



**Republic of North Macedonia  
Radiation Safety Directorate**

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**7<sup>th</sup> National  
Report under the  
Convention on Nuclear Safety**

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**August, 2022**



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Abbreviations:

BSS	Basic Safety Standards
CMC	Crisis Management Centre
CNS	Convention on Nuclear Safety
EC	European Commission
ECURIE	European Community Urgent Radiological Information Exchange
EURDEP	European Radiological Data Exchange Platform
EMERCON	Emergency Convention
ENAC	Early Notification and Assistance Convention Website
EPREV	Emergency Preparedness Review
IAEA	International Atomic Energy Agency
IRRS	Integrated Regulatory Review Service (of IAEA)
ITDB	Illicit Trafficking Database Programme
PRD	Protection and Rescue Directorate
RSD	Radiation Safety Directorate
USIE	Unified System for Information Exchange in Incidents and Emergencies (of IAEA)



## **A. Introduction**

The Republic of North Macedonia became a member of the IAEA in 1994.

The Convention on Nuclear Safety (here-and-after: CNS) was acceded by the Republic of North Macedonia on 17 January 2006. The Law on ratification of the Convention of Nuclear Safety [1] was published in Official Gazette of the Republic of North Macedonia, No. 10/06. The CNS entered into force on 13 June 2006 and the first report under Article 5 of the CNS was submitted in February 2008. The Republic of North Macedonia participated for its first time in the 4th Review Meeting under the Article 20 of the CNS held in 2008, on the following review meetings and submitted national reports.

This National Report is the seventh report submitted by the Republic of North Macedonia concerning the Article 5 of the CNS. The report as an outline of the national policy of the Republic of North Macedonia towards nuclear activities, gives overview on the status of implementation of the CNS, as well as changes made since the last National Report. The 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.6 dating from 19 January 2018. Having no nuclear installation, as well as no intention to future implementation of nuclear program in the country, only Articles 7, 8, 15 and 16 of the CNS will be reported. No changes are being made since the last report in connection with Articles 9 and 10 of the CNS. The other articles of the CNS are not applicable for the Republic of North Macedonia and therefore they will not be reported.

In this report is given outline on the activities undertaken to meet the challenges identified for the Republic of North Macedonia on the last CNS Review Meeting.

Republic of North Macedonia has no nuclear installation, according to definition of the CNS, on its territory. Republic of North Macedonia has no nuclear power reactor units, no research reactors, nor does it operate any other nuclear installations or uranium or thorium mines. The main use of ionising radiation in the country is in medicine, industry, and education/research. All radioactive sources and radiation generators used in the country are imported from abroad. Radioactive waste is produced mainly in nuclear medicine applications.

However, legislative, regulatory, and administrative measures have been undertaken in the past to maintain a high level of radiation and nuclear safety in the country. Therefore, this report addresses the means of achieving the relevant objectives of the CNS by the Republic of North Macedonia.



## **B. Summary**

The main piece of legislation governing radiation and nuclear safety in the Republic of North Macedonia is the “Law on Ionizing Radiation Protection and Safety” (here-and-after: “the Law”) [2], enacted in 2002, and its subsequent amendments in 2007 which refer to the main Euratom Directives, IAEA safety standards and the recommendations from the 2005 RaSSIA Mission. The Law applies to any planned, existing, or emergency exposure situation involving a risk from exposure to ionizing radiation with a view of long- term human health and environmental protection.

Elements of the national policy and strategy for safety are embedded in the legal framework and the ratified international agreements.

The Government has established a governmental, legal, and regulatory framework for safety.

The legal framework makes provision in all relevant areas relating to radiation safety and applies to all types of facilities and activities in the country, providing clear allocation of responsibilities to the various stakeholders and authorized parties. The legislative framework assigns clear responsibility for safety to authorized parties responsible for the radiation facilities and activities. The legislation also establishes clear role, responsibilities, and powers to the RSD as the single independent regulatory body exercising discretion to oversee radiation protection, accounting for nuclear materials and nuclear security, including the authority to make the relevant regulations.

Since there are no nuclear facilities in the country, the framework establishes safety requirements for facilities and activities using radiation sources in medicine, industry, and education/research.

The Law [2] clearly assigns prime responsibility for safety to the persons or organizations (as legal entities) responsible for operating a facility or conducting practice involving radiation sources, and require them to comply with regulatory requirements, as well as to demonstrate such compliance.

The legal framework makes adequate provision for the effective conduct of RSD regulatory function, avoiding any omissions or undue duplication or conflicting requirements being placed on various parties. Also, the Government has provided for the effective coordination of the functions of the various authorities having other responsibilities within the regulatory framework, such as in emergency preparedness and response, and in environmental radioactivity monitoring.

Republic of North Macedonia participates in the relevant international arrangements to enhance radiation and nuclear safety and security on the national, regional and global level and fulfil its respective obligations. In that regard, the country has ratified, signed, or accessed to a large number of International Conventions, Protocols, Agreements and other Instruments in the area of radiation safety and nuclear security. In accordance with Articles 2 and 3 of the Protocol Additional to the Agreement between the Republic of North Macedonia and the IAEA for the Application of Safeguards in connection with the Treaty on the Non-proliferation of Nuclear Weapons, the Republic of North Macedonia fulfills its obligations by submission declarations. (Since February 2008).



The Republic of North Macedonia, in October 2010 has submitted the first national report on Joint Convention on the Safety of the Spent Fuel Management and on the Safety on the Radioactive Waste Management (ratified in the Republic of North Macedonia on 11 September 2009). The last (fourth) National Report was submitted for the 7<sup>th</sup> Review Meeting of the Joint Convention, held in 2022.

The RSD has established the National Register on Nuclear Material and submitted the initial report in August 2009 under the Small Quantity Protocol (revised) to the Agreement between the Republic of North Macedonia and the IAEA for the Application of Safeguards in connection with the Treaty on the Non-proliferation of Nuclear Weapons.

