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# INTEGRATED REGULATORY REVIEW SERVICE (IRRS) FOLLOW-UP MISSION

TO

#### Armenia

Yerevan, Armenia

11 to 17 June 2019

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY







## INTEGRATED REGULATORY REVIEW SERVICE (IRRS) FOLLOW-UP REPORT TO ARMENIA





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#### **ARMENIA**

Mission dates:	11 to 17 June 2019
Regulatory body visited:	Armenian Nuclear Regulatory Authority (ANRA)
Location:	Tigran Mets 4; Yerevan, Armenia
Regulated facilities and	Armenian Nuclear Power Plant; Waste Storage Facility; Dry Spent Fuel
activities in the mission scope:	Storage Facility; National Centre of Oncology; Radiation Sources in
	Industrial Facilities.
Organized by:	International Atomic Energy Agency (IAEA)

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The number of rec	commendations, suggest	ions and good practic	es is in no way a measure
of the status of the	regulatory body. Compantries should not be atte		ers between IRRS reports
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#### **EXECUTIVE SUMMARY**

At the request of the Government of Armenia, an international team of senior safety experts met representatives of the Armenia Nuclear Regulatory Authority (ANRA) from 11 to 17 June 2019 to conduct an Integrated Regulatory Review Service (IRRS) follow-up mission. The mission took place at ANRA Headquarters in Yerevan.

The purpose of the IRRS follow-up mission was to review Armenia's progress against the recommendations and suggestions identified in the initial IRRS mission which was carried out from 31 May to 12 June 2015. The scope of the IRRS follow-up mission was the same as the scope of the 2015 mission.

The IRRS team consisted of nine senior regulatory experts from nine IAEA Member States, two IAEA staff members and one IAEA administrative assistant.

The IRRS team carried out a review of the progress made on each recommendation and suggestion that is documented in the 2015 IRRS mission report related to the following areas: responsibilities and functions of the government; the global safety regime; responsibilities and functions of the regulatory body; management system of the regulatory body; the activities of the regulatory body including authorization, review and assessment, inspection, enforcement and development and content of regulations and guides; emergency preparedness and response; control of medical exposure, occupational radiation protection; control of radioactive discharges and materials for clearance; environmental monitoring; control of chronic exposures, transport of radioactive materials, and interface with nuclear security.

In preparation for the mission, the IRRS team reviewed the advance reference materials including ANRA's self-assessment. During the IRRS mission, the IRRS team interacted with their counterparts in ANRA and ANRA's Technical and Scientific Support Organization, the Nuclear and Radiation Safety Centre (NRSC), to develop additional understanding and insights regarding the status of the Armenian programme, particularly in relation to the progress made to address the recommendations and suggestions from the 2015 mission. These peer-to-peer interactions were beneficial to all involved because of the opportunity to share ideas and experience in implementing the IAEA standards as a benchmark for nuclear and radiation safety.

Throughout the mission, the IRRS team received the full cooperation in regulatory and technical areas by all parties. In particular, the staff of ANRA and NRSC provided excellent assistance and demonstrated extensive openness and transparency.

Nuclear power contributes significantly to the electricity generation in Armenia. Armenia is currently waiting for the government's decision on the construction of a new NPP.

The IRRS team recognized that ANRA has used efficiently its limited human resources to make substantial progress in several areas, in particular the elaboration of a policy and a corresponding strategy for safety, the adoption of a strategy for spent fuel and radioactive waste management, and emergency preparedness and response.

The IRRS team acknowledged that ANRA faces many challenges in regulating nuclear safety, in particular the lifetime extension of the Armenia Nuclear Power Plant (ANPP) unit 2, which ANRA has granted until 2021 with envisaged updates in steps of 5 years. This makes lifetime extension a continuous process. The Government of Armenia required ANRA and the ANPP to join the EU initiative related to conduct of stress tests. ANRA drafted a corresponding National Action Plan based on the findings of the international peer review. ANPP submits periodical status reports to ANRA on the implementation of the National Action Plan.

A major challenge for ANRA, and also for its technical support organization NRSC, is the critical human resource situation. As a consequence, several recommendations and suggestions could not be closed, for example, in the various areas related to exposure situations. The shortage of competent personnel facing ANRA and NRSC, due to their employee benefits packages not being competitive to recruit and retain suitably qualified and experienced staff, needs to be addressed urgently.

After the adoption of the new Constitution on 6 December 2015, Armenia is in the midst of a comprehensive legislative revision process, including the new Atomic Law. Some recommendations and suggestions from the 2015 mission could therefore not be closed at this time.

18 out of 35 recommendation and 13 out of 27 suggestions identified in 2015 have been closed. During the follow-up mission, the IRRS team provided Armenia with 1 new recommendation and 1 new suggestion, both related to the management system of ANRA.

At the end of the mission an IAEA press release was issued.

#### I. INTRODUCTION

At the request of the Government of Armenia, an international team of senior safety experts met representatives of the Armenian Nuclear Regulatory Authority (ANRA) from 11 to 17 June 2019 to conduct an Integrated Regulatory Review Service (IRRS) follow-up mission. The purpose of the follow-up mission was to review the implementation of the recommendations and suggestions given to the Government of Armenia during the IRRS Mission in June 2015. The follow-up mission was formally requested by the Government of Armenia in May 2018. A preparatory meeting was conducted on 11 December 2018 at ANRA's Headquarters in Yerevan to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in Armenia and related safety aspects.

The IRRS team consisted of nine senior regulatory experts from nine IAEA Member States, two IAEA staff members and one IAEA administrative assistant. The IRRS team carried out the review in the areas covered by the initial mission in June 2015.

Armenia prepared a self-assessment follow-up report addressing the findings of the initial mission. This report and supporting documentation were provided to the IRRS team as advance reference material (ARM) for the mission. During the mission, the IRRS team performed a systematic review of all topics by reviewing the advance reference material, additional information provided, and by conducting interviews with management and staff of ANRA. The IRRS team met also with the Nuclear and Radiation Safety Centre (NRSC) representatives to discuss the topics related to the technical support it provides to ANRA.

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

#### II. OBJECTIVE AND SCOPE

The purpose of this Integrated Regulatory Review Service (IRRS) follow-up mission was to conduct a review of the implementation of the recommendations and suggestions given to the Government of Armenia during the IRRS Mission in June 2015 and to exchange information and experience in the areas covered by the IRRS. The IRRS follow-up review scope included all facilities and activities regulated in Armenia by ANRA. The review was carried out by comparison of existing arrangements against the IAEA safety standards.

It is expected that the IRRS follow-up mission will facilitate regulatory improvements in Armenia and other Member States from the knowledge gained and experiences shared between Armenian Counterparts and IRRS reviewers, and through the evaluation of the effectiveness of Armenia's regulatory framework for nuclear and radiation safety.

#### III. BASIS FOR REVIEW

#### A) Preparatory work and IRRS team

At the request of the Government of Armenia, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) follow-up mission was conducted at ANRA's Headquarters in Yerevan, Armenia, on 11 December 2018. The preparatory meeting was carried out by the appointed Team Leader Mr Hans Wanner, the Deputy Team Leader Mr Fred Brown, and IAEA representatives Mr Jean-René Jubin and Mr Teodros Hailu.

The IRRS follow-up mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of ANRA represented by Mr Ashot Martirosyan, Chairman of ANRA, other senior management and staff of ANRA and representatives of NRSC. The discussions resulted in agreement that the regulatory functions covering the following facilities and activities were to be reviewed by the IRRS follow-up mission:

- Nuclear power plants;
- Radiation sources facilities and activities;
- Fuel cycle facilities
- Waste management facilities;
- Decommissioning;
- Transport of radioactive materials;
- Medical exposures;
- Occupational radiation protection;
- Control of radioactive discharges, materials for clearance;
- Environmental monitoring for public radiation protection, and existing exposure situations;
- Emergency preparedness and response;
- Interfaces with nuclear security.

Presentations were made on the national context, the current status of the regulatory body and the progress made since the initial mission of June 2015.

IAEA staff presented the IRRS principles, process and methodology of conducting a follow-up IRRS mission. This was followed by a discussion on the tentative work plan for the implementation of the follow-up mission in Armenia in June 2019.

The proposed IRRS follow-up review team composition (senior regulators from Member States to be involved in the review) was discussed and the size of the IRRS team was tentatively confirmed. Logistics including meeting and work space, counterparts and Liaison Officer identification, lodging and transport arrangements were also addressed.

The Armenian Liaison Officer for the preparatory meeting and the IRRS follow-up mission was Ms Anna Melkumyan from ANRA.

The Terms of Reference (TOR) of the IRRS follow up mission were discussed and agreed at the end of the preparatory meeting.

Armenia provided the IAEA and the IRRS with the advance reference material for the review in April 2019. In preparation for the mission, the IRRS team members conducted a review of the advance reference material and provided their initial review comments to the IAEA Team Coordinator and Team Leader prior to the follow-up mission.

#### B) Reference for the review

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

#### C) Conduct of the review

An initial IRRS follow-up review team meeting was conducted on Monday 10 June, in Yerevan by the Team Leader and the IAEA Team Coordinator to discuss the general overview, the focus areas and specific issues of the mission, to clarify the basis for the review and the background and objectives of the IRRS and to agree on the methodology for the review and the evaluation among all reviewers. They also presented the agenda for the mission. The Liaison Officer Ms Anna Melkumyan was present at the initial IRRS team meeting, in accordance with the IRRS guidelines, and presented logistical arrangements planned for the mission.

The reviewers reported their first impressions of the Advance Reference Material (ARM) and progress made by Armenia to address the recommendations and suggestions formulated in 2015.

The IRRS follow-up entrance meeting was held on Tuesday 11 June 2019, with the participation of ANRA, and NRSC senior management and staff. Opening remarks were delivered by Mr Ashot Martirosyan, Chairman of ANRA and Mr Hans Wanner, IRRS Team Leader. An overview on of the nuclear and radiation safety regulation in Armenia and the major changes since 2015 were presented. ANRA also made a presentation on the follow-up self-assessment that was conducted and the main conclusions drawn from it.

During the mission, a review was conducted for all the mission scope areas with the objective of reviewing the Armenian response to the recommendations and suggestions identified during the initial mission. The review was conducted through meetings, interviews and discussions regarding the national practices and activities.

The IRRS team performed its activities based on the mission programme given in Appendix II.

The IRRS follow-up exit meeting was held on Monday, 17 June 2019. The opening remarks were made by Mr Ashot Martirosyan, Chairman of ANRA. Then, the IRRS Team Leader, Mr Hans Wanner, presented the results of the IRRS follow-up mission highlighting the main findings. Closing remarks were delivered by Grzegorz Rzentkowski IAEA Director, Division of Nuclear Installation Safety.

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

#### 1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

#### 1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

#### 2015 MISSION RECOMMENDATIONS, SUGGESTIONS

**Observation:** Explicit national safety policy and corresponding strategy are not in place that would reflect the existing situation and development plans for use of nuclear energy and ionising radiation in

	including plans for new nuclear plant unit) and that would express the long term commitment f the government.
	BASIS: GSR Part 1 Requirement 1, para. 2.3 states that "The national policy and strategy for safety shall express a long term commitment to safety. The national policy shall be promulgated as a statement of the government's intent. The strategy shall set out the mechanisms for implementing the national policy. In the national policy and strategy, account shall be taken of the following: []
(1)	<ul> <li>(c) The specification of the scope of the governmental, legal and regulatory framework for safety;</li> <li>(d) The need and provision for human and financial resources;</li> <li>(e) The provision and framework for research and development;</li> <li>(f) Adequate mechanisms for taking account of social and economic developments;</li> <li>(g) The promotion of leadership and management for safety, including safety culture."</li> </ul>
(2)	BASIS: GSR Part 1 Requirement 1, para. 2.4 states that "The national policy and strategy for safety shall be implemented in accordance with a graded approach, depending on national circumstances, to ensure that the radiation risks associated with facilities and activities, including activities involving the use of radiation sources, receive appropriate attention by the government or by the regulatory body."
R1	<b>Recommendation:</b> The Government should promulgate a policy and corresponding strategy for safety with all the elements required by the respective IAEA safety requirements that would include necessary measures to demonstrate its long term commitment to safety.
applicatio a facility o managemo	tion: The safety objective in the Atomic Law does not explicitly mention the scope of its n (all facilities and activities) and the duration of its application (all stages over the lifetime of or an activity). Fundamental safety principles such as responsibility for safety, leadership and tent for safety or protection of present and future generations are not fully embedded in the legislative framework for safety.

Armenian legislative framework for safety.

(1)	BASIS: GSR Part 1 Requirement 1, para. 2.5 states that "The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:  (1) The safety principles for protecting people — individually and collectively — society and the environment from radiation risks, both at present and in the future;"
(2)	<b>BASIS: GSR Part 1 Requirement 1 states that</b> "The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals".

	2015 MISSION RECOMMENDATIONS, SUGGESTIONS		
(3)	<b>BASIS: GSR Part 1 Requirement 5 states that</b> "The government shall expressly assign the prime responsibility for safety to the person or organization responsible for a facility or an activity, and shall confer on the regulatory body the authority to require such persons or organizations to comply with stipulated regulatory requirements, as well as to demonstrate such compliance".		
R2	<b>Recommendation:</b> The Government should ensure that the fundamental safety objective and fundamental safety principles of IAEA SF-1 are fully incorporated in to the Armenian framework for safety.		

**Recommendation 1:** ANRA has published a Policy Statement on Nuclear Safety and Security in 2016. On this basis, ANRA has developed a Strategy on Nuclear and Radiation Safety for 2019-2029, the current version of which contains the IAEA Safety Fundamentals SF-1, which are also planned to be incorporated in the new Atomic Law. The work is still in progress. In particular, the RA Government's decision on the construction of a new NPP is pending, because the search for an investor has not been successful yet. ANRA will complete the strategy document after the Government has taken a decision. ANRA's estimate is the end of 2019.

**Recommendation 2:** A new Atomic Law is being developed, in which the fundamental safety principles of IAEA SF-1 will be incorporated. A draft Strategy on Nuclear and Radiation Safety has also been developed but has not been finalized yet. It gives an indication of the substantial progress made to date. The new Atomic Law is planned to be submitted to the RA Government in September 2022 and is expected to enter into force in 2023.

#### Status of the finding in the initial mission

Recommendation 1 (R1) is closed on the basis of progress made and confidence in effective completion in due time as the RA Government will soon decide on a new NPP, and the corresponding Strategy on Nuclear and Radiation Safety can be completed by the end of 2019.

**Recommendation 2 (R2) remains open** as the enactment of the new Atomic Law and the subsequent completion of the Strategy on Nuclear and Radiation Safety are pending.

#### 1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

#### There were no findings in this area in the initial IRRS mission.

#### 1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

	2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
<b>Observation:</b> ANRA is not provided adequate financial and human resources to fulfil its regulatory control of nuclear and radiological safety in Armenia.		
(1)	<b>BASIS: GSR Part 1 Requirement 3, states that</b> "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."	

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
R3	<b>Recommendation:</b> The Government should provide ANRA with human and financial resources to ensure adequate discharge of its statutory obligation for the regulatory control of safety.

**Recommendation 3:** The annual budget requested by ANRA is included in the state budget. The number of staff required by ANRA received governmental approval. The government raised civil servants' salaries by 25% as of January 2019 and promised further increase in the future. However, ANRA is still losing employees to industry. The number of staff approved for ANRA is 45 (NRSC: 43), but only 37 (NRSC: 30) positions are currently filled. Hence, the staffing situation continues to be unsatisfactory, even more so as two key technical positions — Head of Nuclear Safety Department and Head of Radiation Safety Department — are currently vacant. Since these key positions are planned to be filled through external recruitment, it is essential that ANRA become a competitive state body.

#### Status of the finding in the initial mission

**Recommendation 3 (R3) remains open** as the granting of further, substantial salary increases for ANRA and NRSC staff to make them competitive with the ANPP is pending.

1.4. COMPLIANCE WITH REGULATIONS AND RESPONSIBILITY FOR SAFETY

#### There were no findings in this area in the initial IRRS mission.

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

#### There were no findings in this area in the initial IRRS mission.

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

#### There were no findings in this area in the initial IRRS mission.

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

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
<b>Observation:</b> National policy for the final stage of the spent nuclear fuel does not exist. The National Strategy on Radioactive Waste and Spent Fuel Management was not yet finalised.	
(1)	<b>BASIS: GSR Part 1 Requirement 5 states that</b> "The Government shall provide a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals."
(2)	BASIS: GSR Part 1 requirement 1 and Para. 2.3 states that "The Government shall establish a national policy and strategy for safety", "National policy and strategy for safety

	2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
	shall express a long term commitment to safety", "The national policy shall be promulgated as a statement of the government's intent. The strategy shall set out the mechanisms for implementing the national policy."	
R4	<b>Recommendation:</b> The Government should promulgate a national policy for the final stage of spent nuclear fuel management and consequently finalize the National Strategy on Radioactive Waste and Spent Fuel Management.	

**Recommendation 4:** The Armenian government approved on 5 Oct. 2017 the "Strategy on safe management of radioactive waste and spent fuel in RA", and on 10 Jan. 2019 the corresponding Action Plan 2019-2026 (Decree 3-L), including an implementation schedule, which is very extensive and will require a sufficient number of trained specialists, both at ANPP and at ANRA/NRSC.

