



Albania

National Report on the measures taken
by Albania to fulfill the obligations laid
down in the:

“Joint Convention on the Safety of Spent
Fuel Management and on the Safety of
Radioactive Waste Management”

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2. SECTION A: INTRODUCTION

2.1 General Introductory Remarks

Albanian Parliament on February 24th 2011 approved the law on adhering in the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. Albania deposited an instrument of accession to the Joint Convention on 29 June 2011. The Convention entered into force on 27 September 2011.

Albania has no nuclear power plant, no other fuel-cycle facility, no research reactor. Thus many requirements of the Joint Convention do not apply to Albania. Albania has no spent nuclear fuel on its territory.

The actual total amount of radioactive waste is mainly in the form of the disused sealed sources of low and high activity. The approval for import of a radioactive sealed source category one and two is granted only by the national regulatory authority which is Radiation Protection Commission (RPC) under the condition that the foreign supplier certifies the return of the disused sealed radioactive sources to the country of origin, or if an agreement is in place in advance for the management of the disused sealed sources at the end of the working life with the Institute of Applied Nuclear Physics (IANP) which is responsible for the management of the national radioactive waste storage facility.

Albania has not been a country with use and installation of radioactive smoke detectors and of radioactive lightning rods. Most of the radioactive waste is coming from disused sealed and unsealed radioactive sources which have been used in research, industry and medicine and all of them are collected in the national radioactive waste storage facility, which is established since 2000 at the Institute of Applied Nuclear Physics (IANP) in Tirana.

In the past all radioactive waste were stored in a small bunker (called radioactive waste grave) near the former Institute of Nuclear Physics. The sources were collected and stored inside concrete tranches covered by removable concrete roofing. Due to construction of public buildings around that bunker in 2000, the old radioactive waste grave was decommissioned and a new radioactive waste management facility was constructed inside the territory of the former Institute of Nuclear Physics. Decommission of old bunker and commission of the new facility has been carried out and respecting all regulatory requirement in force.

The Government of Albania has approved the regulation No. 638, date 7.9.2016 “On the safe management of radioactive waste in the Republic of Albania”, which reflects the IAEA standards in this field, as well as the EU Directive Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste (OJ L 199, 2.8.2011, p. 48)

Albania has established a waste management storage facility - with storage capacity of 300 m³. Institute of Applied Nuclear Physics (IANP) is the centralized institution for the processing of all radioactive waste produced in Albania based on waste acceptance criteria. IANP has to fulfil all the criteria to obtain the license by Radiation Protection Commission for all the activities related to the management of the radioactive waste.

The waste management facility has been licensed by the Radiation Protection Commission by the license No.652, date 01 December 2021 for ten years. During the licensing process RPO has assessed the all the elements and requirements relayed with radiation protection, safety and security. IANP has submitted the safety case as well as security plan for the radioactive waste facility. Safety case is prepared by IANP, while the security plan, based on the Memorandum of Understanding between Ministry of Interior and Ministry of Health and Social Protection, is prepared by IANP in cooperation with State Police. Security plan is prepared in line with the document no. 444/8 date 29.03.2019 “Guidance on preparation of the security plan of the facility”.

The safety case has taken into account the main elements as below:

- 1.Introduction, Purpose
- 2.Requirements for the storage of radioactive waste
 - 2.1 Waste arising
 - 2.2 Boundary conditions, regulatory framework, time 30 -50 years
3. Current situation at IANP
 - 3.1 Description of storage building
 - 3.2 Building features relevant for safety
 - 3.3 Current status of waste storage
4. Current/planned procedures for waste management at IANP
 - 4.1Waste acceptance
 - 4.2 Waste pre-treatment
 - 4.3 Waste processing
 - 4.4 Radiation protection of the public
 - 4.5 Radiation protection of workers
 - 4.6 Operational procedures for waste management
 - 4.7 Emergency planning
 - 4.8 Quality assurance
 - 4.9 Preliminary planning for decommissioning
5. Radiological impacts from waste storage facility
 - 5.1 Impact to public
 - 5.2 Impact to workers
6. Safety Assessment of waste storage facility

RPC supports the policy of returning the radioactive sources to the producer or suppliers but this is not a pre-condition for granting the license. For granting the license it is necessary to have a contract for returning of disused sources to producer (or supplier) or with IANP. In Albania radioactive wastes are produced by the use of radioactive sources in industry, medicine and research only. The total activity of conditioned and in temporary storage of radioactive waste and DSRS is 80.76 TBq (as result of transfer of one DSRS ⁶⁰Co radiotherapy source of category 1, from Mother Theresa Hospital premises at IANP storage facility).

Since 1972, Albania has a regulatory framework on radiation protection, which cover all relevant radiological safety issues. In 1995 entered in force the new Radiation Protection Law approximated with international standards. In 2008 there was an amendment to the Law taking into account new security issues and increasing the effective independence of regulatory body. There

are also sets of regulations. These regulations are revised recently in order to be in line with the provisions of the European Union Directives. Albania has approved the National Policy and Strategy on Radioactive Waste Management as well as the Regulation on the Safe Management of Radioactive Waste. The last revision of the Regulation on the “Safe Management of Radioactive Waste in Republic of Albania” has been approved by Albanian Council of Ministers as decision No.638, date 7.9.2016.

2.2 Observations and Comments

The national inventory and tracking of the radioactive sources, from the moment of importing till its return to the supplier or at radioactive waste management facility, is established at the Radiation Protection Office. Clear procedures for managing sources of unknown origin are defined in the regulation on “Physical protection of radioactive material in Republic of Albania”, No.877, date 30.10.2015 Article 13. This regulation states that the Radiation Protection Commission (RPC) has the support of the Institute of Applied Nuclear Physics (IANP) to keep under control all orphan sources. IANP performs all procedures for the safety and security of orphan sources in the waste management facility. The expenses, in case the owner of sources is not identified, are covered by State.

3. SECTION B: POLICIES AND PRACTICES (ARTICLE 32.1)

3.1 Radioactive Waste Management Policy

“National Policy for Radioactive Waste Management”, No 1319/3, date 25 March 2013 and the document “Strategic steps for safe management of radioactive waste in the Republic of Albania” No.435 dated 14.10.2015, are the basic documents for safe management of radioactive waste up to 2030. The Government of Albania has approved the regulation No. 638, date 7.9.2016 “On the safe management of radioactive waste in the Republic of Albania” based on IAEA documents, Albanian policy and strategy, the national conditions, as well as EU Directives.

The strategy specifies how the national radioactive waste management policy will be implemented; it defines an Action Plan which elaborates the procedures the various types of radioactive waste will be managed during all phases of the radioactive waste life cycle. The document describes waste classification and characterization, development and necessary solution for final disposal, minimization of radioactive waste, regulatory control, clearance from regulatory control and control of discharge.

The objective of the national strategy is to ensure the development and implementation of a coherent, integrated, optimized and sustainable management for all types of radioactive sources that are not in use, as well as radioactive waste produced in Albania. The national strategy also requires implementation in accordance with the relevant provisions of law and regulations on safety, security and environmental protection. Legislative elements that are not in line with this strategy should be changed.

The purpose of the preparation of this strategy is to provide a safe management of the disused sealed radioactive sources and radioactive waste in the country, in all stages of storage up to final disposal, ensuring protection of the public, future generation environment.

3.2 Elements of the National Strategy

3.2.1 National registry of disused sealed radioactive sources and radioactive waste.

Institute of Applied Nuclear Physics keeps data on disused sealed radioactive sources and radioactive waste stored at the National radioactive waste storage facility. These data include the institution from which are produced the waste, type and quantity, as well as their physical, chemical and radiological characteristics. Also, the inventory should include whether these sources are conditioned, are in temporary storage and their half-life. In the case where radioactive sources are still in use, all the information is held by the user and sent to the Radiation Protection Commission, which on the basis of this information creates a national registry of radioactive sources, which are in use. A copy of the inventory of DSRS and Rad waste is sent from Institute of Applied Nuclear Physics to RPC. Institutions that produce radioactive waste should make available all the necessary information, to the Radiation Protection Commission, which consolidates the national inventory of all disused sealed radioactive sources and radioactive waste produced in the country, their origin, the type and quantity, their characteristics in order to assess the situation in the future.

3.2.2 Classification of radioactive waste

The waste classification scheme provides a very useful structure for managing radioactive waste, generally indicates the most appropriate option for long-term management. IAEA's recommendations for the scheme are based on specific activity and the half-life period. The following scheme is easy to apply for DSRS and takes into account the safety of radiation protection. This scheme provides a quantitative approach to the actual values of the specific activity and the half-life period by dividing the waste into different classes. The following scheme also provides possible options regarding DSRS up to final disposal.

The system of classification of the radioactive waste in Albania

Half Life	Activity Bq	Preferred option		Alternative option	
		Processing	Final steps	Processing	Final steps
<100d	all	Decay	Clearance	Conditioning in a standard waste package	Place it near surface disposal
>100d <30a	<10 ⁶	Conditioning in a standard waste package	Place it near surface disposal	Packaging for transport	Return to the supplier

>100d <30a	>10 ⁶	Packaging for transport	Return to the supplier	Conditioning in a special waste package	Place in deep geological disposal
>30a	<10 ³	Conditioning in a standard waste package	Place in near surface disposal	Packaging for transport	Return to the supplier
>30a	>10 ³	Packaging for transport	Return to the supplier	Conditioning in a special waste package	Place in deep geological disposal

3.2.3 Optimal Strategy

RPC drafts the regulation for the management of disused sealed radioactive sources and radioactive waste, taking into account the classification of waste set out in the table above. Levels of exemption / release will be determined in the regulations, in accordance with the values recommended by the IAEA, as well as safety standards.

3.2.4 Characterization of radioactive waste

Safe management of disused sealed radioactive sources as well as radioactive waste, is depended on their characteristics. Their characterization is intended to determine the type and amount of radioactive waste that will be accepted as well as the successive steps of their management, including transportation, storage, and to meet the acceptance criteria of radioactive waste in the final disposal. Demonstration of a convenient characterization regime is assisted by application and implementation of a quality management system. Quality management system will also include training, method of development, qualification and documentation. Determination of the final disposal is necessary to be in line with security policies, both to the public and for the environment.

3.2.5 Institute of Applied Nuclear Physics (IANP)

Institute of Applied Nuclear Physics has established procedures for the characterization of disused radioactive sealed sources as well as radioactive waste. Users have to submit documentation on radioactive source at the RPC. While IANP must submit to RPC information at the time of transfer of waste in the disposal. IANP documentation should check whether it complies with the outcome of characterization. IANP is responsible for characterization of orphan sources when they are found. RPC must ensure that this characterization is done in accordance with the available license of IANP. IANP determines the radioactive sources acceptance criteria in the storage facility through the implementation of the Procedure for Acceptance of Radioactive Waste and DSRS. For a safe radioactive waste management should be taken into consideration at every step Law No.

10379 dated 24.2.2011, on the accession of the Republic of Albania in the Join convention "For the safe management of spent fuel and management of radioactive waste "as well as the EU directive 2011/70 / Euratom, 19 July 2011, for the safe management of spent fuel and radioactive waste.

3.2.6 Optimal strategy of IANP

All the disused sealed radioactive sources and radioactive waste should be characterized before being accepted in temporary storage. Priority should be given to volume reduction of radioactive waste, which needs a long-term management in Albania. To facilitate this process, RPC applies and implement the Code of Conduct on the safety and security of all radioactive sources imported into the country and its additional guides. In pursuant of this, it will require importers of radioactive sources to ensure their return to the manufacturer or to a waste management facility abroad. Disused sealed radioactive sources which are not processed by IANP should be exported abroad.

IANP will evaluate technical options suitable for the final disposal in connection with existing radioactive sources in the country. IANP should make a study on the best option for the final storage of radioactive sources. The export of radioactive sources that are included in the category 1 and 2 and long-life radionuclides are one of the possible choices that need to be assessed by IANP. IANP will see also the feasibility study related to the determination of the final disposal, which can be on the near surface and built according to the required parameters or a final deep underground disposal for all types of sources and radioactive waste.

IANP will remain the centralized national centre for radioactive waste processing and storage and for determining the final disposal option.

3.2.7 Orphan Sources

IANP performs processing of orphan sources in the country. Radiation detection portals that are installed at customs points are monitored by competent authorities in custom. As for portal monitors installed at private companies (example. scrap companies) these companies are responsible for monitoring. The undertaking shall maintain and where necessary improve existing detection system at customs regarding the safety and security of the public. All portal monitors have to be adjusted to their activity. As a first responder in case of detection of an event, IANP will be responsible for further managing of the found sources which will be transported to waste management storage facility in accordance with the emergency plan.

3.2.8 Infrastructure for management of disused sealed radioactive sources and radioactive waste

Radiation Protection Commission pursuant to Law no. 8025, dated 11.09.1995 "For the protection against ionizing radiation" is independent and reports to the government. IANP is legally responsible for managing the disused sealed radioactive sources and radioactive waste through waste management storage facility.

3.2.9 International Standards

Safety standards of IAEA require that the RPC be independent from the operating institutions. International standards require that RPC apply all regulatory procedures, such as licensing, inspection and sanctions for safety and security of radioactive waste in the country. RPC implement the relevant requirements through regulations and guidelines. The government provides financial and human resources to RPC and ensures that the legislation gives power to license, inspect and enforce regulations to related activities of radioactive waste management.

The government is responsible to ensure the necessary mechanisms that radioactive waste management is implemented safely and efficiently through determined safety regulations, providing and promoting a safety and security culture. Efficiency is ensured through adequate funding and a better functioning of IANP, defining clearly the responsibility, proper training and a performance monitoring system. The government provides a financing mechanism to IANP. IANP determines the actual costs of services.

3.2.10 Requirements for the development of short and midterm infrastructure for the implementation of strategy.

IANP will continue to improve and expand opportunities for the existing centre of radioactive waste management, in particular the process of waste treatment, waste temporary storage and sending to the final storage all radioactive waste produced in the country, which can't be returned to the manufacturer or who are excluded from regulatory control. RPC will monitor and assess the adequacy of the existing national system for the detection of orphan sources. When necessary, RPC will make recommendations for improvement. IANP will investigate possibilities for the safety and security of the final storage for all disused sealed radioactive sources or will take into account the possibility of sending abroad some high activity radioactive sources with long half-life. To complete documentation for obtaining a license for final disposal facility it is necessary to present the strategic environmental assessment concerning the impact of the final disposal to the environment. In the future, the development of the final disposal facility will allow that radioactive waste which are placed in the waste management storage facility to be permanently removed.

