RADIATION SAFETY DIRECTORATE
REPUBLIC OF NORTH MACEDONIA

FOURTH NATIONAL REPORT

ON THE JOINT CONVENTION ON THE SAFETY OF SPENT FUEL MANAGEMENT AND ON THE SAFETY OF RADIOACTIVE WASTE MANAGEMENT

October 2020

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Section A: Introduction

The Republic of North Macedonia has accessed the "Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management" in 2009, 7 September, through ratifying it in the National Parliament, whereas the Law on Ratification was published in the Official Gazette of the Republic of Macedonia No.113 of 11 September 2009. The instrument of accession was deposited 31 December 2009 and the Joint Convention entered into force 31 March 2010.

The Republic of North Macedonia became a member of the International Atomic Energy Agency in 1994, 25 February.

The first Macedonian national report on the implementation of the obligations of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management was prepared for the fourth review meeting on the Joint Convention in May 2012. The second one was prepared for the fifth review meeting on Joint Convention in 2015.The third report was prepared for the sixth review meeting on Joint Convention in 2018.

This fourth report has been prepared according the *Guidelines regarding the Form and Structure of National Reports* (INFCIRC/604/Rev.1 of 19 July 2006) established by the Contracting Parties. It gives an outline of National policy of radioactive waste management, state institutional framework and general legislation governing the aspects of the implementation of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management in North Macedonia.

The basis of the fourth report is in fact the previous third report, including progress made by Governmental decisions (adopted National Policy and Strategy for management with radioactive waste and DSRS proposed by RSD, proposed new facility for National storage facility, decision of Operator for National Storage facility), IAEA assistance in removing and exporting the Co-60 therapeutic 1st category source, change of ownership of some legal entities and thus of radioactive sources placed in temporary storage facilities and other activities.

The Republic of North Macedonia has neither nuclear power plants not any research nuclear reactors or fuel cycle facility, so there is no spent nuclear fuel and no high level radioactive waste. However, the radioactive waste management is an issue in the Republic of North Macedonia that originates from the use of radioactive sources in medicine and industry as well historical waste. The Republic of North Macedonia has no National Storage Facility for radioactive waste management. . Currently, the disused radioactive sources are stored either in the temporary storage facilities or in the own premises of the legal persons/users of the radioactive sources, regularly controlled by the Radiation Safety Directorate as competent regulatory authority for control of radiation sources, and radioactive waste as well.

The legal basis for radioactive waste management in the Republic of North Macedonia is covered by the Law on ionizing radiation protection and radiation safety and the regulations adopted thereto. In addition, the Republic of North Macedonia as a candidate country for European Union is obliged to transpose the *EU Acquis* into national legislation and the Radiation Safety Directorate is a responsible institution for transposing the legislation concerning radiation protection, radiation and nuclear safety and security.

Section B: Policies and Practices

Article 32 (Reporting), paragraph 1

Radioactive waste management policy

The radioactive waste issue is covered by the Law on Ionizing Radiation Protection and Radiation Safety (Official Gazette of the Republic of Macedonia, No. 48/02, 135/07, .154/10, 53/11, 43/14, 149/15, 37/16), and the Regulation on the managing, collecting, handling, conditioning, transporting and disposing of radioactive waste (Official Gazette of the Republic of Macedonia, No. 130/10) - in the following text, *Regulation on radioactive waste management*.

Within the IAEA project INT/9/176 on Strengthening Cradle-to-grave Control of Radioactive Sources in the Mediterranean Region, the RSD by help of the Agency prepared draft document on policy and strategy for radioactive waste management. The RSD finalized the document on National Policy and Strategy and proposed to the Government. The Government of the Republic of North Macedonia adopted the policy and strategy on 1 st of April 2019.

The National radioactive waste management policy is consistent with the requirements of the national legislative system, relevant international principles and all international agreements to which the Republic of North Macedonia is signatory. Radioactive waste management policy is based on the Law on ionizing radiation protection and safety, Regulation on radioactive waste management, Strategic Plan of the Radiation Safety Directorate, and of the practical needs of the country.

In addition, the Radiation Safety Directorate (RSD), each year, is adopting the *Strategic Plan of the Radiation Safety Directorate* (last one for the period 2021 – 2023), whereas the radioactive waste issue is considered with great importance. According the Strategic Plan, *the mission of the RSD is establishment of effective system of control over all ionizing radiation sources, ensuring safe and secure management with radioactive/nuclear material and radioactive waste in order to protect the public, occupational exposed workers as well as the environment from the exposure to ionizing radiation.* Among the priorities stated in the Strategic Plan, one is improving the radioactive waste management in the country, whereas the objective needed for this priority is: establishment of National Storage Facility for radioactive waste, dismantling, conditioning and storage of radioactive lightning rods and transfer of the radioactive sources from the temporary storage facilities to the National Storage Facility.

Furthermore, the cooperation in the field of nuclear safety and radiation protection between the Republic of North Macedonia, as a candidate country, and the European Union is provided by the *Stabilization and Association Agreement (ASA) (Official Journal of European Unio,n No. L 084, 20.03.2004),* article 103, item 4, whereas it is stated that the cooperation in the field of nuclear safety, among other topics, could also cover radioactive waste management and that North Macedonia undertakes to provide to the Stabilization and Association Council information concerning any intention to import or store radioactive waste.

According the Accession Partnership between the Republic of North Macedonia and EU (*Council Decision of 18 February 2008 on the principles, priorities and conditions contained in the Accession Partnership with the Republic of Macedonia and repealing Decision 2006/57/EC, Official Journal of European Union, No. L 080, 19.03.2008*), construction of an appropriate storage facility for radioactive materials is stated as short term key priority, as well as ensuring the proper and independent functioning of the RSD, as regulatory body in the field of radiation protection and radiation and nuclear safety and security.

Safety assessment report for the proposed location for National Storage Facility has been prepared and reviewed by IAEA expert under the project RER/9/096 in an expert mission "To assist the Regulatory body of North Macedonia in assessing the Safety Report for the Licensing of the Storage Facility", 19-30 July 2010. According that mission the report has been prepare (*Mission Report No. IAEA-TCR-05477*), and received by the RSD on 15 September .2010, whereas the recommendations for improvement of safety and security, as well as recommendations for public information have been pointed out. However, the Environmental impact assessment still needs to be developed by the Operator of National Storage Facility.

In the Law on ionizing radiation protection and radiation safety, ***radioactive waste*** is defined as "*material in any physical form which is a residue of related activities or interventions which are not anticipated for further use, which contains or is contaminated by radioactive materials and has activity or activity concentrations higher than the level which is not a subject of control and exposure to their radiation, is not excluded by the Law and regulations adopted pursuant to the Law*". The National radioactive waste management policy is based on the Law on Ionizing Radiation Protection and Radiation Safety, where according articles 22 and 13, includes the legal person responsibility *to maintain the activity and the volume of radioactive waste which is as result from practice with the source to lowest possible level and to ensure that the waste is managed (collected, stored, conditioned, transported and disposed) in accordance with the Law and the regulations adopted pursuant to it*.

The disposal (defined in the Law as "*emplacement of radioactive waste in an appropriate facility without the intention of retrieval"*) of disused radioactive sources and radioactive waste shall be conducted in storage on a location established by the Government of the Republic of North Macedonia upon the proposal of the Directorate, on the basis of the opinion of the Ministry of Environment and Spatial Planning and the Ministry of Health (article 24 of the Law). By the time the central storage to be established, the legal person is obliged to dispose the radioactive waste in their own site or in other site and in a manner approved by the RSD (article 37 of the Law).

Within the National project under the IAEA, MAK/4/002, locations and objects were assessed and considered as possible sites for National Storage Facility. The preliminary Safety Assessment Report for one possible location and already existed object has been prepared and two expert missions (one from the EC and one from the IAEA) took place (June 2010 and July 2010) for reviewing the preliminary Safety Assessment Report. Report from the last IAEA mission has been delivered to the RSD, and the Government of the Republic of North Macedonia, through the RSD, has been informed for the conclusions and recommendations given in the report (November 2010). Within this project Republic of North Macedonia in period of 2009-2010 received the equipment for storage radioactive waste and DSRS (drums for store DSRS and radioactive waste, several servey meters , fork lift for drums, gloves cell for manipulation with sources, tongs, ambient dose meter and other equipment).

