, all drafts and proposals are published on NARNRA’s website with the announcement of the time period in which interested members of the public can give their opinions or comments.

Some of the international safety standards are incorporated into the Republic of Moldova’s legislation. The IRRS team was informed that the IAEA GSR Part 3 and Council Directive 2013/59/Euratom of 5 December 2013 will be implemented in the new Law on Radiation Protection and Government Decisions. This has been recognized in the action plan. **Related Recommendation R2 is provided in Section 1.2.**

NARNRA does not currently have practices to systematically assess operating experiences in order to identify potential improvements to their regulatory framework and support continuous enhancement of safety. **Related Recommendation R7 is provided in Section 2.2.**

3.7. SAFETY RELATED RECORDS

There are requirements on establishing, maintaining and retrieving adequate records that apply to both regulatory body and authorized persons. Article 11 of Law 132 states responsibilities and duties of NARNRA to keep the National Register.

Government decision on the National Register of Ionizing Radiation Sources and Authorized Physical and Legal Persons (Government decision 1017) has established the National Register of Ionizing Radiation Sources and Authorized Physical and Legal Persons, which is used for all authorizations with Ionizing Radiation Sources, Nuclear Material and or Radioactive Waste.

Government Decision #1017 also established requirements for authorized persons to maintain records and report them to the National Register (Decision 1017). Furthermore, the frequency for reporting is prescribed (once per year) in the case of loss of control or other significant changes. They also have to provide supporting evidence on safety records if required, however NARNRA has not established reporting criteria for safety related events by authorized parties. **Related Recommendation R7 is provided in Section 2.2.**

The National Public Health Agency within the Ministry of Health, Labour and Social Protection is responsible for maintaining the Dose Register of Occupationally Exposed Workers (Article 14 of Law132). However, there are no procedures for register operation including maintaining and retrieving of adequate records.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Ministry of Health, Labour and Social Protection is responsible for maintaining the Register of Occupational Exposures. However, there are no procedures for register operation including maintaining and retrieving of adequate records.	
(1)	BASIS: GSR Part 1 (Rev 1) Requirement 35 states that <i>“The regulatory body shall make provision for establishing, maintaining and retrieving adequate records relating to the safety of facilities and activities.”</i>
(2)	BASIS: SSG-44 para 4.119 states that <i>“...a national dose register has considerable advantages ..., in particular with regard to itinerant workers and</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<i>foreign workers. Therefore, the regulatory body should promote the establishment of such a national dose register ...”</i>
(3)	BASIS: GSG-7 para 7.265 states that “ <i>Consideration should be given to the establishment of a national dose registry as a central point for the collection and maintenance of dose records... ”</i>
S3	Suggestion: The Ministry of Health, Labour and Social Protection should consider establishing a national dose register and provide access to this register to NARNRA.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

In accordance with Law 132, NARNRA is required to establish an appropriate system for informing the public concerning ionizing radiation protection. NARNRA does not have a strategy or procedures for informing and communicating with the public in place but has established a dedicated website that reports on the activities of NARNRA. The website provides information on NARNRA, references to relevant legislation and information on their authorizations. More comprehensive information is provided in an annual report of NARNRA; the first having been issued in 2007. **Related Suggestion S4, related to communication with the public, is provided in Section 4.2.**

The annual reports on the work of the NARNRA and report on the implementation of the Action Plan on NSRAWM are also published on the website. The annual inspection plan is published through the Governmental platform which is used for all inspection authority in the country. NARNRA occasionally organizes press conferences to report on their activities.

In accordance with Law on Normative Acts #100, the stakeholders as well as population shall be consulted in the process of preparation of the legislation and regulation and more details are provided in Section 9.

3.9. SUMMARY

The Republic of Moldova established NARNRA as an independent state regulatory body for the regulatory control of facilities and activities. NARNRA has independence in the exercise of the regulatory functions.

The Government, should ensure that NARNRA is provided with access to technical and other expert professional support and advice, as necessary and NARNRA should:

- develop and implement a human resources plan and specific training programme for staff, which is based on analysis of the necessary competence and skills;
- have access to a dedicated legal expert to support in drafting regulation and guide;
- advisory body of technical experts to support its decision making and preparation of regulatory requirements.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

The Existing NARNRA management system is based on general administration rules of the country and it is not fully in line with GSR Part 2 requirements with respect to leadership and management for safety. Nevertheless, top management of NARNRA is aware of deficiencies and is ready to start activities in order to establish a management system.

4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

The top management of NARNRA has recognized a need to describe and document core processes of the regulatory body in order to promote safety culture and leadership for safety. To proceed with the activities a policy and strategy for safety has to be in place. There is a need to create a common mission and policy document as the initial step to find a clear connection between the mandate of the NARNRA and the role of each individual staff member.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no documented safety policy of NARNRA that defines the mission and vision of the organization.	
(1)	BASIS: GSR Part 2 Requirement 3 para 4.2 states that <i>“Senior management shall be responsible for establishing safety policy.”</i>
(2)	BASIS: GSG-12 para 4.2 states that <i>“vision, values, policies, strategies and goals of the regulatory body should be commensurate with the legal framework, the mission of the regulatory body and the needs and expectations of interested parties...”</i>
R10	Recommendation: NARNRA senior management should develop and establish a safety policy in line with IAEA safety standards and the needs and expectations of interested parties.

4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

Although certain information is published on the NARNRA website (see Section 3.5) there is no mechanism in place or appropriate means of communicating routinely and effectively with and informing interested parties with regard to radiation risks associated with the operation of facilities and the conduct of activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no NARNRA strategy on how to inform interested parties with regard to radiation risks associated with the operation of facilities and the conduct of activities.	
(1)	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</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<i>appropriate strategy for interaction with them.”</i>
(2)	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>
S4	Suggestion: NARNRA should consider identifying interested parties for their organization and formalize an appropriate strategy for interaction with them.

4.3. THE MANAGEMENT SYSTEM

NARNRA has not established and implemented a management system that is aligned with its safety goals and contributes to their achievement. Goals, strategies, plans and objectives for the organization that are consistent with the organization’s safety policy are not developed. Existing elements of a management system are based on general administration rules and do not integrate nor contain safety, health, environmental or security components. These processes are understood as supported processes. Core processes and adequate procedures including emergency preparedness procedures have not been recognized and documented, except for inspection, where NARNRA has an approved Guide on the procedure for organizing, conducting and finalizing the results of state control in the field of nuclear and radiological activities. Processes for measurement, assessment and improvement in order to enhance safety performance in line with GSR Part 2 are also needed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: A Guide for the inspection procedure is implemented. However, other core processes (development and revision of regulation, review and assessment, authorization and enforcement) of NARNRA have not been recognized and documented. There is no documented Integrated Management System that includes development of all processes, description of interactions between processes, internal procedures to perform different tasks, and promotion and support of strong safety culture in the organization. This is part of NARNRA’s Action Plan.	
(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 3 states that <i>“Senior management shall be responsible for establishing, applying, sustaining and continuously improving a management system to ensure safety.”</i>
R11	Recommendation: NARNRA should develop and document an Integrated Management System, with priority on core processes.

4.4. MANAGEMENT OF RESOURCES

NARNRA has not determined the needed competence, resources and training requirements against the strategies and regulatory functions and implemented measures to ensure it has sufficient resources to fulfil its obligations to achieve safety goals. Consequently, no competences for leadership or needed resources for the development and improvement of the management system and training of staff have been determined.

Related Recommendation R8 is provided in Section 3.3.

4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

NARNRA has developed and implemented some processes with respect to organizational and general administration aspects, but the NARNRA's core processes have not been recognized and documented. Documentation of processes, process maps, interfaces and interactions between the processes and most of the procedures does not exist. There are no documented processes on retaining responsibilities during receiving supply or service to NARNRA. Qualification and oversight of the supply chain has not been established.

Related Recommendation R11 is provided in Section 4.3.

4.6. CULTURE FOR SAFETY

No special arrangements on culture for safety exist. **Related Recommendations R10 and R11 are provided in Sections 4.1 and 4.3.**

4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

NARNRA has not established a system for measurement, assessment and improvement in the organization. Due to the fact that there is no documented management system in place there is no possibility to regularly evaluate effectiveness of the processes. That includes regular assessments of leadership for safety and of safety culture in the organization. Consequently, no independent assessment or periodic review by senior management of the management system is possible.

Related Recommendation R11 is provided in Section 4.3.

4.8. SUMMARY

Based on the Laws and regulations on state administration, NARNRA has developed and implemented some elements of a management system that can be recognized as supporting processes. These processes include elements on documentation, financial planning and control, human resources, etc. However, NARNRA has not established a documented integrated management system in accordance with GSR Part 1 (Rev 1) and GSR Part 2. The Recommendations are made for NARNRA to:

- Develop safety policy
- Identify interested parties and define strategy for interaction with interested parties
- Develop and document Integrated Management System

The preliminary NARNRA Action plan foresees the establishment and implementation of management system.

5. AUTHORIZATION

5.1. GENERIC ISSUES

Article 19 of the Law 132 provides for authorization of facilities and activities including partial authorization for the implementation of a phase of an activity, such as transfer, import, export, testing operation, etc.

Authorizations are issued by NARNRA’s Authorization and Evaluation Service, which is currently comprised of two persons. NARNRA has 519 authorized parties of which there are 32 industrial and research facilities. Authorizations are issued free of charge and valid for 5 years.

Not all types of facilities and activities that pose significant radiation risk are subject to authorization under the Law 132. For example, manufacture of unsealed sources using a cyclotron; and installation, commissioning, repair or modification of sealed source generators such as cobalt therapy machines. There is also no requirement for authorization of unsealed sources for therapy. The scope appears to have been limited to facilities and activities currently in operation in Moldova.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Not all types of facilities and activities that pose significant radiation risk are subject to authorization under the Law 132. Examples are: manufacture of unsealed sources using a cyclotron; and installation, commissioning, repair, modification of sealed radioactive sources such as cobalt therapy machines.	
(1)	BASIS: GSR Part 1 (Rev 1) Requirement 23 states that <i>“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.”</i>
(2)	BASIS: GSR Part 3 Requirement 7 para 3.8 states that <i>“Any person or organization intending to carry out any of the actions specified in para. 3.5 shall, unless notification alone is sufficient, apply to the regulatory body for authorization, which shall take the form of either registration or licensing.”</i>
R12	Recommendation: The Government should ensure that all facilities and activities that are not either explicitly exempted or approved by means of a notification process are subject to and are authorized.

NARNRA has advised that although the law requires the issuance of authorizations to users, radiation protection officers and certified experts taking into account their knowledge, skills and training, such authorizations are not issued. This is because NARNRA does not have regulations on education, training, qualification and competence in protection and safety, or any guides or procedures for granting such authorizations and formal recognition of qualified experts. **Related Recommendations R2 and R11 are provided in Sections 1.2, and 4.3.**

The IRRS review team has also noted that, while NARNRA places conditions on authorizations, these are not based on specific safety assessment of the facility or activity. Rather, generic conditions of requirements that are already in the Law or regulations are used as a basis for authorization. Authorization conditions are a mechanism for placing additional safety controls and limits on the operation of an authorized facility or activity to ensure that appropriate safety measures are implemented.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: NARNRA does not impose specific safety conditions that place appropriate controls on the authorized parties' subsequent activities, as part of authorization. Additionally, NARNRA has not established and implemented competence requirements for individuals as required by the Law 132.</p>	
(1)	<p>BASIS: GSR Part 1 (Rev 1) Requirement 23 states that <i>“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.”</i></p>
(2)	<p>BASIS: GSR Part 1 (Rev 1) Requirement 24 para 4.31 states that <i>“In the granting of an authorization for a facility or an activity, the regulatory body may have to impose limits, conditions and controls on the authorized party’s subsequent activities.”</i></p>
(3)	<p>BASIS: GSR Part 1 (Rev 1) Requirement 24 para 4.31 states that <i>“The regulatory body shall verify, by appropriate means, the competence of individuals having responsibilities for the safety of authorized facilities and activities.”</i></p>
R13	<p>Recommendation: NARNRA should grant authorizations for a facility or an activity by:</p> <ul style="list-style-type: none"> • imposing appropriate limits, conditions and controls necessary for safety on the authorized party’s subsequent activities; and • verifying competence of individuals having responsibilities for the safety of authorized facilities and activities.

