



ALBANIA

SECOND NATIONAL REPORT

On the measures taken to fulfill the obligations for

The Convention on Nuclear Safety

To the

Eighth Review Meeting of Contracting Parties in 2019

November 2019

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A – INTRODUCTION

This National Report is the second one submitted by the Republic of Albania in compliance with the Article 5 of the Convention on Nuclear Safety. Therefore, this report, presenting the national policy of Republic of Albania regarding nuclear activities, giving an overview on the current status of implementation of Convention on Nuclear Safety in Albania.

Republic of Albania has no nuclear power plants, no research reactor, no other fuel-cycle facility and no other nuclear installation operation in its territory and has no intention to have such in a short- and mid-term future.

Albania has a considerable activity in applying radiation and radioisotopes in human health, industry, agriculture and environment. Albania has a strong cooperation with the IAEA TC department and the Division of the Nuclear Security.

Legislative, regulatory and administrative measures have been undertaken in order to maintain a high level of radiation protection and nuclear safety. Therefore, this report addresses how the Republic of Albania has achieved the relevant objectives of the CNS regarding non-nuclear countries.

Albania ratified the Convention on Nuclear Safety (CNS) on 29.06.2011, and the CNS is officially in force in Albania since 27.09.2011.

Sources of ionizing radiation in Albania are mainly used in medicine, industry, science and education. When performing activities in medicine, such as radiotherapy, nuclear medicine, diagnostic and interventional radiology, have been applying telecobalt machines with Co-60, brachytherapy machines with Ir-192, linear accelerators and other sources of ionizing radiation. Nuclear medicine uses Tc-generator for diagnosis and I-131 for therapy. X-ray machines (conventional X-ray and CT) are used in routine for diagnostic purposes. The Non-destructive techniques (NDT) with X-ray machines and radioisotope sealed sources (mostly Ir-192 source) are used by public and private companies in several industrial sectors. X-ray machines are used in borders for baggage inspection.

Since in Albania there are no nuclear installation and no government commitment has been shown to have such in short and middle term future, the nuclear activities in Albania are related with nuclear international agreements signed with IAEA and emergency preparedness. Albania has nuclear materials, not currently in use but previously used research activities by universities and in geological survey. They are mainly in powder form consisting of oxides of uranium, thorium and also depleted uranium shielding for ionizing radiation sources used in medicine. These materials are located in a single repository and subjected to the safeguard agreement rules that Albania has signed with IAEA.

Radiation Protection Commission as the responsible body for the implementation of CNS ensures that Albania is fully committed to the obligations regarding the provisions of the Convention.

This National Report was prepared in accordance with the suggestions contained in the Guidelines regarding National Reports under the Convention on Nuclear Safety, INFCIRC/572/Rev.4 dating from 16 April 2013. Having no nuclear installations, Articles 7, 8, 11 and 16 of the CNS will be reported.

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The IAEA conducted the first International Physical Protection Advisory Service (IPPAS) mission in Albania on 16-27 May 2016. The mission reviewed Albania's nuclear security-related legislative and regulatory framework for radioactive material and associated facilities and activities. The IPPAS team concluded that Albania has taken important steps to strengthen nuclear security. The team identified a number of good practices while also making recommendations and suggestions for continuous improvement (see Appendix I). The status of implementation of the recommendations will be treated in the following chapters.

B – SUMMARY

This is the Second National Report submitted according to the requirements of CNS. Albania, after 1995, when Law on Radiation Protection was adopted, has made significant progress when it comes to radiation safety in the country. Particularly significant is the progress in the establishment of the regulatory body and strengthening of its capacity, as well as the adoption of laws in the field of radiation safety. Also, it is important to emphasize that Albania has ratified most major international instruments in the nuclear field and is deeply committed to the implementation of its international obligations. Through the adoption of regulations, the latest IAEA standards are taken in consideration, especially BSS, Code of Conduct on Safety and Security of Radioactive Sources and its supplementary Guidance.

This report has been prepared in accordance with the Guidelines regarding national reports and is applicable to non-nuclear countries and includes areas relevant to the work of the regulatory body. The report focusses on the description of the legislative and regulatory framework, the establishment and the status of the regulatory body, as well as on the preparation and response to emergencies (extraordinary circumstances).

C – REPORTING ARTICLE BY ARTICLE

Article 7 CNS – Legislative and regulatory framework

(1) Establishment and maintenance of the legislative and regulatory framework

Based on the IAEA Radiation Protection Advisory Teams (RAPAT) recommendations the Parliament of Albania approved the Radiation Protection Act No. 8025 “On ionizing radiation protection” of 09/11/1995, which is the basic law on radiation protection. Amendments to the Law on radiation protection have been approved to bring it in line with EU legislation. The Law 8025 was amended and promulgated in 2008 as Law No. 9973 and in 2013 as Law No 26/2013. The Radiation Protection Commission (RPC), which members are appointed by the Council of Ministers, is the Regulatory Authority with independent status and competences. Key structures in the field of radiation protection, safety and security are Radiation Protection Commission (RPC) and Radiation Protection Office (RPO), respectively as regulatory and executive organs. The strategic objective of the Radiation Protection Commission (RPC), as the national independent authority nominated by the Council of Ministers under the Ministry of Health, is to protect workers health, public and environment from the effects of ionizing radiation, taking maximum benefits of using ionizing radiations.

Also, regarding the international agreements that Albania has signed with IAEA, INFCIRC 359, INFCIRC 359a 1 and INFCIRC 359m 1 the Council of Ministers Decree no.23 dt. 30.01.2010 and no.637 dt. 19.02.2012 have been issued in order to establish the responsible institutions the competencies for ensuring the fulfillment of these agreements. The law no. 10379 dt 24.02.2011 on “the accession of Republic of Albania in the joint convention for the safety management of spent fuel and radioactive waste” regulates safety and security issues related with existing nuclear installation and future planned nuclear installations.

Law no 118/2012 on “transport of dangerous goods” in line with EU directives 95/50/EC and 2010/35/EU and partially aligned with directive 2008/68/EC establishes the requirements and responsible institutions for issuing licenses for the transport of radioactive and nuclear materials in line with ADR requirements.

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Other conventions ratified by law are:

- On the early notification in case of a nuclear accidents approved by the law no. 9026 dt. 13.03.2003
- On the assistance in case of nuclear accidents, approved by the law no. 9015 dt. 20.02.2003

With this legislative framework the most outstanding issues have been addressing, in particular recommendations by RaSSIA on security and physical protection of radioactive materials according to General Safety Requirements (GSR) part 3. At the moment the legislation is approximate to EU legislation.