Radioactive waste in North Macedonia originates from medicine and industry, as well as the historical waste. Only low-level and intermediate-level waste is generated from these sources. For such waste, the national policy includes on-site storage, exporting the disused radioactive sources to the manufacturer/supplier, decay and discharge, clearance from regulatory control or long term storage in National Storage Facility. The producers of radioactive waste have to bear the full costs of treatment, interim storage and long term storage.

North Macedonia supports the idea nuclear countries to cooperate closely with non-nuclear countries in developing regional solutions for final disposal of radioactive waste.

Radioactive waste management practices

In the Republic of North Macedonia there are three nuclear medicine departments that use unsealed radioactive sources (I-131, Tc-99m, I-125, and much less Sr-89, Cr-51, Y-90, Sm-153): Institute of Pathophysiology and Nuclear Medicine within the Medical Faculty in Skopje, Clinical Hospital "Dr. Trifun Panovski" in Bitola, and a private Clinical Hospital "Acibadem Sistina" in Skopje. These institutions generate radioactive waste which is temporary stored in their premises for decay and clearance or treat as conventional medical waste. The management practices in these institutions are explained below.

1) **Management practices in Clinical Hospital "Dr. Trifun Panovski" in Bitola**

The radioactive waste is collected in a plastic bag placed in a wooden bin shielded with lead foils and signposted with the radioactive trefoil. The cleaning staff collects the bags each day and transfers them in the storage room. The bags carry a label indicating the date of storage and radioactive trefoil. They are stored for decay at least for ten half-lives in a wooden cabinet shielded with lead. In practice, the bags are released when place is needed. Before release, the dose rate of the bags is measured and compared to the background level. The number of bags released is registered and the records are kept during 2 years. About 20 bags are released per year.

The spent generators are dismantled. The vials from the generators and from the spent sources of I-131 are kept two weeks for decay. Afterwards, the residual activity is measured with dose calibrator. If no activity is detected, the vial is further treated as other medical waste. Only one waste container is available in the hot lab which results in the mixing of isotopes when both Tc-99m and I-131 are used.

2) **Management practices in the Institute of Pathophysiology and Nuclear Medicine in Skopje**

A physicist from the radiation protection staff is appointed to the radioactive waste management program. Procedures are established for the management of radioactive waste. The waste is collected in a plastic bag placed in shielded containers. In each room where radioactive waste is produced, a shielded container is available. All the containers are signposted with the radioactive trefoil.

In the radiopharmacy for Tc-labeling, the waste is segregated between vials and paper or needles. The waste contaminated with technetium and iodine is collected separately, while the waste resulting from the therapeutic application of I-131 is stored in a dedicated container which is labeled with the radioactive symbol. The bags are removed by the cleaning staff under the supervision of a technician when they are full. They are labeled with the date and the isotope. Then, the radioactive waste is stored for decay for at least ten half-lives. After decay, the dose rate is measured and the waste package is released if the measured value is lower than 0.5 μSv/h. If biological radioactive liquid waste coming from cell labeling (samples of blood and blood elements) would be produced, the I-125 and Cr-51 waste is stored in two separate containers for decay (ten half-lives) before treatment as biological material.

The generator is usually used two weeks. After use, the spent generator is stored in the waste storage room for at least 2 months, separately from other radioactive material. After the decay period, the column is separated and stored in a different bunker outside of the Institute.

A detailed inventory recording the results of the dose rate measurement, the signature of the physicist, the date and the number of released packages is kept at least for 5 years.

3) Management practices in Clinical Hospital "Acibadem Sistina" Skopje

Clinical hospital Acibadem Sistina is a private hospital performing nuclear medicine practice, licensed since May 2011. The radioactive waste is collected in plastic bags and stored in a lead container located in a separate storage room for radioactive waste until decay, for at least ten half -lives and then it is treated as conventional medical waste. There is also a separate appropriate room equipped for all necessary stuffs for hospitalization of treated patients with I-131, and there is also tank to keep the effluents for decay.

4) Management practice in the University Clinic of Oncology and Radiotherapy in Skopje

The University Clinic of Oncology and Radiotherapy does not use unsealed radioactive sources but takes care of patients undergoing a therapeutic treatment with I-131 at the Institute of Pathophysiology and Nuclear Medicine requiring hospitalization. The I-131 capsule is prepared at the Institute of Pathophysiology and Nuclear Medicine and transported in its shielded container in a box placed on a cart. The infrastructure at the University Clinic of Oncology and Radiotherapy consists in one room with 2 beds.

In the room, two beds and a bathroom are available. The room is cleaned every day with equipment specifically dedicated to this purpose. The Institute of Pathophysiology and Nuclear Medicine is responsible for deciding when the patient may be released after having measured the dose rate at different distances. The patient is released once the dose rate at 2 meters is 7 μSv/h, i.e., after about 3-4 days. However, the waste management is part of the duty of the University Clinic of Radiotherapy and Oncology.

The patients have their own belongings and receive written instructions on how they have to treat them at home.

5) Cyclotron and PET/CT facilities

In the Republic of North Macedonia in the past years PET/CT practices are introduced in one public company (PET Center in Skopje) and two private hospitals (Acibadem Sistina in Skopje and One Hospital in Tetovo) that use short lived F-18. Furthermore, the PET Center in Skopje in 2017 obtained a first license by the RSD for cyclotron radioisotope production (F-18, C-11, N-13). The cyclotron is intended to produce radionuclides such as F-18, C-11, N-13 and O-15 for clinical and research applications. During the process of licensing, the PET Center submitted to the RSD a radioactive waste management plan, plan for radioactive discharges into environment, as well as decommissioning plan, as a part of the Radiation protection programme. The decommissioning plan is foreseen after 20 years of operation of the cyclotron. Two main issues, activation of the cyclotron components, and activation of the shielding material and vault, are taken into consideration. Dose estimation and plan for management of the activated material

have been provided as a part of the safety assessment report during the process of licensing of the cyclotron facility.

Management of orphan sources

Orphan source found in old metal scrap either importing to or exporting from and transit through the Republic of North Macedonia is a possibility of generation of radioactive waste. In North Macedonia there is one metal recycling facility located in Skopje, whereas the scrap metal is recycled either originating from Macedonia or from import.

For importing scrap metal the dosimetry control is performed at the border crossings whereas the particular control is provided by the Customs Administration using fixed, installed radiation monitors (panel detectors), pocket type instruments (pager detectors), hand-held instruments (survey meters) and other equipment, as well as border police equipped with pocket type instruments (pager detectors). In addition, all scrap metal imported in North Macedonia has to have a Certificate of non-radioactivity provided by the authorized technical service in North Macedonia.

In case of detection of a radiation higher than the background the customs officers and border police inform the RSD for performing inspection which consists of assessment and localization, as well as identification of the sources. The RSD can deploy technical services for performing special and detail measurements, decontamination procedures, transport and/or storage. In case of import and transit of scrap metal if radiation is detected, import of scrap metal is not allowed and the scrap metal is returned back to the country of origin. In such case the RSD notifies the country of origin and neighboring countries.

Total scrap metal collected in the Republic of North Macedonia, originating from all metal scrap yards, intended for a private metal recycling facility in Skopje, is controlled at the entrance of the metal recycling facility. At the two entrances, a railway and road, there are installed stationary panel detectors. The second control is inside the metal scrap facility, before recycling the old scrap metal, and control is performed by means of stationary detectors. If radioactive source is detected the RSD is notified. The RSD performs inspection, undertakes necessary measures and deploys a technical service to collect, transport and store the radioactive source at the temporary storage facility. The third control is taking samples of slabs for gamma spectrometry analysis in the accredited laboratory in the technical services authorized by the RSD according the Law on ionizing radiation protection and radiation safety and regulations therein. The fourth control is done when the slabs are converted into the sheet metal and the control is done by survey meters, and the final control is at the two exits/entrances of the facility.

Categorization of radioactive waste

In the *Regulation on radioactive waste management*, characterization, classification and categorization of radioactive waste are prescribed. It is stated that the radioactive waste shall be ***characterised*** according to the following:

1. Source origin;
2. Physical and chemical form;
3. Volume and/or mass;

4. Radiological characteristics (activity concentration, total activity, radionuclides contained and their relative representation);

5. Radioactive waste classification;

6. Radioactive waste categorisation;

7. All chemical, pathogenic or other hazards related to radioactive waste and concentrations of the hazardous material; and

8. Any special management which is of interest to the critical operation regime, the need for removing the heat generated from radioactive decay.