In addition, spent fuel and radioactive waste management is a priority issue not only within the scope of the Joint Convention on the safety of Spent Fuel Management and on the safety of Radioactive Waste Management, but also under the recent Comprehensive & Enhanced Partnership Agreement between the European Union & Armenia (CEPA) which was ratified by the National Assembly on 11 April 2018.

Delays in the implementation of the Action Plan have to be expected due to the staff shortage at ANRA and NRSC.

#### Status of the finding in the initial mission

**Recommendation 4 (R4) is closed** as the Strategy on Safe Management of Radioactive Waste and Spent Fuel in RA and the corresponding 2019-2026 Action Plan and implementation schedule were issued.

#### 1.8. COMPETENCE FOR SAFETY

#### There were no findings in this area in the initial IRRS mission.

#### 1.9. PROVISION OF TECHNICAL SERVICES

	2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
<b>Observation:</b> Technical services for personal monitoring and training services do not need authorization from the regulatory body.		
(1)	BASIS: GSR Part 3 Requirement 20, para. 3.73 states that "The regulatory body shall be responsible, as appropriate, for  c) Authorization or approval of services provider for individual monitoring and calibration services."	
(2)	BASIS: GSR Part 1 Requirement 13, para 2.41 states, that "Technical services do not necessarily have to be provided by the government. However, if no suitable commercial or non-governmental provider of the necessary technical services is available, the government may have to make provision for the availability of such services. The regulatory body shall authorize technical services that may have significance for safety, as appropriate."	

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
(3)	BASIS: GSR Part 3 Requirement 2, para 2.21 states, that "The government shall ensure that requirements are established for:  (c) The competence of organizations that have responsibilities relating to protection and safety."
(4)	BASIS: GSR Part 3 Requirement 3, para 2.32 states, that "The regulatory body shall ensure the application of the requirements for education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety."
R5	<b>Recommendation:</b> The Government should establish requirements to authorize technical services.

**Recommendation 5:** A new Atomic Law is being developed which will provide the basis for establishing requirements to authorize technical services. The Licensing Law, which is currently under revision, will provide an additional basis for authorizing technical services such as monitoring and calibration. Hence, the need for regulatory authorization of technical services has been recognized, but the legal basis (Atomic Law, Licensing Law) still remains to be created.

#### Status of the finding in the initial mission

**Recommendation 5 (R5) remains open** as the enactment of the new Atomic Law and the amended Licensing Law is pending.

#### 2. THE GLOBAL SAFETY REGIME

#### 2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

#### There were no findings in this area in the initial IRRS mission.

#### 2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
<b>Observation:</b> Assessment of the lessons learnt from the TEPCO Fukushima Daiichi accident, in particular from the stress test analyses, is not yet finalised. Relevant corrective actions and safety improvements need to be enforced by ANRA. In addition, the measures identified in the RA's national report submitted in CNS-2012 have not been yet fully implemented.	
(1)	<b>BASIS: GSR Part 1 Requirement 15 para 3.4 states that</b> " The regulatory body shall require appropriate corrective actions to be carried out to prevent the recurrence of safety significant events. This process involves acquisition of the necessary information and its analysis to facilitate the effective utilization of international networks for learning from operating experience and regulatory experience."
S1	<b>Recommendation:</b> ANRA should consider making all necessary arrangements to finalise the identification of the lessons learned from the TEPCO Fukushima Daiichi accident. As a result of this, ANRA should require appropriate corrective actions to be implemented by ANPP and should determine appropriate actions to improve the regulatory framework, in a timely manner.

#### Changes since the initial IRRS mission

**Suggestion 1:** ANPP carried out the stress test according to ENSREG specifications, including a peer review by an independent group of international experts and their corresponding country visit. ANRA drafted a corresponding National Action Plan NAcP containing the conclusions and recommendations, as well a plan for their implementation by ANPP. The NAcP contains 80 actions and was submitted to ENSREG in 2017. It also includes measures identified at the 2nd Extraordinary Meeting to the CNS (CNS-2012).

ANPP reports to ANRA on the current status of implementation every 6 months. ANRA is satisfied with the recent progress reports. An ENSREG Follow-up mission on the implementation of the stress test findings is planned for late 2019.

#### Status of the finding in the initial mission

**Suggestion 1 (S1) is closed** as the 2017 National Action Plan to implement the Fukushima lessons from the EU stress test and from the CNS-2012 was submitted to ENSREG.

#### 3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
<b>Observation:</b> The structure of ANRA can be changed only by the decision of the Government. This limits ANRA's ability to respond as necessary for effective regulatory control over safety when conditions and workload change.	
(1)	BASIS: GSR Part 1 Requirement 16 states that "The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively"
(2)	BASIS: GS-G-1.1 paragraph 3.2 states that "A regulatory body, its structure and size, and the technical skills of its staff will change as the regulatory body passes through various phases, starting with its early organization and the preparation of its regulatory foundation to the stage where it is considered fully operational. The structure and composition of the regulatory body should be adapted in the course of time for it to be able to act effectively and to address key issues that arise at any time during the siting, design, construction, commissioning, operation and decommissioning of nuclear facilities, or closure in the case of waste disposal facilities."
R6	<b>Recommendation:</b> The Government should provide ANRA with the authorization to structure its organization and manage its available resources so as to fulfil its statutory obligations effectively.

#### Changes since the initial IRRS mission

**Recommendation 6:** According to Chapter III of the new Statute of ANRA, adopted by Decree № 747-L of June 11, 2018 "On approval of Statute of Armenian Nuclear Regulatory Authority" and signed by Premier Minister of RA, ANRA has the authority to define its organizational structure (and make changes as needed) and submitting to the Government for approval.

In case of necessity to adapt the structure of the ANRA to a changed situation (for example, the Government's decision on a new build), there are no authority to do so independently.

There are small exceptions – to move one specialist inside ANRA without increasing/decreasing of the total number of the ANRA staff could be approved by the National Civil Service agency without requiring approval by the Prime Minister.

#### Status of the finding in the initial mission

**Recommendation 6 (R6) remains open** as ANRA still does not have the authority to structure its organization and manage its available resources on an as needed basis.

#### 3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY ACTIVITIES

#### There were no findings in this area in the initial IRRS mission.

#### 3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

#### There were no findings in this area in the initial IRRS mission.

#### 3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

2015 MISSION RECOMMENDATIONS, SUGGESTIONS		
this can lea	<b>Observation:</b> The NRSC provides technical support to the ANPP while also being the TSO for ANRA, this can lead to conflicts of interest. IRRS team concluded that ANRA is always informed by NRSC about any cooperation with ANPP, but only in an informal manner.	
(1)	BASIS: GSR Part 1, Requirement 20, paragraphs 4.21 states that "If the necessary advice or assistance can be obtained only from organizations whose interests potentially conflict with those of the regulatory body, the seeking of this advice or assistance shall be monitored, and the advice given shall be carefully assessed for conflicts of interest."	
R7	<b>Recommendation:</b> ANRA should establish a formal process which ensures that the technical assistance provided by NRSC to a licensees including the ANPP is monitored so that any conflict of interest can be avoided.	
<b>Observation:</b> NRSC staff also participates in the inspections of facilities and activities together with staff of the ANRA and the measurements for verification of safety are conducted by the NRSC. During inspection of a facility or activity using radiation sources ANRA did not demonstrate the independent decision making with regards to advice provided by the TSO and regulatory decisions are based on this advice.		
(1)	BASIS: GSR Part 1 Requirement 20, paragraph 4.22 states that "The obtaining of advice and assistance does not relieve the regulatory body of its assigned responsibilities. The regulatory body shall have an adequate core competence to make informed decisions. In making decisions, the regulatory body shall have the necessary means to assess advice provided by advisory bodies and information submitted by authorized parties and applicants".	
R8	<b>Recommendation:</b> ANRA should ensure that its staff has adequate technical competence to make informed decisions including the means to assess advice provided by NRSC.	

#### Changes since the initial IRRS mission

**Recommendation 7:** NRSC provides technical support to ANRA on a contract basis. NRSC's main customer in Armenia is ANRA. Yet, the support provided by NRSC to ANRA contributes only for about 20-25 % in average per year to the NRSC annual budget. To supplement the ANRA work, NRSC works for other local and foreign companies and organizations. This includes, inter alia, ANPP.

New provisions to deal with potential conflicts of interest that may arise if NRSC is involved in projects of ANRA's licensees, including ANPP, are established under Process MP-001 Introduction of the ANRA Management System.

In such a case, NRSC is required to inform ANRA about the contract offer which may lead to a potential conflict of interest situation. ANRA approves the NRSC's participation in the project proposed by an ANRA's licensee if, as described in Process MP-001:

- NRSC does not participate in the development of safety-related documents at the request
  of ANPP and other ANRA licensees if review of these documents could subsequently be
  requested by ANRA;
- NRSC makes strict separation between its staff who will participate, or have already participated, in work for licensees and staff who will review the submittals at the request of ANRA:
- NRSC informs ANRA officially on the possibility of potential cooperation prior to the decision to participate in a project with ANRA licensees and does not participate in the initiatives without having ANRA's approval.

There are a limited number of NRSC experts who perform thermo-hydraulic calculations, PSA work, and radiation safety and protection assessment. In a case where NRSC experts perform work for ANRA licensee's in these areas, ANRA obtains any necessary support for associated safety reviews through cooperation with the European Commission or IAEA.

**Recommendation 8:** All ANRA personnel have a university degree in engineering, and new hires pass training according to the requirements of the job descriptions (training duration can be up to 3 years). In addition, ANRA staff are periodically trained internally and through international cooperation programmes (international training and tutoring courses and technical meetings organized by the IAEA, European Commission and other organizations). The professional staff of ANRA have the relevant knowledge to review safety justifications, including for instance the professional conclusions provided by NRSC in its specific areas of expertise, including thermohydraulic calculations, PSA applications, and radiation safety and protection assessments, including measurement results. The professional staff of ANRA are able to understand and discuss all support work provided by NRSC during common inspections.

During the interviews with the IRRS team, ANRA personnel demonstrated the ability to analyse information and measurements results received from NRSC.

#### Status of the finding in the initial mission

**Recommendation 7 (R7) is closed** as a clear procedure and criteria have been established and implemented to avoid conflicts of interest.

**Recommendation 8 (R8) is closed** as ANRA personnel have adequate technical competence to make informed decisions.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

#### There were no findings in this area in the initial IRRS mission.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

#### There were no findings in this area in the initial IRRS mission.

3.7. SAFETY RELATED RECORDS

**(1)** 

#### 2015 MISSION RECOMMENDATIONS, SUGGESTIONS

**Observation:** ANRA has only a register on the use of ionizing radiation sources and the rest of registers are in the process of development.

**BASIS: GSR Part 1 Requirement 35 states that** "The regulatory body shall make provision for establishing, maintaining and retrieving adequate records relating to the safety of facilities and activities"

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
S2	<b>Suggestion:</b> ANRA should consider finalizing the development of adequate safety related records, including records that might be necessary for the decommissioning of ANPP, records of events, including non-routine releases of radioactive material to the environment.

**Suggestion 2:** Since 2015, ANRA has developed and maintained the Advanced Regulatory Information System (ARIS) database that consists of modules:

- The state register of ionizing radiation sources RASOD;
- Database on nuclear materials existing in locations outside facilities NUCMAT;
- Database containing information on licenses granted, license holders and data contained in applications submittals, authorizations and permissions AUTHORIZATION;
- Database of inspections of performed by regulatory authority, including preparation, performing and submission of inspection results INSPECTION;
- Database of questions and answers for attestation of personnel TESTING;

A module OCCUDOSES - is a database designed to record doses received by personnel will be put in trial operation in 2 weeks.

The records on solid and liquid radioactive wastes (volumes, radionuclides composition and other properties), discharges and releases (including non-routine releases of radioactive material to the environment) and personnel dosimetry are reported by the operating organization to ANRA on a quarterly basis. These records are not retained in an electronic database.

#### Status of the finding in the initial mission

**Suggestion 2 (S2) is closed** as ANRA maintains relevant records.

#### 3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

	2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
	<b>Observation:</b> There is no formal process to consult the public, among other stakeholders, in the regulatory decision making process.	
(1)	BASIS: GSR Part 1 Requirement 36 states that "The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body."	
(2)	BASIS: GSR Part 1 Requirement 36 para 4.67 states that "In particular, there shall be consultation by means of an open and inclusive process with interested parties residing in the vicinity of authorized facilities and activities."	
S3	<b>Suggestion:</b> ANRA should consider establishing a formal process to consult the interested parties including the public as appropriate.	

**Suggestion 3:** Regarding drafting of the new regulations and laws - ANRA uses a unique website, i.e., e-draft.am, established and maintained by the Ministry of Justice for publication of drafts of legal acts. The website makes publicly available drafts of legal acts prepared by Ministries, the Government and the authorities reporting to the Prime Minister, including ANRA. The drafts are placed on the website for one month.

In addition to make available drafts of legal acts, the website allows to everyone to follow the development, review and approval process and provides opportunities to organize online public discussions and commenting.

In compliance with the Ministry of Justice's letter № 01/16/5659-17 as of April 10, 2017, ANRA is required to collect all the comments, analyse them and submit to the Government of RA results of such analysis together with drafts of new documents.

Regarding the formal process to consult the interested parties, including the public, Instruction IN-002 Communication and Consultation, developed under Process MP-001 revised in March 2019, establishes a formal procedure on communication and consultation with:

- Public and mass media:
- Ministries, state authorities and various organizations;
- Licensees, operators, users of ionizing radiation sources;
- International organizations and regulatory authorities of other countries.

Communication and consultations are expected to be organized for the following topics:

- Nuclear and radiation safety situation at the ANPP and other facilities where nuclear and radioactive materials are used;
- Radiation risks associated with operation of facility, implementation of activities, including results of safety assessments;
- Implementation of measures related to protection and safety;
- Events occurred in and outside the Republic of Armenia;
- Practices subject to ANRA licensing and registration;
- Implementation of ANRA's requirements;
- New regulatory requirements;
- ANRA's decision process;
- Information about safety of radioactive waste management, new NPP construction;
- decommissioning of the existing NPP within its jurisdictions;
- Other information that might affect the safety.

#### Status of the finding in the initial mission

**Suggestion 3 (S3) is closed** as ANRA has established a formal process to consult interested parties, including the public, as appropriate.

#### 4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

#### 4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

2015 MISSION RECOMMENDATIONS, SUGGESTIONS		
In addition	<b>Observation:</b> The ANRA management system does not comply with several key requirements of GS-R-3. In addition, the ANRA Management Handbook does not describe a process to evaluate and identify the human resource needs according to the graded approach.	
(1)	BASIS: GSR Part 1 Requirement 19 states that "The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement."	
(2)	BASIS: GS-R- 3 para. 2.1. states that "A management system shall be established, implemented, assessed and continually improved. It shall be aligned with the goals of the organization and shall contribute to their achievement. The main aim of the management system shall be to achieve and enhance safety by:  - Bringing together in a coherent manner all the requirements for managing the organization;  - Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied;	
	Ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety.	
(3)	<b>BASIS: GS-R-3 para. 2.2. states that</b> "Safety shall be paramount within the management system, overriding all other demands."	
(4)	BASIS: GS-R-3 para. 2.5. states that "The management system shall be used to promote and support a strong safety culture."	
(5)	BASIS: GS-R-3 para. 5.27. states that "Internal communication concerning the implementation and effectiveness of the management system shall take place between the various levels and functions of the organization."	
(6)	BASIS: GS-R-3 para. 5.28. states that "Organizational changes shall be evaluated and classified according to their importance to safety and each change shall be justified."	
(7)	<b>BASIS: GS-R-3 para. 4.1 states that</b> "Senior management shall determine the amount of resources necessary and shall provide the resources to carry out the activities of the organization and to establish, implement, assess and continually improve the management system."	
R9	<b>Recommendation:</b> ANRA should upgrade its management system in compliance with the GS-R-3 requirements, and should implement, assess and continuously improve it, in particular with respect to safety culture, internal communication, organizational change management and human resources management.	

**Recommendation 9:** ANRA has updated its process-based management system documentation and has completed its set of processes to cover the missing elements identified in 2015, including provisions related to the ANRA culture for safety, communication, human resource, and organizational changes.

Process MP-001 Introduction was revised to provide, in addition to provisions related to external communication, an overview on how internal communication is conducted by ANRA. These provisions were completed by Instruction IN-002 Communication and Consultation. IN-002 identifies the main interested parties of ANRA, the key topics subject to communication, and the communication means used to reach out to interested parties.

Arrangements in relation to organizational changes are established in Instruction IN-015 Management of Organizational Changes.

ANRA now has a formal goal to support and promote safety culture in order to achieve a high level of safety by ensuring a high quality of the regulatory performance. Process MP-001 Introduction describes the Safety Culture Reference Framework based on the approach developed by the IAEA. However, no provisions have been developed to foster culture for safety in ANRA. The 2019-2024 ANRA Strategy does not address safety culture at all. On the other hand, Instruction IN-005 Quality Policy clearly identifies the ethical values of ANRA as well as the behaviours expected from its staff for the daily work and when interacting with external parties, including ANRA's Licensees.