The Republic of North Macedonia participates in the Illicit Trafficking Database Program of the International Atomic Energy Agency for reporting incidents within the scope of illicit trafficking and other unauthorized activities involving radioactive material.

As a party of the Assistance Convention and Convention on Early Notification, the RSD uses the Agency's Incident and Emergency Center's website (USIE) for secure exchange of emergency information and for requesting assistance, if needed. The country participates in mechanism of the European Community Urgent Radiological Information Exchange (ECURIE) system. Under the Agreement for joining ECURIE, the RSD is nominated as national competent authority and the CMC as point of contact. The country participates in the European Radiological Data Exchange Platform (EURDEP) for the continuous exchange of data from the national radiological monitoring network in almost real-time through the Institute of Public Health.

The Law assigns to the RSD the function of coordinating the State's actions in respect to international cooperation on radiation and nuclear safety.

RSD, as regulatory body, has signed Memoranda of Understandings in the field of radiation protection and safety with the regulatory bodies of the following countries: Bulgaria, Romania, Slovenia, Bosnia and Herzegovina, Montenegro, Kosovo. Furthermore, concerning the bilateral cooperation with the neighbouring countries, initial steps have been taken to strengthen the cooperation with Albania and Serbia through signing the Memoranda of Understanding.

The national interinstitutional cooperation is improved through Memoranda of understanding/agreements between the RSD and CMC (2008); with other institutions participating in the integrated border management (2008) and with the PRD (2009). Moreover, the RSD participate in the National Coordination Body for Prevention, Risk Reduction, and Protection against Chemical, Biological, Radiation and nuclear weapons and Materials.

Information to the public and interested parties regarding radiation safety and nuclear security, intervention situations and regulatory processes is provided through the RSD web site. ([www.drs.gov.mk](http://www.drs.gov.mk)). Any interested party may request information from the RSD on free access to information of public interest. Based on the national legislation, the public is consulted in the process of preparation of the legislation and regulation through announcement of the content and the timeframe for issuance of the regulations, organization of public consultations and obtaining opinion by the interested parties. In addition, the RSD also conducts additional informal communication activities with the public, if necessary.



At the request of the Government of the Republic of North Macedonia, an international team of senior radiation safety experts met with representatives of the Government and of the RSD from 30 October to 7 November 2017 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the IRRS mission was to perform a peer review of the Republic of North Macedonia national regulatory framework for radiation safety. The IRRS mission covered all civilian radiation source facilities and activities regulated in the country. The review compared the national regulatory framework for safety against IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS team members and the counterparts in the areas covered by the IRRS. The invitation of the IRRS mission demonstrates the Government's and the RSD's commitment to improve the national legal and regulatory framework for radiation safety. The key objectives of this mission were to enhance the national legal, governmental, and regulatory framework for radiation safety and nuclear security, and national arrangements for emergency preparedness and response.

The IRRS team noted that the regulatory body faces challenges, identified a good practice, and made recommendations (34) and suggestions (7) that indicate where improvements are necessary or desirable to continue enhancing the effectiveness of regulatory functions in line with IAEA safety standards. The good practice identified by the IRRS team concerns a web-based system (EXIM) commonly used by RSD and Customs for the authorization of import and export of radioactive materials that significantly enhances transparency of RSD and promotes the effective cooperation among the two authorities.

Following the 7-th Review Meeting under the CNS, the Republic of North Macedonia continuously is undertaking efforts in strengthening the radiation and nuclear safety infrastructure in the country. The main efforts are focused on establishing radiation protection and safety requirements with the national legislation and regulations in compliance with the international standards and EU Acquis. Previously, the RSD has prepared and promulgated 26 regulations covering specific radiation protection, radiation safety and nuclear security provisions considering the relevant international safety standards and the EU Acquis.

In the Country Review Report for the Republic of North Macedonia from 2020 were addressed two Challenges:

***Challenge 1: North Macedonia should further improve its regulatory infrastructure also considering technical and administrative capacities of the RSD. The legal framework should be amended to be fully in line with the latest IAEA Safety Standards.***

Regarding the **administrative capacities**, the RSD employs qualified staff with the essential knowledge, skills, and abilities to perform the necessary regulatory functions. Currently the total number of the RSD staff is 10 (director plus 9 employees), of which 2 are administrative and support staff. Since in the RSD was decreased the number of the employees (from 14 in 2008 to 10 in 2022) the RSD undertakes measures of employing qualified staff. The procedure of recruitment of new staff in the RSD is prescribed in detail in the Law on administrative servants. The Law explains in detail the required steps for recruitment of new staff in the state institution, the planning of new employments - preparation of annual plan for recruitment by the RSD, the public announcement, etc. Further details and explanation of the procedure for employments is established in detail in the Decree for conducting the procedure for employment of administrative servants, that is promulgated by the Government. In





accordance with the national provisions, RSD prepares annual plan for employment based on the analyses of the current needs and proposes to the relevant ministries (for finance, for administration, for inter-community relations). The plan needs to be approved by the named ministries and afterwards follows the implementation of the plan. The preparation of the Annual plan is in August each year and the approval is by November each year for the following year. For the following year, the RSD has prepared the analyzes of the current needs for the staff and is preparing the Annual Plan on Employments for 2023.

The employees of the RSD continuously participate in general trainings organized by the Ministry of Information Society and Administration, as well on specialized trainings organized by the International Atomic Energy Agency IAEA, EC, US Embassy in the Republic of North Macedonia etc. The participation on the trainings strengthens the administrative capacities and the human resources of the Directorate.

The **technical capacities** of the RSD are further strengthened with the donation of equipment for the inspection and emergency response in the frames of IAEA project in 2021.

Ongoing process is upgrading of the National Register of sources kept by the RSD. The process should be realized by the end of 2022.