(2)/(i) National safety requirements and regulations

The Council of Ministers has adopted an appropriate set of regulations that cover the area of security, safety and radiation protection to ionizing sources as follows:

- The Regulation "**On safe management of radioactive waste**", Decision No. 8, date 7.01.2010, which addresses:
the management of liquid and solid radioactive wastes, the obligation of the user of the source for the treatment of the waste, the transport of radioactive waste, conditioning and storage of radioactive waste, limits of concentrations and the total activity of the main radioisotope for the liquid waste released into municipal sewer system, categorization of the radiotoxicity group of radionuclide's.
- The Regulation "**On the categorization of radioactive sources in the Republic of Albania**" Decision No.9, date 7.01.2010, which addresses:
basic elements for the assessment of the categorization, the effects of the radioactive materials according to the categorization, categorization of the radioactive materials.
- The Regulation "**On Licensing and Inspection of the Activities with Ionizing Radiation**" Decision No. 10, Date 7.01.2010, which addresses:
exclusions, licensing conditions, the validation time of the license, inspection, duties of inspectors, actions of the inspectors when is a risk, the right of the inspectors, complain against the decisions, licensing application forms.
- The Regulation "**On the safe transport of the radioactive materials**" Decision No.488, date 23.6.2010, which addresses:
definitions, notification for transport, classification of the packages, contamination, limit levels, limit radiation levels during the transport, transport categorization, package label, additional conditions, accompanying documentation during the transport, passage through custom, final provisions, values of the radionuclides for the transport, limit activity for the excepted packaging, perform of radioactive danger and labels of transport categories.
- The Regulation "**On safe handling of ionizing radiation sources**" Decision No.543, date 7.7.2010, which addresses:
responsibility of subjects for the application , rules and requirements, the general obligations for practices and sources, requirements for the practices, requirements for sources , justification of practices, dose limitation, optimization of protection and safety, dose constraints, exposures, license, clearance release from controls, quality assurance, guidance levels for medical exposure, measures for the reduce of human errors, radiation protection experts , security of sources, safety and security assessment, defense in depth, intervention, notification requirements, interpretation of terms ,list I-exemption and list II-dose limits.

- The regulation “**On the security of radioactive sources in Republic of Albania**”, Decision No 877; date 30.10.2015, which addresses:

object of the regulation, purpose, definitions, security of radioactive sources, requirements for security of radioactive sources, requirements for physical protection of radioactive sources group A, requirements for physical protection of radioactive sources group B, requirements for physical protection of radioactive sources group C, transport of radioactive sources, responsibilities of Radiation Protection Commission, responsibilities of the licensees, report, lost and orphan sources, cooperation with law enforcement agencies, cooperation with custom, contact point with the IAEA, appendix 1-physical protection plan and appendix 2-objectives of the physical protection for different security groups of radioactive sources.

- The regulation “**On the protection of workers occupationally exposed to ionizing radiation**” Decision No 590, date 18.08.2011, which addresses:

responsibilities, conditions of service, classification of areas, classification of workers, local rules and supervision, personal protective equipment, co-operation between employers, licensees, individual monitoring and exposure assessment, category A and B workers, monitoring of the workplace, health surveillance, records, special circumstances.

- The Regulation “**On guidance levels for indoor radon concentration and the concentration of radionuclides in goods, to protect the public**”, Decision No 957, dated 25.11.2015, which addresses:

The object of the regulation are definitions of guide and reference levels as follows:

- PART I-Guide levels for concentration of radon indoor. The action plan for radon, concentration of radon in working places, radon concentration in residential buildings and public buildings.
- PART II-Guide levels for radio nuclides in water for public consumption, monitoring of compatibility, non compatibility, exemptions.
- PART III-Levels of reference for agricultural products contaminated as a result of nuclear accident or radiological emergency. The maximum permitted levels of food contaminated with radioactive substances. The maximum permitted levels of radioactive contamination on animal food. The maximum permitted levels of radioactive contamination for cosmetics. Review of the maximum permitted levels, control of imports, exports control.
- PART IV-The reference levels of gamma radiation emitted by building materials, control of construction materials, trading of building materials, import and export of construction materials.
- PART V-Control of scrap, special provisions for the scrap recycling installations, information for employers regarding scrap import and export of scrap
- PART VI-Other provisions on Quality control
 - ✓ Annex 1-maximum levels of radioactive contamination, allowed of food products after a nuclear accident or radiological emergency
 - ✓ Annex 2- maximum levels of radioactive contamination allowed of food products for animals after a nuclear accident or radiological emergency
 - ✓ Annex 3- example. export certificate for agricultural products
 - ✓ Annex 4 -types of building materials taken into account for the emission of gamma radiation
 - ✓ Annex 5- activity indexes concentration of gamma radiation emission from building materials
 - ✓ Annex 6-example for certificate of monitoring of the load scrap.

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- The regulation “**On public protection from the discharges in environment, determination of the sampling, regions and measurements frequency**”, Decision No 313, dated 09.05.2012, which addresses:

The Ministry of Environment, Forests and Waters Administrations is responsible for the environmental control, objective of regulation is network monitoring, the conception of national network for radioactivity monitoring, strategy of sampling and measurements, related with every types of samples, types of samplers, types of measurements and periodicity.

- The regulation “**On safety of the public to the exposure of the ionizing radiation sources**” Decision No 481, dated 25.07.2012, which addresses:

Responsibilities, control of visitors, sources of external irradiation, radioactive contamination in enclosed spaces, radioactive waste, discharge of radioactive substances to the environment, consumer products, monitoring of public exposure.

- The Regulation “**On safety to medical exposures with ionizing radiation sources**”, Decision No. 229, dated 20.03.2013, which addresses:

Responsibilities of the licensees, justification of medical exposures, optimization for protection for medical exposures, requirements for equipment and radiant generators using sealed sources for diagnostic radiology, requirements for radiation generators and radiation installation for radiotherapy, diagnostic exposure, nuclear medicine, therapeutic exposure, calibration, clinical dosimetry, quality assurance for medical exposures, guidance levels, dose constraint, maximum activity for patients in therapy with open or sealed radio nuclides on discharge from hospital, investigation of accidental medical exposures, records, procedures.

- The Regulation “**For the basic rules of the radiological installations in medicine**” Decision No 404, date 18.06.2014, which addresses:

Rules for X-ray applications in radiology system, radioscopy system, computerized tomography and dental radiography.

- Guidance, “**Training Program in the field of Radiation Protection**”, No 1438/6 date 12 March 2011, which addresses:

- The categories of persons to be trained
- Qualified expert
- Responsible of radiation protection (RPO)
- Employees who use the ionizing radiation sources
- Employees of regulatory body
- Institutions to carry out the training of employees
- Retraining
- Assessment and recognition of training
- Syllabus of courses for radiation protection
- Recognition of qualified expert

- Guidance on “**the procedures of the evaluation of the applications for recognition by the RPC as a medical physicist**”, No. 4629/1, dated 1.11.2012.

- Guidance on “**Procedures for the physical move of radioactive materials, goods and response in case of incident with radioactive sources in customs points**”, No 1526/2 dated 13.04.2012.

