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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

GEORGIA

Tbilisi, Georgia

18-28 February 2018

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

IAEA | Integrated Regulatory Review Service IRRS

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Review Service

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

Integrated Regulatory Review Service

IAEA | IRRS

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INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
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Mission dates:	18 to 28 February 2018
Regulatory body visited:	Agency of Nuclear and Radiation Safety
Location:	200 Tsinamdzgvrishvili/11 Tsabadze, 0112, Tbilisi, Georgia
Regulated facilities and activities in the mission scope:	Radioactive waste management facilities, radiation sources in industrial and medical facilities, emergency preparedness and response, transport, decommissioning, occupational radiation protection, patient protection, discharges and clearance

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

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EXECUTIVE SUMMARY

At the request of the Government of Georgia, an international team of senior safety experts met representatives of Agency of Nuclear and Radiation Safety (ANRS) from 18 to 28 February 2018 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the peer review was to review the Georgia regulatory framework for radiation safety.

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

The IRRS team consisted of 10 senior regulatory experts from 9 IAEA Member States, 1 IAEA staff member and 1 IAEA administrative assistant. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, patient protection, discharges and material clearance, transport, waste management and decommissioning.

In addition, policy issues were discussed, including: culture for safety promotion and enhancing regulatory effectiveness and competence.

The mission included observations of regulatory activities and interviews and discussions with ANRS staff, representatives from the Ministry of Environmental Protection and Agriculture, Ministry of Labour, Health and Social Affairs and the Georgian National Academy of Sciences. The IRRS team members observed the working practices during inspections carried out by ANRS, including discussions with the licensee personnel and management, at three sites: medical facility “St. John the Merciful Private Clinic” LLC, industrial facility LTD “AIC Forwarding” and the radioactive waste management facility “Centralised Storage Facility”.

ANRS provided the IRRS team with advance reference material and documentation including the results of the self-assessment in all areas within the scope of the mission. Throughout the mission, the IRRS team was extended full cooperation in regulatory, technical, and policy issues by all parties; in particular, the staff of ANRS provided the fullest practicable assistance and demonstrated extensive openness and transparency.

The IRRS team concluded that Georgia has established and implemented governmental, legal and regulatory framework for safety.

The IRRS team made the following general observations:

- Significant progress has been made to improve the nuclear and radiological regulatory framework; and

- The Action Plan for further developing the nuclear and radiological regulatory framework clearly demonstrates ANRS' commitment to enhancing the regulatory framework.

The IRRS team believes that Georgia faces challenges over the next several years, which include:

- Development of competence for persons with responsibilities for safety;
- Clear separation between the regulatory body and the organization assigned responsibility for the operation of the radioactive waste facilities; and
- ANRS human resources development.

Over the long term, the IRRS team believes Georgia faces challenges, which include:

- Defining a plan for radioactive waste disposal which includes financial provisions for disposal; and
- Ensuring that the national policy and strategy for safety takes due account of the promotion of safety culture.

The IRRS team identified a good practice and made recommendations and suggestions where improvements will enhance the effectiveness of the regulatory framework and functions in line with the IAEA Safety Standards. The IRRS Team recognized that the IRRS findings broadly correlated with the preliminary Action Plan prepared by ANRS as a result of the self-assessment.

An effective tool to communicate with applicants and authorized parties through an electronic portal was recognized by the IRRS team as a good practice. This tool implementation has led to a significant increase in operators' safety compliance oversight and enhancing communications, in particular dissemination of best practices and notifications of upcoming changes to regulatory requirements.

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

- ensuring that all facilities and activities in Georgia that pose radiation risk are authorised and subject to regulatory control;
- further development and implementation of a radioactive waste management strategy and establishment and implementation of funding mechanism and financial provisions for decommissioning and disused radioactive sources;
- analysing, identifying and disseminating operating and regulatory experience;
- ANRS management system development including establishing of the procedures for core regulatory processes;
- further development of graded approach in radiation sources safety regulation;
- further development of regulations and guides on safety and their harmonization with international standards;
- further development of emergency preparedness and response regulatory capacities and activities; and
- qualified experts recognition.

The IRRS team findings are summarized in Appendices V.

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

I. INTRODUCTION

At the request of the Government of Georgia, an international team of senior safety experts met representatives of the Agency of Nuclear and Radiation Safety of Georgia (ANRS) from 18 to 28 February 2018 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the Georgia regulatory framework for radiation safety. The review mission was formally requested by the Government of Georgia in April 2016. A preparatory mission was conducted 4-5 July 2017 at ANRS Headquarters in Tbilisi, Georgia to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in Georgia and their related safety aspects and to agree on the scope of the IRRS mission.

The IRRS team consisted of 10 senior regulatory experts from 9 IAEA Member States, 1 IAEA staff member, and 1 IAEA administrative assistant. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection; control of medical exposure; discharges and material clearance; transport of radioactive material; waste management; and decommissioning. In addition, policy issues were discussed, including: culture for safety promotion and enhancing regulatory effectiveness and competence.

ANRS conducted a self-assessment in preparation for the mission and prepared a preliminary Action Plan for developing radiological regulatory framework of Georgia. The results of ANRS' self-assessment 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 within the agreed scope through review of the advance reference material of Georgia, conducted interviews with management and staff from ANRS and directly observed ANRS regulatory activities at regulated facilities. Meetings with the Ministry of Labour, Health and Social Affairs and the Georgian National Academy of Sciences were also organized.

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

II. OBJECTIVE AND SCOPE

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

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

a) providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;

b) providing the Georgia (regulatory body and governmental authorities) with a review of its regulatory technical and policy issues;

c) providing the Georgia (regulatory body and governmental authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;

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

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

f) providing Georgia with recommendations and suggestions for improvement;

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

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

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

j) promoting the application of IAEA Safety Requirements; and

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

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Georgia, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 4 to 5 July 2017. The preparatory meeting was carried out by the appointed Team Leader Ms Catherine Haney and the IRRS IAEA Team Coordinator Ms Olga Makarovska.

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

- Waste management (policy and strategy, predisposal and disposal);
- Radiation sources facilities and activities;
- Decommissioning;
- Transport of radioactive materials;
- Control of medical exposure;
- Occupational radiation protection;
- Discharges and material clearance;
- Selected policy issues.

Mr Nodar Nadirashvili and Ms Ina Grigalashvili made presentations on the national context, the current status of ANRS and the self-assessment results to date.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in Georgia in February 2018.

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

The ANRS Liaison Officer for the IRRS mission was confirmed as Mr Vasil Gedevanishvili.

ANRS provided IAEA with the ARM for the review at the end of December 2017. In preparation for the mission, the IAEA review team members reviewed the ARM and provided their initial impressions to the IAEA Team Coordinator, prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

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

C) CONDUCT OF THE REVIEW

The initial IRRS team meeting took place on Sunday, 18 February 2018, directed by the IRRS Team Leader and the IRRS IAEA Team Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, the bases for the review and the background, context and objectives of the IRRS programme. The methodology for review was reinforced. The agenda for the mission was presented to the team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

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

The IRRS entrance meeting was held on Monday, 19 February, 2018 with the participation of ANRS senior management and staff. Opening remarks were made by Mr Vasil Gedevanishvili, Head of ANRS, Mr Nodar Kereselidze, Deputy Minister of Environmental Protection and Agriculture, Ms Catherine Haney, IRRS Team Leader and Ms Olga Makarovska, IRRS Team Coordinator. Ms Ina Grigalashvili gave an overview of the Georgia programme, ANRS activities and the preliminary Action Plan prepared as a result of the pre-mission self-assessment.

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

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

The IRRS exit meeting was held on Wednesday, 28 February, 2018. The opening remarks at the exit meeting were presented by Mr Vasil Gedevanishvili and were followed by the presentation of the results of the mission by the IRRS Team Leader Ms Catherine Haney. Closing remarks were made by Mr Peter Johnston, Director, Division of Radiation, Transport and Waste Safety, IAEA.

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

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

Georgia is a constitutional democratic republic with a multi-party system. Georgia is governed by a 3-branch system, consisting of the executive, legislative and judicial powers. The executive power is vested with the Government, represented by the Prime Minister, who is selected by Parliament, following parliamentary elections. The President is elected by direct voting and has a mostly representative function. The legislative power is held by Parliament and the Constitution is the main law of the country (Constitutional Law of Georgia #786 of 24 August 1995). The judicial Branch is headed by the Supreme Court of Georgia and involves a hierarchical series of different courts.

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

In its self-assessment, the Agency of Nuclear and Radiation Safety (ANRS) identified that "Georgia does not have a policy and strategy for safety." During the mission, the IRRS team identified that most elements of a national policy and strategy for safety are in place and documented in national laws and regulations, in particular in the Law of Georgia on Nuclear and Radiation Safety (the Law, #5912-RS; 20.03.2012). The Law was adopted by the Parliament and signed and promulgated by the President of Georgia on 20 March 2012.

The Law establishes the policy of Georgia solely for peaceful use of nuclear materials and avoidance of any illegal use of nuclear material and radiation sources. The Law (Article 2) establishes the fundamental safety objective as “protect humans and the environment from harmful exposure to ionising radiation.” Furthermore, the Law specifies that this objective shall be fulfilled in compliance with the international obligations of the country and through harmonization with the international standards.

The safety fundamental principles, as stated in the IAEA Fundamental Safety Principles (SF-1), have been incorporated in Article 4 of the Law. According to this Article, any nuclear or radiation activity in the country should comply with the all core principles established by the Law.

The policy and strategy for safety does not take account the safety culture principle.

The Law also establishes some of the mechanisms for implementing the safety policy (Article 5 - Core goal of regulating the safety of nuclear and radiation activity). The scope of the governmental, legal and regulatory framework for safety is specified in Chapter II - State Regulation of Nuclear and Radiation Activity.

The IRRS team could not find enough evidence that the safety principles, established by the Law have been actively promoted by ANRS. Further efforts are needed to raise the awareness of all parties on the contents and ways for the practical implementation of the national policy and strategy for safety. Those efforts will assist the country in ensuring that radiation risks associated with facilities and activities receive appropriate attention.

The Law sets a definition for the graded (gradual) approach, which only applies to physical protection issues. Nevertheless, the rules and the respective requirements provide a basis for the application of a graded approach with respect to licensing, regulatory requirements, etc. For example, the regulations take account, the IAEA Categorization of sources, as well as the Emergency response categories for facilities and activities, depending on the associated radiological hazard and risk. The legislation also introduces the principles of ‘exemption’ and “clearance.” However, the graded approach to safety is not explicitly stated in the Law.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The national policy and strategy for safety of Georgia are established by the national laws and regulations. The Laws do not reference the "promotion of safety culture" and the application of a graded approach to nuclear and radiation safety.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 1, para. 2.3 states that** *"…. In the national policy and strategy, account shall be taken of the following:* *…….* *(g)The promotion of leadership and management for safety, including safety culture."*
(2)	**BASIS: GSR Part 1 (Rev.1) Requirement 1, para. 2.4 states that** *"The national policy and strategy for safety shall be implemented in accordance with a graded approach, depending on national circumstances, to ensure that the radiation risks associated with facilities and activities, including activities involving the use of radiation sources, receive appropriate attention by the government or by the regulatory body…."*
R1	**Recommendation: The Government should ensure that the national policy and strategy for safety takes due account of the promotion of safety culture and that the policy and strategy for safety is implemented in accordance with a graded approach.**

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The legislation in Georgia is hierarchically structured. The top tier consists of laws with the Constitution being the supreme law. Laws are adopted by the Parliament and signed and promulgated by the President. International treaties and agreements have superior effect over laws. According to the Constitution and the Law on Normative Acts, these acts being approved and ratified by Georgia are directly applied and have precedence over national laws and regulations. The second tier in the legislation includes bylaws adopted by the Government. These acts are called Decrees of the Government of Georgia and they are binding to everyone in the country. Ministers are also vested with the power to issue binding legislative acts called Decrees adopted by the Minister (both Governmental and Ministerial Decrees are herein after referred to as "Regulations"). Legislation is published on the Ministry of Justice official legislation site (Legislative Herald of Georgia) www.matsne.gov.ge.
The main Law in the area of safety is the Law of Georgia on Nuclear and Radiation Safety (the Law). It sets out the basis for the legal and regulatory framework for safety and establishes the ANRS as the Regulatory Body. ANRS is designated as a Legal Entity of Public Law (LEPL), which raises its statute to a self-standing authority and provides the Regulatory Body with improved independence in regulating nuclear and radiation safety in the country.

Other Laws and regulations that are related to the safety of facilities and activities and the operation of the Regulatory Body are included in Appendix VI.

The Law, in combination with the abovementioned regulations, establishes the regulatory body, empowers the regulatory body for development of regulatory requirements, requires authorization for the operation of facilities and for the conduct of activities and provides for the inspection of facilities and activities and for the enforcement of regulations.

Article 16 - License for nuclear and radiation activity of the Law specifies the types of regulated facilities and activities and that any license shall be issued for an indefinite period. The Law also specifies the limitations to the conduct of activities and operation of facilities, e.g.:

- Nuclear and radiation activities shall not be performed without an authorization under the Law;
- Licensee shall not make changes to any licensed activity unless authorized by the ANRS; and
- A revocation of a license shall not release its holder from the responsibility to ensure radiation safety or physical protection of the sources.

The rationale for granting licenses and permits is described in Article 11 and includes submission by the applicant of a safety justification (radiation protection programme for radiation sources and safety assessment report for high radiation risk facilities or activities). Based on an analysis of documents submitted with the application, the ANRS makes a decision whether to issue or refuse a license. In addition, Article 23 (r) specifies the principle that transfer of any radiation source or nuclear material or its ownership may not be done without the respective permit by ANRS.

The Law designates some other authorities with responsibilities under the Law. The IRRS team did not identify any evidence of overlapping or conflicting requirements.

The provisions covering appeals against regulatory decisions are given in the Licenses and Permits Law of Georgia. Appeals against decisions of ANRS shall be with the Minister and then to the various levels of the Common Court. Decisions of the Supreme Court of Georgia shall be final.

The IRRS team concluded that the Government of Georgia has promulgated laws and regulations which establish the basis for an effective governmental, legal and regulatory framework for safety.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The Law establishes ANRS as the regulatory body for facilities and activities posing radiation risk. It specifies the functions and responsibilities of ANRS, to inter alia:

- Carry out state regulation in the field of nuclear and radiation safety;
- Authorize nuclear and radiation activities;
- Inspect nuclear and radiation activities;
- Undertake enforcement actions in cases of unauthorized activities or in violations of applicable requirements and license conditions;
- Take part in the emergency preparedness and response;
- Ensure, within its competence, fulfilment of the international obligations;
- Inform the public in the field of nuclear and radiation safety.

The IRRS team identified that in addition to those functions the Law authorizes ANRS to provide some services in the area of nuclear and radiation safety, which include radiological surveys of land, materials, buildings, transport vehicles, scrap, etc., as well as temporary storage of sources, waste or X-ray tubes. Those assigned responsibilities do not jeopardize ANRS' independence and do not compromise or conflict with ANRS capabilities to discharge its responsibilities for regulating the safety of facilities and activities.

The ANRS is under the Ministry of Environmental Protection and Agriculture (MEPA), formerly Ministry of Environmental and Natural Resources Protection. Even, being under of MEPA, the Government has ensured that ANRS is independent in its safety related decision-making and that functional separation from entities having responsibilities or interest that could unduly influence its decision-making is ensured. However, the authority of the ANRS to license and inspect all nuclear and radiation facilities and activities in Georgia is diminished by the provisions of the Licenses and Permits Law. This law exempts ministries of Georgia from licensing and regulatory supervision, irrespective of the fact that they may pose radiation risk and, according to international standards, should be subject to licensing and control. Furthermore, the Licenses and Permits Law explicitly excludes ANRS from licensing. As the Department

of Radioactive Waste Management (hereinafter referred to as Department) is part of ANRS and at the same time operates the country RAW management facilities, this provision does not allow ANRS to license the radioactive waste (RAW) management facilities. As a result, the RAW management facilities operated by the Department are not licensed. The recommendation R7 on separation between regulatory body and RAW management facilities operator is done in section 3.2.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The Government, through the Licenses and Permits Law, has exempted facilities and activities of ministries from licensing and regulatory supervision. The same Law exempts ANRS from licensing hence the RAW management facilities are not licensed.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 4, para. 2.8 states that** *"To be effectively independent, the regulatory body shall have sufficient authority….. for the proper discharge of its assigned responsibilities …."*
(2)	**BASIS: GSR Part 1 (Rev.1) Requirement 4, para. 2.11 states that** *"In the event that a department or agency of government is itself an authorized party operating an authorized facility or facilities, or conducting authorized activities, the regulatory body shall be separate from, and effectively independent of, the authorized party."*
R2	**Recommendation: The Government should ensure that all facilities and activities in Georgia that pose radiation risk are authorized and are subject to regulatory control.**

ANRS funding is provided by the state budget through the MEPA budget. There is some flexibility in this arrangement, as upon request by the Head of ANRS, MEPA may allocate additional funds to the ANRS budget without the approval of the Ministry of Finance or an amendment of the Law on State Budget. ANRS prepares the budget request and submits it to MEPA. Through MEPA the budget request is sent to the Ministry of Finance. Following discussions and consultations, the budget is approved and included in the annual budget of MEPA as a separate programme.

The budget does not include specific funds for some of the main and support regulatory functions, i.e. international cooperation, training and retraining of regulatory staff, contracting external reviews and assessments, drafting regulatory requirements, drafting internal procedures, etc. These funds are included in the general expenditure part of the budget. This approach also allows flexibility to manage financial resources. The IRRS team was advised that the ANRS budget is sufficient for the effective operations of the agency. ANRS could benefit from additional funds to cover international training of staff or drafting of regulations and internal procedures.

The ANRS management stated that the number of qualified and competent staff dedicated to licensing and inspection is sufficient and commensurate with the nature and the number of regulated facilities and activities in Georgia.

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

As mentioned in section 1.1, the Law adopts the IAEA fundamental safety principles (SF-1) as binding for the country. This leads to the fact that the first principle of SF-1 is binding for every authorised party and assigns the prime responsibility for safety to the person or organization responsible for facilities and activities that give rise to radiation risks. Licensees retain the prime responsibility for safety throughout the lifetime of facilities and activities, and this responsibility cannot be delegated. Furthermore, the Law specifies that no license issued by ANRS may be transferred to third parties, directly or indirectly, without

its prior authorization.

The principle of "compliance with regulations and requirements established or adopted by the regulatory body does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety" is embedded in the overall philosophy of the Law, as licensees are required to comply with the legislation and ANRS is empowered to undertake enforcement action in cases of non-compliance.

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

According to the Law, Article 9 - Other executive authorities in the field of nuclear and radiation safety, the Ministry of Economy and Sustainable Development, the Ministry of Internal Affairs, the Ministry of Defence, the Ministry of Labour, Health, and Social Affairs, the Ministry of Foreign Affairs, and the Ministry of Finance are designated as other executive authorities in the field of nuclear and radiation safety. Their respective functions are designated in the Law.

Coordination of authorities is provided by Decrees of Government on allocation of responsibilities in respect to a specific joint activity. The IRRS team was not able to follow-up on all intergovernmental arrangements and their effectiveness. Such intergovernmental arrangements are usually based on the joint efforts of the staff of the different authorities and their dedication to work collaboratively. However, as the legislation does not completely specify the allocation of responsibilities among those authorities, ANRS would benefit from a review of its coordination arrangements with other executive authorities and, if needed, propose further regulations or joint procedures. This would help to minimize the likelihood of omissions or undue duplications of efforts and requirements.

For example, by Decree of Government #177, the Ministry of Economy and Sustainable Development is assigned as the Competent Authority for the European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) and ANRS as the Competent Authority for Class 7 dangerous goods materials. These arrangements have not been reported on the United Nations Economic Commission for Europe (UNECE) where the list of all Competent Authorities is published. Even if the Competent Authority for class 7 has been determined, there are other authorities that may have certain responsibilities and need to be involved in the process.

Another example could be the case when the Ministry of Labour, Health and Social Affairs, authorised under Decree of the Government of Georgia On Approval of Technical Regulations - Radiation Safety Requirements in the Sphere of Medical Irradiation (#317, 2016) to issue permits for work activities, revokes a license in a medical facility. The licensee is expected to inform ANRS about license revocation, while the ministry itself take no actions to directly inform ANRS.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Formal arrangements have been established for some but not all joint activities with other national executive bodies. ANRS could further benefit from more effective and efficient coordination with the other authorities having responsibilities for safety.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 7, para. 2.18 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the responsibilities and functions of each authority shall be clearly specified in the relevant legislation. The government shall ensure that there is appropriate coordination of and*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	liaison between the various authorities concerned …….. *This coordination and liaison can be achieved by means of memoranda of understanding, appropriate communication and regular meetings. Such coordination assists in achieving consistency and in enabling authorities to benefit from each other's experience."*
S1	**Suggestion: ANRS should consider establishing coordination arrangements with other national executive authorities in the field of safety.**

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

There are radiation risks in Georgia that arise in situations other than in facilities and activities that are under regulatory control. The IRRS team was informed that large scale operations were conducted to identify potential contaminated sites or orphan sources. As a result, one contaminated site had been identified and evaluated. Site evaluation is being carried out. A project for site remediation has been initiated. However, the Government has not yet designated the organization to be responsible for making necessary arrangements for protection of workers, the public and environment in unregulated risk situations for the site.

Article 16 of the Law empowers ANRS to authorise site decommissioning activities. There are no specific requirements, including licensing, for this type of activity. At the moment certain general requirements for the existing exposure situation are in Technical Regulations, "Radiation Safety Norms and Basic Requirements related to Handling of Ionizing Radiation Sources" (#450; 2015) - referred as TR450. Regulatory requirements and criteria for protective actions to reduce existing risks arising from contaminated sites are not established.

According to the Law, the Government assumes the responsibility for the management of orphan radioactive sources. According to the National Civil Safety Plan (approved by Decree of the Government #508; 2015) the emergency response function to ensure chemical and radiation safety leading authority is MEPA. Based on this function, ANRS executes measures to regain control over orphan radioactive sources and provide safe and secure management (including storage) of these sources. ANRS has its own technical resources to manage category 4 and 5 orphan sources and can engage additional resources for the other sources by using state contingency funds.

The current practice of orphan sources management is as follows: orphan source search and recovery is done at the border crossing points, in harbours and adjacent areas as well as at scrap metal yards as established in the Decree of the Government on the Approval of Technical Regulations - Procedure for Radiation Monitoring of Metal Scrap (#756; 2014) and the Decree of the Government On the Approval of rules on taking joint measures in case of alarm on nuclear and radioactive materials at check-points, airports, harbours and maritime space (#397; 2010). These regulations include provisions for the division of responsibilities and interaction between authorities in case of detection of radioactive and nuclear substances and, training and qualification requirements for the staff involved in the recovery of an orphan source.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *One contaminated site is identified and evaluated. The site evaluation is being carried out and a project for site remediation has been initiated. The Government has not yet designated the organization to be responsible for making necessary arrangements for protection of workers, the public and environment in unregulated risk situations for the site. Regulatory requirements and criteria for protective actions are not established. This issue is part of the Action Plan.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 9 states that** *"The government shall establish system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural or artificial origin) and contamination from past activities or events, consistent with the principle of justification and optimization."*
S2	**Suggestion: The Government should consider designating an organisation to be responsible for the contaminated site and respective protective actions. In addition, the Government should consider establishing requirements and criteria for protective actions.**

1.7. PROVISIONS FOR THE MANAGEMENT OF RADIOACTIVE WASTE

Management of radioactive waste and decommissioning

In Georgia there are few facilities generating and managing radioactive waste (RAW). Historically, the country had one nuclear research reactor (IRT-M) that operated from 1959 to 1989. Its decommissioning was completed in 2016. Currently, the entombed reactor core remains on the site. There is no spent fuel or fissile material from subcritical assemblies in Georgia.

RAW streams include the RAW from the decommissioning of the research reactor IRT-M as well as radioactive sources from activities undertaken in Georgia. To manage this RAW, a "Centralised Storage Facility" (CSF) has been in operation since 2007. Another facility, an old, Soviet type "disposal" facility RADON at Saakadze site, still contains a substantial amount of RAW. This facility does not comply with recommendations for a disposal facility (for example the site includes liquid RAW), so it can only be considered a storage facility. The single tank of liquid RAW is expected to be treated and conditioned in March 2018.