***The legal framework should be amended to be fully in line with the latest IAEA Safety Standards***

There are activities undertaken in order of further improvement of the **legal framework** considering the relevant international safety standards and the EU Acquis.

In the frames of IPA project “Further Enhancement of the Technical Capacity of Nuclear Regulatory Bodies in Albania, Bosnia and Herzegovina, Republic of Macedonia, Montenegro and Serbia, as well as Kosovo” the RSD received support in the field of further transposition of the EU legislation in the national legislation in the field of the radiation and nuclear safety. The analyze of the national legislation was realized against the following EU directives: Nuclear Safety Directive 2009/71; RAW Directive 2011/70/; BSS Directive 2013/59/ (EU BSS Directive), Shipment Directive 2006/117. Based on the results and the recommendations received, the activities regarding the preparation of amendments in the national legislation are ongoing.

In the frames of the IAEA project was provided support of the RSD in the process of review of the Law [2] regarding the latest IAEA standards and were provided comments to the RSD. The comments and the recommendations are to be implemented in the process of the preparation of drafts which is ongoing.

The activities regarding the amendments of the national legislation considering the latest IAEA Safety Standards and EU acquis are planned as a midterm goal regarding the decrease of the qualified staff in the RSD and the limited administrative capacities of the RSD.

With objective of establishing and maintaining high level of safety and security in the field of radioactive waste management and disused radioactive sources in the Republic of North Macedonia through strengthening of the national measures and in accordance with the international recognized principles and standards, especially for the protection of the occupationally exposed persons, the population and the environment from the harmful effects of the ionizing radiation now and in the future, the RSD prepared **National Policy for**





**Management of Radioactive Waste Management and Disused Radioactive Sources in the Republic of North Macedonia** and proposed it to the Government for adoption. The National Policy was adopted in April 2019.

Although a progress in the field was achieved by now, the efforts in the upcoming period are to be directed towards further improvement of the national regulatory infrastructure considering not only the legislative and regulatory framework, but also the technical and administrative capacities of the RSD.

***Challenge 2: North Macedonia should strengthen its Emergency Preparedness and Response capabilities through exercising the National Emergency Response Plan and evaluating the exercise.***

The Republic of North Macedonia is a Party to the IAEA Conventions on Early Notification and Assistance; the CMC is the National Contact Point, and the RSD is the National Competent Authority for emergencies within the country or abroad. In that regard, the country is participating in the ConvEx exercises organized by the International Atomic Energy Agency (IAEA). The Republic of North Macedonia, RSD, participated in number of ConvEx exercises since the last review meeting. With the participation on the exercises were tested the national arrangements established with the National Radiation Emergency Plan regarding: requesting assistance and the procedures for providing assistance; the response throughout the evolution of the emergency (receipt of messages; activation of national emergency response arrangements; the determination and implementation of the national response to the emergency to protect foreign nationals potentially affected; sharing of relevant information with the international community and the public regarding the national response to the emergency); are the NWP available continuously and can NCAs promptly respond to received notifications; testing the ability of NCAs to complete the appropriate reporting forms; testing the national arrangements for a request and the provision of assistance; testing national arrangements for a transnational radiological emergency.

Regarding the Emergency Preparedness and Response, the RSD participate in EU project “Emergency Preparedness and Response in the Western Balkan Region”. The realization of the project started at the beginning of 2020. The objective of the project is through the integration of the JRODOS system to be achieved strengthening of the emergency preparedness and response in each participating country.

In the frames of the same project was realized “Table-top emergency response exercise: Protective measures in the urgent, early, and late phases of a hypothetical nuclear accident (generic evaluation and country specific evaluation), on which representatives from all the participating countries in the project were present. The JRODOS system was used and in this occasion were tested some of the national arrangements in the decision-making process for radiation protection of the population and the environment established with the National Emergency and Response Plan.

The representatives of the RSD in 2022 participated on exercise organized by US Embassy in Skopje for response to crises situations where were implemented the arrangements established with the National Plan [8].



***Area of Good Performance 1: The continued establishing and signing of Memoranda of Understanding between some of the neighboring countries and countries within the region to exchange information between regulators.***

The RSD will continue in its efforts of strengthening the bilateral cooperation by Memoranda of Understandings with regulatory bodies of other countries.

In that regard, at the beginning of 2020, are started activities for signing Agreement with the regulatory body of Serbia. The signing of the Agreement will establish the bilateral cooperation between the two regulatory bodies in the field of the radiation and nuclear safety and security and will enable the exchange of technical information in the field of the illicit trafficking and response in case of radiation emergency, as well as experiences in the implementation of the EU acquis. It is still ongoing process.

**C. Reporting article by article**

**Article 7 Legislative and Regulatory Framework**

- 1. Each Contracting Party shall establish and maintain a legislative and regulatory framework to govern the safety of nuclear installations.*
- 2. The legislative and regulatory framework shall provide for:*
  - i) the establishment of applicable national safety requirements and regulations;*
  - ii) a system of licensing with regard to nuclear installations and the prohibition of the operation of a nuclear installation without a license;*
  - iii) a system of regulatory inspection and assessment of nuclear installations to ascertain compliance with applicable regulations and the terms of licenses;*
  - iv) the enforcement of applicable regulations and of the terms of licenses, including suspension, modification or revocation.*

**Legislation and regulations**

The legislative and regulatory framework for radiation and nuclear safety in the Republic of North Macedonia is established through the international instruments in the field (treaties, agreements) ratified, signed, or accessed in accordance with the Constitution, the Law on Ionizing Radiation and Protection adopted in 2002 with the additional amendments (2007, 2011, 2013, 2014, 2015, 2016, 2018) [2] and the regulations issued in accordance with the provisions from the Law [2].