Furthermore, the radioactive waste shall be ***classified*** into:

1. *Cleared waste*;

2. *Radioactive waste with radionuclides with a very short half-life* – radioactive waste that may be stored over a limited period of time of a few years and be subsequently released from control; this class includes radionuclides used for research and medical purposes;

3. *Very low activity radioactive waste*;

4. *Low activity radioactive waste* – radioactive waste that is above release levels, but with limited amounts of long-lived radionuclides; such radioactive waste requires robust isolation and containment for periods of up to a few hundred years and is suitable for disposal in engineered near surface facilities; low activity radioactive waste may include short-lived radionuclides at higher levels of activity concentration and long-lived radionuclides, but only at relatively low levels of activity concentration;

5. *Intermediate activity radioactive waste* – radioactive waste that, because of its content, particularly of long-lived radionuclides, requires a greater degree of containment and isolation than that provided by near surface disposal; such waste needs only limited provision for heat dissipation during its storage and disposal; it may contain long-lived radionuclides, in particular alpha emitters, that will not decay to a level of activity concentration acceptable for near surface disposal; such radioactive waste requires disposal at greater depths, in the order of tens of metres to a few hundred metres; and

6. *High activity radioactive waste* – such radioactive waste requires disposal in stable geological formations several hundred metres below the surface.

The criteria used for ***categorization*** of radioactive waste are based on the following characteristics:

a) Non-radioactive and radioactive materials;
b) Half-life of radionuclides present: short lived radionuclides (for example, half-lives not exceeding 100 days) suitable for decay storage or long lived radionuclides (for example, half-lives exceeding 30 years);
c) Activity and radionuclide content;
d) Physical and chemical form:
    a. Liquid
        i. Aqueous
        ii. Organic;

b. Non-homogeneous (e.g. containing sludges or suspended solids);
c. Solid
    i. Combustible/non-combustible
    ii. Compactable/non-compactable
    iii. Metallic or non-metallic;

e) Fixed or non-fixed surface contamination;
f) Spent sealed sources;
g) Non-radiological hazards characteristics (e.g. chemical and biological toxicity).

Categorization of radioactive sources shall be done taking into account the ***waste acceptance criteria*** established for the subsequent step within the overall waste management process (handling, processing, transport or storage).

Historical waste

Disused radioactive sources in the past in the Republic of North Macedonia have been stored in the premises of the legal persons/users and/or owners of the radioactive sources, mainly legal persons involved in industrial application. The current sites and facilities that have temporary stored disused radioactive sources are given in Section D: Inventories and Lists and in Annex 2 of this Report.

Nowadays, the normal procedure for a disused source is such that it to be returned to the country of origin (manufacturer or supplier) as prescribed in the Regulation for radioactive waste management. In addition, within the process of management with radioactive waste recycle and reuse should be taken into account.

In order to ensure safe and secure storage of disused radioactive sources, when there is a need, such as orphan sources or any other source that needs to be stored there are temporary storage facilities that still accepts disused sources – Institut za zavaruvanje JUG AD Skopje (Weldding Institure Skopje) and RZ Tehnicka Kontrola AD Skopje.

Section C: Scope of Application

Article 3 (Scope of Application)

The report does not apply to the safety of spent fuel management since the Republic of Macedonia has no nuclear facilities.

The Republic of North Macedonia has not declared waste that contains only naturally occurring radioactive material as radioactive waste for the purpose of this Convention.

The Republic of Macedonia has no military or defense programme that produce radioactive waste.

Section D: Inventories and Lists

Article 32 (Reporting), paragraph 2

As mentioned before, the Republic of North Macedonia is non–nuclear country and therefore has no spent fuel facilities subject to this Convention.

Disused radioactive sources and radioactive waste are stored, under the control of the RSD, on the user premises until decayed or transferred to National Storage Facility.

The RSD maintains a database, the National Registry of radioactive sources in the Republic of North Macedonia. According the data in the registry, mainly the radioactive waste and disused radioactive sources stored in the temporary storages are radioactive sources from radioactive lightning rods, nuclear gauges (thickness, density or level gauges), smoke detectors, and some disused sources that were used in medicine - radiotherapy.

The inventories of disused radioactive sources stored in the temporary storage facilities in the Republic of Macedonia are given in Annex 2.

Section E: Legislative and Regulatory System

Article 18 (Implementing measures)

The Republic of North Macedonia has adopted the Law on ionizing radiation protection and radiation safety, whereas the RSD is established as national regulatory body in the field of radiation and nuclear safety and security in the Republic of North Macedonia. The Joint Convention has been ratified by the Law on ratification the Joint Convention, whereas the RSD is responsible governmental institution for implementing the Joint Convention.

Obligations from the Joint Convention have been implemented mainly in the following regulations:

1. Regulation on the managing, collecting, handling, conditioning, transporting and disposing of radioactive waste (Official Gazette of the Republic of Macedonia No. 130/10);
2. Regulation on the premises, devices, equipment and persons who may work with ionizing radiation sources (Official Gazette of the Republic of Macedonia, No. 78/2012), and
3. Regulation on the maximum permitted limits for discharge of radioactive materials in the environment, the manner of monitoring, maintaining records and reporting (Official Gazette of the Republic of Macedonia No. 162/09).

Article 19 (Legislative and regulatory framework)

The legislative framework for radiation safety is provided through the Law on ionizing radiation protection and radiation safety, regulations pursuant to this Law, as well as the ratified international conventions and agreements. According the Law the licensing system for practice with ionizing radiation source has been established, unless the source is exempted from regulatory control according the Regulation for the criteria for exemption of an ionizing radiation source and exclusion of a defined source from regulatory control (Official Gazette of the Republic of Macedonia, No. 162/09).

Article 20 (Regulatory Body)

Radiation Safety Directorate - the Regulatory Body was established in 2002 by promulgation of the *Law on ionizing radiation protection and radiation safety (OG RM, No. 48/02)*, and it began to function in 2005 with appointment of first director. The first employments in the RSD were realized in August 2006 and since then it started to be operational. Currently the total number of the RSD staff is 10.

In order of achieving the harmonization of the regulatory framework in the field of radiation protection and radiation and nuclear safety and security with the International Basic Safety Standards it was neccesary to ammend the Law 48/02. The ***Law amending and supplementing the Law on Ionizing Radiation Protection and Safety*** was promulgated in November 2007 *(OG RM, No. 135/07).* During drafting of the Law the standards from the IAEA documents (IAEA BSS, Code of conduct) and EU Acquis were taken into account, and partial harmonization with these standards was achieved. In 2011, set of different Laws covering the administrative procedures of issuing licenses and permits, have been amended, among which ***Law amending and supplementing the Law on ionizing radiation protection and radiation safety*** was promulgated in April 2011, *(OG RM, No. 53/11).* The amendments from 2011 cover in details the issue of submission of complaints by the user of radiation sources, deadlines and procedure for issuing licenses, as well as introducing new institution for deciding upon complaints of the users according the changes in the national legislative system.

Section F: Other General Safety Provisions

Article 21 (Responsibility of the licence holder)

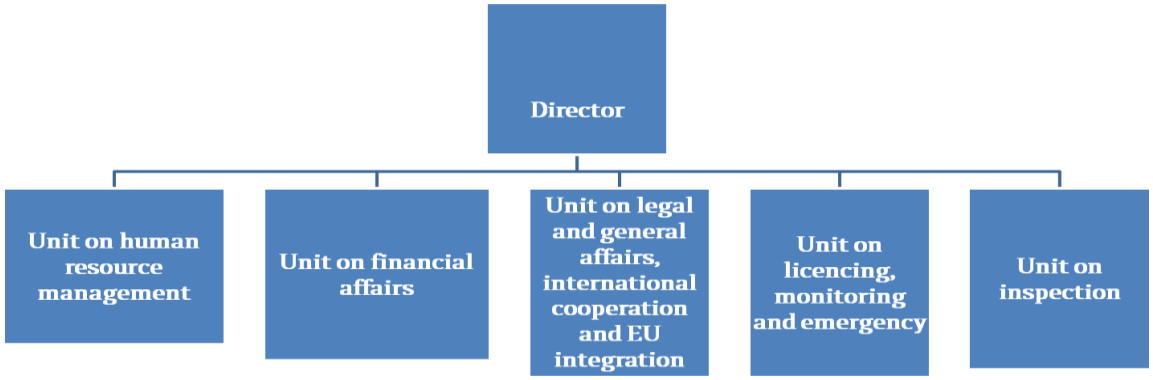
The prime responsibility for the safe management of radioactive sources including radioactive waste management rests within the legal person performing a practice (the license holder)

according to the Law on ionizing radiation protection and radiation safety. This includes the responsibility to ensure that disused sealed sources are handled in a safe manner and returned to the manufacturer/supplier or disposed of in another legal way accepted by the regulatory authority. Article 37 of the Law states that: *by the time the central storage to be established, the legal persons is obliged to store the radioactive waste in their own site or in other site in a manner approved by the RSD*. According this provision, the RSD has issued Decisions to the legal persons that posses and stores disused radioactive source. With those decisions the legal persons are obliged to keep the sources in safe storage, keep evidence of the sources, to undertake necessary measures to limit the exposure on radiation in accordance with the prescribed dose limits and dose constraints in the regulations, and any other measure for safe and secure storage of disused radioactive sources.