#### Status of the finding in the initial mission

**Recommendation 9 (R9) is closed** as it is superseded by Recommendation RF1.

#### New observation from the follow-up mission

**(1)** 

ANRA has updated its management system with the objective to bring it in compliance with GS-R-3 Requirements. A number of documents have been revised accordingly. The new revision of Process MP-001 Introduction, describes ANRA's tasks, organizational structure, duties, responsibilities and processes. This revision was approved in March 2019 to incorporate the missing elements identified in 2015 in the management system. Meanwhile, GS-R-3 was superseded in 2016 by a new publication GSR Part 2 Leadership and Management for Safety. Consequently, updated requirements or new requirements established by GSR Part 2 are not reflected in the management system of ANRA. For instance, in relation to the lack of provisions to promote safety culture within ANRA already identified above, contrary to GSR Part 2 Requirement 14, assessments of leadership for safety and of safety culture within the organization are not taken into account in ANRA's management system.

#### FOLLOW UP MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** The management system of ANRA has been updated without considering the newly established IAEA Safety Requirements GSR Part 2, including those related to culture for safety.

BASIS: GSR Part 1 (Rev 1), Requirement 19 states that "The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement."

#### FOLLOW UP MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

RF1

Recommendation: ANRA should upgrade its management system in line with the GSR Part 2 requirements, in particular with respect to requirements related to culture for safety.

#### 4.2. MANAGEMENT RESPONSIBILITY

2015 MISSION RECOMMENDATIONS, SUGGESTIONS		
	<b>Observation:</b> It was observed that the ANRA management is not sufficiently involved in the implementation of the management system.	
(1)	BASIS: GS-R-3 para. 3.1. states that "Management at all levels shall demonstrate its commitment to the establishment, implementation, assessment and continual improvement of the management system and shall allocate adequate resources to carry out these activities."	
(2)	BASIS: GS-R-3 para. 5.26. states that "Information relevant to safety, health, environmental, security, quality and economic goals shall be communicated to individuals in the organization and, where necessary, to other interested parties."	
(3)	<b>BASIS: GS-G-3.1 para 3.2 states that</b> "3.2. The senior management is responsible and accountable for the planning and implementation of a management system that is appropriate to the organization. It is the role of senior management to establish and cultivate principles that integrate all requirements into daily work."	
R10	<b>Recommendation:</b> ANRA Management should demonstrate its commitment to the implementation, assessment and continual improvement of the management system in line with the IAEA safety standard GS-R-3.	
	<b>cion:</b> ANRA`s policy statement does not make sufficiently visible the principle of 'Safety is an priority', the ANRA values and the behavioural expectation of the staff.	
(1)	BASIS: GS-R-3 para. 5.26. states that "Information relevant to safety, health, environmental, security, quality and economic goals shall be communicated to individuals in the organization and, where necessary, to other interested parties."	
(2)	<b>BASIS: GS-R-3 para. 2.2. states that</b> "Safety shall be paramount within the management system, overriding all other demands."	
(3)	BASIS: GS-R-3 para 3.3 states that "Management at all levels shall communicate to individuals the need to adopt these individual values, institutional values and behavioral expectations as well as to comply with the requirements of the management system."	
S4	<b>Suggestion:</b> The ANRA senior management should consider revising its policy statement to place emphasis that safety is an overriding priority and to clarify the ANRA organizational values and expected staff behaviour.	

Recommendation 10: Several initiatives have been undertaken since 2015 to demonstrate ANRA's management commitment to the implementation, assessment and continual improvement of the management system. Instruction IN-005 Quality Policy has been updated and approved by the Chairman. This document clearly states that ANRA's management is committed to the management system. Quality Policy Statement embedded in the instructions and displays in ANRA at several place repeats again the commitment of the ANRA management in addition to request ANRA Staff to contribute to the objectives of Quality Policy Statement. The role of ANRA's senior management to review the management system for suitability and effectiveness is clearly established in Process MP-005 Measurement and Improvement. The first review of the management system was conducted in May 2019. The report of the review, approved by the Chairman on 6 June 2019, identified actions to further improve the management system.

**Suggestion 4:** The updated Instruction IN-005 Quality Policy clearly spells out that: "Safety - commits ANRA's staff to recognizing the importance of safety as an overriding consideration in daily work". Furthermore, the document establishes clearly the values of the organization and expected behaviours in order to guide the organization and its staff in performing their duties and discharging their responsibilities.

The Quality Statement of ANRA Chairman is now embedded in Instruction IN-005 *Quality Policy*. This Statement is used for the internal communication to provide the staff with direction when performing their regulatory functions.

#### Status of the finding in the initial mission

**Recommendation 10 (R10) is closed** as evidence demonstrating ANRA management's commitment to the management system has been provided.

**Suggestion 4 (S4) is closed** as ANRA's policy states that the principle of safety is an overriding priority and clarifies organizational values and behavioural expectations of staff.

4.3. RESOURCE MANAGEMENT

#### There were no findings in this area in the initial IRRS mission.

#### 4.4. PROCESS IMPLEMENTATION

#### There were no findings in this area in the initial IRRS mission.

#### 4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

	2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
<b>Observation:</b> The ANRA management did not conduct any management system review to measure, evaluate and ensure the suitability and effectiveness of the management system.		
(1)	<b>BASIS: GS-R-3 para. 6.7. states that</b> "A management system review shall be conducted at planned intervals to ensure the continuing suitability and effectiveness of the management system and its ability to enable the objectives set for the organization to be accomplished."	
(2)	BASIS: GS-G-3.1 para. 6.45. states that "Senior management should develop activities for management system review into a process that extends to the whole organization. Management system reviews should be platforms for the exchange of new ideas, with open	

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
	discussion and evaluation of the inputs, and should be stimulated by the leadership of senior management."
S5	<b>Suggestion:</b> ANRA should consider conducting a regular review of its management system to ensure its continuing suitability and effectiveness.

**Suggestion 5:** The first review of the ANRA's management system to ensure its continuing suitability and effectiveness was conducted in May 2019. The report, approved by the Chairman on 6 June 2019, identified actions to further improve the management system.

Furthermore, the requirement to conduct management system review is set up in the Process MP-005 Measurement and Improvement. The IRRS team was informed that the periodicity to conduct such a review will be added in Process MP-005 document.

#### Status of the finding in the initial mission

**Suggestion 5 (S5) is closed** as ANRA has established provisions for management system reviews and a first review has been conducted in 2019.

#### New observation from the follow-up mission

The measurement and improvement process, described in MP-005, integrates several mechanisms to measure and assess the performance of the IMS in order to identify opportunities for improvement. These mechanisms are feedback forms; performance indicators; internal audits; non-conformities; and senior management review.

Like for all governmental organizations, a dedicated section, namely the Audit section, has been created within ANRA to ensure compliance of ANRA's organization and activities, including from a financial perspective, with the legal requirements. To do so, the Audit section, which has two staff, has the responsibility to prepare and then, after endorsement by the ANRA Chairman, to implement the audit programme. The audit reports are sent to the Minister of Finance and the ANRA Chairman. Corrective actions to address non-compliance are taken accordingly

The audits conducted in ANRA are not directly designed to perform independent assessment of the performance of the management system. However, by virtue of the topics addressed by the Audit section, most of the components of the management system are covered by the audits but not in a comprehensive manner. Indeed, some management system processes, such as the Measurement and Improvement process (MP-005), have never been audited.

In addition, the involvement of the process owner of Process MP-005, head of the Nuclear Information and International Cooperation section, is limited in the audit process to provide information upon request by the auditors. This process owner is not at all involved in the formulation of the audit programme and does not receive the audit reports. It was recognized in ANRA that there is a room for better integration of the existing audits within the process MP-005 in order to properly cover the different aspects of the management system.

Regarding the reporting system available to individuals to provide feedback and report on non-compliance, the IRRS team was informed that the feedback forms have never been used.

#### FOLLOW UP MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** The owner of process MP-005 is not involved in the formulation of the audit programme and its implementation. The audit programme does not cover all management system processes. Feedback forms exist but have never been used.

(1)	BASIS: GSR Part 2, Requirement 13, para. 6.2 states that "All processes shall be regularly evaluated for their effectiveness and for their ability to ensure safety."
(2)	<b>BASIS: GSG-12, para. 5.15 states that</b> "The process owner should be assigned appropriate authority and resources to discharge his or her responsibilities; however, he or she might not have line management authority over all the staff who implement the process. Such circumstances might lead to processes not being implemented as intended."
(3)	BASIS: GSG-12, para. 5.52 states that " Internal audits are the basic instrument available for the regulatory body to assess the functioning of its integrated management system processes and to investigate performance problems."
(4)	BASIS: GSG-12, para. 5.55 states that " Senior management should foster an organizational culture that encourages individuals to identify and report non-conforming processes and outcomes of the regulatory work."
SF1	Suggestion: ANRA should consider evaluating the effectiveness of the measurement and improvement process, including whether currently assigned roles and responsibilities lead to processes being implemented as intended.

#### 5. AUTHORIZATION

#### 5.1. GENERIC ISSUES

2015 MISSION RECOMMENDATIONS, SUGGESTIONS		
<b>Observation:</b> The binding decrees applicable to the licensing of facilities and activities do not identify the specific safety standards that are applicable for the various types of licenses. There are no supporting implementing procedures and guidance documents to provide specifically applicable technical requirements and the associated acceptance criteria.		
(1)	BASIS: SSG-12 para. 2.19 (f) states that "A clear and explicit set of requirements, criteria and standards forming the licensing basis should be defined by regulation and by the regulatory body.	
<b>S</b> 6	<b>Suggestion:</b> ANRA should consider identifying clear and explicit requirements, criteria and standards forming the licensing basis for specific types of facilities and activities.	
<b>Observation:</b> The adequacy of the stipulated periods for completing the licensing processes for a new NPP need to be verified in light of the severe constraints existing on ANRA's human resource.		
(1)	BASIS: GS-R-3 Requirement 2.2, para. 2.2 (X) states that "2.2. Safety shall be paramount within the management system, overriding all other demands."	
S7	<b>Suggestion:</b> Government should consider re-evaluating the adequacy of the current licence approval timelines with respect to the new NPP.	

#### Changes since the initial IRRS mission

**Suggestion 6:** ANRA has analysed the licensing process regarding listed requirements, criteria and standards. For ANPP there is a clear procedure for each type of activity in place. The documents that have to be submitted to the authority (ANRA) are specified and also the format and the content of the relevant documents are clearly specified.

ANRA recognized as a result of the analysis that in the field of radiation safety there are some deficits. Therefore, ANRA has started the process to establish additional documents defining technical requirements. According to ANRA's 2019 workplan, the radiation safety requirements during the construction and operation of X-ray devices should be finalized and approved by the ANRA chairman at the end of 2019. Additionally, within the framework of cooperation with the US-NRC, in 2019 it is planned the assist ANRA in defining the requirements for the format and content of documents to be submitted during the licensing process. The strategy of ANRA to implement the suggestion seems comprehensive but the process has just started. Up to now there are only draft versions available.

**Suggestion 7:** The related provisions in the Atomic Law (license approval timelines) are unchanged since 2015. ANRA intends to consider adequate timeframes for reviewing license application in the new draft of the Atomic Law. Up to now ANRA has not finished the internal discussion on this topic (assessment of the adequate timeframes).

#### Status of the finding in the initial mission

**Suggestion 6 (S6) remains open** as ANRA has just started the process to establish additional documents defining technical requirements.

Suggestion 7 (S7) remains open as the related provisions in the Atomic Law are unchanged.

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

#### There were no findings in this area in the initial IRRS mission.

5.3. AUTHORIZATION OF FUEL CYCLE FACILITIES

#### There were no findings in this area in the initial IRRS mission.

5.4. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

#### There were no findings in this area in the initial IRRS mission.

#### 5.5. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

2015 MISSION RECOMMENDATIONS, SUGGESTIONS		
<b>Observation:</b> There are no internal processes established by ANRA for the review and assessment of safety assessment of facilities or activities using radiation sources.		
(1)	BASIS: GSR Part 1 Requirement 24, para. 4.33 states that "Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body"	
(2)	BASIS: GSR Part 1 Requirement 24, para. 4.26 states that "The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by the individual staff members of the regulatory"	
R11	<b>Recommendation:</b> ANRA should establish a process and procedures for conducting verification of the safety assessment submitted with application for authorization of radiation sources, including during the amendment and/or renewal of the authorization.	
<b>Observation:</b> There are no clearly established procedures for amendment or renewal of an authorization for the use of radiation sources.		
(1)	<b>BASIS: GSR Part 1 Requirement 24, para. 4.37 states that</b> "Any subsequent amendment, renewal, suspension or revocation of the authorization for a facility or an activity shall be undertaken in accordance with a clearly specified and established procedure".	
R12	<b>Recommendation:</b> ANRA should establish internal procedures for amendment or renewal of an authorization of radiation sources.	
<b>Observation:</b> Legislation on detection and isolation of radioactive materials approved by the Government is established, but there is no internal procedure established by ANRA for its implementation.		

	2015 MISSION RECOMMENDATIONS, SUGGESTIONS		
(1)	BASIS: GSR Part 3 Requirement 2, para. 2.26 states that "The government shall ensure that arrangements are in place for regaining control over radioactive sources that have been abandoned, lost, misplaced, stolen or otherwise transferred without proper authorization"		
(2)	Code of Conduct on the Safety and Security of Radioactive Sources, para. 22 states that "Every State should ensure that its regulatory body is prepared, or has established provisions, to recover and restore appropriate control over orphan sources, and to deal with radiological emergencies and has established appropriate response plans and measures".		
S8	<b>Suggestion:</b> ANRA should consider establishing an internal procedure for the implementation of the legal provisions and make arrangements for regaining control over radioactive sources.		

**Recommendation 11:** Review and assessment of a license application and supporting documents is made by the Licensing Section and Radiation Safety Section of ANRA. If necessary, additional information and documentation can be requested from the applicant. Based on the safety conclusion of the relevant sections of ANRA, a licensing committee makes the final decision.

The Decree specifies a time limit for granting an authorization or for requiring additional information from the applicant. It also includes procedures and content of review and assessment to be made during the authorization process for use of radioactive materials and radiation generators.

The same process of review and decision-making process is followed during renewal of an authorization. In such a review, mainly the safety assessment reports submitted annually to ANRA by the facilities and activities are considered.

If a facility acquires a new radiation source, the licensee is required to notify ANRA, and submit the related safety assessment report and expert conclusion for review and assessment. The modification of the authorization is evaluated based on this information.

**Recommendation 12:** A document on the process for licensing, MP-010, has been updated to describe the process and procedures for renewal of a license and for any modification thereof. The licensee is required to apply for renewal of a license three months before the expiration date of the license. When an application is received, review and assessment, mainly of the annual safety reports, is made by the relevant sections of ANRA. Depending on the conclusions of the review and assessment a decision is made to renew the authorization or modify the authorization including provision of additional conditions.

When a license is renewed, it is normally valid for the same period as the previous license.

Amendment of an authorization is made when an application is received from a licensee for modification as a result of some changes in the facility or activity, such as change of the licensee or address of the facility. An application for amendment is reviewed by the relevant section of ANRA, in the same manner as other applications for authorization. According to the established procedures, decisions on modification to an authorization should be made within three days after receiving an application.

Decisions on both renewal and modification of a license do not normally require a review by the license committee. Only application for amendment of a license because of a change in location requires the review of the licensing committee before a decision is made.

**Suggestion 8:** ANRA annually develops a plan for radiation source search and recovery, which is implemented in coordination with NRSC. ANRA has developed a draft procedure for search and recovery of orphan sources, with the support of the Pacific Northwest Laboratory in the United States. The draft procedure includes identification of potential sites for orphan sources; developing a search plan; implementation of search and identification of the physical, chemical and radiation characteristics of any sources found; and handling and recovery of orphan sources. The draft procedure is currently under internal review by ANRA. The IRRS team was informed that according to ANRA's annual plan, the draft procedure will be finalized and issued before the end of 2019.

#### Status of the finding in the initial mission

**Recommendation 11 (R11) is closed** as the process and procedures for review and assessment are in place including during renewal and amendment of an authorization.

**Recommendation 12 (R12) is closed** as procedures for renewal and amendment of authorizations have been established.

Suggestion 8 (S8) is closed on the basis of progress made and confidence in effective completion in due time as a draft procedure on search and recovery of orphan sources has been developed and is planned to be issued by the end of 2019.

#### 5.6. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

2015 MISSION RECOMMENDATIONS, SUGGESTIONS		
<b>Observation:</b> There is no mechanism in place which ensures that the financial provisions made by the Government for decommissioning of existing NPPs are adequate to provide for all activities associated with the safe decommissioning, and the Government has not established means to augment the existing decommissioning funds if the funds are found to be inadequate.		
(1)	BASIS: GSR Part 6 Requirement 2, para. 2.5 (16) states that "Responsibilities in respect of financial provisions for decommissioning shall be set out in national legislation. These provisions shall include establishing a mechanism to provide adequate financial resources and to ensure that they are available when necessary, for ensuring safe decommissioning";	
(2)	BASIS: GSR Part 1 Requirement 2, para. 2.5 (16) states that "The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following responsibilities and obligations in respect of financial provision for the management of radioactive waste and of spent fuel, and for decommissioning of facilities and termination of activities";	
(3)	BASIS: GSR Part 6 Requirement 9, para. 6.2 states that "The cost estimate for decommissioning shall be updated on the basis of the periodic update of the initial decommissioning plan or on the basis of the final decommissioning plan. The mechanism used to provide financial assurance shall be consistent with the cost estimate for the facility and shall be changed if necessary".	

# R13 Recommendation: The Government should formally establish a mechanism to provide adequate financial resources for ensuring safe decommissioning of NPPs. The mechanism should also update the cost estimate in light of a periodic update of the decommissioning plan.