The Law [2] regulates the system of control of all ionizing radiation sources, as well as the protection of population and environment against the exposure or potential exposure to ionizing radiation. The Law [2] also regulate the management of radioactive and nuclear material, as well as the implementation of the measures of radiation safety and nuclear security. The main objectives of the Law [2] are:



- Adequate protection of population, society, and environment against harmful effects of ionizing radiation and safety of ionizing radiation sources and radioactive waste and the safety and the security of radioactive sources;
- The beneficial and peaceful uses of nuclear energy and its applications; and
- Ensuring that the Republic of North Macedonia fulfils all the obligations pursuant to the ratified international agreements.

From the aspect of providing adequate terminological understanding in the area that is regulated, the Law [2] in its initial provisions (Article 2) provides definitions for the terms that are further used in the provisions of the Law or are relevant for the application of the Law.

The Law [2] is divided into eight chapters: General Provisions; Regulatory Body; Authorized Technical Services and Legal Entities for Decontamination, Requirements for Conducting Practice with Ionizing Radiation Sources, Radiation Protection and Safety Requirements; Regulations; Inspection and Enforcement; and Transitional and Final Provisions.

Based on the Law [2], the RSD adopted the necessary regulations and guidelines to specify the principles, requirements and associated criteria for safety and security upon which its regulatory judgments, decisions and actions are implemented. The authority to the RSD for preparing and issuing regulations and guides is given by the Law [2] and is one of its main regulatory activities. Following this authority, the RSD has prepared and issued regulations in the field of radiation safety, and nuclear security. The regulations are issued in the period 2009-2016 and published in the Official Gazette of the Republic of North Macedonia. In the preparation of the regulations are considered the IAEA and EU standards. The total number of the regulations are 26 on different issues as: authorization, public, medical and occupational exposure; radioactive waste; transport, etc.

The legislation and regulations in the Republic of North Macedonia in the relevant field is in line with the IAEA standards and the EU acquis, but it should be updated considering the latest international basic safety standards.

The RSD, as relevant competent authority, is responsible for performing analysis of the national legislation and regulations to identify possible gaps in relation to international standards. The incorporation of lessons learned is considered when drafting or amending regulations. Regulations are drafted by the working group established by the RSD with representatives of stakeholders. The RSD publishes the drafts of the regulations on its web page for comments of the interested parties and communicates the drafts for comments to the relevant national institutions with given timeframe for providing comments. The final regulations are signed by the director of the RSD and published in the Official Gazette. The laws and regulations are published on RSD web site.

According to the national legislation system, all conventions and international agreements ratified by the Parliament, in accordance with the Constitution are integral part of the national legislative framework: The list is as follows:

1. Statute of the International Atomic Energy Agency (entered into force on 17 November 1991),
2. Vienna Convention on Civil Liability for Nuclear Material (entered into force on 17 November 1991),
3. Convention on Physical Protection of Nuclear Material (entered into force on 17 November 1991),



4. Convention on Assistance in a case of Nuclear Accidents and Radiological Emergency (entered into force on 17 November 1991),
5. Convention on Early Notification in a case of Nuclear Accidents (entered into force on 17 November 1991),
6. Convention on Nuclear Safety (entered into force on 13 June 2006),
7. Agreement between the Republic of North Macedonia and the International Atomic Energy for the Application of Safeguards in connection with the Treaty on the Non-proliferation of Nuclear Weapons (entered into force on 16 April 2002),
8. Additional Protocol to the Agreement between the Republic of North Macedonia and the International Atomic Energy for the Application of safeguards in connection with the Treaty on the Non-proliferation of nuclear weapons (entered into force on 11 May 2007),
9. Small Quantity Protocol (revised) to the Agreement between the Republic of North Macedonia and the International Atomic Energy for the Application of safeguards in connection with the Treaty on the Non-proliferation of nuclear weapons (entered into force on 11 May 2007),
10. Joint Convention on the safety of the spent fuel management and on the safety of radioactive waste management on entered into force (entered into force on March 2010),
11. Amendments to the Convention on Physical Protection of Nuclear Material (entered into force 2010)

The Government of the Republic of North Macedonia has made a political commitment to the Code of Conduct on the Safety and Security of Radioactive Sources and its supplementary Guidance on the Import and Export of Radioactive Sources and thus, endeavors to follow the guidance in the Code and its accompanying Guidance on the Import and Export of Radioactive Sources. In that sense, are nominated national contact points for the purpose of facilitating the export and/or import of radioactive sources in accordance with the Code of Conduct on the Safety and Security of Radioactive Sources and the Guidance on the Import and Export of Radioactive Sources.

## **Licensing**

In accordance with the Law [2], the RSD is empowered to conduct the procedure of notification, licensing and control of the ionizing radiation sources. Furthermore, the Law [2] prescribes the conditions that have to be fulfilled in order the license to be obtained.

The general requirements for licensing are introduced in the Law [2]. The procedures for issuing the licence shall be conducted pursuant to the rules on general administrative procedure, if not otherwise stipulated by the Law [2]. An appeal against the decision on the issue of license may be lodged to the competent commission of the Government of the Republic of North Macedonia, within eight days from the date of receiving the decision. The appeal shall not postpone the enforcement of the decision.

The requirements of the Law [2], as well the licensing procedure are prescribed in detail in the provisions of the Regulation on licensing [9]. According to the Law [2], a legal person may start practice with ionizing radiation sources and use radioactive and/or nuclear material only after obtaining a license from the RSD and after being recorded into the unique register of legal persons conducting practice with ionizing radiation sources. Furthermore, the Law [2] prescribes the conditions that have to be fulfilled in order the license to be obtained. The



license will be granted by the RSD only if the legal entity ensures compliance with the national radiation protection and safety requirements. The license is issued for performing practice with ionizing radiation sources for the purposes of: import, export, transit, transport, diagnostic and intervention radiology, dental X-ray machines, nuclear medicine, radiotherapy, industrial radiography, industrial gauges, consignment control, load and baggage, lending/taking over, geological investigations with radioactive sources and other practices with ionizing radiation sources.