Article 22 (Human and financial resources)

The RSD has qualified staff for performing the duties prescribed by the Law and regulations concerning the issue of radioactive waste and disused radioactive sources. Staffing and job descriptions of the Radiation Safety Directorate are regulated by the internal acts: "*Rulebook on the Internal Structure of the RSD*", and "*Rulebook on Staffing and Job Descriptions of the RSD*" developed by the RSD Director and approved by the Ministry of Information Society and Administration.

The organizational structure of the RSD is shown below.



Organizational chart of the Radiation Safety Directorate

The RSD is financed through the state budget, according the Law on budgets and the national legislation as a whole. In addition, the RSD has its own incomes provided through the authorization fees in the licensing procedure, which are part of the state budget.

Article 23 (Quality assurance)

The Law on ionizing radiation protection and radiation safety includes the concept of Quality Assurance, within the Radiation Protection Program for any practise with ionizing radiation sources. In addition to the Law, the Regulation on the content of the radiation protection program, emergency plan and quality assurance program (Official Gazette of the Republic of Macedonia, No. 157/09), prescribes the content of a quality assurance program as following:

- periodic review of the radiation protection program and internal procedures;
- training program of the staff,
- quality control of the equipment;
- records keeping for:
    - occupational exposure,
    - workplace monitoring,
    - calibration of instruments,
    - radiation emergency,
    - review of the radiation protection program,
    - maintenance of equipment,
    - training of personnel,
    - health surveillance.

According the Regulation on radioactive waste management, the storage of radioactive waste shall be performed upon established waste acceptance criteria.

Article 24 (Operational Radiation Protection)

Any legal person that have disused radioactive sources in interim storage is under regulatory control of the RSD, according the Law on ionizing radiation protection and radiation safety, and is obliged by the RSD (Decision by the Directorate) to own and use or to store according to the Law and the regulations therein, that means the sources to be keep and store in a safe and secure manner ensuring that the doses received are within the prescribed national limits for the workers and public, which are in line with the International BSS.

Discharges and discharge limits, as mentioned in Section B, are prescribed by the Regulation on the discharge limits. The largest release from medical use in Macedonia is from nuclear medicine department - patients treated with iodine-131.

The individual monitoring of all occupationally exposed workers is performed by the Institute of Public Health and Technical services authorized by the RSD, by using thermo-luminescent dosimeters (TLDs), where the records are kept. The workers take part in a medical surveillance programme.

Routine environmental radiation monitoring, performed by the Institute of Public Health, of food, water, air, radon and goods is performed in accordance with the National program of environmental monitoring and in accordance with the Regulation on the manner and the measurement of the public exposure, maintaining records and reporting (Official Gazette of the Republic of Macedonia, No. 126/10).

The RSD performs control and inspection over implementation of the radiation protection measures for the public, occupationally exposed workers, and the environment.

Article 25 (Emergency Preparedness)

The RSD, according the Law on ionizing radiation protection and radiation safety, is empowered to undertake interventions in a case of emergency, to establish intervention levels and to prepare Plan on protection of the population in case of radiation emergency in the Republic of North Macedonia (article 3 of the Law). Based on article 25 of the Law, the Government of the Republic of North Macedonia, upon the proposal of the RSD, adopts this Plan. The first *Plan on*

protection of the population in case of radiation emergency in the Republic of Macedonia was adopted on 14 June 2011 and published in the Official Gazette of the Republic of Macedonia, No. 84/11. This Plan establishes the system for radiation emergency preparedness and response in the Republic of North Macedonia.

The objective of this Plan is establishment of a bases for preparedness and effective response to radiation emergency in the Republic of North Macedonia, integrated with the response not only on a national level, but both in international and local level through ensuring coordination among the institutions, organizations and other bodies involved in the response to radiation emergency and through providing support to local forces. In addition, in this Plan, beside the RSD, all institutions and governmental bodies that have responsibilities and duties in a case of radiation emergency such as Crisis Management Centre, Protection and Rescue Directorate, Ministries (Environment, Health, Agriculture, Interior, Transport etc), technical services, academic community and non-governmental organization such as professional associations, and other legal entities that could provide any support are included as well.

The legal entity with a license for the ionizing radiation source is obliged to notify the RSD promptly when a situation requiring protective action arise or is expected to arise, and shall keep them informed of the development of the situation, the measures taken for the protection of the population and the potential exposure (article 25-a of the Law).

In addition, all legal entities, in order to obtain a license for practise with ionizing radiation sources are obliged to submit to the RSD a Radiation Protection Program that contains the Emergency Plan.

Article 26 (Decommissioning)

Currently, the issue of the decommissioning is not fully addressed in the national legislation and regulations. The Regulation on radioactive waste management only states that for National Storage Facility there shall be a plan for decommissioning and financial resources for decommissioning.

Section G: Safety of Spent Fuel Management

This section does not apply to the Republic of North Macedonia (articles 4-10), having in mind that there is no any nuclear reactor nor spent fuel storage facility.

Section H: Safety of Radioactive Waste Management

Article 11 (General Safety Requirements)

General safety requirements for radioactive waste in the Republic of North Macedonia are prescribed by the Law on ionizing radiation protection and radiation safety whereas, the legal entity is obliged to ensure *the activity and volume of any radioactive waste as low as reasonably achievable, to collect, keep, conditioning, transport and dispose according the provisions of the Law and regulations therein*. The regulation on radioactive waste management specifies the procedures for waste minimization.

All regulations covering radiation protection, radiation safety and nuclear security of ionizing radiation sources apply to legal persons regarding radioactive waste management as well.

Article 12 (Existing Facilities and Past Practices)

Currently in the Republic of North Macedonia, the disused radioactive source and radioactive waste are stored in 14 temporary locations, see Annex 1.

Four out of these 14 locations (Institut za zavaruvanje "JUG" AD Skopje, RZ Technicka Kontrola AD Skopje, FZC "11 Oktomvri" Kumanovo and formerly "Institute of radioisotopes in industrial application" (so-called Centre of radioisotopes) which is now bankrupted and new owner is the Faculty of Mechanical Engineering, Ss. Cyril and Methodius University in Skopje) have been using for storing radioactive sources originating from other institutions mainly radioactive lightning rods, nuclear gauges, smoke detectors and few radioactive sources used in medicine for radiotherapy.

Three out of these four companies perform practise with radiation sources in industrial radiography and have licenses for industrial radiography practice issued by the RSD. Only the Faculty of Mechanical Engineering does not perform practice with ionizing radiation sources.

The other 10 locations where disused radioactive sources are stored belongs to the companies that have performed practise with ionizing radiation sources in the past and the radioactive source stored in their own premises are mainly nuclear gauges, few lightning rods and radioactive sources for medical application.

Article 13 – 15 (Siting of proposed facilities, Design and construction of facilities and Assessment of safety of facilities)

According the Law on ionizing radiation protection and radiation safety (article 24), disposal of disused radioactive sources and radioactive waste shall be performed in a location approved by the Government of the Republic of North Macedonia, upon proposal of the RSD, in accordance with the Ministry of Environment and Physical Planning and the Ministry of Health.