A large number of low activity disused radioactive sources are kept at the stores of the State Military Scientific-Technical Centre "Delta," which belongs to the Ministry of Defence.

Governmental policy and strategy on radioactive waste management and decommissioning

A national RAW Management Strategy for 2017-2031 was developed and adopted in 2016. The document contains a description of the RAW management policy and considers disposal as the end point for all RAW generated in the country. Legal requirements are clearly identified and interim targets and end states for 2017-2018 are well described in the Strategy. The IRRS team was advised that the action plan will be updated on a 2 year basis. RAW from decommissioning the former research reactor is considered in the RAW management strategy but no further details on decommissioning of operational facilities are provided.

The strategy also discusses the need to further investigate designating the Saakadze site as the new storage facility. This facility will replace the CSF.

Long-term plans on the development of a disposal facility are not in place because the Government wants to focus on the safe storage of RAW until 2031. A Policy for clean-up and release of sites from regulatory control is not established in the national strategy as well, even if some sites have been remediated in the past (Anaseuli site).

The National strategy does not pay attention to the availability of decommissioning funds (no decommissioning fund established). With regards to funding the safe management of RAW including disused sealed radioactive sources (DSRS), the Law on Radioactive Waste specifies that the owner of the RAW is responsible to fund the disposal of this waste. The owner of DSRS may choose to pay 300 or 1000 GEL/source or 1000 GEL/one piece of RAW to the ANRS budget in order to store the RAW by ANRS and the Department (Technical Regulations #319).

No radiation sources are manufactured in Georgia. Since 2010, new permits for import of radioactive sources contain a condition to return any disused source to the supplier in the country of origin. There is no requirement assuring the availability of financial provisions for the return of disused sources to the country of origin. GS-G-1.5 recommends that Regulations should require, as a condition for granting an authorization for … sources, that adequate funds be made available for the timely … management of … spent radiation sources, including disposal. The arrangements for financial assurance proposed by an applicant should be incorporated as a condition of the authorization.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *No long term plans for RAW management are established in the national RAW Management Strategy. A policy for the clean-up and release of sites from regulatory control is not in place as well.*	
(1)	**BASIS: SSR 5 Requirement 1, para. 3.7 states that** *"Matters that have to be considered include:* – *defining the national policy for the long term management of radioactive waste of different types;"*
(2)	**BASIS: WS-G-5.1, para. 3.1 states that** *"The government should formulate a policy for the release of sites, including clean-up. It should ensure that an adequate legal and regulatory framework, supported where necessary by appropriate guidance, is in place so that workers, the public and the environment are protected during clean-up and after the release of sites from regulatory control. It should also specify the responsibilities of the parties involved."*
S3	**Suggestion: The Government should consider revising the RAW strategy to define long term plans for management of RAW (disposal facility). In addition, the Government should consider formulating a policy for site clean-up and release from regulatory control.**
RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Appropriate provisions for funding of decommissioning of facilities and for financial provisions for safe management of disused radioactive sources are not in place.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 10, para 2.33 states that** *"Appropriate financial provision shall be made for:* (a) *Decommissioning of facilities;…"*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSR Part 6 Requirement 4 states that** *"The government shall establish and maintain a governmental, legal and regulatory framework within which all aspects of decommissioning, … . This framework shall include … requirements in respect of financial assurance for decommissioning."*
(3)	**BASIS: Code of Conduct on the Safety and Security of Radioactive Sources 22 (b) 22. states that** *"Every State should ensure that its regulatory body:* *(b) ensures that arrangements are made for the safe management and secure protection of radioactive sources, including financial provisions where appropriate, once they have become disused;"*
R3	**Recommendation: The Government should establish and implement a clear mechanism for assuring sufficient funding of decommissioning activities and establish requirements for availability of financial provisions for the return of disused sources to the country of origin.**

1.8. COMPETENCE FOR SAFETY

Georgia does not have an overall national policy and strategy for education and training in radiation, transport and waste safety. The Law sets the safety principles and provisions for developing a strategy, as well as the obligations to ensure appropriate professional education and training in radiation protection for workers involved in the operation of facilities and conduct of activities.

As Georgia realizes the need for well qualified and experienced experts, a steering committee (SC) for establishing a national strategy has been formed. The SC is coordinated by ANRS. The SC is comprised of representatives from a number of governmental entities in the field of radiation and nuclear safety and the Ministry of Education and Science (MES). Nevertheless, a national policy and strategy on education and training in radiation, transport and waste safety is still missing and a systematic and comprehensive evaluation of training needs has not been performed.

The Law introduces the term "person responsible for radiation protection" that corresponds to the "radiation protection officer" (RPO) according to the IAEA safety standards. According to the Law, licensees shall appoint workers having adequate knowledge as the persons responsible for radiation protection. There are no specific minimum educational levels or training requirements for the RPOs. For personnel dealing with ionizing radiation, the Law has only a general requirement, namely "adequate level of knowledge". For the ANRS staff, the possession of a university diploma is sufficient to verify this "adequate level of knowledge."

The Law and TR450 assign the licensee with the responsibility to provide training to the relevant workers in nuclear and radiation safety. The IRRS team could not find any additional guidance on the required content of this training. The information on trained workers and RPOs is provided to ANRS by application documents for authorization and by licensee reports. The certificates of attendance of training courses are checked during inspections.

The MES has the responsibility for the accreditation of all education and training courses, including Degrees, Masters Degrees and specialist courses in radiation protection. The ANRS is not a member of the Board and has limited advisory power to change or modify course content. It must be informed of new radiation protection courses and provided with information on the contents.

There is no single ministry or agency with the responsibility for all radiation protection education and

training. Furthermore, only a limited number of training courses in radiation protection are available nationally. These have been mainly designed for specific roles in the health sector.

The Ministry of Labour, Health and Social Affairs has responsibility for ensuring the availability of appropriate training for health professionals. Postgraduate residency training programmes are available for nuclear medicine specialists and radiation oncologists, which contain some radiation protection components. The Ministry of Labour, Health and Social Affairs has a National Training Centre for the continuous professional development of medical staff and nurses. However, there are no specific radiation protection training requirements for radiographers, nurses or supporting staff. Furthermore, there is only one accredited training course for medical physicists, no formal training programme, and no certification process.

The licensee is required to agree with the regulatory body on programmes of retraining and professional development in radiation protection. These programmes shall provide a worker with up-to-date information on radiation risks relating to the occupational exposure of a worker, activity-specific requirements, and review of the requirements established in the field of radiation safety according to the effective legislation. However, the licensee is not required to maintain a record of the training provided to individual workers.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no requirements on the competence of RPOs and radiation technicians. There are no specific training courses or arrangements for the workers involved in industry, research and education. The education and training programmes for medical physicists are in an early stage of development. Furthermore, there were no evidences that the Government has established adequate arrangements for increasing, maintaining and regularly verifying workers technical competence.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 11, para. 2.36 states that** *"The government:* *(a) Shall stipulate a necessary level of competence for persons with responsibilities in relation to the safety of facilities and activities;…* *(c) Shall make provision for adequate arrangements for increasing, maintaining and regularly verifying the technical competence of persons working for authorized parties."*
(2)	**BASIS: GSR Part 3 Requirement 2, para. 2.21 states that** *"The government shall ensure that requirements are established for:* *(a) Education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety;…"*
(3)	**BASIS: GSR Part 3 Requirement 4, para. 2.41 states that** *"Other parties shall have specified responsibilities in relation to protection and safety. These other parties include:* *…(b) Radiation protection officers;… (d) Medical physicists;(e) Medical radiation technologists;(f) Qualified experts or any other party to whom a principal party has assigned specific responsibilities;(g) Workers other than workers listed in (a)–(f) in this paragraph;…"*
R4	**Recommendation: The Government should stipulate the necessary level of competence for persons with responsibilities for safety and should ensure that adequate arrangements are in place for increasing, maintaining and regularly verifying their technical competence.**

1.9. PROVISION OF TECHNICAL SERVICES

Technical services providers are licensed in accordance with the Law to perform expert and instrumental

measurements, metrology, adjustment and installation of ionizing radiation sources. There are two licensed technical services providers for dosimetry monitoring (workplace monitoring and external individual monitoring), preparation of authorization applications and documents like radiation protection program, monitoring programmes and quality assurance program. In addition, calibration of measuring devices is provided by a metrology laboratory.

There are no arrangements in Georgia for carrying out internal exposure dosimetry and image quality checks for diagnostic radiology (evaluation of X-ray diagnostic image quality). As a result, despite having expectations for these activities, ANRS does not currently enforce compliance.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Requirements for internal exposure monitoring and quality assurance in diagnostic radiology are defined in regulations. There are no arrangements for carrying out internal exposure monitoring or evaluation of X-ray diagnostic image quality.*	
(1)	**BASIS: GSR Part 3 Requirement 2 para. 2.22 states that** *"The government shall ensure arrangements are in place for the provision of technical services related to protection and safety, such as services for personal dosimetry…".*
(2)	**BASIS: GSR Part 3 Requirement 20 states that** *"The regulatory body shall establish and enforce requirements for the monitoring and recording of occupational exposures in planned exposure situations".*
(3)	**BASIS: GSR Part 3 Requirement 37 para. 3.170 states that "***Registrants and licensees…shall establish a comprehensive programme of quality assurance for medical exposure."*
R5	**Recommendation: The Government should make arrangements for provision of internal exposure monitoring and diagnostic radiology image quality assessments.**

1.10. SUMMARY

Georgia has established a structured and mature legislative and regulatory framework in the field of nuclear and radiation safety. The Government's commitment to nuclear safety is demonstrated through the Law and its implementing regulations.

The team has identified areas for improvement and recommends that the Government should:

- take due account of the promotion of safety culture and graded approach;
- ensure that all facilities and activities are licensed and controlled;
- assure sufficient funding for decommissioning and the return of disused sources;
- stipulate the competence for radiation workers and ensure maintaining of technical competence; and
- ensure availability of internal exposure monitoring and image quality assessments.

The IRRS team also suggested that consideration should be made of establishing coordination arrangements among all national authorities; designating a responsible organisation for the contaminated site; defining long term plans for management of RAW; and formulating a policy for release of sites from regulatory control.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Georgia is a party to most international conventions, including the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, the Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency. In addition, Georgia has made the decision to endorse principles of the Code of Conduct on the Safety and Security of Radioactive Sources and follow the Guidance on the Import and Export of Radioactive Sources.

The Convention on Nuclear Safety provides a number of benefits, allowing the regulator to receive peer review and feedback on their national nuclear safety program. Further, the Convention would allow Georgia to engage in discussions and peer reviews of neighbouring countries, particularly those with nuclear reactors. This allows Georgia to gain confidence and influence the safe management of nuclear facilities in proximity to Georgian territory. Georgia is not a party to the Convention on Nuclear Safety.

Georgia has established agreements with some states for cooperation in nuclear safety. Georgia has not, however, established any agreements with neighbouring states, including some states that have nuclear power plants. This has led to some recent challenges, for example a vehicle with minor contamination suspected to be from the Fukushima accident has been stuck between the border of Georgia and Armenia for three years, as neither country will allow the vehicle to enter their territory. A bilateral agreement between the two countries may help resolve this challenge. In addition, in the event of an accident at a reactor facility in a country near Georgia, a bilateral agreement would help ensure that Georgia receives timely information and support to address public concerns or undertake protective measures if necessary.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Georgia is not a party to the Convention on Nuclear Safety.*	
(1)	**BASIS: GSR Part 1 (Rev.1) requirement 14, para. 3.2(a) states that** *"The features of the global safety regime include international conventions that establish common obligations and mechanisms for ensuring protection and safety."*
S4	**Suggestion: The Government should consider becoming a party to the Convention on Nuclear Safety.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Georgia has established some bilateral arrangements with other countries, however none are in place with neighbouring countries in the region.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 14, para. 3.2A states that** *"The government shall ensure that bilateral and multilateral arrangements are in place for benefiting from international cooperation and, as appropriate, from the provision of assistance in connection with a nuclear or radiological emergency."*
S5	**Suggestion: The Government should consider establishing bilateral or multilateral arrangements for cooperation with neighbouring countries.**

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

ANRS has requirements for receiving information from authorized parties, who are required to report all off-normal occurrences. However, there is limited guidance provided to licensees on determining occurrences that should be considered off-normal, which might risk a lack of common understanding between the authorized parties and the regulatory body on what should be reported. Further, because the regulatory system requires enforcement action for all violations, if there is any doubt whether an occurrence should be reported, the licensee might choose not to report an occurrence that might otherwise have been reported.

While ANRS does collect and analyse these reports, it does not analyse the potential implications of the events on other authorized parties. As a result, authorized parties do not benefit from the lessons learned of other organizations. In some cases, this could mean that some accidents may have been averted had the authorized party implemented corrective actions identified by another authorized party. Similarly, ANRS does not have mechanisms to report or to learn from events occurring internationally. For example, ANRS has not nominated a national International Nuclear Events Scale (INES) coordinator and does not report or review INES reports.

ANRS has made effective use of international regulatory experience, both through engagement with the IAEA, and through bilateral arrangements with experienced regulators such as the United States and the Swedish regulatory bodies. For example, in anticipation of an application for a CyberKnife device, ANRS has contacted the IAEA for support to build regulatory knowledge on these devices. ANRS has established some practices to share regulatory experience, including mentoring of new staff by more experienced staff, and assigning work to allow for development of regulatory experience. There was no evidence that ANRS systematically reviews its practices and experience in order to identify and act on lessons learned from regulatory experience.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ANRS does not have mechanisms to review international events and has not nominated an INES coordinator. In addition, ANRS has not established clear reporting criteria, and does not identify and share operating experience with authorized parties, nor does it systematically implement lessons learned from regulatory experience.*	
(1)	**BASIS: GSR Part 1 (Rev.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."*
R6	**Recommendation: ANRS should establish and implement mechanisms to analyse and identify lessons to be learned from operating and regulatory experience, and for the dissemination of the lessons learned to appropriate parties.**

2.3. SUMMARY

Georgia has mechanisms in place to meet their international obligations, is a party to most major conventions, and collects operating experience.

The IRRS team identified opportunities to improve in this area. In order to better learn and benefit from international engagement and from regulatory and operating experience, the IRRS team:

- Suggests that the Government consider becoming a party to the Convention on Nuclear Safety and establishing bilateral arrangements with neighbouring countries; and
- Recommends that ANRS establish and implement mechanisms to collect, analyse, disseminate and use lessons from operating and regulatory experience.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

ANRS is established by the Law, which designates it as the regulatory body, and describes generally its duties and functions. Further, ANRS is designated as a Legal Entity under Public Law (LEPL) in accordance with the Law of Georgia on Legal Entities under Public Law (Law on LEPL). In practice, this means that ANRS has authority to conclude agreements, and perform a series of activities that are related to the scope of its mandate.

Article 10 of the Law on LEPL specifies the authorities of LEPL management, noting that the head shall solely manage the entity and acts independently within the scope of this Law. Further, Article 12 specifies that an LEPL, with the consent of the state control body, may acquire immovable property, determine the budget, staff list, salaries and payroll. The Law on LEPL requires that an LEPL have a statute published as a regulation, which was most recently approved by Order #237 of the Minister of Environmental and Natural Resources Protection of Georgia (now called the Minister of Environmental Protection and Agriculture - MEPA). The Statute reiterates the powers provided by the Law on LEPL and designates MEPA as the state control body for ANRS.

The structure of the regulatory body is established in the Statute, which details the four functional groups in the ANRS:

1. Department of Radioactive Waste Management (Department), responsible for development and implementation of the National Waste Management Strategy, management of state-owned radioactive waste and operation of the waste storage and disposal facilities
2. The Administrative Service, responsible for supporting the operations of the ANRS
3. The Authorization Service, responsible for granting, revoking, refusing or modifying licenses or permits for nuclear and radiation activities and supporting program work
4. The Inspection and Response Service, responsible for performing planned and unplanned inspections of nuclear and radiation facilities with associated enforcement actions and supporting program work

The organizational chart is included in Appendix VIII. Resources are allocated proportionally to each section of ANRS, as prepared and recommended by the Head of ANRS and approved by the Minister. While some activities are graded, there is an opportunity to apply further grading so as to better perform their regulatory functions. Recommendation 11 is made in Section 5.1.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

As discussed in Section 1, the Law and the ANRS Statute establish the regulatory body as effectively independent. ANRS manages its operations in such a way as to maintain this independence. The Law and Statute specify a number of matters that are subject to the Minister's approval or agreement, including recommendations for budget, staffing, salaries, etc. ANRS manages these approval requirements effectively, so as to discharge its responsibilities in such a way as to preserve its effective independence.

The Law of Georgia on Conflict of Interest and Corruption in Public Authorities imposes obligations on public servants to mitigate any real or perceived conflicts of interest. Upon recruitment, staff are made aware of this obligation. Further, when staff may have a perceived conflict of interest, such as a family member working at a licensed facility, the IRRS team was informed that ANRS puts in place effective

measures to mitigate any real or perceived conflicts of interest.

While established under a separate act, the Law of Georgia on Radioactive Waste, the Department is structured within the regulatory body. The Department is responsible for the operation of two waste management facilities. Under the National Strategy on Waste Management, the Department is also working towards the consolidation of these two facilities. During the mission, ANRS explained that this arrangement was necessary to bring the facilities up to modern standards and to revitalise waste management ('Saakadze' Site) operation, as they were the only department with competency for this work. In this regard, improvements have been made to the safety of these facilities since responsibility for their management was transferred to ANRS.

Further, there are some measures in place to maintain a separation between the Department and the ANRS regulatory services, and there is inspection oversight of facilities operated by the Department. These measures may be sufficient in the short term, however, this arrangement is in conflict with international standards, which requires a clear separation from organizations or bodies that have been assigned responsibilities for facilities or activities. ANRS indicated that their long term plan is to transfer responsibilities for the operation of the eventual storage facility to another organization although this plan was not documented in the national strategy, which has only a 15 year outlook.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The Department of Radioactive Waste Management is responsible for operation of the waste storage facilities. The Department is included in the structure of the ANRS although in the long term Georgia plans on transferring this responsibility to another organization.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 17, para. 4.9 states that** *"…the regulatory body shall ensure that…it has a clear separation from organizations or bodies that have been assigned responsibilities for facilities or activities…"*
R7	**Recommendation: The Government should ensure that there is a clear separation between the regulatory body and the organization assigned responsibility for the operation of the Georgian radioactive waste management facilities.**

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

International Safety Standards require ANRS to have sufficient and competent staff to perform its functions and to discharge its responsibilities. As part of the creation of ANRS, the IRRS team was informed that an assessment of the required resources was performed, which supported requests made to the Government to establish the structure of ANRS, and the number of positions therein. However, this assessment was not documented and did not cover recruitment, rotation of staff or a strategy to compensate for the departure of qualified staff, which are necessary elements of a human resources plan. For the staffing of positions, ANRS followed the hiring requirements and practices for the Georgian public service, which requires documenting competency requirements and development of job descriptions.

ANRS also has informal practices for maintaining the necessary competence and skills of the regulatory body, including attending IAEA conferences and training courses and facilitating sharing of regulatory experience with other national nuclear regulatory bodies. In addition, the IRRS team was informed that ANRS has informal knowledge transfer arrangements, including mentoring junior staff with more experienced staff. ANRS has not, however, developed a specific training programme that is based on an analysis of the necessary competence and skills and covers principles, concepts and technological aspects of their work. Once the relevant processes and procedures discussed in section 4 are established, the

training programme should cover the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities and for enforcing regulatory requirements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ANRS has practices in place for human resource planning and training of their personnel, however, these practices are not documented nor are they based on a systematic analysis of the necessary competence and skills. This is part of the Action Plan.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 18, para. 4.11 states that** *"A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions."*
(2)	**BASIS: GSR Part 1 (Rev.1) Requirement 18, para. 4.13 states that** *"A process shall be established to develop and maintain the necessary competence and skill of staff of the regulatory body... This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills."*
R8	**Recommendation: ANRS should develop and implement a human resources plan and a training programme to ensure that it has and can maintain a sufficient number of qualified and competent staff to perform its functions and to discharge its responsibilities.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

ANRS does not have a dedicated technical support organization however there are two private companies to provide support for the ANRS oversight of medical and other facilities, and third for site characterization of contaminated lands to inform decommissioning strategies (supported by an IAEA project). In addition, ANRS has a memorandum of understanding with the National Academy of Science to provide technical support, although the Academy has little capacity to provide extensive support. Given the scope of nuclear and radiation activities undertaken in Georgia, the regulatory body has sufficient competence to effectively discharge its regulatory duties.

Further, ANRS is empowered to contract and employ temporary workers, or to enter into contracts to obtain specific technical expertise. If that expertise is not available domestically, ANRS does not have any restrictions to seeking that expertise internationally. The budget for ANRS is developed by the Head of ANRS and subject to approval of the Minister and does not allocate substantive funds for external technical support. In the event of applications for complex or new activities or facilities, ANRS could be challenged to fund contracts to obtain the necessary technical support. However, provisions do exist for ANRS to request additional resources when faced with such challenges, and the IRRS team was informed that there were no examples where such requests, supported by a rationale for the request, were not granted by the Government.

ANRS has entertained the possibility of establishing advisory bodies in some areas, for example waste management, and is empowered to do so. At this time, however, ANRS does not see the need or value of establishing such a body.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

ANRS has effective communications with authorized parties. However, ANRS has not established formal and regular meetings with regulatory parties, and there may be an opportunity to improve consultations

and engagement with regulated parties through adopting a practice of regularly holding meetings open to authorized parties to discuss matters of mutual interest. This could include discussions on upcoming changes to regulatory requirements, performance trends identified through inspection or events that have lessons learned or corrective actions that should be considered for implementation.

During the authorization process, ANRS staff communicates with applicants in the event of missing or insufficient information. Following review of applications, the authorization service documents their analysis in a recommendation to the Head of ANRS. Decisions are subject to appeal, which provides an opportunity for applicants to review the rationale for regulatory decisions.

As permitted by the respective expertise of inspectors or their capacity, the IRRS team was informed that ANRS has informal arrangements to rotate locations so as to minimize repeat locations at the same location by the same inspector. Site visits performed by IRRS team members confirmed that ANRS and authorized parties maintain a constructive relationship that is frank, open and yet formal.

In 2016, ANRS launched an electronic tool for applying, processing and communicating decisions to authorized parties. The tool also allows for electronic submittal of annual compliance reports. The tool uses the Government of Georgia's electronic portal, which is a single window for citizens and businesses to do any business with the Government or LEPLs. Implementation of the tool led to a significant increase in compliance with annual reporting requirements. In addition, the portal allows for authorized parties to register for SMS alerts as soon as the regulator sends them a message through this portal. Further the portal allows for payment of regulatory fees, and includes a clock function based on ANRS' service standards that counts down the time until the applicant can expect a regulatory decision. In addition, ANRS can use this portal to issue notifications of upcoming changes to regulatory requirements. The associated internal system allows for efficient workflow management, providing for electronic processing, approval and issuance of license and permitting authorizations, with embedded service standards for decisions. These allow for prompt regulatory response to urgent applications for example, those needed for patient care.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ANRS has an effective tool to communicate with authorized parties, and allow them to electronically submit applications and reports. This system includes a number of features that both improve transparency of the regulatory process for authorized parties and support efficient processing of applications.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 21, para. 4.23 states that** *"The regulatory body… shall liaise with authorized parties to achieve their common objectives in ensuring safety."*
GP1	**Good Practice: ANRS leverages the Government of Georgia's single window portal to communicate with licensees, and allow submission of license applications and annual reports through an electronic portal, which has led to a significant increase in compliance with annual reporting requirements. This portal allows for authorized parties to register for SMS alerts as soon as the regulator sends them a message through this portal. In addition, ANRS can use this portal to issue notifications of upcoming changes to regulatory requirements. The associated internal system allows for efficient workflow management, providing for electronic processing, approval and issuance of license and permitting authorizations, with embedded service standards for decisions. These allow for prompt regulatory response to urgent applications such as, for example, those needed for patient care.**

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

ANRS benefits from experienced staff, and has leveraged this experience to transfer knowledge to new staff, helping to maintain a common understanding of regulatory expectations. Authorizations are done according to established criteria. These criteria are documented in regulations and available for review by authorized parties and applicants. Similarly, inspections are conducted according to the established criteria. However, some areas were identified that might benefit from additional guidance to ensure clarity of regulatory requirements. Recommendations are made in: R10 in section 4.2.; R11 in Section 5.1 and S 13 in Section 9.1.