The licensing process starts with submission of the notification as prescribed with the Regulation on Notification [10]. Simultaneously or afterwards, the legal entity submits the license application to the RSD as prescribed in the Regulation on Licensing [9]. The submitted application is intended to demonstrate the fulfillment of all the radiation protection, safety and security requirements given in the national radiation protection and safety legislation. The application for the license with the accompanying documentation is reviewed and evaluated in the Unit of Licensing, Monitoring and Emergency and with inspection within the licensing process by the Unit on Inspection before issuing the license. If positively evaluated the license is prepared. Depending on the findings during license application assessment and the inspection, the license shall be issued, or the license application shall be rejected. The director of the RSD issues the licence for practice with sources of ionising radiation.

The procedure for issuing a license to legal entities to work with materials that are sources of ionizing radiation includes assessment of compliance with legally prescribed conditions, such as: to provide appropriate technical standards for work, qualified and trained staff, to have a radiation protection program, including an emergency plan, quality and safety control at work, to ensure radiation and nuclear safety of ionizing radiation sources, to have established an appropriate internal organizational set-up with certain duties and responsibilities, etc.

The license is granted if all the requirements given in the national legislation and regulations are fulfilled by the legal entity. The Regulation on Licensing [9] empowers the RSD to set up conditions to the license relevant to the practice to be performed.

There is established electronic system for application and issuing licenses for import/export and transit of ionizing radiation sources through the EXIM system. This system is a modern and helpful tool for simple issuing licenses, for establishing a unique database and it represents a harmonized system for exchanging information between the governmental, public and private legal entities in the Republic of North Macedonia. EXIM represents an electronic system used by 16 institutions in the country which have competencies in the field of foreign-trade operations. It enables searching by goods tariff number and obtaining information for the needed licenses for import, export or transit.

EXIM also enables electronic application for import, export and transit licenses, as well as electronic issuing licenses from the competent governmental institutions. There are many advantages of the implementation of the EXIM. Firstly, 24 hours 7 days in a week accessibility of the service; saving time and costs of the entities for the application procedures, because of the electronic communication; increasing the efficiency of the process of issuing licenses; standardized and harmonized data in the applications for licenses which will enable general data exchange between the governmental institutions; electronic monitoring of the final date of validity of the licenses; database about issued licenses etc.

In accordance with the Law [2], the license is granted, upon request, for a fixed term period up to 5 years, depending on the categorization of radioactive sources. Any modification of the





conditions for practice, laid down with the Law [2] and the regulations adopted pursuant to the Law, may be made only based on a permission granted by the Directorate and after their recording into the Register. The license shall not be transferred to other legal entity. Nevertheless, when the licensee ceases to fulfill the regulatory requirements or its practice is not in accordance with the Law [2] and the regulations adopted thereto, the RSD is empowered to revoke the license.

## **Inspection and Enforcement**

Another aspect of the ionizing radiation sources control is the inspection. The RSD carries out inspections of facilities and activities to verify that the authorized party follows the safety requirements and the conditions specified in the authorization.

According to the Article 27 of the Law [2], the RSD is empowered to enforce the Law itself and the regulations adopted pursuant to it through the radiation safety inspectors.

The radiation safety inspectors perform inspections in medicine (diagnostic and therapeutic medicine), nuclear medicine, industrial (industrial radiography, industrial gauges), transport of radioactive sources, transit of radioactive sources and nuclear material, and all temporary storage facilities. In addition, inspections are also performed in case of incidents which could happen on the territory of Republic of North Macedonia and on the border crossing points.

The Law [2] empowers the radiation safety inspector to perform announced and unannounced inspections. In addition, the inspection shall be regular (intended to verify the compliance with the regulatory requirements), extraordinary (inspection based on initiations and proposals of governmental authorities, legal and physical persons, as well as in cases of doubt of the inspector) and control inspection (inspection after the period determined with the decision of the inspector for undertaking some corrective actions). According to the Law [2], the legal entities are obliged to allow the radiation safety inspector to perform the inspection at any time and on any place in the facility. The radiation safety inspectors when determining non-compliance with relevant regulatory requirements have the right to order undertaking corrective actions as to order undertaking other necessary radiation protection and safety measure; to prohibit carrying out the practice or use the equipment; to prohibit operations involving radioactive and nuclear material; to prohibit handling with radioactive waste etc. There is inspection guidance and systematic plan for inspections established in the RSD. The RSD is preparing an annual inspection program which is regularly updated with monthly plans. Annual Plan for inspection is based on Methodology for risk assessment of legal persons who are dealing with sources of ionizing radiation. Some provisions prescribed with the Law on General Administrative Procedure [3] are also applicable regarding the inspections. Joint inspections are performed with the Customs Administration when there is a suspicion at the border that cargo is related to illicit trafficking of radioactive material. In addition, joint inspection could be performed with inspectors for transport issues, inspectors for protection of environment issues etc.

The legislation provides sufficient tools to be used for enforcement which are exercised by the RSD, including prohibition of carrying out a practice, including transport. The legislation also provides for appealing a decision taken by an inspector. The penalty provisions are set in the Law [2] in separate chapter, where fees are foreseen to be charged from the legal entity and/or the responsible person within the legal entity if it fails to comply with the provisions



set in the Law [2]. In addition to the fees, sanction could be also applied depending on the non-compliance. The sanction consists of temporary prohibition of the practice. Fees are also applied for any person employed by the legal entity should it fail to apply the provisions set forth in the Law [2] and the regulations adopted thereto.