#### Changes since the initial IRRS mission

**Recommendation 13:** In accordance with Article 19 (superscript 1) of the Law of the RA on Safe Utilization of Atomic Energy for Peaceful Purposes the operator of a nuclear facility shall allocate normative financial assignments for nuclear, radiation, and technical safety, fire protection, physical protection, nuclear material account and control, implementation of safety improvement measures, scientific and technical support, as well as securities needed for storage of spent nuclear fuel and for decommissioning to the Public Services Regulatory Commission of the Republic of Armenia.

Financial securities for decommissioning of nuclear installations are accumulated on a special account opened in the treasury of the state authority empowered by the Government with the public finance management.

The IRRS team was informed that funds for decommissioning of the ANPP Unit №2 are not sufficient, but according to the Article 6 of the Law of the RA on Safe Utilization of Atomic Energy for Peaceful Purposes:

- 1. Nuclear facilities and nuclear materials are the property of the RA.
- 2. Spent nuclear fuel and radioactive wastes generated in nuclear facilities located on the territory of the Republic of Armenia are the property of the Republic of Armenia.

The IRRS team was informed that a draft of the new Atomic Law includes a provision requiring periodic review of the adequacy of funds for decommissioning.

#### Status of the finding in the initial mission

**Recommendation 13 (R13) remains open** as a mechanism to provide adequate financial resources for ensuring safe decommissioning of NPPs has not been submitted for approval.

#### 5.7. AUTHORIZATION OF TRANSPORT

There were no findings in this area in the initial IRRS mission.

#### 6. REVIEW AND ASSESSMENT

#### 6.1. GENERIC ISSUES

#### 6.1.1 MANAGEMENT OF REVIEW AND ASSESSMENT

#### There were no findings in this area in the initial IRRS mission.

6.1.2 ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

#### There were no findings in this area in the initial IRRS mission.

6.1.3 BASES FOR REVIEW AND ASSESSMENT

#### There were no findings in this area in the initial IRRS mission.

6.1.4 PERFORMANCE OF REVIEW AND ASSESSMENT

#### There were no findings in this area in the initial IRRS mission.

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

2015 MISSION RECOMMENDATIONS, SUGGESTIONS		
<b>Observation:</b> Safety criteria for life time extension are not specified systematically in the regulatory requirements.		
(1)	BASIS: GSR Part 1 Requirement 32 states that "the regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."	
R14	<b>Recommendation:</b> ANRA should specify the principles, requirements and associated safety criteria applicable to the design lifetime extension in the regulatory documents.	
<b>Observation:</b> The scope of the ANRA internal procedure on operational experience feedback is limited to the information from IRS and misses important information from other countries. The regulations do not require the licensee to utilize operating experience from abroad.		
(1)	BASIS: GSR Part 1 Requirement 15 states that "The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory 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.	
(2)	BASIS: GSR Part 1 Requirement 15 para 3.4 states that "The regulatory body shall establish and maintain a means for receiving information from other States and from authorized parties, as well as a means for making available to others lessons learned from operating experience and regulatory experience. The regulatory body shall require appropriate corrective actions to be carried out to prevent the recurrence of safety significant events. This process involves acquisition of the necessary information and its analysis to facilitate the effective utilization of international networks for learning from operating experience and regulatory experience.	

# 2015 MISSION RECOMMENDATIONS, SUGGESTIONS commendation: ANRA should make the necessary arrangements to it

R15

**Recommendation:** ANRA should make the necessary arrangements to identify lessons from operating and regulatory experience in other States, in particular by extending the scope of operational experience feedback and by establishing a regulation on OEF for all operating stages. In addition, ANRA should require appropriate corrective actions to be implemented at the ANPP.

#### Changes since the initial IRRS mission

**Recommendation 14:** ANRA has developed and enforced additional documents since 2015. These documents contain a comprehensive set of principles and requirements for aging management. Based on these documents ANPP submitted to ANRA the methodology used for the assessment of residual lifetime of elements and complex surveys during the LTE. Within their evaluation, especially of the methodology ANRA and NRSC take the results of the IAEA NULIFE VERLIFE into account.

**Recommendation 15:** ANRA's procedure on operational feedback has been changed significantly since 2015. Major input for the procedure is the assessment of information from different databases (especially IRS) from the National Coordinator (Director of NRSC). The contract between NRSC and ANRA allows to expand the used databases if there is a need defined by ANRA. ANRA gets a report with the evaluation results from NRSC and performs an assessment. If there is a safety relevant aspect identified, ANRA transfers a request to the ANPP licensee. ANRA requires the licensee to do an independent assessment and report the results to ANRA for verification.

The regulations (including the license conditions) do not require the licensee to utilize operational experience feedback from abroad. Although there is no regulatory requirement, the licensee has adopted a process to evaluate national and international experience. The results of these evaluations are needed also for mandatory reports which have to be sent to ANRA (e.g., Report on Implementation of Safety Operation Program, Safety Analysis Report, Report on Aging Management). For these reports, ANRA requires that national and international operation feedback has to be considered. If there are safety relevant findings, they have to be transferred to the Corrective Action Program and the Safety Operation Program, which have to be sent to ANRA twice a year.

#### Status of the finding in the initial mission

**Recommendation 14 (R14) is closed** as ANRA has developed new regulatory documents containing a comprehensive set of principles and requirements for aging management.

**Recommendation 15 (R15) is closed** as ANRA's procedure on operational feedback was changed significantly.

6.3. REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILITIES

#### There were no findings in this area in the initial IRRS mission.

6.4. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

#### There were no findings in this area in the initial IRRS mission.

# 6.5. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

There were no findings in this area in the initial IRRS mission.

6.6. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

There were no findings in this area in the initial IRRS mission.

6.7. REVIEW AND ASSESSMENT FOR TRANSPORT

There were no findings in this area in the initial IRRS mission.

# 7. INSPECTION

# 7.1. GENERIC ISSUES

# 7.1.1. INSPECTION PROGRAMME

# There were no findings in this area in the initial IRRS mission.

# 7.1.2. INSPECTION PROCESS AND PRACTICE

2015 MISSION RECOMMENDATIONS, SUGGESTIONS  Observation: There is no internal guidance for inspectors for the conduct of inspections in specific areas, e.g., transport, NPP maintenance, etc.	
(2)	BASIS: TS-G-1.1 Para. 307.5. states that "This should inform users about the way the competent authority expects them to comply with the Transport Regulations and about new developments in the regulatory field".
S9	<b>Suggestion:</b> ANRA should consider establishing inspection guidance to ensure a systematic and consistent approach for inspection of facilities and activities.
	tion: The results of inspection are not used systematically as feedback for improving the ess of the regulatory processes.
(1)	BASIS: GS-G-1.3 Para 4.12 states that "The regulatory body should establish a process of periodically evaluating the findings of inspections, identifying generic issues and making arrangements to enable inspectors from various plants, locations or projects to meet to exchange views and discuss the findings and issues."
S10	<b>Suggestion:</b> ANRA should consider establishing a systematic mechanism for using feedback from inspections as input for improving the effectiveness of the regulatory processes.
annual ins	tion: In the established inspection documents of ANRA (such as the inspection procedure and spection work plan) the approach with regard to the prioritization of transport inspection and a frequency is not established. Additionally, ANRA is preparing an annual plan for inspection ion sources. However, frequencies of inspections for this plan are determined without d criteria.
(1)	BASIS: GSR Part 1 Requirement 29 states that "Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."
(2)	BASIS: GSR Part 1 Para. 4.50 states that "The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with

	2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
	regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach."	
R16	<b>Recommendation:</b> ANRA should implement an inspection programme and planning process, related facilities and activities using radiation sources and transport of radioactive material, to that defines a baseline, includes frequency of inspections and areas and programmes to be inspected based on established criteria and should allow for prioritization.	

**Suggestion 9:** In parallel to revising the inspection procedure (both covering ANPP and facilities where ionising radiation sources are used), a number of new guidelines for the inspections are at different stages of development. The general guidelines developed in accordance with IAEA safety standard GSG-13 describe the purpose, scope (including feedback) of the given inspection, the sections involved in the inspection, the documents and elements to be monitored, the legal basis, the sequence of actions, the acceptance criteria, the procedure and grounds for decision making, the summary of results, responsibilities of involved persons and also enforcement guidance. General inspection guidance for nuclear facilities is ready for ANRA Chairman approval, general guidance for facilities and activities using radiation sources are in advanced stage of development. With respect to specific guidance, the procedure for licensee safety culture inspection is ready for approval, the inspection guidelines for NPP systems and components surveillance and metal testing are in advanced stage of development.

**Suggestion 10:** The MP-009 "Inspection" process of the ANRA QMS has been supplemented with a new section describing a mechanism for using feedback from inspections as input for improving the effectiveness of the regulatory processes. General guidelines, which were developed for inspections, will give more details on feedback mechanisms. The above feedback mechanisms still need to be implemented. The IRRS team was told that the general guidance for nuclear facilities should be approved in time to be used for the next inspection planning period.

**Recommendation 16:** The ANRA inspection program on facilities and activities using radiation sources is based on the IAEA safety standard RS-G-1.9. General guide for inspections at facilities and activities using radiation sources is in an advanced stage of development. General content of the guide is similar to the one for nuclear facilities (both based on GSG-13). The document defines the types and frequencies of inspections of facilities and requirements on planning, preparation and conducting of inspections, on training of personal, individual monitoring, workplace monitoring, medical exposure, protection of public, radiation safety and security, and the transport of ionizing radiation sources. The guide also addresses summarizing the results of inspections, exchange of inspection results, and recording of the inspection results in the inspection database. The above-mentioned table has been developed based on the graded approach. The criteria for the frequency of inspections were defined based on the type of practice and category of the source. For the planning of annual inspections schedule, previous inspections results as well as annual reports submitted by the licensees were also taken into account. The guideline still needs to be discussed internally, approved by ANRA Chairman, and implemented.

#### Status of the finding in the initial mission

Suggestion 9 (S9) is closed on the basis of progress made and confidence in the effective completion in due time as a number of inspection guides are ready or in advanced stages of development.

**Suggestion 10 (S10) remains open** as the systematic mechanism for using feedback from inspections as input for improving the effectiveness of the regulatory processes still needs to be implemented.

**Recommendation 16 (R16) remains open** as the new guidance on inspection programme and inspection planning related to facilities and activities using radiation sources and transport of radioactive material needs to be finalized and implemented.

#### 7.1.3. INSPECTORS

#### There were no findings in this area in the initial IRRS mission.

#### 7.2. INSPECTION OF NUCLEAR POWER PLANTS

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
<b>Observation:</b> ANRA's inspections do not cover oversight of the licensee's safety culture.	
(1)	BASIS: GSR Part 1 Req. 29 Para.4.53 states that "In conducting inspections, the regulatory body shall consider a number of aspects, includingmanagement system; safety culture"
R17	<b>Recommendation:</b> ANRA should establish and implement in a systematic manner a programme to oversee licensee's safety culture, including during inspection.

#### **Changes since the initial IRRS mission**

Recommendation 17: ANRA has developed the "Guidelines for Regulatory Oversight of Safety Culture in Licensees' Organizations". Document is waiting for final approval of ANRA Chairman. In development of this guidance ANRA used experience of Bulgarian nuclear safety authority. English translation of new guidance was available for review by the IRRS team. In general, the guidance is well structured and contains all necessary information to allow ANRA to perform systematic programme of overseeing licensee's safety culture, including during inspection. Guidance is yet to be implemented to regulatory activities of ANRA. According to information received, in nuclear facilities it is planned to approve and apply the new guidelines for the next semi-annual inspection period.

#### Status of the finding in the initial mission

Recommendation 17 (R17) is closed on the basis of progress made and confidence in the effective completion in due time as the new comprehensive guide for the programme to oversee licensees' safety culture was developed and is ready for implementation.

#### 7.3. INSPECTION OF FUEL CYCLE FACILITIES

#### There were no findings in this area in the initial IRRS mission.

#### 7.4. INSPECTION OF WASTE MANAGEMENT FACILITIES

#### There were no findings in this area in the initial IRRS mission.

#### 7.5. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
<b>Observation:</b> ANRA is not allowed to conduct inspections in facilities and activities using radiation sources if the annual income of the facility is below a certain limit set by Government Decree irrespective of the radiation risk associated with the facility or activity.	
(1)	BASIS: GSR Part 1 Requirement 28, para. 4.52 states that "Provision shall be made for free access by regulatory inspectors to any facility or activity at any time"
R18	<b>Recommendation:</b> The Government should authorise ANRA to have free access to any facility or activity to conduct inspection to verify safety and compliance with regulatory requirements.

# Changes since the initial IRRS mission

**Recommendation 18:** A government Decree № 594-A of 2009 on organization and conduct of audits, that included provisions which prohibit government organizations from conducting inspections if a facility's annual income is below a certain limit set by the government, has been replaced by another, Decree №839, issued in July 2015. The provision limiting inspection based on income has been repealed. At present, ANRA's inspectors have free access to any facility or activity for the purpose of performing inspections.

#### Status of the finding in the initial mission

**Recommendation 18 (R18) is closed** as the legal provision that limited ANRA's free access to facilities and activities for the conduct of inspection has been repealed.

#### 7.6. INSPECTION OF DECOMMISSIONING ACTIVITIES

# There were no findings in this area in the initial IRRS mission.

#### 7.7. INSPECTION OF TRANSPORT

	2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
<b>Observation:</b> ANRA does not enforce the current regulatory requirement for quality assurance. Additionally, ANRA has not yet provided any guidance for implementation of the required quality assurance for the licensee.		
(1)	BASIS: SSR-6 para. 307 states that "The competent authority shall assure compliance"	
(2)	BASIS: GSR Part 1 Requirement 27 states that: "The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization."	
R19	<b>Recommendation:</b> ANRA should enforce compliance with the national regulatory requirements for quality assurance system in transport.	

**Recommendation 19:** The established regulatory requirement for quality assurance in transport of radioactive material is not being enforced due to human resource constraints. The IRRS team was informed that ANRA is currently scheduled to address this recommendation in the 2020 to 2021 timeframe.

# Status of the finding in the initial mission

**Recommendation 19 (R19) remains open as** the implementation of ANRA's planned action to establish regulatory requirements for quality assurance for transport is pending.

#### 8. ENFORCEMENT

#### 8.1. ENFORCEMENT POLICY AND PROCESSES

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
<b>Observation:</b> ANRA imposes penalties for non-compliance with regulatory requirements on individuals working in the facilities or conducting activities rather than to the organizations, since the code of administrative offenses requires that individuals should be penalized.	
(1)	<b>Basis: GS-G-1.3 Para 5.13 states that "</b> Experience in some States shows that imposing penalties on the organization rather than on individuals is preferable and is more likely to lead to improvements in safety performance."
S11	<b>Suggestion:</b> The Government should consider amending the code on administrative offences so that ANRA is able to impose penalties on organizations.

#### Changes since the initial IRRS mission

**Suggestion 11:** A new code on administrative offenses has been developed by the Ministry of Justice changing conceptual approach to law enforcement in Armenia. The new code was drafted in consultation with legal experts from the European Union. ANRA was able to discuss and comment relevant parts of this proposal. Among others, the new code adds possibility to impose penalties also on organisations. The new bill is now on agenda of National Assembly.

#### Status of the finding in the initial mission

Suggestion 11 (S11) is closed on the basis of progress made and confidence in the effective completion in due time as the new code on administrative offences that includes the possibility to impose penalties on organisations is on the agenda of the National Assembly.

#### 8.2. ENFORCEMENT IMPLEMENTATIONS

	2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
<b>Observation:</b> ANRA has not established an enforcement policy and defined criteria for taking corrective actions for responding to non-compliance of regulatory requirements or conditions of authorization. There is also no established guidance related to enforcement.		
(1)	<b>BASIS: GSR Part 1 Requirement 30, states that</b> "The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to noncompliance by authorized parties with regulatory requirements or with any conditions specified in the authorization".	
(2)	BASIS: GSR Part 1 Requirement 30, para. 4.58 states that "The regulatory body shall establish criteria for corrective actions, including enforcing the cessation of activities or the shutting down of a facility where necessary".	
R20	<b>Recommendation:</b> ANRA should establish within Armenia's legal framework enforcement guidance and criteria for requiring corrective actions, and develop guidance for inspectors on the implementation of enforcement actions.	

**Recommendation 20:** The Ministry of Justice drafted the new code on administrative offences in consultation with ANRA. The new bill is now on agenda of the National Assembly. The Code establishes principally new approaches to enforcement. It also includes newly defined general criteria for requiring corrective actions. Once the new code is enacted, ANRA will need to establish a new enforcement policy and update its internal enforcement guidance on the implementation of enforcement actions, which is part of general inspection procedures and guides.

#### Status of the finding in the initial mission

**Recommendation 20 (R20) remains open** as ANRA awaits National Assembly approval of the new code to establish relevant enforcement policy and guidance.

#### 9. REGULATIONS AND GUIDES

#### 9.1. GENERIC ISSUES

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
<b>Observation:</b> ANRA does not have a systematic approach to including the revision of existing regulations and guides into the annual plan of regulatory documents development and revision.	
(1)	BASIS: GSR Part 1 Requirement 33 states that "Regulations and guides shall be reviewed and revised as necessary to keep them up to date"
S12	<b>Suggestion:</b> ANRA should consider implementing a systematic approach to ensure that regulations and guides are reviewed and revised as necessary to keep them up to date.