Consistency in decision making is provided by established review and approval mechanisms. These process controls help to prevent subjectivity in decision making of individual members of the regulatory body. However, not all regulatory processes are documented, and some activities do not follow a formal process based on specified policies and principles. As a result, there is a risk that the regulatory body is inconsistent in the application of its regulatory duties. Recommendation 10 is made in Section 4.2.

The process for developing and modifying regulatory requirements is discussed further in section 9, however, it is worth noting here that the process includes public consultation, to ensure that any proposed changes to requirements are transparent and that authorized parties are informed ahead of any changes to regulatory requirements. ANRS does not currently have practices to systematically assess operating experience to identify potential improvements to their regulatory framework in order to support continuous enhancement of safety. Recommendation 6 is made in Section 2.2

3.7. SAFETY RELATED RECORDS

The Law contains requirements for authorized parties to maintain records and report on information related to their activities, including records of events, inventories of radioactive sources and radiation generators and worker doses from occupational exposure.

In addition, ANRS uses a regulatory information system, ARIS, for records management, supplemented by the electronic workflow management tool mentioned in section 3.5. These systems include records of doses from occupational exposure, records related to the safety of facilities and activities, records of events, including non-routine releases of radioactive material to the environment and records that might be necessary for the shutdown and decommissioning of facilities. Further, ANRS is charged with establishing and maintaining a registry of sealed and unsealed radioactive sources and radiation generators. This registry is in place.

Dose reports are received annually from authorized parties and are maintained in electronic format. There is an opportunity to enhance the management of records of doses form occupational exposure in order to facilitate trending of doses and assessment of individual doses across multiple work locations. Suggestion 14 is made in Section 11.2.

In addition, although historical records had been lost, current inventories of radioactive waste exist. These records are not currently available through ARIS, however the inventory is available in paper form and is maintained by the Department.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

ANRS maintains a website that provides general information on its activities. The website provides information on the ANRS, references to relevant legislation and information on their authorizations, including providing a copy of all licenses. In addition, the website includes specific information on significant events that have occurred in Georgia. The website includes a Section for members of the public, which provides general information on radiation and clearly states the ANRS's commitment to

openness, specifying that the ANRS will release any information not constituting a commercial or state security secret to the public upon request. Further the website includes information for applicants and authorized parties, including links to their electronic services.

Under the Law, ANRS is obliged to submit an annual report on its activities to the Government, through the Minister, which is available on their website. In addition, ANRS submits their annual inspection plan to the Minister and, once approved, publishes the plan, which includes the locations of all planned inspections for the year, on their website.

ANRS has experienced occasions where communities have expressed concerns about facilities in their vicinity. In such cases, ANRS has held public meetings and performed other outreach activities (e.g. TV interviews) to inform the public of their regulatory oversight and the relative risks of those facilities. In addition, ANRS is obliged to respond to public inquiries, and if there is a public concern, to perform radiation surveys.

As discussed in section 9, ANRS uses the Government of Georgia's regulation making process. This process includes an obligation for ANRS to consult with interested parties in the preparation of draft regulations. ANRS accomplishes this through their website, or through meetings with interested parties as appropriate.

Authorised parties are required to keep the public informed on nuclear and radiation issues not constituting a state or commercial secret. This is only a responsive practice. During authorization, ANRS staff ensures that the licensee has committed to respond to any inquiries from the public, and only investigates if they are informed that a licensee has not met this commitment. There may be an opportunity for some major licensees to be more proactive, and publish information on their activities proactively to mitigate public concerns. With that said, the most significant facilities are the two waste management facilities for radioactive waste storage operated by the Department, and there is information available on their activities on the ANRS website.

3.9. SUMMARY

Georgia has put in place a competent and effective regulatory body. ANRS effectively interfaces with its stakeholders.

The IRRS team identified a good practice of the regulatory body that other regulatory bodies would benefit from having. The IRRS team would like to recognize the:

- Good practice of ANRS that uses an effective electronic tool to communicate with authorized parties, and allow them to electronically submit applications and reports, which includes a number of features that both improve transparency of the regulatory process for authorized parties and support efficient processing of applications.

In order to improve the structure and operation of the regulatory body, the IRRS team recommends that :

- The Government implement mechanisms to ensure an effective separation of the regulatory body from the organization responsible for operating waste management facilities, and
- ANRS establish and implement a human resources plan and training programme.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

The Law of Georgia on Nuclear and Radiation Safety (the Law) and the Statute of the Legal Entity of Public Law for ANRS places the responsibility for its management on the Head of ANRS and senior managers. The Head of ANRS is empowered to issue Internal Rules (Orders and Procedures) covering various employee related issues. Current rules contain an article that stresses the importance of workplace safety, which does not however reflect the safety policy for the organisation or highlight the safety goals and strategies that are needed for fostering a strong safety culture. The Labour Code of Georgia gives provisions for employers to include special rules concerning work practices, which presents an opportunity for ANRS to include the safety policy as required by GSR Part 2.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ANRS has not formalised its policy for the management of safety.*	
(1)	**BASIS: GSR Part 2, Requirement 2, Paragraph 3.1 states that** *"The senior management of the organization shall demonstrate leadership for safety by:* *(a) Establishing, advocating and adhering to an organizational approach to safety that stipulates that, as an overriding priority, issues relating to protection and safety receive the attention warranted by their significance;"*
(2)	**BASIS: GSR Part 2, Requirement 3, Paragraph 4.2 states that** *"Senior management shall be responsible for establishing safety policy."*
(3)	**BASIS: GS-G-3.1, para 3.10 states that** "*As part of the management system, senior management should develop and disseminate throughout the organization a documented set of policies that establish the management's plans, objectives and priorities with regard to safety, health, environmental, security, quality and economic considerations. The policies should reflect the commitment of senior management to attaining their goals and objectives; their priorities; and the means by which continual improvement will be implemented and measured."*
R9	**Recommendation: Ministry of Environmental Protection and Agriculture/ANRS should formalise and implement a safety policy, defining the safety goals of the organisation.**

4.2. MANAGEMENT SYSTEM OF THE REGULATORY BODY

International Safety Standards mandate that regulatory bodies establish, implement, assess and continually improve management systems that are aligned to their safety goals. The current system for the management of ANRS is based on various elements with the state legislation system consisting of various laws, governmental decrees, ministerial orders and internal rules. However, the current efforts do not fully meet the international safety standards which include the integration of all elements into a single management system supported by adequate internal documentation in ANRS and the establishment of mechanisms for their assessment and measurement to ensure the continuous improvement of regulatory functions.

To address the gaps in the management system and to align with GSR Part 2, ANRS efforts should include:

- Identification and documentation of all elements, following a graded approach;
- Establishing a system for the control, identification, access and use of management system documentation; and
- Adequate training and instruction of users of the management system.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The current system applied to the management of ANRS is not consistent with GSR Part 2. Some elements of regulatory functions and processes have not been internally documented and integrated. The methodology for the assessment, measurement and improvement of the regulatory functions has not been adequately defined. The Action Plan has identified strategies to develop a management system that integrates all elements, in line with GSR Part 2*	
(1)	**BASIS: GSR Part 1 (Rev.1), Requirement 19 states that** *"The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement."*
(2)	**BASIS: GSR Part 1 (Rev.1) Requirement 22, 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."*
(3)	**BASIS: GSR Part 2, Requirement 3 states that** *"Senior management shall be responsible for establishing, applying, sustaining and continuously improving a management system to ensure safety."*
(4)	**BASIS: GSR Part 2, Requirement 6 states that** *"The management system shall integrate its elements, including safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements, so that safety is not compromised."*
(5)	**BASIS: GSR Part 2, Requirement 8 states that** *"The management system shall be documented. The documentation of the management system shall be controlled, usable, readable, clearly identified and readily available at the point of use."*
(6)	**BASIS: GSR Part 2, Requirement 10 states that** *"Processes and activities shall be developed and shall be effectively managed to achieve the organization's goals without compromising safety."*
(7)	**BASIS: GSR Part 2, Requirement 13 states that** *"The effectiveness of the management system shall be measured, assessed and improved to enhance safety performance, including minimizing the occurrence of problems relating to safety."*
R10	**Recommendation: ANRS should continue the development and implementation of the management system in line with GSR Part 2. Specific attention should be given to documenting core processes and implementing mechanisms to assess and improve the management system.**

4.3. MANAGEMENT OF RESOURCES

Information on the funding of ANRS is provided in section 3.

The IRRS team was informed that current ANRS human resources are adequate for the scope of work. Further, should there be an urgent need for additional staff to cover unforeseen work demands, the Head of the ANRS is empowered to conduct temporary recruitment of staff to meet the demand.

ANRS has not developed a comprehensive staff development plan that ensures continuous development of staff competencies. This is a critical requirement for all staff with responsibilities in areas of safety such as inspectors and those responsible for review and assessment so they may keep updated on changes in international standards and technological developments. Implementation of Recommendation 8 from Section 3.3 will address this shortcoming.

4.4. MANAGEMENT OF PROCESSES AND ACTIVITIES

The structure and management of ANRS recognizes the contribution of different processes to the achievement of the overall responsibility as defined by the enabling legislation. Key processes of ANRS that include regulation development, authorization, inspection and enforcement have been, to some extent, defined in the legislation. However, these descriptions are generic and do not address specific activities that are important in the functions of ANRS.

ANRS utilizes the Government's single window portal to manage the authorization process integrated with an electronic document management system which has been identified as a good practice in section 3.

ANRS has not identified, documented or appointed owners for the different core and management support processes as part of its management system to ensure consistency and stability. Identified processes, should cover ANRS' activities related to radioactive waste management, transport, radiation sources use, decommissioning, emergency preparedness and response, etc. The IRRS team identified the need for processes on:

- Authorization;
- Review and Assessment;
- Inspection;
- Development and review of regulations and guides;
- Assessment and measurement; and
- Procedure for materials clearance.

It will be beneficial for ANRS to develop criteria for periodic assessment of the effectiveness of the processes and illustrating the interaction between or among process by use of process maps or charts. Implementation of Recommendation 10 in Section 4.2 will address the shortcomings in the management of processes.

4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

ANRS has not developed a methodology for the measurement and assessment of regulatory processes to ensure continual improvement in the organisation. Article 6 of the Law establishes a responsibility for ANRS to provide annual reports to the Government through the Minister of Environmental Protection and Agriculture. Similarly, the Department of Radioactive Waste Management under ANRS is mandated to submit half-yearly reports. Further, ANRS develops an annual inspection programme, approved by the Minister, which, inter alia, serves as the basis of reporting. However, there is no guidance on the system for measuring and assessing the performance of regulatory functions.

Internal audits by the MEPA and external audits conducted biennially by the Office for State Audits are only limited to financial transactions. The preliminary Action Plan developed by ANRS includes strategies to implement a system of measurement and assessment of regulatory processes and activities in order to achieve continual improvement. Therefore, ANRS will benefit in this regard from implementation of Recommendation 10 in Section 4.2.

4.6. SUMMARY

The ANRS management system is based on a number of elements that are either missing or have not been integrated. ANRS should identify all processes essential for the achievement of its regulatory objectives and ensure that they are documented. This will support the consistency and stability of regulatory functions. Further, ANRS should establish a methodology to assess and measure the performance of the various elements of the management system and to implement corrective actions for its continual improvement. A graded approach should be adopted, prioritizing processes that are related to safety.

5. AUTHORIZATION

5.1. GENERIC ISSUES

The Law requires that nuclear and radiation activity may not be performed without the authorization (system of issuing licenses and permits). The eighteen types of activities that must be licensed are listed in the Law. The activities which need a license are:

- designing of a high risk nuclear and radiation facility;
- operation of a high risk nuclear and radiation facility;
- removal from service and decommissioning of a high risk nuclear and radiation facility;
- production (preparation), possession, temporary retention, use and sale of radioactive materials;
- using of a generator of ionizing radiation for medical purposes;
- using of a source of ionizing radiation for medical (therapeutic) purposes;
- using of radioactive substances (radiopharmaceuticals) for medical diagnosis; h) using of radioactive substances (radiopharmaceuticals) for medical treatment;
- using of a generator of ionizing radiation and/or radioactive substances for delivery of service;
- using of a generator of ionizing radiation for industrial purposes;
- using of a source of ionizing radiation for industrial purposes;
- using of a generator of ionizing radiation for research and education purposes;
- using of a source of ionizing radiation for research and education purposes;
- maintenance and repair of a generator of ionizing radiation and equipment containing radioactive material;
- transportation of nuclear materials, radioactive sources, and radioactive wastes;
- conditioning, storage, and burial of radioactive sources and wastes, decontamination of equipment, territory and/or storeroom contaminated with radioactive substances;
- preparation of containers for shipment and storage of radioactive sources and wastes;
- expert and instrumental measurements, metrology, adjustment, and installation of the sources of ionizing radiation.

Licenses are issued in accordance with the Licenses and Permits Law, TR450 and other national regulations. Licenses are issued for an indefinite period. As such, they do not have to be renewed periodically.

The Law specifies that permits may be issued for purchase and transfer of radioactive substances, import and export of radioactive materials, raw material from which nuclear material can be obtained or produced, equipment containing radioactive substances, nuclear technologies or know how, as well as for export of radioactive waste. Permits are granted to authorize a one-time act and are valid for a maximum of one year with the exception of import of radiopharmaceuticals which may be granted for performing multiple imports over a period of one year.

Exempted practices are listed in TR450 and include practices that are unamenable to control. These include exposure from cosmic radiation, exposure from naturally originating radionuclides whose concentration does not exceed prescribed limits, exposure from ionizing radiation generating devices whose maximum energy does not exceed 5 keV and ionizing radiation generating devices with a dose rate of less than 1μSv/h at 0.1 meters. In addition, radioactive sources are exempted if their radioactivity does not exceed prescribed limits.

The self-assessment performed by the ANRS notes that a graded approach in the authorization process is not fully implemented and the preliminary Action Plan considers the potential implementation of additional authorization types – notification and registration – to fully reflect a graded approach. Requirements for authorization submittals in order to obtain or amend a license are prescribed by the Law, TR450 and other relevant Regulations. These requirements are only partially in accordance with a graded approach. Specific requirements exist for safety assessment for high radiation risk facilities and radiation protection programmes for different medical applications (therapeutic or diagnostic). However, a graded approach is not applied to sealed sources of different categories, transport activities and industry, research and education applications of both radioactive sources and generators.

In some areas, such as transport activities, there was insufficient guidance on information expectations for applications. As a result, some applicants may have insufficient information on expectations for the content of the documents that must be submitted, leading to a lack of clarity of regulatory expectations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *With the exception of medical facilities and high radiation risk facilities, the requirements for authorization submittals are not graded. Implementation of a graded approach, such as notification and/or registration, is part of the Action Plan. In addition no guidance on the content of the application and supporting safety documentation for different types of licenses and permits is provided. Moreover, the annual report form is the same for all the authorized parties without the regard of the type of the facility or activity.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 24, para. 4.33 states that** *"……The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."*
(2)	**BASIS: GSR Part 3 Requirement 7, para. 3.7 states that** *"Any person or organization intending to carry out any of the actions specified in para. 3.5 shall submit a notification to the regulatory body of such an intention. Notification alone is sufficient provided that the exposures expected to be associated with the practice or action are unlikely to exceed a small fraction, as specified by the regulatory body, of the relevant limits, and that the likelihood and magnitude of potential exposures and any other potential detrimental consequences are negligible. Notification is required for consumer products only with respect to manufacture, maintenance, import, export, provision, distribution and, in some cases, disposal."*
(3)	**BASIS: GSR Part 3 Requirement 7, para. 3.8 states that** *"Any person or organization intending to carry out any of the actions specified in para. 3.5 shall, unless notification alone is sufficient, apply to the regulatory body for authorization, which shall take the form of either registration or licensing."*
(4)	**BASIS: GSR Part 1 (Rev.1) Requirement 24, para. 4.34 states that** *"The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization…".*
R11	**Recommendation: ANSR should continue to implement a graded approach in authorization by establishing a system of notification and registration; by grading requirements for documents submitted by applicants in support of an application for non-medical use of radiation sources and by providing guidance on the content of the documents to be submitted by an applicant or authorized party.**

The basis for denying a license or permit and the procedure for appealing such a denial is governed by the Licenses and Permits Law. If an issuer refuses to issue an authorization, they shall immediately notify the applicant of the refusal. According to the Licenses and Permits Law, the refusal to issue an authorization to operate may be appealed to a higher administrative body (official) or to a court. This information is provided in the decision sent to the applicant.

The ANRS annual report for 2017 includes information about issued, amended and revoked licenses. In 2017, ANRS granted 59 licenses, refused 1 license, amended 150 licenses, revoked 22 licenses and granted 144 permits. Overall, there are more than 100 sealed sources in use; more than 45 unsealed sources in use; more than 2000 x-ray generators, including medical applications; 61 luggage scanners; 25 diffractometers and 24 radiography devices.

The form for licenses is governed by Ministry of Environmental and Natural Resources Protection Order (#239; 2015). A license certificate includes a license number assigned by Authorization Service of ANRS, the date of issue, the name of the licensee, the official address of the authorized party and the type of activity defined in Article 16 of the Law. The license is signed by the Head of ANRS.

License conditions are defined in the Law. They include the list of agreed documents that are submitted in authorization process and the relevant requirements set out in Article 23 of this Law. According to the Licenses and Permits Law, the regulatory body is required to provide control over the fulfilment of permit and license conditions. The Licenses and Permits Law determines procedures for ensuring control over fulfilment of permit and license conditions as well as procedures for revocation of licenses and permits. Although they are empowered to and have previously included license conditions in the license, this practice was stopped. ANRS licenses do not currently include any license conditions. The IRRS team found that there is an opportunity to improve regulatory control if ANRS were to include certain conditions in its authorizations. For example, in the absence of limitations on use and possession (e.g. maximum inventories) an authorized party may expand operations to a point that its radiation safety programme is no longer sufficient to effectively manage its operations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ANRS does not include any conditions in licenses and permits.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 24, para. 4.31 states that** *"In the granting of an authorization for a facility or an activity, the regulatory body may have to impose limits, conditions and controls on the authorized party's subsequent activities."*
(2)	**BASIS: GS-G-1.5 para 3.44 states that "***3.44. "The regulatory body 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):* *(a) the facilities, activities or inventories of sources covered by the authorization;* *(b) the requirements for notifying the regulatory body of any modifications to safety related aspects;* *(c) the obligations of the operator in respect of its facility, equipment, radiation source(s) and personnel;* *(d) any limits on operation and use (such as dose or discharge limits, action levels or limits on the duration of the authorization);* *(e) conditioning criteria for radioactive waste processing for existing or foreseen waste management facilities;* *(f) any additional separate authorizations that the operator is required to obtain from the*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	regulatory body; *(g) the requirements for incident reporting;* *(h) the reports that the operator is required to make to the regulatory body;* *(i) the records that the operator is required to retain and the time periods for which they must be retained; and* *(j) the emergency preparedness arrangements"*
S6	**Suggestion: ANRS should consider renewing the practice of imposing limits, conditions and controls on the authorized party's subsequent activities as part of an authorization.**

5.2. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES AND DECOMMISSIONING

In Georgia there are 4 producers of RAW which are licensees for RAW management. Two more licensees are managing RAW produced or owned by other organizations.

The Law requires authorization for the "removal from service and decommissioning of high risk nuclear and radiation facility." Regulation on development of a disposal facility is provided mainly in Article 10 of Technical Regulations #189. Provisions to close a disposal facility and to conduct institutional control of the facility and site are available as well. But no license conditions for closure of disposal facilities are identified.

In Georgia, entombment is considered a viable option and was used for decommissioning the research reactor. For regulated facilities and activities, there is no obligation to select and justify a decommissioning option. As a result, no link to the national RAW management strategy can be established.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no conditions for closure of a disposal facility set by the regulatory body.*	
(1)	**BASIS: SSR 5 Requirement 19, para 4.39 states that** *"The disposal facility has to be closed in accordance with the conditions set for closure by the regulatory body in the facility's authorization, with particular consideration given to any changes in responsibility that may occur at this stage. Consistent with this, the installation of closure features may be performed in parallel with waste emplacement operations."*
S7	**Suggestion: ANSR should consider introducing license conditions for closure of a disposal facility.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no requirement on selection of licensees' decommissioning strategy, its justification and its compliance with national policy on RAW management.*	
(1)	**BASIS: GSR Part 6 Requirement 8 states that** *"The licensee shall select a decommissioning strategy that will form the basis for the planning for decommissioning. The strategy shall be consistent with the national policy on the management of radioactive waste."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSR Part 6 Requirement 8, para 5.2 states that** *"The selection of a decommissioning strategy shall be justified by the licensee."*
R12	**Recommendation: Ministry of Environmental Protection and Agriculture/ANRS should establish and implement requirements on selection and justification of decommissioning strategy by the licensee consistent with national policy on the management of radioactive waste.**

5.3. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

Licensing of industrial radiation sources facilities and activities

Aside from the general authorization process described above, there is no specific authorization process for radiation sources facilities and activities.

There are some facilities that are not licensed because of exemptions provided in the Licenses and Permits Law. Ministries and public sub-agencies within the ministries are exempted from the scope of the Licenses and Permits Law. These include radioactive waste management facilities that are managed by Department of Radioactive Waste Management, as well as approximately five other state organizations that may undertake activities that may otherwise be licensed. For example, the Ministry of Legal Aid and Corrections uses non-medical imaging body scanners and x-ray equipment for luggage scanning. Similarly, the Ministry of Internal Affairs carries out activities with x-ray equipment for luggage scanning. However, these activities are not subject to regulatory control. Recommendation 2 is done in Section 1.3.

The statue of ANRS assigns the responsibility for maintaining a registry of radiation sources to the Authorization Service. ANRS assigns an individual number to each source. The authorized party is provided with the number and is required to label the source, the container or the associated equipment and must submit a picture of the labelled source. This picture of radiation sources is included in the ARIS.

Categorization of radioactive sources (sealed and unsealed) is introduced by the Technical Regulations on Procedure for Establishing and Maintaining the Departmental Register of Ionising Radiation Sources, Radioactive Waste; Authorization; and Categorization of Ionising Radiation Sources (No 689). Radioactive sources are categorized in five categories based on the ratio of activity of the source to the D-value of the radionuclide.

TR450 defines high radiation risk facilities as facilities performing activities according to hazard categories I and II (Article 25 para. 8). Five hazard categories are defined in these Regulations. According to the ARM report and SARIS report, the only high radiation risk facilities in Georgia are radioactive waste storage and disposal facilities.

A safety assessment for high risk facilities is required by the Law. The safety demonstration for all of the rest of facilities and activities includes the radiation protection programme, individual monitoring and workplace monitoring programmes and emergency preparedness plan. However, there are no legislative or regulatory requirements for safety assessment to be carried out in any facility other than high risk facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Safety assessments are only required for high radiation risk facilities and are not required for any radiation sources facilities.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 24, para. 4.33 states that** *"Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment [8], which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."*
(2)	**BASIS: GSR Part 3, Requirements 7, para 3.9 states that** "*Any person or organization applying for authorization: ... (d) Shall, if there is a possibility for an exposure to be greater than a level as specified by the regulatory body, have a safety assessment made and submitted to the regulatory body as part of the application."*
S8	**Suggestion: ANRS should consider defining the radiation sources facilities for which an applicant is required to submit safety assessment.**

The regulatory requirements for import, export and transit of radioactive sources are defined in the Law. The procedure for granting these permits is laid out in the Law and in the Licenses and Permits Law.

A permit for export of radioactive materials may be issued only if: the conditions in consignor's notification are adequate; there is an assurance that the consignee will receive the radioactive materials; transport is performed with appropriate transport and package licenses and approvals; appropriate information on radioactive materials is submitted; and the safety and physical protection of radioactive material during transport is ensured.

The permit for import of radioactive materials may be issued only if: the consignee holds a license for radioactive material; radioactive materials are transported under appropriate transport and package license or approvals; and the safety and physical protection of radioactive materials is ensured during transportation.

A permit for transit of radioactive materials is granted only if: the applicant provides information on the destination of the radioactive materials; the acceptance of the radioactive materials by consignee; the fulfilment of transport and package requirements mentioned in Georgian legislation; and a document (contract) between consignor and consignee exists. The safety and physical protection of radioactive materials during transportation shall be ensured.