3.2.11 The system of training for regulators, employees and users.

IANP will cooperate with the IAEA on developing and implementing a systematic and comprehensive system of training and qualification of its staff. This will be based on international best practices, to regulate radiation activities in general and, in particular, for the management of radioactive waste. RPC approves training program. Users of radioactive materials should ensure that persons who are engaged in work with these sources, have the proper experience and training for radiation safety. RPC ensures that the public will be informed immediately of any significant potential or actual impact on the health and safety of the public and the environment, which may come from the management of disused sealed radioactive sources and radioactive waste as well as any potential incident.

3.2.12 Quality management system.

Radiation Protection Commission and IANP will develop and implement a suitable system of quality management, to facilitate planning, control and supervision of all aspects. Special attention will be paid to safety and security assessment.

3.2.13 Implementation of the Strategy

IANP is the responsible institution for the implementation of a strategy for safe management of radioactive waste. RPC is responsible for all regulatory aspects of the safe management of radioactive waste. Based on the Action Plan, the Government should take a decision to move forward to determine the final disposal for radioactive waste, or export them abroad.

3.2.14 Action Plan

Priority Action 1a : approximation of Albania legislation with the EU directives, in particular the revision of the regulation on the management of radioactive waste, which will be in line with the EU directive 2011/70 Euratom 19 July 2011 for the safe management of radioactive waste	Deadlines for the implementation	Responsible Institutions
<i>Strategic Goals:</i> Fulfillment of the requirements and obligations pursuant to Law No.10379, dated 24.02.2011 on the accession of the Republic of Albania in the Joint Convention for safe management of spent fuel and for safety of radioactive waste management, as well as the Code of conduct, IAEA document .		
Radiation Protection Commission will review the regulation on the management of the radioactive waste, in accordance with EU EU directive	2020	MoH / RPC

2011/70/Euratom 19 July 2011		Completed
Priority Action 1b : Feasibility Study		
<i>Strategic goal:</i> Finding a possible alternative for Albania as the final disposal		
Institute of Applied Nuclear Physics should start studying the feasibility regarding the determination of final disposal, which can be near surface and built according with the required parameters or deep geological disposal for all types of sources and radioactive waste.	2020	IANP
Priority Action 1 c: Selection of place		
<i>Strategic goal :</i> Determination of the best variant for the final disposal		
The government should decide on the final version of the final disposal basis on a feasibility study to perform the strategic environmental assessment. Selection of the place will be carried out in cooperation with IANP and Ministries of line.	2025	IANP and ministries of line
Priority action 1 d : Study on safety and security for final disposal.		
<i>Strategic Goal :</i> Preparation of study regarding the safety and security of radioactive waste.		
Study regarding on safety and security for final disposal will be prepared by IANP, after the government has decided for final disposal place, according of estimation given by IANP in cooperation with line institutions .	2030	IANP
Priority Action 1 e : Application for license		
<i>Strategic Goal :</i> Licensing of final disposal		
The construction for the final disposal will begin after applying for license and approving it by Regulatory Body.	2030	IANP

3.3 Safety and Security Aspects at the Centralized Radioactive Waste Storage Facility

The facility represents a solid concrete construction with outside concrete walls of a thickness between 20 and 40 cm. All main entrances to the facility are protected with double security locks. There exists an alarm system, which is monitored by cameras at the main entrance of the IANP by state police guards. The waste storage concept is based on a defence-in-depth approach, protecting the integrity of the waste and avoiding unauthorized access to the waste by their immobilization in concrete, the solid building structures and the physical access control. The guards permanently secure the IANP territory for 24 hours and visitors are checked and accompanied by IANP staff. Centralized Radioactive Waste Storage Facility is protected by several physical parameters like: solid building structure in concrete, cameras and lights at the four corners of building and fence around the IANP territory and organizational access control barriers as well as some more security measures.

A TC project for the cycle 2018-2019 on Upgrading the Radioactive Waste Storage Building According to International Standards was implemented. This project was focused on creating the infrastructure necessary to implement the new National Strategy for radioactive waste management in the Republic of Albania.

The objective of this project was to:

1. Improve the safety of the personnel in the RWSF, protection of public and environment.
2. Upgrade the Equipment's used in the RW Management Activities.
3. Upgrade the existing Infrastructure of the RWSF Building.
4. Ensure retrievability of waste packages for final disposal

Under this project are carried out Refurbishment activities listed below.

The exterior refurbishment activities:

- Front door and stairs renovation
- Renovation of facade
- Roof reconstruction works (leaking of roof was fixed)
- Regulation of meteoric drainage
- Renovation of electrical installations

Also, many improvements are implemented inside the RWMF building:

- The floorplan was changed (some walls were moved, and certain doors were reallocated)
- Renovation of rooms and offices for personnel
- Renovation of shower and toilet
- Renovation of electrical installations,
- Renovation of lighting
- The server was relocated in another building at the IANP premises.

After the Second IAEA Expert Mission in the period 8-12 April 2019 under the ALB 9010” National Project the Experts Recommended the following activities:

1. Repacking of 4 cracked drums;
2. Overpacking of other cemented drums;
3. Overpacking of cement drum with neutron source in special container;
4. Conditioning the unconditioned sources (gamma and neutron) in two storage rooms into 1 or 2 containers;

This campaign was completed in June 2022 in the frame of the above project and were performed only the following activities

1. Repacking of 4 cracked drums;
2. Overpacking of other 11 cemented drums with cemented radioactive waste;

The other activities recommended by IAEA Experts were not completed due to lack of funds.

Also, there is in place a good infrastructure and legal system for safe and secure management of radioactive sources. It was a need for establishing the national policy and strategy on safe management of radioactive waste and DSRS. The policy and strategy needed to establish clear view for the future management of radioactive waste and serve as basis for the preparation, review or revision of related legislation;

- to implement IAEA requirements, JC requirements & EU directives;
- to define more (further) clearly the roles and responsibilities for ensuring the safe management of radioactive waste;
- to be as a starting point for further developments and modifications to existing national practices;
- to provide for the safety and sustainability of radioactive waste management over generations, and for the adequate allocation of financial and human resources over time;
- to establish the final disposal;
- to specify how the national radioactive waste management and policy will be implemented by the IANP and other stakeholders using the available technical measures and financial resources;
- to define how and when the identified goals and requirements will be achieved (action PLAN);
- to identify the competencies needed;
- to elaborate the ways in which the various types of radioactive waste in the country, will be managed during all phases of the radioactive waste life cycle;

As defined by legislation all facilities using radioactive substances exceeding the exemption levels must be licensed in advance by the competent authority, according to the licensing system established in Albania. These facilities are fully responsible for the safety and the security of the radioactive sources they use and for the management of the radioactive waste

resulting from this use. The regulation No.638 dated 7.09.2016 on “Safe management radioactive waste in Republic of Albania” has been taken into account.

3.3.1 Objective of the Regulation

The objective of the regulation No.638 dated 7.09.2016 is to establish the requirements for the safe management of radioactive waste and to establish special requirements for the authorization of radioactive waste management facilities and activities.

3.3.2 General Requirements

3.3.2.1 Responsibilities

Responsible structure for the safety and security of radioactive waste are, as below:

- (1) the holders of authorizations for activities and facilities generating that radioactive waste.
- (2) The prime responsibility for the safety of radioactive waste management facilities shall rest with the licensee operating that facility and it shall not be delegated.
- (3) The Radiation Protection Commission (RPC) shall define the national policy for radioactive waste management, in collaboration with the other competent authorities of Albania.
- (4) RPC shall establish a national programme and steps for the implementation of the radioactive waste management policy.

3.3.2.2 National program for radioactive waste management

- (1) The national program for the management of radioactive waste shall cover all types of radioactive waste existing in Albania and all stages of radioactive waste management from generation to disposal.
- (2) The national program for the management of radioactive waste shall include the following information:
 - a) the overall objectives of the national policy of Albania for radioactive waste management;
 - b) the significant milestones and clear timeframes for the achievement of those milestones;
 - c) an inventory of all radioactive waste and estimates for future quantities, including those from decommissioning of generator facilities, clearly indicating the location and amount of the radioactive waste in accordance with the classification of radioactive waste;
 - d) the concepts or plans for the post-closure period of a disposal facility's lifetime, including the period during which appropriate controls are retained and the means to be employed to preserve knowledge of that facility in the longer term;
 - e) the best practice, development and demonstration activities that are needed in order to implement solutions for the management of radioactive waste;
 - f) the responsibility for the implementation of the national program and the key performance indicators to monitor progress towards implementation;
 - g) an assessment of the national program costs and the underlying basis and hypotheses for that assessment, which must include a profile over time;
 - h) the financing scheme(s) in force;

- i) a transparency policy;
- (3) The national programme and steps for the management of radioactive waste shall be regularly reviewed and updated, taking into account technical and scientific progress as appropriate as well as recommendations, lessons learned and good practices from peer reviews.

3.3.2.3 Operational programs for radioactive waste management

- (1) The holders of authorizations for activities or facilities generating radioactive waste shall establish and implement operational programs for radioactive waste management, in accordance with the national program for radioactive waste management.
- (2) The operational radioactive waste management programs shall cover the following aspects:
 - a) all types of radioactive waste generated during the activity or operation and decommissioning of the facility;
 - b) all steps of radioactive waste management, from generation to disposal, taking into consideration the interdependencies among them and the impact of the anticipated disposal option.
- (3) The operational radioactive waste management programs shall be periodically reviewed and updated, taking into account technical and scientific progress, as appropriate.
- (4) The operational radioactive waste management program shall include the following information:
 - (a) an inventory of the existing radioactive waste quantities and previsions of future quantities, including those from decommissioning, with a clear indication of the location and amount of the material and, through operational classification, the level of hazard;
 - (b) the concepts, plans and technical solutions for radioactive waste management, from generation to disposal;
 - (c) major milestones, clear timeframes and responsibilities for implementation of the programme;
 - (d) key performance indicators to monitor progress towards implementation of the programme;
 - (e) an assessment of the programme costs for the waste management.
- (5) The operational radioactive waste management programs shall be approved by RPC during the authorization process of the activity or facility generating radioactive waste.

3.3.2.4 Management systems of the radioactive waste

- (1) The holders of authorizations for activities or facilities generating radioactive waste as well as the licensees of radioactive waste management facilities shall ensure that a management system which provides for the assurance of quality is applied to all aspects of the radioactive waste management.
- (2) The licensees of radioactive waste management facilities shall ensure that a management system which provides for the assurance of quality is applied to all safety related activities, systems and components throughout all the stages of the development of the radioactive waste management facility.

- (3) The level of assurance for each aspect mentioned in paragraphs (1) and (2) shall be commensurate with its importance to safety level.
- (4) The holders of authorizations for activities or facilities generating radioactive waste shall register.
- (5) The management systems shall specify:
 - (a) the role of the management and the organizational structure to be used for implementing processes for all safety related activities;
 - (b) the responsibilities and authorities of personnel and organizations involved in managing and implementing the processes and assessing the quality of all work relating to safety.
- (6) The management systems shall be designed to provide for:
 - (a) the preparation and retention of documentary evidence to demonstrate that the necessary quality of data has been achieved, that components have been supplied and used in accordance with relevant specifications, that the waste packages and unpacked waste comply with the waste acceptance criteria and that they have been properly processed, stored or disposed of;
 - (b) the collection of all information important to safety, its recording at all steps of the development and operation of a facility, and its preservation.

3.3.2.5 Training

The holders of authorizations for activities or facilities generating radioactive waste as well as the licensees of radioactive waste management facilities shall put in place adequate arrangements for education and training of the personnel involved in radioactive waste management.

3.3.2.6 Security

- (1) The holders of authorizations for activities or facilities generating radioactive waste as well as the licensees of radioactive waste management facilities shall take all measures to ensure the security of all radioactive waste in their possession or under their control in order to ensure:
 - (a) prevention of unauthorised access to the radioactive waste storage area;
 - (b) prevention of the entrance of the unauthorised radioactive waste in the storage;
 - (c) protection of the radioactive waste from theft, loss and sabotage.
- (2) Safety and security measures shall be implemented in an integrated manner.
- (3) The level of security shall be commensurate with the level of radiological hazards and the nature of the radioactive waste.

3.3.2.7 Emergency preparedness and response

- (1) The licensees of radioactive waste management facilities shall establish emergency response plans and procedures in accordance with the legislation in power to protect the community and the environment in case of an incident during the management of radioactive waste from the production, disposal to the storage till the full reduction of the risk in the community and the environment.
- (2) The holders of authorizations for activities or facilities generating radioactive waste shall consider into their emergency response plans and procedures the radioactive waste present on site, the radioactive waste management operations performed on site, as well as any radioactive management facility existing on site.

3.3.2.8 Transport of radioactive waste

The holders of authorizations for activities or facilities generating radioactive waste shall ensure the transport of radioactive waste on public roads, railways, by air or by international waters in accordance with the Regulations in power on the safe transport of radioactive material.

3.3.2.9 Management of radioactive waste

The holders of authorizations for activities or facilities generating radioactive waste as well as the licensees of radioactive waste management facilities shall identify and take into consideration, during the management of radioactive waste, all other non-radiological hazards associated with the radioactive waste, including chemical, biological or flammable hazards, and shall comply with all other laws and regulations concerning such hazards.

3.3.2.10 Funding of radioactive waste management

The holders of authorizations for activities or facilities generating radioactive waste shall be legally required to ensure the necessary funds to cover the costs associated with the management of the radioactive waste generated by them and shall be directly responsible to clean-up the contaminated working places or environment caused by them.

3.3.2.11 Transparency

The holders of authorizations for activities or facilities generating radioactive waste as well as the licensees of radioactive waste management facilities shall make available to the workers and the public the necessary information to demonstrate that the radioactive waste under his possession or control is safely managed, provided that such information will not affect the safety and the security of the radioactive waste.

3.4 Radioactive Waste Management

3.4.1 General conditions for control of radioactive waste generation

- (1) The holders of authorizations for activities or facilities generating radioactive waste shall ensure the identification and control of the radioactive waste, in terms of both volume and radioactivity content.
- (2) The holders of authorizations related with the disused sources and radioactive waste shall use the form in Annexes of regulation.
- (3) The authorization holders shall consider the following control measures, in the following order:
 - a) reduce radioactive waste generation;
 - b) reuse disused radioactive sources when is possible;
 - c) recycle disused radioactive sources;
 - d) release radioactive material from the regulatory control or discharge radioactive effluents within the authorized discharge limits;
 - e) dispose of radioactive waste.