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- Guidance on “**Elements for recognition by Radiation Protection Commission for legal, physical persons, who perform measurements with ionizing and non ionizing radiation, calibration of radiometric and measuring the radiation devices, training and personal dosimetry service**”, no 1526/1, date 13.04.2012
- Guidance on “**Import export and transit of radioactive sources of category 1 and 2 in Republic of Albania**” No 134, date. 12.4.2011

Radiation Protection Commission (RPC), in order to provide more support in the process of implementation of obligations about protection from radiation, has adopted a set of codes of practices as follows:

- -Code of Practice in Radiotherapy No. 804 / 1 date 15.03.2005
- -Code of practice in Radiology No 804 / 2 date 15.03.2005
- -Code of practice in Nuclear Medicine No 5027/2 date 2/12/2010
- Code of conduct for the safety and security of radioactive sources, No. 1388, dated 14.04.2004

Radiation Protection Commission adopted a declaration in support of "Code of Conduct on Safety and Security of Radioactive Sources" IAEA Nr. 1388 14/04/2004 and a letter was sent to the Director General of the IAEA about.

Radiation Protection Office (RPO) in support of its tasks has drafted:

- -List of controls in Radiology
- -List of controls in Nuclear Medicine
- -List of controls in Radiotherapy
- -List of controls for sealed sources.

These check lists include all elements that an inspector has to check during an inspection.

The existing regulations, guidance's and codes of practice address occupational and public exposure, dose limits, medical exposure, transport of radioactive materials, waste management and emergency situations. However, some medical practices, such as dental radiography, are not yet addressed and there are no dedicated codes of practice for industrial applications. Some draft regulations are in preparation to address these aspects.

(ii) Licensing system

The authorization 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 ". Part of this regulation are two application forms; one is for activities with X ray generators and one for sealed/unsealed radiation sources.

Regulation describes the rules for the process of authorizations. The authorization is preceded by notification. The authorization application must contain details of the radiation sources, the purpose of use, the radiation protection measures regarding optimization, justification, dose limits, shielding calculation and emergency countermeasures. Particular information is required on the qualifications and work experience of the radiation protection officer and staff. The new requirement is that except of training in the radiation protection field, staff should be subjected

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to testing the knowledge obtained in the training. RPC has recognized the Institute of Applied Nuclear Physics to perform this process for all categories.

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

Radiation Protection Commission (RPC) has approved:

- The document on procedures, explanatory format and evaluation of the application for license of the activities with ionizing radiation sources No.3618/5 dated 13.05.2014
 - The document on “The status of medical physicist in Albania”, No. 459/1, date 31.1.2012.
 - The guidance on procedures of application for recognition by the RPC, as medical physicist No.4629/1 dated 01.11.2012
-
- The procedures of evaluation of the application for the recognition by the RPC as qualified experts for ionizing radiation protection No. 3618/4, dated 13.05.2014

The document No 494/7, date 7/2/2011 includes:

- The evaluation procedures of the application for license of the activities with ionizing radiation sources
- Inspection procedures, inspection protocol
- Model of preparation of the inspection report
- Instruction format related to the license application fulfillment
- Format application delivery.
- Evaluation model of the application for license.

There are some practices and radiation sources, which are exempted from licensing and this list is in compliance with the IAEA BSS. The authorizations are currently renewed every 5 year, but risk of practice is taken into account during assessment of applications (graded approach). Law no 118/2012 on “transport of dangerous goods” establishes the institutions responsible for transport license issuing and quality control regarding radioactive and nuclear materials separately.

(iii) Regulatory inspection and assessment system

In accordance with Law 8025, Article 8(c) amended on the Regulation on Licensing and Inspection, the RPC has established a systematic inspection program. All ionizing radiation sources are subject to physical check and planned inspections are scheduled annually for higher risk sources and less frequently for others. The system of authorization and inspection was established in 2000.

The Radiation Protection Office (RPO) applies checklists and written inspection procedures according to the RPC guidance “Basic model for the inspection report, Nr 5027/3, date 2/12/2010. The RPC has established procedures that require the completion of inspection reports within two weeks and the communication of the results of inspections to the registrant or licensee within 1 month.

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The RPC has been preparing written, formal procedures for follow-up inspections as required by the regulation on inspection that includes:

- Evaluation procedures of the application for license of the activities with ionizing radiation sources
- Inspection procedures, inspection protocol
- Model of the preparation of the inspection report
- Instruction format related to the license application fulfillment
- Format application delivery.
- Evaluation model of the application for license

Based on the law No.8025 dated 9.11.1995 as well as amendments No.26/2013, article 8, point 2; Council of Ministers defines cooperation between RPO and the Central State and the State Health Inspectorates and the State Health Inspectorate regarding the protection from ionizing radiation.as amended and the regulation of the State Health Inspectorate, No. 321, dated 31.07.2015, the For technical aspects, responsible for the inspection will be Radiation Protection Office (RPO).

(iv) Implementation of the existing regulations and license conditions

There are legislative provisions for enforcement including the imposition of fines for violations where legal prosecution is not being pursued. Law 8025, Article 10, makes provision for the enforcement of regulatory actions, including sanctions. The enforcement actions are based on the type and severity of non-compliance and the fine is prescribed by the law (100 000 -300 000 Lek).

Articles 6, 8 and 9 of the Regulation on Licensing and Inspection set out the rights and responsibilities of RPC inspectors and detail actions available to them. Law 8025 and the regulation together provide the authority and guidance for inspectors on the enforcement policy of the RPC

It seems that the new amendments in 2008, establish clear enforcement actions (e.g. instructions, sanctions, fines, suspensions) based on the nature of non-compliance and the implications for safety.

The RPC has not established formal arrangements with relevant government agencies where enforcement requires the involvement of the police, Ministry of Justice or other authorities. In accordance with Article 8 of the Regulation on Licensing and Inspection, RPC may require the operator to cease activities and to take prompt actions to restore an adequate level of safety in situations deemed to pose an imminent radiological hazard to workers, the public or the environment.

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 however.

In case of enforcement provisions, the dual nature of the regulatory body, namely the RPC and the RPO makes it difficult for the inspector to maintain on-the-spot authority and retain the inspector's integrity as an authorized person, who is independent in enforcing the law.

Article 8 CNS. The Regulatory Body

(1) The establishment of the Regulatory body

The Radiation Protection Act No 8025, date 09.11.1995 amended, establishes the:

- Radiation Protection Commission (RPC) as the Regulatory Body; and the
- Radiation Protection Office (RPO) as its Executive Body.

Council of Ministers Decree no.23 dt. 30.01.2010 and no.637 dt. 19.02.2012 establishes the National Nuclear Agency of Albania as the responsible institution for the following duties:

- Development, following and progress of the Albanian nuclear program.
- Preparation of nuclear legal framework for the development of the nuclear program
- Responsible for safety and security of spent fuel and all the radioactive materials derived from the process of producing nuclear energy.
- Responsible for the inspection and verification of the inventory of the materials included in the “Protocol Additional of Safeguards to all Nuclear Activities for Albania”
- Responsible for communication with IAEA regarding the report of nuclear materials safety and security status as specified in, INFCIRC 359, INFCIRC 359a 1 and INFCIRC 359m 1
- The owners and users of materials such as are mentioned in the INFCIRC 359, INFCIRC 359a 1 and INFCIRC 359m 1 agreements are obligated to create the necessary condition for the inspection and verification of the nuclear material status according to the requirements of the abovementioned agreements.