# Changes since the initial IRRS mission

**Suggestion 12:** The regulatory body revised the related process for legislation review and revision. It now contains a section dealing with "Timeframes for revision of legal acts" in which it is stated that all legal acts and also other legal acts (especially guides) are revised periodically. The revision of regulations and guides is part of ANRA's Workplan for 2019.

# Status of the finding in the initial mission

Suggestion 12 (S12) is closed as ANRA has revised the related process.

#### 9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

	2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
supersedes the Decre	<b>Observation:</b> Decree 1411 on requirements for new NPP does not address the concept of DEC which supersedes the concept of severe accident in IAEA SSR-2/1 revised in 2012. Para. 7 of the Section 3 of the Decree 1411-N states that design limits for NPPs will be defined in guidance published by the regulatory body. No guidance defining design limits is in place.	
(1)	BASIS: GSR Part 1 Requirement 3 states that "Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained."	
(2)	BASIS: SSR 2/1 Requirement 15, para. 5.4 states that "The design limits shall be specified and shall be consistent with relevant national and international standards and codes, as well as with relevant regulatory requirements."	
R21	<b>Recommendation:</b> ANRA should revise Decree 1411 to reflect the current IAEA safety standards on design extension conditions and establish the associated guidance.	

**Recommendation 21:** The regulatory body has revised the "Design Safety Requirements to New NPP" regulation. The concept of design extension conditions is now reflected adequately in the regulations. ANRA has decided to develop additional guidance documents for the existing NPP and as a next step for the new NPP. In addition, ANRA has assigned NRSC to evaluate if the related WENRA-Guideline is applicable for WWER reactors. This approach to implement the recommendation is constructive and reasonable.

#### Status of the finding in the initial mission

Recommendation 21 (R21) is closed on the basis of progress made and confidence in the effective completion in due time as the design extension conditions are adequately reflected in the regulations for new NPPs.

#### 9.3. REGULATIONS AND GUIDES FOR FUEL CYCLE FACILITIES

#### There were no findings in this area in the initial IRRS mission.

#### 9.4. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
<b>Observation:</b> There is no requirement to characterize radioactive wastes to facilitate their future disposal.	
(1)	Basis: GSR Part 5 Requirement 9 states that "Characterization and classification of radioactive waste. At various steps in the predisposal management of radioactive waste, the radioactive waste shall be characterized and classified in accordance with requirements established or approved by the regulatory body."
(2)	Basis: GSR Part 5 Para. 4.10 states that "Radioactive waste has to be characterized in terms of its physical, mechanical, chemical, radiological and biological properties."
(3)	Basis: GSR Part 5 Para. 4.12 states that "Radioactive waste may be classified for different purposes, and different classification schemes may be used in the successive steps in waste management. The most common classification is that made from the perspective of its future disposal."
(4)	<b>Basis:</b> GSG-1 Para. 2.17 states that "Substantial amounts of waste arise from the operation and decommissioning of nuclear facilities with levels of activity concentration in the region of or slightly above the levels specified for the clearance of material from regulatory control.[] The management of this waste, in contrast to exempt waste, does require consideration from the perspective of radiation protection and safety, but the extent of the provisions necessary is limited in comparison to the provisions required for waste in the higher classes (LLW, ILW or HLW) []."
R22	<b>Recommendation:</b> ANRA should establish the requirements for the characterization of radioactive waste to facilitate its future disposal.
Observat	ion: No integrated consideration of effectiveness of RW predisposal management is in place

and the waste acceptance criteria for storage and disposal of radioactive waste are not established.

	2015 MISSION RECOMMENDATIONS, SUGGESTIONS		
(1)	BASIS: GSR Part 5 Requirement 6 states that "Interdependences among all steps in the predisposal management of radioactive waste, as well as the impact of the anticipated disposal option, shall be appropriately taken into account"		
(2)	BASIS: GSR Part 5 Requirement 6 para. 3.21 states that "It is particularly important to consider the established acceptance criteria for disposal of the waste or the criteria that are anticipated for the most probable disposal option".		
(3)	BASIS: SSR-5 Requirement 20 states that "Waste packages and unpackaged waste accepted for emplacement in a disposal facility shall conform to criteria that are fully consistent with, and are derived from, the safety case for the disposal facility in operation and after closure".		
R23	<b>Recommendation:</b> The Government should establish waste acceptance criteria for the storage and the disposal of radioactive waste packages.		
	<b>Observation:</b> Only general requirements for the development of different types of disposal facilities for radioactive waste are in place.		
(1)	<b>BASIS: SSR-5 Requirement 2 states that</b> "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".		
S13	<b>Suggestion:</b> ANRA should consider establishing specific regulatory requirements for different types of disposal facilities and setting out the procedures for meeting the requirements established.		

**Recommendation 22:** The requirements for radioactive waste characterization are established in the Government Decree № 631-N of 04 June 2009 as amended under Government Decree № 1424-N of 09 November 2017.

**Recommendation 23:** The IRRS team was informed that the draft waste acceptance criteria have been developed and will be specified in a draft document on radioactive waste management that will replace Government Decree  $N_0$  631-N of 04 June 2009. The development of the draft document is scheduled for the end of 2019.

**Suggestion 13:** The IRRS team was informed that draft safety requirements for radioactive waste disposal have been developed which is for near-surface disposal facilities. This draft document will be used during the development of a regulatory document on radioactive waste management, which will replace Government Decree N = 631-N of 04 June 2009. The document will cover both predisposal and disposal radioactive waste management aspects. It is ANRA's plan to develop the document by the end of 2019.

#### Status of the finding in the initial mission

Recommendation 22 (R22) is closed as ANRA has established the requirements for the characterization of radioactive waste to facilitate its future disposal.

**Recommendation 23 (R23) remains open** as the acceptance criteria for the storage and the disposal of radioactive waste packages have not been submitted to the Government for approval.

**Suggestion 13 (S13) remains open** as the specific regulatory requirements for different types of disposal facilities have not been submitted to the Government for approval.

9.5. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

# 2015 MISSION RECOMMENDATIONS, SUGGESTIONS Observation: Import and export of radiation sources are authorized. ANRA does not have a requirement for financial provisions for the long-term management of high activity radioactive sources, and the financial resources are not verified during the process of authorization. BASIS: GSR Part 3 Requirement 17, para. 3.60 states that "Registrants and licensees shall ensure that arrangements are made promptly for the safe management of and control **(1)** over radiation generators and radioactive sources, including appropriate financial provision, once it has been decided to take them out of use." Code of Conduct on the Safety and Security of Radioactive Sources, para. 22 states that "Every State should ensure that its regulatory body...ensures that arrangements are **(2)** made for the safe management and secure protection of radioactive sources, including financial provisions where appropriate, once they have become disused...' Suggestion: ANRA should consider establishing the requirements to ensure financial provisions for safe management of high activity radioactive sources, once **S14** they have become disused, and verify these arrangements during the process of authorization.

#### Changes since the initial IRRS mission

**Suggestion 14:** Government Decree No 1790-N, adopted 2004 (amended in December 2015), provides requirements for the licensing of import and export of radioactive materials and equipment containing radioactive materials. Based on this Decree, ANRA requires that an application for authorization to import category 1, 2, or 3 radioactive sources should show that the procurement contract provides for the return of the radioactive source to the supplier at the end of its useful life.

Orphan sources are normally transferred to the RADON waste storage facility. The IRRS team was informed that if a source cannot be returned to its supplier for some reason, such as legacy sources where the supplier does not exist anymore, ANRA makes a case-by-case decision to transfer responsibility for the source to the waste storage facility. The waste storage facility is a state-owned company and accepts sources at no cost.

According to the Rules on Radiation Safety, a licensee should create all conditions for radiation source purchase, account, storage, use and disposal so as to prevent their loss or uncontrolled use. When a radioactive source of category less than 3 becomes disused, it is considered as waste and is transferred to the waste storage facility.

#### Status of the finding in the initial mission

**Suggestion 14 (S14) is closed** as ANRA has established requirements that Category 1, 2 and 3 radioactive sources should be returned to the supplier and requires a contract that stipulates this requirement in the authorization process.

#### 9.6. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

2015 MISSION RECOMMENDATIONS, SUGGESTIONS		
	<b>Observation:</b> The regulatory requirements for safe decommissioning of nuclear facility different from NPPs have not been established by ANRA.	
(1)	BASIS: GSR Part 1 Requirement 10, states that "The government shall make provision for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities, and the safe management of spent fuel.	
(2)	BASIS: GSR Part 1 para. 2.28 states that "The decommissioning of facilities and the safe management and disposal of radioactive waste shall constitute essential elements of the governmental policy and the corresponding strategy over the lifetime of facilities and the duration of activities. The strategy shall include appropriate interim targets and end states"	
(3)	BASIS: GSR Part 6 Requirement 10, para. 7.1 & 7.5 states that "The regulatory body shall ensure that the licensee takes decommissioning into account in the siting, design, construction, commissioning and operation of the facility, by means which include features to facilitate decommissioning, the maintenance of records of the facility, and consideration of physical and procedural methods to limit contamination and/or activationthe decommissioning plan shall be updated by the licensee and shall be reviewed by the regulatory body periodically	
(4)	<b>BASIS:</b> GSR Part 6 Requirement 3, states that "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	
R24	<b>Recommendation:</b> ANRA should establish the regulatory requirements for decommissioning in line with the IAEA safety standards.	

#### Changes since the initial IRRS mission

**Recommendation 24:** The IRRS team was informed that ANRA will establish the requirements for decommissioning in the new Atomic Law and develop an associated detailed regulation in line with the IAEA safety standards. This new Atomic Law will take into consideration also the requirements coming from the Comprehensive & Enhanced Partnership Agreement between the European Union & Armenia (CEPA).

#### Status of the finding in the initial mission

**Recommendation 24 (R24) remains open** as the regulatory requirements for decommissioning of facilities other than NPPs have not been submitted to the Government for approval.

#### 9.7. REGULATIONS AND GUIDES FOR TRANSPORT

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
<b>Observation:</b> The existing Transportation Decree is based on IAEA Transport Regulations of 1996. This Decree has not yet been reviewed and updated according the actual IAEA Transport Regulation SSR-6.	
(1)	<b>BASIS: GSR Part 1 Requirement 33 states that:</b> "Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained."
(2)	BASIS: TS-G-1.1 Para. 307.5 states that: "A compliance assurance programme can only be implemented if its scope and objectives are conveyed to all parties involved in the transport of radioactive material (i.e. designers, manufacturers, consignors and carriers). Therefore, compliance assurance programmes should include provisions for information dissemination. This should inform users about the way the competent authority expects them to comply with the Transport Regulations and about new developments in the regulatory field. All parties involved should use trained staff."
R25	<b>Recommendation:</b> ANRA should review and revise the Transportation Decree to ensure that it is in compliance with the current IAEA Transport safety standards.
S15	<b>Suggestion:</b> ANRA should consider providing guidance for users and applicants to meet the requirements of the transport regulations.

#### Changes since the initial IRRS mission

**Recommendation 25:** The RA Government Decree №978-N on the transportation of nuclear and radioactive materials, approved on 9 August 2016, revised Government Decree № 1263 of 24 December 2001, which had been based on out of date IAEA standards.

Government Decree №978-N addresses previous discrepancies such as the values of A1 and A2 which had not agreed with the values from Table 2 of the IAEA Regulations for the Safe Transport of Radioactive Material - Specific Safety Requirements 6 (SSR-6). Other changes also included new provisions related to deviation from the transportation requirements stipulated in the rules, transportation in special conditions, exempted packages, and UN numbering and labelling.

Since Government Decree №978-N was issued in 2016, it did not reflect the most recent (2018) edition of SSR-6 (Rev. 1). The ANRA's schedule to review and update its requirements is every three years, and an update to Government Decree №978-N is scheduled in 2019. This update is expected to address relevant changes in SSR-6, Rev. 1.

Suggestion 15: Government Decree № 931-N of 27 June 2002, provides guidance on the transport regulations to users and applicants. While ANRA plans to update this document to reflect the most recent requirements, it has not yet done so due to higher priority work and human resource constraints.

# Status of the finding in the initial mission

Recommendation 25 (R25) is closed on the basis of progress made and confidence in the effective completion in due time as Government Decree №978-N was revised to reflect the thencurrent transport safety standards and another update is planned in 2019.

**Suggestion 15 (S15) remains open** as a planned update to the guidance on the transport regulations for users and applicants is pending.

#### 10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

#### 10.1. GENERAL EPR REGULATORY REQUIREMENTS

2015 MISSION RECOMMENDATIONS, SUGGESTIONS		
<b>Observation:</b> The legislative framework includes only some general requirements on emergency preparedness and response for the operating organizations that ANRA uses as basis for their regulatory control, mainly in relation to the ANPP. There are no specific EPR requirements in place for all operating organizations.		
(1)	BASIS: GS-R-2 para. 3.9 states that "In fulfilling its statutory obligations, the regulatory body shall establish, promote or adopt regulations and guides upon which its regulatory actions are based; shall provide for issuing, amending, suspending or revoking authorizations, subject to any necessary conditions, that are clear and unambiguous and which shall specify (unless elsewhere specified): the requirements for incident reporting; and emergency preparedness arrangements."	
R26	<b>Recommendation:</b> ANRA should develop and promulgate regulatory requirements for EPR for all operating organizations covering all relevant general, functional and infrastructure aspects of IAEA GS-R-2 in relation to response to nuclear and/or radiological emergencies.	
<b>Observation:</b> There are no specific guidelines for the operating organizations on developing threat assessments as basis for their on-site emergency response plans.		
(1)	<b>BASIS: GS-R-2 para. 3.15 states that</b> "The nature and extent of emergency arrangements [for preparedness and response] shall be commensurate with the potential magnitude and nature of the [threat] associated with the facility or activity. The full range of postulated events shall be considered in the threat assessment. In the threat assessment, emergencies involving a combination of a nuclear or radiological emergency and a conventional emergency such as an earthquake shall be considered. []"	
S16	<b>Suggestion:</b> ANRA should consider developing guidelines to support the threat assessment of all operating organizations.	

# Changes since the initial IRRS mission

**Recommendation 26:** Development and completion of the legislative and regulatory framework represent a priority for ANRA and it is referenced in both the "ANRA Strategic Plan for the period 2019 - 2024" approved by ANRA Chairman in March 2019 and the draft "Strategy on Nuclear and Radiation Safety in the Republic of Armenia for the period 2019-2029". With respect to this, actions have been initiated by ANRA for the development of a new Atomic Law and of revised radiation safety and protection requirements. According to "ANRA Workplan for 2019", a first draft of the Atomic Law and revised radiation safety and protection requirements will be available for discussions at the end of 2019.

Although steps have been initiated for the development and revision of regulatory requirements in line with IAEA safety standards, including regulatory requirements on emergency preparedness and response (EPR), the process has been just initiated and it will be completed in the years to come. During the interviews it has been highlighted that ANRA should revise and update the regulatory requirements on EPR in line with GSR Part 7, which superseded GS-R-2 in November 2015.

**Suggestion 16:** The development of guidelines to support the threat assessment of all operating organizations has not been yet started. ANRA plans to elaborate such guidelines after the new Atomic Law will be promulgated.

#### Status of the finding in the initial mission

**Recommendation 26 (R26) remains open** as the process to develop and promulgate regulatory requirements for EPR in line with IAEA safety standards for all operating organizations is in its initial phase.

**Suggestion 16 (S16) remains open** as the process to develop guidelines to support the threat assessment of all operating organizations has not been started.

#### 10.2. FUNCTIONAL REGULATORY REQUIREMENTS

#### 2015 MISSION RECOMMENDATIONS, SUGGESTIONS

**Observation:** Although it is based on a graded approach, ANRA's regulatory control is rather weakly enforced, mainly because of limited availability of human resource; the inspections on EPR are very limited in number for the ANPP (mainly one per year) and randomly performed at radiological facilities.

(1)	BASIS: GS-R-2 para. 3.8 states that "The regulatory body shall require that arrangements for preparedness and response be in place for the on-site area for any practice or source that could necessitate an emergency intervention.[] The regulatory body shall ensure that such emergency arrangements are integrated with those of other response organizations as appropriate before the commencement of operation. The regulatory body shall ensure that such emergency arrangements provide a reasonable assurance of an effective response, in compliance with these requirements, in the case of a nuclear or radiological emergency."

**Recommendation:** ANRA should strengthen its regulatory control on EPR through comprehensive inspections, in order to ensure that the on-site EPR arrangements provide a reasonable assurance for an effective response.

**Observation:** Although a generic requirement for operating organizations to have in place a system for emergency classification is included in the Basic requirements, a system for emergency classification and specific criteria are not yet adopted by ANRA.

(1)	BASIS: GS-R-2 para. 4.20 states that "The emergency classification system for facilities or practices in threat category I, II, III or IV shall take into account all postulated nuclear and radiological emergencies. The criteria for classification shall be predefined emergency action levels (EALs) that relate to abnormal conditions for the facility or practice concerned, security related concerns, releases of radioactive material, environmental measurements and other observable indications.[]"
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**R28** Recommendation: ANRA should adopt a system and develop criteria for emergency classification that follows the requirements of IAEA GS-R-2.

**Observation:** ANRA has no specific requirements for the operating organizations and no developed criteria for the termination of the emergency and transition to the recovery phase.