3.4.2 Minimization of radioactive waste generation

- (1) The activities generating radioactive waste as well as the siting, design, construction, commissioning, operation and decommissioning of a facility generating radioactive waste shall be planned in such a manner so as to keep the volume and the radioactive content of the radioactive waste to the minimum practicable.
- (2) The holders of authorizations for activities or facilities generating radioactive waste shall ensure that the generation of radioactive waste and its impact to the environment is kept to the minimum practicable.

3.4.3 Reuse and recycle of disused sources

- (1) The holders of authorizations for activities or facilities generating radioactive waste shall, before declaring disused sources as radioactive waste, consider whether he or any other person can make use of or recycle those sources.
- (2) If the authorization holder decides to transfer the disused sources for recycle or reuse to another person, the authorization holder shall obtain an approval from RPC prior to the transfer.
- (3) The authorization holder shall ensure that the person to whom the disused sources are to be transferred has a valid authorization issued by RPC to use or recycle those sources.
- (4) If the authorization holder is unable to transfer the disused sources to an authorized person, he shall declare those sources as radioactive waste.
- (5) The authorization holder shall obtain an approval from RPC prior to sending the radioactive waste to a radioactive waste management facility authorised by RPC.
- (6) Upon the takeover, the authorization holder who transfers the disused sources or the radioactive waste and respectively, the authorization holder who receives the disused sources or the radioactive waste, shall document the transfer of ownership of the disused sources or, respectively, the radioactive waste.

3.4.4 Return of disused sources

- (1) The persons who intend to obtain a radioactive sealed source shall:
 - a) require the supplier to include a condition in the contract for purchase or in the document for acceptance of the source as a donation, to accept the return of the source after its use period;
 - b) submit a copy of relevant parts of the contract or acceptance document to RPC as part of the authorization documentation, before the purchase of the source; and
 - c) return the disused source to the supplier at the end of its use period.
- (2) If an authorization holder is unable to return the disused source to its supplier, he shall consider to reuse it or recycle it, or if this is not possible, to declare it as radioactive waste, in accordance with the relevant provisions of Article 16.
- (3) Authorization holders shall ensure that no disused source is dismantled.

3.4.5 Release from the regulatory control

- (1) Radioactive sources, material and other object which are no longer used may be released from the regulatory control provided that:
 - a) the concentrations of activity do not exceed the clearance levels set out in Annexes of regulation or
 - b) the concentrations of activity comply with specific clearance levels and associated requirements for specific materials or for materials originating from specific types of practices, established by RPC in addition to the general clearance levels set out in Annexes of regulation.
- (2) The release of materials from the regulatory control shall be approved by RPC on a case by case basis.

3.4.6 Interdiction to dilute radioactive waste

- (1) The deliberate dilution of radioactive waste, other than the mixing of materials taking place in normal operation when radioactivity is not a consideration or in case of approved discharge of liquid and airborne radioactive effluents, shall be prohibited.

3.4.7 Discharge of radioactive waste

- (1) The transfer into the environment of solid radioactive waste exceeding the clearance levels specified in Annexes of the regulation shall be prohibited, except for disposal in adequate facilities, authorized by RPC.
- (2) The transfer into the environment of airborne and liquid radioactive waste shall be allowed, provided that the following conditions are observed:
 - a) the total activity or activity concentrations do not exceed the discharge limits approved by RPC during the authorization process;
 - b) the liquid effluents are in the form of neutral solutions, perfectly miscible with water and do not contain suspended material, hot particles, toxic materials or any other hazardous substance exceeding the legal limits;
 - c) all radioactive discharges are kept as far below the authorized discharge limits as reasonably achievable;
 - d) all radioactive discharges are monitored with sufficient detail and accuracy to demonstrate compliance with the authorized discharge limits and to allow estimation of public exposure;
 - e) all radioactive discharges and estimated public exposures are recorded and periodically reported to RPC;
 - f) Whenever RPC so requires, complement the monitoring of radioactive discharges by environmental monitoring in the manner as approved by RPC.
- (3) If the discharge limits and conditions are not observed, the authorization holder shall temporarily store the radioactive effluents and take one of the following measures, as appropriate:
 - a) wait for decay, if the radionuclide's exceeding the discharge limit are short-lived;
 - b) filter the effluents; or
 - c) ensure their adequate treatment.
- (4) For each discharge in environment shall be kept note as the format in Annexes of regulation.

3.4.8 Radioactive waste not suitable for reuse, recycle, discharge or clearance

Radioactive waste which, due to its characteristics, is not suitable to be reused, recycled, released from the regulatory control or discharged, shall be processed as radioactive waste in radioactive waste treatment facilities authorized by RPC.

3.4.9 Characterization of radioactive waste

- (1) The holders of authorizations for activities or facilities generating radioactive waste shall characterize the radioactive waste, in terms of its physical, mechanical, chemical, radiological and biological properties.
- (2) The relevant characteristics of the waste shall be recorded, in such a way so as to facilitate its further management.

3.4.10 Classification of radioactive waste

- (1) The radioactive waste shall be classified in terms of the disposal options, into the following classes, as specified in Annexes of regulation.
- (2) The disused radioactive waste shall be classified in terms of the disposal options, into the following classes, as specified in Annexes of regulation.
- (3) The holders of authorizations for activities or facilities generating radioactive waste shall establish and implement an operational classification of the radioactive waste, based on the conceptual classification provided in Annexes of regulation and using the following criteria, as applicable:
 - a) the origin of the radioactive waste, including the installation, structure, system or component generating the radioactive waste;
 - b) the types of radioactive waste, including spent filters, used components, demolished structures, various debris, spent sealed sources, other residues;
 - c) the radiological properties of the waste, including ambient dose rate, surface contamination, activity concentration, radionuclide composition and half-lives of the predominant radionuclides;
 - d) other than radiological properties, including physical, chemical or biological hazards, corrosiveness, the content of free liquids, volatility, flammability, gas formation and gas content, solubility, miscibility, volatility, swelling capacity, the content of organic substances, complexing and chelating agents, reactivity, radionuclides sorption, void fraction and presence of other dangerous substances;
 - e) subsequent management options, including compaction, incineration, immobilisation, segmentation, decontamination or melting.

3.4.11 Segregation of radioactive waste

- (1) The holders of authorizations for activities or facilities generating radioactive waste shall ensure the segregation of the radioactive waste in accordance with the operational classification scheme.
- (2) After the segregation, each radioactive waste category shall be kept separately, in different types of containers.

- (3) The containers shall be robust and compatible with the radioactive waste category and shall allow the safe filling and un-filling during the expected storage period.
- (4) The containers shall be positioned in accessible places inside the controlled areas and they shall be clearly marked with the radiation symbol and the radioactive waste category.
- (5) After filling, each container shall be weighted and the radioactive waste content characterised.
- (6) Before each reuse of a container, the surface contamination shall be checked, both inside and outside the container.
- (7) The authorization holder shall record and keep the records of all radioactive waste containers produced during the operation and decommissioning of the facility generating radioactive waste.
- (8) The records specified in paragraph (7) shall include:
 - a) the total number of containers for each category of radioactive waste produced in one year;
 - b) the total mass of each category of radioactive waste produced in one year;
 - c) the total volume of each category of radioactive waste produced in one year;
 - d) the total activity of each category of radioactive waste produced in one year;
 - e) the radionuclide composition of each category of radioactive waste produced in one year, if possible with activities for each radionuclide;
 - f) the origin(s) of the waste, for each category; and
 - g) other actual or potential hazards (chemical, biological or flammable,) associated with each category of the waste, as the case may be

3.4.12 Treatment and conditioning

- (1) The holders of authorizations for activities or facilities generating radioactive waste shall ensure the treatment and conditioning of radioactive waste, if necessary to improve the characteristics of radioactive waste in order to meet the criteria for acceptance in authorized radioactive storage or disposal facilities.
- (2) Treatment and conditioning of radioactive waste shall be performed by the authorization holder in adequate radioactive waste treatment facilities, authorized by RPC.
- (3) Radioactive waste shall be processed in such a manner that the resulting waste form can be safely stored and retrieved from the storage facility up until its ultimate disposal.
- (4) The licensees for radioactive waste treatment facilities shall make provisions for identifying, assessing and dealing with radioactive waste which does not meet the waste acceptance criteria.
- (5) Secondary radioactive waste which might be generated during treatment and conditioning of radioactive waste shall be adequately taken into consideration by the authorization holder for the radioactive waste treatment facility.

3.4.13 Packaging

- (1) The authorization holders shall ensure that treated and conditioned radioactive waste is packaged in packages meeting the criteria for acceptance in storage or disposal.
- (2) Radioactive waste packages shall be designed and produced so that the radioactive material is appropriately contained both during normal operation and accident conditions that could occur during handling, transport, storage and disposal.

- (3) RPC shall approve the use of a particular type of packaging during the authorization process of the radioactive waste treatment facility, based on the following documents which shall be submitted by the applicant:
 - a) a drawing and a description of the packaging;
 - b) the results of any tests performed for the packaging;
 - c) any other document confirming the suitability of the packaging for the intended purpose.
- (4) Each package containing radioactive waste shall be marked with the radiation symbol.
- (5) Each package containing radioactive waste shall be labelled with the following data:
 - a) a unique identification number;
 - b) the package weight;
 - c) the category of the radioactive waste;
 - d) the maximum dose rate measured at contact with the outer surface.
- (6) Both the mark specified in paragraph (4) and the label specified in paragraph (5) shall be affixed at visible locations, clearly legible and durable during the entire period expected for the future radioactive waste management steps.

3.4.14 General conditions for storage

- (1) The holders of authorizations for activities or facilities generating radioactive waste may store the radioactive waste generated until the transfer to a radioactive waste management facility or until the release from the regulatory control, in a temporary storage located on site, provided that the relevant requirements and legislations.
- (2) The holders of authorizations for activities or facilities generating radioactive waste shall ensure the storage of the radioactive waste in adequate storage facilities, authorized by RPC.
- (3) The licensees for radioactive waste storage facilities shall ensure that the radioactive waste is stored in such conditions that it can be inspected, monitored, retrieved and preserved, during the expected period of storage, taking into consideration its subsequent management.
- (4) The licensees for radioactive waste storage facilities shall take the following actions:
 - a) adequate measures to prevent degradation of the containment of radioactive waste, especially for storage on long term;
 - b) periodically review the storage capacity, taking into account the predicted waste arising, both from normal and abnormal operation, the expected lifetime of the storage facility and the availability of disposal options;
 - c) verify, through periodic inspections, the adequacy of packaging for the storage conditions, with the frequencies and methods specified in the safety case used for the authorization of the storage facility operation.
- (5) Only radioactive waste meeting the waste acceptance criteria approved by RPC shall be permitted in storage facilities.
- (6) Storage of radioactive waste shall be permitted only in packaging approved for storage.

3.4.15 Temporary storage

- (1) Radioactive waste storage facilities shall provide for the safe, stable and secure storage of radioactive waste before it is disposed of.

- (2) The licensees for radioactive waste storage facilities shall ensure the development and the operation of the facility in such a manner so as to ensure the containment of the radioactive waste;
- (3) The licensee shall take measures to ensure that the safety functions are maintained during all operational states of the facility and accident conditions, taking into consideration that:
 - a) the radioactive waste shall be immobile;
 - b) a multibarrier approach shall be adopted in ensuring containment, with account taken of all elements that can be demonstrated to be reliable and competent;
 - c) the radioactive waste form and its container shall be resistant to degradation;
 - d) the radioactive waste packages shall be able to be inspected and shall be retrievable to for inspection and reworking;
 - e) the safety systems shall be designed to:
 - achieve their safety functions with minimum need for monitoring and maintenance;
 - function with minimum human intervention;
 - f) the storage building shall be resistant to the hazards taken into consideration in the safety assessment;
 - g) the storage environment shall not adversely affect the properties of the radioactive waste, the radioactive waste packages or the storage system;
 - h) the storage facility shall enable the retrieval of the radioactive waste;
 - i) security and access controls shall be compatible with the safety measures applied at the facility;
 - j) the lifetime of the storage facility shall be appropriate for the intended storage period.

3.4.16 Decay-storage

- (1) The holders of authorizations for activities or facilities generating radioactive waste shall undertake the decay-storage of radioactive waste in temporary storages or radioactive waste storage facilities.
- (2) When, during the decay-storage phase, the concentration of activity of the radionuclides contained decreases below the clearance levels or the authorized discharge limits, the radioactive waste shall be released from the regulatory control or respectively, discharged, provided that any other clearance criteria or discharge conditions set up by RPC are observed.

3.4.17 Long term storage

- (1) The licensees for radioactive waste storage facilities proposed to be operated for more than 30 years shall ensure that:
 - a) during the siting stage, passive safety features are taken into consideration to the extent possible and the degradation of such features over the proposed operational period of time is considered in the safety assessment;
 - b) during the design of the facility, the impact of time dependent processes including corrosion, creep, fatigue, shrinkage, radiation induced changes and associated radiation fields, are taken into account when selecting the construction materials.
- (2) The licensees for radioactive waste storage facilities shall establish:
 - a) an ageing management programme addressing the ageing related degradation of the facility and its systems, structures and components important for the containment of the radioactive

waste, which shall include provisions for the necessary monitoring to ensure early detection of any such deficiencies;

- b) a plan for the safe handling of radioactive waste, following the period of storage, which shall take into consideration the potential effects of degradation of the radioactive waste or of any elements of the containment systems on the ability to retrieve the radioactive waste.

3.4.18 Radioactive waste disposal

- (1) The holders of authorizations for activities or facilities generating radioactive waste shall ensure the disposal of the radioactive waste in adequate radioactive waste disposal facilities, authorized by RPC.
- (2) Disposal of radioactive waste shall be allowed only in packaging approved for disposal.
- (3) The establishment of the final disposal shall be defined by Council of Ministers.

3.4.19 Management of very low level waste

- (1) The holders of authorizations for activities or facilities generating very low level waste may dispose it of in near surface landfill repositories, with approval of regional directorate and environment and the relevant municipality where the deposit is to be made.
- (2) The observance of the general criteria for clearance shall be demonstrated in RPC.

3.5 Authorization of Radioactive Waste Management Facilities and Activities

3.5.1 Authorization of activities

- (1) No person shall commence any activity generating radioactive waste without a valid authorization issued by RPC.
- (2) The authorizations issued by RPC for activities generating radioactive waste shall cover the radioactive waste management operations performed on site by the authorization holder, provided that the relevant requirements of these Regulations are observed.
- (3) The licenses issued by RPC for the operation of radioactive waste management facilities shall give the right to the licensee to perform the radioactive waste management activities for which the facility was constructed.