The Law 132 provides for some sources to be exempted from authorization. The levels for the exemption of sources from authorization are taken from the Schedule 1 of GSR Part 3. According to the International Standards, such sources may be automatically exempted without further consideration from regulatory control, including requirements for notification, registration or licensing, inspection and enforcement. This is because the radiation risks arising from the practice or from a source within the practice are sufficiently low as not to warrant regulatory control.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: The Law 132 does not provide for sources and practices that present lowest radiation risks to be exempt from regulatory control.</p>	
(1)	<p>BASIS: GSR Part 3 Requirement 8 states that <i>“The government or the regulatory body shall determine which practices or sources within practices are to</i></p>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<i>be exempted from some or all of the requirements of these Standards. The regulatory body shall approve which sources, including materials and objects, within notified practices or authorized practices may be cleared from regulatory control.”</i>
(2)	BASIS: GSR Part 3 Requirement 8 para 3.10, states that <i>“The government or the regulatory body shall determine which practices or sources within practices are to be exempted from some or all of the requirements of these Standards, including the requirements for notification, registration or licensing, using as the basis for this determination the criteria for exemption specified in Schedule I or any exemption levels specified by the regulatory body on the basis of these criteria.”</i>
R14	Recommendation: The Government should ensure that sources and practices that present lowest radiation risks are exempted from regulatory control.

The Law 132 has not established or implemented a graded approach in the exercise of regulatory control. The IRRS team noted that the current authorization process does not incorporate notification alone, or either registration or licensing, consistent with the radiological risk of the facility or activity.

The IRRS team also noted that a number of authorizations are required to be issued for each facility or activity under the Law 132. In addition to a general radiological approval, certificates of safety for each source or facility, exercise permissions for users, radiation protection officers and certified experts associated with the facility or activity, are also required to be issued. There is significant scope for rationalising the number of authorizations issued to optimise the limited regulatory resources of NARNRA.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Law 132 does not require a graded approach to regulatory control which is commensurate with the radiation risks associated with facilities and activities.	
The authorization process established by NARNRA incorporates multiple authorizations in addition to the general radiological approval. NARNRA also undertakes preauthorization inspections of all facilities or activities regardless of the radiological risk. This does not lead to optimisation of regulatory resources and is also not consistent with the graded approach.	
(1)	BASIS: GSR Part 1 (Rev 1) Requirement 24 para 4.33 states that <i>“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>
(2)	BASIS: GSR Part 3 Requirement 7 para 3.7 states that <i>“Any person or organization intending to carry out any of the actions specified in para. 3.5 shall submit a notification to the regulatory body of such an intention. Notification alone is sufficient provided that the exposures expected to be associated with the practice or action are unlikely to exceed a small fraction, as specified by the regulatory body, of the relevant limits, and that the likelihood and magnitude of potential exposures and any other potential detrimental consequences are negligible.”</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<i>Notification is required for consumer products only with respect to manufacture, maintenance, import, export, provision, distribution and, in some cases, disposal.”</i>
(3)	BASIS: GSR Part 3 Requirement 7 para 3.8 states that <i>“Any person or organization intending to carry out any of the actions specified in para. 3.5 shall, unless notification alone is sufficient, apply to the regulatory body for authorization, which shall take the form of either registration or licensing.”</i>
(4)	BASIS: GSR Part 1 (Rev 1) Requirement 16 states that <i>“The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities.”</i>
R15	Recommendation: The Government should ensure that the extent of regulatory control incorporates notification alone for low risk facilities and activities, and categorised requirements for the authorization process which is commensurate with the radiation risks associated with facilities and activities.
S5	Suggestion: NARNRA should consider revising the authorization process and implementing measures for optimising available resources in a manner commensurate with the radiation risks associated with facilities and activities.

5.2. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

Under the Law 132, authorization can be issued for “temporary and/or final disposal, use, handling, processing and treatment of radioactive waste”. Partial authorization may be issued for design, location, construction, commissioning and modification of waste management facilities. Partial authorization is also issued for “relocation, transfer, disposal at disposal of end-of-life radioactive sources or expired use”. Financial aspects are also considered in issuing authorization for waste management facilities.

As part of such authorizations, NARNRA does not require the development of a safety case or a safety assessment for its review. A safety case should take into consideration requirements of GSR Part 4 and IAEA Guidance GSG-3 and SSG-23.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The requirements for developing of Safety Case and conducting of Safety Assessment for radioactive waste management facilities are not elaborated.	
(1)	BASIS: GSR Part 3 Requirement 13 states that <i>“The regulatory body shall establish and enforce requirements for safety assessment, and the person or organization responsible for a facility or activity that gives rise to radiation risks shall conduct an appropriate safety assessment of this facility or activity. Para. 3.29 “The regulatory body shall establish requirements for persons or organizations responsible for facilities and activities that give rise to radiation risks to conduct an appropriate safety assessment. Prior to the granting of an</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<i>authorization, the responsible person or organization shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body. ”</i>
(2)	BASIS: GSR Part 5 Requirement 14 states that <i>“The safety case for a predisposal radioactive waste management facility shall include a description of how all the safety aspects of the site, the design, operation, shutdown and decommissioning of the facility, and the managerial controls satisfy the regulatory requirements. The safety case and its supporting safety assessment shall demonstrate the level of protection provided and shall provide assurance to the regulatory body that safety requirements will be met.”</i>
R16	Recommendation: NARNRA should develop and implement requirements for operators to conduct and submit Safety Case and conducting of its supportive Safety Assessment for radioactive waste management.

5.3. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

According to article 9 of the Law 132, import, export, re-export, transit, temporary admission or temporary export of ionizing radiation sources (including for calibration or measurement of medical equipment) requires appropriate authorization by NARNRA. At the end of their use, sources could be transferred to another authorized person, returned to a supplier, or delivered to a Radioactive Wastes Storage Facility. Radioactive sources may only be imported on the basis of being returned to the manufacturer at the end of useful life. Authorized parties are required to provide financial assurance in case of bankruptcy or loss of legal capacity.

Moldova has made a political commitment to Code of Conduct on the Safety and Security of Radioactive Sources and the Guidance on the Import and Export of Radioactive Sources. However, internal procedures for implementing this guidance have not been established to ensure appropriate consent and notification or responding to notification received from other countries.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Moldova has made a political commitment to Code of Conduct on the Safety and Security of Radioactive Sources and the Guidance on the Import and Export of Radioactive Sources. However, internal procedures for implementation this guidance have not been established.	
(1)	BASIS: GSR Part 1 (Rev 1) requirement 14 para 3.2 <i>“The features of the global safety regime include:.....(c) Internationally agreed IAEA safety standards that promote the development and application of internationally harmonized safety requirements, guides and practices.”</i>
S6	Suggestion: NARNRA should consider developing internal procedures for implementation Guidance on the Import and Export of Radioactive Sources.

5.4. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

Under the Law 132, decommissioning of facilities requires authorization or partial authorization by NARNRA. The requirements for issuing authorization and partial authorization for the decommissioning activity are not specified in the Law 132 or Decision 727. Further, there is no requirement to justify and define the decommissioning strategy including actions and timeframes for authorized parties. The IRRS team notes that the approved radioactive waste management strategy does not adequately consider decommissioning. **Related Recommendation R25 is provided in Section 9.4.**

5.5. AUTHORIZATION OF OCCUPATIONAL EXPOSURE

Under the Law 132, authorized parties are responsible for the protection of workers and to ensure that protection and safety is optimized. Dose limits are set for workers, students and apprentices. However, the dose limits for the lens of the eyes are not consistent with GSR Part 3. **Related Recommendation R26 is provided in Section 9.5.**

According to the Law 132 and Government Decisions, authorized parties are obliged to ensure that dose estimation of workers is performed on the basis of systematic individual dosimetry monitoring including the provision of appropriate medical supervision. Personnel dose monitoring records are maintained centrally by NAPH, and also by the respective authorized parties. However, there are no procedures on proper operation of the register at a state level, including for maintaining and retrieving of the records. The IRRS team noted that NARNRA has limited access to dose records. **Related Suggestion S3 is provided in Section 3.7.**

The period for record keeping under the Law 132 is up to 75 years of age or 30 years from the time of cessation of activity in the field of ionizing radiation. However, the records keeping requirements for authorized parties is inconsistently described in regulation and are not consistent with the Law 132 or GSR Part 3. **Related Recommendation R26 is provided in Section 9.5.**

According to FRPN-2000 para. 14, authorized parties must not provide special compensation, preferential treatment or other consideration as a substitute for safety and protection measures of workers.

5.6. AUTHORIZATION OF MEDICAL EXPOSURE

The Law 132 and regulations (Decision # 451- Radiation Protection, Radiation Safety in Diagnostic Radiology, and Interventional Radiology Practices, Decision # 632 - Radiation protection in radiotherapy practices and Decision #1210 - Radiation protections in nuclear medicine) provides for protection and safety in medical exposures.

In Moldova, there are 227 dental, 131 diagnostic, 1 radiotherapeutic, and 5 nuclear medicine facilities.

Obligations for protection and safety of medical exposures are placed on both, the authorized parties, and radiological medical practitioners. There are requirements including the use of dose constraints for protection of patients including for paediatric and pregnant or breast feeding patients, carers and volunteers in biomedical research. Radiological examination for medical surveillance for professional or legal or health insurance purposes is not justified under the Law 132.

The IRRS team was advised that the Ministry of Health, Labour and Social Protection and appropriate professional bodies are involved in the generic justification for given radiological procedures including of new and evolving clinical technologies. However, the final level of

justification for the application of a radiological procedure to a given individual has not been implemented in Moldova. Appropriate referral guidelines which take into account specific objectives of the exposure, the clinical circumstances and the characteristics of the individual to be subject to medical exposures should be made available to referring medical practitioners.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Ministry for Health, Labour and Social Protection has not developed a referral guideline for medical imaging procedures, including image guided interventional procedures for use by referring medical practitioners.	
(1)	BASIS: GSR Part 3 Requirement 37 para 3.158 states that “ <i>Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure.</i> ”
R17	Recommendation: The Ministry for Health, Labour and Social Protection should ensure that referral guidelines for medical imaging procedures, including image guided interventional procedures, are developed and made available to referring medical practitioners to comply with the justification requirements in the national legislation.

The Law 132 has placed obligations on the NAPH for “*radiation protection for medical exposures*”. While these appear to be in relation to the provision of radiation monitoring, quality control and dosimetry services and clinical hygiene, there is a lack of clarity or common understanding about the respective roles and responsibilities between the two agencies including amongst the authorized parties. NARNRA should give consideration to this as a matter of priority. **Related Recommendation R4 is provided in Section 1.5.**

National diagnostic reference levels (DRLs) and criteria for the release of patients who have been administered with radionuclides are promulgated under Fundamental Radiation Protection Norms - Requirements and Hygienic Rules (“FRPN-2000”) which has adopted the BSS 115. The IRRS team was informed that authorized parties are required to adopt and follow DRLs as appropriate. The DRLs could be reviewed and updated to ensure appropriate relevance for Moldova.

In the field of nuclear medicine and radiotherapy, other personnel such as medical radiation technologists and the medical physicists are involved in protection and safety including calibration, dosimetry and quality assurance. The requirement to involve medical physicists in such measures has been missed under Decision #451 for diagnostic and interventional radiological procedure and should be corrected. **Related Recommendation R26 is provided in Section 9.5.** The IRRS team was advised that quality control checks are done on an annual basis or after repair and maintenance.

The regulations have placed requirements on authorized parties to investigate and take corrective action and for timely reporting of the incidents to the Ministry of Health, Labour and Social Protection and NARNRA.

The Decisions # 451, 1210 and 632 provide in detail measures for design, and operational considerations for facilities and activities involved in medical procedures. These regulations are not fully consistent with international standards. **Related Recommendation R26 is provided in Section 9.5.**

5.7. AUTHORIZATION OF PUBLIC EXPOSURE

Information is provided in Section 9.7.

5.8. SUMMARY

The Law 132 and regulations have established authorization requirements for facilities and activities. There is some level of consistency with the International Standards. The requirements cover protection and safety for medical, occupational and public exposures. Measures for waste management and decommission have also been considered.

The scope of authorization requirements under the Law should be increased to cover all facilities and activities that may be available or needed in the future rather than being limited to what is currently available in Moldova.

