

REPUBLIC OF BULGARIA
FIFTH NATIONAL REPORT (2016-2018)

**ON IMPLEMENTATION OF THE CODE OF CONDUCT ON THE
SAFETY AND SECURITY OF RADIOACTIVE
SOURCES AND THE GUIDANCE ON THE IMPORT AND EXPORT
OF RADIOACTIVE SOURCES**

INTRODUCTION

The IAEA plays a global role and pays special attention to the issues and problems relating to ensuring the safety and security of radioactive sources worldwide. The IAEA undertakes an active policy in this field and in cooperation with other international organisations and competent national authorities carries out complex measures for guaranteeing the safety and security of radioactive sources worldwide. The culmination of the IAEA's activities and efforts in this field within the last decade is the **Code of Conduct on the Safety and Security of Radioactive Sources** and its associated **Guidance on the Import and Export of Radioactive Sources** and **Guidance on the Management of Disused Radioactive Sources**. The Code of Conduct and its associated Guidance are fundamental and guiding documents for IAEA Member States to ensure the safety and security of radioactive sources used for peaceful purposes, implementing and harmonizing policies and strategies in this area. The compliance with the Code of Conduct and the Guidance significantly contributes to not discredit the use of nuclear technologies and radioactive sources for the human needs.

The Nuclear Regulatory Agency (NRA) as a State Regulatory Body has notified the IAEA of the acceptance of the obligations to implement the Code of Conduct and supplementary Guidance on the Import and Export of Radioactive Sources in Republic of Bulgaria. During the international conferences organized by the IAEA in 2007, 2010, 2013 and 2016, the NRA presented four national reports on the implementation of the Code of Conduct and the Guidance on the Import and Export of Radioactive Sources.

These fifth National Report includes general information about the current status and development of the Bulgarian regulatory infrastructure (legislation, regulatory body, regulatory system, resources), activities and results related to the safety and security of radioactive sources, taking into account the objectives laid down in the Code of Conduct:

- to maintain a high level of safety and security of radioactive sources in order to ensure that the radioactive sources are safely managed and securely protected during their useful lives and at the end of their useful lives;
- to prevent unauthorized access or damage to, and loss, theft or unauthorized transfer of, radioactive sources, so as to reduce the likelihood of accidental harmful exposure to such sources or the malicious use of such sources to cause harm to individuals, society or the environment;
- to mitigate or minimize the radiological consequences of any accident or malicious act involving a radioactive source;
- to promote safety culture and security culture with respect to radioactive sources.

According to the Act on the Safe Use of Nuclear Energy (ASUNE) the NRA is the Bulgarian state regulatory body responsible for safety and security of radioactive sources. The National Regulatory Infrastructure is established in order to ensure radiation protection, including safety and security of radioactive sources used and stored in the country. The National Regulatory Infrastructure is based on the principles and requirements laid down in the ASUNE, European legislation, Code of Conduct and other IAEA documents related to radiation protection, safety and security of radioactive sources.

All areas of the NRA's competence are covered by regulations and a few regulatory guides. The need for each regulation is explicitly defined by ASUNE. These regulations and guides reflect the IAEA safety standards and other relevant international requirements. The procedures to develop, amend and revise regulations and regulatory guides are stringent. Well-defined review periods trigger regular updates which are keeping regulations and guides up to date. A comprehensive renewal programme for all regulations is presently undertaken and already in an advanced stage.

The legislative framework and the system for regulatory control related to safety and security of radioactive sources were presented in details in the previous four National Reports on the implementation of the Code of Conduct..

Many measures have been taken to upgrade the national infrastructure and to ensure that radioactive sources in the country are safely managed, properly stored and securely protected during their useful lives and safely disposed in compliance with the conditions of an authorization and related safety requirements. The NRA implements such measures as, inter alia, the promulgation and publication of regulations and guides, the establishment of a scheme for the submission to the Regulatory Body of applications for authorizations, the inspection of operations with radioactive sources and the enforcement of compliance with the regulations.

CHAPTER 1

LEGISLATIVE FRAMEWORK

EU legislation in the field of radiation protection was implemented. In December 2017, the National Assembly adopted the Act on the Amendment and Supplement on the Act on the Safe Use of Nuclear Energy (AAS ASUNE). With the AAS ASUNE the requirements of Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionizing radiation have been introduced. The new ASUNE was elaborated in accordance with the NRA policy for updating the normative requirements in conformity with the development of the international standards. The ASUNE covers the activities associated with the state regulation of the safe use of sources of ionizing radiation and with the safety and security of radioactive sources.