The National Nuclear Agency is an institution of the Ministry of Infrastructure and Energy administratively depending on the Minister of Infrastructure and Energy. The National Nuclear Agency of Albania has 7 full time employers.

Radiation Protection Commission (RPC) is established on the Decision No 123, dated 5.3.2014 of the Council of Ministers “For the establishment, composition and form of organization, operation, remuneration of the Radiation Protection Commission”. The RPC has six non-permanent members and five experts from different Ministries, institutions and agencies.

The Radiation Protection Office (RPO) is established as the executive organ of the RPC. The Chairman of RPO is Secretary of RPC.

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 functions, powers and duties of the RPC include:

- preparation of regulations, and issues guides and Codes of Practice for radiation protection and safety;
- overseeing enforcement;
- issuing licenses;
- technical management of all national and local authorities for immediate enforcement of necessary procedures for mitigation of the effects of nuclear accidents;
- making recommendations and proposals for the improvement of the radiation protection legislation;

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- cooperating with national and international organizations on radiation protection issues;
- defining the structure of the RPO;
- nomination/dismissal of the Chairman of RPO; and
- cooperation with the State Inspectorate.

The functions, powers and duties of the RPO include:

- preparation of information on licenses (applications, suspension or cancelation) for RPC approval;
- enforcement;
- inspection;
- collection of information and performance of necessary analysis and measurements for radiation protection control;
- keeps national inventory of sources; and
- preparation of relevant information, including reports, for Commission.

RPO have eight full technical staff and two extra administrative supporting staff.

The RPO is equipped with an X- Ray test device, dose rate meters, a multichannel analyzer, a Field Spec unit, dosimeters of different types, phantoms, etc.

According to Law 9973 all regulatory activities associated with the system of authorization, inspection and enforcement are implemented by the RPC and RPO.

In support of the Albanian RPC, there are four technical service organizations (TSOs):

- The Institute of Applied Nuclear Physics (IANP), which has responsibilities relating to radiation protection expertise, calibration, dosimetry service, waste management, training programs, environmental control, and emergency response.
- The Institute of Public Health, which covers medical surveillance of occupationally exposed workers.
- The Institute of Radiation covers issues on expertise and training program for users.
- The Institute of Radiation Protection covers issues on expertise and training program for users.

The RPO has signed a memorandum of understanding with the Institute of Applied Nuclear Physics (IANP) for technical assistance and other provisions. For the moment the medical surveillance is covered by the Institute of Public Health due to merging of the department of professional diseases at University Hospital Centre of Mother Theresa (UHCMT).

Below is the RPC Organizational Chart of the government of Albania as it pertains to radiation users:

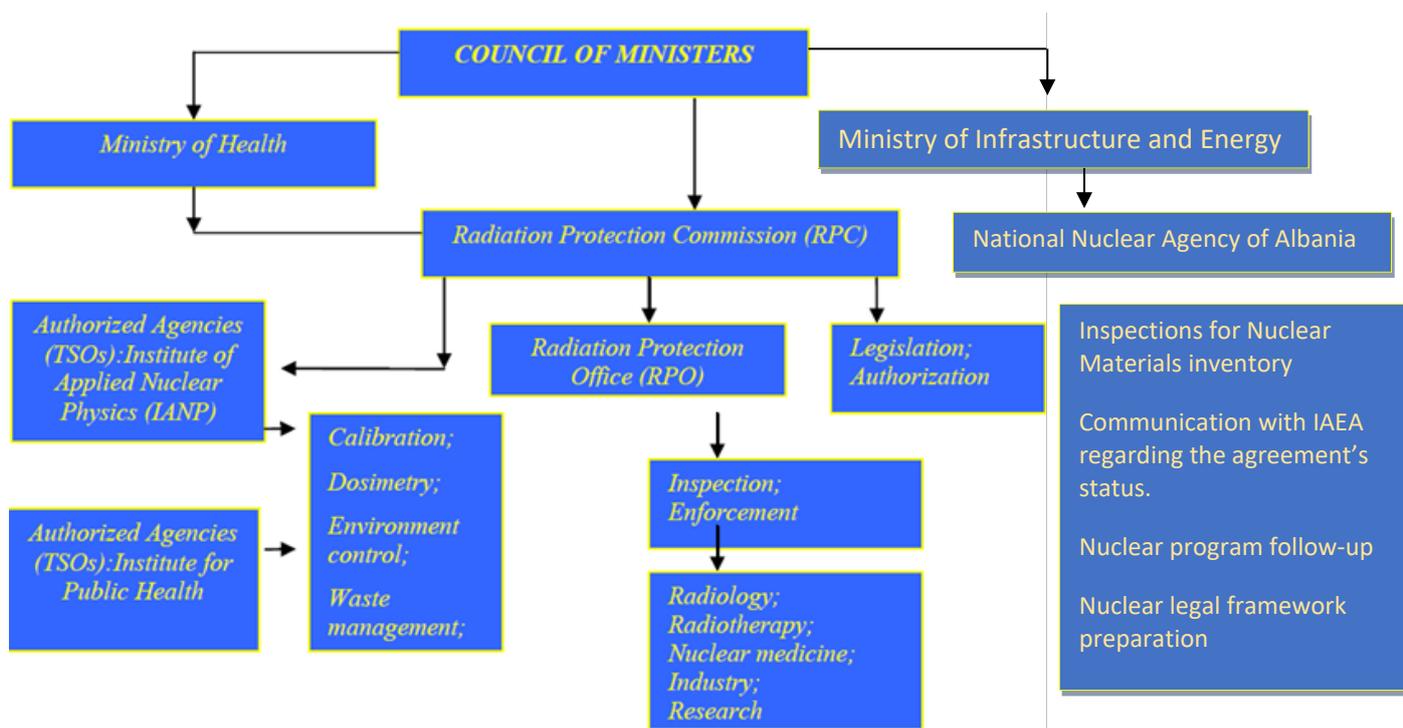


Fig. 1 Organizational Chart

(2) Status of the regulatory body

The distribution of responsibilities among organizations having responsibility for radiation safety in Albania appears to be well defined. The regulatory body appears to be effectively independent of operating organizations by reporting to the Council of Ministers via Minister of Health.

The RPO has sufficient facilities and equipment to perform its duties and responsibilities as the executive body of the RPC. The RPO has 10 technical and administrative staff. As necessary and appropriate, the RPO uses the services of experts from the Institute of Applied Nuclear Physics, Institute of Radiation and Institute of Radiation Protection to undertake technical activities.

The National Nuclear Agency of Albania reports directly to the Minister of Infrastructure and Energy upon request. Radiation Protection Office and National Nuclear Agency of Albania are financed by the government budget the composition of which is fixed by the responsible government instances.