3.5.2 Notification

- (1) Any person having the intention to initiate a project for the development of a radioactive waste management facility shall notify in writing his intention to RPC and relevant municipality where the facility has to be made.
- (2) The person sending the notification shall be responsible for initiating communication with RPC in order to obtain all the necessary information on the documentation to be submitted and actions to be taken in the authorization process, in addition to the requirements specified in these Regulations.

3.5.3 Application for authorization

- (1) Any person having the intention to develop a radioactive waste management facility shall send to RPC an application for authorization, which shall include as a minimum the following information:
 - a) the name and contact details of the person applying for authorization;
 - b) the purpose of the application, with the identification of the activity and the description of the facility intended to be developed, which shall include an indicative schedule of the facility development.
- (2) The application shall be accompanied by the following documents:
 - a) a safety case, which shall include a safety assessment report and all other documents specific for each stage of the facility development, as requested in these Regulations;
 - b) a proof of payment of the necessary fees and tariffs;
 - c) any other information considered important by the applicant;
 - a) any other information requested by RPC.
- (3) The safety case accompanying the application for authorization is an integral part of the authorization and shall not be unilaterally modified by the applicant.
- (4) Authorizations for radioactive waste management facilities shall be issued only if the applicant fulfils the following general conditions, as appropriate:
 - a) is able to demonstrate the fulfilment of all the applicable laws and regulations;
 - b) is able to prove that he has the necessary technical facilities, technologies, and financial resources;
 - c) is able to prove that he has organizational capability and responsibility for the prevention and limitation of the consequences of accidents;
 - d) is able to prove that he has implemented a management system, addressing all matters important to safety and is able to exercise effective control and supervision of the work performed by his suppliers of products and services;
 - e) is able to prove that his staff with positions important to safety has the necessary professional qualification and competences;
 - f) takes all the necessary steps, at the level of current technical standards in force, in order to prevent the occurrence of accidents;
 - g) has adequate and sufficient technical and financial arrangements for the collection, transport, treatment, conditioning, and storage of radioactive waste generated from his activities, and for the decommissioning or closure of the facility, as appropriate;
 - h) institutes and maintains a public information system in accordance with the applicable legislation;

3.5.4 Authorization process stages

- (1) Authorizations for radioactive waste management facilities shall be applied for and issued in the following stages:
 - a) Site Licence;
 - b) Construction Licence;
 - c) Permission for commissioning;
 - d) Operation Licence;
 - e) Operation Beyond Design Life License, for predisposal facilities;

- f) Decommissioning Licence, for predisposal facilities;
- g) Closure Licence, for disposal facilities.

3.5.5 General authorization conditions

- (5) The authorizations for radioactive waste management facilities shall be valid only for the activities and facilities for which they have been issued.
- (6) The expiry, suspension or revocation of the authorization does not exonerate the holder of the authorization, or the person having taken over the property title over the radioactive waste or radioactive waste management facilities, as appropriate covered by the authorization, from the obligations provided in the Law No.8025 from 9.11.1995 "On ionizing radiation protection", as amended, and these Regulations.

3.5.6 Safety case and safety assessment

- (1) Any applicant for an authorization for a radioactive waste management facility shall prepare, as part of the application, a safety case and a supporting safety assessment covering all stages in the development of the facility.
- (2) The safety case and its supporting safety assessment for disposal facilities shall address the safety of the facility during all stages of the facility development and after the closure of the facility, aiming to demonstrate in particular how the safety will be ensured by passive means to the maximum extent possible.
- (3) The extent and level of detail of the safety case and its supporting safety assessment shall be commensurate with the complexity of the operations and the magnitude of the hazards associated with the respective facility or activity.
- (4) The safety case and its supporting safety assessment shall describe all safety-relevant aspects of the site, the design of the facility, the managerial control measures and the regulatory controls.
- (5) The safety case and its supporting safety assessment shall demonstrate the level of protection provided and shall provide assurance to RPC and other interested parties that the safety requirements will be met.
- (6) The safety case and its supporting safety assessment shall be documented at a level of detail and to a quality sufficient to demonstrate safety, to support the decisions to be made at each step in the development of the facility and to allow for independent review.
- (7) The documentation of the safety case shall be clearly written and shall include arguments justifying the approaches taken during the development of the safety case, on the basis of traceable information.
- (8) The safety case shall specify the standards applied for the safety assessment.
- (9) RPC shall approve the safety case and its supporting safety assessment during the authorization process of the radioactive waste management facility.
- (10) The safety case and supporting safety assessment shall be updated during the evolution of the facility or activity, and in the event of any modification which could affect the safety.

3.5.7 Modification of licenses

- (1) The licensees for radioactive waste management facilities intending to incorporate a modification of the facility, the activity or its organisation, which may affect the safety of the facility or lead to changes in its safety case shall submit an application to RPC for approval and, as necessary, for modification of the license.
- (2) The application shall include updated information as specified in Article 43 and shall be supported by documents fully describing the desired changes, the justification of the proposed modifications, along with an updated Safety Assessment Report.
- (3) Upon review of the submissions, RPC shall make a decision on approving the proposed modification or modifying the license.
- (4) The licensee shall implement the proposed modifications only after approval has been obtained from RPC.

3.5.8 Siting and design of predisposal facilities

- (1) The holders of a license to site a predisposal radioactive waste management facility shall locate and design the facility in such a manner so as to ensure the safety during the operation and decommissioning of the facility, under normal operation conditions and under accident conditions.
- (2) The licensee shall ensure that the properties, the total inventory and all potential hazards, radiological and non-radiological, associated with the radioactive waste are appropriately taken into consideration in the design of the facility.
- (3) The licensee shall ensure that the need for operational maintenance, testing, examination and inspection is addressed starting from the conceptual design stage.

3.5.9 Site characterization

- (1) The holders of licenses to site a radioactive waste management facility shall characterise the selected site in sufficient detail to allow an understanding of the characteristics of the site and the evolution of the site in time, including the following aspects:
 - a) its present conditions;
 - b) its probable natural evolution and possible natural events that could affect its safety;
 - c) the possible human activities in the vicinity of the site that could affect its safety.
- (2) The licensee shall ensure that the site characterization is focused on those features, events and processes relating to the site that could affect the safety of the radioactive waste management facility, as identified by the safety case.
- (3) The licensee shall ensure that the results of the site characterisation demonstrate an adequate geological, geomorphological or topographical stability of the site, the features and processes that shall contribute to safety, and that other features, events and processes will not undermine the safety of the facility.

3.5.10 Construction License from the safety and security radiation protection point of view

- a) After the completion of the site preparation activities, the licensee shall submit to RPC an application for a Construction License, which shall include:
- b) the Preliminary Safety Assessment Report;
- c) the preliminary design of the radioactive waste management facility;
- d) a synthesis of the site characterisation data;
- e) the execution programme for the construction works;
- f) the preliminary operational limits and conditions, including waste acceptance criteria, as resulted from the preliminary safety assessment;
- g) the initial decommissioning plan for predisposal facilities or the initial closure plan for disposal facilities;
- h) the preoperational monitoring programmes;
- i) the Quality Assurance programme for construction;
- j) an organisational procedure for the management of modifications;
- k) the revised conceptual security arrangements, in accordance with relevant regulations;
- l) the revised conceptual radioactive waste management programme;
- m) the revised conceptual radiation protection programme;
- n) an instrument of financial security for performance of all works related with the construction, operation, decommissioning or closure of the radioactive waste management facility including the coverage of long-term monitoring costs of a disposal facility after its closure.

3.5.11 Construction of radioactive waste management facilities

- (1) After receiving the Construction License, the licensee shall ensure the construction of the radioactive waste management facility in accordance with the preliminary design described in the safety case.
- (2) The licensees for construction of a radioactive waste disposal facility shall ensure that the disposal facility is constructed in such a manner as to preserve the safety functions of the host environment, as identified by the safety case to be important for post-closure safety.
- (3) The licensee shall perform any necessary verification tests of the construction.
- (4) RPC and National Council of Territory Regulation shall have the right to oversee the construction activities and to assist the verification tests.

3.5.12 Permission for commissioning

After the completion of the construction works, the licensee shall submit to RPC an application for Permission for commissioning, which shall include an updated safety case with the following content, as appropriate:

- a) the Pre-Operational Safety Assessment Report;
- b) the commissioning tests schedule;
- c) the testing procedures and the acceptance criteria for each system important to safety;
- d) an organisational procedure for the management of modifications;
- e) a list of the commissioning procedures;
- f) the operational limits and conditions, including waste acceptance criteria, as resulted from the pre-operational safety assessment;

- g) the decommissioning plan for predisposal facilities or the revised closure plan for disposal facilities;
- h) the results of the preoperational monitoring programmes at the time;
- i) the operational monitoring programmes;
- j) the Quality Assurance Programme for commissioning;
- k) the security arrangements, in accordance with relevant regulations;
- l) the radioactive waste management programme;
- m) the radiation protection programme;
- n) the emergency preparedness and response plan;
- o) the training and qualification programme for the staff with jobs important to safety.

3.5.13 Commissioning of radioactive waste management facilities

- (1) In order to obtain RPC's approval for the commissioning the licensee shall submit to RPC an application in accordance and a report providing evidence of the successful completion of the tests performed in the previous commissioning step, including a description of the tests performed and the schedule of the tests planned for the following commissioning step.
- (2) RPC shall have the right to oversee the commissioning activities performed by the licensee.

3.5.14 Completion of commissioning

- (1) After the completion of the commissioning operations, the authorization holder shall produce a final commissioning report to document the as-built status of the radioactive waste management facility.
- (2) The final commissioning report shall describe all the commissioning tests performed and shall present the results of the tests performed and any modification made to the radioactive waste management facility during the commissioning stage, in such a manner so as to demonstrate the compliance with all the conditions imposed by the Permission for commissioning.
- (3) The final commissioning report shall be maintained by the authorization holder up until the decommissioning or closure of the radioactive waste management facility, when it shall be used to develop the final decommissioning plan or closure plan.

3.5.15 Operation License

- (1) After the completion of the commissioning tests, the authorization holder shall submit to RPC an application for an Operation License, which shall include an updated safety case with the following content, as appropriate:
 - a) the Final Safety Assessment Report;
 - b) the final commissioning report;
 - c) the description of the as-built design of the facility;
 - d) documented evidence of the financial resources of the authorization holder to cover all the operational and decommissioning or closure and long term surveillance costs, as the case may be;
 - e) the programme for periodic maintenance, testing and inspection of the systems, structures and components important to safety;
 - f) a list of the operating procedures;

- g) the operational limits and conditions, including waste acceptance criteria, as resulted from the final safety assessment;
 - h) the revised decommissioning plan for predisposal facilities or the revised closure plan for disposal facilities;
 - i) the results of the preoperational monitoring programmes;
 - j) the revised operational monitoring programmes;
 - k) the revised radiation protection programme;
 - l) the Quality Assurance Programme for operation;
 - m) the revised emergency preparedness and response plan;
 - n) the revised radioactive waste management programme;
 - o) the conceptual post-closure plan for a disposal facility;
 - p) a programme for feedback of operational experience;
 - q) the revised security arrangements, in accordance with relevant regulations;
 - r) the revised training and qualification programme for the staff with jobs important to safety.
- (2) The validity of the Operation License shall be determined by the fulfilment of the terms and conditions established by RPC based on the results of the review of the safety case submitted by the authorization holder.

3.5.16 Operation of radioactive waste management facilities

- (1) The licensees shall ensure the operation of radioactive waste management facility in such a manner as to maintain safety during the operational period of the facility and, in case of a disposal facility, to preserve the safety functions shown by the safety case to be important after closure.
- (2) The licensee shall ensure that all activities and operations important to safety:
 - a) are subject to documented limits, conditions and controls;
 - b) are based on documented procedures;
 - c) are performed by trained, qualified and competent personnel.
- (3) The licensee shall establish and implement a program of periodic maintenance, testing and inspection of those systems which are important for safety, which shall be approved by RPC during the licensing process.
- (4) The licensee shall send to RPC for approval any other operating procedure required by RPC.

3.5.17 Waste acceptance criteria

- (1) The licensee shall accept in storage or disposal only radioactive waste complying with the waste acceptance criteria specified in the safety case of the facility and approved by RPC.
- (2) Waste acceptance criteria shall be specified for individual packages, storage or disposal units and for the storage or disposal facility as a whole.
- (3) The criteria for acceptance of radioactive waste in storage or disposal shall specify the limits for the following characteristics, as relevant:
 - a) radionuclide content and activity concentrations;
 - b) ambient gamma dose rate at contact and at 1 meter distance from the package surface;
 - c) surface contamination;
 - d) structural strength;

- e) leachability;
- f) corrosiveness;
- g) chemical stability;
- h) heat generation;
- i) degradation effects induced by radiation;
- j) flammability;
- k) gas formation and gas content;
- l) toxin content;
- m) content of organic substances with potential effect on microbiological degradation;
- n) free liquid content;
- o) presence of chelating or complexing agents;
- p) explosive properties;
- q) combustibility;
- r) corrosion resistance;
- s) criticality.

3.5.18 Non-compliance with waste acceptance criteria

The licensee shall make provisions for the safe management of radioactive waste which are approved by RPC. The waste acceptance criteria shall be in accordance with all radioactive sources in Albania. When the waste acceptance criteria fail to meet it is RPC decision for the case.

3.5.19 Monitoring programs

- (1) The licensee shall establish, implement and periodically review and update monitoring programs aiming to:
 - a) collect and update the necessary information for the safety assessments;
 - b) obtain the information to confirm the conditions necessary for the safety of the workers and members of the public and the protection of the environment during the operational stage of the facility;
 - c) confirm the absence of any conditions that could affect the safety after the shutdown and decommissioning of a predisposal facility or after the closure of a disposal facility, as the case may be.
- (2) The licensee shall establish and implement an environmental radioactivity monitoring program starting from the siting stage up until the decommissioning or closure stage of the facility, where applicable.
- (3) The licensee shall establish and implement, during the operational and decommissioning stage of the facility, programs for monitoring of radioactive discharges at the source.
- (4) The licensee shall establish and implement, during the operational stage of the facility, programs for monitoring the effectiveness of the radioactive waste containment systems.
- (5) In case of radioactive waste long-term storage facilities, the licensee shall establish and implement, during the operational stage of the facility, programs for monitoring the ageing related degradation of the radioactive waste containment systems.
- (6) All monitoring programmes shall be approved by RPC, during the licensing process of the radioactive waste management facility.