In 2017, The Council of Ministers adopted the Regulation on the Application of the Safeguards in connection with the Treaty on the Non-Proliferation of Nuclear Weapons. With the adoption of the Regulation, the regulatory framework related to the NPT has been brought into line with the new requirements regarding the country's obligations under the Safeguards Agreement between the Euratom, IAEA and Republic of Bulgaria and the Additional Protocol to the Agreement. The Regulation also facilitates the implementation of Commission Regulation (Euratom) No 302/2005 of 8 February 2005 on the application of Safeguards by persons liable in the Republic of Bulgaria.

In 2017, amendments were adopted in the Regulation of the Conditions and Procedure for Notification of the Nuclear Regulatory Agency about Events in Nuclear Facilities and Sites with Sources of Ionizing Radiation. This Regulation updates the criteria for the reporting of events during the transport of nuclear material and at sites with SIR. Provisions have been added regarding the reporting events related to the transport of radioactive substances to the Nuclear Regulatory Agency. The amendments are related to the differentiating the reporting criteria according to the type of the facility or activity, which allows a clearer

definition of the reporting criteria for each particular case.

In 2017, the Guide on the Implementation of the Requirements for the Safe Transport of Radioactive Materials was developed.

At the end of 2017, the State Gazette published the Amendments to the ASUNE entering into force on 1.01.2018 and implementing the requirements of Directive 2013/59/Euratom of 5 December, 2013 for Basic Safety Standards for Protection Against the Dangers Arising from Exposure to Ionising Radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom. The amendments to the ASUNE introduce the graded approach to the regulatory control as well as notification, registration and licensing regimes for activities.

In accordance with the NRA Policy Statement the legislative documents continued to be updated in 2018 in compliance with the development of international standards and European legislation and aligned with the current changes in national legislation. In order to comply with the newly introduced ASUNE regimes, the following subdelegated legislation of the Council of Ministers was amended in 2018:

- Regulation on the Procedure for Issuing Licenses and Permits for the Safe Use of Nuclear Energy;
- Tariff for fees collected by the Nuclear Regulatory Agency under the Safe Use of Nuclear Energy Act;
- Regulation on the Procedure for Payment of the Fees Collected Pursuant to the Safe Use of Nuclear Energy Act.

With the amendments in 2018 in the Regulation on the Procedure for Issuing Licenses and Permits for the Safe Use of Nuclear Energy, the procedure for application of the registration regime and the procedure for submission of notification of activities were determined.

In 2018, the Council of Ministers adopted new Regulation for Radiation Protection, covering all radiation situations - planned, existing and emergency exposure. It harmonizes the national legislation in the field of radiation protection by ensuring the consolidation, codification and supplementation of the existing legal acts in the field of radiation protection. The new Regulation systematizes the basic principles, norms and requirements for radiation protection.

A Guide on Aging Management of Structures, Systems and Components of Nuclear Power Plants, SG – 20/2018 was issued in 2018.

The ASUNE and the regulations related to its implementation establish the regulatory framework in accordance with IAEA and ICRP recommendations and European legislation. The basic principles for radiation protection, safety and security of radioactive sources and the graded approach in the application of regulatory activities (authorization, inspection, enforcement) are included appropriately in the ASUNE and relevant regulations. Maximal term of validity of granted licenses for activities with sources of ionizing radiation is to 10 years.

The concept for exemption and clearance was upgraded taking into account the new IAEA Publication № GSR Part 3.

The system for categorization of radioactive sources based on the “dangerous source” concept and IAEA documents “Safety Guide RS-G-1.9 - Categorization of Radioactive Sources”, TECDOC-1344 and “Dangerous Quantities of Radioactive Material (D-Values)” has been implemented by the ASUNE, Regulation on radiation protection and Regulation on emergency planning and emergency preparedness in case of nuclear or radiological accident.

A new definition of “high activity source” and respective activities for various radionuclides above which sealed sources are classified as high-activity sources are given in the Regulation on radiation protection.

Radioactive sources category 1, 2 and 3 are “dangerous sources” and fall into the “high activity sources” group under the Council Directive 2013/59/Euratom.

Specific requirements for licensees and permit holders have been introduced in the legislation for safe management and control of high activity sources, including record-keeping, inventory control, leak testing, identification and marking, control of the transfers and physical protection of the radioactive sources, taking into account the Code of Conduct and Council Directive 2013/59/Euratom.

The typical form and content of an instruction on radiation protection and an emergency plan in facilities with radioactive sources are given in the Regulation on radiation protection. Specific requirements for facilities with radioactive sources and for storages are introduced in this regulation as well as a requirement to licensees and permit holders to provide technical maintenance of systems and equipment for radiation protection.