### Article 8 – Regulatory Body

- 1. Each Contracting Party shall establish or designate a regulatory body entrusted with the implementation of the legislative and regulatory framework referred to in Article 7, and provided with adequate authority, competence and financial and human resources to fulfill its assigned responsibilities.*
- 2. Each Contracting Party shall take the appropriate steps to ensure an effective separation between the functions of the regulatory body and those of any other body or organization concerned with the promotion or utilization of nuclear energy.*

The RSD is single regulatory body in the Republic of North Macedonia for carrying out managing and professional activities in radiation protection as independent state administrative body with the capacity of legal entity. The RSD was established in 2002 with the entry into force of the Law [2] and the appointment of the first director by the Government in 2005. In this way, the Government has adopted appropriate provisions for the effective conduction of the regulatory functions in radiological safety and nuclear security, avoiding any omissions, overlapping of competencies, or conflicting requirements being placed on various authorized parties. The legal authority to the RSD is conferred with the Law [2]. The RSD: conduct notification, licensing and control of the IRS; establishes the intervening levels and radiation protection and safety requirements; issues and withdraws license; maintains National register on IRS and occupationally exposed workers, as well as register on nuclear material; supervises the legal entities working with IRS; cooperates with other state administrative bodies and institutions; initiate researches in the area of ionizing radiation protection, radiation safety and nuclear security; establishes appropriate mechanisms for informing the public; prepares Plan on the protection of the population in case of radiological emergency in the Republic of North Macedonia; plans and conduct the international cooperation in the field of ionising radiation; conduct inspection; and undertakes any other activities in the area of ionising radiation protection.

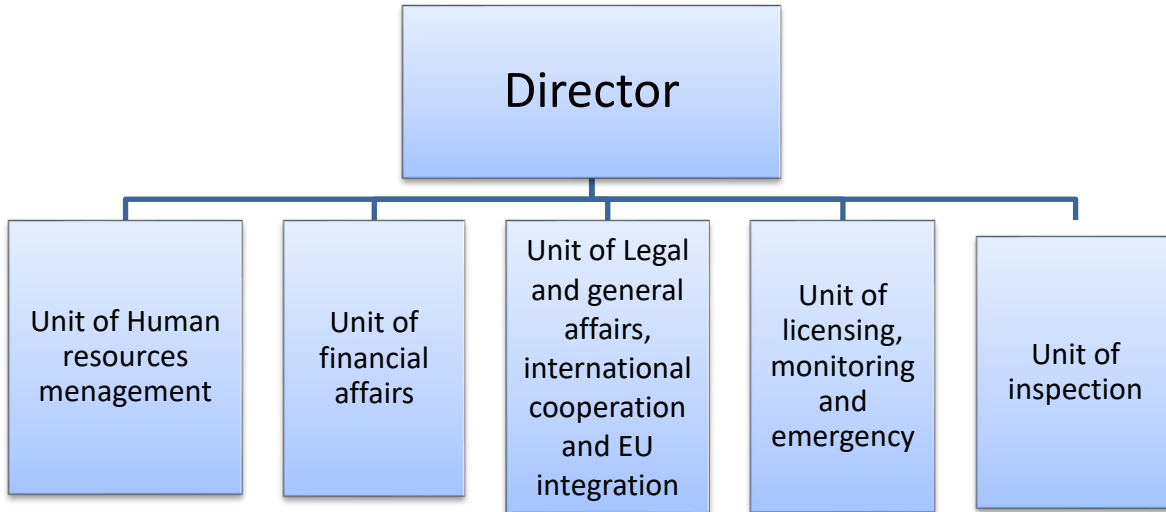
Responsibilities of the RSD and its position within the governmental structure are presented in the previous reports.

Since the RSD is established as independent state administrative body the general provisions from the Law on employees in the public sector and the Law on administrative servants are applicable in its functioning and in relation to the employees in the Directorate. The internal organization of the RSD and job description are set out in the regulations prepared by the RSD and implemented after approval by the relevant government administration. The financial resources of the RSD are provided through the Ministry of finance i.e., central budget of the Republic of North Macedonia. Currently, the RSD has 10 employees, including the director.





In the following Chart 1 of this report is shown the organizational structure of the RSD.



**Chart 1- Organizational structure of the Radiation Safety Directorate**

There is adequate provision in the national legislation regarding the technical support in relation to safety. The Institute of Public Health (IPH) has been designated as technical service provider by the Law [2]. The responsibilities of the IPH, as defined under the regulatory framework, include the following: monitoring the content of the radionuclides in water, air, soil and food; measuring the occupational exposure of persons working with radiation sources, as well as of the population; conducting continuous medical control and keeping records of occupationally exposed persons to ionising radiation; performing calibration on radiation protection measuring instruments; and, submitting reports to RSD on the promotion of radiation protection when using ionization radiation sources, as well as controlling them.

In addition to the services provided by IPH, the RSD may request other expert institutions to provide expert services necessary for the implementation of the Law on, for example other expert services authorized by the Ministry of Environment and Physical Planning, the Ministry of Health, the Directorate and the Ministry of Agriculture, Forestry and Water Economy.

The regulations establish detailed requirements for authorized technical services, including requirements for education, qualification and training of the staff. The authorized expert technical service must keep records regarding the performed activities and submit reports to the RSD. The work of the authorized expert technical services is supervised by the RSD. The director of the RSD can withdraw the license of the authorized expert technical service if it does not conduct the services for which it has been authorized



## Article 15 – Radiation Protection

*Each Contracting Party shall take the appropriate steps to ensure that in all operational states the radiation exposure to the workers and the public caused by a nuclear installation shall be kept as low as reasonably achievable and that no individual shall be exposed to radiation doses which exceed prescribed national dose limits.*

The Law [2] promotes the three basic principles on radiation protection: justification, optimization, and dose limitation. The Law and the regulations adopted thereto, regulates the radiation protection issues, safe use of ionizing radiation, as well as with security of radioactive sources.

The RSD has adopted Regulation on the Dose limits [11], whereas the dose limits for the occupationally exposed persons and for the members of the public are set in accordance with the IAEA BSS No. 115 and in compliance with the EU Council Directive 96/29.