The government should review the Law 132 and the relevant regulations to optimise the limited regulatory resources of NARNRA, namely:

- remove sources or practices that present lowest radiation risk from regulatory control;
- implement a graded approach to authorization which encompasses notification alone, or either registration or licensing, consistent with the radiation risk of the facility or activity;
- review the number of authorizations issued to a facility or activity.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

Preauthorization site visits/inspections are a major component of the review and assessment by NARNRA as specified by Article 20 of the Law 132. NARNRA informed the IRRS team that 133 and 108 preauthorization site visits/inspections were carried out during 2017 and 2018 respectively. Although the Law 132 has specified time frames for granting of authorizations, NARNRA has advised that there are cases where these time frames have not been met. NARNRA should ensure that appropriate arrangements are made to ensure that prescribed time frames are met. This may be achieved by optimizing the requirements for preauthorization site visits/inspections using the graded approach. That is, facilities with very low risk (dental) may not require preauthorization visits/inspections in order to focus NARNRA's limited regulatory resources. **Related Suggestion S5 is provided in Section 5.1.**

NARNRA would benefit from the establishment of more detailed regulatory requirements on safety assessment for facilities and activities. These may include:

- conduct and submit an appropriate safety assessment with the application for authorization;
- conduct safety assessments at different stages, including the stages of siting, design, manufacture, construction, assembly, commissioning, operation, maintenance and decommissioning of facilities;
- undertake a systematic critical review of safety systems and process structures, systems and components that includes software, and procedures related to protection and safety;
- ensure that the safety assessment is documented and, where appropriate, that it is independently reviewed under the relevant management system;
- perform additional reviews of the safety assessment as necessary to ensure that the technical specifications or conditions of use continue to be met during all times including after significant changes to operating procedures or modifications of facilities, etc.

NARNRA does not require the responsible person or organization to undertake an appropriate safety assessment or submit a safety assessment for its review as part of the application for authorization. This is done by NARNRA at the time of preauthorization site visit/inspection. The responsible person or organization is only required to submit a file containing documents, relevant to the type of facility or activity requiring authorization. Annexes 4 and 5 of the Law 132 specify the required documents. While some consideration has been given to the radiation risk, the depth and scope of the review and assessment does not fully consider the radiation risks associated with the facility or the activity.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: NARNRA does not require the responsible person or organization to undertake an appropriate safety assessment or submit a safety assessment for its review as part of the application for authorization.

(1)

BASIS: GSR Part 1 (Rev 1) Requirement 26 states that *“Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.”*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	BASIS: GSR Part 3 Requirement 13 states that <i>“The regulatory body shall establish and enforce requirements for safety assessment, and the person or organization responsible for a facility or activity that gives rise to radiation risks shall conduct an appropriate safety assessment of this facility or activity.”</i>
R18	Recommendation: NARNRA should require the responsible person or organization to submit a safety assessment as part of the application for authorization, commensurate with the radiation risks associated with the facility or activity.

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

There are no procedures or approved checklists for preauthorization site visits/inspections. Additionally, there are no guides for applicants on how to prepare the documents for authorization application. NARNRA’s Authorization Service has informed the IRRS team that they do not have the full range of expertise to undertake review and assessments of all aspects for protection and safety of facilities and activities. **Related Recommendation R3 is provided in Section 3.4.**

NARNRA has established processes and criteria for decision making. However, feedback from inspections, reviews and assessments, as well as records of operational performance are not properly coordinated among all NARNRA divisions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: While there is some exchange of results between the Licensing Officers and Inspectors within NARNRA, cooperation and coordination could be strengthened to ensure appropriate and timely exchange of information on inspections and reviews and assessments to ensure an integrated safety assessment as part of regulatory process, in accordance with a graded approach.	
(1)	BASIS: GSR Part 1 (Rev 1) Requirement 26 para 4.46 states that <i>“For an integrated safety assessment, the regulatory body shall first organize the results obtained in a systematic manner. It shall then identify trends and conclusions drawn from inspections, from reviews and assessments for operating facilities, and from the conduct of activities where relevant. Feedback information shall be provided to the authorized party. This integrated safety assessment shall be repeated periodically, with account taken of the radiation risks associated with the facility or activity, in accordance with a graded approach.”</i>
(2)	BASIS: GSR Part 1 (Rev 1) Requirement 29 para 4.51 states that <i>“Results of inspections shall be used as feedback information for the regulatory process and shall be provided to the authorized party.”</i>
S7	Suggestion: NARNRA should consider ensuring that there is feedback of results from inspections and reviews and assessments of facilities and activities to ensure an integrated safety assessment as part of regulatory process, in accordance with a graded approach.

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

An internal procedure has been in force since 2013 that requires the sharing of information among NARNRA divisions, namely the Authorization and Evaluation Service, State Control and Surveillance Section, and the Accounting and Planning Unit. The procedure requires sharing of information on a monthly basis. However, in practice, the procedure is not adequately met and information is shared on an inconsistent basis. NARNRA could optimise the use of its regulatory resources to focus on review and assessment of facilities and activities based on the radiation risk of facilities and activities. **Related Suggestion S5 is provided in Section 5.1.**

NARNRA would further benefit from more close coordination and information sharing between its units, as well as the optimisation of authorizations to be issued. This would allow more attention to be paid to review and assessment of safety submissions.

Additionally, as discussed in Section 3 of this report, there are no TSOs to help NARNRA review and assess technical information provided by applicants in case of a more complex facility. **Related Recommendation R9 is provided in Section 3.4.**

6.1.3. BASES FOR REVIEW AND ASSESSMENT

Legislation does not establish specific requirements for periodic review and assessment of the safety of facilities and activities. This issue is partially covered as a part of the authorization renewal, as well as in regulatory inspections.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

According to Regulation 1017, authorized persons should submit to NARNRA information in case of changing inventory. Information on inventory should be provided to NARNRA on an annual basis (till 31 December) that includes: presence, location, quantity, circulation, export, import, cessation temporary or permanent storing of radiation sources, nuclear material and radioactive waste. There are no requirements that authorized persons submit to NARNRA information on the safety of facilities and activities on a periodic basis. As a result, such information is not submitted to NARNRA and no related review and assessment is performed.

Review and assessment is performed against the provisions of a set of practice-specific regulations, issued by the Government. However, there are no internal NARNRA guidelines for conducting reviews and assessments. **Related Recommendation R11 is provided in Section 4.3.**

6.2. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

The Republic of Moldova does not operate nuclear power plants or nuclear research reactors and does not accept used nuclear fuel from abroad. Therefore, there is no spent nuclear fuel in the country. Basic requirements for radioactive waste management are defined by Law 132 and Regulation 388 on the Management of Radioactive Waste. Some safety requirements are also included in the regulation FRPN-2000. **Related Recommendation R2 is provided in Section 1.2.** Existing legal acts cover mainly predisposal management of radioactive waste and only some aspects for safety of radioactive waste disposal.

The IRRS team identified that there is no clear separation in the legislation of the terms “storage” and “disposal”. This is the case for both Law 132 and Regulation 388.

All above-mentioned issues create obstacles for the review and assessment of radioactive waste management facilities and activities.

According to Law 132, any holder of an authorization for radioactive waste management should submit an annual report to NARNRA. However, the contents of such a report have not been defined. Additionally, any holder of an authorization for radioactive waste management should notify NARNRA for receiving of a new DSRS within 24 hours (Law 132).

Law 132 includes the list documents that should be submitted to NARNRA by an applicant.

6.3. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The list of documents to be provided as part of the application is prescribed in Law 132. The information required depends to some extent on the type of practice and associated risks. Review and assessment of the documentation demonstrating safety is performed by NARNRA's Authorization and Evaluation Service.

6.4. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

Law 132 requires that every authorized person should develop a decommissioning programme (plan) and submit it to NARNRA for approval. The legislation does not require the periodic update of decommissioning plans, or the elaboration of a final decommissioning plan.

Law 132 defines the list of documents to be submitted to NARNRA in order to obtain a decommissioning authorization.

The IRRS team could not discuss NARNRA practices in issuing of a decommissioning authorization, as such authorizations have not been issued till now. **Related Recommendation R25 on the development of the decommissioning requirements is provided in Section 9.4.**

6.5. REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE

During the authorization process, the applicant must provide to NARNRA the documents related to different aspects of radiation protection. The list of required documents to obtain an authorization is contained in Law 132. Information concerning occupational exposure provided with the application usually contains details on the sources, radiation protection officer, exposed workers, management of controlled and supervised areas, procedures, personal protective and dosimetry equipment, individual and workplace monitoring, design of the facility or equipment, occupational exposure reports, etc. This information is reviewed and assessed by NARNRA.

Once per year, NARNRA is provided with the report on the doses of occupational exposure. Such a report is being prepared by NAPH. NARNRA evaluates this report and occupational exposure reports from authorized persons in order to estimate potential exceeding of dose limits. Verification of compliance of an authorized practice with the requirements on the control of occupational exposure is performed.

6.6. REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE

According to the Law 132, NARNRA is required to verify that medical radiological practitioners, medical physicists, persons working with radiation generators including installation, repair and maintenance have appropriate education, training and competence in radiation protection. However, this is partially verified by NARNRA. **Related Recommendation R11 is provided in Section 4.3.**

The review and assessment of medical exposures by NARNRA are on the basis of Articles 20 and 23 of the Law 132. The regulations (No. 1210, 632 and 451) specify detailed criteria in relation to justification and optimisation measures for medical exposures.

The documents required to be submitted by the applicant for activities and facilities involved in medical exposures are provided for in the Law 132.

NARNRA undertakes pre-authorization site visits/inspections of all medical facilities, as well as when there is a change. NARNRA may also undertake selective quality control checks, particularly to verify safety requirements.

The requirements for review and assessment for radiotherapeutic and nuclear medicine facilities should have due regard for requirements prescribed under regulation 451, 632 and 1210. **Related Recommendation R26 is provided in Section 9.5.**

6.7. REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE

No specific requirements exist for review and assessment of public exposure.

6.8. SUMMARY

Provisions for review and assessment of facilities and activities are not completely established under the Law 132. As a priority NARNRA should require the responsible person or organization to submit a safety assessment as part of the application for authorization, commensurate with the radiation risk associated with the facility or activity. The requirements for review and assessment must be strengthened in consistent with GSR Part 3.

7. INSPECTION

7.1. GENERIC ISSUES

Law 132 empowers NARNRA to perform state control and supervision of the nuclear and radiological activities and facilities. However, recent amendment of the Law 132 also empowers the central public administration authority in the field of health protection to perform “...*control of compliance with the radiological safety conditions, radioprotection in the use of radiological facilities in the field of health, medical devices and products radiopharmaceuticals, which have an impact on health and are sources of ionizing radiation*”. This situation limits the scope of facilities and activities to be inspected by NARNRA only to non-medical facilities and activities, despite the fact that authorization performed by NARNRA covers all activities and facilities according to the legislation. **Related Recommendation R4 are provided in Section 1.5.**

NARNRA has developed and implemented a programme of inspection of facilities and activities that covers all facilities and activities under its state control and supervision. Inspections are performed by qualified and well-trained inspectors. Inspectors have been trained in various training courses organized by the IAEA and participated in an exchange of experience with inspectors within the regulatory body in Romania. Due to the lack of human resources NARNRA currently has only two inspectors available for its inspection programme. **Related Recommendation R3 is provided in Section 1.3.**

Government Decisions #694 from 2013 on *General Methodology for Planning the State Control over the Entrepreneurial Activity*, based on the analysis of the risk criteria, says that the estimated level of risk for each legal person determines the level of frequency and intensity of the necessary control actions over the legal person that is concerned and establishes the basis for planning the state control. However, this general methodology has not been adopted by NARNRA.

According to Law 132, Article 20: “*the frequency of control and state supervision are determined by the nuclear and radiological risk that the activities and installations may represent...*” but there are no provisions in the regulations that stipulate the frequency of inspections related to the various facilities and activities. While planning the inspections, NARNRA staff are using mandatory criteria set in Government Decision 694 and IAEA recommendations on frequency of inspection and category of radioactive sources.

Law 132 empowers NARNRA inspectors to carry out planned and unannounced inspections. However, Law#131 of 8 June 2012 on State Control over Entrepreneurial Activity (Law 131), Article 19, limits them only to unplanned unannounced (reactive) inspections. The IRRS team observed that the authority and procedures for conducting reactive inspections are not consistently understood by NARNRA staff. All unannounced inspections should be approved by the State Chancellery on the basis of the Law 131. A legislative basis is not provided for planned unannounced inspections, so such inspections are not being performed in practice. The Law 132 authorization procedure provides the possibility for pre-licensing (e.g. unplanned announced) site visit/inspection to be carried out by NARNRA. Pre-licensing site visits focus on the evaluation of radiation safety of the installations/sources to ensure that all necessary measures relevant for protection and safety are taken and are in compliance with national safety requirements. Pre-licensing site visits/inspections are being performed by NARNRA's Authorization and Evaluations Service.