The regulatory regime for import of radiation sources defined:

- import of sealed sources of categories 1, 2 or 3 whose half-life period is greater than five years can be made only under condition that there is provided for return to respective manufacturers after cancellation of use;
- recipients of sealed sources shall send in advance to the manufacturer (supplier) declaration following the form in accordance with Annex I to Regulation No. 1493/93/ (Euratom).
- when import/export of sources of ionizing radiation to/from the Republic of Bulgaria is to be effected respectively from/to a country which is a member of the European Union, no permit for import of radioactive sources is required;
- when import/export of sources of ionizing radiation to/from the Republic of Bulgaria is to be effected respectively from/to a country which is not member of the European Union, a permit is required.

The requirements for physical protection are imposed on equal terms with requirements for nuclear safety and radiation protection and are defined in the relevant regulation. The holders of licenses are obliged to ensure the physical protection in facilities with radioactive sources.

Guidance for control of scrap metal and response to incidents with radioactive scrap was published, developed according to the European Union Resolution № 2002/C119/05 and IAEA recommendations in this area.

According to the Regulation on the terms and procedures for acquiring professional qualifications and the procedures for issuing licenses for specialized training and certificates of competence to use nuclear energy, the job positions of the personnel in facilities with radioactive sources are classified into three qualification levels (highest level 3 – radiation protection experts). Individuals who perform functions specified in job descriptions for specific positions must have the necessary professional qualification. A system for specialized training (initial and refreshing) is applied.

CHAPTER 2

REGULATORY AUTHORITY AND MEASURES IMPLEMENTED TO ENSURE THE SAFETY AND SECURITY OF RADIOACTIVE SOURCES

Pursuant to the ASUNE, the NRA Chairman is an independent specialized authority of the executive power, delegated with the state regulation of all activities and facilities using ionizing radiation or causing radiation risk. The NRA structure, work organization and activities are stipulated in the rules, proposed by the NRA Chairman and adopted by the Council of Ministers.

The main mission of the NRA is the protection of individuals, the society, future generations and the environment from the harmful impact of ionizing radiation. The NRA priorities are set forth in its “Policy Statement”. The activities are oriented mainly towards the elaboration of the standard requirements for nuclear safety, radiation protection, emergency planning and preparedness and physical protection, and the regulatory control of their strict observance. This includes both the process of issuance of licenses and permits and the on-site control and independent analysis of the documentation being submitted within the licensing process and periodically.

The NRA implements a graded approach and ensures and controls that:

- arrangements are made for the safe management and secure protection of radioactive sources, including financial provisions where appropriate, once they have become disused;
- inventory controls are conducted on a regular basis by authorized persons;
- are marked by users with appropriate signs to warn workers or members of the public, as applicable, of the radiation hazard;
- the areas where radioactive sources are managed and radioactive sources and their containers are marked by users with an appropriate signs to warn of the radiation hazard;
- radioactive sources are identifiable and traceable or alternative processes for identifying and tracing those sources are in place;
- the authorized persons have emergency plans prepared as appropriate;
- the regulatory principles and criteria remain adequate and valid taking into account operating experience and internationally endorsed standards and recommendations.

A licensing regime under ASUNE is introduced for all activities with radioactive sources used and stored in the country. Guidelines for the effective implementation of this regime are published. The NRA establishes procedures for dealing with applications for authorization which publishes as appropriate and maintains records of persons with authorizations in respect of radioactive sources as well as records of the transfer and disposal of the radioactive sources. According to the ASUNE the prime responsibility for the safe management and security of radioactive sources is placed on the persons being granted the relevant authorizations. Any person or organization that manufactures, processes, stores or uses radioactive sources, is obligated to make inventory and keep records of the sources and to provide periodic information on the records to the NRA Chairman. Anyone who loses or finds any source of ionizing radiation is obligated immediately to notify the NRA Chairman. The NRA requires prompt reporting by authorized persons of loss of control over, and of incidents with radioactive sources and promotes the establishment of a safety and security culture among all individuals and in all bodies involved in the management of radioactive sources.

The NRA Chairman has the authority to issue, amend, renew, suspend and revoke licenses and permits. Internal rules and processes followed for issuing authorization are described in procedures and instructions issued under the management system of the NRA. During the authorization process, the NRA inspectors overseeing the proposals for issuing/renewing licenses or permits perform a review of the documents submitted by the applicants. A graded approach to review and assessment of a facility or an activity with radioactive sources is applied by the NRA personnel. Inspectors might also conduct inspections should they decide these are necessary to support the review and assessment process.