The staff qualification is adequate. All staff attended IAEA regional and post-graduate training courses, which have covered radiation safety and to certain extend the security of radiation sources. Existing continuous educational and training programs in Albania serve the requirements of agencies involved in regulation or those of the users of ionizing radiation.

There are shortcomings related with financial and administrative aspects of the RPO as part of the budget and administration of the Institute of Public Health (IPH). The RPO has no financial independence and its own budget. RPO does not prepare an annual budget based on the needs of its regulatory program. RPO obtains vehicles on request from dispatcher center at the Institute of Public Health; however, vehicles may not always be available when required.

Article 11 (2) Human Resources

Given that there are no nuclear installations in Albania and the decision for pursuing a nuclear program remains a political one the staff selection is focused on the requirements on safety related needs. The Public Administration Department reporting to the Prime Minister`s Office is the responsible institution for the human resources provision for the National Nuclear Agency of Albania and Radiation Protection Office, depending on the qualification requirements issued by NNA and RPO. All the staff are subjected to continuous training related with radiation and nuclear safety and security from NNA, RPO and also from IAEA courses and workshops. Periodical evaluation on staff qualification is performed and delivered to the government instances.

Having in mind the recommendations and suggestions of IPPAS mission periodical improvements are done on Guidance, “**Training Program in the field of Radiation Protection**”, No 1438/6 date 12 March 2011 in order to address the recommendations 4, 5 and 6 (see Appendix I) regarding the trustworthiness verification on RPO staff in charge of security assessments, inspections also the personnel having access of sensitive information.

Article 16 Emergency Preparedness

(1) Plans and programs in case of emergencies

In the Republic of Albania, radiation sources are mainly used in different applications including medicine, industry, agriculture, research and education. The previous experiences in the country as well as in many other countries require enforcement of rules and regulations on radiation protection to prevent any probable accident with radioactive sources. Due to a human and/or design error such sources might cause a radiological accident leading to overexposure of patients, radiation workers and public. On the other hand, although Albania does not have any research reactor or nuclear power plant (herein referred to as NPP), it is in relatively close distances from some NPPs in operation in some neighboring countries, which in case of accidents could affect the territory of Albania, such as: Kozloduy NPP in Bulgaria, Krcko NPP in Slovenia, Paks NPP in Hungary and Cernavoda NPP in Romania (Fig 2).

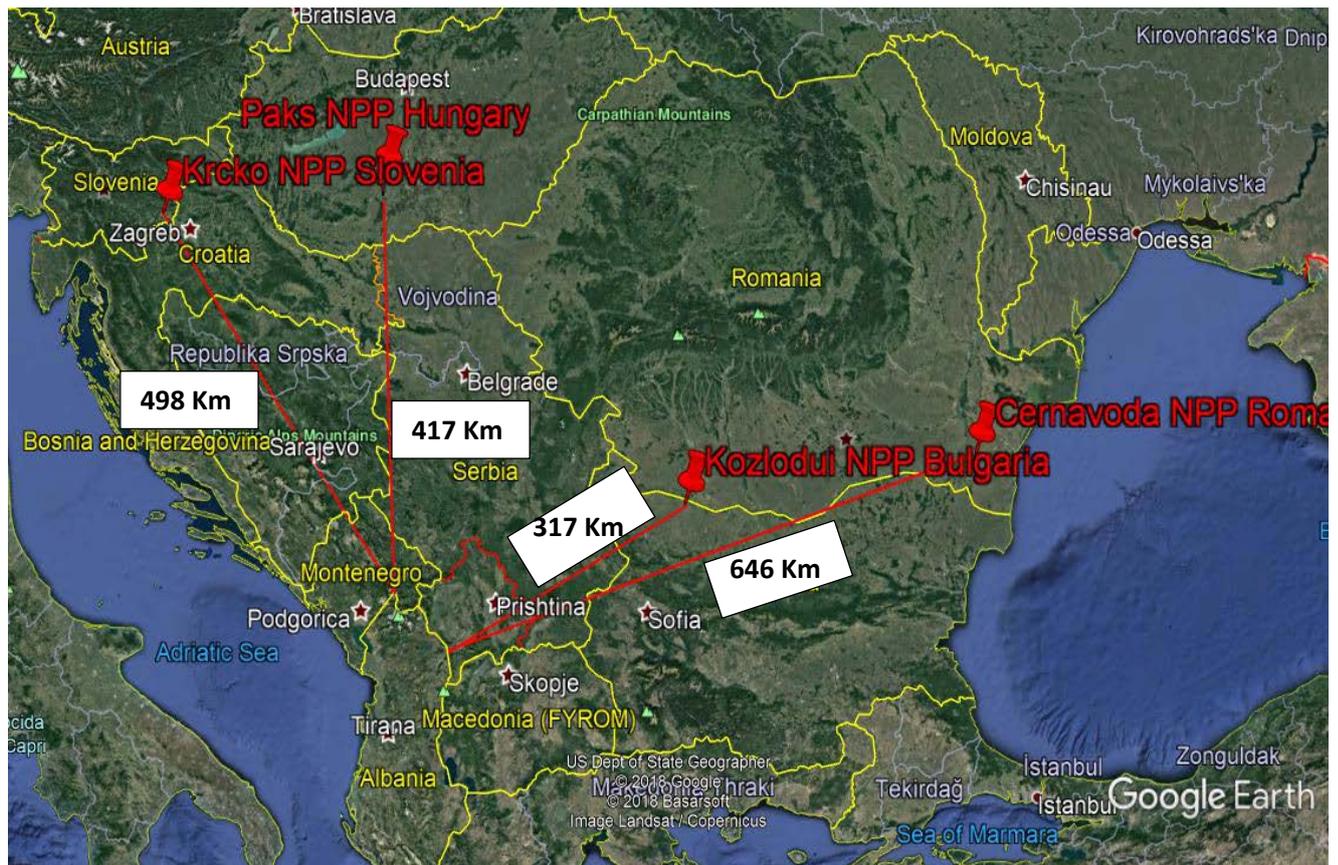


Fig. 2 Schematic map of NPP-s in neighboring countries of Albania

By considering the existing radiation sources in the country and the geographic position of the country towards the neighboring NPPs, Albania falls into threat categories III, IV and V.

Based on the above stated information, and keeping in mind the need to be ready to respond to any radiological emergency, it is prepared the National Response Plan to Radiological Emergencies for the RPC, IANP and RPO, 2007. The main purpose of this Plan is to establish and organize the necessary infrastructure in Albania to mitigate and eliminate the consequences of each type of radiological emergency, in an integrated manner. Therefore, this Plan should be read and applied in correlation with the National Plan for civil emergencies, No.853 date 3.12.2004.