The Republic of North Macedonia has no yet National Storage Facility for radioactive waste. Within the National IAEA project MAK/4/002/ on Management of radioactive waste in the Republic of Macedonia that has been finished in 2009 necessary equipment for radioactive waste management has been supplied by the IAEA in period 2009-2010). Moreover, the RSD within the IAEA project INT/9/176 on Strengthening Cradle-to-grave Control of Radioactive Sources in the Mediterranean Region has prepared Safety Guide for Safety Case and Safety Assessment.

The possible location for the National Storage Facility has been proposed to the Government of the Republic of North Macedonia in 2008, whereas the decision has been taken

on a closed session of the Government. Since then, all activities concerning the National Storage Facility are confident and treat as classified information. The RSD has required to the Government of the Republic of North Macedonia to change the status of confidentiality of those information and activities related to this issue, in accordance with the obligation arising from the Joint Convention and accession to this Convention through ratification by the Parliament and its entry into force (March 2010).

In December 2018, RSD made declassification of confidentiality of those information .

In that period representatives from RSD and Ministry of Defence decided, that the previous facility is strategic important point for the Army as a future member of NATO.

The Ministry of Defence proposed new facility (ex military facility) as a new National Storage facility. RSD established commission with representatives from Ministry of Environment and Physical Planning and the Ministry of Health. After several meetings and visits of that facility the representatives from the both Ministries submitted the positive report to the Government for the future National Storage facility.

New facility for National Storage Facility

In April 2019 the Government of Republic of North Macedonia, at the same government session when the National Policy and Strategy were adopted, decided the Institute of Public Health to be named as a future operator of the National Storage Facility.

Decommissioning of the waste storage facility

The Republic of North Macedonia has no yet National Storage Facility and decommissioning is an issue that shall be considered into the Safety assessment report for the National Storage Facility in the process of licensing.

Article 17 (Institutional measures after closure)

North Macedonia has no yet centralized waste storage facility and therefore there is no plan or requirement concerning post closure institutional control (e.g. monitoring, security etc.).

Section I: Transboundary movement

Article 17 (Transboundery movement)

Any national or international transport of radioactive source is a subject of licensing procedure in North Macedonia, and therefore each legal person performing a transport of radioactive material shall be authorized by the RSD. Concerning the transport of radioactive source the following legislation shall be considered:

1. Law on ionizing radiation protection and radiation safety (OG No. 48/02, 135/07, 53/11);
2. Law on transport of dangerous goods (OG No. 92/07);
3. Regulation on radioactive waste management (OG No. 130/10);
4. Regulation on transport of radioactive and nuclear material (OG No. 160/10);
5. Regulation on the form and content of the template of the application for a license for practice with ionizing radiation sources, the form and content of the template of the license and the manner of and procedure for issuing the license (OG No. 157/09) and others.

In addition to the above mentioned legislation the provisions of the ADR (European Agreement Concerning the International Carriage of Dangerous Goods by Roads) and RID (Regulation Concerning the International Carriage of Dangerous Goods by Rail) are applied (article 3 of the law on transport of dangerous goods) in the Republic of Macedonia.

The regulation on radioactive waste management, states that the transport of radioactive waste and disused radioactive source shall be performed in accordance with the provisions for transport of radioactive material in force.

In addition, according the Law on ionizing radiation protection and radiation safety the import of radioactive waste in the Republic of North Macedonia is prohibited (article 22).

Moreover, the legal person that transport nuclear material shall be liable for damage in amount of 100000000,00 EUR, and is obliged to submit financial security to the RSD for compensation of the eventual damage.

Technical Instructions of the International Civil Aviation Organisation (ICAO) and the Dangerous Goods Regulations of the International Air Transport Association (IATA) are directly applicable.

Section J: Disused sealed sources

Article 28 (Disused sealed sources)

The disused sealed radioactive sources, imported in Macedonia *shall be returned to the manufacturer or the supplier* (in accordance with the Regulation on radioactive waste management, article 27).

No manufacturing or remanufacturing of sealed radioactive sources does take place in North Macedonia.

According the Law on ionizing radiation protection and radiation safety (article 22-b), the legal or physical person who possesses ionizing radiation source and/or radioactive waste not in accordance with the provisions of the Law is obligated to cover the costs for the repossession, transport and storage. In addition, article 22-c of the Law states that the transport and the storage of the orphan sources and/or radioactive waste shall be managed by the authorized technical services upon the request of the RSD, whereas the next paragraph of the article states that the costs for the transport and the storage of the orphan sources and/or radioactive waste shall be covered by the national budget of the Republic of North Macedonia.

Fixed portal monitors are installed in main road border crossings, and the customs administration officers and border police officers are equipped with portable monitors, pagers, survey meters, etc. In addition, all scrap metal imported in North Macedonia intended for metal recycling facility is measured by technical service. Moreover, the metal recycling facility itself has additional control at the entrance whereas the panel detectors are installed, second control is inside the metal recycling facility, third control is gamma spectroscopy measurements of the slab in accredited laboratory and final, forth control is control of final products (when slabs are converted into the sheet metal), whereas control is done by survey meters and at the two exits/entrances of the facility, as well, as explained in more detail in *Radioactive waste management practices*. When radioactive source is found the RSD is immediately informed, and the technical service is employed to find and collect the source in the temporary storage.

Section K: Planned activities to improve safety

RSD aims at achieving high level of radiation protection, safety and security and to enforce all legal requirements concerning radiation protection and safety in the Republic of North Macedonia. In particular, concerning disused radioactive sources and radioactive waste there are several measures and activities to improve safety and security.

Implementation a National Policy and Strategy for Radioactive Waste Management, commensurate with the application and inventory of sources as well as with international trends is the activity that will contribute to improve safety.

Establishing the National Storage Facility and performing the licensing procedure in accordance with the national legislation, international standards and recommendations, and the best IAEA and EU practices is also the activity that has to be finished as soon as possible, which would be supplementary to the national policy of radioactive waste management.

The public information issue, concerning the radioactive waste management and management of disused sealed radioactive sources has to be considered to the great extend and is of high importance.

The following activities of the RSD to improve the safety and security in the country are considered to be:

- providing the support to the Government of the Republic of North Macedonia and all other relevant interested parties to finish the issue of establishment of a National Storage Facility;
- regular inspection on the users/owners of radioactive sources and owners of temporary storages for radioactive waste and/or disused sealed radioactive sources;
- transfer of radioactive waste and disused sealed radioactive sources from temporary storages to the National Storage Facility;
- continuously improvement of radioactive waste management practices, according the best international practice;
- participation in national, bilateral and regional/international projects in the field of radiation protection, safety and security, particularly in radioactive waste management; and
- raising awareness on the radioactive waste management, radiation and nuclear safety and security.

Section L: Completed activities

Through IAEA Project RER/9/143 ,, Strengthening the capabilities of management of radioactive waste and DSRS " and INT/9/176 on Strengthening Cradle-to-grave Control of Radioactive Sources in the Mediterranean Region , RSD started negotiations with the Agency for removing and returning the Category 1 teletherapy source (Co-60) from the University Clinic of Radiotherapy and Oncology in Skopje and exported. In March 2019 after finished all procedures between IAEA and the operator IZOTOP from Budapest, Hungary the Co-60 source was removed to Hungary, while shielding material from machine (depleted uranium) was exported to Czech Republic.

In this period number of temporary storage facilities was reduced from 16 to 14. Namely, the sources from the temporary storage facilities Pivara AD Skopje and EMO Ohrid were transferred to the temporary storage facility of TZ Tehnicka Kontrola AD Skopje.

Section M: Current Project regarding managing the radioactive waste and DSRS

The Republic of North Macedonia is involved in several IAEA and EU project for management of radioactive waste and DSRS.

IAEA Projects:

INT 9/186/ Sustaining Cradle to grave of radioactive source
RER 9/154/ Enhancing of Implementation of Integrated Programmes for the Safe Management of Radioactive waste.