However, there are no requirements for notification to and, in the case of Category 1 sources, consent from, the importing State prior to authorizing their export.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: *ANRS requests assurance that the consignee consents to receive radioactive sources. However, ANRS has no mechanism in place to notify and request the consent from the importing State.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: Code of Conduct on the Safety and Security of Radioactive Sources, Requirement 23, states that "***Every State involved in the import or export of radioactive sources should take appropriate steps to ensure that transfers are undertaken in a manner consistent with the provisions of the Code and that transfers of radioactive sources in Categories 1 and 2 of Annex 1 of this Code take place only with the prior notification by the exporting State and, as appropriate, consent by the importing State in accordance with their respective laws and regulations.*
(2)	**BASIS: Guidance on the Import and Export of Radioactive Sources, Requirement 6, states that "***Each State should establish export authorization procedures... for the export of Category 1 sources…. Prior to authorizing the export of these sources, the exporting State should obtain consent from the importing State. The nature of the consent should be determined through appropriate bilateral channels or agreements. The exporting State or exporting facility should provide prior notification under paragraph 9(b) to the importing State."*
R13	**Recommendation: ANRS should ensure that export of radioactive sources of Categories 1 and 2, in particular disused sources, takes place only with the prior to notification of the exporting State and only after the consent by the importing State for Category 1 radioactive sources.**

In addition, TR450 prescribes that disused sealed sources must be returned to the source manufacturer/supplier or transferred to the radioactive waste storage or disposal facility. Further, the import of radioactive material is granted only with guarantees for the return of radioactive materials after use. In this respect, the applicant of an import permit must submit a guaranty letter signed by a responsible person of the organization. However, no evidence was provided that guaranties for the return of the radioactive sources include financial provisions. Recommendation 3 for this is in Section 1.7.

Licensing of medical sources and facilities

Decree of the Government of Georgia On Approval of Technical Regulations - Radiation Safety Requirements in the Sphere of Medical Irradiation (#317, 2016) (hereinafter referred to as TR317) prescribes the radiation protection program information required to be submitted by an applicant seeking authority to conduct medical activities using nuclear materials or devices generating ionizing radiation. Article 14 of the Law specifies that only radiopharmaceuticals registered by the Ministry of Labour, Health, and Social Affairs of Georgia may be used for medical (diagnostic and therapeutic) purposes. Article 16 of the Law identifies several types of activities for which licenses may be issued, including use of ionizing radiation generators for diagnostic and therapeutic purposes, use of radiopharmaceuticals for diagnostic and therapeutic purposes, and use of a radiation source for therapeutic purposes.

For medical physicians and physicists authorized on the license, information concerning the individual's training and certification must be provided as part of the RPP. For medical physicians named on the license, ANRS generally relies upon certification obtained from the Ministry of Labour, Health and Social Affairs or other similar health authority. For medical physicists, ANRS has relied upon training records for the majority of the medical physicists authorized on medical licenses, and in only limited cases, training records as well as certification by an appropriate professional body or organization. This is due to the absence of an appropriate professional body, health authority or appropriate organization within

Georgia for acknowledging competency of medical physicists. A recommendation concerning this issue is provided below.

If a medical licensee wishes to add another medical physician or physicist to the license, the licensee must provide notification to ANRS along with the appropriate documentation as specified above. If a medical licensee wishes to add additional equipment similar to that already authorized under the license, for the same use, the licensee must provide notification and include registration information for the device, as appropriate. The RPP must only be resubmitted if the licensee proposes to expand its authorized activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The majority of medical physicists authorized in medical licenses issued by ANRS have met respective requirements for education, training and competence in radiation protection; however, they do not meet the requirement for specialization in the appropriate areas of practice.*	
(1)	**BASIS: GSR Part 3, Requirement 35, para. 3.150 states** *" The regulatory body shall ensure that the authorization for medical exposures to be performed at a particular medical radiation facility allows personnel to assume the responsibilities specified in these Standards only if they are specialized in the appropriate area. "Specialize" means specialized as acknowledged by the relevant professional body, health authority or appropriate organization. The "appropriate area" means…diagnostic radiology, image guided interventional procedures, or radiation therapy or nuclear medicine.*
R14	**Recommendation: The Government should ensure that provisions for acknowledgement by relevant professional bodies, health authorities or appropriate organizations in the areas of diagnostic radiology, image guided interventional procedures, radiation therapy, and nuclear medicine are available for personnel assuming responsibility as a medical physicist.**

5.4. AUTHORIZATION OF TRANSPORT

According to the Law the transport of nuclear materials, radioactive sources and radioactive waste is under regulatory control and is licensed by ANRS.

The packaging, preparation, consigning and loading of radioactive materials are performed by a licensed consignor. The unloading and receipt at the final destination of loads of radioactive material and packages are performed by licensed consignee.

Only exempted, type A and B(U) packages are used in Georgia, all containing radioactive sources or radiopharmaceuticals produced and imported to Georgia. Georgia does not produce or manufacture any radioactive material, nor does it design, produce or repair any packaging or package. The transport is performed mainly by road and is regulated by ANRS. Air and sea shipments are controlled by other governmental authorities. There is no current practice of issuing approval or validation certificates but requirements are included in the newly issued transportation regulations.

Georgia acceded to ADR and described a plan for its implementation in Decree of the Government #1422. The plan defines actions and responsible organizations. The Ministry of Economy and Sustainable Development of Georgia and Land Transport Agency, with advice of ANRS and other units of MEPA, will be preparing regulations which will cover the training program for drivers, testing container/packages, approval procedures/packages, road routes for transportation and how ADR will be

determined in Georgia. With a number of agencies involved in the transport of radioactive material, coordination of the respective agencies is important. Suggestion 1 is done in Section 1.5.

The Order of Director of National Air Agency N263 regulates transport of dangerous goods by air. The Ministry of Economics and Sustainable Development is assigned as the competent authority by Decree of the Government #177. Additionally, by Order of the Minister of Economy and Sustainable Development (#1-1/470; 2017), ANRS was assigned as a responsible organization for regulation of transport of nuclear and radioactive materials.

The Law sets requirements for issuing a license for transportation of any nuclear and radioactive materials. The procedure for issuing a license is defined by Licenses and Permits Law and defines the list of documents which should be submitted by an applicant to ANRS in order to obtain the license.

A radiation protection program is required in accordance with paragraph 302 of IAEA SSR-6. General requirements on the content of the RPP are defined by TR450 as well as in transport regulation. Implementation of a management system in line with paragraph 306 of IAEA SSR-6 is required as part of the RPP. A license is issued for one or more activities mentioned in the Law. Few licenses have been issued for transport as most transport activities are covered by consignor or consignee licenses.

In the Decree of the Government approving "Rules for Transport of Nuclear and Radioactive Materials" several provisions on management of non-compliances in transport are missing.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Some elements for management of non-compliances in transport of radioactive materials are in legislation. However, a comprehensive system of information exchange, immediate mitigation steps, non-compliance investigation, appropriate actions to remedy and to prevent recurrence, immediate steps to mitigate the consequences, communication with relevant competent authority(ies) and time frame for communication, which is a mechanism to manage non compliances in transport of radioactive materials, is not in place.*	
(1)	**BASIS: IAEA SSR-6 Requirement 309 states that** *"In the event of non-compliance with any limit in these Regulations applicable to radiation level or contamination:* *(a) The consignor, consignee, carrier and any organization involved during transport who may be affected, as appropriate, shall be informed of the* *(i) The carrier if the non-compliance is identified during transport; or* *(ii) The consignee if the non-compliance is identified at receipt.* *(b) The carrier, consignor or consignee, as appropriate, shall:* *(i) Take immediate steps to mitigate the consequences of the noncompliance;* *(ii) Investigate the non-compliance and its causes, circumstances and consequences;* *(iii) Take appropriate action to remedy the causes and circumstances that led to the non-compliance and to prevent a recurrence of circumstances similar to those that led to the non-compliance;* *(iv) Communicate to the relevant competent authority(ies) on the causes of the non-compliance and on corrective or preventive actions taken or to be taken.* *(c) The communication of the non-compliance to the consignor and the relevant competent authority(ies), respectively, shall be made as soon as practicable and it shall be immediate whenever an emergency exposure situation has developed or is developing.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S9	**Suggestion: ANRS should consider developing and implementing mechanisms to manage non-compliances in transport of radioactive materials**

5.5 SUMMARY

Legislative provisions are in place to ensure that most nuclear and radiation facilities and activities are authorized.

The IRRS team identified opportunities to improve in these areas:

- Graded approach in the authorization process and the issuance of guidance on applications;
- Decommissioning strategy;
- Export notification and consent for Category 1 and 2 radioactive sources; and
- Competency recognition for medical physicists.

6. REVIEW AND ASSESSMENT

6.1 GENERIC ISSUE

Review and assessment of information relating to radiation safety is performed when an applicant submits an application to receive a license or when a licensee submits an application or notification to amend or modify its license. In addition, review and assessment is performed annually through the requirement for licensees to submit an annual report regarding compliance with the license conditions. Review and assessment of radiation safety is also ensured through regular inspections. Review and assessment applies to all the licensed facilities and activities.

A graded approach to review and assessment is partially implemented in the review process of authorization applications as described in Section 5. The content of the annual report required under the Law Article 23 is similar for all licensees. The requirement for the authorized party to submit annual report is not in accordance with a graded approach as there are no specific requirements or guidance on preparing the annual report based on the risks associated with the facility or activity. Moreover, the annual report form is the same for all the authorized parties without regard to the type of the facility or activity. Recommendation 11 is made in Section 5.1

According to the Administrative Code of Georgia Article 83 para. 1, review of the authorization applications is performed in two steps:

1) technical review of the type and number of documents submitted has to be carried out within 3 working days. If the requirements are not met from a technical perspective, ANRS informs the applicant and sets a deadline of 15 working days (maximum) for making changes to application;

2) review of content of documents and information submitted by applicant has to be carried out within 30 days.

Review and assessment is performed by the Authorization Service of ANRS which consists of two chief specialists, one head specialist and the head of department who is in charge of conducting review and assessment. Competence and resources of the Authorization Service are sufficient for the review and assessment function. ANRS does not have a documented internal procedure for review and assessment to guide the staff in the process. However, it has been recognised in the self-assessment and included in the preliminary Action Plan (Item 26) that such a procedure should be developed and implemented to ensure consistency in application reviews. Recommendation 10 is made in Section 4.2. An Order has been issued by the Head of ANRS to provide guidance to the staff on expectations for processing licenses in the ARIS.

6.2 REVIEW AND ASSESSMENT FOR RADIOACTIVE WASTE MANAGEMENT FACILITIES AND DECOMMISSIONING

Procedures for application, review and assessment, license issuing, information which needs to be submitted to ANSR are defined in the Law. For facilities and activities managed by the State organization (Department) only an environmental impact assessment (EIA) has to be performed to obtain a permit from MEPA.

The Law and Technical Regulations #123 contain provisions on periodic reviews of any "high risk nuclear and radiation facilities" to be performed by the licensee at least every 10 years and to be reviewed and assessed by the ANRS.

The decommissioning plan, as a part of the RPP, is not updated by the licensee and thus is not reviewed by the regulatory body on periodic base. RAW coming from decommissioning is not considered in legal documents, but this issue has already been identified in ANRS" Action Plan. A decommissioning safety assessment is not required and performed for other than "high risk nuclear and radiation facilities".

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *A decommissioning plan is a part of radiation protection programme, but it is not maintained throughout the lifetime of the facility, reviewed by the regulatory body periodically and the final decommissioning plan is not approved by the regulator. No requirement on safety assessment for all facilities for which decommissioning is planned and for all facilities undergoing decommissioning is in place. Decommissioning plans are not supported by a safety assessment and management of RAW from decommissioning is not considered. The ANRS Action Plan identifies a general need to improve the decommissioning regulation.*	
(1)	**BASIS: GSR Part 6 Requirement 3 states that:** *"Safety shall be assessed for all facilities for which decommissioning is planned and for all facilities undergoing decommissioning."*
(2)	**BASIS: GSR Part 6 Requirement 10 states that:** *"The licensee shall prepare a decommissioning plan and shall maintain it throughout the lifetime of the facility, in accordance with the requirements of the regulatory body, in order to show that decommissioning can be accomplished safely to meet the defined end state."*
(3)	**BASIS: GSR Part 6 Requirement 10, para 2.6 states that:** *"The final decommissioning plan shall be supported by a safety assessment addressing the planned decommissioning actions."*
(4)	**BASIS: GSR Part 6 Requirement 14 states that:** *"Radioactive waste shall be managed for all waste streams in decommissioning."*
(5)	**BASIS: GSR Part 6 Requirement 11 states that** *"Prior to the conduct of decommissioning actions, a final decommissioning plan shall be prepared and shall be submitted to the regulatory body for approval."*
R15	**Recommendation: Ministry of Environmental Protection and Agriculture/ANRS should establish and implement requirements on the periodic review of decommissioning plan. ANRS should perform regulatory review of updated decommissioning plan and approve final decommissioning plan supported by safety assessments developed by the licensee.**

6.3. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES AND TRANSPORTATION

As identified above, information required to be submitted in the license application is specified in the Law, Article 17. This includes a description of activities, details of sources and materials possessed, location of activities, information about designated person responsible for radiation safety and a list of workers (including evidence of qualification, as applicable, expertise and medical examination), information about the waste that will originate from the use of sources and management of such waste. Also, the radiation protection programme has to be submitted in accordance with TR450. The content of programme is prescribed by TR450 Article 16 para. 8.

In the review and assessment process for applications involving activities with radioactive sources the application is also forwarded to the Ministry of Internal Affairs for review of security arrangements. In this case additional time for the review of application with regard to security aspects is prescribed. Besides the Ministry of Internal Affairs there are no other requirements for external coordination in carrying out review and assessment. There are no advisory committees or arrangements for obtaining external expert advice.

6.4 REVIEW AND ASSESSMENT FOR MEDICAL FACILITIES

Review and assessment processes for medical facilities are similar to those described above for industrial sources. The same review timeliness goals apply to all license application reviews. However, the requirements for submitting information for the RPP for medical activities, as specified in TR317 which is specific to the use of radioactive sources (sealed and unsealed) and devices that generate ionizing radiation for diagnostic and therapeutic purposes is more comprehensive. The list of requirements which must be addressed in the applicant's proposed RPP includes, in part, the following:

- names and qualifications of medical physicians and physicists who will be authorized to perform specified activities;
- devices and materials proposed for use and the associated medical activities to be conducted;
- radiation protection procedures for workers, the public and patients;
- procedures for optimizing exposure to patients, including guidance dose;
- proposed procedures for determining patient doses (for diagnostic radiographic procedures, nuclear medicine procedures and therapeutic procedures);
- equipment calibration procedures and quality control and assurance programs;
- patient justification; and
- record requirements and retention periods.

Information requirements in TR317 are consistent with requirements in GSR Part 3 and RS-G-1.5.

During the review and assessment of applications for medical licenses, particular attention is paid to the content of the RPP since it is more complex than an RPP for an industrial source application. If a reviewer identifies an omission in the RPP submittal, the applicant is contacted and additional information is requested. If a satisfactory response is not received or if a new authorization for a higher risk activity is being requested, the licensing staff may request an observation visit by the inspection staff.

One issue was identified with an applicant/licensee's ability to meet a specific requirement of the quality assurance program. TR317 prescribes a comprehensive quality assurance program for diagnostic radiology which includes a requirement for assessing image quality. This quality assurance requirement is consistent with IAEA Safety Guide RS-G-1.5. The IRRS team was informed that licensees authorized for diagnostic radiology are not presently able to perform this assessment because they do not have the equipment, and the technical service providers that service the majority of the diagnostic radiology licensees are also unable to provide this testing service. This issue is discussed in Recommendation 5 in Section 1.9.

As noted above and in Section 4, ANRS currently does not have a procedure to guide the staff in performing acceptance reviews of license applications. The lack of a procedure to guide the staff in performing reviews of license applications may contribute to oversights in identifying omissions in the applicant's RPP which, for medical applications, can be complex. The IRRS team identified that one

license authorizing diagnostic radiology activities is lacking a commitment to perform image quality assessments. The ANRS licensing staff can require correction of this omission.

6.5. SUMMARY

Provisions for review and assessment of facilities and activities are established in Georgia.

The following areas for improvement were identified:

- Periodic reviews of decommissioning plans and regulatory reviews and approval of updated and final decommissioning plans; and
- Procedure to guide the review and assessment for applications for industrial and radiation source facilities, transportation and medical applications.

7. INSPECTION

7.1. GENERIC ISSUES

One of the functions of ANRS prescribed by the Law is state control of nuclear and radiation activity through inspection. The Decree of the Minister of Environmental and Natural Resources Protection of Georgia On Approval Rules for Inspection of Nuclear and Radiation Activity (# 2; 2016) – hereinafter referred to as Rules for Inspection, prescribes the inspection objectives – to determine the compliance of activities with the legislative requirements in the field of nuclear and radiation safety.

The Law prescribes the conditions of conducting inspection and the types of inspections. Inspections are carried out to assess the safety conditions of nuclear and radiation activities, during execution of licensed activities, in case of revoking a license and in case of revoking the right for one or several licensed activities. According to the Law, inspection may be planned and unplanned. In the case of a radiation accident, an unforeseen event or an alleged violation, a reactive inspection may also be conducted.

Planned inspections are regulated by the requirement that a planned inspection shall be conducted pursuant to a developed and approved inspection programme, and the Regulatory Body shall give the license holder a well-grounded notice in advance of such inspection. There is a provision in the Law for unannounced inspection (unplanned or reactive). Criteria for carrying out unplanned inspections are defined in the Rules for Inspection. There is a provision to carry out unplanned inspections for the detection of unlicensed nuclear and radiation activities.

Unplanned inspections may be conducted prior to operations. ANRS considers the risk of the nuclear or radiation activity when making a decision to conduct such an inspection. Such pre-authorization inspections are carried out by ANRS if the Authorization Service, together with the Inspection and Response Service, decide that inspection will be necessary. There are no documented criteria for deciding when the pre-authorization inspection should be carried out.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Pre-authorization inspection is carried out by the Inspection and Response Service if, after consultation with Authorization Service, a pre-authorization inspection is deemed to be necessary. However, there are no documented criteria for deciding when the pre-authorization inspection has to be carried out.*	
(1)	**BASIS: GS-G-1.5 para. 3.42 states that** *"A fundamental feature of the process of review and assessment of an application for authorization by the regulatory body is its consideration of the documentation submitted by the applicant. For significant risk sources or unusual or complex practices, the regulatory body should also verify the contents of the documents submitted by means of inspection of the site where the radiation sources are to be installed or used. These inspections will also allow the regulatory body to supplement the information and data needed for."*
S10	**Suggestion: ANRS should consider developing and implementing criteria for carrying out pre-authorization inspections.**

7.2. INSPECTION PROGRAMME

Planned inspections are carried out in accordance with inspection programme that is established by ANRS and approved annually by the Minister of Environmental and Natural Resources Protection of Georgia (MENRP), now-MEPA (see section 1.1).

Rules for Inspection define the frequency of inspections partially in accordance with a graded approach:

a) Application of radioactive sources in medicine, industry and science – shall be inspected at least once in a year;
b) Radioactive waste management – shall be inspected at least once in a year;
c) Accelerators of different applications (medicine, industry and other) – shall be inspected at least once in a year;
d) Medical diagnostic radiology – shall be inspected at least once in two years;
e) Dental radiography and service delivery using radiation sources- shall be inspected at least once in five years;
f) Other types of licensed activities - shall be inspected at least once in five years.

If any changes to the inspection programme have to be made, the programme has to be re-approved by MENRP of Georgia. Re-approval is required in case of changes such as a change in the name of the facility or facility closure.

Inspection frequencies are used to establish an annual inspection programme. Every year 30-40 facilities, which have not been inspected since 2015 when ANRS started to carry out periodic inspections with a clearly defined frequency, are included in the annual inspection programme.

The ANRS annual report for 2017 includes information about types and number of inspections carried out during 2017 – in total 95 planned and 12 unplanned inspections. There were 74 inspections in medical practices and 33 inspections in industrial or scientific practices. At the moment there are approximately 700 licensed facilities).

There is a legislative provision to carry out joint inspections with other competent authorities; however, this is not practiced by ANRS. No technical support organizations or consultants are involved in carrying out inspections.

7.3. INSPECTION PROCESS AND PRACTICE

Inspections are carried out by the Inspection and Response Service of ANRS. According to the Rules for Inspection, an individual inspection plan is drawn up prior the inspection and is agreed upon with the Head of ANRS. An individual inspection plan includes delegation of rights and obligations of the members of the group, a list of necessary technical equipment, main activities of the inspection and the inspection questionnaire.

Rules for Inspection define inspection methods such as observation of activities, review of documentation, interviews with personnel, taking radiation measurements, taking samples for laboratory radiological evaluation, and determining radiation emergency preparedness.

ANRS has developed and is using inspection check lists in practice, but has not approved the practice of using specific inspection check-lists for medical and non-medical applications. There are no practice-specific check-lists for technical service providers and for facilities licensed to perform transport of radioactive sources.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ANRS has developed practice- specific checklists (except for technical service providers and for facilities licensed to perform transport of radioactive sources), however they have not been approved yet, but are implemented by ANRS.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 22, 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."*
(2)	**BASIS: GS-G-1.5 para. 3.61 states that** *"To ensure that all operators are inspected to a common standard and that the level of safety is consistent, the regulatory body should establish procedures for its inspectors. The procedures should be such as to ensure a systematic and consistent approach to inspection, allowing sufficient flexibility for inspectors to take the initiative in identifying and addressing new concerns as they arise. Appropriate information and guidance should be provided to the inspectors concerned and each inspector should be given adequate training in following the procedures."*
S11	**Suggestion: ANRS should consider developing, if not already developed, and finalizing inspection check-lists for medical and non-medical facilities, including technical service providers and for facilities licensed to perform transport of radioactive sources.**

After completion of the inspection, the head of the inspection team or the person conducting the inspection draws up the inspection act describing the actions undertaken during the inspection process and prescribing the corrective actions for licensee. The inspection act is signed by persons involved in the inspection –the inspector as well as the inspected party.

The inspection outcomes with the inspection act attached to it are presented to the Head of ANRS no later than 5 working days after the inspection.

When violations are identified, the inspector completes a protocol of administrative offenses. The administrative protocol has to be prepared and signed at the place of inspection. Administrative protocol has to be prepared for each violation/enforcement action separately.

Within 10 days after drawing up the protocol of administrative offenses the relevant structural subdivision of the Ministry of Internal Affairs has to be notified.

Inspection findings are recorded in the ARIS, where the inspection act can be prepared electronically based on the inputs in the database.

INSPECTORS

Inspection and Response Service consists of seven inspectors – Head of the Service, 3 Chief Specialists and 4 Senior Specialists. Functions of the Inspection and Response Service are clearly prescribed by the Decree of the Minister of Environmental and Natural Resources Protection of Georgia On approval of the Statute of the Legal Entity of Public Law - Nuclear and Radiation Safety Agency (#237; 2015). Powers of inspectors are defined in the Law and guidance for inspectors is provided in the ANRS internal inspection procedure; however, this procedure has not been approved yet. The draft procedure also includes code of conduct for inspectors. Recommendation 10 on inspection procedures is made in Section 4.2.

Hiring requirements for public servants are unified in Georgia. Qualification requirements for hiring inspectors and license reviewers are established and include higher education in physics, chemistry and other natural sciences, or in medicine. There is no documented training programme for ANRS staff, but training is provided by IAEA and other countries that ANRS has an agreement with. Recommendation 8 on the training programme is made in Section 3.3.

Inspectors are authorized to suspend activities under prescribed circumstances, to initiate enforcement measures before presenting the finding to the Head of ANRS and to draw up an enforcement act (protocol of administrative offences).

7.4. INSPECTION OF WASTE MANAGEMENT FACILITIES AND DECOMMISSIONING ACTIVITIES

There are no specific rules for inspections of RAW management facilities and decommissioning activities. The RAW management facilities are inspected once a year, including Department facilities. The first inspections of the CSF and 'RADON' facilities being operated by Department are planned for 2018 (before this date, inspections were performed at the Institute of Nuclear Physics, which operated CSF; operation of 'RADON' facility was started in 2015).