According to the Law 131, Article 15, NARNRA has an obligation to develop an inspection plan for the following year. The inspection plan should be registered in the State Control Register until December 1. NARNRA has no power to change the sequence of planned inspections after registration and publication of the inspection plan. It also does not have powers to carry out

planned inspections not included in the inspection plan. In order to coordinate joint inspections, the inspection plan must be harmonized with the inspection plans of other competent authorities. The legal entities to be inspected are listed in the inspection plan in accordance with NARNRA’s internal inspections guidance. For informative purposes, the inspection plan contains an indication of the quarter in which control of each legal person is scheduled. Inspections are planned and approved according the procedures set in the Law 131 through specialized information platform.

There are no external resources (TSOs, independent organizations or committees) available to support NARNRA while implementing its inspection programme. **Related Recommendation R9 is provided in Section 3.4.**

According to the Law 132, NARNRA inspectors have the right and responsibility to perform inspections jointly with the representatives of other control authorities

On a monthly basis, the Department of Authorization publishes generalized information on issued, suspended or withdrawn authorizations. Along with the inspectors, they have the authorization files with the assessment carried out during the authorization process (the basis on which the permissive documents were issued). However, during interviews and inspection, it was observed that there is a lack of coordination between the Authorization and Evaluation Service and State Control and Surveillance Service. **Related Suggestion S7 is provided in Section 6.1.1.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: Law 132 empowers NARNRA inspectors to carry out planned and unannounced inspections. However, Law 131 limits them only to unplanned unannounced inspections. Also, NARNRA does not have authority to carry out independent unannounced inspections as NARNRA has to seek approval from the State Chancellery in accordance with Law 131.</p>	
(1)	<p>BASIS: GSR Part 1 (Rev 1) Requirement 28 states that <i>“Inspections of facilities and activities shall include programmed inspections and reactive inspections; both announced and unannounced.”</i></p>
(2)	<p>BASIS: GSR Part 3 Requirement 29 para 4.52 states that <i>“Regulatory inspections shall cover all areas of responsibility of the regulatory body, and the regulatory body shall have the authority to carry out independent inspections. Provision shall be made for free access by regulatory inspectors to any facility or activity, at any time, within the constraints of ensuring operational safety at all times and other constraints associated with the potential for harmful consequences. These inspections may include, within reason, unannounced inspections. The manner, extent and frequency of inspections shall be in accordance with a graded approach.”</i></p>
R19	<p>Recommendation: The Government should ensure: that planned unannounced inspections are carried out as appropriate; and that NARNRA has authority to carry out independent unannounced inspections.</p>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: The general methodology for planning the state control over the entrepreneurial</p>	

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

activity has not been adopted by NARNRA. The list of practices and the frequency of their control or the risk criteria for the calculation of the inspection frequency is not set in the legal documents.

(1)	BASIS: GSR Part 1 (Rev 1) Requirement 29 states that <i>“Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.”</i>
(2)	BASIS: GSR Part 1 (Rev 1) para 4.52 states that <i>“The manner, extent and frequency of inspections shall be in accordance with a graded approach.”</i>
R20	Recommendation: The NARNRA should stipulate the frequency of inspections in accordance with a graded approach.

7.2. INSPECTION OF WASTE MANAGEMENT FACILITIES

There are checklists for inspection of radioactive waste management which are approved by NARNRA.

7.3. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

For the year 2018, 72 inspections were planned and for 2019, 90 inspections are planned.

Law 132 gives the authority to NARNRA to issue an inspection protocol and to issue prescriptions and to apply compulsory enforcement measures for physical and legal entities.

Law 132 gives the power to NARNRA inspectors to access any place where nuclear and radiological activities subject to authorization and control are conducted and requires physical and legal entities subject to control to comply with the provisions of the law, regulations in the field of nuclear and radiological activities, as well as limits and conditions of authorization.

General procedures on inspections are set in Law 131. Specific provisions related to the NARNRA inspection programme are set in Law 132 Article 29. Law 132 takes precedence.

Regulations and guides related to inspection are listed in Section 9: Government Decisions 153 and 694. NARNRA has developed and uses the Guide on the procedure for organizing, conducting and finalizing the results of state control in the field of nuclear and radiological activities. This guide sets out the coherent, unitary and mandatory action of inspectors in organizing, conducting and concluding state controls. It also contains the questionnaires for some practices, e.g. X-ray diagnostics, nuclear medicine, radiotherapy, interventional radiography, transport, industrial radiography, and radioactive waste). Inspectors have the ability to take measurements during inspections.

NARNRA inspectors use various inspection methods from reviewing technical documentation provided with the application for authorization, to interviews of authorized persons' staff, taking measurements, observation of activities in progress, equipment, facilities and work areas, etc. On completion of inspection, inspection findings and conclusions of the inspector, including any corrective or enforcement actions, are communicated to the authorized person. Inspection documents are registered in the Inspection Registry and used by NARNRA inspectors when preparing further inspections.

Authorized persons are required to correct violations within at most one month from the day they were handed over against a signature. The term could be extended.

The IRRS team observed an inspection by NARNRA inspectors at the Oncology Institute of the Republic of Moldova, Radiotherapy Department. The inspection started with an entrance meeting with the director of the Institute; Radiation Protection Officer (RPO), who is a medical physicist; and the Head of the radiotherapy department. After welcome words for the IRRS team members and the inspectors, inspection at the radiotherapy department started. The radiotherapy department is authorized for use of cobalt machines (2) and a linear accelerator. While using the check list, all information on the sources, staff and their training, inner procedures and instructions, individual and workplace monitoring, etc. was collected. After the review of the various documents, the radiotherapy rooms were inspected. Related documents and records were also checked by the inspectors. As a last step, the inspection check list was finalized, and main findings of the inspection presented to the director of the institute. The authorized person offered favourable comments about the value of inspection in improving safety and protection.

The IRRS team notes that the inspection was carried out in a thorough, methodical and professional manner. The IRRS team also observed an inspection by NARNRA inspectors at the “Special Facilities 5101, 5102” (National Radioactive Waste Management Company). The inspection was focused on compliance with authorization conditions and covered year 2018. The inspection was officially announced in advance. Discussions were held with the RPO. During the inspection all visitors were officially registered for entry as required for such type of facility. Inspectors reviewed the information for dose records and disused sealed radioactive sources (DSRS) received by the facility during the last year. Special measurements were taken for randomly chosen DSRS. The IRRS team noted that the inspection was carried out in a professional manner. The inspector demonstrated knowledge and experience in using inspection procedures. Additionally, the representative of the Authorization and Evaluation Service demonstrated deep knowledge of the facility.

7.4. INSPECTION OF DECOMMISSIONING ACTIVITIES

There are no specific provisions for the inspection of decommissioning activities

7.5. INSPECTION OF OCCUPATIONAL EXPOSURE

NARNRA enforces the requirements to ensure that occupational radiation protection and safety is optimized, and that dose limits for occupational exposure are complied with.

During inspections, authorized persons’ compliance with the requirements on occupational exposure, contained in various regulations dedicated to particular practices, are evaluated. Areas of investigation cover responsibilities of authorized persons with regard to occupational exposure, such as protection of female workers during pregnancy and breastfeeding, personal dose monitoring and recording of occupational exposures, medical fitness for work, appointment of a person responsible for protection (RPO), professional and radiation protection training of exposed workers. Additionally, various documentation, such as radiation protection programme, related policies, procedures, organizational arrangements, etc. are reviewed.

7.6. INSPECTION OF MEDICAL EXPOSURE

Planned inspections for radiotherapy facilities, nuclear medicine and medical facilities with category 1 to 3 sources are undertaken on an annual basis. For diagnostic X-ray and dental facilities, the frequency is two and three years respectively.

NARNRA has advised that 53 and 67 inspections of medical facilities were undertaken in 2017 and 2018 respectively. Of these, 6 and 3 inspections respectively were unannounced during 2017 and 2018.

The IRRS team was informed that protection and safety measures verified during inspection include records of medical exposures including calibration, dosimetry and quality assurance, measures for image quality, etc. These are undertaken to the best ability of the inspectors with some limitations in medical physics expertise within NARNRA.

7.7. INSPECTION OF PUBLIC EXPOSURE

NARNRA does not perform specific inspections in the area of public exposure. Some aspects of public exposure are being covered when performing inspections for nuclear medicine facilities.

7.8. POLICY DISCUSSIONS: RISK-INFORMED INSPECTION PLANNING

The basis of this policy issue is GSR Part 1 (Rev.1), Requirements 27-29. Para 4.50 states that: *“The regulatory body shall develop and implement a programme of inspection of facilities and activities...In this programme, it shall...stipulate the frequency of inspections and the areas and programmes to be inspected...”*. Additionally, GSG-13 “functions and Processes of Regulatory Body” advises: *“3.254. For each technical area to be inspected, the intervals between inspections and the level of effort to be applied to the inspection will depend on the following factors:(a) The type of facility or activity;(b) The safety significance of the technical area to be inspected; (c) The inspection methods and approaches used ...; (d) The performance record of the authorized party and the facility; for example, the number of non-compliances with regulatory requirements, violations of conditions in the authorization, deficiencies, events and the number of reactive inspections; (e) The results of regulatory review and assessment; (f) The personnel and other resources available to the regulatory body; (g) The results of previous inspections.”*

The Republic of Moldova established the general methodology for planning the state control over the entrepreneurial activity, which NARNRA plans to adopt. NARNRA reported that this methodology includes 3 criteria for inspection planning that are general for all agencies: duration of activities (i.e. duration of the authorization), interval after the latest inspection, and degree of compliance with the regulations according to the latest inspection report. NARNRA plans to add criteria that are specific for radiological activities and facilities, such as: category of the radioactive source; type of activity; equipment life time, etc. NARNRA looks for national experience of other countries to consider when implementing risk-informed inspection planning. NARNRA expects that implementation of a risk-informed approach will lead to more efficient use of NARNRA’s human resources.

The experience of Australia, Croatia, Georgia, Lithuania, Slovenia and the USA was exchanged. The following issues were proposed for NARNRA consideration as potential inputs for inspection planning:

- Different inspection frequencies: using different frequencies for planned inspections for different types of facilities, which can be taken from IAEA TECDOC 1526 “Inspection of Radiation Sources and Regulatory Enforcement” (once per 5 years minimum frequency);
- Performance: prioritizing inspections using information from prior facility inspections, such as the significance and number of any non-compliances identified;
- Changes in authorization: any significant changes in the authorized person’s program, such as amendments to the authorization or turnover of key personnel since the last

inspection;

- Analyzing: analyzing data on the inspection and review and assessment from the regulatory body's database should always be a first step in planning;
- Inspection scope: Adjusting the inspection scope according to the graded approach and inspection feedback (not all inspections need to be full scope);
- Other agencies inputs: using information relevant to radiation safety from the inspections that are done by other agencies;
- Complexity: complexity of activity, including extent of support that shall be provided by qualified experts such as medical physicists;
- Time when the visit to the facility should be done;
- Operating experience, including event (accident and incidents) reporting analysis for different types of activities (e.g. different treatment techniques);
- Reporting from the authorized persons (e.g. responses to pre-inspection surveys of authorized persons);
- Additional factors: factors other than radiation risk should always be considered. For example, consideration could be given to using inspectors from other inspectorates to check pre-defined aspects of facilities or activities for lower risk uses of radiation (i.e., think "out of the risk box");
- Cooperation: ensuring close cooperation of review and assessment experts and inspectors when planning, more over the first draft of the inspection plan can be prepared by the authorization unit based on the compliance with authorization conditions.

Reviewers stressed that critical elements of an effective inspection programme include: compliance promotion vs enforcement; knowledgeable inspectors; fitting of the regulatory body inspection methodology to the generic national methodology. Additionally, certain aspects of the pre-licensing evaluation site visits/inspections and enforcement policy were discussed.

7.9. SUMMARY

NARNRA has developed and implemented an inspection programme.

Although there are some shortcomings in specialist expertise in inspecting medical exposures NARNRA using the inspection programme makes strong efforts to ensure that protection and safety is optimized.

While some improvement to the programmes can be made, the inspection process is utilized and documented in a structured and appropriate manner. The IRRS team considered the inspectors observed to be trained, competent, and respected by their regulated entities. They conducted their inspections in accordance with internal procedures and in a professional manner.

The IRRS team noted that inspectors are limited by the Law 131 to perform planned unannounced inspections. Also, that unannounced inspections conducted by NARNRA are not fully independent and NARNRA does not stipulate the frequency of inspections in accordance with a graded approach. Recommendations are made to:

- Government to empower NARNRA to perform planned unannounced inspections and ensure that unannounced inspections are independent;
- NARNRA to stipulate the frequency of inspections in accordance with a graded approach.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

The Law 132 and Decision 153 provide for NARNRA to enforce corrective actions by authorized persons.