	2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
(1)	<b>BASIS: GS-R-2 para. 4.97 states that</b> "The transition from the emergency phase to long term recovery operations and the resumption of normal social and economic activity shall be planned and made in an orderly manner and in accordance with international standards and guidance."	
(2)	<b>BASIS: GS-R-2 para. 4.100 states that</b> "Decisions to cancel restrictions and other arrangements imposed in response to a nuclear or radiological emergency shall be made by a formal process that is in accordance with international guidance. The regulatory body shall provide any necessary input to the intervention process. Such input may be advice to the government or regulatory control of intervention activities. Principles and criteria for intervention actions shall be established and the regulatory body shall provide any necessary advice in this regard."	
S17	<b>Suggestion:</b> ANRA should consider developing criteria for the termination of the emergency and the transition to long term recovery operations that follows the requirements of IAEA GS-R-2.	

**Recommendation 27:** Progress has been made by ANRA in the last years for strengthening the regulatory control on EPR through inspections. In May 2016, ANRA performed a comprehensive inspection of on-site EPR arrangements at ANPP. For all deficiencies identified, corrective actions have been imposed and their implementation has been monitored till final completion in February 2018. Since 2017, ANRA has appointed a site inspector who is responsible to inspect regularly also the on-site EPR arrangements and observe the on-site emergency response exercises of the ANPP. When non-compliance is identified during an inspection or during the observation of an on-site emergency response exercise, the site inspector issues an inspection protocol with requests for corrective actions and establishes deadlines for the ANPP to comply with. ANRA is regularly checking the implementation status of corrective actions at ANPP. Examples of such acts issued in the period 2016 – 2018 have been provided as evidence.

Facilities and activities using radioactive sources in categories 1, 2 and 3 are periodically inspected by ANRA inspectors: for category 1 sources, annually; and for category 2 and 3 sources, once in 2 - 3 years. During inspections, the on-site EPR arrangements are verified, based on pre-defined check lists. Inspection plans from previous years and filled-in check lists including elements of on-site EPR arrangements have been provided as evidence.

**Recommendation 28:** At ANRA's request, ANPP has revised its existing emergency classification system to be in line with IAEA safety standards GSR Part 7 (which superseded GS-R-2 in November 2015). The revised system of classification, including general emergency, site-area emergency and alert is thoroughly described in the revised ANPP on-site emergency plan approved through ANPP Order 718/28.06.2017. Emergency Action Levels (EALs) have been developed and they are included in the "ANPP Guide for emergency classification at the ANPP" approved by ANPP Order 183/14.03.2016. This document is now being updated to bring it in line with the revised emergency classification system, and is expected to be in force by the end of 2019. ANRA has included the revised system for emergency classification at ANPP into its internal procedure EP-EO-01 approved by the ANRA Chairman (Order 71-A/10.03.2019).

The revised ANPP on-site emergency plan, the ANPP Guide and the ANRA Procedure have been presented as evidences during the interviews.

**Suggestion 17:** Criteria for the termination of the emergency and the transition to long term recovery operations haven't been yet established by ANRA. Plans exist for developing such criteria in the future, after the promulgation of the new Atomic Law.

# Status of the finding in the initial mission

Recommendation 27 (R27) is closed on the basis of progress made and confidence in the effective completion in due time as ANRA has intensified its inspections of EPR arrangements at ANPP and at facilities and activities using radioactive sources.

**Recommendation 28 (R28) is closed** as, upon ANRA's request, the emergency classification system at ANPP has been harmonized with the IAEA safety standards and EALs have been developed and included in ANPP's Guidelines.

**Suggestion 17 (S17) remains open** as criteria for the termination of the emergency and the transition to long term recovery operations have not been established by ANRA.

#### 10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
<b>Observation:</b> ANRA has no methodology in place for evaluating the training and exercise programs of the ANPP or any other operating organization. Brief evaluations are performed by ANRA during inspections and immediately after the end of exercises.	
(1)	<b>BASIS: GS-R-2 para. 5.31 states that</b> "5.31. The operator and the response organizations shall identify the knowledge, skills and abilities necessary to be able to perform the functions specified in Section 4. The operator and the response organizations shall make arrangements for the selection of personnel and for training to ensure that the personnel have the requisite knowledge, skills, abilities, equipment, and procedures and other arrangements to perform their assigned response functions []".
(2)	<b>BASIS: GS-R-2 para. 5.33 states that</b> "Exercise programmes shall be conducted to ensure that all specified functions required to be performed for emergency response and all organizational interfaces for facilities in threat category I, II or III [] are tested at suitable intervals. These programmes shall include the participation in some exercises of as many as possible of the organizations concerned. The exercises shall be systematically evaluated and some exercises shall be evaluated by the regulatory body []".
S18	<b>Suggestion:</b> ANRA should consider elaborating an internal methodology for the evaluation of training and exercise programmes of all operating organizations; the methodology should include evaluation criteria needed to ensure that training and exercise programmes of operating organizations are periodically reviewed and updated in the light of experience gained.

**Suggestion 18:** Although ANRA evaluates training and exercise programmes of operating organizations on a regular basis, especially those of ANPP, a methodology including evaluation criteria has not been yet developed.

# Status of the finding in the initial mission

**S19** 

**Suggestion 18 (S18) remains open** as ANRA has not developed a methodology for the evaluation of training and exercise programmes of all operating organizations.

#### 10.4. ROLE OF REGULATORY BODY DURING RESPONSE

considered for refresher training.

10.1. ROLI	10.1. ROLL OF REGULATION FRONT BOD'S BURNING RESPONSE	
	2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
<b>Observation:</b> Each position of the Emergency Response Organization is staffed with an insufficient number of experts (one or two, but not more). Therefore the resilience of the emergency organization cannot be guaranteed in case of a long term response during a severe accident at the ANPP.		
(1)	BASIS: GS-R-2 para. 5.9 states that "Sufficient numbers of qualified personnel shall be available at all times in order that appropriate positions can be promptly staffed as necessary following the declaration and notification of a nuclear or radiological emergency."	
R29	<b>Recommendation:</b> ANRA should qualify and assign an increased number of personnel for each position within the Emergency Response Organization, so that ANRA can work in shifts during long term response in case of accident at the ANPP, in order to fulfil its responsibilities effectively and sustainably.	
job training	<b>Observation:</b> The training of ANRA's staff on EPR related issues is mainly achieved through on-the- job training, seminars and internal exercises. There is no internal training programme in place for the personnel assigned to be part of the emergency response organization.	
(1)	BASIS: GS-R-2 para. 5.31 states that "The operator and the response organizations shall identify the knowledge, skills and abilities necessary to be able to perform the functions specified in Section 4. [] The arrangements shall include ongoing refresher training on an appropriate schedule and arrangements for ensuring that personnel assigned to positions with responsibilities for emergency response undergo the specified training."	
	Suggestion: ANRA should consider developing an internal training programme, including initial and refresher training, for its staff for performing the response	

**Observation:** In the last years, ANRA conducted only one major exercise in 2008 with EC support. Although ANRA organizes annually internal drills and exercises for testing its functions during a nuclear or radiological emergency, there is not enough testing of its performance in relation to the interactions with other organizations within the national crisis management system.

functions in case of a nuclear or radiological emergency; criteria should be adopted in order to evaluate the quality of the training. An annual periodicity should be

(1) BASIS: GS-R-2 para. 5.33 states that "Exercise programmes shall be conducted to ensure that all specified functions required to be performed for emergency response and all organizational interfaces for facilities in threat category I, II or III [...]. These programmes

2015 MISSION RECOMMENDATIONS, SUGGESTIONS			
	shall include the participation in some exercises of as many as possible of the organizations concerned. The exercises shall be systematically evaluated and some exercises shall be evaluated by the regulatory body. The programme shall be subject to review and updating in the light of experience gained".		
S20	<b>Suggestion:</b> ANRA should consider conducting large scale emergency response exercises more frequently, in order to test its performance as response organization within the national crisis management system; special methodology for evaluating its performance during exercises should be developed as part of the exercise programmes of ANRA.		
	<b>Observation:</b> There is no entity within the organizational structure of ANRA responsible for emergency planning and preparedness activities for both its roles, as regulatory body and response organization.		
(1)	BASIS: GSR Part 1 Requirement 16 states that "The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities."		
S21	<b>Suggestion:</b> ANRA should consider structuring its organization so that an entity should be created within the organizational chart to be responsible for ANRA's emergency planning and preparedness activities as regulatory body and as response organization.		

**Recommendation 29:** The revised ANRA emergency plan, approved by ANRA Chairman (Order 332-A/21.12.2017), includes a list of personnel of ANRA and NRSC assigned to perform response functions within the emergency organization of ANRA. Although the human resources of both ANRA and NRSC are very limited, all positions within the emergency organization are filled in with personnel so that ANRA could work in 3 shifts per day for longer duration in case of nuclear emergency at ANPP. Internal procedure EP-EO-05.4 has been revised by ANRA (revision 4 of May 2019) to fill in the shifts in case of emergency, based on the list provided in the emergency plan. The ANRA emergency plan and the relevant procedure have been provided as evidences during the interviews.

Suggestion 19: At ANRA's request, NRSC developed in the second part of 2015 the first version of a training package (NRSC-RT-A112-T3.6-001) for the training of ANRA and NRSC personnel, including newcomers, with duties within the emergency organization of ANRA. The training package has been approved by ANRA Chairman Order 51/24.12.2015. A revised comprehensive version (Revision 1) of the training package has been developed by NRSC and adopted in March 2019 (NRSC-RT-A118-4.4-001). While NRSC is mainly responsibe for elaborating training materials and delivery of training, ANRA is responsible for planning, implementation and evaluation of training events. When modifications are made to internal procedures, NRSC conducts special training events for all personnel with duties within the emergency organization of ANRA. Special training sessions have been conducted by NRSC in March and April 2018. In addition, before each internal emergency response exercise, the personnel is trained by ANRA designated expert within ANRA emergency response centre on their specific duties. Training activities are included in the ANRA annual workplans, one activity for every quarter.

Although a methodology for evaluation of training events hasn't been yet developed, the evaluation of training events in ANRA is well performed. The quality of training is evaluated mainly through discussions with the trainees and findings resulted from internal emergency response exercises. After each training event, feedback is collected in an evaluation report and submitted to the ANRA Chairman for approval and for initiation of official requests for implementing corrective actions. The training packages and training plans have been provided as evidences during the interviews.

Suggestion 20: Significant progress has been made by ANRA in the last years in relation to its participation in exercises at national level in order to test its performance as response organization within the national crisis management system. ANRA, ANPP and the Ministry of Emergency Situations have signed Memorandum for Cooperation (last revision signed in 27 August 2013) to collaborate and coordinate their preparedness activities and response actions in case of nuclear emergencies. Since 2016, twice a year ANRA, ANPP and the Ministry of Emergency Situations participate in joint emergency response exercises, to test their respective EPR arrangements. Although these exercises do not involve other partner ministries or governmental agencies, having the Ministry of Emergency Situations as partner gives ANRA the opportunity to test its plan and performance within the national crisis management system. In addition, in October 2017, ANRA participated in a full scale national emergency response exercise with a scenario on severe accident at ANPP. Evidences have been provided during the interviews on emergency response exercises conducted between 2016 – 2019 with participation of ANPP, ANRA and the Ministry of Emergency Situations.

While these exercises are evaluated by ANRA and issues identified are reported to ANRA Chairman and then corrected, there is no written methodology yet in place for the evaluation of ANRA's performance in emergency response exercises.

**Suggestion 21:** ANRA organizational structure includes the Technical Section assigned with responsibilities for physical protection, and emergency preparedness and response, according to ANRA Chairman Order 84-A/22.05.2019. The statute of the Technical Section is under revision.

#### Status of the finding in the initial mission

**Recommendation 29 (R29) is closed** as ANRA has appointed for each position within the emergency response organization a sufficient number of qualified personnel from ANRA and NRSC to cover 3 shifts per day in case of a nuclear emergency at ANPP.

Suggestion 19 (S19) is closed on the basis of progress made and confidence in the effective completion in due time as ANRA, with NRSC support, has implemented a training programme for its staff performing response functions in case of a nuclear or radiological emergency.

Suggestion 20 (S20) is closed on the basis of progress made and confidence in the effective completion in due time as ANRA has increased its participation as a response organization in joint emergency response exercises with ANPP and the Ministry of Emergency Situations.

Suggestion 21 (S21) is closed on the basis of progress made and confidence in the effective completion in due time as the section responsible for ANRA's emergency planning and preparedness activities is established, its statute is being revised, and the process for appointing the head of this section is close to finalization.

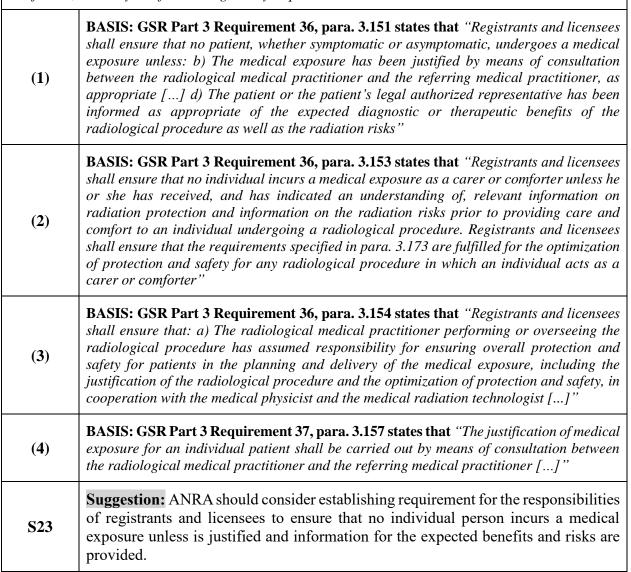
# 11. ADDITIONAL AREAS

# 11.1. CONTROL OF MEDICAL EXPOSURES

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
<b>Observation:</b> Dose constraints for volunteers participating in the programme of biomedical research are not established. The criteria for patients with implanted sealed sources as well as guidelines for release of patients after therapeutic radiological procedure are yet not established.	
(1)	<b>BASIS:</b> GSR Part 3 Requirement 34, states that "The government shall ensure that relevant parties are authorized to assume their roles and responsibilities, and that diagnostic reference levels, dose constraints, and criteria and guidelines for the release of patients are established".
(2)	BASIS: GSR Part 3 Requirement 34, para. 3.148 states that "The government shall ensure []: a) Dose constraints, to enable the requirements of paras 3.173 and 3.174, respectively, to be fulfilled for (i) exposures of carers and comforters (ii) Exposures due to diagnostic investigations of volunteers participating in a programme of biomedical research; b) Criteria and guidelines for the release of patients who have undergone therapeutic radiological procedures using unsealed sources or patients who still retain implanted sealed sources"
S22	<b>Suggestion:</b> The government should consider ensuring the establishment, in consultation with relevant bodies, of dose constraints for exposure of carers and comforters and for volunteers participating in the programme of biomedical research. The government should consider also establishing criteria for the release of patients with implanted sealed sources as well as guidelines for release of patients after therapeutic radiological procedure with sealed or unsealed sources.
health prof requiremen	on: There are no established requirements for the specialization in appropriate area for fessionals with responsibilities for medical exposure. There are currently no established ts for appropriate education, training and competence for health professionals with ities for medical exposure.
(1)	BASIS: GSR Part 3 Requirement 35, states that "The regulatory body shall require that health professionals with responsibilities for medical exposure are specialized in the appropriate area and that they fulfil the requirements for education, training and competence in the relevant specialty".
(2)	BASIS: GSR Part 3 Requirement 35, para. 3.150 states that "The regulatory body shall ensure that the authorization for medical exposures to be performed at a particular medical radiation facility allows personnel (radiological medical practitioners, medical physicists, medical radiation technologists and any other health professionals with specific duties in relation to the radiation protection of patients) to assume the responsibilities specified in these Standards only if they: a) are specialized in the appropriate area; b) Meet the respective requirements for education, training and competence in radiation protection."
R30	<b>Recommendation:</b> The regulatory body should establish requirements for education, training and competence in protection and safety of all health professionals with responsibilities for medical exposure, including for any specialization required.

#### 2015 MISSION RECOMMENDATIONS, SUGGESTIONS

**Observation:** The responsibilities for consultation of the referring medical practitioner and the radiological medical practitioner are not included in the regulatory requirements. The responsibilities of licensees and radiological medical practitioners for informing the benefits and risks of medical exposure before incurring medical exposure, as well as for the protection and the safety of carers and comforters, are not yet defined in regulatory requirements.



**Observation:** The requirements related to arrangements in place for appropriate radiation protection in cases where a female patient is or might be pregnant or is breast-feeding are not yet established. There are currently no requirements for the review, for records and for investigation of any unintended or accidental medical exposure. There are currently no established specific requirements for optimization of medical exposures related to operational considerations, calibration, dosimetry of patients and quality assurance.