3.5.20 Periodic safety reviews

- (1) The licensee shall carry out periodic safety reviews, at least every ten years during the operational stage of the facility, and shall implement any safety upgrades required by RPC following such review.
- (2) The licensee shall submit the results of the Periodic Safety Review, documented in a report, to RPC, together with the updates of the documents as support documentation for continuous operation.
- (3) RPC shall have the right to revise the terms and conditions specified in the Operation License following the review of the support documentation for continuous operation.

3.5.21 Operation beyond design lifetime

- (1) Any licensee having the intention to operate a radioactive waste management the facility beyond its design lifetime shall:
 - a) re-evaluate the facility design, the operations, maintenance, ageing management and any other safety related aspects of the facility, as appropriate; and
 - b) update the safety case and its supporting safety assessment in order to evaluate the impact of the proposed extended operation of the facility on safety, taking into consideration the ageing related degradation of the facility and its systems, structures and components important to safety.
- (2) The licensee shall submit to RPC, before the end of the design lifetime of the facility, an application in accordance with Article 43, which shall include the updated safety case as specified in paragraph (1) with the following content, as appropriate:
 - a) a justification for the proposed extension of the facility design lifetime, supported by the results of the updated safety assessment demonstrating, with due consideration of the ageing of structures, systems and components important to safety, that sufficient safety margins will be maintained;
 - b) the latest Periodic Safety Review report;
 - c) the safety upgrades implemented during the operational stage of the facility;
 - d) the results of all operational monitoring programmes;
 - e) updates of all documents specified.
- (3) In addition, RPC may require the licensee to:
 - a) assess the integrity of the stored radioactive waste packages, through testing and examination;
 - b) submit a plan with the necessary measures to mitigate the consequences of the potential changes into the stored radioactive waste, including the following:
 - the generation of hazardous gases;
 - the generation of combustible or corrosive substances;
 - the corrosion of metals;
 - the degradation of the radioactive waste containment system.
- (4) RPC shall, upon review of the documents required under paragraphs (2) and (3), make a decision on issuing a license to operate the predisposal facility beyond its design life, for the duration requested in the application or as determined by RPC.

- (5) RPC may revise the terms and conditions specified in the Operation License following the review of the support documentation for operation beyond design lifetime.

3.5.22 Decommissioning of predisposal facilities

The decommissioning of radioactive waste predisposal facilities shall be carried out by the licensee on the basis of the final decommissioning plan approved by RPC and in accordance with the limits and conditions imposed by RPC under the Decommissioning License.

3.5.23 Records of radioactive waste

- (1) The authorization holders who store, temporarily or on long term, condition or dispose of radioactive waste, or who discharge radioactive effluents, shall keep records of radioactive waste, including information about the following aspects, as appropriate:
 - (a) its temporary storage;
 - (b) its conditioning process;
 - (c) its storage;
 - (d) its disposal;
 - (e) its discharge;
 - (f) its clearance;
 - (g) its transfer.
- (2) For each package or item in storage or disposal or under conditioning, the records specified in paragraph (1) shall include information on the management history, information relevant for acceptance in storage or disposal or for further management steps, as appropriate, in accordance with Annexes of regulation.
- (3) For each radioactive discharge, the records prescribed in specified in paragraph (1) shall provide, as a minimum, information on the discharge route, the quantity of the radioactive waste discharged and information showing compliance with the authorised discharge limits, as specified in Annexes of regulation.
- (4) For each package or item cleared or transferred to an off-site radioactive waste management facility, or to another person authorized for recycle or reuse, or returned to the supplier, as appropriate, the records specified in paragraph (1) shall include, in addition to the information specified in paragraph (2), the date and location of transfer, in accordance with Annexes of regulation.
- (5) The authorization holder shall retain the records on radioactive waste during the operational and decommissioning stage of the facility.
- (6) In case of winding-up or liquidation, the authorization holder shall transfer the records on radioactive waste to the receiver or liquidator and shall notify accordingly RPC.
- (7) The licensees operating a radioactive waste disposal facility shall retain information on the radioactive waste disposed of at the facility during the whole period of the long-term surveillance of the facility.

3.5.24 National register of radioactive waste

- (1) A national register of radioactive waste shall be maintained by RPC.

- (2) The national register shall keep information on radioactive waste:
 - (a) in the possession or control of all holders;
 - (b) having been discharged into the environment;
 - (c) having been released from the regulatory control;
 - (d) having been transferred;
 - (e) having been returned to the supplier;
 - (f) having been sent abroad for treatment or permanently exported.
- (3) The national register shall also keep information on annual predictions of radioactive waste generation expected during operation and decommissioning of all facilities generating radioactive waste.
- (4) The national register shall be updated annually, based on the information sent by the authorization holders.

3.5.25 Reporting of information on radioactive waste

The authorization holders shall submit to RPC the forms given in Annexes of regulation as appropriate, filled in with the data as of 31 December of each year of operation.

3.5.26 Notification and report of unauthorized discharges

- (1) In the event of unauthorised discharges or discharges exceeding the authorized limits or conditions, the authorization holder shall take the following measures:
 - (a) notify RPC not later than twenty four hours;
 - (b) take all the necessary measures to stop the discharge, if possible;
 - (c) submit a complete report to RPC within thirty days after the notification.
- (2) The report specified in point (c) of paragraph (1) shall include the following information:
 - (a) a description of the incident;
 - (b) a characterization of the discharge including the discharge route, discharge point, total activity, radionuclide content, discharged quantity and volume, chemical and physical form;
 - (c) the possible radiation exposure of individuals, circumstances under which the exposures may occur, and the extent of potential hazard to members of the public;
 - (d) the actions which have been taken to stop the discharge;
 - (e) the measures which have been or shall be taken to prevent a recurrence of similar events;
 - (f) any other information as deemed necessary by the authorization holder or requested by RPC.

3.5.27 Notification and report of loss, theft or sabotage

- (1) The authorization holders shall, upon discovering any theft, loss or sabotage of any radioactive waste in their possession or under their control take the following measures:
 - (a) notify RPC of such theft, loss or sabotage within twenty four hours after discovering the theft, loss or sabotage;
 - (b) take actions to recover the radioactive waste and secure the facility if necessary;
 - (c) submit a complete report to RPC within thirty days after the notification.

- (2) The report specified in point (c) of paragraph (1) shall contain the following information:
 - (a) a description of the radioactive waste, including its class, quantity, chemical and physical form;
 - (b) a description of the circumstances under which the theft, loss or sabotage occurred;
 - (c) a statement of the location or probable location of the radioactive waste;
 - (d) the possible radiation exposure to individuals, circumstances under which the exposures may occur, and the extent of potential hazard to members of the public;
 - (e) the actions which have been taken, or will be taken, to recover the radioactive waste;
 - (f) the procedures or measures which have been or will be adopted to prevent a recurrence of similar events;
 - (g) any other information as deemed necessary by the authorization holder or requested by RPC.
- (3) Any person who discovers radioactive waste out of control shall immediately notify RPC who shall take all the necessary measures to restrict the access of the public to the area.

3.5.28 Transitional provisions

- (1) The holders of authorizations for activities or facilities generating radioactive waste, valid at the time of entry into force of these amended Regulations shall comply with the new requirements within two years starting from the date of entry into force of these amendments.
- (2) The licensees operating radioactive waste management facilities at the time of entry into force of these amended Regulations shall review the safety of the facility in order to verify the compliance with the new requirements, within two years starting from the date of entry into force of these amendments.
- (3) Safety related upgrades shall be made by the licensees operating radioactive waste management facilities, if so determined by RPC following the safety review specified in paragraph

Regulation on “Safe Management of Radioactive Waste in Republic of Albania” No.638, date 7.9.2016 has 6 annexes which includes the information below.

3.5.29 Clearance criteria

Radiation risks arising from the cleared material are sufficiently low so as to not warrant regulatory control.

Material may be accepted without further considerations, in conditions that in all reasonably foreseeable situations the effective dose expected to be incurred by any member of the public due to the cleared material is 10 μ Sv or less in a year.

Table I. Levels for clearance of solid material without further consideration - activity concentrations of radionuclides of artificial origin

Table II. Levels for clearance of solid material without further consideration - activity concentrations of radionuclides of natural origin

3.5.30 Radioactive waste classification

Class	Description
Cleared Waste (CW)	Radioactive waste that meets the criteria for clearance specified in Annex I.
Very Short Lived Waste (VSLW)	Radioactive waste containing only radionuclides with very short half-lives (less than 100 days generally) with activity concentrations above the clearance levels, but that can be stored for decay over a limited period of time (up to few years), for subsequent clearance. Typical examples: radioactive waste generated from research medical and industrial applications of short-lived radionuclides.
Very low level waste (VLLW)	Radioactive waste containing low levels of activity concentrations (slightly above the clearance levels) and very limited concentrations of longer lived radionuclides, but which does not need a high level of containment and isolation (being suitable for disposal in near surface landfill with limited regulatory control). Typical examples: soil and rubble originating from the operation and decommissioning of nuclear facilities, waste containing naturally occurring radionuclides originating from mining or processing of ores or minerals.
Low Level Waste (LLW)	Radioactive waste containing such an amount of radioactive material that robust containment and isolation for limited period of time (up to few hundred years) are required; such waste is suitable for disposal in near surface repositories (up to 30m from the surface). LLW may contain 400 Bq/g in average for long-lived alpha-emitting radionuclides (half-life exceeding 30 years) and up to 4000 Bq/g for individual packages.
Intermediate Level Waste (ILW)	Radioactive waste containing long-lived radionuclides requiring disposal at intermediate depths (from tens to few hundred of meters), with no or only limited provision for heat dissipation.
High Level Waste (HLW)	Radioactive waste with high activity concentrations generating significant decay heat or with large amounts of long lived radionuclides, necessitating disposal in deep, stable geological formations (several hundred meters or more below the surface). Typical examples: fresh spent fuel from power reactors, conditioned waste from reprocessing of spent fuel, with activity concentrations in the range of 10^4 - 10^6 TBq/m ³ .

3.5.31 Radioactive waste inventory form

#	Data	Type
1	Authorization holder	The name and address of the authorization holder
2	Facility	The name and address of the facility where the radioactive waste is located
3	License	The number and the type of the holder's authorization

4	Package/item ID	The unique identification number of the radioactive waste package or item (in case of unpacked radioactive waste)
5	Location	The exact location (building, room, area) of the package or item within the facility
6	Category	The category of radioactive waste, according to the operational classification
7	Type	Short description of relevant properties of radioactive waste
8	Generated	Date of generation of radioactive waste
9	Producer	The name and address of the radioactive waste producer, if different from the reporting authorization holder
10	Packaging	The approved type of packaging or the description of the item (in case of unpackaged radioactive waste)
11	Mass	Package or item mass (kg)
12	Volume	Package or item volume (m ³)
13	Conditioning	Conditioning process performed or needed to be performed
14	Radioactive contamination	Measured value of surface contamination of the package or item (Bq/cm ²)
15	Ambient dose rate	Maximum value of dose rate measured at contact with the package or item and at 1m distance from the package or item (Sv/h)
16	Total activity	Activity of the radioactive waste (Bq)
17	Radionuclide inventory	A list of the radionuclides and their activity concentrations (Bq/unit mass), identified by measurement at the date

3.5.32 Radioactive waste discharge form

#	Data	Type								
1	Authorization holder	The name and address of the authorization holder								
2	Facility	The name and address of the facility discharging radioactive effluents into the environment								
3	License	The number and the type of the holder's authorization								
4	Type of discharge (thick the appropriate box)	<table> <tr> <td>Liquid</td> <td><input type="checkbox"/></td> <td>Airborne</td> <td><input type="checkbox"/></td> </tr> </table>	Liquid	<input type="checkbox"/>	Airborne	<input type="checkbox"/>				
Liquid	<input type="checkbox"/>	Airborne	<input type="checkbox"/>							
5	Discharge route (thick the appropriate box)	<table> <tr> <td>Atmosphere</td> <td><input type="checkbox"/></td> <td>Sewage system</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Water body</td> <td><input type="checkbox"/></td> <td>Other (please indicate)</td> <td><input type="checkbox"/></td> </tr> </table>	Atmosphere	<input type="checkbox"/>	Sewage system	<input type="checkbox"/>	Water body	<input type="checkbox"/>	Other (please indicate)	<input type="checkbox"/>
Atmosphere	<input type="checkbox"/>	Sewage system	<input type="checkbox"/>							
Water body	<input type="checkbox"/>	Other (please indicate)	<input type="checkbox"/>							
6	Discharge point (thick the appropriate box)	<table> <tr> <td>Ventilation stack</td> <td><input type="checkbox"/></td> <td>Other (please indicate)</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Discharge channel</td> <td><input type="checkbox"/></td> <td></td> <td></td> </tr> </table>	Ventilation stack	<input type="checkbox"/>	Other (please indicate)	<input type="checkbox"/>	Discharge channel	<input type="checkbox"/>		
Ventilation stack	<input type="checkbox"/>	Other (please indicate)	<input type="checkbox"/>							
Discharge channel	<input type="checkbox"/>									
7	Duration	Start of the discharge – end of the discharge								
8	Quantity	Discharged volume (m ³)								
9	Total activity	Total activity discharged in one year (Bq)								
10	Radionuclide inventory	A list of the radionuclides discharged, their activity concentrations (Bq/unit mass), their share to the total activity (%) and their quotient (discharged activity/authorized limit)								

3.5.33 Radioactive waste transfer form

#	Data	Type
1	Authorization holder	The name and address of the authorization holder
2	Facility	The name and address of the facility from where the radioactive waste has been transferred or cleared
3	License	The number and the type of the holder's authorization
4	Package/item ID	The unique identification number of the radioactive waste package or item (in case of unpacked radioactive waste)
5	Category	The category of radioactive waste, as per operational classification
6	Type	Short description of relevant properties of radioactive waste
7	Packaging	The approved type of packaging or the description of the item (in case of unpackaged radioactive waste)
8	Mass	Package or item mass (kg)
9	Volume	Package or item volume (m ³)
10	Conditioning	Conditioning process performed (if any)
11	Radioactive contamination	Measured value of surface contamination of the package or item (Bq/cm ²)
12	Ambient dose rate	Maximum value of dose rate measured at contact with the package or item and at 1m distance from the package or item (Sv/h)
13	Total activity	Activity of the radioactive waste (Bq)
14	Radionuclide inventory	A list of the radionuclides and their activity concentrations (Bq/unit mass), identified by measurement at the date.....
15	Date of transfer	The date when the radioactive waste package or item has been removed from the facility
16	Transfer type (thick the appropriate box)	clearance
		Reuse
		recycle
		treatment
		storage
		disposal
		Return
		other
		(please describe)
17	Transfer destination	The name and address of the receiver of the radioactive waste package or item
18	Approval	The number and the date of the approval for clearance or transfer, issued by RPC

3.6 Management of Orphan Sources

The scrap metal industry is problematic for illicit trafficking of nuclear and other radioactive materials, as radioactive sources have been found in scrap metal all over the world. It is estimated that there are approximately 100 scrap yards in Albania. The Kurum international (Sh.p.k) Ltd it has an annual production capacity of 550,000 tons for rod structural iron and 400,000 tons for liquid steel. While most of the raw materials required by the smelter installations are acquired from the domestic market, growing capacity also necessitates scrap imports from

abroad. RPM is currently installed at Kurum international. In the meantime, each truck undergoes a check for radiation before being authorized in the smelter and prior to the weighing process. There are two teams on IANP which perform control of scrap in Tirana Custom and Durrës Port. The entrance point of Albania has different type of equipment's for radiation monitoring. Some of them are equipped with radiation portal monitors and some of them with pagers and handheld equipment's. If there is found any orphan sources on scrap IANP is responsible for taking, transporting and putting in safe and secure condition at IANP premises.