The IRRS team was informed that an enforcement policy has not been developed by NARNRA. Development and implementation of an enforcement policy that considers safety significance of non-compliance's and a graded approach would establish criteria and requirements for consistent implementation of the corrective actions allowed under the Law 132, such as issuing of penalties, revocation or suspension of authorization, seizure or sealing of sources and facilities, etc. by inspectors. It would also provide confidence that enforcement actions by any inspector within NARNRA are appropriate and based on sound reasoning about the severity of non-compliance, which has the potential to impact protection and safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: NARNRA does not have an enforcement policy which incorporates criteria for corrective actions in response to the safety significance of non-compliances in accordance with a graded approach.</p>	
(1)	<p>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></p>
(2)	<p>BASIS: GSR Part 1 (Rev 1) Requirement 31 para 4.54 states that <i>“The response of the regulatory body to non-compliances with regulatory requirements or with any conditions specified in the authorization shall be commensurate with the significance for safety of the non-compliance, in accordance with a graded approach.”</i></p>
(3)	<p>BASIS: GSR Part 1 (Rev 1) Requirement 31 para 4.58 states that <i>“The regulatory body shall establish criteria for corrective actions, including enforcing the cessation of activities or the shutting down of a facility where necessary. On-site inspectors, if any, shall be authorized to take corrective action if there is an imminent likelihood of safety significant events.”</i></p>
R21	<p>Recommendation: NARNRA should establish and implement an enforcement policy which incorporates criteria for enforcement actions on the basis of safety significance of non-compliance in accordance with a graded approach.</p>

8.2. ENFORCEMENT IMPLEMENTATIONS

Article 29 of the Law 132 empowers the Chief State Inspector to suspend or revoke authorization, shut down or seize (sealing) facility and sources, issue written notification and issue penalties.

Under the Law 132, enforcement activities are required to be performed in accordance with article 51 of Law 131 on state control over entrepreneurial activity. Accordingly, the Chief State Inspector must submit the reports on contraventions, drawn up by the state inspectors, to the courts for the examination and application of appropriate sanctions. NARNRA is not empowered to take enforcement actions without prior approval of the courts other than the sealing of a source or facility. The Law 132 allows for NARNRA inspectors to take immediate sealing of sources or facilities if there is an imminent likelihood of safety significant event. However, prior approval by the Chief State Inspector is required. Further, documentation must be submitted to the courts within two days of such actions for approval.

NARNRA has advised that recorded verbal notification, imposition of additional regulatory requirements and conditions, and written warnings are not permitted under the Law 132. **Related Recommendation, R13 on authorization conditions is provided in Section 5.1.**

Under the Decision No. 153, the State Inspectors may issue on the spot ‘prescriptions’ requiring the remedying of non-compliances by the authorized party. If, however, there is a disagreement between the State Inspector and the authorized party, the ‘prescription’ is sent via registered mail within 10 days of the inspection to the authorized party seeking remedying of non-compliances within one month. If the authorized party fails to cooperate and the non-compliance issue remains unresolved, the State Inspector is required to repeat this process for a second time. The continued non-compliance may be used as evidence for additional actions. This process and timeframe described in the regulation allows for non-compliances to continue unremedied. The IRRS review team suggests that this process could be reviewed and simplified in order to obtain more timely remedying of non-compliance’s.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Decision 153 under the Law has prescribed process and timeframes which allow non-compliances identified during inspections to continue unremedied for an extended period of time by the authorized party.	
(1)	BASIS: GSG-13 para 3.309 states <i>“The extent of the authority of regulatory inspectors to take immediate enforcement actions should be determined by the regulatory body, in accordance with the national legal framework and regulations ...”</i>
(2)	BASIS: GSG-13 para 3.310 states that <i>“... inspectors are empowered to implement immediate enforcement actions for non-compliances with regulatory requirements or violations of authorization conditions, to enable a more rapid response and improvement in safety. ...”</i>
S8	Suggestion: The Government should consider reviewing the process and timeframes prescribed under Decision 153 for remedying of non-compliances which are identified at the time of inspections, to be remedied in a timely manner.

NARNRA has advised that 25 penalties were applied during the last two years. There is a process for documenting and following-up to ensure that authorized parties rectify non-compliances. The IRRS team observed that record keeping is both electronic and paper based. The typical period allowed for rectification of non-compliance is 30 days. This however, may vary depending on the safety significance of non-compliance and feasibility for compliance. NARNRA has advised

the IRRS team that rectification of safety issues subject to enforcement are followed up by the inspectors. There have been no failures in this regard to report.

Despite the suspension or withdrawal of radiological authorization, authorized persons are bound by obligations under the Law 132 including any additional conditions resulting from the enforcement activity.

8.3. SUMMARY

NARNRA takes enforcement actions as required by the Law 132. NARNRA should develop and implement enforcement policy that considers safety significance of non-compliances applied in accordance with a graded approach. Such a policy would provide confidence that enforcement actions by a NARNRA inspector are appropriate and based on sound reasoning about the severity of non-compliance, which has the potential to impact on protection and safety.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

Law 132 together with Regulations issued by the Governmental Decisions (Decrees) and Orders of the Minister of Health, Labour and Social Protection and Orders issued by NARNRA compose the legislative framework covering activities and facilities. Main normative acts in the field of radiation safety are:

- Government Decree #458 of 24.07.2015 on approving the Regulation on the organization and functioning of the NARNRA the structure and its staff limit;
- Government Decree #54 of 24.01.2014 on approving of the modifications in GD no. 1017 of 1 September 2008 on the National Register of ionizing radiation sources and authorized physical and legal persons;
- Government Decision #153 of 28.02.2014 on approval of the Regulation on state control and supervision of nuclear and radiological activities, and nuclear non-proliferation regime;
- Government Decision #727 of 09.08.2014 on approving the Regulation on the authorization of nuclear and radiological activities;
- Government Decision #388 of 26.06.2009 on approving the Regulation on the management of radioactive waste, modified by Government Decision no. 31079 of 30.12.2013;
- Government Decision #434 of 16.06.2015 on approving the Regulation on the safe transport of radioactive materials;
- Government Decision #451 of 24.07.2015 on approving the Regulation on radiation protection, radiation safety in diagnostic radiology practices and interventional radiology;
- Government Decision #632 of 24.08.2011 on Radiation protection and radiological safety in radiotherapy practices;
- Government Decision #1210 of 03.11.2016 on Radiation protection and radiological safety in practices of nuclear medicine;
- Government Decision #608 of 03.07.2018 on radiological safety and protection in activity of unshielded facilities;
- Government Decision #1268 of 23.11.2016 on Security in nuclear and radiological activities;
- Fundamental Radioprotection Norms. Requirements and Hygienic Rules (FRPN-2000) - Order of the Minister of Health of 27.02.2001 – nonbinding;
- Guide on the procedure for organizing, conducting and finalizing the results of state control in the field of nuclear and radiological activities (NARNRA Order no. 19 of 28.11.2016);
- Guide on requirements submitted to operators for the implementation of quality control in roentgen diagnostic and check-list on quality control (NARNRA Order no. 04 of 18.04.2017);

- Regulation on requirements for ensuring radiological and nuclear safety in the collection, processing / treatment, conditioning and storage of solid radioactive waste (NARNRA Order no. 06 of 03.05.2017).

The IRRS team was informed that the following regulations are planned to be issued in the near future:

- The draft of Law on radiation safety based on IAEA GSR Part 3 and Council Directive 2013/59/EURATOM;
- Regulation on radiation protection in medical exposures;
- Regulation on environmental releases of radioactive material;
- Regulation on monitoring and recording of occupational exposure.

A formal process for issuing or review of regulatory requirements, including guides, is prescribed by Law 100. In accordance with the Law 132, for the purpose of consultation with interested parties and the public, all drafts and proposals are published on NARNRA’s website, with the announcement of the period of time for interested parties to provide their opinions or comments.

The fact that NARNRA is empowered to issue normative acts does not diminish the need for NARNRA to prepare and issue guides. Although these are legally non-binding documents, guides provide detailed guidance to the authorized persons on how to comply with the safety requirements. A limited number of guides for certain regulated areas has been developed. However, the majority of regulated areas, including guidance for applicants’ submittals, are still not covered with appropriate guides. For that purpose, NARNRA should draft and issue non-binding guides on how to comply with the safety requirements in all regulated areas.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: NARNRA has the legal power to propose and draft normative acts and approve non-binding guides. Approved guides developed by NARNRA to be used by applicants for authorization cover only a small part of regulated activities and facilities.	
(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 related information as specified in advance or as requested in the authorization process.”</i>
R22	Recommendation: NARNRA should draft and issue non-binding guides on how to comply with the safety requirements for all regulated activities and facilities.

9.2. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

The NSRAWM, together with the Action Plan was approved in 2017.

Regulation No. 388 does not include requirements for development of Waste Acceptance Criteria (WAC) based on a safety case.

In order to ensure subsequent management of radioactive waste, the storage facility for radioactive waste should be organized to easily inspect and monitor waste packages. Current

regulation does not contain adequate provision on inspection and monitoring of stored waste in order to ensure safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: There are no requirements to develop and implement Waste Acceptance Criteria based on a Safety Case, or for radioactive waste to be stored in a manner that it can be inspected, monitored, retrieved and preserved in a condition suitable for its subsequent management.</p>	
(1)	<p>BASIS: GSR Part 5 Requirement 12 states that <i>“Waste packages and unpackaged waste that are accepted for processing, storage and/or disposal shall conform to criteria that are consistent with the safety case. Para. 4.24: “Waste acceptance criteria have to be developed that specify the radiological, mechanical, physical, chemical and biological characteristics of waste packages and unpackaged waste that are to be processed, stored or disposed of; for example, their radionuclide content or activity limits, their heat output and the properties of the waste form and packaging.”</i></p>
(2)	<p>BASIS: GSR Part 5 Requirement 11 states that <i>“Waste shall be stored in such a manner that it can be inspected, monitored, retrieved and preserved in a condition suitable for its subsequent management....”</i></p>
R23	<p>Recommendation: NARNRA should establish requirements for operators to develop waste acceptance criteria and for storing of radioactive waste in storage facilities in such manner that it can be inspected, monitored, retrieved and preserved for subsequent management.</p>

Regulation No. 388 defines three classes of radioactive waste. This classification does not correspond with IAEA radioactive waste classification defined by GSG-1.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: Classification for radioactive waste exists but it is not in line with current IAEA Safety guides on radioactive waste classification.</p>	
(1)	<p>BASIS: GSR Part 5 Requirement 3 para 3.8 states that <i>“To facilitate compliance with regulatory requirements, the regulatory body has to do the following: ...” - Establish an appropriate definition and/or classification of radioactive waste.”</i></p>
(2)	<p>BASIS: GSG-1 para 2.2 states that <i>“In accordance with the approach outlined in the Appendix, six classes of waste are derived and used as the basis for the classification scheme ...”</i></p>
S9	<p>Suggestion: NARNRA should consider updating classification in accordance with IAEA safety guides on radioactive waste classification.</p>

Even though the NSRAWM defines disposal as a final destination for radioactive waste, there are no requirements for safe disposal. As one of the first activities for disposal of radioactive waste NARNRA should develop and implement requirements for safe disposal.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: The radioactive waste management strategy defines disposal as the end point for radioactive waste, but regulatory requirements have not been developed in Accordance of IAEA standards.</p>	
(1)	<p>BASIS: SSR Part 1 Requirement 2 states that <i>“The regulatory body shall establish regulatory requirements for the development of different types of disposal facility for radioactive waste and shall set out the procedures for meeting the requirements for the various stages of the licensing process. It shall also set conditions for the development, operation and closure of each individual disposal facility and shall carry out such activities as are necessary to ensure that the conditions are met.”</i></p>
R24	<p>Recommendation: NARNRA should develop and implement requirements for safe disposal of radioactive waste.</p>

9.3. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

Government Decisions No. 1017, 727 and 153 articulate the procedures for National Register, Permissive activities and Inspection activities (see Sections 3.7 and 9.1)

9.4. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

Decommissioning activity is covered by Law 132. and Regulation 388. (see Section 1.7). A number of requirements defined by IAEA GSR Part 6 are not established and development of a regulation on decommissioning is necessary.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: Requirements for safe decommissioning contained in regulations do not cover all aspects for safe decommissioning of facilities.</p>	
(1)	<p>BASIS: GSR Part 6 Requirement 5 states that <i>“The regulatory body shall regulate all aspects of decommissioning throughout all stages of the facility’s lifetime, from initial planning for decommissioning during the siting and design of the facility, to the completion of decommissioning actions and the termination of authorization for decommissioning. The regulatory body shall establish the safety requirements for decommissioning, including requirements for management of the resulting radioactive waste, and shall adopt associated regulations and guides. The regulatory body shall also take actions to ensure that the regulatory requirements are met.”</i></p>
R25	<p>Recommendation: NARNRA should further develop and implement safety requirements for safe decommissioning.</p>

9.5. REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE

Responsibilities of employers, registrants and authorized persons with regards to occupational exposure in planned as well as in existing exposure situations, and main principles of radiation protection (justification, optimization and dose limits) are set in:

- Fundamental Radioprotection Norms. Requirements and Hygienic Rules (FRPN-2000);
- Government Decision 1210 On radiation protection in nuclear medicine;
- Government Decision 451 On radiation protection in X-Ray practices in medicine;
- Government Decision 632 On radiation protection in radiotherapy;
- Government Decision 608 On radiation protection when working outside the specially designed premises;

The regulations listed above also set requirements on monitoring and recording of occupational exposure, cooperation between employers and authorized persons, compliance by workers, radiation protection programme, assessment of occupational exposure and workers' health surveillance, information, instruction and training of exposed workers and RPO, protection of female and under-age workers. Regulations require authorized persons not to offer benefits as substitutes for measures for protection and safety, exposure at working places due to existing exposure situation. However, there are some inconsistencies in the regulations on definitions, categorisation of the workers, classification of the areas, dose limits, maintenance of the records of occupational exposure, etc. The recommendation that is made in this Section is closely connected to the recommendation R2 that is provided in Section 1.2.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: There are regulations on radiation protection for various practices. However, there are some inconsistencies in the regulations on definitions, categorisation of the workers, classification of the areas, dose limits, maintenance of the records of occupational exposure, etc. This is part of NARNRA's Action Plan.