ANRS has 2-3 inspectors performing inspections at licensees for RAW management and the Department facilities. There is no internal ANSR guide on the conduct of regulatory inspections at RAW management facilities, although ANRS staff follow a specific check-list for these inspections. Recommendation 10 is made in Section 4.2.

Site visit

Team members visited the RAW storage facility CSF, which was constructed in the 1960's as a research reactor pumping station and modified for storage of RAW in 2007. Originally, the storage facility was managed by the Applied Research Centre of the Institute of Physics. Transfer of function occurred on 7 August 2017 and since then the facility has been operated by the Department, which has 4 staff members.

CSF has 2 levels and at each level there are 4 modules (boxes) for RAW storage (total of 8 modules). CSF provides storage for 26, 200, litre concrete drums with RAW generated during the decommissioning of the IRT-M research reactor. There are also disused radioactive sources stored: 945 sealed and 486 unsealed sources. Sources are placed in boxes and containers are marked with an ANRS inventory number. Boxes and containers show signs of degradation, provide only very limited safety functions and are not labelled with radioactive signs and labels (see Recommendation 19 on WAC and criteria of storage containers in Section 9.2). New containers are already ordered to re-pack some of stored sources. Hot cells at the Institute of Nuclear Physics may be used for this action.

Inspection by ANRS started with presentation of an inspection order of the Head of ANRS to Department staff. The order defines details of inspection (who and when an ANRS inspection will be performed, legal provisions, etc). The inspection was conducted based on checklist. There are no operating procedures, WAC and inspection guides are utilized but they are under development (see Recommendations 19 and 20 on WAC and criteria of storage containers and on development of operating procedures in Section 9.2). Considering the high potential of removable contamination, particular attention should be given to radiation protection operating procedures for both the operator and regulator (see Recommendation 4 on competence for persons with responsibilities for safety in Section 1.8 and Recommendation 20 on development of operating procedures in Section 9.2).

The first part of the inspection took place at the CSF site and was focused on following areas:

- Monitoring programme – details of personnel monitoring and record keeping procedures, adequacy of personnel monitoring equipment, assessment of dose records, maintenance of built-in environmental monitors (10 indoors and 2 outdoors gamma monitors);
- Performance of equipment – manual fork lifts, ventilators, fire protection equipment;
- Checking of inventory, by records and surface dose measurements of randomly selected DSRS; and
- Physical protection and emergency arrangements.

The second part of inspection was performed at the Department office and was not observed by the IRRS team.

7.5. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

Inspection of radiation sources facilities and activities is carried out in accordance with the general procedure.

Although categorization of radioactive sources into five categories according to IAEA Standards is established, it is not used for implementation of a graded approach in the inspection process as the frequency of inspections is the same for all the radioactive sources (once in a year).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *A Graded approach is not implemented to the full extent in the inspection process considering that radioactive sources of categories 1 to 5 are inspected with the same frequency.*	
(1)	**BASIS: GSR Part 1 (Rev.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: RS-G-1.9 para. 3.2 states that** *"The regulatory body should use the categorization system described in this Safety Guide to provide a consistent basis for implementing these requirements in different areas, including the following:* *- Regulatory measures: To provide one of the factors to be taken into account in developing a graded system for notification, registration, licensing and inspections [1, 2, 26, 27]. The categorization system also assists in ensuring that the allocation of human and financial resources to protection measures is commensurate with the degree of risk associated with the source."*
S12	**Suggestion: ANRS should consider introducing a graded approach in the inspection frequency of radioactive sources of categories 1 to 5.**

Inspection check-lists for specific medical and non-medical practices are in development but have not been approved by ANRS. Check-lists are prepared for the following non-medical practices – well logging, research and industrial irradiators, industrial radiography and the use of gauges (general, fixed, portable). Check-lists prepared for medical activities include diagnostic radiology, nuclear medicine and radiation therapy.

Inspection check-lists include references to previously conducted inspections and revealed violations as well as a brief incident and radiation event history. Requirements for transport, receipt and transfer of

radioactive sources and appropriate packaging and labelling and marking procedures are assessed. Training and instruction of workers is clearly covered in inspection check-lists. Review of personnel dosimetry arrangements and application of the optimization principle is covered in inspection check-lists. Testing of sources and equipment, as well as calibration of measuring devices and monitoring equipment arrangements are verified according to the inspection check-lists. Also, independent measurements are carried out by ANRS inspectors according to the inspection check-lists.

Although very detailed check-lists are prepared by ANRS as a part of draft internal procedure and are used in practice, they have not been approved by ANRS. In addition, there is no inspection procedure or check-list for inspection of the technical service providers. In Georgia, technical services such as individual dosimetry, workplace monitoring, development of radiation protection programme and quality management documentation are carried out by two licensed technical services providers. Inspections of the technical service providers have not been implemented. Suggestion 11 concerning inspection check-lists is made in Section 7.3.

Site visit of industrial radiation sources facility

During the mission IRRS team members observed an inspection of a well-logging facility, LTD "AIC Forwarding." The facility has been licensed for using radioactive sources in industry since 2012. In 2015, instead of amending the old license, a new license was issued for the facility taking into account changes in the regulatory system. The facility is using one Category 4 source and 15 Category 5 sources in addition to 12 exempted radioactive sources that are listed in the source inventory. Both gamma and neutron sources are used for geophysical investigations for petrol, gas and water. Geophysical investigations have been temporarily suspended

During the site visit, IRRS team members observed that ANRS inspectors were well prepared and had appropriate protective clothing, gloves, flashlight and camera. Protective measures included so a TLD personal dosimeter and EPD dosimeter for each inspector. ANRS inspectors followed the Inspection Rules and also used the specific check-list for well logging. Inspectors carried out independent measurements of the dose rate near the sources in the field and in the underground storage facility for neutron sources. Measuring devices used by ANRS inspectors included Radiagem 2000, RedSeeker CS, InSpector 1000. ANRS measuring devices were calibrated.

The scope of the inspection covered all the relevant regulatory requirements. The inspection process included the necessary steps such as preparation for inspection by using ARIS, drawing up an individual inspection plan, preparing an inspection check-list, carrying out interviews with the licensee and summarizing inspection findings. Identified non-compliances were communicated to the licensee in an appropriate manner. IRRS team members observed that ANRS communications with the licensee were effective and were focused on enhancing safety culture of the licensee.

Site visit of Diagnostic Radiology Facility

An IRRS team member accompanied two ANRS inspectors during an inspection of a licensee authorized to perform diagnostic radiology activities, "St. John the Merciful Private Clinic" LLC. The inspectors prepared for the inspection through a thorough review of license documents using ANRS' electronic document system. Pre-inspection reviews included the license data, the radiation protection programme (RPP), notifications received from the licensee, past inspection records and the annual report.

The inspectors were well prepared for the inspection and reviewed all relevant portions of the licensee's RPP and facilities. Occupational doses, patient doses, training records, X-ray unit calibration records, and patient exposure records were reviewed through selective sampling. The inspectors confirmed that guidance doses for patients were established, that standard techniques were established for various procedures to optimize patient exposures, and that patient doses were being recorded as required.

The inspectors conducted interviews of the RPO, also the medical physician, and technical staff to confirm how activities required by the RPP were conducted. They confirmed that the process for justification of procedures was being completed by the medical physician and that records of the physician's review were being maintained by the licensee.

The inspectors conducted independent assessments of radiation levels in all areas adjacent to the controlled areas while the X-ray units were activated to verify that dose rates in areas adjacent to the controlled areas were within allowable limits. Surveys were performed in adjacent hallways, waiting areas and in uncontrolled spaces above the rooms housing the X-ray and computed tomography unit.

At the conclusion of the inspection, the inspectors provided a briefing to the medical facility director and RPO. A completed inspection record was provided to the licensee at the conclusion of the inspection.

7.6. INSPECTION OF TRANSPORT

The check-lists developed by ANRS for medical and non-medical practices include a section about the transport of radioactive sources. There is not a comprehensive check-list for inspection of all transport activities. Suggestion 11 about inspection check-lists is made in Section 7.3.

7.7. SUMMARY

Inspection process of regulated facilities and activities has been established and implemented by ANRS. Elements of internal procedures for carrying out inspections are included in Rules for Inspection. In addition, drafts of inspection procedures have been developed, but have not been approved by ANRS. Check-lists for inspecting different practices in medical and non-medical applications are being developed, however, check-lists for inspection of technical service providers and comprehensive check-lists for inspection of transport activities have not been prepared.

The inspection programme is approved annually by MEPA. Frequency of inspection of different facilities and activities is prescribed in partial accordance with a graded approach, however, the categorization of radioactive sources is not fully implemented, for example, to provide for graded inspection frequency. Not all of the licensed facilities and activities have been inspected since the establishment of ANRS.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

General enforcement policy is applied in Georgia in accordance with the Law On Code of Administrative Offences of Georgia (#161; 1984) and the Law On Criminal Code of Georgia (#2287; 1999). The Law defines the functions of ANRS to include implementation of coercive measures (enforcement) in case of detection of unauthorized nuclear and radiation activity and violation of license or permit conditions. These coercive measures are described in the Law. ANRS as a regulatory body is responsible for identifying violations of safety, for giving the offender a written notice and for setting a reasonable term for corrective actions. In addition to these provisions, the Law also states the rights of an inspector – an inspector may suspend the activity of the regulated facility and immediately notify ANRS for filing an application in court.

The authorized party has the right to appeal every decision of ANRS. This information is also provided to authorised parties through the administrative acts issued by ANRS.

Follow up of enforcement actions is carried out. If the identified violation does not give rise to an administrative action, implementation of corrective actions is checked during the next planned inspection or through review of the annual report submitted by the licensee.

8.2. ENFORCEMENT IMPLEMENTATIONS

Enforcement actions are carried out by the Inspection and Response Service. ANRS has authority to initiate the following enforcement actions - suspending nuclear and radiation activity, revocation of the license, preparing the protocol of administrative offenses, prescribing a reasonable timeframe for corrective action and ensuring administrative correspondence with the authorized party for the improvement or compliance with certain minor importance license conditions.

In practice, two types of enforcement actions are applied by the Authorization Service and several enforcement actions by the Inspection and Response Service. A decision for revocation of the license in the necessary cases is prepared by the Authorization Service based on the report provided by the Inspection and Response Service. The Authorization Service also issues protocol for fines in cases when the annual report is not submitted. If the report is incomplete, a fine is not applied and a reasonable timeframe for repeated submission is set by ANRS. The authorized party may appeal the fine. In practice, 20% of appealed fines in the court have resulted in repeal of the fine (monetary penalty) as a warning was applied by the court instead.

The Inspection and Response Service may issue recommendations during the inspection if minor violations, such as incompleteness of some documents, are revealed. However, if a document is missing or the legislative and regulatory requirements are not complied with, the Inspection and Response Service prepares administrative protocol for issuing a monetary penalty. Monetary penalties depend on the risk of the non-compliance in accordance with a graded approach. In addition, criminal activities are penalized according to the Law On Criminal Code of Georgia (#2287; 1999).

In addition to recording general inspection findings in ARIS, ANRS inspectors also record the non-compliances, the applied enforcement actions and the proposed corrective actions. All the decisions and administrative correspondence inside of ANRS, as well as with the authorized party and MEPA, is attached to the file in the ARIS. For follow up of the enforcement actions, the ARIS database is effectively used as it contains a process for automatically sending a warning signal for the enforcement record if the deadline for submission of corrective actions by the authorized party has passed.

Although the enforcement process is carried out by all the inspectors and new staff is trained on the enforcement process, there is no documented procedure for enforcement and there are no criteria established for application of corrective actions. The consistency of decision making by different ANRS inspectors, training of new inspectors on enforcement, and knowledge management in case of changes in the staff is not documented in an enforcement procedure. Recommendation 10 is made in Section 4.2.

In addition, there are no criteria for application of different enforcement actions with regard to the risks associated with the discovered violation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ANRS does not have criteria for application of corrective actions in a consistent manner and with a regard to the risks associated with the discovered violation.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 31 para. 4.54 states that** *"The response of the regulatory body to non-compliances with regulatory requirements or with any conditions specified in the authorization shall be commensurate with the significance for safety of the non-compliance, in accordance with a graded approach."* **BASIS: GSR Part 1 (Rev.1) Requirement 31 para. 4.58 states that** *"The regulatory body shall establish criteria for corrective actions, including enforcing the cessation of activities or the shutting down of a facility where necessary. On-site inspectors, if any, shall be authorized to take corrective action if there is an imminent likelihood of safety significant events."*
(2)	**BASIS: GSR Part 1 (Rev.1) Requirement 22, 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."*
R16	**Recommendation: ANRS should establish and implement criteria for application of corrective actions in a consistent manner and with a regard to the risks associated with the discovered violation.**

8.3. SUMMARY

Enforcement actions in Georgia are generally governed by Law On Code of Administrative Offences of Georgia and Law On Criminal Code of Georgia. ANRS implements different enforcement actions in accordance with a graded approach – there are timeframes for providing information in case of small non-compliances with regulatory requirements and there are graded monetary penalties depending on the severity of violations and criminal penalties.

Although the enforcement process is carried out by all the inspectors and new staff is trained on the enforcement process, there is no documented procedure for enforcement and there are no criteria established for application of corrective actions.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

The primary radiation and nuclear safety legislation in Georgia is the Law of Georgia on Nuclear and Radiation Safety (35912-RS; 2015), hereinafter referred to as "the Law", the Licenses and Permits Law of Georgia (#1775; 2005), the Law of Georgia on Normative Acts (#1876; 2009) and the Law of Georgia on Radioactive Waste (#4487-IS; 2012), as well as Decrees issued by the Government of Georgia and Decrees issued by the Minister of Environmental and Natural Resources Protection of Georgia (now - Minister for Environmental Protection and Agriculture of Georgia (MEPA)).The complete list of national legislation and regulations is attached to this report in Appendix VI.

The formal process for issuing new regulatory requirements, or changing existing ones, is prescribed by the Law of Georgia on Normative Acts (#1876; 2009). The legal basis for developing new decree is in the legislative document of a higher hierarchy (e.g., the legal basis for developing Decree of Government shall be in the Law of Georgia, and for developing Decree of MEPA shall be in a Law of Georgia or in a Decree of the Government).

Decree #237 of MEPA on the approval of the Statute of the Legal Entity of Public Law defines that the Regulatory Body is responsible for developing draft legal acts in the field of nuclear and radiation safety, and for submitting them to MEPA. This means that ANRS is responsible for preparing drafts at the level of Law, Decree of Government or Decree of MEPA. Due to a limited number of staff available for reviewing draft regulations, in some cases ANRS may use external experts as well as IAEA expert missions for support. When preparing regulations ANRS will also prepare explanatory notes.

Article 6 para.7 of the Law defines the functions of MEPA where one of the Ministry's functions is to coordinate draft preparations of laws and other normative acts in the field of nuclear and radiation safety. According to the Decree of Government #77, MEPA coordinates the submission process with other authorities, including interfaces with other Ministries and other bodies of Government. Other governmental bodies are given a timeframe to provide their comments or suggestions on draft regulations. The final version of a draft regulation is then adopted by MEPA or initiated by MEPA before the Government (in case of the Law or Decree of Government). The IRRS team was informed that the Legal Department of the MEPA only verifies the prepared regulations for concordance with higher hierarchy regulations or legislation.

Internal ANRS procedures for development of legislation and draft guide have not been established as part of the quality management system. Recommendation 10 is done in Section 4.2.

According to the Law on Normative Acts, all interested parties are involved in the preparation of any kind of legislation (law, decree, technical regulations). For this purpose, all drafts and proposals are published on the ANRS website and distributed to interested parties, along with an announcement of the timeframe in which interested parties can provide their opinions and comments. The process of public consultation guides the ANRS in the preparation of the final proposed version. In case of different views or misunderstandings, work meetings are arranged between ANRS and interested parties.

No formal process has been established for review of the legislative framework; there are no conditions or timeframes within which the governmental authority is obliged to review legislative framework.

Most of the international safety standards are incorporated into Georgian legislation. The main objective of ANRS in drafting technical regulations is to transfer international requirements into the Georgian legislation. ANRS does not prepare a map or table of concordance when preparing changes to existing regulations to demonstrate a clear correspondence with international safety requirements and national regulatory requirements and there is no mechanism to ensure that regulations are fully harmonized and updated with the latest requirements of IAEA safety standards. There is no uniform glossary for all legally based regulatory documents. In some cases, different terms are used for similar or identical concepts.

According to the Law and Statute of the ANRS, the ANRS is not currently authorized to issue regulations that have binding force or to issue non-binding guides. There is no practice of ANRS for the preparation of regulatory guides. Although these are legally non-binding, guides provide detailed guidance to authorized parties on how to comply with safety requirements. ANRS already recognized this issue in their Action Plan.

All existing regulations are available to interested parties and the public through the ANRS website, the Legislative Herald of Georgia and on the website of MEPA. Licensees are informed about new legislation through notification letters and through the single window portal (see Good Practice in Section 3.5).

ANRS does not have a detailed annual work plan to develop or revise regulations and guides. The plan of action is derived from transitional provisions of the Law, where a timeframe for developing regulations is defined.

The IRRS team was informed that, in the short term, one new regulation is envisaged to be issued. Georgia is in the process of finalizing regulatory requirements for industrial radiography, the use of radiation sources in research applications and the use of radiation sources for well-logging. These regulatory requirements have been prepared by ANRS and submitted to MEPA for adoption in accordance Decree of the Government of Georgia On the Approval of Technical Regulations on Radiation Safety Requirements in Industry, Science, and Education (#558; 2016) – hereafter referred to as TR558.

IRRS team noted many examples in various areas where regulatory requirements were not consistent with international safety standards and areas where certain regulatory requirements were missing. Some examples include requirements for the derivation of operational limits, passive safety for RAW management facilities, operational written procedures for RAW management facilities, criteria for packages used in RAW storage or disposal facilities, approved final decommissioning plans, a graded approach for different practices and facilities, and requirements for transport. More information regarding these and other examples of inconsistencies in regulations with international standards can be found in Sections 9.2, 9.3 and 9.4.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ANRS is not authorized to issue non-binding guides to licensees on how to comply with the safety requirements. This has also been identified by ANRS in their Action Plan.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 32 states that "***The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.*
R17	**Recommendation: Ministry for Environmental Protection and Agriculture of Georgia**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	should empower ANRS to issue non-binding guides on how to comply with the safety requirements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no arrangements for periodic review and revision of regulatory framework in order to consider updates in the IAEA safety standards, latest developments of science and technology, and lessons learned from own and international regulatory experience.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 32 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained.*
R18	**Recommendation: ANRS should ensure that regulations are periodically reviewed and revised, considering international standards, latest developments of science and technology, and lessons learned.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no uniform glossary to be used for all legally based regulatory documents*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 34 paragraph 4.62 states that** *…"The regulations and guides shall be kept consistent and comprehensive…"*
S13	**Suggestion: ANRS should consider compiling a uniform glossary to be used for all regulatory documents.**

9.2. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES AND DECOMMISSIONING

Georgia has recently put in force regulations on facilities and activities in the area of RAW management and decommissioning.

A suite of technical regulations completes the legal framework of Georgia in this area. Two Technical Regulations #123 and #124 contain requirements on the safety assessment of RAW management (predisposal) and disposal facilities, Technical Regulations #640 deals with details of the RAW management strategy and Technical Regulations #189 provides specific requirements for each step in the RAW management process. There are no specific technical regulations on decommissioning but some details on this subject are provided in TR450, which implements GSR Part 3 in the national legal framework. Classification of RAW is provided in Technical Regulations #689.

There are deficiencies in regulations that are related to the:

- derivation of waste acceptance criteria from safety cases;
- development of conditions of storage and disposal facilities including passive safety features of storage and disposal facilities and containment of RAW; and
- provisions to ensure safety is not compromised by measures undertaken to account for and control nuclear material.

The definition of a safety case, its content and link to safety assessment are largely addressed in Article 6 of Technical Regulations #123 and #124, which includes documents not directly needed to perform safety assessment, such as a description of the physical protection system, emergency response plan, radiation monitoring (plan) and the evaluation of human and social factors. However, to complete the list of documents needed for a safety case for RAW management facility additional documents could be considered, such as:

- the management system of the licensee,
- the plan for funding of RAW management and decommissioning/closure activities,
- the definition or revision of operational limits, conditions and controls including waste acceptance criteria,
- the evaluation of clearance and discharge activities;

Additional areas for improvement include:

- RAW package design requirements, as no comprehensive criteria on storage packaging are in force (only requirement on compatibility of the inner surface of packaging's with its content is included in Technical Regulations #189);
- approval of the final decommissioning plan by ANRS;
- conditions for site characterisation for a disposal facility (although Article 7 of Law on Radioactive Waste introduces the site selection of storage or disposal facility, no provisions on site characterisations are provided);
- availability of operating procedures (there is no legal provision for operation of a RAW management facility in accordance with operating procedures).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Requirements for waste acceptance criteria exist in the legislation. No requirement on consistency of these criteria with safety case is in place and the WAC do not exist for RAW storage facilities operated by Department. ANRS in its Action Plan has addressed this issue. Operational limits, conditions and controls concept is not in the regulations. Criteria for waste package used for storage of RAW are not established in the regulations.*	
(1)	**BASIS: GSR Part 5 Requirement 12 states that** *"Waste packages and unpackaged waste that are accepted for processing, storage and/or disposal shall conform to criteria that are consistent with the safety case.*
(2)	**BASIS: GSR Part 5 Requirement 9, para 3.11 states that "***Depending on the complexity of the operations and the magnitude of the hazards associated with the facility or the activities concerned, the operator has to ensure an adequate level of protection and safety by various means, including:…Derivation of operational limits, conditions and controls, including waste acceptance criteria, to assist with ensuring that the predisposal radioactive waste management facility is operated in accordance with the safety case;"*
(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."*
(4)	**BASIS: GSR Part 5 Requirement 10 states that** *"…Waste packages shall be designed and produced so that the radioactive material is appropriately contained both during normal operation and in accident conditions that could occur in the handling, storage, transport and*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	disposal of waste."
(5)	**BASIS: GSR Part 5 Requirement 12, para 4.24 states that** *"Waste acceptance criteria have to be developed that specify the radiological, mechanical, physical, chemical and biological characteristics of waste packages and unpackaged waste that are to be processed, stored or disposed of; for example, their radionuclide content or activity limits, their heat output and the properties of the waste form and packaging."*
R19	**Recommendation: Ministry of Environmental Protection and Agriculture/ANRS should establish and implement requirements on derivation of operational limits, conditions and controls including waste acceptance criteria from the safety case and on criteria on packages used in RAW storage or disposal facilities to comply with these waste acceptance criteria.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Regulations on RAW storage and disposal facilities are in place. The following areas are not fully addressed:* – *passive means of storage and disposal facilities,* – *containment and isolation of RAW in disposal facilities,* – *priority of safety arrangements over the system of accounting for and control of nuclear material,* – *development of written operator`s procedures considering also provisions for safe management of RAW that fails to meet the waste acceptance criteria.*	
(1)	**BASIS: GSR Part 5 Requirement 11 states that** *"Waste shall be stored in such a manner that it can be inspected, monitored, retrieved and preserved in a condition suitable for its subsequent management. Due account shall be taken of the expected period of storage, and, to the extent possible, passive safety features shall be applied. For long term storage in particular, measures shall be taken to prevent degradation of the waste containment."*
(2)	**BASIS: SSR 5 Requirement 5 states that** *"The operator shall evaluate the site and shall design, construct, operate and close the disposal facility in such a way that safety is ensured by passive means to the fullest extent possible and the need for actions to be taken after closure of the facility is minimized.*
(3)	**BASIS: SSR 5 Requirement 7 states that** *"...Containment and isolation of the waste shall be provided by means of a number of physical barriers of the disposal system. ... The overall performance of the disposal system shall not be unduly dependent on a single safety function."*
(4)	**BASIS: SSR 5 Requirement 8 states that** *"...Containment shall be provided until radioactive decay has significantly reduced the hazard posed by the waste. ..."*
(5)	**BASIS: GSR Part 5 Requirement 21 states that** *"For facilities subject to agreements on nuclear material accounting, in the design and operation of predisposal radioactive waste management facilities the system of accounting for and control of nuclear material shall be implemented in such a way as not to compromise the safety of the facility."*
(6)	**BASIS: SSR 5 Requirement 20 states that** *"In the design and operation of disposal facilities subject to agreements on accounting for and control of nuclear material,*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	consideration shall be given to ensuring that safety is not compromised by the measures required under the system of accounting for and control of nuclear material."
(7)	**BASIS: GSR Part 5 Requirement 20 states that** *"Predisposal radioactive waste management facilities shall be operated in accordance with national regulations and with the conditions imposed by the regulatory body. Operations shall be based on documented procedures. Due consideration shall be given to the maintenance of the facility to ensure its safe performance. …"*
(8)	**BASIS: GSR Part 5 Requirement 12, para 4.26 states that** *"The operators' procedures for the reception of waste have to contain provisions for safely managing waste that fails to meet the acceptance criteria; for example, by taking remedial actions or by returning the waste.*
R20	**Recommendation: The Ministry of Environmental Protection and Agriculture/ANRS should establish and implement requirements on RAW storage and disposal facilities in compliance with GSR Part 5 and SSR 5 with particular focus in these areas:** – **passive means of storage and disposal facilities,** – **containment and isolation of RAW in disposal facilities,** – **priority of safety arrangements over the system of accounting for and control of nuclear material,** – **development of written operator`s procedures also considering provisions for safe management of RAW that fails to meet the waste acceptance criteria.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no regulation on characterisation of a disposal facility site.*	
(1)	**BASIS: SSR 5 Requirement 15 states that "***The site for a disposal facility shall be characterized at a level of detail sufficient to support a general understanding of both the characteristics of the site and how the site will evolve over time. This shall include its present condition, its probable natural evolution, and possible natural events and also human plans and actions in the vicinity that may affect the safety of the facility over the period of interest. It shall also include a specific understanding of the impact on safety of features, events and processes associated with the site and the facility."*
R21	**Recommendation: ANRS should ensure that the planned disposal facility site is characterised.**

9.3. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The current regulations for radiation sources facilities and activities are based on the Law. A set of regulations focusing on implementing IAEA GSR Part 3 was recently prepared. Regulations in Georgia do not fully reflect a graded approach. Some detailed regulations have been established, for example, for medical application. However, there are no detailed specific requirements for other types of facilities and activities, such as industrial, research and education applications. Practice-specific requirements for industrial radiography (one of the practices that can result in high doses to workers, discussed in SSG-11

"Radiation Safety in Industrial Radiography") have been drafted, but have yet to be established and implemented. Recommendation 11 is made in Section 5.1.