Project : European Commission & Centers of Excellence

Section N: Annexes

Annex 1. List of radioactive waste management facilities

Annex 2. Inventory of radioactive waste management facilities

Annex 3. References to national laws, regulations, requirements, guides, etc

Annex 4. References to reports on international review missions performed at the request of a Contracting Party

Annex 5. Other relevant material

Annex 1. List of radioactive waste management facilities

1. RZ Tehnicka kontrola AD Skopje
2. Institut za zavaruvanje JUG AD Skopje
3. APAVE SEEDO Skopje
4. Mechanical faculty Skopje, University Ss.Ciril and Methodius Skopje (formerly known Centre of radioisotopes Skopje)
5. Construction Institute Macedonia AD Skopje
6. JZU University clinic of radiotherapy and oncology Skopje
7. AD ELEM Podruznica Oslomej Kicevo
8. Silmak DOOEL Jegunovce
9. US Construction DOOEL Kumanovo (former Kiro Kucuk Veles)
10. FZC 11 Oktomvri AD Kumanovo
11. JZU Institute of Public Health Skopje
12. Eksim komerc delovna edinica Gostivar (former Goteks Gostivar)
13. Tutunski kombinat Prilep
14. Sanos DOO Skopje (former bus factory 11 Oktomvri Skopje)

Annex 2. Inventory of radioactive waste management facilities

1. RZ Tehnicka kontrola AD Skopje

No.	Radionuclide	Activity (GBq)	Date of activity	Date of storage	Remarks
1	Am-241	-	-	14.12.2003	Lightning rod
2	Am-241	-	-	14.12.2003	Lightning rod
3	Am-241	-	-	14.12.2003	Densitometer
4	Am-241	-	-	14.12.2003	Lightning rod
5	Am-241	-	-	14.12.2003	Lightning rod
6	Am-241	-	-	14.12.2003	Lightning rod
7	Co-60	7,4	01.01.1971	14.12.2003	Lightning rod
8	Co-60	7,4	01.01.1971	14.12.2003	Lightning rod
9	Co-60	-	-	13.03.2004	Lightning rod
10	Co-60	7,4	01.01.1971	23.10.2004	Lightning rod
11	Co-60	104	26.05.1965	Before 1986	Industrial radiography
12	Eu-152	-	-	28.02.2004	Lightning rod
13	Eu-152	14,8	05.04.1975	25.07.2004	Lightning rod
14	Eu-152	14,8	24.11.1970	11.09.2004	Lightning rod
15	Eu-152	-	-	14.01.2006	Lightning rod
16	Eu-152	-	-	24.12.2005	Lightning rod
17	Eu-152	14,8	-	10.12.2006	Lightning rod
18	Eu-152	12,2	02.10.1987	20.10.1998	Lightning rod
19	Unknown	-	-	20.01.2006	Source in scrap metal
20	Unknown	-	-	15.09.2005	Nuclear gauge (scrap metal)
21	Unknown	-	-	Before 1980	Nuclear gauge (densitometer)
22	Unknown	-	-	Before 1980	Nuclear gauge (densitometer)
23	Am-241	0,0027	-	-	Smoke detectors total 28
24	Am-241	-	-	-	12 smoke detectors
25	Co-50	-	-	27.10.2014	Lightning rod
26	Eu-152	-	-	05.06.2015	Lightning rod
27	Ra-226	-	-	26.04.2017	2 smoke detectors
28	Ra-226	-	-	29.05.2017	Smoke detector
29	Ra-226	-	-	23.05.2017	13 smoke detectors
30	Am-241	-	-	23.05.2017	3 smoke detectors
31	Eu-152	14.8	01.01.1986		Lightning rod

32	Eu-152	14.8	01.01.1986		Lightning rod
33	Eu-152	14.8	01.01.1986		Lightning rod
34	Eu-152	14.8	01.01.1986		Lightning rod
35	Eu-152-154	14.8	01.01.1986	03.05.2017	Lightning rod
36	Eu-152-154	14.8	01.01.1986	17.02.2018	Lightning rod
37	Eu-152-154	14.8	28.07.1986	07.08.2018	Lightning rod
38	Eu-152-154	14.8	28.07.1986	07.08.2018	Lightning rod
39	Eu-152-154	14.8	28.07.1986	07.08.2018	Lightning rod
40	Eu-152-154	14.8	28.07.1986	07.08.2018	Lightning rod
41	Depleted Uranium	Shielding SU50Typ B	Gamma volt	07.08.2018	Industrial camera
42	Depleted Uranium	Shielding SU50Typ B	Gamma volt	09.10.2020	Industrial camera
43	Depleted Uranium	Shielding SU50ATyp B	Gamma volt	09.10.2020	Industrial camera
44	Am-241	1,67	09.05.1991	12.10.2020	Nuclear gauge
45	Am-241	7,4	11.12.1990	12.10.2020	Nuclear gauge

2. Institut za zavaruvanje JUG AD Skopje

No.	Radionuclide	Activity (GBq)	Date of activity	Date of storage	Remarks
1	Eu-152	14,8	15.02.1979	30.10.2000	Lightning rod
2	Co-60	7,4	15.02.1979	30.10.2000	Lightning rod
3	Cs-137	-	-	Before 1986	Densitometer
4	Co-60	7,4	Before 1986	Before 2002	Lightning rod
5	Co-60	7,4	01.01.1985	Before 2002	Lightning rod
6	Co-60	7,4	01.01.1985	Before 2002	Lightning rod
7	Co-60	7,4	01.01.1985	Before 2002	Lightning rod
8	Co-60	7,4	01.01.1985	Before 2002	Lightning rod
9	Co-60	7,4	Before 1986	Before 2002	
10	Cs-137	-	-	Before 2002	Densitometer
11	Cs-137	-	-	Before 2002	Densitometer
12	Eu-152	14,8	Before 1986	Before 2002	Lightning rod
13	Eu-152	14,8	Before 1986	Before 2002	Lightning rod
14	Eu-152	14,8	Before 1986	Before 2002	Lightning rod
15	Eu-152	14,8	Before 1986	Before 2002	Lightning rod
16	Cs-137	-	-	Before 2002	Densitometer
17	Cs-137	1,85	01.07.1976	Before 2002	Densitometer
18	Cs-137	1,85	01.07.1981	Before 2002	Densitometer
19	Eu-152	14,8	Before 1986	Before 2002	Lightning rod
20	Eu-152	14,8	27.05.1975	14.11.2002	Lightning rod
21	Eu-152	14,8	Before 1986	Before 2002	Lightning rod
22	Co-60	7,4	Before 1970	Before 2002	Lightning rod
23	Co-60	7,4	01.01.1978	30.10.2000	Lightning rod
24	Co-60	7,4	01.01.1977	31.03.2003	Lightning rod
25	Am-241	0,4	01.03.1975	04.10.2002	Lightning rod
26	Co-60	7,4	01.03.1975	23.10.2002	Lightning rod
27	Co-60	7,4	01.03.1985	07.10.2002	Lightning rod
28	Co-60	7,4	01.07.1970	30.10.2000	Lightning rod
29	Eu-152	14,8	-	04.08.2010	Lightning rod
30	Co-60	7,4	31.10.1977	29.04.2008	Lightning rod
31	Co-60	7,4	26.04.1973	26.11.2009	Lightning rod

32	Co-60	7,4	29.09.1971	29.10.2009	Lightning rod
33	Eu-152	14,8	01.12.1979	20.11.2009	Lightning rod
34	Eu-152	14,8	01.12.1979	20.11.2009	Lightning rod
35	Eu-152	14,8	-	04.09.2009	Lightning rod
36	Unknown	-	-	18.07.2007	Source in scrap metal
37	Unknown	-	-	10.07.2008	Smoke detectors total 66
38	Cs-137	7,4	1978	22.06.2006	Densitometer
39	Cs-137	7,4	1978	22.06.2006	Densitometer
40	Cs-137	7,4	2000	22.06.2006	Densitometer
41	Cs-137	7,4	1978	22.06.2006	Densitometer
42	Cs-137	7,4	1978	22.06.2006	Densitometer
43	Unknown	-	-	15.11.2008	Source in scrap metal
44	Unknown	-	-	04.08.2011	Source in scrap metal - total 15
45	Eu-152	14.8	Before 1986		Lightning rod
46	Co-60	Unknown	Unknown		Lightning rod
47	Unknown	Unknown	Unknown		Lightning rod
48	Co-60	Unknown	Unknown		Lightning rod
49	Ra-226	Unknown	Unknown		Parts of measuring instruments
50	Ra-226	Unknown	Unknown		Parts of measuring instruments
51	Ir-192	Unknown	Unknown		Gamma-defectoscope
52	Eu-152	Unknown	Unknown	04.06.2015	Lightning rod
53	Eu-152	Unknown	Unknown	04.06.2015	Lightning rod
54	Eu-152	Unknown	Unknown	04.06.2015	Lightning rod
55	Th-232	Unknown	Unknown	27.05.2015	Unknown
56	Am-241			05.11.2018	Smoke detectors total 252