(1)	BASIS: GSR Part 3 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>
R26	Recommendation: NARNRA should review its regulations on radiation protection for various practices and revise them to be consistent with each other and GSR Part 3.

9.6. REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE

The Decisions #451, 1210 and 632 provide in detail measures for design, and operational considerations including quality assurance of facilities and activities. These are largely consistent with IAEA SSG 46 – Radiation Protection and Safety in Medical Uses of Ionising Radiation, however there are some gaps. For example, the need for radiopharmaceuticals to be manufactured according to good manufacturing practice, the need for medical equipment used for dental radiography to have a minimum tube potential of 60 kVp, etc. NARNRA should review and update the regulations to be fully consistent with SSG - 46 at the time of the next review, as appropriate. **Related recommendation R26 is provided in Section 9.5.**

9.7. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE

FRPN-2000 defines 1 mSv as an annual dose limit for population. The concept 10 μ Sv annual dose for high probability events and 1mSv annual dose for low probability events is not applied. Existing legal acts do not contain requirements for clearance as required by GSR Part 3. Regulation No. 388 defines a gamma dose rate of 1 μ Sv/h at 10cm distance from the surface of waste as clearance criteria. The site release criteria are not developed. Discharges of radionuclides to the environment are covered by several regulations. Regulation No. 388 has a special annex for discharges from radioactive waste facilities, but there are no requirements for or established dose constraints. Only Regulation 1210 on nuclear medicine (annex 13) contains specific activities (Bq/m³) for radionuclides that can be discharged.

Establishment and implementation of materials clearance criteria, levels, clearance procedure; site release requirements and procedure; dose constraints for public exposure is covered under **Recommendation R2 in Section 1.2.**

9.8. SUMMARY

The Law 132 concerning the safety and protection has been in force since 2012. Together with a set of regulations and orders it composes the legislative framework covering facilities and activities. Safety requirements for some activities are missing or are not in line with IAEA safety standards. In order to improve and update safety requirements in the national legal framework, recommendations are made for NARNRA to:

- Issue additional guidance;
- Revise radioactive waste safety regulations; develop and implement requirements for safe disposal of radioactive waste and for decommissioning;
- Review its regulations on radiation protection for various practices and make them consistent and in accordance with GSR Part 3.

The preliminary NARNRA Action plan foresees the establishment of a working group composed from NARNRA and relevant governmental institutions for drafting, review and amendments of the regulations in accordance with the international standards.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

According to the IAEA categorization of radiation-related hazards, the Republic of Moldova is currently a country with facilities and activities belonging to Emergency Preparedness Categories (EPC) III and IV.

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

NARNRA is established by the Law 132, which designates it as the regulatory body. Its regulatory mandate in the field of Emergency Preparedness and Response (EPR) for operating organizations (OO) can be concluded indirectly via the provisions stipulating EPR requirements for the OO. In general, the national system of EPR for any type of emergency has been built based on an all-hazards approach. The authority responsible for emergency management has its responsibilities defined in the Law 132, but those are not related to regulating the EPR. The responsibility for emergency management is at the General Inspectorate for Emergency Situations (GIES) within the Ministry of Internal Affairs. NARNRA implements its regulatory function in cooperation with GIES and this is formalized in a Memorandum of Understanding.

The authority to verify implementation of EPR regulations at OO is contained in the Law 132 and its secondary legislation, as well as in the civil protection legislation. This verification comprises (i) review and assessment of the EPR arrangements during the authorization process, (ii) inspections on EPR arrangements during operation and (iii) evaluating exercises conducted by the operating organizations.

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

The requirements for EPR for OOs are provided in the legislative framework, mainly in the Law 132 and in the Governmental Decisions (Decree), however it was found that the existing requirements have not been updated in line with international standards and some of the international standards requirements have not been addressed.

The IRRS team identified that the following areas, relevant to the OO, of the IAEA GSR Part 7, are not covered in the Law 132:

- Developing a hazard assessment by the OOs as a basis for a graded approach in establishing the on-site EPR, as well as revising OOs emergency arrangements prior to any changes in the facility or activity that affect the existing hazard assessment.
- The transition from normal operations to operations under emergency conditions, which includes declaration of an emergency and classification of the event,
- Taking mitigatory actions on-site,
- Assessing and foreseeing conditions initially and throughout the emergency and take necessary urgent protective actions to protect all persons present at the site in an emergency,
- Protection of the people on-site including OO staff, not part of the OO emergency response organization, in line with the protective actions' strategy,

- Protect emergency workers responding on the site,
- Communicate with the public effectively and consistently during an emergency,
- Managing radioactive waste generated in an emergency safely and effectively,
- Criteria and objectives to be met before the emergency on the site is terminated,
- Document and preserve data and information needed for analysis of the emergency response,
- Analyse the emergency and the emergency response to improve EPR arrangements (after emergency),
- Assignment of responsibilities in the on-site response organization, as well as assignment of responsibilities for preparedness in normal organizational structure,
- Ensuring coordination with other organizations during emergency response,
- Developing emergency plans, procedures and analytical tools for emergency response,
- Ensuring adequate communication means for on-site and off-site communication and equipment (tools, personal protection equipment, instruments), supplies, emergency response facilities and documentation,
- Developing and implementing training and exercise programmes;

There are several pieces of secondary legislation regulating mainly practices in the medical field. Some of these clearly define the content of the EPR plans for activities in question, while the others do not.

The updating of legislation in line with the above findings and in line with the graded approach would ensure a comprehensive and consistent approach to authorization requirements in the EPR area for all facilities and activities. Currently the EPR authorization provisions are inconsistently contained in different secondary legislation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The regulations and regulatory guides for on-site emergency preparedness and response of the OOs are not in line with the relevant GSR Part 7 requirements and gaps have been identified.	
(1)	BASIS: GSR Part 7 para 4.12 states that <i>“The regulatory body is required to establish or adopt regulations and guides These regulations and guides shall include principles, requirements and associated criteria for emergency preparedness and response for the operating organization (see also paras 1.12 and 4.5).”</i>
(2)	BASIS: GSR Part 7 para 4.5 states that <i>“The government shall make adequate preparations These preparations shall include adopting legislation and establishing regulations for effectively governing the preparedness and response for a nuclear or radiological emergency at all levels (see para. 1.12).”</i>
(3)	BASIS: GSR Part 7 para 1.12 states that <i>“These requirements are intended to be applied by the government at the national level by means of adopting legislation and establishing regulations, and by making other arrangements,</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<i>including assigning responsibilities (e.g. ... to the regulatory body) and verifying their effective fulfilment.</i>
(4)	BASIS: GSR Part 1 (Rev 1) para. 4.31 states that <i>“In the granting of an authorization for a facility or an activity, the regulatory body may have to impose limits, conditions and controls on the authorized party’s subsequent activities.”</i>
R27	Recommendation: The Government should develop and implement a comprehensive set of requirements addressing all the IAEA GSR Part 7 provisions relevant to the operating organizations.

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

NARNRA requires the EPR Plans of OOs in the authorization process. The evaluation of the OO’s emergency plans or instructions is in line with the requirements in regulations, which have been adopted for different activities.

The scope of inspection of EPR is contained in the inspector’s checklists, which are activity specific. For the time being NARNRA is in the process of revising those checklists to add a legal basis to each inspection item. These checklists are intended to be published in the Moldova Official Gazette.

NARNRA inspectors do inspect the EPR area and their findings and requirements are recorded in the inspection reports for further follow-up. Although there was a case when implementation of exercises was required, there are not any legal requirements that OOs shall implement exercises (see section 10.2). The OO did the exercise and reported about the findings. However, verification of OO EPR arrangements by exercises and their evaluation is not addressed in relevant NARNRA inspection planning documents.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no systematic verification of operation organization EPR arrangements by exercises.	
(1)	BASIS: GSR Part 7 para 6.30 states that <i>“The exercises shall be systematically evaluated (see para. 4.10(h)) and some exercises shall be evaluated by the regulatory body.”</i>
S10	Suggestion: NARNRA should consider implementing periodical verification of operating organization EPR arrangements by exercises.

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

The Statute defines the organizational structure of NARNRA. In this structure the responsibility for EPR is not designated, neither to the NARNRA unit nor to an individual. Additionally, the NARNRA roles during an emergency are not clearly defined. In discussion with NARNRA counterparts, the following NARNRA roles, based on experience from the past and existing regulatory requirements, can be identified:

- Intervention in case of emergencies, e.g. recovery of sources, a NARNRA mobile expert team (established in the framework of illicit trafficking) performs radiation measurements and assists in recovery. Transport and storage of the source is done by GIES.
- In case of emergencies requiring national response, the representative of NARNRA will become a member of the committee, which prepares draft decisions for the committee of ministers. The NARNRA representative receives support from NARNRA staff in the headquarters, but this has not been formalized by internal documents.

In addition, for interventions, which do not require activation of national level, NARNRA can act as advisor to off-site response and communicate with the public and these roles may be considered too.

The Law 132 defines the following GIES roles in the EPR area:

- coordination of the implementation of the provisions of the international conventions for notification of a nuclear accident, and assistance in the case of a nuclear or radiological accident;
- the IAEA contact point for early notification and assistance conventions;
- organizing the national network of environmental monitoring laboratories and collecting data from them.

Thus, these roles cannot be assigned to NARNRA.

NARNRA, in cooperation with the General Inspectorate of Border Police, Customs Service and GIES developed the Concept of Operation, which is aimed at illicit trafficking, as well as the pocket handbook for response in case of detection of radiation at the border posts. In this framework, NARNRA operates a mobile expert unit that can provide response in case of emergencies. However, NARNRA is not in a position of ensuring operation of this unit outside of working hours. This unit took part in identification and recovery of radioactive sources, as well as in remediation activities. In addition, this unit played in numerous exercises, organized within the illicit trafficking context, for search and identification of radioactive sources. Thus, it can be concluded that their members have the experience and expertise. However, the future role of the mobile expert team in response needs to be clarified. The IRRS team notes that NARNRA's role in illicit trafficking is undisputed and not within the scope of this mission.

The Republic of Moldova is a party to the early notification and assistance conventions and GIES has responsibility for their implementation.

NARNRA has been implementing systematic searches for radioactive sources in the Republic of Moldova since 2015. The main idea of this search is to identify and retrieve sources by tracking down the persons who were affiliated to installations or objects with radioactive sources. This is accomplished by sending them messages and questionnaires. Annually about 200-400 sources are discovered, mainly smoke detectors, but also sources with tens of GBq. However, this search may be aligned with the results of the national hazard assessment. The systematic measures need to be in place to search in places where there is a lot of transit (airports, seaports, border crossings) or scrap metal collection takes place, which can be enforced by requiring that measurements of radioactivity are taken at those places.