TR558 refers to the main principles already established by the Law and TR450. These principles include the protection of humans and environment from harmful exposure to ionising radiation, adherence to radiation safety requirements, ensuring radiation monitoring, ensuring security and ensuring emergency preparedness. In the practice-specific TR558, one of the ANRS functions is stated to be the development of guidelines and recommendations for activities related to ionising radiation sources and equipment containing such sources in industry, science and education. These Regulations (Article 5 para. z) refer to the "Methodical guidelines on specific requirements of radiation safety during non-destructive control, use of radioisotope tools and radiation research in wells" which was planned to be adopted by January 1st 2018, but remains in draft form. Therefore, there are no approved and published guidance materials at the moment.

9.4 REGULATIONS AND GUIDES FOR TRANSPORT

Transportation of dangerous goods by road is regulated by Decree of the Government of Georgia on the Approval of Technical Regulations – rules of carriage of cargo by vehicle (#32; 2014) and transportation by air - with the Order of Director of National Air Agency #263.

Decree of Government #32 sets general requirements, but is not detailed. The existing legal requirements were not sufficient to regulate transport of radioactive substances in accordance with international standards. Therefore new Technical Regulations "Rules for Transport of Nuclear and Radioactive Materials" was drafted in 2017 and was recently adopted. With this regulation most elements of ADR and SSR-6 have been transposed in Georgian legal system.

Article 3 paragraph 2 c) of new Technical Regulations specifies that these regulations do not apply to the transport of nuclear and radioactive substances if it is carried out by ANRS. Recommendation 2 is made in Section 1.3.

In Order #1422 of the Government of Georgia, a special plan for implementation of ADR has been established. The plan defines actions and responsible organizations. The Ministry of Economy and Sustainable Development of Georgia and Land Transport Agency will prepare the new regulations with the advice of ANRS and other units of MEPA.

9.5 SUMMARY

The legal basis for developing regulations for nuclear and radiation safety is clearly defined through the Law on Nuclear and Radiation Safety and the Law on Radioactive Waste. The formal process for issuing new regulatory requirements, or changing the existing ones, is prescribed by the Law of Georgia on Normative Acts. Most of the regulations are established in accordance with IAEA safety standards however, there is no mechanism to ensure that the regulations are fully harmonized with the requirements in IAEA safety standards.

The ANRS is responsible for developing draft regulations in the field of nuclear and radiation safety and submitting them to MEPA, which coordinates the submission process to other authorities and interfaces with other Ministries and units of administration. In addition, the public is involved in the process of proposing or changing any kind of legislation (law, ordinance, regulation).

However, the IRRS team identified areas for improvement and recommends that the Ministry for Environmental Protection and Agriculture of Georgia and ANRS:

- empower ANRS to issue non-binding guides and
- ensure that regulations are developed and reviewed in a systematic way.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

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

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

Georgia has a legal framework in place that clearly defines and allocates the regulatory mandate and responsibilities of the Agency of Nuclear and Radiation Safety (ANRS) in the field of Emergency Preparedness and Response (EPR). ANRS is established by the Law, which designates it as the regulatory body, and describes generally its duties and functions. Further, ANRS is the only regulatory authority in the field of EPR for operating organizations (OOs) involved in nuclear or radiological activities.

The core EPR functions of ANRS are specified in the Statute of the Statute of the Legal Entity of Public Law - Agency of Nuclear and Radiation Safety (#237; 2015) which states that the Regulatory Body is responsible for developing draft legal acts in the field of nuclear and radiation safety including EPR; performing radiation incident and accident response; investigating radiation accidents and assessing the results of investigations.

In accordance with the Law, to obtain a license the OOs shall submit a Radiation protection programme to ANRS. A plan of prevention of radiation incidents and accidents and liquidation of their consequences (EPR Plan) is an essential part of the Radiation protection programme. Before the license is issued, the EPR Plan shall be evaluated by the Authorization Service of the ANRS. It was noted that EPR Plans were not approved by the ANRS. It was further noted that there is no obligation for ANRS to conduct inspections before authorizing nuclear and radiation activities and that EPR arrangements before commencement of operations are not verified.

There are no regulatory requirements for OOs to integrate EPR arrangements with contingency plans nor do existing regulations refer to contingency plans. To introduce the contingency plan into relevant legislation is part of the Action Plan.

In the existing regulatory requirements for EPR for OOs, there are no defined requirements to organize on-site emergency exercises or for systematic evaluation of the exercises by ANRS.

According to the Statute of ANRS, the responsibility to prepare regulations on EPR belongs to the Inspection and Response Service. Technical and human resources are sufficient for preparing draft regulations. In addition, competent Inspection and Response Service staff are prepared and available to respond to nuclear or radiological accidents.

Hazard assessment

In 2015 the five hazard categories were adopted in TR450, but they are not used to provide a graded approach to on-site EPR planning. For example, the regulatory requirements for OOs using radioactive sources apply to all radioactive sources, irrespective of their activity and the associated radiological risk. The regulation does not include criteria and guidance for OOs to perform hazard assessments as a planning basis for their preparedness and response arrangements.

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

The requirements for EPR for OOs are provided in the regulatory framework of Georgia.

The core regulatory requirements for EPR of OOs are in the Law. In the event of a radiation accident or incident, the OOs shall: immediately notify ANRS; inform the population of the potential hazard; mitigate the consequences of a radiation accident or incident; take actions to protect workers and other persons from its harmful impact; monitor the irradiation of workers and the spread of radionuclides in the environment; and limit and control the radiation exposure for workers involved in the response to the radiation accident or incident consequences.

TR450 describes in detail components of the OOs EPR Plan. It defines reference levels, generic criterion and operation intervention levels for making decisions on undertaking protective actions and other response actions as well as protection of emergency workers.

The OOs shall notify ANRS of all cases of radiation accidents or incidents requiring intervention. Notifications must include information on the current situation and its development, measures undertaken for the purpose of protecting public and workers, their exposure doses and a list of activities required for the mitigation of harmful effect to the environment. After the radiation accident or incident is terminated, the OOs should submit a final report to ANRS which includes an analysis of the event.

Identifying, notifying and activating

According to Decree of the Government on the Approval of Technical Regulations - Procedure for Radiation Monitoring of Metal Scrap (#756; 2014), in cases of detection of radioactive sources or radioactive contamination in scrap metal, a scrap metal recycler must inform the Ministry of Interior Affairs of Georgia and ANRS. The procedure for detection of and response to radioactive contamination or radioactive sources in scrap metal is also described in the Decree.

The Decree of the Minister of Environmental and Natural Resources Protection of Georgia On Approval of Regulation for Responding to Illicit Traffic of Nuclear and Radioactive Substances (#150; 2014) establishes the requirements for notification ANRS in cases of illicit trafficking of radioactive material. The Decree of the Government of Georgia On the Approval of Rules on Taking Joint Measures in Case of Alarm on Nuclear and Radioactive Materials at Check-Points, Airports, Harbours and Maritime Space (#397; 2010) covers cases of detection of nuclear and radioactive substances. ANRS must ensure there is an officer on duty 24 hours a day and 7 days a week to receive notifications.

ANRS ensures the continuous (24 hours a day, 7 days a week) reception of notifications by phone. After a notification is received, ANRS initiates appropriate response actions.

Taking mitigating actions

Provisions are included in the regulatory requirements for OOs to take mitigation actions in the case of a nuclear or radiological emergency. ANRS has established the requirements for OOs to mitigate the on-site consequences of a nuclear or radiological emergency.

Taking urgent protective actions

Generic criteria and operational intervention levels for taking urgent protective actions and other response actions in emergency exposure situations are addressed in TR450, regulatory requirements for the radius of inner cordoned area (safety perimeter) in a radiological emergency are not established in the regulations, but are included in the Draft of Technical Regulations, "Preparedness and Response Plan for Nuclear and Radiological Emergencies" (draft Response Plan) which are currently under development.

Providing instructions, warnings and relevant information to the public for emergency preparedness and response

There are no established guides for OOs on the content of information that should be provided to the public in the case of nuclear or radiological emergency however, guides are included in the draft Response Plan.

Management the medical response in a nuclear or radiological emergency

TR450 defines generic and operational criterion for other response actions (medical treatment, consultation, longer term medical actions). However, in the existing regulatory requirements there is no described on-site medical response in case of nuclear or radiological emergency. These requirements are included in the draft Response Plan.

Management of radioactive waste

The regulatory framework does not define regulatory requirements for radioactive waste management generated in the case of nuclear or radiological emergency that might arise from protective actions and other response actions. The existing legislation does not contain recommendations on management of human remains and animal remains that were contaminated due to a nuclear or radiological emergency. These requirements are included in the draft Response Plan.

Terminating a nuclear or radiological emergency

Detailed objectives and prerequisites for transition from an emergency exposure situation to an existing or planed exposure situation are missing although they are included in the draft Response Plan.

There is no protection strategy developed in Georgia to address radiological emergencies. Recommendation 22 is made in Section 10.4.

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

ANRS evaluates the EPR Plans of OOs during inspections. According to the Rules for Inspection one of the objectives of the inspection is to assess the EPR of OOs.

The criteria for carrying out unplanned inspections are defined in the Rules for Inspection. There is a provision to carry out unplanned inspections in the case of a radiation incident or accident or an unforeseen event.

As discussed in section 7, inspections conducted may be followed by administrative sanctions, which might even include repealing a license or suspending a nuclear and radiation activity that is being inspected. This is equally applicable in the event of EPR violations.

As it is mentioned in section 10.1, there are no regulatory requirements for OOs to organize on-site emergency exercises for workers who are specified in the EPR Plans and therefore ANRS does not

perform the verification of EPR arrangements during exercises. Recommendation 23 is made in Section 10.4.

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

ANRS has clearly allocated roles and responsibilities as the response organization within the national system for emergency management. The main responsibilities of ANRS in this area are defined in the legal framework.

The ANRS is obliged by Law to investigate a nuclear or radiological emergency and assess the results of the investigation. In addition, ANRS is required to assess the consequences of a radiation accident and to determine the damage incurred to the environment.

Order No 150 of the Minister of Environmental and Natural Resources Protection of Georgia, "On Approval of Regulation for Responding to Illicit traffic of Nuclear and Radioactive Substance" requires that ANRS:

- provide on-site operational mobilization of relevant human and technical resources for the purpose of initial radiological assessment;
- assess radiation situation and, if necessary, decide on changing the boundaries of the safe zone;
- perform radiological measurements;
- ensure the registration of nuclear and radioactive substances removed from illicit traffic for the purpose of further control; and
- inform the International Atomic Energy Agency of illicit traffic of nuclear and radioactive substances.

According to the draft Response Plan, among other responsibilities regarding nuclear or radiological emergency response, the ANRS is the contact point for the Convention on Early Notification of a Nuclear accident and performs the role of competent authority in the framework of the Convention on Assistance in Case of a Nuclear Accident or Radiological Emergency.

It should be noted that ANRS, having an important functions in response to radiological or nuclear accidents, does not have its own EPR Plan, procedures, and EPR structural organisation. ANRS does not have an internal programme for organizing the training of its staff and for conducting emergency exercises.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no protection strategy developed in Georgia to address radiological emergencies. The draft of Technical Regulations – Preparedness and Response Plan for Nuclear and Radiation Emergency covers most of the missing requirements for preparedness and response to the nuclear or radiological emergencies.*	
(1)	**BASIS: GSR Part 7, requirement 5 states that** *"The government shall ensure that protection strategies are developed, justified and optimized at the preparedness stage for taking protective actions and other response actions effectively in a nuclear or radiological emergency.*
(2)	**BASIS: GSR Part 7, requirement 23 states that** "*The government shall ensure that*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	plans and procedures necessary for effective response to a nuclear or radiological emergency are established".
R 22	**Recommendation:** **The Government should:** • **ensure that an appropriate protection strategy is developed so that protective actions and other response actions are taken during a radiological emergency.** • **take appropriate steps to approve the Technical Regulations – Preparedness and Response Plan for Nuclear and Radiation Emergency.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The existing regulatory requirements do not include: approving operating organizations' EPR Plan by ANRS; verifying EPR arrangements before commencement of operations; integrating EPR arrangements with a contingency plan; criteria and guidance for performing on-site hazard assessments; and organizing on-site emergency exercises and their evaluation by ANRS.*	
(1)	**BASIS: GSR Part 7 para. 6.19. states that** *"The operating organization of a facility or for an activity in category I, II, III or IV shall prepare an emergency plan. This emergency plan shall be […]submitted to the regulatory body for approval"*
(2)	**BASIS: GSR Part 7 para. 4.13. states that** *„The regulatory body shall require that arrangements for preparedness and response for a nuclear or radiological emergency be in place for the on-site area for any regulated facility or activity that could necessitate emergency response actions. Appropriate emergency arrangements shall be established by the time the source is brought to the site, and complete emergency arrangements shall be in place before the commencement of operation of the facility or commencement of the activity. The regulatory body shall verify compliance with the requirements for such arrangements"*
(3)	**BASIS: GSR Part 7 para 4.14. states that** *„Before commencement of operation of the facility or commencement of the activity, the regulatory body shall ensure, for all facilities and activities under regulatory control that could necessitate emergency response actions, that the on-site emergency arrangements […] (b) are integrated with contingency plans […].*
(4)	**BASIS: GSR Part 7, requirement 4 states that** *„The government shall ensure that a hazard assessment is performed to provide a basis for a graded approach in preparedness and response for a nuclear or radiological emergency"*
(5)	**BASIS: GSR Part 7, para 6.30. states that „***Exercise programs shall be developed and implemented to ensure that all specified functions required to be performed for emergency response, all organizational interfaces for facilities in category I, II or III, and the national level programs for category IV or V are tested at suitable intervals. These programs shall include the participation in some exercises of, as appropriate and feasible, all the organizations concerned, people who are potentially affected, and representatives of news media. The exercises shall be systematically evaluated […] and some exercises shall be*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	evaluated by the regulatory body. Programs shall be subject to review and revision in the light of experience gained…[…].
(6)	**BASIS: GSR Part 7, para 6.31. states *that*** *„The personnel responsible for critical response functions shall participate in drills and exercises on a regular basis so as to ensure their ability to take their actions effectively"*
(7)	**BASIS: GSR Part 7, para. 4.12. states that** *"The regulatory body is required to establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based […]. These regulations and guides shall include principles, requirements and associated criteria for emergency preparedness and response for the operating organization".*
R23	**Recommendation: The Ministry of Environmental Protection and Agriculture/ANRS should:** • **update the existing regulatory requirements to establish the requirement for ANRS to evaluate and approve the operating organization's plan of prevention of radiation incidents and accidents and liquidation of their consequences;** • **review, update and complete appropriate regulatory requirements to ensure that before commencement of operations EPR arrangements are evaluated by ANRS, and that operating organizations' EPR arrangements are integrated with contingency plans;** • **prepare criteria and guidance for operating organizations to perform and periodically review the on-site hazard assessment as a basis for a graded approach to emergency preparedness arrangements; and** • **update the existing regulatory requirements for operating organizations to establish the obligation to organize on-site exercises on a systematic basis and ensure that some on-site exercises are evaluated by ANRS.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ANRS does not have EPR Plan and procedures, emergency response organizational structure, programme for organizing the training and emergency exercises inside of ANRS.*	
(1)	**BASIS: GSR Part 7, para 6.17. states that** *"Each response organization shall prepare an emergency plan or plans for coordinating and performing their assigned functions […]*
(2)	6.1. **BASIS: GSR Part 7, para 6.28. states that „***The operating organization and response organizations shall identify the knowledge, skills and abilities necessary to perform the functions specified in […]. The operating organization and response organizations shall make arrangements for the selection of personnel and for training to ensure that the personnel selected have the requisite knowledge, skills and abilities to perform their assigned response functions. The arrangements shall include arrangements for continuing refresher training on an appropriate schedule and arrangements for ensuring that personnel assigned to positions with responsibilities in an emergency response undergo the specified training."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(3)	**BASIS: GSR Part 7, para 6.30. states that** *„Exercise programs shall be developed and implemented to ensure that all specified functions required to be performed for emergency response, […]. The exercises shall be systematically evaluated […]. Programs shall be subject to review and revision in the light of experience gained […].*
R 24	**Recommendation: the ANRS should prepare its own EPR Plan and procedures, establish an EPR structural organization, conduct training of personnel, and implement the exercise programme.**

10.5. SUMMARY

A legislative framework is in place, which defines the regulatory mandate and responsibilities of ANRS in the field of EPR.

Regulatory requirements for the OOs in some EPR areas are not in line with international standards (IAEA) such as;

- there are no defined requirement to approve the EPR Plans of OOs;
- there are no approved criteria and guidance for OOs on how to perform hazard assessments as the planning basis for their preparedness and response arrangements;
- there are no defined requirements to organize on-site emergency exercises and systematic evaluation of them by ANRS;
- there is no obligation for ANRS to conduct inspections before authorizing nuclear and radiation activity and to verify EPR arrangements before commencement of operations.

Despite the fact that ANRS has a large number of emergency response functions and performs them with due responsibility, ANRS preparedness to implement its functions in emergency response should be improved.

The Government should take steps to develop a protection strategy to address radiological emergencies and to approve the Technical Regulations – Preparedness and Response Plan for Nuclear and Radiation Emergency**.**

11. ADDITIONAL AREAS

11.1. CONTROL OF MEDICAL EXPOSURES

TR317 prescribes elements of the radiation protection programme (RPP) required for medical activities involving the use of radiation sources (sealed and unsealed) and devices that generate ionizing radiation. TR317 requires the licensee to establish several processes, applicable to specific medical procedures, to optimize patient dose while achieving the desired diagnostic or therapeutic outcome. The requirements prescribed by TR317 are consistent with the requirements specified in GSR Part 3 and Safety Guide RS-G-1.5.

Justification is required for all diagnostic and therapeutic medical procedures. Records of the request by a referring physician for a diagnostic or therapeutic medical procedure involving ionizing radiation as well as the decision to perform the procedure by the nuclear medicine physician, radiologist or radiation oncologist are required to be maintained.

TR317 requires that guidance doses (diagnostic reference levels) be established for diagnostic radiographic and nuclear medicine. Guidance doses are normally based on guidance doses referenced in IAEA Safety Guide RS-G-1.5, which are accepted by ANRS. In addition to establishing guidance doses, standardized techniques are used in diagnostic radiographic procedures to maintain patient exposures to an optimal level, and standardized dosages are used for diagnostic nuclear medicine procedures. Patient exposures during diagnostic radiographic procedures are determined either by calculation, using the parameters (e.g. kilovoltage, milliampere-seconds, fluoroscopy time) established for the procedure, or through use of direct dose measurement using digital devices (doses-area products). TR317 requires that patient exposures and dosages of radiopharmaceuticals be recorded and maintained.

Another element of optimizing medical exposures is equipment calibrations. TR317 specifies the requirements for quality assurance programmes and quality control programmes for equipment used in both therapeutic and diagnostic radiographic and nuclear medicine procedures. The specific testing requirements for equipment used for diagnostic and therapeutic medical procedures are consistent with IAEA Safety Guide RS-G-1.5. Testing frequencies and record requirements are specified by ANRS. TR317 also requires that quality control testing for devices used in diagnostic and therapeutic medical procedures be performed by qualified personnel using appropriately calibrated equipment. In accordance with TR317, applicants and licensees must describe their quality control and assurance programmes as part of the RPP. Testing frequencies, results, and information relating to the equipment used to perform the test are reviewed during routine inspections.

11.2. OCCUPATIONAL RADIATION PROTECTION

Legal and Regulatory Framework

The Law defines the general optimization principle and sets out responsibilities of the licensee, including, to appoint a radiation protection officer, to employ qualified workers, to ensure protection of workers, to provide special occupational education and regular training for workers as well as an annual occupational health examination and to monitor and record occupational radiation doses of workers. In addition, TR450 prescribes basic safety standards for protection of workers and establish dose limits, intervention levels for emergency workers and the principle of dose constraints to be used for optimization of occupational exposure. TR450 defines the responsibilities of the licensee to include determining the

radiation protection and safety measures, which will be optimized, and implementing them to protect workers from the harmful effects of ionising radiation.

During the authorization process, ANRS reviews and assesses the radiation protection programme, which includes quality assurance programme and monitoring programme, and reviews and assesses necessary arrangements for individual monitoring, workplace monitoring, personal and collective protective measures and calibration of measuring equipment. The design of the facility, radiation source and protective and monitoring system is checked during the authorization process. Occupational doses of workers are reviewed as a part of the annual report submitted by the authorized party. In addition, during inspections, occupational radiation protection measures are verified.

Although an electronic dose register does not exist, the dose records of workers are submitted annually by authorized party through the single-window portal. These records are attached in ARIS, however, it is not possible to easily analyse dose data and to evaluate received doses for the workers who are employed by more than one licensee. ANRS may request the Ministry of Justice to compile information from the annual reports of licensees into one file to facilitate the analysis of data, however, ANRS has not yet approved and implemented this as an ongoing practice. During the IRRS mission, ANRS demonstrated an Excel file with dose data from the annual reports that were received in 2017. However, there are no provisions for the use of the register in accordance with a specified procedure that would foresee requesting and receiving the information from the Ministry of Justice in a systemic way and tracking dose trends year over year. The ANRS Action Plan includes the establishment of a National occupational dose register.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ANRS receives, reviews and keeps the dose records provided by authorized parties in the annual report, however, there is no approved electronic dose register with the purpose to analyse dose data and to evaluate received doses by the workers who are employed by more than one licensee. ANRS may request the Ministry of Justice to compile information from the annual reports of licensees in one file to facilitate the analysis of data, however, ANRS has not yet approved and implemented this practice. Development of a National dose register has been included in the Action Plan.*	
(1)	**BASIS: GSR Part 3 Requirement 25, para. 3.105 states that** *"Records of occupational exposure shall include:* *(a) Information on the general nature of the work in which the worker was subject to occupational exposure;* *(b) Information on dose assessments, exposures and intakes at or above the relevant recording levels specified by the regulatory body and the data upon which the dose assessments were based;* *(c) When a worker is or has been exposed while in the employ of more than one employer, information on the dates of employment with each employer and on the doses, exposures and intakes in each such employment;* *(d) 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 assessments of doses, exposures and intakes due to normal conditions of work and which shall include references to reports of any relevant investigations".*
(2)	**BASIS: GSR Part 1 (Rev.1) Requirement 35, para. 4.63 states that** *"The regulatory body shall make provision for establishing and maintaining the following main registers and inventories:…- Records of doses from occupational exposure…".*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S14	**Suggestion: ANRS should consider establishing electronic occupational dose register to facilitate analysis of dose data and to include all the information of the occupational exposure records.**

Dose limits for workers and for apprentices of 16 to 18 years are in compliance with GSR Part 3. Dose limit for the lens of the eye has been established in accordance with GSR Part 3. Compliance with dose limits is enforced through a requirement to notify if dose limits have been exceeded and through the inspection process where occupational dose records are checked.