3. APAVE SEE DOO Skopje

No.	Radionuclide	Activity (GBq)	Date of activity	Date of storage	Remarks
1	Cs-137	0,925	-	14.01.2011	Industrial radiography
2	Ir-192*	37	-	14.01.2011	Industrial radiography
3	Yb-169*	333	-	14.01.2011	Industrial radiography

* Source No.2 and 3 are in same container

4. Mechanical faculty Skopje, University Ss.Ciril and Methodius Skopje (formerly known Centre of radioisotopes Skopje)

No.	Radionuclide	Activity (GBq)	Date of activity	Date of storage	Remarks
1	Co-60	0,185	14.12.1974	10.10.1999	Nuclear gauge
2	Co-60	0,37	14.12.1974	14.12.1999	Nuclear gauge
3	Co-60	0,185	14.12.1974	14.12.1999	Nuclear gauge
4	Co-60	7,4	01.12.1977	Before 2002	Lightning rod

5	Co-60	7,4	01.12.1977	Before 2002	Lightning rod
6	Co-60	7,4	01.12.1977	Before 2002	Lightning rod
7	Co-60	7,4	06.09.1972	Before 2002	Lightning rod
8	Co-60	8,5	05.06.1974	Before 2002	Lightning rod
9	Co-60	14,8	07.06.1974	Before 2002	Lightning rod
10	Co-60	7,4	03.04.1975	Before 2002	Lightning rod
11	Co-60	7,4	26.07.1972	Before 2002	Lightning rod
12	Co-60	7,4	07.11.1975	Before 2002	Lightning rod
13	Eu-152	-	01.01.1974	14.07.2003	Lightning rod
14	Eu-152	22,2	01.12.1977	30.01.1997	Lightning rod
15	Eu-152	22,2	01.12.1977	Before 2002	Lightning rod
16	Eu-152	22,2	01.12.1997	Before 2002	Lightning rod
17	Eu-152	14,8	06.04.1977	Before 2002	Lightning rod
18	Eu-152	22,2	06.04.1977	Before 2002	Lightning rod
19	Eu-152	14,8	01.12.1980	Before 2002	Lightning rod
20	Eu-152	14,8	26.07.1972	Before 2002	Lightning rod
21	Eu-152	14,8	01.01.1974	Before 2002	Lightning rod
22	Eu-152	14,8	04.07.1972	Before 2002	Lightning rod
23	Eu-152	22,2	04.07.1972	Before 2002	Lightning rod
24	Eu-152	22,2	04.07.1972	Before 2002	Lightning rod
25	Eu-152	22,2	04.07.1972	Before 2002	Lightning rod
26	Eu-152	14,8	04.07.1972	Before 2002	Lightning rod
27	Eu-152	14,8	24.04.1973	-	Lightning rod
28	Eu-152	14,8	17.11.1980	-	Lightning rod
29	Cs-137	3,7	01.01.1980	Before 2002	Nuclear gauge
30	Cs-137	1,85	01.01.1975	Before 2002	Radiotherapy source
31	Cs-137	3,7	01.01.1975	Before 2002	Radiotherapy source
32	Cs-137	3,7	01.01.1975	Before 2002	Nuclear gauge
33	Cs-137	1,85	14.12.1974	Before 2002	Nuclear gauge
34	Cs-137	1,85	14.12.1974	Before 2002	Nuclear gauge
35	Cs-137	37	01.01.1975	Before 2002	Radiotherapy source
36	Cs-137	37	01.01.1975	Before 2002	Radiotherapy source
37	Cs-137	37	01.01.1975	Before 2002	Radiotherapy source
38	Cs-137	1,85	01.01.1975	Before 2002	Radiotherapy source
39	Cs-137	1,85	01.01.1978	Before 2002	Radiotherapy source
40	Cs-137	1,85	01.01.1975	Before 2002	Radiotherapy source
41	Sr-90	37	10.03.1998	Before 2002	Nuclear gauge
42	Unknown	-		Before 2002	Lightning rod
43	Unknown	-		Before 2002	Lightning rod
44	Unknown	-		Before 2002	Lightning rod
45	Unknown	-		Before 2002	Lightning rod
46	Unknown	-		Before 2002	Lightning rod
47	Unknown	-		Before 2002	Lightning rod
48	Unknown	-		Before 2002	Lightning rod

5. Construction Institute Macedonia AD Skopje

No.	Radionuclide	Activity (GBq)	Date of activity	Date of storage	Remarks
1	Cs-137	0,37	04.10.1982	14.04.2006	Nuclear gauge
2	Am-241/Be	3,9	28.12.1980	14.04.2006	Nuclear gauge

6. JZU University clinic of radiotherapy and oncology Skopje

No.	Radionuclide	Activity (GBq)	Date of activity	Date of storage	Remarks
1	Au-198	-	15.01.1970	20.09.1999	Contaminated syringe (liquid gold in syringe)
2	Au-198	-	-	10.05.2000	Liquid gold in vial
3	Ra-226	0,37	10.10.1979	20.09.1999	Standard (Siemens E2:S8)
4	Ra-226	37	01.01.1970	10.05.2000	Radiotherapy
5	Ra-226	37	01.01.1970	10.05.2000	Radiotherapy
6	Cs-137	1,74	28.02.1979	10.05.2000	Oxide residues
7	Cs-137	1,74	28.02.1979	10.05.2000	Oxide residues
8	Ir-192	-	15.05.1970		Radiotherapy
9	Sr-90	0,033	01.01.1983	20.09.1999	Radioactive wire
10	Co-60	236630	15.09.1998	2014	Teletherapy source

7. AD ELEM Podruznica Oslomej Kicevo

No.	Radionuclide	Activity (GBq)	Date of activity	Date of storage	Remarks
1	Co-60	4,11	24.01.1979	03.04.2006	Nuclear gauge
2	Co-60	4,11	24.01.1979	03.04.2006	Nuclear gauge
3	Co-60	4,11	24.01.1979	03.04.2006	Nuclear gauge
4	Co-60	4,11	24.01.1979	03.04.2006	Nuclear gauge
5	Co-60	6,92	25.01.1979	03.04.2006	Nuclear gauge
6	Co-60	6,92	25.01.1979	03.04.2006	Nuclear gauge

8. Silmak DOOEL Jegunovce

No.	Radionuclide	Activity (GBq)	Date of activity	Date of storage	Remarks
1	Co-60	0,111	01.07.1975	01.07.1979	Nuclear gauge
2	Co-60	0,111	01.07.1975	01.07.1979	Nuclear gauge
3	Co-60	0,111	01.07.1975	01.07.1979	Nuclear gauge
4	Co-60	0,111	01.07.1975	01.07.1979	Nuclear gauge
5	Co-60	0,111	01.07.1975	01.07.1979	Nuclear gauge
6	Co-60	0,111	01.07.1975	01.07.1979	Nuclear gauge
7	Co-60	0,111	01.07.1975	01.07.1979	Nuclear gauge
8	Co-60	0,111	01.07.1975	01.07.1979	Nuclear gauge

9. US Construction DOOEL Kumanovo (former Kiro Kucuk Veles)

No.	Radionuclide	Activity (GBq)	Date of activity	Date of storage	Remarks
1	Co-60	7,4	27.05.1985	24.02.1995	Lightning rod/ own
2	Co-60	7,4	27.05.1985	24.02.1995	Lightning rod/ own
3	Eu-152	14,8	14.01.1982	17.07.2003	Lightning rod/ own

4	Cs-137	3,7	01.01.1979	10.05.1999	Level gauge/ own
5	Sr-90	1,85	01.01.1979	10.05.1999	Level gauge/ own
6	Sr-90	1,85	01.01.1980	10.05.1999	Level gauge/ own

10. FZC 11 Oktomvri Kumanovo

No.	Radionuclide	Activity (GBq)	Date of activity	Date of storage	Remarks
1	Eu-152	14,8	27.05.1975	23.01.1995	Lightning rod

11. JZU Institute of Public Health Skopje

No.	Radionuclide	Activity (GBq)	Date of activity	Date of storage	Remarks
1	Ra-226	Unknown	Unknown	1998-1999	Checkup source

12. Eksim komerc delovna edinica Gostivar (former Goteks Gostivar)

No.	Radionuclide	Activity (GBq)	Date of activity	Date of storage	Remarks
1	Unknown	-	-	14.07.2003	Lightning rod/ own