3.7 Management of Disused Consumer Goods Containing Small Amounts of Radioactive Substances

Ionizing chamber smoke detectors (ICSD) are not used in Albania. Consumer goods as watches, compasses, fishing floats, etc, containing radio luminescent paintings or other consumer goods containing radioactive substances, as technical porcelain, optical glasses are not allowed to enter in Albania.

Regulation No. 801 date 11.12.2019 article 43, for consumer products, describes regulatory aspects related to these products as below:

1. Providers of consumer products ensure that consumer products are not available to the public, unless their use by members of the public has been justified, and their use is excluded, or their supply to the public is authorized.
2. Providers of consumer products ensure that consumer products are not available to the public, unless the rationale for their new use by members of the public is approved by the Radiation Protection Commission, or their use is excluded based on the criteria of the legislation in force, or their provision to the public is authorized.
3. After receiving a request for authorization to offer consumer products to the public, the Radiation Protection Commission:
 - a) requires the provider of the consumer product to provide documents to demonstrate compliance with the requirements;
 - b) verifies the evaluations and selection of parameters presented in the request for authorization;
 - c) determines whether the final use of the consumer product can be excluded;
 - c) authorizes the provision to the public of consumer products, when appropriate, subject to the specific conditions of authorization.
4. Provider of consumer products:
 - a) will respect the conditions of authorization to offer consumer products to the public;
 - b) ensures that consumer products comply with the requirements of this regulation;
 - c) will plan for the appropriate measures for service, maintenance, recycling or disposal of consumer products.
5. The design and production of consumer products, in cases that may affect exposure during normal handling, transport and use, as well as in case of misuse, accidents or destruction, will be subject to the optimization of protection and safety. In this regard, designers, manufacturers and other providers of consumer products will take into account:
 - a) different radionuclides that can be used in consumer products and their types of radiation, energy, activity and decay;
 - b) chemical and physical forms of radionuclides that can be used in consumer products and their importance for protection and safety in normal and abnormal conditions;

- c) control, protection of radioactive substances in consumer products as well as access to them under normal and abnormal conditions;
- ç) the need for service or repair of consumer products and the ways in which these can be realized;
- d) related experience with similar consumer products;
- 1. Providers of consumer products ensure that:
 - a) when possible, a legible label is placed on a visible surface of each consumer product that:
 - i. indicates that the consumer product contains radioactive substances and identifies radionuclides and their activities;
 - ii. the consumer product for the public is authorized by the regulatory body;
 - iii. provides information on required or recommended options for recycling or disposal.
 - b) the information specified in point (a) above is also valid for retail packaging consumer product
- 2. Providers of consumer products provide clear and appropriate information and instructions for each product of the consortium regarding:
 - a) installation, use and maintenance of the consumer product;
 - b) service and repair;
 - c) radionuclides and their activities on a certain date;
 - ç) dose rate in normal operation and during service and repair;
 - d) requested or recommended opportunities for recycling or disposal.
- 3. Providers of consumer products provide retailers of consumer products with appropriate safety information as well as instructions for their transportation and storage.

4. SECTION C: SCOPE OF APPLICATION (ARTICLE 3)

The present report applies to the safety of the management of radioactive waste resulting from civilian applications (and some from military use in the past) and containing artificial radionuclide exceeding the regulatory clearance levels for the unconditional release.

As Albania has no nuclear fuel cycle, the present report does not apply to the safety of spent fuel management.

5. SECTION D: INVENTORIES AND LISTS (ARTICLE 32.2)

The inventories of the radioactive wastes stored up to July 2024 at IANP (national radioactive waste interim storage) Annex I.

The relevant regulation attributes the responsibility to the RPO for maintaining a national database of all radioactive sources above exemption level. This includes radioactive wastes. Licensees have to notify the RPC of any modification of their inventory. The database contains information about the type, activity and registration number of the sources.

6. SECTION E: LEGISLATIVE AND REGULATORY SYSTEM

6.1 Article 18: Implementing Measures

The legislative and statutory framework for radiation safety in Albania has been established through the Radiation Protection Act No. 8025, 1995 and the amendment of the Law No. 8025 promulgated on July 2008 as Law No. 9973. With this legislative framework the most outstanding

issues were addressed, such as numerous recommendations by RASSIA, EPREV and IPPAS. The current legislation is almost in line with the EU Acquis. In May 2016 Albania had IPPAS mission, who assessed everything regarding the physical protection of radioactive sources in Albania, comparing them with international best practices as well as to give recommendation in order to improve and strengthen the national system, and also to integrate much more the other institutions which are part of the security issues. The main elements assessed during the mission were:

- Government organization: competent authorities and their security responsibilities;
- Physical protection legislation;
- Regulations;
- Licensing and inspections;
- Integration of other organizations; and
- Facility implementation of physical protection measures.
- Staff training and related human resources development;
- Development of physical protection regulations and laws; and
- Improvement of physical protection systems.

The existing Decision of Council of Ministers, Regulations and Codes of Practice address occupational, public and medical exposure control, dose limits, transport, security, authorization, inspection, sanctions, limits on food and construction materials, radon concentration, import/export, categorization of radioactive sources, waste management and emergency situations. Codes of Practice cover some of the main practices and facilities in Albania but not all. For the moment the RPC is working toward approximation of Albanian legislation to EU directives. All set of regulation which are in force are approved by Council of Ministers reviewed in line with EU directives, as well as IAEA requirements. A regulatory program for all facilities for safety and security of radioactive sources is in place and regulatory control concerning security take into account three security group.

Law No.8025, reviewed in 2008 and 2013, establishes the Radiation Protection Commission (RPC) as the regulatory body for radiation safety and the security of radioactive sources. With new an amendment is increased the effective independence of regulatory Body. Members are without conflict of interest and are appointed by Council of Ministers. The Radiation Protection Office (RPO) is RPC's Executive Body with 9 staff members. The distribution of responsibilities among organizations in Albania is well defined. There is no overlap but also no gaps in coverage by relevant organizations. National Agency of Civil Protection under the Ministry of Defense is identified as main agency responsible for emergency preparedness and response. RPC, IANP have advisory role on the process. Existing continuous educational and training programs in Albania established by decision of RPC in December 2009 adequately serve the requirements of agencies involved in regulation or those of the users of ionizing radiation.

National coordination and cooperation has been established. There is a clear definition of the scope of roles and responsibilities of the RPC in relation to other agencies and TSO which have an involvement in the regulatory process of radiation safety but not fully to security of radioactive sources. The Republic of Albania has assigned the memorandum of understanding on radiation safety, early notification and exchange of information with Bosnia and Herzegovina and Kosovo, also has in process, with North Macedonia,

6.1.1 Activities of the Regulatory Authority

The authorization and inspection system was established in 2000.

The authorization process in Albania is regulated with the Regulation No.10, date 07 January 2010 for "Licensing and inspection of activities with sources of ionizing radiation ". which is amended in 20.12.2023.

Attached of this regulation are 7 application formats for license as below:

- 1-Application for license for the activities with radioactive sources, (storage and treatment).
- 2-Application for license for the activities with radioactive sources, (use).
3. Application for license for the activities with radioactive sources, (transport).
4. Application for license for the activities with x ray generators, (use).
5. Application for license for the activities with radioactive sources, (import-export).
6. Application for license for the activities with x ray generators/ x ray tube, (import-export).
7. Application for license for the activities with x ray generators, x ray tube (installation and maintenance).

„ There is established a process for the authorizations. The authorization is preceded by notification. The application formats requires the details of the radiation sources, the purpose of use, the radiation protection measures regarding optimization, justification, dose limits, shielding calculation and radiological emergency measures. Particular information is required on the qualifications and work experience of the radiation protection officer and staff. The requirement is that except of training in the radiation protection field, staff is subject to test the knowledge obtained in the training. RPC has recognized the Institute of Applied Nuclear Physics to perform this process for all categories. There are also other private Institutions recognized by RPC to perform the training programme on ionizing radiation protection.

The system for assessment of the applications for license is based on current IAEA recommendations. There are clear procedures on application, assessment of application up to issue the license. There are established procedures on assessment of preparation of report on application for license.

The RPC's programme of approval for the import, export and transit of radioactive sources appears to be consistent with the Code of Conduct's "Guidance on the Import and Export of Radioactive Sources", including security of sources.

There are established procedures for applications assessment and issuing the license. The authorizations are currently renewed every 10 year. Authorization process is based on a system of source categorization and risk coming from practice and appears to be appropriate to the current regulatory requirement for Albania. From January 2020 up to July 2024, Radiation Protection Commission has issued in total 326 licenses.

The RPC has established procedures designating different levels of safety and security based on source categorization and have a graded approach to the security based on security group

A, B, C. Based on the regulation on physical protection, RPC has taken the appropriate measures to ensure that all radioactive sources of categories 1, 2 and 3 are registered, controlled and securely protected during and at the end of their useful lives.

The inspection process has been established taking into account the procedures for inspection and sanctions. An inspection program has been established and it is fully implemented. Legislation and regulations make provision for enforcement, including penalties, sanctions and the actions and responsibilities of inspectors; however, the enforcement policy of the RPC has been implemented recently. There is a regulation on functioning of RPC and RPO, which has general issues concerning quality management system.

From 2015, RPO has cooperated with the Central Inspectorate and the Inspectorate of Health. Cooperation with Central Inspectorate has consisted in adapting of all the existing documentation in accordance with the law 10433, dated 16.06.2011 on Inspection in the Republic of Albania and to implement them during e-inspection process.

Annual programme for inspection of the activities with ionizing radiation sources, approves by the General Inspectorate and Radiation Protection Commission. Annual inspection programme is prepared taking into account the risk of ionizing radiation sources as well as the past performance of the licensee. Based on this is defined the frequency of the inspection. The frequency for inspection of the IANP, waste management facility is defined every year.

RPC has established and implement a security inspection programme to verify that the physical protection of radioactive sources is effectively maintained and the management of the radioactive sources is done according to the regulation on security. RPC has approved the check list on security of radioactive sources.

6.2 Article 19: Legislative and Regulatory Framework

Radiation Protection, safety and security in the Republic of Albania, is regulated by the law "On protection from ionizing radiation" No. 8025, dated 9.11.1995, amended in July 2008 and March 2013. This law, is in accordance with EU directive 96/29 and BSS No. 115 and especially the subject of law is fully compliant. Radiation protection law provides an effective independence of regulatory Body, which was reinforced with amendments, where the Radiation Protection Commission members are nominated by the Council of Ministers without conflict of interest with users.

- Law No. 8025, dated 9.11.1995 includes security and safety of radiation sources, duties and functions of Regulatory body, regulatory responsibilities, the way of the completion of legislation in the field of radiation protection, duties of office for radiation protection. This law also provides for the licensing of all activities and practices related to ionizing radiation as defined in relevant regulations. Law also opens the way to full inspection process and sanctions. The law has four basic pillars such as legislation, licensing, inspection and sanctions that are fully defined in law. The amended law took into consideration elements as security of source, increasing the independence of regulatory body, increasing the level of adoption of relevant regulations through decisions of Council of Ministers, RPO is responsible to keep the national inventory of ionizing radiation. Radiation Protection Commission since 2004 is working toward implementation of the "Code of Conduct on Safety and Security of Radioactive Sources" IAEA.

Last year Albania has submitted to the IAEA a political commitment related with the Guidance on safe management of DSRS.

Albania has implemented the process of the import and export of radioactive sources through the Decision No. 158, dated 13.02.2008 “On import /export of radioactive materials in the Republic of Albania”, approved by Council of Ministers. The law 8025, covers only the activities and practices with radioactive sources and X-ray generators.

The National Regulatory Authority in Albania is Radiation Protection Commission. NRA in Albania has two levels, Radiation Protection Commission (RPC) is Decision maker and Radiation Protection Office (RPO) is executive and inspection body of the Radiation Protection Commission. Based on Article 7, Law No.8025, dated 9.11.1995, RPC has rights and duties to:

- Prepare regulations, guidance and codes of practice related to protection from ionizing radiation and nuclear safety, obligatory to be implemented by the legal and physic users.
- Control the implementation of the legal and other acts related to protection from ionizing radiation
- Issue license to the subjects that follow the practices as foreseen in the Article 3 of this Law.
- Guide, from the technical point of view, all the national and local authorities to proceed immediately following the steps to reduce the effects of nuclear accidents.
- Recommend and proposes for the improvement of the legislation in power.
- Approve the standards of the safety from radiation.
- Coordinate the work with specialized institutions, for the calibration of ionizing radiation devices, personal dosimetry, environmental monitoring, medical control of the workers professionally exposed, training of the staff by independent experts for activity with ionizing radiation, and with other institutions, according to the needs, based on the memorandum of understanding to solve national problems in the field of radiation protection.
- Determine the organizational structure of the radiation protection office, and appoints and dismisses its leader.
- Cooperate with the State Labor Inspectorate and with the Inspectorate who cover the field of health.

One of the main objectives of the amended Law No. 8025, dated 9.11.1995 is to increase the independence of regulatory body. Article 6, of the amended Law defines that “Composition, organization, operation and method of remuneration of members of the Radiation Protection Commission is determined by decision of the Council of Ministers”.