The legal basis of the National Response Plan to Radiological Emergencies is the Law No. 8025 of 09.11.1995 „On Ionizing Radiation Protection” as amended No. 9973 on 28.07.2008, Law No. 9756 from 26.03.2001 “For civil emergencies”, Law on Environmental Protection No. 10431 from 09.06.2011 and other specific laws. This Plan also provides for personnel and equipment necessary, according to the procedures developed and recommended by the IAEA, to face with radiological emergencies.

The main objectives of the National Response Plan to Radiological Emergencies are:

- Aware the attention of users and relevant authorities to the possibility of the occurrence of a radiological accident and to the implementation of the necessary measures to avoid it;

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- Reduce the risk of accidents and / or to mitigate the consequences of accidents when they occur;
- Avoid serious deterministic effects (such as deaths from accidents);
- Reduce as much as possible the stochastic effects.

The prime responsibility for ensuring safety and radiation protection belongs to the physical/legal person who operates with ionizing radiation sources. Planning for the protective measures towards radiological emergency is based on the goals of defining the responsibility of the users, the regulatory authority as well as the other organizations responsible for the implementation of this Plan. When the consequences of the emergency are inside the premises or in their immediate vicinity, the responsibility for countermeasures belongs to the user.

Each user of radiation sources is responsible for the following:

- Strictly to apply all the regulatory requirements and precautionary measures to prevent any possible accident within its premises;
- To prepare an emergency response plan related to the activities that he performs;
- To test the effectiveness of its emergency response plan through periodic exercises for mitigating the consequences of all possible accidents;
- To immediately inform NOEC about whatever type of accident occurrence, giving an overview and its opinion regarding possible assistance that can be given.
- To classify the emergency and to take all the necessary actions to mitigate the consequences of the accident and to protect his personnel and emergency workers, as well as the public on site, as requested in this Plan;
- To advise the local authorities about the necessary protection measures of the offsite public, if necessary.

The NOEC (National Operational Emergency Center) has to inform the other actors like IANP, RPO and local authorities regarding further measures for mitigating the consequences of the accident or activating this Plan. The NOEC (National Operational Emergency Center) has to establish appropriate channels of coordination and communication.

When the accident consequences are not only located within the premises or in their immediate vicinity, but are influencing a greater area, then for mitigation of the consequences of the accident the user, the IANP, local authorities and any other first response organization (e.g. Police or fire brigades) with responsibilities by law and/or designated through this Plan are responsible and shall be engaged to mitigate the accident consequences.

In line with recommendation no.7 of IPPAS mission, RPC will provide technical adviser to DPCCE (Directorate for Planning and Coordinating of Civil Emergencies) for taking the necessary measures to deal with the emergency and ensure the timely communication and share the information. RPC has to gather and analyze information from the emergency response teams and first responders to give appropriate advice to DPCCE. Meanwhile, DPCCE will organize and coordinate the work of different organizations under the Ministry of Health, Ministry of Agriculture, Rural Development and Water Administration, the Ministry of Defense, Ministry of Interior Affairs, the Ministry of Environment, Ministry of Transport and Infrastructure, General Directorate of Customs and mass-media.

The National Response Plan to Radiological Emergencies includes the main duties for the RPC, RPO and IANP in advising the DPCCE. The specific tasks of each responsible organization, for all applicable radiological threat categories in Albania, are defined in this plan.

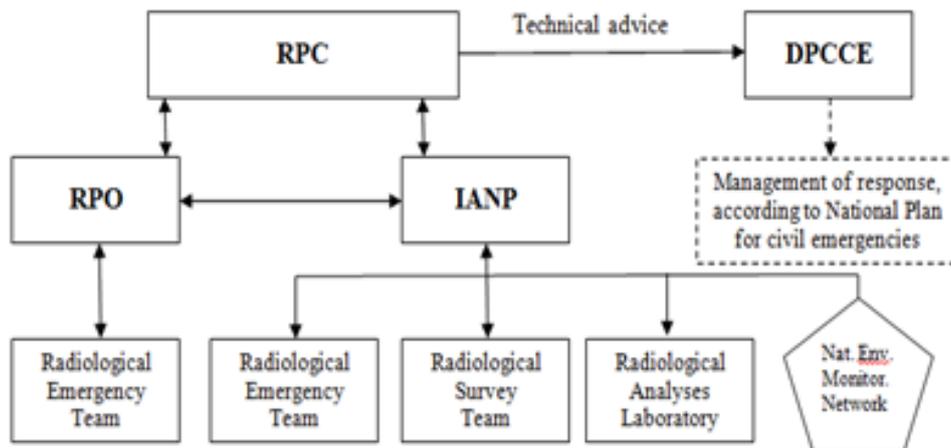


Fig.3 Diagram of the national response organization for radiological emergencies in Albania

There are two types of emergency response teams:
Radiological Emergency Teams and
Environmental Survey Teams.

RPO has one Radiological Emergency Team, while IANP has besides a Radiological Emergency Team, Environmental Survey Teams and the National Environmental Monitoring Network.

The plan provides the classification of emergencies, elements on main response action during the transport of radioactive material, elements on protection of emergency workers, training of this category of workers, testing the plan, quality assurance etc.

Appendix I. Synopsis of Recommendations, Suggestions and Good Practices IPPAS

Recommendation No. 1:

Clear guidelines on how to protect and manage sensitive information should be developed and provided to the operators.

Recommendation No. 2:

A classification system should be established to ensure that proper procedures and systems are implemented and also ensure that sensitive information is correctly marked, properly controlled and protected by both the operators and the competent authorities.

Recommendation No. 3:

Access to sensitive information should be provided only to authorized individuals who have an operational need-to-know and who have been deemed trustworthy on the basis of background checks.

Recommendation No. 4:

Appropriate State authorities should ensure that trustworthiness verification is carried out on RPO staff in charge of security assessments and security inspections and who may have access to sensitive information or, as applicable, to radioactive material, associated facilities and associated activities. This process should be reviewed periodically (e.g. every 5 years).

Recommendation No. 5:

Appropriate State authorities should ensure that trustworthiness verification is carried out on personnel such as driver(s) and individuals handling Categories 1, 2 and 3 radioactive material during transport and those having access to sensitive information.

Recommendation No. 6:

The RPO should develop guidelines and identify clear expectations to assist operators in meeting this requirement.

Recommendation No. 7:

To facilitate the implementation of efficient and effective security measures to address the threat, a formalized and documented process should be established between the State police, RPO, operators, carriers and relevant stakeholders to ensure timely communication and sharing of threat information. This process should be tested regularly to ensure rapid and effective communication needed to address any threat.

Recommendation No. 8:

RPO should develop, implement, and maintain an appropriate and effective integrated management system.

Recommendation No. 9:

The State should establish a sustainability policy and program for its physical protection regime.

Recommendation No. 10:

The RPO should require licensees to establish sustainability programmes containing elements described in IAEA NSS No. 13, para. 3.57.

Recommendation No. 11:

The State, including the RPC, should develop, implement and promote a nuclear security culture through a program involving all organizations with a role in nuclear security in order them to establish and maintain one.