The finalization of the National Radiological Emergency Response Plan (quoted as “National First Response Plan in case of radiological urgencies”) is acknowledged by the team as one of the NARNRA Action Plan items, which are outside of the mission scope, but it is important for

the effective and efficient implementation of the recommendations and suggestions, which are within the scope of this mission.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: NARNRA does not have its tasks during an emergency clearly defined. Although there are some internal guidance documents and NARNRA has experience in response, NARNRA does not have its own emergency response plan and procedures.</p> <p>There is no dedicated unit or a clearly designated person for emergency preparedness in NARNRA.</p>	
(1)	<p>BASIS: IAEA GSR Part 7 para 6.17 states that <i>“Each response organization shall prepare an emergency plan or plans for coordinating and performing their assigned functions as specified in Section 5 and in accordance with the hazard assessment and the protection strategy.”</i></p>
(2)	<p>BASIS: GSR Part 7 para 6.12 states that <i>“Arrangements shall be developed, as appropriate, for the coordination of emergency preparedness and response and of protocols for operational interfaces between operating organizations and authorities at the local, regional and national levels.”</i></p>
(3)	<p>BASIS: GSR Part 7 para. 6.16 states that <i>“Plans, procedures and other arrangements for effective emergency response, including coordinating mechanisms, letters of agreement or legal instruments, shall be made for coordinating a national emergency response.”</i></p>
(4)	<p>BASIS: GSR Part 7 para 6.8 states that <i>“The positions responsible in each operating organization, in each response organization and in the regulatory body for the performance of activities at the preparedness stage, in accordance with these requirements, shall be assigned as part of the routine organizational structures and shall be specified, as appropriate, in the emergency plans and procedures.”</i></p>
R28	<p>Recommendation: NARNRA should define its tasks for all types of emergencies and prepare an internal emergency response and preparedness plan for coordinating and performing these tasks, as well as appropriate procedures.</p> <p>NARNRA should formalize responsibilities for EPR inside their routine organizational structure.</p>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: NARNRA operates the mobile expert team, which can be used for response to radiological emergencies. This is an important capability, but it cannot operate around-the-clock. For the time being, this unit lacks clear operational procedures (activation, staffing, operation and communication protocols, equipment lists, etc.).</p>	

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	BASIS: GSR Part 7 para 4.7 states that <i>“The government shall ensure that all roles and responsibilities for preparedness and response for a nuclear or radiological emergency are clearly allocated in advance among operating organizations, the regulatory body and response organizations.”</i>
S11	Suggestion: NARNRA should consider defining the role of the mobile expert team during emergencies and take appropriate steps based on this decision.

10.5. SUMMARY

A legislative framework is in place, which defines the regulatory mandate and responsibilities of NARNRA in the field of EPR. However, the existing legislative framework in the field of regulating EPR of operating organizations is not in line with the international standards, thus it should be amended and aligned with the IAEA GSR Part 7 requirements.

The operating organization EPR is verified during the authorization stage and with the inspection, however verification with periodic witnessing of exercises and their evaluation should be considered by NARNRA.

In spite of the fact that NARNRA has a large number of emergency response responsibilities and performs them with due responsibility, these tasks have not been clearly defined and agreed upon with other stakeholders. NARNRA needs to develop its internal EPR plan, which needs to be aligned with the national emergency response plan, which has not yet been fully developed to address, inter alia, NARNRA’s role and responsibilities.

NARNRA has the mobile expert team, which may be used in emergencies, Mobile expert team emergency response status has not been well defined and NARNRA needs to take decision and determine the future status of this team. While the team’s experience and expertise are valuable, its around-the-clock availability cannot be assured due to current fiscal constraints. Additionally, NARNRA has no positions in its routine organizational structure for emergency preparedness and this gap needs to be rectified.

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Vaidas STATKUS Giorgi NABAKHTIANI Uma RAMASAMY	Natalia VASILIEEVA Sergiu VIRLAN
INSPECTION	
Vaidas STATKUS Giorgi NABAKHTIANI Uma RAMASAMY	Vasile BENEĂ Serghei MOLDOVAN

ENFORCEMENT

Vaidas STATKUS
Giorgi NABAKHTIANI
Uma RAMASAMY

Vasile BENEĂ
Serghei MOLDOVAN

REGULATIONS AND GUIDES

Saša MEDAKOVIĆ

Ionel BALAN

EMERGENCY PREPAREDNESS AND RESPONSE

Igor GRASICAREV

Ion APOSTOL
Serghei MOLDOVAN

APPENDIX III MISSION PROGRAMME

MOLDOVA IRRS MISSION PROGRAMME 9 to 19 December 2018		
Sunday 9 December 2018		
IRRS Initial IRRS Review Team Meeting		
13:00 - 18:30	<p>Opening remarks by the IRRS Team Leader</p> <p>IRRS Team Members - Self-introduction: <i>Each team member to give a brief statement of their careers and current responsibilities (2 min each)</i></p> <p>Presentation of the IRRS Process and Guidance for Reporting (TC)</p> <p>Review of Mission Schedule (TC, LO) Logistical Arrangements (LO)</p> <p>Report of Initial Review of Advance Reference Material: <i>Reviewers to briefly present (10 min each) their initial impressions of the advance reference material. This is also an opportunity to raise any initial concerns or specific requests for clarification with the liaison officer.</i></p> <p><i>The order of the presentations is that of IRRS Modules</i></p> <p>Closing Remarks/Questions Preparation for daily Interviews: <i>(The team members may continue working in their subject areas, after the closure of the meeting, to agree upon their approach for conducting the interviews)</i></p>	<p>Venue: Aria Hotel meeting room</p> <p>Participants: the IRRS Team + the LO</p>

MOLDOVA IRRS MISSION PROGRAMME 9 TO 19 DECEMBER 2018

Monday 10 December 2018

IRRS Entrance Meeting

09:00 – 12:00	09:00 Arrival, registration, coffee 09:15 Welcoming Address by the Hosts 09:30 Expectations for the Mission and introduction of the IRRS Team by Dan Collins (Team Leader) 09:45 Introduction of the Main Moldova Counterparts by Liaison Officer 10:15 Regulatory Overview, Self-assessment results by LO 10:45 Group photo 11:00 Moving to NARNRA	Venue: NARNRA Participants: Government Official, NARNRA Management and staff, Officials from relevant organizations, the IRRS Team + the LO
11:30 – 17:00	Interviews and Discussions with Counterparts (parallel discussions) with the break for standing lunch from 12:00 to 13:00	Venue: NARNRA, IRRS interviews schedule Participants: IRRS Team + Counterparts
17:30 - 18:00	Daily IRRS Review Team meeting	Venue: ARIA Hotel meeting room Participants: the IRRS Team + the LO
18:30 -	Writing the report	IRRS Team

Tuesday 11 December 2018

Daily Discussions / Interviews

09:00 – 17:00	Interviews and Discussions with Counterparts (parallel discussions)	Location NARNRA Participants: IRRS Team Reviewers + Counterparts
12:00 – 13:00	Lunch	

MOLDOVA IRRS MISSION PROGRAMME 9 TO 19 DECEMBER 2018		
13:00 – 16:00	Meeting with Government officials TL, TC, M1-3 reviewers	Venue: according to the Governmental officials meeting schedule Participants: IRRS TL, TC Reviewer Modules 1,2, and 3
17:30 – 18:00	Daily IRRS Review Team meeting. Preliminary findings discussions	Venue: ARIA Hotel meeting room Participants: the IRRS Team + the LO
18:30-	Writing the report	IRRS Team
Wednesday 12 December 2018		
Daily Discussions / Interviews		
09:00 – 12:00	Interviews	Venue: NARNRA
09:00 – 15:00	Site Visits to observe inspection of RS medical facility	NARNRA Inspectors and IRRS Team Members for Modules 5-9 for sources
12:00 – 13:00	Lunch	
13:00 – 16:00	Writing first draft of preliminary findings (Rs, Ss and GPs)	Venue: NARNRA IRRS Team
16:00 – 17:00	Deliver First draft of written preliminary finding Rs, Ss and GPs to be compiled to report	
17:30 – 18:00 extended as needed	Quick briefing on site visits Daily IRRS Review Team meeting: discussion of findings (Rs, Ss and GPs)	Venue: ARIA Hotel meeting room
18:30 -	Writing the report	
Thursday 13 December 2018 2018		
Daily Discussions / Interviews		
9:00 -16:00 extended as needed	Follow-up Interviews and Discussions with Counterparts (parallel discussions), as appropriate	Venue: NARNRA Participants: the IRRS Team

MOLDOVA IRRS MISSION PROGRAMME 9 TO 19 DECEMBER 2018		
09:00 – 15:00	Site Visits to RW facility medical facility	Inspectors and IRRS Team
12:00 – 13:00	Lunch	
17:30 – 18:30 extended as needed	Daily Team Meeting: Briefing from site visits Discussion of findings – feedback from discussion with Counterparts	Venue: ARIA Hotel meeting room Participants: IRRS Team + the LO.
Friday 14 December 2018		
Daily Discussions / Interviews		
09:00 – 12:00	Follow up interviews and discussion of the report text with counterparts	Venue: NARNRA Participants: IRRS Team
09:00 – 12:00	AA and TC writers introductory part	TC + AA
12:00 -13:00	Lunch	
13:00 – 14:00	Report preparation	IRRS Team
14:00 – 16:00	Policy issue discussion:	Venue: NARNRA Participants: Reviewers and Counterparts
17:30 – 18:00 Extended as needed	Daily Team Meeting: Finalization of the “boxes”: observations, basis, R/S/GP	Venue: ARIA Hotel meeting room Participants: IRRS Team + LO
Saturday 15 December 2018		
Report finalization		
09:00 – 11:00	Individual report inputs finalizing and submission to AA	Venue: ARIA Hotel meeting room IRRS Team
11:00 – 12:00	AA complies the report	
12:00 – 13:00	Lunch	
13:00 – 18:00	Cross reading and report editing	
18:00 –	TI, TC and AA continue to edit the report	

MOLDOVA IRRS MISSION PROGRAMME 9 TO 19 DECEMBER 2018

Sunday 16 December 2018

09:00	IRRS Team rest day and Social Event	
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Monday 17 December 2018

Report commenting and discussions

09:00 – 11:00	TL, TC, AA and ‘editors’ finalise the report	Venue: ARIA Hotel meeting room
11:00	Submission of draft report to NARNRA	
12:00 – 13:00	Lunch	
13:00 – 18:00	Tl, TC draft executive summary	

Tuesday 18 December 2018

Report reviewing and finalization

09:00 – 11:00	TL, TC draft exit presentation and coordinate press release preparation	Venue: NARNRA
11:00 – 12:00	NARNRA submits written comments IRRS Team reviews NARNRA comments individually	
12:00- 13:00	Lunch	
13:00- 16:00	IRRS team revises report online	
16:00 – 18:00	Discussion with Hosts on findings, if required	
18:00 – 20:00	Report editing and executive summary finalization IAEA official briefing	

Wednesday 19 December 2018

IRRS exit meeting

MOLDOVA IRRS MISSION PROGRAMME 9 TO 19 DECEMBER 2018

9:00 -11:00	<ul style="list-style-type: none">• Main findings of the IRRS mission (Team Leader)• Remarks by NARNRA in response to the mission findings• Closing remarks by IAEA Official (Director NSRW) IAEA press release	Venue: ARIA Hotel Participants: Government officials, NARNRA management and staff, officials from relevant organizations, the IRRS Team + LO
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APPENDIX IV SITE VISITS

1. Oncological Institute of the Republic of Moldova
2. Special Facilities 5101, 5102. (National Radioactive Waste Management Company)

APPENDIX V RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1.	RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	R1	<p>The Government should ensure that the national policy and strategy for safety takes due account of:</p> <ul style="list-style-type: none"> • The promotion of leadership and management for safety; • The need and provision for human and financial resources; • The provision and framework for research and development. <p>The Government should ensure that the policy and strategy for safety is implemented in accordance with a graded approach.</p>
		R2	<p>The Government should, working with NARNRA and as a matter of urgency, establish national Basic Safety Standards and legal requirements on education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety; on the formal recognition of qualified experts; and on competence of organizations that have responsibilities relating to protection and safety.</p>
		R3	<p>The Government should ensure that NARNRA is provided with sufficient human and financial resources to effectively perform its functions and to discharge its responsibilities.</p>
		R4	<p>The Government should ensure that clear allocation of responsibilities and formal coordination arrangements are established between NARNRA and the Ministry of Health, Labour and Social Protection.</p>