Based on the Decision No.123, dated 5.3.2014 of Council of Ministers “For the establishment, composition and form of organization, operation, remuneration of the Radiation Protection Commission” the RPC has 6 non-permanent members and 5 experts from different Ministries, departments and organizations. Members come from different Ministries and Agencies. The Secretary of the RPC is the Chairman of Radiation Protection Office. The mission statement of the RPC is “to provide for the safe & secure use of radiation sources and to protect people and the environment against potential harmful effects, for now and future simultaneously ensuring to community the maximum benefit from use of radiation sources”.

The regulatory body functions as independent body, but the regulatory independence from financial point of view, as well the small number of staff of Radiation Protection Office remains problems to be solved.

The existing legislative framework for radiation safety and source security includes the:

- Radiation Protection Law, No.8025, date 9.11.1995
- Amended Radiation Protection Law (approved by the Parliament), No.9973 date 28.7.2008

The Albanian parliament also has approved the amendments as Law No 26/2013 “On some amendments in the Law 8025, date 09.11.1995 “On ionizing radiation protection”, amended” enforcing more inspection process to Radiation Protection Commission. Amendments of the Law on radiation protection have been in progress to bring it in line with European legislation.

RPC has prepared a full set of regulations that cover the area of security, safety and radiation protection to ionizing sources as follows:

-Decision No.403 date 19.06.2024 of Council of Ministers for the approval of the Regulation on "Permitted levels of radionuclides in the water for human consumption for the protection of public health", in line with the Council Directive 2013/51/Euratom of 22 October 2013 laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption (OJ L 296, 7.11.2013, p. 12),

- Decision No.1005 dt. 09.12.2020 of Council of Ministers for the approval of the Regulation “On the safe process of decommissioning of the objects that perform activities with radioactive materials”.

- Decision No.801 dt.11.12.2019 of Council of Ministers for the approval of the Regulation “On the public protection and employees professionally-exposed to ionizing radiation and safety from medical exposers with ionizing radiation, in line with IAEA document GSR part 3 and EU BSS, Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionizing radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L 13, 17.1.2014, p. 1)

- Decision No. 700, dated 21.11.2018 of Council of Ministers for the approval of the Regulation "On preparation and response in cases of radiological emergency, for the protection of workers and public"

- Decision No. 815, dated 16.11.2016 of Council of Ministers for the approval of the Regulation "On safe transport of radioactive materials", in compliance with IAEA document SSR-6 and ADR law.

- Decision No.638, dated 7.09.2016 of Council of Ministers for the approval of the regulation "On safe management of radioactive waste in the Republic of Albania", partly in compliance with Directive 2013/59/EURATOM, laying down basic safety standards for protection against the dangers arising from exposure to ionizing radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom and with IAEA documents.

- Decision No.957, dated 25.11.2015 of Council of Ministers for the approval of the regulation “For guidance levels for radon concentration indoor and the concentration of radio nuclides in goods, to protect the public”, partly in compliance with Directive 2013/59/EURATOM, laying down basic safety standards for protection against the dangers arising from exposure to ionizing radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.
- Decision No.877, dated 30.10.2015 of Council of Ministers for the approval of the regulation “On the security of radioactive sources in Republic of Albania”,
- Order No 435, dated 14.10.2015 of Minister of Health for approval of the document on “Strategic steps for the safe management of radioactive waste in Republic of Albania”.
- Order No 434, dated 14.10.2015 of Minister of Health for approval of the document on “Education and training for protection and safety from ionizing radiation and steps for implementation”.
- Decision No 404, dated 18.06.2014 of Council of Ministers for approval of the regulation “The basic rules of the radiological installations in medicine”, in compliance with IAEA documents.
- Decision No.123, dated 5.3.2014 of Council of Ministers “For the establishment, composition and form of organization, operation, remuneration of the Radiation Protection Commission”.
- Policy on safe management for the radioactive waste in the Republic of Albania, No.1319/3, date 25.03.2013.
- Decision No. 229, dated 20.03.2013 of Council of Ministers for approval of the regulation "On safety to medical exposures with ionizing radiation sources", partly in compliance with Directive 97/43 / EURATOM of 30 June 1997 " On health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom". This regulation defines the conditions for protection in medical exposures to ionizing radiation sources, and requirements in relation to medical exposure in planned exposure situations, that include exposures from incidents with these kinds of sources.
- Decision No.313, dated 09.05.2012 of Council of Ministers for the approval of the regulation “On public protection from the discharges in environment, determination of the sampling, regions and measurements frequency”, partly in compliance Euratom Treaty and the Commission Recommendation of 8 June 2000 “On the application of the Article 36 of the Euratom Treaty concerning the monitoring of the levels of radioactivity in the environment for the purpose of assessing the exposure of the population as a whole”.
- Decision No.10, dated 7.01.2010 of Council of Ministers for the approval of the Regulation "On licensing and inspection of activities with ionizing radiation sources ", partly in compliance with EC 96/29 EC Euratom, " laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation. ", amended in 20.12. 2023
- Decision No.9, dated 7.01.2010 of Council of Ministers for the approval of the Regulation "On the categorization of radioactive sources in the Republic of Albania in function of radiation protection, safety and security of ionizing radiation sources", in compliance with IAEA documents.
- Decision No. 158, dated 13.2.2008 "On the import / export of ionizing radiation sources in Republic of Albania”, in compliance with Guidance of import/exports of IAEA, IAEA/CODEOC/IMP-EXP/2005.
- RPC adopted a declaration in support of "Code of Conduct on Safety and Security of Radioactive Sources" IAEA No. 1388, dated 14.04.2004 and a letter was sent, and the Director

General of ANEA stressing the fact, that Albania is working towards the implementation of this Code.

- Guidance on import export and transit of radioactive sources of category 1 and 2 in Republic of Albania. No. 134, dated 12.4.2011.

Albania last year has submitted to the IAEA a political commitment related with the Guidance on safe management of DSRS

Radiation Protection Commission in order to provide more support in the process of implementation of obligations in the protection from radiation has adopted a set of codes and practices.

6.3 Article 20: Regulatory Body

The legislative and executive competence in the field of radiological safety, security and radiation protection is attributed to the radiation protection Commission (RPC). The RPC is responsible for enforcing radiation protection legislation. The RPO, placed under the authority of RPC, is the designated as executive regulatory body. Similarly, to a number of other small countries, the RPO centralizes as a single department covering all issues on radiation protection, safety and security. All activities and projects of the RPO are financed via state budget. The RPO is composed of 9 members, specialized in radiation protection.

7. SECTION F: OTHER GENERAL SAFETY PROVISIONS

7.1 Article 21: Responsibilities of the License Holder

According to regulation in force there are clear provisions on responsibility of license holders Regulation No.638, date 7.9.2016 “On the safe management of radioactive waste in the Republic of Albania” in article 3 (d) define Responsible structure for the safety and security of radioactive waste as below:

1. The holders of authorizations for activities and facilities generating that radioactive waste,
2. The prime responsibility for the safety of radioactive waste management facilities shall rest with the licensee operating that facility and it shall not be delegated.
3. The Radiation Protection Commission (RPC) shall define the national policy for radioactive waste management, in collaboration with the other competent authorities of Albania.

RPC shall establish a national programme and steps for the implementation of the radioactive waste management policy.

The obligation of the user of the source for the treatment of the waste:

Users of radioactive sources during the process of authorizations to get the license for their activities are obliged to inform RPC how they will treat the radioactive waste generated from this source (if any) or what they will do with spent sources. For radioactive sealed sources the return to the producer (or supplier) must be foreseen. In case when return to producer is not foreseen, as well as in all other cases when the treatment of the waste is done by IANP, the user is obliged to have a contract with IANP in which will be defined technical and financial aspects.

A copy of this contract must be documented in the application for license that the user presents at the Radiation Protection Commission.

Regulation No.801 dt.11.12.2019, article 11 specifies the responsibilities of Licensees in planned exposure situations.

1. Licensees are responsible for protection and safety in planned exposure situations.
2. Licensees are responsible for establishing and implementing technical and organizational measures that are necessary for protection and security for the practices and resources for which they are authorized. Licensees may appoint suitably qualified persons to perform duties related to these responsibilities, but they retain primary responsibility for protection and safety. The licensees will document the names and responsibilities of the persons designated to be insured compliance with the requirements of this regulation.
3. Licensees notify the Radiation Protection Commission of any modification of practice or source for which they are authorized, whenever the changes may have important consequences for protection and safety, and they will not carry out any such modification, unless they are authorized by the Radiation Protection Commission.
4. Licensee:
 - a) Will create clear lines of responsibility for protection and security for the resources for which they are authorized, and will create organizational measures for protection and security;
 - b) Ensures that every delegation of responsibilities by a main party is documented;
 - c) For the resources for which they are authorized and for which a security assessment is required, to make such a security assessment and keep it updated.
 - ç) For the sources for which they are authorized and for which the Radiation Protection Commission requests that a future assessment be made for radiological environmental impacts, to carry out such an assessment in cooperation with at least one environmental expert, certified by the responsible ministry for the environment and update it;
 - d) It will evaluate the likelihood and magnitude of possible exposures, their possible consequences and the number of individuals who may be affected by them;
 - dh) There will be established operating procedures and measures for protection and security that are subject to periodic review and updating under a management system;
 - e) Establish procedures for reporting and learning from accidents and other incidents;
 - e) Establish measures for the periodic review of the overall effectiveness of protection and security measures;
 - f) Ensures that maintenance, testing are performed as needed so that the resources remain capable of meeting their design requirements for protection and safety throughout their life.
 - g) It will ensure the safe administration and control of all radioactive waste that are produced, and will dispose of these wastes in accordance with regulatory requirements.

7.2 Article 22: Human and Financial Resources

By legislation, facilities using or holding radioactive sources or radioactive waste are bound to provide adequate human and financial resources to guarantee the safety and security of their sources and waste. All licensees have to designate a qualified radiation protection officer who is responsible to implement the obligations of the licensee. RPC accept in justification base a

national contract for management of disused sources at the end of the contract. The policy of Albania, related to the radioactive waste, support the concept that polluters pay, where each legal or physical person should provide the necessary and indispensable funds for the treatment of waste

Regulation on “Safe radioactive waste management in Republic of Albania” No.638, Date 7.9.2016 define, cover of the radioactive waste treatment cost. Producers of radioactive waste shall be legally required to ensure the necessary funds to cover those costs of radioactive waste management that require further processing and in any case are direct responsible to clean up the contaminated working place or the environment, caused by them.

7.3 Article 23: Quality Assurance

The designated radiation protection officer (RPO) is responsible to establish and implement a quality assurance program with regard to the implementation of internal procedures, such as regular verifications and calibrations of the used radiation measurement equipment. These processes need a further development especially for implementation process.

Tasks in the field of protection against ionizing radiation are carried out by radiation protection officer in the work with radioactive materials and measuring devices.

The main tasks in the ionizing radiation protection system are:

- Radiological control of personnel and population,
- Radiological control of the working environment,
- Radiological control of the radioactive waste storage facility environment.

Guidelines for protection against ionizing radiation are provided in internal orders and working procedures. The procedures are based on the country's legal provisions and the rules governing the field of radiation protection, while respecting the IAEA recommendations.

Ionizing radiation protection procedures include the Radiological Surveillance Area of People, radiological surveillance of the working environment in the storage and the monitoring of the surrounding storage environment.

Internal Orders and Working Procedures are:

Internal Orders

1. Internal order no. 3 On Physical Security of Group B Radioactive Sources at IANP, dated 30.12.2013.

2. Internal order no. 4 For Physical Security of Group A Radioactive Sources at IANP, dated 30.12.2013.

3. Internal order no. 5 For the transport of radioactive sources of Group A and B at IANP, dated 30.12.2013.

4. Internal order no. 6 On Administrative and Technical Measures for the Physical Security of Radioactive Sources at IANP, dated 30.12.2013.

5. Internal order no. 7 On Responsibilities of Radioactive Sources Users at IANP, dated 30.12.2013.

6. Internal order no. 8 On Cooperation and Coordination with the Radiation Protection Commission (RPC) on Physical Security of Radioactive Sources, dated 30.12.2013.

7. Internal order no. 9 On Cooperation and Coordination with Customs Authorities and Law Enforcement on Physical Security of Radioactive Sources, dated 30.12.2013.

Procedures

1. Procedure for entry and exit into the Institute of Applied Nuclear Physics (IANP).
2. Procedure for entry and exit in the radioactive waste storage facility.
3. Procedure for entry and exit in the Secondary Standard Dosimetry Laboratory.
4. Procedure for entry and exit in the Irradiation Laboratory.
5. Procedure for Acceptance of Radioactive Waste and DSRS
6. Procedure for Characterization of DSRS
7. Procedure for Characterization of Radioactive Waste
8. Procedure for Temporary Storage of Radioactive Waste and DSRS
9. Procedure for preparation of the operational zone for encapsulation of DSRS
10. Procedure for Capsulation of DSRS
11. Procedure for Preparation of Pre-Concrete Drums and conditioning of DSRS in the 200-liter Drums.
12. Procedure for the control and storage of conditioned radioactive waste packaging
13. Procedure for Compression of Solid Radioactive Waste.
14. Procedure and Program for Radiation Protection
15. Procedure for Identification and Traceability
16. Procedure for Transportation of Radioactive Materials.
17. Procedure for Radioactive decontamination of surfaces, contaminated objects, vehicles of transport.
18. Procedure for Clearance Levels of Radioactive Materials

All radioactive waste storage facility staff and IANP staff is included in the personal dosimetry control program. Personal dosimetry control consists of daily exposure control with personal radiation detectors and also by TL dosimetry control.

7.4 Article 24: Operational Radiation Protection

The licensee is fully responsible to implement internal radiation protection following the principles described above and the control of actual or potential discharges according to the national regulations on radioactive waste.

In terms of radiological protection of workers and the environment, it is important to ensure quality in the field of ionizing radiation protection. It discusses three areas with the appropriate operating instructions, which are listed below:

1. Radiological control of staff and population:
 - Natural ventilation of the radioactive waste storage facility
 - Measurement of personal contamination
 - Personal dosage
 - Decontamination of people
 - Entry, exit and retention in a controlled area
 - Work with ionizing radiation sources

2. Radiological control of the working environment:

- Supervision of radiation and contamination in radioactive waste storage facility
- Measuring equipment work
- Decontamination of the contaminated area

3. Radiological control of surrounding environment:

- Environmental Controls

Protection against ionizing radiation in the radioactive waste storage facility is provided through:

- The design and construction project of building
- Room layout and organization of work
- Systems and tools for packaging of radioactive waste
- Technical systems of protection in case of normal operation and accident
- Systems and procedures for access control
- Other administrative procedures

7.5 Article 25: Emergency Preparedness

Albania has approved the decision No. 700, Dated 21.11.2018 "For the Preparation and Response in the Case of Radiological Emergency for the Protection of Employees and the Public".