Recommendation No. 12:

The executive management of the relevant competent authorities should establish a statement on security policy and implement a security awareness program based on this policy. The program should underline the importance of, and managements' commitment to, the security of radioactive material and associated facilities. Further, the program should promote awareness of all staff members' responsibilities and their important role in the continuous improvement of the security system.

Recommendation No. 13:

The competent authorities should establish a policy and long-term plan to sustain the safety and security of radioactive material at the national level and to ensure that the RPO has adequate training and financial resources to fulfil its mandate.

Recommendation No. 14:

The State should provide additional resources to establish a training program on security to inspectors and to RPO staff and allocate adequate resource in the interim while the security training program is being developed and implemented for all relevant stakeholders.

Recommendation No. 15:

The regulation should take into account the security requirements defined in the Chapter 1.10 of the ADR.

Recommendation No. 16:

To establish a nuclear security culture, the operator should develop and implement a security awareness training program to provide security instructions and ongoing security awareness briefings to staff and contractors,

Recommendation No. 17:

The operator should establish a documented nuclear security culture policy.

Recommendation No. 18:

The operator and competent authorities should ensure that dedicated training and financial resources are available to fulfil activities in security of radioactive sources.

Recommendation No. 19:

The IANP should implement a minimum of two effective physical barriers to protect the Category 1 radioactive source by increasing delay.

Recommendation No. 20:

Financial and human resources should be allocated to ensure a trained and qualified operator is available to continuously monitor the CAS and ensure that immediate detection, assessment and notification capabilities are implemented.

Recommendation No. 21:

The operator should implement a trustworthiness and reliability verification program to conduct security background checks on individuals with unescorted access to high risk radioactive sources and to sensitive information. This process should be periodically reviewed (e.g. every 5 years).

Recommendation No. 22:

The operator should implement a process and/or procedure to identify sensitive information.

Recommendation No. 23:

The operator should develop a security plan to conform to regulatory requirements and provide for response to increased threat levels.

Recommendation No. 24:

The operator should implement additional delay measures for the HDR source, such as a chain or security cable to provide a sufficient delay after detection to allow response personnel to interrupt unauthorized removal of the source.

Recommendation No. 25:

The operator should allocate appropriate financial and human resources to enable a trained and qualified operator to continuously monitor the central alarm station located at IANP and to ensure that immediate detection, assessment and notification capabilities are implemented.

Recommendation No. 26:

The operator should implement a trustworthiness and reliability verification program to conduct security background checks on individuals with unescorted access to high risk radioactive sources and sensitive information. The process should be reviewed regularly (e.g. every 5 years).

Recommendation No. 27:

The operator should implement a process and/or procedure to identify sensitive information.

Recommendation No. 28:

The operator should develop a security plan which conforms to regulatory requirements and which provides for response to increased threat levels.

Recommendation No. 29:

To establish a nuclear security culture, the operator should develop and implement a security awareness training program to provide security instructions and ongoing security awareness briefings to staff and contractors,

Recommendation No. 30:

The operator should establish a documented nuclear security culture policy.

Recommendation No. 31:

The operator and competent authorities should ensure that dedicated training and financial resources are available to fulfil activities in security of radioactive sources.

Suggestions

Suggestion No. 1:

The State should consider implementing a documented process to establish and identify the roles and responsibilities of the IANP inside the RPC.

Suggestion No. 2:

The State should consider increasing the punishments for malicious acts or other criminal acts, such as unauthorized removal involving radioactive material or substances.

Suggestion No. 3:

The State should consider establishing transitional provisions for the implementation of some elements in the legislation, as necessary.

Suggestion No. 4:

The annual program of inspection should take into considerations more elements regarding the security of radioactive material.

Suggestion No. 5:

The RPO should consider developing operational procedures for conducting security inspections for radioactive material in use, storage or in transport and conducting a readiness review (i.e. technical assessment) of security documentation to provide a clear and consistent approach for verifying compliance. These procedures should involve checklists and/or readiness review templates and should include specific provisions to adequately protect sensitive information from unauthorized disclosure.

Suggestion No. 6:

The RPO should consider establishing guidelines on the security requirements to provide assistance to the operator on how to meet these requirements.

Suggestion No. 7:

The State authorities involved in nuclear security matters should consider establishing procedures to conduct trustworthiness verification.

Suggestion No. 8:

The State should consider reviewing the regulations to avoid overlap with the inspection law.

Suggestion No. 9:

The RPO should consider establishing clear procedures for sanctions in the nuclear security field for administrative sanctions and sanctions pursuant to the Criminal Code.

Suggestion No. 10:

Consideration should be given to require the operator to include, in the security plan, a description of the quality control procedures used for reviewing and assessing the overall effectiveness of the implemented security measures.

Suggestion No. 11:

The State should consider insider analysis in the threat assessment.

Suggestion No. 12:

The relevant competent authorities should consider ensuring that their nuclear security culture program is tailored for both the general staff as well as for personnel with security responsibilities.

Suggestion No. 13:

The relevant competent authorities should consider using IAEA NSS No. 7 on Nuclear Security Culture in the development of a nuclear security culture in Albania and requesting a nuclear security culture workshop from the IAEA.

Suggestion No. 14:

The RPC should consider establishing a nuclear security forum allowing the various organizations involved in security of nuclear and radioactive material to work together in order to build and

maintain an effective nuclear security culture. The forum should coordinate the development and maintenance of nuclear security culture by making all parties aware of, and have a common understanding of the threat as well as each organization's responsibilities regarding nuclear security.

Suggestion No. 15:

In order to provide more independence to the RPO, the State should consider allocating a separate budget to the RPO for fulfilling its mandate on the safety and security of radioactive material.

Suggestion No. 16:

The relevant stakeholders should consider developing a target folder for the MTH that contains useful information that RENEA and other response stakeholders could use for quick reference in the case of a radiological security event.

Suggestion No. 17:

The RPO should consider ensuring that specific requirements and/or guidance are provided for transport security plan to operators, shippers and carriers for shipment during transport and including in-transit phase. Compliance with an approved transport security plan should be a condition of the authorization once granted. When radioactive material is temporarily stored in transit sites (such as warehouses, marshalling yards, etc.), appropriate security measures should be applied to the radioactive material consistent with the measures applied during use and storage. In addition, the RPO should consider specifying in the license the criteria for which the operator shall advise the RPC and submit the changes to its transport security plan for approval.

Suggestion No. 18:

The IANP should plan to allocate long term financial and human resources to sustain the maintenance of the IANP's PPS when the contracts expire.

Suggestion No. 19:

The IANP should consider installing barbed wire along the top of the guard post and equivalent measure on the top of the entrance gate to deter and delay a potential adversary from taking this pathway.

Suggestion No. 20:

The IANP should consider ensuring that windows and other pathways are adequately protected to provide appropriate detection and delay.

Suggestion No. 21:

The IANP should consider removing the keys from the Lenel panel to prevent tampering.