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R5	The Government should establish and implement an effective system for identifying and reducing unregulated radiation risks.
		S1	The Government should consider formalizing the existing arrangements regarding recovery of orphan radioactive sources and protective actions in case of contamination of areas by residual radioactive material.
2.	THE GLOBAL SAFETY REGIME	R6	The Government should fulfil international obligations by participation in relevant review meetings.
		R7	The Government should establish requirements and criteria for reporting of operating events by authorized persons. NARNRA should establish a system for analysing events and disseminating the lessons learned within the country and internationally.
3.	RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	S2	The Ministry of Agriculture, Regional Development and Environment should consider strengthening legal support to NARNRA in developing and promulgating legal and regulatory requirements and internal procedures, as well as providing legal advice in the authorization and enforcement processes.
		R8	NARNRA should develop and implement a human resources plan. NARNRA should also establish a specific training programme, which is based on analysis of the necessary competence and skills.
		R9	The Government, should ensure that NARNRA is provided with access to technical or other expert professional advice, as necessary.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		S3	The Ministry of Health, Labour and Social Protection should consider establishing a national dose register and provide access to this register to NARNRA.
4.	MANAGEMENT SYSTEM OF THE REGULATORY BODY	R10	NARNRA senior management should develop and establish a safety policy in line with IAEA safety standards and the needs and expectations of interested parties.
		S4	NARNRA should consider identifying interested parties for their organization and formalize an appropriate strategy for interaction with them.
		R11	NARNRA should develop and document an Integrated Management System, with priority on core processes.
5.	AUTHORIZATION	R12	The Government should ensure that all facilities and activities that are not either explicitly exempted or approved by means of a notification process are subject to and are authorized.
		R13	NARNRA should grant authorizations for a facility or an activity by: <ul style="list-style-type: none"> • imposing appropriate limits, conditions and controls necessary for safety on the authorized party's subsequent activities; and • verifying competence of individuals having responsibilities for the safety of authorized facilities and activities.
		R14	The Government should ensure that sources and practices that present lowest radiation risks are exempted from regulatory control.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R15	The Government should ensure that the extent of regulatory control incorporates notification alone for low risk facilities and activities, and categorised requirements for the authorization process which is commensurate with the radiation risks associated with facilities and activities.
		S5	NARNRA should consider revising the authorization process and implementing measures for optimising available resources in a manner commensurate with the radiation risks associated with facilities and activities.
		R16	NARNRA should develop and implement requirements for operators to conduct and submit Safety Case and conducting of its supportive Safety Assessment for radioactive waste management.
		S6	NARNRA should consider developing internal procedures for implementation Guidance on the Import and Export of Radioactive Sources.
		R17	The Ministry for Health, Labour and Social Protection should ensure that referral guidelines for medical imaging procedures, including image guided interventional procedures, are developed and made available to referring medical practitioners to comply with the justification requirements in the national legislation.
6.	REVIEW AND ASSESSMENT	R18	NARNRA should require the responsible person or organization to submit a safety assessment as part of the application for authorization, commensurate with the radiation risks associated with the facility or activity.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		S7	NARNRA should consider ensuring that there is feedback of results from inspections and reviews and assessments of facilities and activities to ensure an integrated safety assessment as part of regulatory process, in accordance with a graded approach.
7.	INSPECTION	R19	The Government should ensure: that planned unannounced inspections are carried out as appropriate; and that NARNRA has authority to carry out independent unannounced inspections.
		R20	The NARNRA should stipulate the frequency of inspections in accordance with a graded approach.
8.	ENFORCEMENT	R21	NARNRA should establish and implement an enforcement policy which incorporates criteria for enforcement actions on the basis of safety significance of non-compliance in accordance with a graded approach.
		S8	The Government should consider reviewing the process and timeframes prescribed under Decision 153 for remedying of non-compliances which are identified at the time of inspections, to be remedied in a timely manner.
9.	REGULATION AND GUIDES	R22	NARNRA should draft and issue non-binding guides on how to comply with the safety requirements for all regulated activities and facilities.
		R23	NARNRA should establish requirements for operators to develop waste acceptance criteria and for storing of radioactive waste in storage facilities in such manner that it can be inspected, monitored, retrieved and preserved for subsequent management.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		S9	NARNRA should consider updating classification in accordance with IAEA safety guides on radioactive waste classification.
		R24	NARNRA should develop and implement requirements for safe disposal of radioactive waste.
		R25	NARNRA should further develop and implement safety requirements for safe decommissioning.
		R26	NARNRA should review its regulations on radiation protection for various practices and revise them to be consistent with each other and GSR Part 3.
10.	EMERGENCY PREPAREDNESS AND RESPONSE	R27	The Government should develop and implement a comprehensive set of requirements addressing all the IAEA GSR Part 7 provisions relevant to the operating organizations.
		S10	NARNRA should consider implementing periodical verification of operating organization EPR arrangements by exercises.
		R28	NARNRA should define its tasks for all types of emergencies and prepare an internal emergency response and preparedness plan for coordinating and performing these tasks, as well as appropriate procedures. NARNRA should formalize responsibilities for EPR inside their routine organizational structure.
		S11	NARNRA should consider defining the role of the mobile expert team during emergencies and take appropriate steps based on this decision.

APPENDIX VI REFERENCE MATERIAL USED FOR THE REVIEW

LIST OF ADVANCE REFERENC MATERIAL	
1.	2017-2026 National Strategy on Radioactive Waste Management, approved by Law no. 68 of 13.04.2017 (Published: 23.06.2017 in Official Gazette no. 201-213 art no: 332) (in English, Russian and Romanian)
2.	Action Plan for the Implementation of the provisions of the 2017-2026 National Strategy on the Radioactive Waste Management, approved by Law no. 68 of 13.04.2017 (Published: 23.06.2017 in Official Gazette no. 201-213 art no: 332) (in English, Russian and Romanian)
3.	Regulation on the National Register of Ionizing Radiation Sources and Authorized Physical and Legal Persons, approved by Government Decision no. 1017 of 01.09.2008 (Published: 09.09.2008 in Official Gazette no. 169-170 art. no: 1025) (in English, Russian and Romanian)
4.	Regulation on security for nuclear and radiological activities, approved by Government Decision no. 1286 of 23.11.2016 (Published: 29.11.2016 in Official Gazette no. 415 art. no: 1375) (in English, Russian and Romanian)
5.	Regulations on State Control and Supervision of Nuclear and Radiological Activities and the Non-Proliferation Regime of Nuclear Weapons, approved by Government Decision no. 153 of 28.02.2014 (Published: 21.03.2014 in Official Gazette no. 66-71 art. no: 195) (in English, Russian and Romanian)
6.	Regulation on the Management of Radioactive Waste, approved by Government Decision no. 388 of 26.06.2009 (Published: 10.07.2009 in the Official Gazette no. 110-111 art. no: 456) (in English, Russian and Romanian)
7.	Regulation for the Safe Transport of Radioactive Material, approved by Government Decision no .434 of 16.07.2015 (Published: 24.07.2015 in the Official Gazette no. 190-196 art no: 491) (in English, Russian and Romanian)
8.	Regulation on radiation protection, radiation safety in diagnostic radiology and interventional radiology practices, approved by Government Decision no. 451 of 24.07.2015 (Published: 31.07.2015 in the Official Gazette no. 197-205 art no: 515) (in English, Russian and Romanian)
9.	Sanitary Regulations on Radioprotection and Radiological Safety in the Practice of Nuclear Medicine, approved by Government Decision no. 1210 of 03.11.2016 (Published: 11.11.2016 in the Official Gazette no. 388-398 art. no: 1309 (in English, Russian and Romanian)
10.	Sanitary Regulations regarding Radioprotection and Radiological Safety in Radiotherapy Practices, approved by Government Decision no. 632 of 24.08.2011 (Published: 06.09.2011 in Official Gazette no. 147 art. no. 711 Date of entry into force: 05.10.2011) (in English, Russian and Romanian)

LIST OF ADVANCE REFERENC MATERIAL	
11.	General Methodology for Planning the State Control over the Entrepreneurial Activity, based on the analysis of the risk criteria, approved by Government Decision no. 694 of 05.09.2013 (Published: 13.09.2013 in the official Gazette No. 198-204 art. no: 796) (in English, Russian and Romanian)
12.	Regulation on authorization of nuclear and radiological activities, approved by Government Decision no. 727 of 08.09.2014 (Published: 12.09.2014 in Official Gazette no. 270-274 art. no. 778) (in English, Russian and Romanian)
13.	Law no. 132 of 08.06.2012 on the Safe Conduct of Nuclear and Radiological Activities, approved by the Parliament (Published: 02.11.2012 in the Official Gazette no. 229-233 art. no: 739) (in English, Russian and Romanian)
14.	Regulation on the organization and functioning of the National Regulatory Agency of Nuclear and Radiological Activities, the structure and its effective – limit, approved by Government Decision no. 458 of 24 July 2015 (Published: 31.07.2015 in Official Gazette No. 197-205 art no: 522) (in English, Russian and Romanian)
15.	Regulation on the classification of emergency situations and the procedure for the collection and submission of information in the field of protection of the population and territory in the event of emergency situations, approved by Government Decision no. 1076 of 16.11.2010 (Published: 19.11.2010 in Official Gazette no. 227-230 art no: 1191) (in Russian)
16.	Law no. 100 of 22.12.2017 on normative acts, approved by the Parliament (Published: 12.01.2018 in the Official Gazette No. 7-17) (in Russian)
17.	Law no. 235 of 20.07.2006 on the basic principles of regulation of entrepreneurial activity, approved by the Parliament (Published: 11.08.2006 in the Official Gazette no. 126-130) (in Russian)
18.	Law no. 10-XVI of 03.02.2009 on State Public Health Supervision, approved by the Parliament (Published: 03.04.2009 in the Official Gazette no. 67/183) (in Russian)
19.	Memorandum of Cooperation between the NARNRA and CNCAN (in Romanian)
20.	Collaboration Agreement between The European (Atomic Energy) Community and NARNRA
21.	Implementing Agreement between NARNRA and Department of Defence of the United States of America
22.	Memorandum of Understanding between the Ministry of Environment of the Republic of Moldova, Represented by the National Agency for Regulation of Nuclear and Radiological Activity and the State Nuclear Regulatory

LIST OF ADVANCE REFERENEC MATERIAL

	Inspectorate of Ukraine on Co-Operation in Radiation and Nuclear Safety and Security
23.	Advanced Reference Material
24.	SARIS Report

APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1. INTERNATIONAL ATOMIC ENERGY AGENCY - Fundamental Safety Principles, Safety Fundamentals No. SF-1, IAEA, Vienna (2006)
2. INTERNATIONAL ATOMIC ENERGY AGENCY - Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements Part 1(Rev 1), IAEA, Vienna (2016)
3. INTERNATIONAL ATOMIC ENERGY AGENCY- Leadership and Management for Safety, General Safety Requirements 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, Vienna, (2014)
5. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety Assessment for Facilities and Activities, General Safety Requirements Part 4 (Rev 1), IAEA, Vienna (2016)
6. INTERNATIONAL ATOMIC ENERGY AGENCY – Predisposal Management of Radioactive Waste General Safety Requirements Part 5, IAEA, Vienna (2009)
7. INTERNATIONAL ATOMIC ENERGY AGENCY – Decommissioning of Facilities General Safety Requirement Part 6, No. GSR Part 6, IAEA, Vienna (2014)
8. INTERNATIONAL ATOMIC ENERGY AGENCY – Preparedness and Response for a Nuclear or Radiological Emergency General Safety Requirements Part 7, IAEA, Vienna (2015)
9. INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Research Reactors, Specific Safety Requirements No. SSR-3, IAEA, Vienna (2017)
10. INTERNATIONAL ATOMIC ENERGY AGENCY - Disposal of Radioactive Waste Specific Safety Requirements No. SSR-5, IAEA, Vienna (2011)
11. INTERNATIONAL ATOMIC ENERGY AGENCY– Assessment of Occupational Exposure Due to Intake of Radionuclides Safety Guide Series No. RS-G-1.2, IAEA, Vienna (1999)
12. INTERNATIONAL ATOMIC ENERGY AGENCY - Assessment of Occupational Exposure Due to External Sources of Radiation Safety Guide Series No. RS-G-1.3, IAEA, Vienna (1999)
13. INTERNATIONAL ATOMIC ENERGY AGENCY - Building Competence in Radiation Protection and the Safe Use of Radiation Sources, Safety Guide Series No. RS-G-1.4, IAEA, Vienna (2001)
14. INTERNATIONAL ATOMIC ENERGY AGENCY – Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)
15. INTERNATIONAL ATOMIC ENERGY AGENCY – Application of the Management System for Facilities and Activities GS-G 3.1 (2006)
16. INTERNATIONAL ATOMIC ENERGY AGENCY – Regulatory Control of Radioactive Discharge to the Environment, Safety Guide Series No. WS-G-2.3, IAEA, Vienna (2000)
17. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No. WS-G.5.2, IAEA, Vienna (2009)

APPENDIX VIII ORGANIZATION CHART

Structure of the National Agency for Regulation of Nuclear and Radiological Activities