(1) BASIS: GSR Part 3 Requirement 38 states that "Registrants and licensees and radiological medical practitioners shall ensure that protection and safety is optimized for each medical exposure

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
(2)	BASIS: GSR Part 3 Requirement 39 states that "Registrants and licensees shall ensure that there are arrangements in place for appropriate radiation protection in cases where a female patient is or might be pregnant or is breast-feeding"
(3)	BASIS: GSR Part 3 Requirement 42 states that "Registrants and licensees shall ensure that radiological reviews are performed periodically at medical radiation facilities and that records are maintained"
(4)	BASIS: GSR Part 3 Requirement 41 states that "Registrants and licensees shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures. Registrants and licensees shall promptly investigate unintended or accidental medical exposures and, if appropriate, shall implement corrective actions"
R31	Recommendation: The regulatory body should establish requirements for the responsibilities of registrants and licensees for:  a) appropriate radiation protection arrangements in place for medical exposure of pregnant or breast-feeding patients;  b) taking measure and investigating unintended and accidental medical exposures;
	<ul><li>c) ensuring that radiological reviews are performed periodically at medical radiation facilities and records are maintained;</li><li>d) ensuring that protection and safety is optimized for each medical exposure.</li></ul>

**Suggestion 22:** Dose constraints for exposure of carers and comforters and for volunteers participating in the programme of biomedical research are not established. Criteria for the release of patients with implanted sealed sources as well as guidelines for release of patients after therapeutic radiological procedure with sealed or unsealed sources are not in place. Currently, Armenia is participating in IAEA TC project on radiation protection of individuals undergoing medical exposure (patients, carers, comforters and volunteers in programmes for biomedical research). The IRRS team was informed that through its participation in the IAEA TC project, ANRA expects to establish:

- dose constraints for exposure of carers and comforters and for volunteers participating in the programme of biomedical research;
- criteria for the release of patients with implanted sealed sources;
- guidelines for release of patients after therapeutic radiological procedure with sealed or unsealed sources.

ANRA has also started development of new Radiation Safety Standards document and has plans to include the provisions stipulated in GSR part 3, requirement 34. However the draft document is at an early stage of development.

**Recommendation 30:** In 2018, NRSC drafted a "Matrix for analysis of similar/field training materials and programs of the IAEA and other organization in the field of personnel training in the

nuclear energy field", based on which a draft of training program for radiation safety and protection for health professionals has been developed.

ANRA has started development of a new Atomic Law, which is foreseen to be in place by 2022-2023. The IAEA review team was informed that provisions related to the requirements for education, training and competence in the area of radiation protection and safety for professionals with responsibilities for medical exposure are planned to be included in the new Atomic Law.

Suggestion 23: The Government Decree  $\mathbb{N}_{2}$  1489-N of 18.08.2006 on approval of radiation safety rules was amended in 2016, in order to include provisions for justification for medical exposure. The draft of the new Atomic Law includes provisions related to responsibilities of licensees' for informing the patient about the health benefits and risks of exposure, and on the need for justification of exposures.

However, requirements for the responsibilities of registrants and licensees to ensure that no individual person incurs a medical exposure unless it is justified and on informing patients on expected benefits and risks are have not been established.

**Recommendation 31:** The Government Decree № 1489-N of 18.08.2006 on approval of radiation safety rules was amended in 2016, in order to include provisions for optimization of protection and safety for persons undergoing medical exposure.

The draft of the new Atomic Law includes provisions that licensed persons in the field of atomic energy should ensure that medical exposure is performed exclusively based on indication of a medical symptom and that radiation protection is optimally rationalized by applying special restrictions to pregnant and breastfeeding women. Additionally, the IRRS team was informed that special restrictions on the medical exposure of pregnant or breastfeeding mothers are planned to be included in the new draft Radiation Safety Standards, which is under development.

The draft of the new Atomic Law includes regulatory requirements for licensees for:

- taking measures and investigating unintended and accidental medical exposure;
- ensuring that radiological reviews are performed periodically at medical radiation facilities and records are maintained.

### Status of the finding in the initial mission

**Suggestion 22 (S22) remains open** as dose constraints, criteria for release of patients and guidelines for release of patients after therapeutic radiological procedure with sealed or unsealed sources have not been established.

**Recommendation 30 (R30) remains open** as requirements for education, training and competence of all health professionals with responsibilities for medical exposure have not been established.

**Suggestion 23 (S23) remains open** as requirements for the responsibilities of registrants and licensees with regard to justification and informing the patient have not been established.

**Recommendation 31 (R31) remains open** as the development of respective legal and regulatory requirements for the responsibilities of registrants and licensees is at an early stage.

# 11.2. OCCUPATIONAL RADIATION PROTECTION

2015 MISSION RECOMMENDATIONS, SUGGESTIONS		
<b>Observation:</b> The regulatory requirements for existing exposure situations are stipulated in regulation but have not been implemented yet.		
(1)	BASIS: GSR Part 3 Requirement 52, states that: "The regulatory body shall establish and enforce requirements for the protection of workers in existing exposure situation"	
S24	<b>Suggestion:</b> ANRA should consider undertaking measures in order to enforce requirements for the protection of workers in existing exposure situations.	
retirement a	<b>Observation:</b> Armenia has a system of benefits with respect to salary, working hours, holidays and retirement as a benefit for workers working in hazard conditions (which includes the work with radiation sources) according to Labour Law which is in contradiction to GSR Part 3.	
(1)	BASIS: GSR Part 3 Requirement 27, para. 3.111 states that "The conditions of service of workers shall be independent of whether, they are or could be subject to occupational exposure. Special compensatory, arrangements, or preferential consideration with respect to salary, special, insurance coverage, working hours, length of vacation, additional holidays or retirement benefits, shall neither be granted nor be used as substitutes for measures for protection and safety in accordance with the requirements of these Standards."	
R32	<b>Recommendation:</b> The Government should ensure that the conditions of service of radiation workers are independent of whether they are or could be professionally exposed.	
Observation	<b>Observation:</b> The following issues are not addressed in regulations or are not currently implemented:	
– The skin	equivalent dose limit for skin is not specifically applicable to the most exposed part of the	
	ords on emergency doses are not distinguished from doses, exposures and intakes due to mal conditions of work;	
	men after the pregnancy is confirmed are excluded from work with ionising radiation, and are moved to another work without radiation;	
	re is only one requirement on keeping records on occupational exposure - records are to be tined at the licensee for the period of 50 years.	
	BASIS: GSR Part 3 Schedule III 1 states that "For occupational exposure of workers over the age of 18 years, the dose limits are:	
(1)	(c) An equivalent dose to the extremities (hands and feet) or to the skin (the equivalent dose limits for the skin apply to the average dose over 1 cm² of the most highly irradiated area of the skin. The dose to the skin also contributes to the effective dose, this contribution being the average dose to the entire skin multiplied by the tissue weighting factor for the skin.) of 500 mSv in a year. "	
(2)	BASIS: GSR Part 3 Requirement 25, para. 3.105 states that "Records of occupational exposure shall include:	
(2)	Records of any assessments made of doses, exposures and intakes due to actions taken in an emergency or due to accidents or other incidents, which shall be distinguished from	

2015 MISSION RECOMMENDATIONS, SUGGESTIONS	
	assessments of doses, exposures and intakes due to normal conditions of work and which shall include references to reports of any relevant investigations."
(3)	BASIS: GSR Part 3 Requirement 28, para. 3.114 states that "Notification of the employer by a female worker if she suspects that she is pregnant or if she is breast-feeding shall not be considered a reason to exclude the female worker from work. The employer of a female worker, who has been notified of her suspected pregnancy or that she is breast-feeding, shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo or foetus or the breastfed infant is afforded the same broad level of protection as is required for members of the public."
(4)	BASIS: GSR Part 3 Requirement 25, para. 3.104 states that "Records of occupational exposure for each worker shall be maintained during and after the worker's working life, at least until the former worker attains or would have attained the age of 75 years, and for not less than 30 years after cessation of the work in which the worker was subject to occupational exposure."
	<b>Recommendation:</b> The regulatory body should update current regulation for compliance with the requirements of GSR Part 3, specifically:
	a) the equivalent dose limit to the skin is applied to the most highly irradiated area of the skin;
R33	b) doses related to emergency exposure situation are to be distinguished from doses, exposures and intakes due to normal conditions of work;
	<ul> <li>c) pregnant or breast feeding women are not automatically excluded from work but allow them to continue to work under specific adjustment of working condition;</li> </ul>
	d) to establish provision for archiving of records of occupational exposure.

**Suggestion 24:** The draft of new Atomic Law, foreseen to be in place in 2022-2023, stipulates provisions related to the protection of the population and the personnel in the existing exposure situations including:

- a) the Government shall ensure:
- Identifying existing exposure conditions by implementing environmental monitoring
- Monitoring of radon gas concentrations and the population exposure controls within the whole territory of the Republic, on a random basis.
- b) For the existing exposure situations identified, the regulatory authority should establish reference levels.
- c) Persons responsible for the recovery of contaminated areas should develop a program on recovery of these areas and implement measures to control the post-recovery and submit to the regulatory authority for approval;
- d) Licensees should optimized protection of personnel, including the RA resident aircraft crew in existing exposure situations, measurement and registration of doses received.

However, ANRA has not undertaken measures in order to enforce requirements for the protection of workers in existing exposure situations.

**Recommendation 32:** The IRRS team was informed that ANRA plans to consider the issue of special conditions of service of radiation workers when the insurance system for the workers subject to occupational exposure will be in place.

**Recommendation 33:** Regulatory requirements on equivalent dose limit to the skin are planned to be included in the new Radiation Safety Standards, which is under development.

The IRRS team was informed that requirements for pregnant or breastfeeding women to allow them to continue to work under specific adjustment of working condition and not be automatically excluded from work are planned to be established in the new Radiation Safety Standards.

According to Decree № 1489-N on approval of radiation safety rules, the radiation monitoring data on the personnel occupational exposures of the categories "A" and "B" nuclear installations that are equal to or exceed the registration level should be recorded in the register of occupational radiation doses. It is required to register the annual equivalent and effective doses, the summary of effective dose and accumulated doses in the last 5 years. The data on the equivalent doses of the personnel is required to be kept for at least 50 years. The draft of the new Atomic Law stipulates requirements that in planned exposure situations, licensees should perform occupational radiation monitoring, registration and control. However, this is not in compliance with GSR Part 3. Provisions for archiving the records of occupationally exposed persons in compliance with GSR Part 3 are not established.

#### Status of the finding in the initial mission

**Suggestion 24 (S24) remains open** as sufficient progress has not been made for enforcing regulatory requirements for the protection of workers in existing exposure situations.

**Recommendation 32 (R32) remains open** as sufficient progress has not been made in relation to conditions of service for radiation workers.

**Recommendation 33 (R33) remains open** as development of updated regulatory provisions in line with GSR Part 3 is at an early stage.

11.3. CONTROL OF RADIOACTIVE DISCHARGES, MATERIALS FOR CLEARANCE, AND EXISTING EXPOSURES; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION

2015 MISSION RECOMMENDATIONS, SUGGESTIONS				
<b>Observation:</b> The concept of clearance and clearance criteria in Armenian regulations are not consistent with GSR Part 3.				
(1)	BASIS: GSR Part 3 Requirement 8 para. 3.12 states that "The regulatory body shall approve which sources, including materials and objects, within notified or authorized practices may be cleared from regulatory control, using as the basis for such approval the criteria for clearance specified in Schedule I or any clearance levels specified by the regulatory body on the basis of these criteria. By means of this approval, the regulatory body shall ensure that sources that have been cleared from regulatory control do not again become subject to the requirements for notification, registration or licensing unless it so specifies".			
(2)	BASIS: GSR Part 3 Schedule I para. I.12 states that "Radioactive material within a notified practice or an authorized practice may be cleared without further consideration			

2015 MISSION RECOMMENDATIONS, SUGGESTIONS				
	provided that: (a) The activity concentration of an individual radionuclide of artificial origin in solid form does not exceed the relevant level given in Table I.2 (p. 124); or (b) The activity concentrations of radionuclides of natural origin do not exceed the relevant level given in Table I.3 (p. 128); or			
	(c) For radionuclides of natural origin in residues that might be recycled into construction materials, or the disposal of which is liable to cause the contamination of drinking water supplies, the activity concentration in the residues does not exceed specific values derived so as to meet a dose criterion of the order of 1mSv in a year, which is commensurate with typical doses due to natural background levels of radiation."			
R34	<b>Recommendation:</b> ANRA should incorporate modifications in the regulations for explicitly addressing the concept of clearance and establishing clearance criteria as specified in GSR Part 3.			
program fo implementin overall dose	On: Due to the lack of logistic capabilities, ANRA does not carry out any parallel monitoring results provided by the operator. There are plans for a nationwide monitoring network that should serve for both the objectives of assessing the ess received by Armenian population and verification of the results of monitoring programs of future) carried out in the country.			
(1)	BASIS: GSR Part 3 Requirement 32, para. 3.135 states that "The regulatory body shall be responsible, as appropriate, for: (c) Making provision for an independent monitoring programme"			
S25	<b>Suggestion:</b> ANRA should continue efforts for implementing an independent monitoring infrastructure, including laboratory capacities for verification of results of ANPP's monitoring program.			
they are nei	<b>On:</b> Studies on radon concentrations in living spaces have been carried out in Armenia, but ther exhaustive nor representative. Nevertheless, obtained results indicate the existence of a which the radon concentrations exceed the reference value of 300 Bq/m3 established in			
	BASIS: GSR Part 3 Requirement 50, para. 5.19 states that "As part of its responsibilities,, the government shall ensure that:			
(1)	(a) Information is gathered on activity concentrations of radon in dwellings and other buildings with high occupancy factors for members of the public through appropriate means, such as representative radon surveys;"			
(2)	BASIS: GSR Part 3 Requirement 50 para. 5.20 states that "Where activity concentrations of radon that are of concern for public health are identified on the basis of the information gathered as required in para. 5.19(a), the government shall ensure that an action plan is established comprising coordinated actions to reduce activity concentrations of radon in existing buildings and in future buildings, which includes: [] (b) Reducing activity concentrations of 222Rn and consequent exposures to levels at which protection is optimized;			

2015 MISSION RECOMMENDATIONS, SUGGESTIONS				
	(c) Giving priority to actions to reduce activity concentrations of <sup>222</sup> Rn in those situation for which such action is likely to be most effective;			
	(d) Including in building codes appropriate preventive measures and corrective actions to prevent the ingress of <sup>222</sup> Rn and to facilitate further actions wherever necessary."			
S26	<b>Suggestion:</b> ANRA should consider implementing measures to ensure that studies related to radon levels and their impact on the public are completed and, where needed, implement an action plan for controlling public exposure due to rador indoors.			
<b>Observation:</b> Criteria for establishing reference levels for foodstuffs, water and selected commodities in Armenian regulations are not fully in compliance with relevant criteria in IAEA standards.				
(1)	BASIS: GSR Part 3 Requirement 51 para. 5.22 states that "The regulatory body or other relevant authority shall establish specific reference levels for exposure due to radionuclides in commodities such as construction materials, food and feed, and in drinking water, each of which shall typically be expressed as, or be based on, an annual effective dose to the representative person that generally does not exceed a value of about 1 mSv".			
(2)	BASIS: GSR Part 3 Requirement 51 para. 5.23 states that "The regulatory body or other relevant authority shall consider the guideline levels for radionuclides in food traded internationally that could contain radioactive substances as a result of a nuclear of radiological emergency, which have been published by the Joint Food and Agriculture Organization of the United Nations/World Health Organization Codex Alimentarius Commission. The regulatory body or other relevant authority shall consider the guideline levels for radionuclides contained in drinking water that have been published by the World Health Organization.			
R35	<b>Recommendation:</b> ANRA should establish reference levels for water, foodstuffs and selected commodities fully in compliance with relevant criteria in GSR Part 3.			

**Recommendation 34:** The concept of clearance and clearance criteria in accordance with GSR Part 3 is currently scheduled to be addressed in a new Radiation Safety Standards, which will supersede Decree 1219 and Decree 1489-N. The IRRS team was informed that the first draft, being prepared by NRSC, is expected to be sent to ANRA by the end of 2020. ANRA will send the draft to the Government for approval after adoption of the new Atomic Law.

Moreover, in Armenian regulations specific values for liquids, gases and groups of radionuclides have been established for conditional clearance. The regulations need to be reviewed to comply with clearance criteria established in GSR Part 3 for specific cases of clearance.

**Suggestion 25:** The IRRS team was informed that in accordance with Decree № 646-A of June 19, 2017, the Government has plans to establish an independent environmental radiation monitoring programme. The Government has provided ANRA with a building to establish a laboratory; funds have been allocated; a project document has been developed; preliminary budget needed has been estimated; and certain laboratory equipment has been purchased. In the time frame of 2019-2024, plans are under way to recruit staff, initiate training in different measurement and

sampling techniques, acquire sampling and monitoring equipment and develop a national environmental radiation monitoring programme.

**Suggestion 26:** In 2016, ANRA and NRSC developed the following documents:

- Radon Action Plan;
- National Radon Programme (NRP);
- Methodology on long-term measurements of indoor radon.

Currently these documents are finalized but are not yet approved.

In 2018 measurements of radon gas in drinking waters were implemented and a report was prepared. According to ANRA's 2019 annual plan, such measurements will also be continued in 2019.

In 2019, 600 radon detectors, which were provided by IAEA, have been installed in schools in Yerevan for a three-month monitoring period.

**Recommendation 35:** The IRRS team was informed reference levels for water, foodstuffs and selected commodities fully in compliance with relevant criteria in GSR Part 3 are scheduled to be addressed in a new Radiation Safety Standards. The first draft, prepared by NRSC, is expected to be sent to ANRA for final review by the end of 2019. ANRA will send to the Government for final approval after adoption of the new Atomic Law.

#### Status of the finding in the initial mission

**Recommendation 34 (R34) remains open** as modification of regulations to address requirements for clearance and to establish clearance criteria is pending.

**Suggestion 25 (S25) remains open** as the implementation of an independent monitoring infrastructure, including laboratory capacities for verification of results of ANPP's monitoring programme, has not been completed.