Suggestion No. 22:

The IANP should consider integrating the radiation level monitor alarms to the central alarm station (CAS) to provide redundant detection in the case of a safety or security event.

Suggestion No. 23:

The IANP should consider hardening the window inside the new CAS or equipping it with tinted and resistant security film to prevent an adversary from attacking or seeing the CAS operator activities inside.

Suggestion No. 24:

The operator should consider installing adequate monitors in the guard post to facilitate assessment capabilities of the on-site police officer and upgrade security measures on the window to increase the survivability of police officers in the case of an exterior attack.

Suggestion No. 25:

The IANP should consider reviewing its key control process to either relocate the key box in a secure room equipped with an adequate access control system and intrusion detection system or implement an equivalent measure to control security keys.

Suggestion No. 26:

The operator should consider taking appropriate measures to minimize the vegetation in the open areas and around the buildings and along the site's perimeter to avoid the unobserved movement of unauthorized individuals and to facilitate assessment with CCTV cameras.

Suggestion No. 27:

The operator should, consider using secure storage, such as locked safe or cabinet and encrypted media (e.g. encrypted USB keys or a hard drive) to protect security plan and other sensitive information from unauthorized access.

Suggestion No. 28:

The IANP should consider using tamper indicating devices on the package and on the external side of the rear door to detect unauthorized access and tampering to the package.

Suggestion No. 29:

Carriers should consider performing security inspections of conveyances and ensuring that these security measures remain effective during transport and document the results. The integrity of locks and seals should be verified before dispatch and on arrival by staffs that are specifically and previously authorized by their employer to undertake this verification. The carrier should consider parking the vehicle in lock-up garage in order to ensure that nothing has been tampered with and that nothing has been affixed to the transport vehicle by unauthorized individuals.

Suggestion No. 30:

The carrier should consider installing security equipment, such as locking systems on the doors and the package, and an immobilizing system to provide delay measures. The security system should be designed following the defense in depth principle.

Suggestion No. 31:

The carrier should consider replacing the truck with a vehicle that has been specially designed in accordance with Albanian regulations and adequate security measures.

Suggestion No. 32:

The carrier should consider installing tracking system such as GPS device and duress button in the cabin crew in order to provide timely response.

Suggestion No. 33:

The carrier should consider including all the procedures on security arrangements in a transport security plan and ensure sensitive information in this plan is protected.

Suggestion No. 34:

The carrier should consider conducting a readiness review to ensure that effective physical protection measures are implemented prior to the shipment and to document this review.

Suggestion No. 35:

The carrier should consider including the contingency plan in a transport security plan, which should be submitted and approved by the RPO.

Suggestion No. 36:

Individuals engaged in the transport of radioactive material should receive training on security. Security awareness training should address the nature of security related threats, with due recognition of security concerns, methods to address such concerns and actions to be undertaken in the event of a security incident. It should also include awareness of security plans (as appropriate) commensurate with the responsibilities of individuals and their part in implementing security plans. Records of all security training undertaken should be kept by the employer.

Suggestion No. 37:

The carrier/operator should consider developing and implementing a process or procedure to protect sensitive information on transport security. (e.g. transport security plan).

Suggestion No. 38:

The carrier should consider conducting exercises or drills involving the response forces. Appropriate exercises may be carried out in advance of a transport of radioactive material to ensure that contingency plans are adequately robust.

Suggestion No. 39:

The MTH should plan for the allocation of long term financial and human resources to sustain the maintenance of physical protection measures at the Oncology Clinic when the existing contracts expire.

Suggestion No. 40:

The operator should consider integrate monitoring of radiation level monitors at the central alarm station to provide redundant detection in the case of unauthorized removal of radioactive sources.

Suggestion No. 41:

The operator should consider removing the keys from the Lenel panel to prevent tampering.

Suggestion No. 42:

The operator should consider protecting the windows to the Elite room and implement effective physical barriers to prevent unauthorized access.

Suggestion No. 43:

The security servers should be relocated in a separate and secure room or cage with adequate access control to prevent unauthorized access and an intrusion detection system.

Suggestion No. 44:

The operator should, consider using secure storage, such as locked safe or cabinet and encrypted media (e.g. encrypted USB keys or a hard drive) to protect security plan and other sensitive information from unauthorized access.

Suggestion No. 45:

For Category 2 radioactive material, the operator should consider installing intrusion detection system in the storage room in order to provide immediate detection unauthorized access and installing access control equipment to sources that effectively restrict access to authorized person only. The involved operators (air and road carriers, operator of the airport) should also consider transferring directly the package from the aircraft to the vehicle to avoid temporary storage at the airport.

Good practices

Good Practice No. 1:

Applying the aggregation approach for the assignment of security level for transport is more conservative than per package approach. This allows the implementation of graded security requirements using a risk informed approach.

Good Practice No. 2:

The IPPAS team was informed that RENEA, the counter-terrorism unit, maintains an information packet or target folder for critical facilities, including the IANP. This packet provides tactical decision makers with information that could be used to successfully resolve a security event at the site.

Good Practice No. 3:

The new regulation requires that the NOCCE be activated at least once a year in order to perform training exercises to test plans associated with radiological emergencies. It also requires users to exercise their emergency plans on an annual basis as well.

Good Practice No. 4:

Customs enforcement conducted a no notice radiological security exercise at a northern border checkpoint. Various capabilities were tested during this scenario-based exercise which required a high degree of information security leading up to the event, which was successfully concluded.

Good Practice No. 5:

The fact that the RPO maintains a national registry for radioactive sources of Categories 1 to 5 with the level of detail for the information stored represents good practice.

Good Practice No. 6:

Cooperation and collaboration with global partnership programs to upgrade the physical protection measures of facilities with high risk radioactive material is a good practice.

Good Practice No. 7:

Use of multiple 'dual authentication' systems to control access to restricted areas such as the biometric system and card access reader is a good practice.

Good Practice No. 8:

Use of duress devices that are strategically located to immediately alert security response personnel in the case of security breach or personnel working under duress conditions is a good practice.

Good Practice No. 9:

Use of tamper indicating devices on the machine containing the high-risk radioactive sources to deter, detect and prevent insider threat(s) is a good practice.

Good Practice No. 10:

Use of concrete shielding around the radioactive devices to provide additional shielding and thereby increase delay time reinforces safety and security is a good practice.

Good Practice No. 11:

Two on-site armed police officers dedicated to the IANP at all times (24/7) to patrol and respond immediately in the case of an intrusion is a good practice.

Good Practice No. 12:

Using multiple 'dual authentication' systems to control access to restricted areas such as a biometric system and card access reader is a good practice.

Good Practice No. 13:

Using duress devices that are strategically located to immediately notify security response personnel in the case of security breach or personnel working under duress conditions is a good practice.

Good Practice No. 14:

Using a tamper indicating device on high risk radioactive sources to deter, detect and prevent insider threat(s) is a good practice.

Good Practice No. 15:

Conducting joint tabletop exercises with MTH security personnel and law enforcement agencies to increase