The Law prescribes requirements for authorized parties to appoint a radiation protection officer. There is no legislative or regulatory provision for recognition of qualified experts in Georgia.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no legislative or regulatory provision for recognition of qualified experts in Georgia.*	
(1)	**BASIS: GSR Part 3 Requirement 2, para. 2.21 states that** *"The government shall ensure that requirements are established for:…(b) The formal recognition of qualified experts…".*
R25	**Recommendation: The Government should establish and implement requirements for formal recognition of qualified experts.**

General Responsibilities of Registrants, Licensees and Employers

Clear responsibilities of licensees to ensure and optimize protection and safety of workers are prescribed in the legislation. Based on the type of activities workers have to be provided with personal protective equipment and monitoring equipment. Periodic verification and calibration of monitoring equipment must be carried out in accordance with the Law. Verification of compliance with these requirements is ensured by ANRS during inspections.

According to the Law, the licensee is required to grant the right to handle radiation sources and radioactive waste only to persons having special professional expertise. In addition, the licensee is obliged to provide regular training of workers. Training of workers is provided either internationally or nationally. However, domestic training courses are available only for radiation protection officers in medical applications and for medical professionals. For industry, research and education applications there are no specific training courses available in Georgia. In this case training in radiation protection and safety is usually received in a foreign country or inside the organisation if the employer ensures such arrangements. ANRS has recognised in the Action Plan the need for development of training programme guidelines that would include guidance for industry, research and education applications. Recommendation 4 is made in Section 1.8.

TR450 have a very general mention of the fact that licensees (employer) must use all optimization measures of radiation protection aimed at reducing the exposure of workers. In practice, ANRS requests these arrangements to be described in the licensee's radiation protection programme. However, there are no legislative or regulatory provisions for cooperation between licensees and employers, which is necessary in order to be fully in line with GSR Part 3. In addition, the existing requirements of TR317 prescribing that workers must fulfil their obligations and carry out their duties for protection and safety

are not sufficient as these requirements are applicable only for medical professionals. There are no generic requirements for compliance of all workers, including workers of industry, research and education applications.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no legislative or regulatory provisions in Georgia governing cooperation between licensees and employers. In addition, aside from medical workers, there are no legislative or regulatory provisions for compliance of workers.*	
(1)	**BASIS: GSR Part 3 Requirement 23 states that** *"Employers and registrants and licensees shall cooperate to the extent necessary for compliance by all responsible parties with the requirements for protection and safety".*
(2)	**BASIS: GSR Part 3 Requirement 22 para. 3.83 states that** *"Workers:* *(a) Shall follow any applicable rules and procedures for protection and safety as specified by the employer, registrant or licensee;* *(b) Shall use properly the monitoring equipment and personal protective equipment provided;* *(c) Shall cooperate with the employer, registrant or licensee with regard to protection and safety, and programmes for workers' health surveillance and programmes for dose assessment;* *(d) Shall provide to the employer, registrant or licensee such information on their past and present work that is relevant for ensuring effective and comprehensive protection and safety for themselves and others;* *(e) Shall abstain from any wilful action that could put themselves or others in situations that would not be in accordance with the requirements of these Standards;* *(f) Shall accept such information, instruction and training in protection and safety as will enable them to conduct their work in accordance with the requirements of these Standards".*
R26	**Recommendation: Ministry of Environmental Protection and Agriculture/ANRS should establish and implement requirements for cooperation between licensees and employers and establish and implement requirements for compliance of workers for non-medical uses.**

General Responsibilities of Workers

Responsibilities of the radiation protection officer include maintaining an inventory of sources, collection and storage of radioactive waste, control and recordkeeping of occupational doses, developing and implementing the emergency preparedness plan and implementing the radiation protection programme. Responsibilities of workers, development of internal instructions and rules for monitoring the implementation of relevant instructions must be included in radiation protection programme.

TR450 requires workers to have special skills in the nuclear and radiation safety field prior to starting their employment. In addition to general occupational radiation protection requirements, TR317 sets out specific qualification requirements, rules and instructions for personnel engaged in medical exposure. TR558 requires qualification of workers to be "in line with the area of use of the radiation source and specificity". However, there are no clearly defined regulatory requirements, guidelines or criteria for

assessing compliance of qualification and competence of radiation protection officer and workers. Recommendation 4 is made in Section 1.8.

Requirements for Radiation Protection Programmes

Development and implementation of a radiation protection programme is required by the Law to obtain an authorization and to demonstrate that radiation safety is ensured. The radiation protection programme must contain a quality assurance programme and monitoring programme, formation of a radiation safety group for high risk sources, identification of controlled and supervised areas, recordkeeping for occupational doses, communication of the received doses to workers, control of workers health state, conditions for handling radioactive waste and a decommissioning plan.

Requirements for identification of controlled and supervised areas and for setting local rules are in accordance with GSR Part 3 requirements.

Monitoring Programmes and Technical Services

Individual monitoring must be carried out for workers constantly or temporarily working in controlled area whose effective annual dose may exceed 6 mSv. Monitoring of external exposure must be carried out with individual dosimeters. It is required that individual dosimetry is performed only based on methods agreed to by ANRS.

Evaluation of occupational doses of workers working in supervised area is required to be based on workplace monitoring results. Periodic monitoring of workplaces within controlled and supervised areas must be carried out. The type and frequency of workplace monitoring must be sufficient for the evaluation of occupational exposure, for the evaluation of controlled and supervised areas and for analysis of conditions on borders of controlled and supervised areas.

Depending on the specifics of activities, monitoring of doses to the lens of the eye and extremities is required when the exposure dose may account for 3/10 of the annual permissible dose limit or when new diagnostic methods are applied or introduced and higher exposure of the lens of the eye and extremities is expected. In the case of application of normal procedures, the equivalent dose of the lens of the eye and extremities is measured within one month of the year. Based on the results, the annual external equivalent doses are determined.

Internal exposure monitoring must be carried out when the intake of radionuclides may exceed 1/10 of annual limit on intake. Personnel working with unsealed sources are subject to skin surface contamination measurements as well as body/thyroid intake equivalent dose evaluation. Requirements for internal exposure monitoring are defined in regulations. During inspections of nuclear medicine facilities ANRS requests the results of scintigraphy of workers to assess the iodine-131 intake dose in the thyroid. Scintigraphy is carried out by the facility itself. There are no provisions for internal exposure monitoring by a technical service provider in Georgia. Recommendation 5 is made in Section 1.9.

11.3. CONTROL OF RADIOACTIVE DISCHARGES AND CLEARANCE

TR450 contains criteria for clearance. For unconditional clearance, activity concentrations based on GSR Part 3 (TR 450, Annex 3) are used. In some cases the licensee may develop and justify scenarios to determine specific clearance criteria using the 10 μSv in a year dose constraint. This is subject to ANRS approval. ANSR can also determine clearance levels to be used for clearance of sites of nuclear and radiation facilities.

Regulatory requirements allows all RAW to be cleared, however, international Safety Standards specify that only exempted waste and very short lived waste after storage for decay can be cleared.

The IRRS team was informed that the license conditions (e.g. decommissioning plan) can include provisions for discharges or clearance. For operating facilities details on discharges or clearance such as the determination of characteristics and activity of the sources to be discharged or cleared and pre-operational study of all significant exposure pathways including assessment of corresponding doses are not included in the radiation protection plan under Article 16 of TR450. In practice, however, licensees submit their radiation protection programme to ANRS during the licensing process which contains details on discharges or clearance of radioactive material for both operating facilities and facilities under decommissioning.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Current legislation considers all RAW to be a subject of clearance.*	
(1)	**BASIS: RS-G-1.7, para 2.13 states that** *"Clearance is defined as the removal of radioactive materials or radioactive objects within authorized practices from any further regulatory control by the regulatory body."*
(2)	**BASIS: GSG 1, para 2.2 states that** *"... six classes of waste are derived and used as the basis for the classification scheme:* *(1) Exempt waste4 (EW): Waste that meets the criteria for clearance, exemption or exclusion from regulatory control for radiation protection purposes as described in Ref. [6].* *(2) Very short lived waste (VSLW): Waste that can be stored for decay over a limited period of up to a few years and subsequently cleared from regulatory control according to arrangements approved by the regulatory body ...."*
S15	**Suggestion: ANRS should consider excluding RAW from the clearance concept except exempted waste and very short lived waste after storage for decay.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The requirements for radiation protection programmes do not contain provisions on clearance and discharges of radioactive material.*	
(1)	**BASIS: GSR Part 3 Requirement 31, para 3.132 states that** *"Registrants and licensees, in cooperation with suppliers, in applying for an authorization for discharges, as appropriate:* *(a) Shall determine the characteristics and activity of the material to be discharged, and the possible points and* methods of discharge; *(b) Shall determine by an appropriate pre-operational study all significant exposure pathways by which discharged radionuclides could give rise to exposure of members of the public;* *(c) Shall assess the doses to the representative person due to the planned discharges;..."*
(2)	**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 further regulatory control, ...".*
S16	**Suggestion: The Ministry of Environmental Protection and Agriculture/ANRS should consider including provisions on clearance and discharges of radioactive material in radiation protection programme requirements.**

11.4. SUMMARY

Basic radiation protection requirements are consistent with International Safety Standards and are implemented.

The following areas for improvement were identified:

- Establishment of an occupational dose registry;
- Recognition of qualified experts; and
- Cooperation between licensees and employees and compliance of workers.

In the area of control of discharges and clearance it is suggested that ANRS include provisions on clearance and discharges of radioactive materials in the RPP requirements.

Policy issue #1:
Promotion of a Culture for Safety

The basis of this policy issue is GSR Part 2, Requirement 2, para 3.1 that states: "*The senior management of the organization shall demonstrate leadership for safety by: … (c) establishing behavioural expectations and fostering a strong safety culture;…*" and Requirement 12: "*Fostering a culture for safety: Individuals in the organization, from senior managers downwards, shall foster a strong safety culture. The management system and leadership for safety shall be such as to foster and sustain a strong safety culture*."

ANRS considers that the lack of recognition and low awareness of workers of radiation hazards causes safety problems. ANRS observes that in the most cases authorized persons' managers do not promote safety culture, which leads to the lack of a proactive approach and potentially even poor safety practices.

ANRS has launched an awareness-raising campaign that includes distribution of awareness material and inspector to operator communications on a culture for safety. ANRS intends to become more active and engaged on promoting safety culture. An Action Plan is to be developed.

The IAEA Coordinator informed ANRS of the IAEA activities in the area of culture for safety promotion such as reports and guides that support GSR Part 2, missions and the Safety Culture Continuous Improvement Process (SCCIP).

The experience of Bulgaria, USA, Canada and Lithuania was provided. Noting the link of poor safety culture with the potential for radiation accidents, participants discussed the following issues: the importance of leadership and reaching individuals with responsibilities for safety, self-assessment, reinforcing safety culture during inspections, options for enforcement of safety culture and the safety culture of regulatory bodies.

Raising awareness on the culture for safety was stressed as the basic element of culture for safety promotion. IRRS team experts noted that although the primary audience is authorized parties, the public is also a target audience for the safety culture promotion.

Policy issue #2:
Enhancing Regulatory Effectiveness and Competence

The basis of this policy issue is GSR Part 1, requirement 18 regarding staffing and competence of the regulatory body that states: "*The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities*". IAEA safety standards also stress that a regulatory body should establish a human resources plan to guide in the recruitment of staff and their training in order to acquire the competences needed in their responsibilities.

The Head of ANRS explained that although regulatory activities have been going on for over ten years, ANRS as a stand-alone agency was only established by its own statute in 2016. The Head of ANRS is empowered to hire and manage the organization's human resources. Currently, ANRS has not developed methodologies for developing and maintain competences and it anticipates the introduction of new medical practices that require the regulatory body to continually improve the competence of staff in order to be able to effectively regulate them.

Reviewers shared the experience of Canada, Ukraine, USA and Slovenia, which highlighted the following:

- The need for regulatory bodies to establish a formal qualification programme that can enable the recruitment and training of new staff in a structured manner. Such a programme results in assessments on the progress of new employees before they can be cleared to carry out work independently.
- Priority should be given to the need to develop Inspectors in order to fully equip them to be able to make informed decisions in the field. For example, inspectors need to be fully conversant with regulations and technologies that they inspect. The use of documented procedures and checklists can be useful in the development of competent inspectors, along with other formal and informal learning opportunities.
- ANRS, like all other regulatory bodies, needs to be proactive and develop competence of their staff with regulatory responsibilities ahead of the introduction of new regulated technologies. This can be achieved through learning from other countries in the region in which similar technologies are already in practice. The IAEA's Technical Cooperation Programme can be used to access support for scientific visits and fellowships in identified areas.
- Inclusion of human resources management and development components in the management system can be helpful. This includes job descriptions and required competences as well as a system for the assessment of individual employee's work to identify performance and competence gaps. The identified gaps should be used to guide the regulatory body in developing its annual training programme as part of the overall organizational annual work plan.

APPENDIX I – LIST OF PARTICIPANTS

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APPENDIX II MISSION PROGRAMME

GEORGIA IRRS INITIAL MISSION SCHEDULE – FIRST WEEK

Time	SAT	SUN 18	MON 19	TUE 20	WED 21	THU 22	FRI 23	SAT 24		Time
09:00-11:00			Entrance Meeting	Interviews (parallel discussions)	Interviews	Follow-up interviews	Follow-up Interviews and discussion of the report text with Counterparts	Individual report inputs finalizing and **submission to AA**	Team rest day. Official dinner	09:00-12:00
11:00-12:00			11:15 – moving to interview rooms				AA and TC writes introductory parts	AA compiles the report		
12:00-13:00			Standing lunch (STL)	STL	STL	STL	STL	Cross reading and report editing		12:00-13:00
13:00-14:00		Initial Team Meeting • TL Opening • Self-introduc-tion s • IRRS Process, Schedule • Presentations of first impression • Administrative	Interviews (parallel discussions)	Interviews / Visits to Ministries: TL, TC, M1, 2, 3 reviewers	Writing first draft of preliminary findings R/S/GP / Site Visits to observe inspections of RS facilities	Discussion of preliminary finding s with Counterparts / Site visit to RW facility	Report preparation			13:00-14:00
14:00-15:00							Policy issues discussion			14:00-15:00
15:00-16:00										15:00 - 16:00

Time	SAT	SUN 18	MON 19	TUE 20	WED 21	THU 22	FRI 23	SAT 24		Time
16:00-17:00		arrangements			**Written preliminary findings delivered** Compiling findings into the report	Daily Team Meeting: Briefing from site visits Discussion of findings – feedback from discussion with Counterparts	Daily Team Meeting: Finalization of observations, basis, R/S/GP			**16:00-17:00**
17:00-18:00		Sub-teams to prepare for interviews	Daily Team Meeting	Daily Team Meeting Preliminary findings discussion	Daily Team Meeting: Briefing from the site visits Discussion of findings					**17:00-18:00**
18:00-20:00	Infor-mal din-ner	Team Dinner	Dinner (D)	D	D	D	D	D		**18:00-19:00**
20:00-24:00			Report Writing (RW)	RW	RW	RW	RW	TL, TC and AA continue edit the report		**20:00-24:00**

GEORGIA IRRS INITIAL MISSION SCHEDULE – SECOND WEEK

<table>
<tr><th>Time</th><th colspan="2">MON 26</th><th colspan="2">TUE 27</th><th>WED 28</th></tr>
<tr><td>09:00-11:00</td><td colspan="2">TL, TC, AA and „editors“ finalise the report text</td><td>TL, TC draft exit presentation and coordinate press release preparation</td><td>Hosts review draft report</td><td>Report editing and executive summary finalization
IAEA official briefing</td></tr>
<tr><td>11:00-12:00</td><td>11:00 Submission of the Draft Report to the Host</td><td rowspan="4">Hosts review draft report</td><td colspan="2">11:00 Written Host’s comments are submitted to the Team
IRRS team reviews Host’s comments individually</td><td rowspan="2">11:00 Final draft report submission to the Host
Exit Meeting
[Press Conference, if decided]</td></tr>
<tr><td>12:00-13:00</td><td>STL</td><td colspan="2">STL</td></tr>
<tr><td>13:00-16:00</td><td rowspan="3">TL, TC draft executive summary</td><td colspan="2">IRRS Team revises report online</td><td rowspan="3">Team Members Departure</td></tr>
<tr><td>16:00-18:00</td><td colspan="2">Discussion with Hosts on findings, if required</td></tr>
<tr><td>17:00-18:00</td><td colspan="2"></td></tr>
</table>

GEORGIA IRRS MISSION PROGRAMME 18 – 28 February 2018

IRRS MISSION PROGRAMME		
18 February, Sunday		
IRRS Initial IRRS team Meeting		
13:00 - 17:00	Opening remarks by the IRRS Team Leader (Mr Catherine Haney) Introduction by IAEA Self-introduction of all attendees IRRS Process (IAEA) Report writing (IAEA) Schedule (TL, IAEA) First impression from team members arising from the Advanced Reference Material (ARM) (all team members): Presentations Administrative arrangements (Liaison Officer, IAEA): Detailed Mission Programme	ANRS conference room IRRS team + the LO
17:00 -18:00	Groups prepare for interviews Module Leaders prepare slides for the TL's presentation for the Entrance Meeting if requested.	ANRS conference room IRRS team
19 February, Monday		
IRRS Entrance Meeting		
09:00 – 12.00	09:00 Arrival, registration, 09:30 *official from Georgia* – Welcoming Address 09:45 IRRS Team Leader – Expectations for the Mission. 10:00 Self-introduction of the IRRS team and the counterparts 10:30 ANRS presentation – Regulatory Overview, SARIS results (strength, challenges, Action Plan) 11:00 IRRS team group photo	ANRS conference room Participants: Deputy Minister MEPA; ANSR Management and staff; Officials from relevant organizations, IRRS Team + the LO

IRRS MISSION PROGRAMME		
	11:15 Moving to the interview rooms and preparation for interviews	ANRS office – rooms according to the attached detailed schedule
12:00 – 13:00	Lunch	
13:00 – 17:00	Interviews and Discussions with Counterparts (parallel discussions)	ANRS office - rooms according to the attached detailed schedule; Counterparts according to the attached list
17:00 - 18:00	Daily IRRS team meeting	ANRS conference room IRRS Team + the LO
20 February, Tuesday		
Daily Discussions / Interviews[1]		
09:00 – 17:00	Interviews and discussions with counterparts (parallel discussions)	ANRS office IRRS Team + Counterparts
12:00 – 13:00	Lunch	
TBD	Visits to: Ministry of Environmental and Natural Resources Protection; Ministry of Labour, Health and Social Affairs.	TL, TC + LO MEPA and MoLHSA sites
17:00 – 18:00	Daily IRRS team meeting, preliminary findings discussion	ANRS conference room IRRS Team + the LO
21 February, Wednesday		
Daily Discussions / Interviews		
09:00 – 17:00	Interviews and discussions with counterparts	ANRS office; IRRS team + Counterparts

[1] TL, DTL, TC: meeting with Head of RB as needed.

IRRS MISSION PROGRAMME		
08:00 – 15:00	Site Visits to observe ANRS inspections to: - High Technology Medical Centre, University Clinic (medical facility, radiotherapy, nuclear medicine and radiology); - Company "MAG-Pi" (non-destructive testing (NDT)).	2 groups of IRRS team members with inspectors in parallel
12:00 – 13:00	Lunch	
13:00 – 16:00	Individual finalizing of preliminary findings (Rs, Ss, GPs)	ANRS conference room IRRS team
16:00	Delivery of preliminary findings in writing to the Administrative Assistant	
17:00 – 18:00	Daily IRRS team meeting: briefing from the site visits; discussion of findings (recommendation, suggestions and good practices)	ANRS conference room IRRS team + the LO
22 February, Thursday		
Daily Discussions / Interviews		
08:00 – 14:00	Site visit to RW facility (Mtskheta)	RW reviewer + inspectors
09:00 – 17:00	Follow-up Interviews as needed and discussion with the counterparts preliminary findings Report preparation	IRRS team +Counterparts
12:00 – 13:00	Lunch	
17:00 – 18:00	Daily IRRS team Meeting: briefing from the site visit; recommendation, suggestions and good practices – feedback from the discussions with the counterparts	Venue ANRS conference room; Participants: the IRRS team + the LO
23 February, Friday		
Daily Discussions / Interviews		
09:00 – 14:00	Follow-up Interviews as needed Report preparation and discussion of the report text factual correctness with the counterparts	ANRS IRRS team + Counterparts
12:00 –	Lunch	

IRRS MISSION PROGRAMME		
13:00		
14:00 – 16:00	Policy issue discussion	ANRS conference room Reviewers & Counterparts TBD
16:00 – 18:00	Daily Team Meeting; Report preparation: finalize observations, basis, recommendations, suggestions and good practices	ANRS conference room IRRS team + the LO
24 February, Saturday		
Daily Discussions/ Interviews (if needed)		
09:00 – 11:00	Team members finalise report and provide inputs to the Administrative Assistant.	ANRS conference room Reviewers + Module Leaders
11:00 – 12:00	Administrative Assistant compiles draft report	
12:00 – 13:00	Lunch	
13:00 – 17:00	Cross reading and draft report editing	ANRS conference room IRRS team
25 February, Sunday		
Team rest day + cultural event/hospitality dinner		
26 February, Monday		
Daily Discussions		
09:00 – 11:00	Draft report editing	Reviewers + TL, TC
11:00	Submission of the draft report to the Host	
12:00 – 13:00	Lunch	
11:00 – 18:00	Review of the draft report by the Host	Counterparts
	Drafting the executive summary	TL, TC
27 February, Tuesday		
Daily Discussions		
08:00 – 11:00 11:00	Hosts review the Draft Host's written comments are submitted to the Team	Counterparts LO
09:00 – 11:00	Exit presentations preparation; press release preparation coordination	TL, TC and press officer
11:00 – 12:00	IRRS team reviews Host's comments	ANRS conference room IRRS team

IRRS MISSION PROGRAMME		
12:00 - 13:00	Lunch	
13:00 – 16:00	IRRS team reviews Host's comments and revise text on-line as appropriate	ANRS conference room IRRS team
16:00 – 18:00	Discussion with the Host on findings (if required)	ANRS conference room IRRS team +Counterparts
28 February, Wednesday		
Daily Discussions		
09:00 – 11:00	Report editing and executive summary finalization IAEA official briefing	ANRS conference room TL, TC, IAEA official, IAEA Press Officer
11:00	Submission of the final draft to the Host	TC
11:00 – 13:00	Exit Meeting	All mission participants and stakeholders' officials

APPENDIX III SITE VISITS

No.	Object
1	Ministry of Labour, Health and Social Affairs
2	Medical facility “St. John the Merciful Private Clinic” LLC
3	Industrial facility LTD “AIC Forwarding”
4	Radioactive waste management facility “Centralised Storage Facility”.
5	Ministry of Environmental Protection and Agriculture