Moreover, the Regulation on Occupationally Exposed Workers [14] and the Regulation on the Health Conditions [15] provide provisions regarding the radiation protection of occupationally exposed persons.

The discharges of radioactive substances into the environment are regulated with the Law [2] and with the Regulation on the Discharge Limits [16]. Regulation on maximum allowed presence of radionuclides in food, water, air, soil, products and raw materials and products of general usage [17] also applies for ensuring radiation protection of the public, while the Regulation on Public Exposure [18] prescribes provisions for environmental monitoring for assessing the radiation exposure of the population.

All regulations adopted by the RSD, concerning radiation protection and radiation safety are prepared in accordance with the IAEA safety standards and documents and in compliance with the EU Acquis (mainly EC Directives 96/29, Medical Directive 97/43, and EU HASS Directive 2003/122. The regulations should be updated to be fully in line with the latest IAEA safety standards.

The prime responsibility for the safe and secure management of radioactive sources in accordance with the Law [2] rests with the legal entities as stated in article 13, paragraph 3: *“Legal entity shall be fully responsible for protection and safe handling with the equipment that contains ionizing radiation sources”*.

Requirements for the environmental monitoring for public radiation protection are included in the Regulation on the Discharge Limits [16]. The general content and other relevant requirements, such as provisions for recording and reporting of the monitoring results, are established.

A nationwide monitoring network with the objectives of providing a warning of unusual or unforeseen event taking place beyond the national borders and, where appropriate, to trigger a special environmental monitoring program, is carried out in the country by the IPH. Periodical reports are evaluated by the RSD. The results of the monitoring are published at the public web site managed by the IPH.



## Article 16 – Emergency Preparedness

*1. Each Contracting Party shall take the appropriate steps to ensure that there are on-site and off-site emergency plans that are routinely tested for nuclear installations and cover the activities to be carried out in the event of an emergency.*

*For any new nuclear installation, such plans shall be prepared and tested before it commences operation above a low/ power level agreed by the regulatory body.*

*2. Each Contracting Party shall take the appropriate steps to ensure that, insofar as they are likely to be affected by a radiological emergency, its own population, and the competent authorities of the States in the vicinity of the nuclear installation are provided with appropriate information for emergency planning and response.*

*3. Contracting Parties which do not have a nuclear installation on their territory, insofar as they are likely to be affected in the event of a radiological emergency at a nuclear installation in the vicinity, shall take the appropriate steps for the preparation and testing of emergency plans for their territory that cover the activities to be carried out in the event of such an emergency.*

### Article 16 (1) Emergency plans and programs

The Law [2] empowers the RSD to act in a case of emergency, to establish intervention levels, to regulate the categorization of radiation and nuclear threats and to prepare a National Plan on Protection of the Population in a case of Emergency.

The functions of the national authorities with responsibilities in a radiological emergency are described in the National Radiation Emergency Plan (NREP). The NREP was prepared by the RSD, adopted by the Government, and published in the Official Gazette No.84/2011.

This Plan has been prepared based on the Regulation on categorization of radiation and nuclear threats [17], which is in accordance with the GS-R-2 [26]. The NREP and other relevant documents are based on previous IAEA safety standards, mainly Preparedness and Response for a Nuclear or Radiological Emergency (GS-R-2), 2002 and EPR-Method 2003.

According to Regulation on categorization of radiation and nuclear threats, Republic of North Macedonia has no facilities in threat categories I and II, but only facilities in threat categories III and IV where radioactive sources are used. The operators of III and IV threat category facilities, as introduced in the previous report, are obliged by the Law [2] to ensure Emergency Preparedness Plan as a Part of the Radiation Protection Program. The content of this Plan is prescribed with the Regulation on the content of the Radiation protection Program [18]. This facility emergency plan is being reviewed and approved by the RSD within the licensing process.

The National Radiation Emergency Plan [8] clearly defines roles and responsibilities of different institutions and response organizations in preparedness for and response to radiation emergencies in the Republic of North Macedonia. This Plan identifies the key actors in



preparedness for and response to radiation emergencies and defines their roles and responsibilities. In case of radiation emergency, the leading authorities are the Radiation Safety Directorate (RSD), Crisis Management Centre (CMC) and the Protection and Rescue Directorate (PRD) supported by all relevant governmental institutions, public enterprises, non-governmental organizations, and the academy society in accordance with the already established crisis management and protection and rescue system in the country in case of any emergency.

This National Plan [8] is also intended to coordinate the on-site and off-site response as well as to specify systematic testing of the emergency response capacities.

The RSD has a role in the emergency preparedness and response. It may vary from active on-site participation to decision support to the CMC.

The CMC is a governmental body, which has the role to coordinate all national institutions in the country in all kinds of emergencies when a crisis is proclaimed by the Government.

The Steering Committee of the Government is the decision-making body (ministry level) in a crisis. The Assessment Group of the Government is a high-level body (director level) for analyzing and proposing decision to the Steering Committee. The RSD director doesn't participate in the Assessment Group of the Government; he is requested when needed (in case of radiation emergency or potential radiation emergency). The Headquarter within the CMC is an operative body composed of representatives of different institutions having role in emergency (depending on emergency) in which RSD has representatives. The Headquarter proposes measures and solutions to the Steering Committee and forwarded to the Government as decision maker. The Headquarter, as operative body implements decisions made by the Government. The coordination of all national stakeholders is established by the NREP, covering EPC III to V, and including some possible scenarios and response to each of them.

So far, the RSD actively participated, including other response organizations and institutions as well, in several exercises conducted in the Republic of North Macedonia to test their coordination in responding to any kind of emergency, involving the radiation emergencies as well. Such exercises were organized and conducted by international organizations, as well as by bilateral cooperation (e.g., USA Embassy in Skopje) in the Republic of North Macedonia.