The objectives of these regulation are:

1. To increase the awareness of users and relevant authorities about the possibility of the occurrence of a radiological accident and the implementation of necessary measures to prevent it.
2. To reduce the risk of accidents and/or mitigate the consequences of accidents when they occur;
3. To avoid serious deterministic effects (such as: deaths from accidents);
4. To reduce stochastic effects as much as possible.

In article 7 of this regulation are described the Organizational and functional responsibilities, as well as coordination regarding the response to the radiological accident.

1. The main responsibility for safety, security and radiation protection rests with the natural or legal person, which exercises the activity with sources of ionizing radiation.
2. When the consequences of the accident are not located only inside the installation or in its vicinity, but affect a larger area, then to mitigate the consequences of this accident, the user, the IANP, the local authorities, as well as other institutions that make the first response (police or

firefighters) according to the responsibilities that are determined by the legislation, are responsible and must be committed to mitigating the consequences of the accident.

3. The RPC cooperates with the National Agency of Civil Protection for taking the necessary technical measures related with radiological emergency. RPC collects and analyzes information from the emergency response teams, and cooperates with national bodies for radiation protection issues.

4. Planning of protective actions against a radiological accident, which is based on the determination of the responsibilities of the users, of the competent authority, as well as of other organizations that are responsible for the implementation of this regulation is detailed in appendix 4 of this regulation.

7.6 Article 26: Decommissioning

Albania has approved Decision No.1005 dt. 09.12.2020 of Council of Ministers for the approval of the Regulation “On the safe process of decommissioning of the objects that perform activities with radioactive materials”. Prior to licensing all users of high activity sources have to introduce a decommissioning plan according to Annex nr.1 Elements of Decommissioning Plan to RPC. This plan includes precautions for avoiding accidents and provisions for the management of incidents and accidents, such as potential contaminations necessitating cleanup and management of radioactive waste generated during the decommissioning process.

The decommissioning of radioactive waste predisposal facilities shall be carried out by the licensee on the basis of the final decommissioning plan approved by RPC and in accordance with the limits and conditions imposed by RPC under the Decommissioning License.

The licensee shall record and keep the records of all radioactive waste containers produced during the operation and decommissioning of the facility generating radioactive waste.

Albania, with the support of the IAEA, has exported to Hungary the conditioned disused ⁶⁰Co radiotherapy source in storage facility and also another disused ⁶⁰Co source which was inside the cobalt machine at Mother Theresa Hospital premises.

8. SECTION H: SAFETY OF RADIOACTIVE WASTE MANAGEMENT

8.1 Article 11: General Safety Requirements

In the safety analysis of radioactive waste storage facility there are identified potentially normal and extraordinary - accidental events. There is given analyses of this events, based on elimination criteria that determine the characteristics of the radioactive waste storage facility (class and type of radioactive waste, location of the facility, working conditions, etc.). On the basis of this realistic scenarios is made also analysis and calculation of radiological impact of this scenarios on the surrounding environment, workers and residents. Derived from analysis of the radiological impact follows limitations, conditions and requirements of control, which will ensure a safe working of facility, security of workers, population and environment.

Based on the analysis of events that may affect the workers, population and environment for the radioactive waste storage facility, we can conclude that the radioactive waste storage facility is organized so that the contribution to the burden of the population, personnel and the environment is below the limits, which are determined by the applicable law and other regulations also international recommendations. Due to radioactive waste storage facility as isolated system also affects that provide built-in filters in the filtration system, radon and its progenies, also other stored radioactive waste, have absolutely no effect on the environment and dose received by surrounding population.

The regular operation of radioactive waste storage facility in Tirana, with the requirements to comply with all technical - technological and security - safety conditions and limitations, can't possibly lead to increased exposure of any of categories of persons or the environment

8.2 Article 12: Existing Facilities and Past Practices

In April 2000 the new radioactive waste storage facility (RWSF) supported financially by Albanian government and equipped by IAEA, was established at the territory of the IANP in Tirana. The dimensions of this building are 17x16x3.2 m and two layers of 200 liters drums can be stacked.

A detailed inventory of all the radioactive waste presently stored at this location is given in Annex I.

8.3 Articles 13, 14 And 15: Sitting, Design, Construction and Assessment

The only radioactive waste storage facility is build for the management and temporary storage of radwaste and DSRS but not as final disposal of radioactive waste. This construction has been subject to prior authorization by the Government.

The preparation of safety assessment in the moment of construction has been going through IAEA experts. Each applicant has to demonstrate full compliance with articles of regulations and laws.

8.4 Article 16: Operation of Facilities

Albania operates a radioactive waste storage facility (RWSF). The radioactive wastes are segregated according to the acceptance criteria established by the IANP radioactive waste storage facility. In order to guarantee a safe and secure storage, the RPO regularly inspects the RWSF once a year, in particular for the segregation and packing of the collected radioactive wastes. The inspectors of the RPO further verify radiation level within the storage room and absence of radioactive contamination on a yearly basis.

IANP has organized activities in the radioactive waste storage facility so that it provides a safe work, respecting the provisions provided in the laws and regulations governing this area and respecting the international recommendations and requirements of governing bodies.

Director of IANP appoints a staff responsible for operation of Storage of radioactive waste, who is authorized to manage the storage of radioactive waste in accordance with applicable laws and good practices. This staff is in charge of the radioactive waste storage facility, including preparation,

processing and storage of radioactive waste also keeping records of radioactive waste which is stored in the facility. The followings are the main activities in the radioactive waste storage facility:

- Radioactive waste management
- Waste analysis and monitoring
- Operation of the equipment in radioactive waste storage facility
- Protection against ionizing radiation

8.5 Article 17: Institutional Measures after Closure

The decommissioning process takes into account elements that no sources of contamination is left behind. The interim storage facility will not be contaminated. Thus, no specific measures, except of a final contamination verification will be needed after closure.

9. SECTION I: TRANSBOUNDARY MOVEMENT (ARTICLE 27)

In Albania, transport of radioactive material is under control of the competent authorities. The provisions of the ADR (European Agreement Concerning the International Carriage of Dangerous Goods by Roads) (adhering on 26 January 2005) and of RID (Class 7) (Regulation Concerning the International Carriage of Dangerous Goods by Rail) have been applied. Also the technical instructions of the ICAO and the Dangerous Goods Regulations of the International Air Transport Association (IATA) are applicable from December 7th 1944.

Only licensed carriers are allowed to transport radioactive materials in quantities above exemption level. The authorization is for 10-year period of time but for each single transport operation the licensee is obliged to receive an approval. For the transfer of radioactive sources, the licensee is obliged to receive an approval too. All the process of transport and transfer is regulated by the regulation on “Safe transport of radioactive material” No.615 dated 16 November 2016. This regulation is in compliance with IAEA document SSR-6 and ADR Law. The transits of radiation sources through Albania have to be prior notified to the RPC. All this information of transfers, imports, exports and transits are collected by the RPO and entered to a database.

Albania has informed the IAEA Director General that fully supports and endorses the IAEA’s efforts to enhance the safety and security of radioactive sources, and applies the guidance on the Import and Export of Radioactive Sources contained in the IAEA Code of Conduct on the Safety and Security of Radioactive Sources.

10. SECTION J: DISUSED SEALED SOURCES

Practices and with regard to disused sealed sources are reported in sections B, under radioactive waste management practices.

11. SECTION K: PLANNED ACTIVITIES TO IMPROVE SAFETY

Albania is determined to constantly consolidate, up-date and improve safety and security of related with radioactive substances, DSRS and radioactive waste. This is a constant process. Planned activities are as follows:

- Radiation Protection Commission/Radiation Protection Office has foreseen on 2025 to prepare the new regulation fully in line with Council Directive 2006/117/Euratom of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel between Member States and into and out of the Community, repealing Council Directive 92/3/Euratom (OJ L 337, 5.12.2006, p. 21)
- Radiation Protection Commission/Radiation Protection Office has foreseen on 2026, to amend the regulation nr. 638/2016 "For safe management of radioactive waste", fully in line with Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste (OJ L 199, 2.8.2011, p. 48)

12. Annex I - Inventory

1. Inventory of radioactive waste which are conditioned in RWSF, at IANP up to July 2024. Actually, in RWSF are 32 drums with conditioned radioactive waste and DSRS.

Unsealed sources

Radionuclide	Physical state	Volume	Total activity (GBq)
⁶⁰ Co	Liquid	100 ml	0.0258

Sealed sources

Radionuclide	Number of sources	Total activity (GBq)
⁶⁰ Co	205	1.428 GBq
¹³⁷ Cs	23	13.014 GBq
²²⁶ Ra	40	0.7569 GBq
⁸⁵ Kr	3	0.922 GBq
⁹⁰ Sr	136	0.0128 GBq
¹⁰⁹ Cd	1	0.000005476 GBq
⁵⁷ Fe	2	1.147 GBq
⁵⁷ Co	1	3.35 E-019 GBq
²⁴¹ Am/Be	6	19.477 GBq
Total	417	36.757 GBq

2. Inventory of radioactive waste which are in temporary storage in RWSF, at IANP, up to July 2024.

Sealed Sources

Radionuclide	Number of sources	Total activity (GBq)
^3H	2	4751.54 - GBq
^{226}Ra	2	0.1856 GBq
$^{241}\text{Am/Be}$	4	697.192 GBq
^{238}Pu	2	1.682 GBq
^{137}Cs	14	5.977 GBq
^{60}Co	16	75271.056 GBq
^{192}Ir	2	1.072783E-028 GBq
^{252}Cf	4	0.05 GBq
^{90}Sr	1	0.01221 GBq
^{152}E	1	0.0000507 GBq
^{241}Am	7	0.0852 GBq
^{239}Pu	2	2.658 E - 006
^{233}U	2	2.1836 E -006
^{244}Cm	2	7.416 E -0007
^{109}Cd	1	6.97 E -015
^{241}Am , ^{57}Co , ^{60}Co , ^{137}Cs , ^{54}Mn , ^{22}Na , ^{85}Sr , ^{85}Y , ^{51}Cr	1 set (9 pieces)	0.00049 GBq
^{22}Na	5	1.75587496e-10
^{85}Kr	5	0.0000161 -
^{57}Co	1	0.009592
Total	82	80,727. 90 - GBq

Unsealed Sources

Radionuclide	Physical state	Volume	Total activity (GBq)
Standard Solution (^{241}Am , ^{109}Cd , ^{57}Co , ^{139}Ce , ^{203}Hg)	liquid	10 ml	0.0002GBq
^{14}C	Liquid	10 ml	1.462 E -05 GBq
^3H	Liquid	10 ml	3.801 E -005 GBq
^{137}Cs	Liquid	5 ml	0.0001875GBq
^{85}Kr	Gas	0.13 cc at s.t.p ; 5%	0.0369 GBq
^{85}Kr	Gas	0.13 cc at s.t.p ; 5%	0.0369 GBq
Total			0.07424 GBq

13. Annex II – Legislative

1. Radiation Protection Law, No.8025, 9.11.1995.
2. Amended Radiation Protection Law, No.9973, 28.7.2008.
3. Decision No.403 date 19.06.2024 of Council of Ministers for the approval of the Regulation on "Permitted levels of radionuclides in the water for human consumption for the protection of public health", in line with the Council Directive 2013/51/Euratom of 22 October 2013 laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption (OJ L 296, 7.11.2013, p. 12),
4. Decision No.1005 dt. 09.12.2020 of Council of Ministers for the approval of the Regulation "On the safe process of decommissioning of the objects that perform activities with radioactive materials".
5. Decision No.801 dt.11.12.2019 of Council of Ministers for the approval of the Regulation "On the public protection and employees professionally-exposed to ionizing radiation and safety from medical exposers with ionizing radiation, in line with IAEA document GSR part 3 and EU BSS, Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionizing radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L 13, 17.1.2014, p. 1)
6. Decision No. 700, dated 21.11.2018 of Council of Ministers for the approval of the Regulation "On preparation and response in cases of radiological emergency, for the protection of workers and public".
7. Decision No. 815, dated 16.11.2016 of Council of Ministers for the approval of the Regulation "On safe transport of radioactive materials", in compliance with IAEA document SSR-6 and ADR law.
8. Regulation on "Safe radioactive waste management in Republic of Albania", Decision No. 638, date 07.09.2016 of Council of Ministers.
9. Regulation on "Categorization of radioactive sources in the Republic of Albania", Decision No. 9, date 07.01.2010 of Council of Ministers.
10. Regulations on "Licensing and inspection of activities with sources of ionizing radiation" Decision No.10, date 07.01.2010 of Council of Ministers, amended on December 2023
11. Regulation on "Physical protection of the radioactive materials in the Republic of Albania", Decision No.877, date 30.10.2015 of Council of Ministers.
12. Regulation on "guidance levels for radon concentration indoor and the concentration of radio nuclides in goods, to protect the public" Decision No.957, dated 25.11.2015 of Council of Ministers
13. Law No.10379, date 24.02.2011 Republic of Albania adhere in the Joint Convention on the Safety of Spent Fuel Management and on the Safety of radioactive waste management.
14. Law No.10380, date 24.02.2011 Republic of Albania adhere in the Convention on Nuclear Safety.
15. Convention on the Physical Protection of Nuclear Material, accession 05.03.2002 and entered in force 04.04.2002.
16. Convention on Early Notification of a Nuclear Accident accession 30.09.2003 and entered in force 30.10.2003.
17. Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency 30.04.2003 and entered in force 30.05.2003.

14. Annex III - Glossary of Abbreviations

NRA	National Regulatory Authority
RPC	Radiation Protection Commission
RPO	Radiation Protection Office
IANP	Institute of Applied Nuclear Physics
RWSF	Radioactive Waste Storage Facility
ICSD	Ionizing chamber smoke detectors
EU	European Union
TSO	Technical Support Organization
IAEA	International Atomic Energy Agency
ADR	European Agreement Concerning the International Carriage of Dangerous Goods by Roads
IATA	International Air Transport Association
ICAO	International Civil Aviation Organization