13. Tutunski kombinat Prilep

No.	Radionuclide	Activity (GBq)	Date of activity	Date of storage	Забелешка
1	Sr-90	0,444	01.09.1979	10.01.1996	Nuclear gauge
2	Sr-90	0,444	01.09.1979	10.01.1996	Nuclear gauge
3	Sr-90	0,444	01.09.1979	10.01.1996	Nuclear gauge
4	Sr-90	93	01.09.1995	10.10.1999	Nuclear gauge
5	Sr-90	0,4,44	01.09.1979	10.01.1996	Nuclear gauge
6	Sr-90	0,4,44	01.09.1979	10.01.1996	Nuclear gauge
7	Sr-90	0,4,44	01.09.1979	10.01.1996	Nuclear gauge
8	Sr-90	0,4,44	01.09.1979	10.01.1996	Nuclear gauge
9	Sr-90	0,4,44	01.09.1979	10.01.1996	Nuclear gauge

14. Sanos DOO Skopje (former bus factory 11 Oktomvri Skopje)

No.	Radionuclide	Activity (GBq)	Date of activity	Date of storage	Remarks
1	Co-60	7,4	01.01.1976	01.09.2009	Lightning rod/ own

Annex 3. References to national laws, regulations, requirements, guides, etc

1. Law on ionizing radiation protection and safety (Official Gazette of the Republic of Macedonia No. 48/02, 135/07, 54/11); (Official consolidation of the 2002 Law and 2007 Amendments to the Law on Ionizing Radiation Protection and Safety, published in Official Gazette No. 154/10, in November 2010);
2. Law on transport of dangerous goods (Official Gazette of the Republic of Macedonia No. 92/07 with ammendments);
4. Regulation on the managing, collecting, handling, conditioning, transporting and disposing of radioactive waste (Official Gazette of the Republic of Macedonia No. 130/10);
5. Regulation on the manner of transporting of radioactive and nuclear material (Official Gazette of the Republic of Macedonia No. 160/10);
6. Regulation on the form and content of the template of the application for a license for practice with ionizing radiation sources, the form and content of the template of the license, as well as the procedure for issuing the license
7. Regulation on the maximum permitted limits for discharge of radioactive materials in the environment, the manner of monitoring, maintaining records and reporting (Official Gazette of the Republic of Macedonia No. 162/09);
8. Regulation on the content for radiation protection program, emergency plan and quality assurance program (Official gazette of the Republic of Macedonia No. 157/09);
9. Regulation for the criteria for exemption of an ionizing radiation source and exclusion of a defined source from regulatory control (Official Gazette of the Republic of Macedonia No. 162/09);
10. Regulation on the manner and the measurement of the public exposure, maintaining records and reporting (Official Gazette of the Republic of Macedonia No. 126/10);
11. Regulation on the categorization of radiation and nuclear threats (Official Gazette of the Republic of Macedonia No. 162/10);
12. Regulation the dose limits of exposure to ionizing radiation and the conditions of exposure in special circumstances and in case of emergency (Official Gazette of the Republic of Macedonia No. 29/10);
13. Regulation on the manner and measuring the exposure of occupationally exposed persons, keeping records and reporting (Official Gazette of the Republic of Macedonia No. 29/10);
14. Regulation on the health conditions for work with sources of ionising radiation, as well as measures, content and manner of the health examination of persons working with sources of ionising radiation (Official Gazette of the Republic of Macedonia No. 28/10);
15. Plan on protection of the population in case of radiological emergency in the Republic of Macedonia, adopted in June 2011, (Official Gazette of the Republic of Macedonia No. 84/11);
16. Rulebook on the Internal Structure of the Radiation Safety Directorate, December 2016;
17. Rulebook on Staffing and Job Descriptions of the Radiation Safety Directorate, December 2016;
18. Regulation on the premises, devices, equipment and persons who may work with ionizing radiation sources (Official Gazette of the Republic of Macedonia, No. 78/2012).

Annex 4. References to reports on international review missions performed at the request of a Contracting Party

1. Infrastructure Appraisal for the Republic of Macedonia of Radiation Safety and the Security of Radioactive Sources, 29 August – 05 September 2005, (RaSSIA Mission Report 2005);
2. Draft report from the National Regulatory Infrastructure for the Control of Radiation Sources Advisory Mission to the Republic of Macedonia, Skopje, Macedonia 01 – 04 November 2010*;*
3. End of Mission Report No. IAEA-TCR-05477, Expert mission: "To assist the Regulatory Body of Macedonia in Assessing Safety Report for the Licensing of the Storage Facility", Skopje, Macedonia,19-30 July 2010;
4. Expert Mission - Evaluation Report Event Nr. INFRA IND/EXP 45808, Skopje, Macedonia, 03-07 October 2011.
5. IRRS Mission, October - November 2017

Annex 5. Other relevant material

1. IAEA Information Circular INFCIRC/604 of 1 July 2002 - Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. Guidelines regarding the form and structure of National Reports.
2. Policies and strategies for Radioactive Waste Management, IAEA Nuclear Energy Series No. NW-G-1.1, 2009 Vienna
3. Strategic plan of Radiation Safety Directorate 2021-2023;
4. Stabilization and Association Agreement between the Republic of North Macedonia, of one part, and the European Communities and their member states of the other part Official Journal of European Union No. L 084, 20.03.2004;
5. Council Decision of 18 February 2008 on the principles, priorities and conditions contained in the Accession Partnership with the Republic of Macedonia and repealing Decision 2006/57/EC, Official Journal of European Union No. L 080, 19.03.2008, 2008/212/EC;
6. Control and Management of Inadvertent Radioactive Material in Scrap Metal in the Republic of Macedonia, poster presentation Tarragona, Spain, February 2009;
   Authors: Goran Trajkov, Rumen Stamenov, Trifce Sandev, and Goran Angelovski
7. Improvement of the radioactive waste waste management regulations in the Republic of Macedonia: Good practice within IAEA supported projects, International Conference on the Safety of Radioactive Waste Management, 21 – 25 November 2016, Vienna, Austria (Book of Papers, Session 1, pp. 91–93)
   Authors: Trifce Sandev, Goran Angelovski, Goran Trajkov, and Nuzi Shahin
8. Project Fiche: *"Management of sealed radioactive sources including radioactive lightning rods"*, 2009 IPA Horizontal Programme on Nuclear Safety and Radiation Protection;
9. The Status of Regulatory Infrastructure and Legislation in the Republic of Macedonia, Task 3 Report ENCO-FR-(09)-25, of the IPA project "Assessment of the regulatory infrastructure in the field of nuclear safety and radiation protection in Albania, Bosnia and Herzegovina, Croatia, Macedonia, Montenegro, and Serbia including Kosovo (as defined by UNSCR 1244)[1]", Ref: EuropeAid/127007/C/SER/Multi;
10. Country Report, Republic of Macedonia of the 2007 IPA project "Assessment of needs and proposed actions to strengthen the safety and security of sealed radioactive sources in the country", EC-IAEA Contribution Agreement for IPA Project 2008/162-682, Vienna, Austria, 4 February 2011;
11. Final Report on the 2007 IPA project: "Assistance to Albania, Bosnia and Herzegovina, Croatia, Macedonia, Montenegro, and Serbia including Kosovo (as defined by UNSCR 1244)[1] to enhance their capabilities to developing regulations on Naturally Occurring Radioactive Materials (NORM) and Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM)", Reference: EuropeAid/127066/C/SER/Multi/
12. Final Report on the 2007 IPA project "Management of medical radioactive waste in Albania, Bosnia and Herzegovina, Macedonia, Montenegro, and Serbia including Kosovo (as defined by UNSCR 1244)[1]", EuropeAid/127065/C/SER/Multi;
13. Final Report of the 2007 IPA project: Assessment of needs and proposed activities to strengthen capabilities for combating illicit trafficking in nuclear and other radioactive materials in Albania, Bosnia & Herzegovina, the former Yugoslav Republic of Macedonia, Montenegro and Serbia including Kosovo (as defined by UNSCR 1244)[1], Contribution Agreement 2008/163-522;

14. Final Report of the 2007 IPA project: “Assessment of the needs and proposed actions in order to perform the monitoring of the radioactivity into the environment in Albania, Bosnia and Herzegovina, Croatia, Macedonia, Montenegro, and Serbia including Kosovo (as defined by UNSCR 1244)[1]”.