In regard of emergency service organizations, according to the national legislation “ people or workers who voluntarily participate in the intervention shall have training in the field of protection against ionizing radiation and are familiar with the risks” Furthermore, in accordance with the National Radiation Emergency Plan [8], the institutions which are part of the national system of preparedness and response to radiological emergency shall provide trainings for the persons who have tasks or participate in the preparedness and response to radiological emergency. The training may be organized by national or international organizations and institutions.

Furthermore, the Law [2] obliges licensees to notify the RSD promptly when situation requiring protective action has arisen, or is expected to arise, and continuously to keep informed the RSD of the development of the situation, measures taken for the protection of the public and the potential exposure.

The RSD has the authority to regulate emergency preparedness and response arrangements of the licensees during the licensing process, whereas the licensee must apply for license, which includes a radiation protection program. The Internal Emergency Plan (IEP) for preparedness



and response is part of this program. Additionally, it is required that the licensee informs the RSD immediately about any emergency and has in place a system to respond to an on-site emergency.

The National Coordinative Body for Prevention, Risk Mitigation and Protection against Chemical, Biological, Radiation and Nuclear Weapons and Materials (National CBRN Commission) was established in 2012 by the Government of the Republic of North Macedonia for strategic support, with several participating institutions, including the RSD.

### **Article 16 (2) Information of the public and neighboring states**

The Republic of North Macedonia is a Party to the IAEA Conventions on Early Notification and Assistance; the CMC is the National Contact Point, and the RSD is the National Competent Authority for emergencies within the country or abroad.

Therefore, the RSD as a contact point uses the IAEA's Unified System for Information Exchange in Incidents and Emergencies (USIE) for early notification of incidents involving radioactive sources with actual or potential transboundary effects, as well as for receiving such notification by other countries. Moreover, the RSD participates in the IAEA Illicit Trafficking Database Programme for notifying and sharing information about incidents within the scope of illicit trafficking and other unauthorized activities involving radioactive sources.

Since February 2011, the Republic of North Macedonia is also part of the European Community Arrangements for Urgent Radiological Information Exchange (ECURIE) where the RSD is the appointed national competent authority and the CMC acts as 24/7 point of contact.

Issuing information to the public and media in a case of radiation emergency no matter whether such emergency happened on its territory or abroad is to be addressed in more details in the National Plan. In a case of radiation emergency, information to the public is to be provided from a single place by both CMC and RSD.

As mentioned earlier, the Republic of North Macedonia, represented by the RSD, has established formal bilateral cooperation on radiation protection and nuclear safety matters with other regulatory bodies from other countries through bilateral agreements or memoranda of understanding (Slovenia; Romania; Bulgaria; Montenegro Bosnia and Herzegovina; Kosovo). In accordance with the agreements/memoranda, with the view to ensuring adequate ionizing radiation protection and to achieve a higher level of nuclear safety, security and preparedness for response in case of a nuclear accident and/or radiological emergency, the parties exchange information related to early notification of significant events of immediate interest to the Parties relating to accidents in connection with the ionizing radiation sources and nuclear materials or to illicit trafficking of nuclear and radioactive materials; information on illicit trafficking of radioactive materials in scrap metals and other practical information and consultation on issues of mutual interest.



### **Article 16 (3) Emergency preparedness for Contacting Parties without nuclear installations**

The Law [2] recognizes the role of the RSD in a case of radiation emergency and it gives the RSD authority to establish the intervention levels, to undertake interventions in a case of radiation emergency, to prepare the National Plan on the Protection of the Population in the Republic of North Macedonia in a case of radiation emergencies, to review and approve the facility emergency plan within the licensing process etc.

Therefore, the RSD undertook activities in the past for implementation of the international standards in radiation emergency preparedness and response on national level and it continues towards the improvement of the current situation regarding the emergency preparedness.

Namely, with the provisions set in the Regulation on the limits of exposure [11] the RSD established the dose levels at which intervention is expected to be undertaken under any circumstances, the intervention levels for undertaking urgent protective actions, the generic action levels for foodstuffs, the guidance levels for the total effective dose for the emergency workers caused by both external and internal exposure as well as some radiation protection requirements for the emergency workers (training, information about risks to be faced, medical examination etc.) in line with the requirements of the GS-R-2 [26]. As previously mentioned, the RSD introduced the categorization of the radiation threats and performed threat assessment for the Republic of North Macedonia in line with the GS- R-2 [26].

In order strengthening the cooperation and coordination in case of radiation emergency, the RSD signed Memoranda of understanding with the main response institutions in the Republic of North Macedonia, the CMC in July 2008, and PRD in December 2009.

The RSD has not still developed a systematic plan for exercising the radiation emergency preparedness capabilities of all the response organizations, institutions, and operators.

EPREV Mission was conducted in June 2009 in Skopje, Republic of North Macedonia. Both the emergency arrangements at a national, at local and facility level were reviewed. The Report from the mission gives an overview of the findings, as well on the recommendations and suggestions based on the findings. These recommendations and suggestions have been considered in the preparation of the National Radiation Emergency Plan [8].

Moreover, the RSD participate in the National Coordination Body for Prevention, Risk Reduction, and Protection against Chemical, Biological, Radiation and Nuclear Weapons and Materials.



#### **D. 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, safety, and security in the Republic of North Macedonia.

In particular, concerning the issue of nuclear safety, future activities of the RSD are to continue with the activities of transposing the EURATOM Directives, in particular the new EU BSS Directive 59/2013 [30], Directive for nuclear safety of nuclear installations [31] and Directive on management of spent fuel and radioactive waste [32], as well as their implementation. The amendments of the Law and applicable regulations will contribute to further harmonization of the national legislation and regulations with the new international standards.

In addition, the RSD is considering review of National Emergency Plan to comply with the IAEA new documents, GSR Part 7 [29], as well as analyzing national legislation and regulations to comply with other IAEA documents.





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