**Suggestion 26 (S26) remains open** as implementation of a national radon programme by ANRA is pending.

**Recommendation 35 (R35) remains open** as reference levels for water, foodstuffs and selected commodities in line with GSR Part 3 have not been established.

#### 12. INTERFACE WITH NUCLEAR SECURITY

#### 12.1. LEGAL BASIS

#### There were no findings in this area in the initial IRRS mission.

#### 12.2. REGULATORY OVERSIGHT ACTIVITIES

#### 2015 MISSION RECOMMENDATIONS, SUGGESTIONS

**Observation:** There is no provision or practice to systematically evaluate the design and implementation of safety and security measures to ensure that conflicts are avoided and optimization occurs. The importance of a systematic process will increase significantly if the RA proceeds with plans to develop a new nuclear power plant.

(1)	BASIS: GSR Part 1 Requirement 12, paragraph 2.40 states that "Safety measures and nuclear security measures shall be designed and implemented in an integrated manner so that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security."			
S27	<b>Suggestion:</b> ANRA should consider ensuring that safety measures and nuclear security measures for new nuclear power plants are designed and implemented in an integrated manner so that neither negatively affects the other.			

#### Changes since the initial IRRS mission

**Suggestion 27:** ANRA plans to address this suggestion when there is greater certainty regarding whether a new nuclear power plant will be pursued.

#### Status of the finding in the initial mission

**Suggestion 27 (S27) remains open** as updated guidance on the safety and security interface for new nuclear power plants is pending.

#### 12.3. INTERFACE AMONG AUTHORITIES

There were no findings in this area in the initial IRRS mission.

# IRRS TEAM



# APPENDIX I - LIST OF PARTICIPANTS

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LIAISON OFFICERS						
MELKUMYAN Anna	Armenian Nuclear Regulatory Authority	a.melkumyan@anra.am				

## APPENDIX II - MISSION PROGRAMME

Time	Mon	Tue	Wed	Thu	Fri	Sat	Sun	Mon
	10 June	11 June	12 June	13 June	14 June	15 June	16 June	17 June
9:00-10:00		Entrance Meeting	Interviews	Interviews	Discussion of findings/ report by the team	Individual reading of the report	Written comments presented by the Host	Final Draft to the Host Exit Meeting
10:00-11:00	Team Arrival					Discussion of results of cross-reading		
11:00-12:00						Collective reading of the report		
13:00-14:00	Initial Team Meeting	Team	Interviews erviews	TM finalize findings/ TM write report	Discussion of findings with counterpart	Finalise draft Report	Review of host's comments	irs
14:00-15:00					ocume.part	Review of the Executive Summary		
15:00-16:00						Submission of Report to IRRS		ат Метре
16:00-17:00			Written preliminary findings delivered	Final findings with text delivered	Team revises report based on discussions	Admin  Submission of the Draft	Discussion with the	Departures of Team Members
17:00-18:00		Daily Team Meeting	Daily Team Meeting	Daily Team Meeting	Daily Team Meeting	Report to the Host Host reads	Host  Preparation of the	Dep
20:00-24:00		TM write findings	Secretariat edits findings TM write report	Secretariat edits report TM Read Draft	Cross reading TL drafts Executive Summary	report  TL prepares  presentation	press release	

## APPENDIX III - MISSION COUNTERPARTS

	IRRS Experts	COUNTERPART			
1.	RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT				
	WANNER, Hans	KARMIRMIRUKYAN, Arshaluys MARTIROSYAN, Ashot			
2.	THE GLOBAL SAFETY REGIME				
	WANNER, Hans	KARMIRMIRUKYAN, Arshaluys			
3.	RESPONSIBILITIES AND FUNCTIONS OF	THE REGULATORY BODY			
	KHALENKO, Roman	KHACHIKYAN, Khachatur			
4.	MANAGEMENT SYSTEM OF THE REGUI	LATORY BODY			
	JUBIN, Jean-Rene	MELKUMYAN, Anna			
		MANOYAN, Gagik GHAZARYAN, Varduhi			
5.	AUTHORIZATION				
	GELEEL, Mohamed Abdel	VARDANYAN, Ashot			
	HAILU, Teodros WILDERMANN, Thomas	GRIGORYAN, Vahe BABAYAN, Armen			
6.	REVIEW AND ASSESSMENT	DIDITIN, IIIICI			
	WILDERMANN, Thomas	GRIGORYAN, Vahe			
	INCORPORTON	VARDANYAN, Ashot			
7.	INSPECTION				
	BROWN, Frederick	HOVHANNISYAN, Levon			
	HAILU, Teodros KRS, Petr	POGHOSYAN, Lusine TADEVOSYAN, Armen			
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	IRRS Experts	COUNTERPART			
8.	ENFORCEMENT				
	KRS, Petr	HOVHANNISYAN, Levon KARMIRMIRUKYAN, Arshaluys			
9.	REGULATIONS AND GUIDES				
	BROWN, Frederick GELEEL, Mohamed Abdel HAILU, Teodros WILDERMANN, Thomas	KARMIRMIRUKYAN, Arshaluys GRIGORYAN, Vahe TADEVOSYAN, Armen			
10.					
	BACIU, Adriana	AMANYAN, Suren KIRAKOSYAN, Khachatur MARTIROSYAN, Ashot			
11.	ADDITIONAL AREAS				
	CANOBA, Analia DOSIEVA, Deyana	BABAYAN, Armen POGHOSYAN, Lusine HAROYAN, Karen VARDANYAN, Satine			
12.	INTERFACE WITH NUCLEAR SECURITY				
	BROWN, Frederick	KIRAKOSYAN, Khachatur TADEVOSYAN, Armen			

## APPENDIX IV - RECOMMENDATIONS (R) AND SUGGESTIONS (S) FROM THE PREVIOUS IRRS MISSION THAT REMAIN OPEN

Module	R/S	Recommendation/Suggestion
1	R2	The Government should ensure that the fundamental safety objective and fundamental safety principles of IAEA SF-1 are fully incorporated in to the Armenian framework for safety.
1	R3	The Government should provide ANRA with human and financial resources to ensure adequate discharge of its statutory obligation for the regulatory control of safety.
1	R5	The Government should establish requirements to authorize technical services.
3	R6	The Government should provide ANRA with the authorization to structure its organization and manage its available resources so as to fulfil its statutory obligations effectively.
5	S6	ANRA should consider identifying clear and explicit requirements, criteria and standards forming the licensing basis for specific types of facilities and activities.
5	S7	Government should consider re-evaluating the adequacy of the current licence approval timelines with respect to the new NPP.
5	R13	The Government should formally establish a mechanism to provide adequate financial resources for ensuring safe decommissioning of NPPs. The mechanism should also update the cost estimate in light of a periodic update of the decommissioning plan.
7	S10	ANRA should consider establishing a systematic mechanism for using feedback from inspections as input for improving the effectiveness of the regulatory processes.

Module	R/S	Recommendation/Suggestion
7	R16	ANRA should implement an inspection programme and planning process, related facilities and activities using radiation sources and transport of radioactive material, to that defines a baseline, includes frequency of inspections and areas and programmes to be inspected based on established criteria and should allow for prioritization.
7	R19	ANRA should enforce compliance with the national regulatory requirements for quality assurance system in transport.
8	R20	ANRA should establish within Armenia's legal framework enforcement guidance and criteria for requiring corrective actions, and develop guidance for inspectors on the implementation of enforcement actions.
9	R23	The Government should establish waste acceptance criteria for the storage and the disposal of radioactive waste packages.
9	S13	ANRA should consider establishing specific regulatory requirements for different types of disposal facilities and setting out the procedures for meeting the requirements established.
9	R24	ANRA should establish the regulatory requirements for decommissioning in line with the IAEA safety standards.
9	S15	ANRA should consider providing guidance for users and applicants to meet the requirements of the transport regulations.
10	R26	ANRA should develop and promulgate regulatory requirements for EPR for all operating organizations covering all relevant general, functional and infrastructure aspects of IAEA GS-R-2 in relation to response to nuclear and/or radiological emergencies.
10	S16	ANRA should consider developing guidelines to support the threat assessment of all operating organizations.
10	S17	ANRA should consider developing criteria for the termination of the emergency and the transition to long term recovery operations that follows the requirements of IAEA GS-R-2.

Module	R/S	Recommendation/Suggestion
10	S18	ANRA should consider elaborating an internal methodology for the evaluation of training and exercise programmes of all operating organizations; the methodology should include evaluation criteria needed to ensure that training and exercise programmes of operating organizations are periodically reviewed and updated in the light of experience gained.
11.1	S22	The government should consider ensuring the establishment, in consultation with relevant bodies, of dose constraints for exposure of carers and comforters and for volunteers participating in the programme of biomedical research. The government should consider also establishing criteria for the release of patients with implanted sealed sources as well as guidelines for release of patients after therapeutic radiological procedure with sealed or unsealed sources.
11.1	R30	The regulatory body should establish requirements for education, training and competence in protection and safety of all health professionals with responsibilities for medical exposure, including for any specialization required.
11.1	S23	ANRA should consider establishing requirement for the responsibilities of registrants and licensees to ensure that no individual person incurs a medical exposure unless is justified and information for the expected benefits and risks are provided.
11.1	R31	The regulatory body should establish requirements for the responsibilities of registrants and licensees for:  a) a) appropriate radiation protection arrangements in place for medical exposure of pregnant or breast-feeding patients; b) taking measure and investigating unintended and accidental medical exposures; c) ensuring that radiological reviews are performed periodically at medical radiation facilities and records are maintained; d) d) ensuring that protection and safety is optimized for each medical exposure.
11.2	S24	ANRA should consider undertaking measures in order to enforce requirements for the protection of workers in existing exposure situations.

Module	R/S	Recommendation/Suggestion
11.2	R32	The Government should ensure that the conditions of service of radiation workers are independent of whether they are or could be professionally exposed.
11.2	R33	The regulatory body should update current regulation for compliance with the requirements of GSR Part 3, specifically:  a) the equivalent dose limit to the skin is applied to the most highly irradiated area of the skin; b) doses related to emergency exposure situation are to be distinguished from doses, exposures and intakes due to normal conditions of work; c) pregnant or breast feeding women are not automatically excluded from work but allow them to continue to work under specific adjustment of working condition; d) d) to establish provision for archiving of records of occupational exposure.
11.3	R34	ANRA should incorporate modifications in the regulations for explicitly addressing the concept of clearance and establishing clearance criteria as specified in GSR Part 3.
11.3	S25	ANRA should continue efforts for implementing an independent monitoring infrastructure, including laboratory capacities for verification of results of ANPP's monitoring program.
11.3	S26	ANRA should consider implementing measures to ensure that studies related to radon levels and their impact on the public are completed and, where needed, implement an action plan for controlling public exposure due to radon indoors.
11.3	R35	ANRA should establish reference levels for water, foodstuffs and selected commodities fully in compliance with relevant criteria in GSR Part 3.
12	S27	ANRA should consider ensuring that safety measures and nuclear security measures for new nuclear power plants are designed and implemented in an integrated manner so that neither negatively affects the other.

# APPENDIX V - RECOMMENDATIONS (RF), SUGGESTIONS (SF) AND GOOD PRACTICES (GPF) FROM THE 2019 IRRS FOLLOW UP MISSION

Section	Module	RF/SF/GPF	Recommendation, Suggestion or Good Practice
4.1	4	ANRA should upgrade its management system in line with the GSR Part 2 requirement in particular with respect to requirements related to culture for safety.	
4.5	4	SF1	ANRA should consider evaluating the effectiveness of the measurement and improvement process, including whether currently assigned roles and responsibilities lead to processes being implemented as intended.

## APPENDIX VI - REFERENCE MATERIAL PROVIDED BY ANRA

[1]	
-	Government Decree 3-L as of 10 January 2019 on approval of 2019-2026 action plan –schedule on implementation of provisions stipulated in strategy on safe management of radioactive waste and spent nuclear fuel in the Republic of Armenia
[2]	
-	Government Decree№ 747-l as of 11 June 2018 of RA Prime Minister on approval of statute of Armenian Nuclear Regulatory Authority
[3]	
-	Government Decree № 931-N as of 01.12.2005 on approval of procedure on safe transportation of nuclear and radioactive materials
[4]	
-	Government Decree № 631-N as of 04.06.2009 on approval of the procedure on radioactive waste management as amended in 2017
[5]	
-	Government Decree № 1411-N as of 23.08.2012 as of 08.11.2012 on approval of Design Safety Requirements to New NPP Unit(s) supplemented under the RA Government Decree №992-N as of 22.09.2016
[6]	
-	Government Decree № 1751-N as of 09.12. 2004 on approval of the licensing procedure and licence form for use of radioactive materials, devices containing radioactive materials, or radiation generators
[7]	
-	Government decree № 839-a as of 30.07.2015 on revoking the RA Government Decree № 594-A as of 29.05.2009 on organization and conduct of audits
[8]	
-	2nd National Report of the Republic of Armenia under the Joint convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management
[9]	
-	7th national Report of Republic of Armenia under Convention on Nuclear Safety
[10]	
-	Strategy on Nuclear and Radiation Safety in the Republic of Armenia for the period 2019-2029
[11]	Parasina and a factoria and an all Charles
[12]	Requirements to equipment qualification
[12]	Degulatory requirements to againg management of SSC
[13]	Regulatory requirements to ageing management of SSC
	Requirements to maintenance effectiveness monitoring requirements
[14]	Requirements to maintenance effectiveness monitoring requirements
11.7	MP-001 Introduction
[15]	WI OUT INCOMENUI
-	MP-003 Human Resources
[16]	
- [-0]	IN-005 Quality Policy
[17]	
	IN-002 Consultation and communication

[18]	
-	IN-015 Organizational changes
[19]	
-	MP-009 Inspection
[20]	
-	MP-006 Legislation
[21]	
-	MP-010 Licensing
[22]	
-	IN-009 ANRA organizational chart
[23]	
_	ANRA Policy Statement on Nuclear Safety and Security
[24]	
_	IN-010 Strategic Plan of Regulatory Body of Armenia, Implementation period: 2019-2024
[25]	
_	IN-011 Knowledge development plan
[26]	
_	ANRA workplan for 2019
[27]	
_	Procedure on orphan source search and recovery
[28]	
-	Safety Requirements for radioactive waste disposal
[29]	
_	Summary Report of IRRS Follow-up Mission to ANRA
[30]	
_	ANRA management review report for 2018
[31]	
-	National Action Plan of Armenia on Strengthening Nuclear Safety of Armenian Nuclear Power
	Plant decided upon lessons learnt from Fukushima Daiichi accident
[32]	
_	Guidelines for Regulatory Oversight of Safety Culture in Licensees' Organisations

#### APPENDIX VII - IAEA REFERENCE MATERIAL USED FOR THE REVIEW

- 1. IAEA SAFETY STANDARDS SERIES No. SF-1 Fundamental Safety Principles
- 2. IAEA SAFETY STANDARDS SERIES No. GSR PART 1 Governmental, Legal and Regulatory Framework for Safety
- 3. IAEA SAFETY STANDARDS SERIES No. GSR PART 3 Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards
- 4. IAEA SAFETY STANDARDS SERIES No. GS-R-2 Preparedness and Response for a Nuclear or Radiological Emergency
- 5. **IAEA SAFETY STANDARDS SERIES No. GS-R-3** The Management System for Facilities and Activities
- **6. IAEA SAFETY STANDARDS SERIES No. NS-R-1** Safety of Nuclear Power Plants: Design
- 7. IAEA SAFETY STANDARDS SERIES No. NS-R-2 Safety of Nuclear Power Plants: Operation
- 8. IAEA SAFETY STANDARDS SERIES No. NS-R-4 Safety of Research Reactors
- 9. IAEA SAFETY STANDARDS SERIES No. GS-G-1.1- Organization and Staffing of the Regulatory Body for Nuclear Facilities
- 10. IAEA SAFETY STANDARDS SERIES No. GS-G-1.2 Review and Assessment of Nuclear Facilities by the Regulatory Body
- **IAEA SAFETY STANDARDS SERIES No. GS-G-1.3-** Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body
- 12. **IAEA SAFETY STANDARDS SERIES No. GS-G-1.4** Documentation for Use in Regulatory Nuclear Facilities
- 13. IAEA SAFETY STANDARDS SERIES No. GS-G-2.1 Arrangements for Preparedness for a Nuclear or Radiological Emergency
- **IAEA SAFETY STANDARDS SERIES No.GS-G-3.1** Application of the Management System for Facilities and Activities
- **IAEA SAFETY STANDARDS SERIES No. GS-G-3.2** The Management System for Technical Services in Radiation Safety
- **IAEA SAFETY STANDARDS SERIES No. RS-G-1.3 -** Assessment of Occupational Exposure Due to External Sources of Radiation
- 17. IAEA SAFETY STANDARDS SERIES No. RS-G-1.4 Building Competence in Radiation Protection and the Safe Use of Radiation Sources
- **18. IAEA SAFETY STANDARDS SERIES No. NS-G-2.10 -** Periodic Safety Review of Nuclear Power Plants Safety Guide
- 19. **IAEA SAFETY STANDARDS SERIES No. NS-G-211 -** A System for the Feedback of Experience from Events in Nuclear Installations Safety Guide
- 20. INTERNATIONAL ATOMIC ENERGY AGENCY Convention on Early Notification of a Nuclear Accident (1986) and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (1987), Legal Series No. 14, Vienna (1987).

### APPENDIX VIII - ANRA ORGANIZATIONAL CHART