APPENDIX IV– LIST OF COUNTERPARTS

№	Participants	Position
1.	**Modules 1-4 (RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT; GLOBAL NUCLEAR SAFETY REGIME; RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY; MANAGEMENT SYSTEM OF THE REGULATORY BODY)**	
	V. Gedevanishvili	*Head of ANRS*
	Kh. Jikuridze	*Deputy Head of ANRS*
	I. Grigalashvili	*Legal Specialist of Administrative Service, ANRS*
2.	**Modules 5-9, 11 (AUTHORIZATION; REVIEW AND ASSESSMENT; INSPECTION; ENFORCEMENT; CONTROL OF MEDICAL EXPOSURES, OCCUPATIONAL RADIATION PROTECTION; TRANSPORT)**	
	G. Nabakhtiani	*Head of Department of Radioactive Waste Management , ANRS*
	G. Basilia	*Head of Inspection and Emergency Response Service, ANRS*
	N. Nadirashvili	*Head of Authorization Service, ANRS*
	K. Jariashvili	*Senor Specialist of Authorization Service, ANRS*
	K. Keshelava	*Chief Specialist of Inspection and Emergency Response Service, ANRS*
	M. Giorgobiani	*Chief Specialist of Inspection and Emergency Response Service, ANRS*
	T. Kimeridze	*Senor Specialist of Inspection and Emergency Response Service, ANRS*
	Kh. Jikuridze	*Deputy Head of ANRS*
	Z. Sichinava	*Chief Specialist of Inspection and Emergency Response Service, ANRS*
3.	**Module 10 (EMERGENCY PREPAREDNESS AND RESPONSE)**	
	Kh. Jikuridze	*Deputy Head of ANRS*
	D. Kolotauri	*Senor Specialist of Inspection and Emergency Response Service, ANRS*
4.	**Modules 5-9, 11 (AUTHORIZATION; REVIEW AND ASSESSMENT; INSPECTION; ENFORCEMENT; CONTROL OF DISCHARGES, MATERIALS FOR CLEARANCE)**	
	G. Nabakhtiani	*Head of Department of Radioactive Waste Management , ANRS*

	G. Maspindzelashvili	*Chief Specialist of Department of Radioactive Waste Management , ANRS*
5.	**Inspection in Medical Facility**	
	Z. Sichinava	*Chief Specialist of Inspection and Emergency Response Service, ANRS*
	M. Giorgobiani	*Chief Specialist of Inspection and Emergency Response Service, ANRS*
6.	**Inspection in Industrial Facility**	
	G. Basilia	*Head of Inspection and Emergency Response Service, ANRS*
	K. Keshelava	*Chief Specialist of Inspection and Emergency Response Service, ANRS*
7.	**Inspection in Radioactive Waste Facility "Centralised Storage Facility"**	
	G. Nabakhtiani	*Head of Department of Radioactive Waste Management, ANRS*
	G. Basilia	*Head of Inspection and Emergency Response Service, ANRS*
	G. Maspindzelashvili	*Chief Specialist of Department of Radioactive Waste Management, ANRS*
	V. Tvaliashvili	*Chief Specialist of Department of Radioactive Waste Management, ANRS*
	Z. Sichinava	*Chief Specialist of Inspection and Emergency Response Service, ANRS*
	K. Keshelava	*Chief Specialist of Inspection and Emergency Response Service, ANRS*
	N. Lobjanidze	*Senor Specialist of Department of Radioactive Waste Management, ANRS*

Meeting with the Deputy Minister for Labour, Health and Social Affairs Mr. Zaza Sopromadze	
Catherine HANEY Olga MAKAROVSKA	Vasil Gedevanishvili – Head of ANRS Marina Darakhvelidze – Head of Health Care Department Natia Nogaideli – Head of Regulation Division, Health Care Department
Meeting with the Professor Georgi Japaridze, President of the Georgian National Academy of Science	
Nikolay Mihaylov VLAHOV Colin MOSES Igor OSOJNIK	Reszo Shanidze - Professor at the Gagnidze State University
Meeting with the Minister of Environmental Protection and Agriculture H.E. Mr. Levan Davitashvili	
Catherine HANEY Peter JOHNSTON Olga MAKAROVSKA	Nodar Kereselidze - Deputy Minister of Environmental Protection and Agriculture Vasil Gedevanishvili – Head of ANRS

APPENDIX V RECOMMENDATIONS (R), SUGGESTIONS (S) AND Error! Bookmark not defined.
GOOD PRACTICES (GP)

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1.	**RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**	R1	**The Government should ensure that the national policy and strategy for safety takes due account of the promotion of safety culture and that the policy and strategy for safety is implemented in accordance with a graded approach.**
		R2	**The Government should ensure that all facilities and activities in Georgia that pose radiation risk are authorized and are subject to regulatory control.**
		S1	**ANRS should consider establishing coordination arrangements with other national executive authorities in the field of safety.**
		S2	**The Government should consider designating an organisation to be responsible for the contaminated site and respective protective actions. In addition, Government should consider establishing requirements and criteria for protective actions.**
		S3	**The Government should consider revising the RAW strategy to define long term plans for management of RAW (development of a disposal facility). In addition, the Government should consider formulating a policy for the clean-up and release of sites from regulatory control.**
		R3	**The Government should establish and implement clear mechanism for assuring sufficient funding of decommissioning activities and establish requirements for availability of financial provisions for the return of disused sources to the country of origin.**
		R4	**The Government should stipulate the necessary level of competence for persons with responsibilities for safety and should ensure that adequate arrangements are in place for increasing, maintaining and regularly verifying their technical competence.**
		R5	**The Government should make arrangements**

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			for provision of internal exposure monitoring and diagnostic radiology image quality assessments.
2.	**GLOBAL SAFETY REGIME**	S4	**The Government should consider becoming a party to the Convention on Nuclear Safety.**
		S5	**The Government should consider establishing bilateral or multilateral arrangements for cooperation with neighbouring countries.**
		R6	**ANRS should establish and implement mechanisms to analyse and identify lessons to be learned from operating and regulatory experience, and for the dissemination of the lessons learned to appropriate parties.**
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**	R7	**The Government should ensure that there is a clear separation between the regulatory body and the organization assigned responsibility for the operation of the Georgian waste facilities.**
		R8	**ANRS should develop and implement a human resources plan and a training programme to ensure that it has and can maintain a sufficient number of qualified and competent staff to perform its functions and to discharge its responsibilities.**
		GP1	**ANRS leverages the Government of Georgia's single window portal to communicate with licensees, and allow submission of license applications and annual reports through an electronic portal, which has led to a significant increase in compliance with annual reporting requirements. This portal allows for authorized parties to register for SMS alerts as soon as the regulator sends them a message through this portal. In addition, ANRS can use this portal to issue communications with best practices or notifications of upcoming changes to regulatory requirements. The associated internal system allows for efficient workflow management, providing for electronic processing, approval and issuance of license and permitting authorizations, with embedded service standards for decisions. These allow for prompt regulatory response to urgent applications such as, for example, those needed for patient care.**

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
4.	MANAGEMENT SYSTEM OF THE REGULATORY BODY	R9	**Ministry of Environmental Protection and Agriculture/ANRS should formalise and implement a safety policy, defining the safety goals of the organisation.**
		R10	**ANRS should continue the development and implementation of the management system in line with GSR Part 2. Specific attention should be given to documenting core processes and implementing mechanisms to assess and improve the management system.**
5.	AUTHORIZATION	R11	**ANSR should continue to implement a graded approach in authorization by establishing a system of notification and registration; by grading requirements for documents submitted by applicants in support of an application for non-medical use of radiation sources and by providing guidance on the content of the documents to be submitted by an applicant or authorized party.**
		S6	**ANRS should consider renewing the practice of imposing limits, conditions and controls on the authorized party's subsequent activities as part of an authorisation.**
		S7	**ANSR should consider introducing license conditions for closure of a disposal facility.**
		R12	**Ministry of Environmental Protection and Agriculture/ANRS should establish and implement requirements on selection and justification of decommissioning strategy by the licensee consistent with national policy on the management of radioactive waste.**
		S8	**ANRS should consider defining which radiation sources facilities applicant is required to submit safety assessment.**
		R13	**ANRS should ensure that export of radioactive sources of Categories 1 and 2, in particular disused sources, takes place only with the prior to notification of the exporting State and only after the consent by the importing State for Category 1 radioactive sources.**
		R14	**The Government should ensure that provisions for acknowledgement by relevant professional**

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			bodies, health authorities or appropriate organizations in the areas of diagnostic radiology, image guided interventional procedures, radiation therapy, and nuclear medicine are available for personnel assuming responsibility as a medical physicist.
		S9	**ANRS should consider developing and implementing mechanisms to manage non-compliances in transport of radioactive materials**
6.	**REVIEW AND ASSESSMENT**	R15	**Ministry of Environmental Protection and Agriculture/ANRS should establish and implement requirements on the periodic review of decommissioning plan. ANRS should perform regulatory review of updated decommissioning plan and approve final decommissioning plan supported by safety assessments developed by the licensee.**
7.	**INSPECTION**	S10	**ANRS should consider developing and implementing criteria for carrying out pre-authorization inspections.**
		S11	**ANRS should consider developing, if not already developed, and finalizing inspection check-lists for medical and non-medical facilities, including technical service providers and for facilities licensed to perform transport of radioactive sources.**
		S12	**ANRS should consider introducing graded approach in the inspection frequency of radioactive sources of categories 1 to 5.**
8.	**ENFORCEMENT**	R16	**ANRS should establish and implement criteria for application of corrective actions in a consistent manner and with a regard to the risks associated with the discovered violation.**
9.	**REGULATION AND GUIDES**	R17	**Ministry for Environmental Protection and Agriculture of Georgia should empower ANRS to issue non-binding guides on how to comply with the safety requirements.**
		R18	**ANRS should ensure that regulations are periodically reviewed and revised, considering international standards, latest developments of science and technology, and lessons learned.**

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		S13	**ANRS should consider compiling a uniform glossary to be used for all regulatory documents.**
		R19	**Ministry of Environmental Protection and Agriculture/ANRS should establish and implement requirements on derivation of operational limits, conditions and controls including waste acceptance criteria from the safety case and on criteria on packages used in RAW storage or disposal facilities to comply with these waste acceptance criteria.**
		R20	**The Ministry of Environmental Protection and Agriculture/ANRS should establish and implement requirements on RAW storage and disposal facilities in compliance with GSR Part 5 and SSR 5 with particular focus in these areas:** **– passive means of storage and disposal facilities,** **– containment and isolation of RAW in disposal facilities,** **– priority of safety arrangements over the system of accounting for and control of nuclear material,** **– development of written operator`s procedures also considering provisions for safe management of RAW that fails to meet the waste acceptance criteria.**
		R21	**ANRS should ensure that disposal facility site is characterised.**
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**	R22	**The Government should:** • **ensure that an appropriate protection strategy is developed so that protective actions and other response actions are taken during a radiological emergency.** • **take appropriate steps to approve the Technical Regulations – Preparedness and Response Plan for Nuclear and Radiation Emergency.**

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R23	**The Ministry of Environmental Protection and Agriculture / ANRS should:** • **update the existing regulatory requirements establishing the requirements for the ANRS to evaluate and approve the operating organizations Plan of prevention of radiation incidents and accidents and liquidation of their consequences;** • **review, update and complete appropriate regulatory acts and ensure that before commencement of operations EPR arrangements are evaluated by the ANRS, operation organizations EPR arrangements are integrated with contingency plans;** • **prepare criteria and guidance for operating organizations to perform and periodically review the on-site hazard assessment as basis for graded approach to emergency preparedness arrangements;** • **update the existing regulatory requirements for operating organizations establishing the obligation to organize on-site exercises on systematic basis and ensure that some of on-site exercises are evaluated by the ANRS.**
		R24	**ANRS should prepare its own EPR plan, procedures, establish EPR structural organization, conduct training of personnel, and implement the exercise programme.**
11.2	**OCCUPTIONAL RADIATION PROTECTION**	S14	**ANRS should consider establishing electronic occupational dose register to facilitate analysis of dose data and to include all the information of the occupational exposure records.**
		R25	**The Government should establish and implement requirements for formal recognition of qualified experts.**

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R26	**Ministry of Environmental Protection and Agriculture/ANRS should establish and implement requirements for cooperation between licensees and employers and establish and implement requirements for compliance of workers for non-medical uses.**
11.3	**CONTROL OF RADIOACTIVE DISCHARGES AND MATERIAL FOR CLEARANCE, ENVIRONMENTAL MONITORING ASSOCIATED WITH AUTHORIZED PRACTICES FOR PUBLIC RADIATION PROTECTION PURPOSES CONTROL OF CHRONIC EXPOSURES**	S15	**ANRS should consider excluding RAW from the clearance concept except exempted waste and very short lived waste after storage for decay.**
		S16	**ANRS should consider including provisions on clearance and discharges of radioactive material in radiation protection programme requirements.**

APPENDIX VI REFERENCE MATERIAL USED FOR REVIEW

[1] IRRS Questions and Answers:

- *Module 1: Responsibilities and Functions of the Government*
- *Module 2: Global Nuclear Safety Regime*
- *Module 3: Responsibilities and Functions of the Regulatory Body*
- *Module 4: Management System of the Regulatory Body*
- *Module 5: Authorization*
- *Module 6: Review and Assessment*
- *Module 7: Inspection*
- *Module 8: Enforcement*
- *Module 9: Regulations and Guides*
- *Module 10: Emergency Preparedness and Response*
- *Module 11: Control of Medical Exposures, Occupational Radiation Protection, Control of Discharges and Materials for Clearance.*

[2] Relevant Documentation

ANRS Documents

1. Law of Georgia (adopted by the Parliament of Georgia):

1.1. on Nuclear and Radiation Safety (№ 5912-RS; 11.11.2015)
1.2. on Radioactive Waste (№ 4487-IS; 20.03.2012)
1.3. On Licenses and Permits (№ 1775; 24.06.2005)
1.4. On Civil Service (№ 4346-IS; 27.10.2015)
1.5. On State Procurement (№ 1388; 20.04.2005)
1.6. On Rules of Salary (№ 229; 29.09.2015)
1.7. On Civil Security (№ 1467-IIS; 29.05.2014)
1.8. On Normative Acts (№ 1876; 20.10.2009)
1.9. On Legal Entities of Public Law (№ 2052; 28.05.1999)
1.10. On General Administrative Code of Georgia (№ 2181; 25.06.1999)
1.11. On Code of Administrative Offences of Georgia (№ 161; 15.12.1984)
1.12. On Administrative Procedural Code of Georgia (№ 2352; 23.07.1999)
1.13. On Criminal Code of Georgia (№ 2287; 22.07.1999)
1.14. On Criminal Procedural Code of Georgia (№ 1772; 09.10.2009)
1.15. On Permission of Impact on Environment (№ 890-IIS; 01.06.2017)

2. Decree of the Government of Georgia:

2.1. On the approval of Technical Regulations - Radiation safety norms and basic requirements related to handling of ionizing radiation sources (№ 450; 27.08.2015)
2.2. On Approval of Technical Regulations - Radiation Safety Requirements in the Sphere of Medical Irradiation (№ 317; 07.07.2016)
2.3. On approval of the Technical Regulations – Individual Monitoring and Control Procedure (№ 359; 20.07.2015)
2.4. On the Approval of Technical Regulations - Procedure for Radiation Monitoring of Metal Scrap (№ 756; 31.12.2014)
2.5. On the Approval of Radioactive Waste Management Strategy and its Action Plan (№ 640; 30.12.2016)
2.6. On approval of the Technical Regulations – Procedure for Establishing and Maintaining the Departmental Register of Ionizing Radiation Sources, Radioactive Waste and Authorization; Categorization of Ionizing Radiation Sources (№ 689; 19.12.2014)

2.7. On the Approval of Technical Regulations - the Main Requirements towards the Assessment of the Safety of Radioactive Waste Disposal Facilities (№ 124; 10.03.2017)
2.8. On the Approval of Technical Regulations - the Main Requirements towards the Assessment of the Safety of Radioactive Waste Storage Facilities (№ 123; 10.03.2017)
2.9. On the Approval of Technical Regulations - Rules for Handling Radioactive Waste (№ 189; 18.04.2016)
2.10. On the Approval of Technical Regulation on Radiation Safety Requirements in Industry, Science, and Education (№ 558; 15.12.2016)
2.11. on the Approval of the services provided by Agency of Nuclear and Radiation Safety and amount of fees (№ 319; 11.07.2016)
2.12. On the Approval of Technical Regulations – rules of carriage of cargo by vehicle (№ 32; 03.01.2014)
2.13. On the Approval of Technical Regulations – rules of transportation of nuclear and radioactive substances (№ 72; 07.02.2018)
2.14. On the Approval of rules on taking joint measures in case of alarm on nuclear and radioactive materials at check-points, airports, harbours and maritime space (№ 397; 24/12/2010)
2.15. On the Approval of National Plan for Civil Security (№ 508; 24.09.2015)

3. **Decree of the Minister of Environment and Natural Resources Protection of Georgia:**
3.1. Concerning the Security of Nuclear and Radiation Facilities, Radioactive Sources, Radioactive Waste and Other Sources of Ionizing Radiation Security (№ 26; 26.07.2017)
3.2. On Approval of Regulation for Responding to Illicit Traffic of Nuclear and Radioactive Substances (№ 150; 08.12.2014)
3.3. On Approval of the Procedure for Carrying out Activities Connected to Nuclear Non-proliferation Safeguards (#508; 24.09.2015)
3.4. On Reporting Form on the Adherence to Licensing Conditions for Nuclear and Radiation Activity (№ 39; 29.11.2016)
3.5. On Approval Rules for Inspection of Nuclear and Radiation Activity (№ 2; 22.01.2016)
3.6. On approval of the Statute of the Legal Entity of Public Law - Agency of Nuclear and Radiation Safety (№ 237; 24.12.2015)

4. Others:
4.1. License documentation of 'St. John the Merciful Private Clinic', LLC:
a) Data about activity of "St. John the Merciful Private Clinic" LLC, description of specific types of activities, data on source of ionizing radiation and its location, information on the radiation protection officer;
b) Data on the staff operating with ionizing radiation generator;
c) Order # 461 of the Ministry of Environment and Natural Resources Protection of Georgia of August 1, 2014 On Granting License for Nuclear and Radiation Activity to "St. John the Merciful Private Clinic" LLC;
d) Order N1/07-RS on appointment of a person responsible for nuclear and radiation activity;
e) Radiation Protection Programme;
f) Statement on applying for a license.
4.2. License documentation of JSC Georgian Oil and Gas Corporation:
a) Statement on applying for a license;
b) Description of Specific Nuclear and Radiation Activity;
c) Data on the staff operating with the source of ionizing radiation;
d) Order №i-53 of the Head of Legal Entity of Public Law Agency of Nuclear and Radiation Safety on Granting Nuclear and Radiation Activity License to Georgian Oil and Gas Corporation, JSC;
e) Radiation Protection Program;
f) Statement of Director of Georgian Oil and Gas on Registration of Generators;
g) Information about the Radiation Protection Officer.

4.3. Inspection check-lists
4.4. Documentation on the record of Georgia in ITDB;
4.5. RASIMS Reports:
a) TSA1;
b) TSA2;
c) TSA3;
d) TSA4;
e) TSA5;
f) TSA6;
g) TSA7.
4.6. Action Plan generated by Georgia as a result of Self-Assessment.
4.7. Template of Annual Report of Licensees.
4.8. Report on activity conducted by Department of Radioactive Waste Management during January-June 2017.
4.9. Annual Report of Agency of Nuclear and Radiation Safety for 2017.
4.10. Description of Authorization System.
4.11. Description of Dosimetry Equipment Calibration Procedure.
4.12. Combined Version of Articles on Enforcement Measures applicable to ANRS Activities.
4.13. Brief Description of Emergency Preparedness and Response System.
4.14. List of Organizations Exempted from Regulatory Control.
4.15. Inspection of Basic X-ray Unit - Individual Plan.
4.16. Information on Publications Developed and Distributed by ANRS.
4.17. Information about Competent Authority in the field of Safe Transport of Radioactive Substances.
4.18. Information about Competent Authority in the field of Nuclear Security.
4.19. Description of Inspection Procedure.
4.20. Template of Inspection Report.
4.21. Statistical Information about the Administrative Offences imposed over Organizations in 2017.
4.22. Order №I-691 of the Minister of Environment and Natural Resources Protection of Georgia on the Adoption of Annual Programme of 2017 regarding Planned Inspection in Nuclear and Radiation Activities.
4.23. Description of Procedures of Taking Enforcement Measures.
4.24. Radioactive Waste Acceptance Criteria.
4.25. Radiation Protection Program of one particular Licensee in the field of Medical Exposure.
4.26. Letter on Submission Draft Annual Inspection Programme to the Minister of Environment and Natural Resources Protection of Georgia by Head of ANRS.
4.27. Draft IRRS Report.
4.28. SARIS Report.
4.29. Country Details regarding the Multilateral and Bilateral Treaties as well as Memorandums of Understanding.
4.30. Chart of ANRS Structure.
4.31. Third Report of Georgia for the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.
4.32. Information about Technical Support Organizations.
4.33. Information about Competent Organization in Radioactive Waste Management.

Policy Issue 1
Culture for Safety Promotion
Policy Issue 2
Enhancing Regulatory Effectiveness and Competence

APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1. No. SF-1 - Fundamental Safety Principles
2. INTERNATIONAL ATOMIC ENERGY AGENCY - Governmental, Legal and Regulatory Framework for Safety General Safety Requirement Part 1(Rev 1) (Vienna2016)
3. INTERNATIONAL ATOMIC ENERGY AGENCY- Leadership and Management for Safety Requirement GSR Part 2 IAEA, Vienna (2016)
4. INTERNATIONAL ATOMIC ENERGY AGENCY – Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, (2014)
5. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety assessment for facilities and activities, General Safety Requirements Part 4, No. GSR Part 4 (Rev 1), IAEA, Vienna (2016)
6. INTERNATIONAL ATOMIC ENERGY AGENCY – Predisposal Management of Radioactive Waste General Safety Requirement Part 5, No. GSR Part 5, IAEA, Vienna (2009)
7. INTERNATIONAL ATOMIC ENERGY AGENCY – Decommissioning of Facilities General Safety Requirement Part 6, No. GSR Part 6, IAEA, Vienna (2014)
8. INTERNATIONAL ATOMIC ENERGY AGENCY – Preparedness and Response for a Nuclear or Radiological Emergency General Safety Requirement Part 7, No. GSR Part 7, IAEA, Vienna (2015)
9. INTERNATIONAL ATOMIC ENERGY AGENCY - Regulations for the Safe Transport of Radioactive Material Specific Safety Requirements 6, No. SSR 6, IAEA, Vienna (2012)8.
10. INTERNATIONAL ATOMIC ENERGY AGENCY - Organization and Staffing of the Regulatory Body for Nuclear Facilities, Safety Guide Series No. GS-G-1.1, IAEA, Vienna (2002)
11. INTERNATIONAL ATOMIC ENERGY AGENCY - Review and Assessment of Nuclear Facilities by the Regulatory Body, Safety Guide Series No. GS-G-1.2, IAEA, Vienna (2002)
12. INTERNATIONAL ATOMIC ENERGY AGENCY - Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, Safety Guide Series No. GS-G-1.3, IAEA, Vienna (2002)
13. INTERNATIONAL ATOMIC ENERGY AGENCY - Documentation for Use in Regulatory Nuclear Facilities, Safety Guide Series No. GS-G-1.4, IAEA, Vienna (2002)
14. INTERNATIONAL ATOMIC ENERGY AGENCY- - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)
15. INTERNATIONAL ATOMIC ENERGY AGENCY – Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna (2011)
16. INTERNATIONAL ATOMIC ENERGY AGENCY– Assessment of Occupational Exposure Due to Intake of Radionuclides Safety Guide Series No. RS-G-1.2, IAEA, Vienna (1999)
17. INTERNATIONAL ATOMIC ENERGY AGENCY - Assessment of Occupational Exposure Due to External Sources of Radiation Safety Guide Series No. RS-G-1.3, IAEA, Vienna (1999)
18. INTERNATIONAL ATOMIC ENERGY AGENCY - Building Competence in Radiation Protection and the Safe Use of Radiation Sources, Safety Guide Series No. RS-G-1.4, IAEA, Vienna (2001)

19. INTERNATIONAL ATOMIC ENERGY AGENCY – Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)

20. INTERNATIONAL ATOMIC ENERGY AGENCY – Regulatory Control of Radioactive Discharge to the Environment, Safety Guide Series No. WS-G-2.3, IAEA, Vienna (2000)

21. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No. WS-G.5.2, IAEA, Vienna (2009)

22. INTERNATIONAL ATOMIC ENERGY AGENCY – Establishing the Safety Infrastructure for a Nuclear Power Programme Specific Safety Guide No SSG-16, IAEA, Vienna (2011)

23. INTERNATIONAL ATOMIC ENERGY AGENCY - Disposal of Radioactive Waste Specific Safety Requirements 5, No. SSR 5, IAEA, Vienna (2011)

APPENDIX VIII ORGANIZAIONAL CHART