In general the legal and regulatory framework for the authorization process and the authorization stages established are in line with the IAEA safety standards.

The NRA prepares provisions to recover and restore appropriate control over orphan sources and to deal with radiological emergencies and establishes response plans and measures in respect of orphan sources and assists in obtaining technical information relating to their safe and secure management.

The NRA organizes campaigns for administrative and physical search of orphan sources in order to

establish regulatory control, to secure them and to send the orphan sources for safe storage. A special procedure has been developed for actions in case of discovering of orphan sources. There is a special program to collect radioactive sources from past practices.

The NRA carries out planned and unplanned, announced and unannounced inspections at an appropriate frequency taking into account the risks presented by the radioactive sources and takes enforcement actions, as appropriate, to ensure compliance with regulatory requirements. The NRA inspectors verify the presence and the condition of registered sources in controlled facilities during inspections.

The possible enforcement actions are described in the ASUNE and can be: prescriptions that are mandatory to the licensee; administrative penalty provisions with different fines depending on the violation; administrative enforcement measures (suspension of a license or permit, suspension or limitation of certain activities). There are also provisions regarding violations of the safety regime for radioactive sources, including punishment in cases of unauthorized transfer or illicit trafficking of radioactive sources. The NRA uses a graded approach to enforcement, with clear delegation and assignment of responsibilities for the inspectors, and for the application of administrative enforcement and administrative penalties.

The NRA maintained a database for control and traceability of radioactive sources since 1992 whereas data from 2004 are maintained similar to IAEA "RAIS". The National Register of sources of ionizing radiation (NRSIR) is electronic database maintained in accordance with Article 11 of the Code. The NRSIR includes information about all sealed sources (category 1 – 5), devices (model, manufacturer, serial No, etc.), licensees, issued licenses and license conditions. Under construction is new database system for control and traceability of radioactive sources which ensure "on line" interface between the national register and registers maintained by undertakings for all radioactive sources.

There is a system for notification in case of emergency events is established. Procedures for responding to emergencies with orphan sources or illegal trafficking are established and applied.

Infrastructure for emergency preparedness and response is created at national, regional and local level. Since 1998 the NRA maintains database for emergency events with radioactive sources, submits relevant reports and publishes information regarding such cases on its web page.

The physical protection of facilities with sources category 1, 2 and 3 has been strengthened and the safe storage of high-activity sources is provided.

A system for radiation control at border checkpoints and response in case of emergency events has been created. Technical equipment for radiation monitoring of cargo passing through the checkpoint have been delivered.

A Strategy for safe management of RAW (disused sources and others) based on the ASUNE was adopted by the Council of Ministers. The national infrastructure for safe RAW management and systems for accounting, control, classification and clearance of RAW are established in accordance with the IAEA recommendations and EU legislation in this area.

State Enterprise "Radioactive Waste" (SE RAW) was established and licensed to operate the facilities for RAW management. Special fund "RAW" based on the ASUNE was assured for long-term financing of activities with RAW.

SE RAW implements special program (coordinated with the NRA) for the acceptance of RAW from past practices, including disused sources, orphan sources and other sources used in the country, transferred to SE RAW in accordance with the Ordinance on the conditions and procedure for transfer of RAW. In Novi Han repository all disused sources, declared as RAW are collected for long-term storage. National disposal low and intermediate level RAW facility for is under construction phase.

According to the ASUNE licensees and permit holders are obliged to hand over to SE RAW their disused sources after being declared as RAW. Decentralized temporary storage of disused sources takes place in appropriate facilities under conditions specified in the licenses and permits issued by the NRA.

After expiration of source operating lifetime it is allowed to reuse it for other purposes if justified and the requirements and conditions for safety are met and after an authorization by the NRA have been obtained for use for certain activity. In the country high activity sources dismantled from medical teletherapy units are used in industrial gamma irradiators. Reuse of radioactive sources is a reasonable alternative when justified and safe from radiation protection viewpoint.

The country does not produce radioactive sealed sources and there is lack of appropriate equipment and technology for the recycling of disused sources. During recycling leak tests, reconstruction and re-seal and re-certification of sources is needed in factory conditions. Sending sources for recycling in other countries where this could happen appears practically impossible due to legal, economic and technical issues.

Return of disused sources to the manufacturer is possible if prior agreement exists.

After the end of their life cycle and transfer to SE RAW sources become state property. The activities of SE RAW related to management of disused sources are under the NRA control.

FACILITIES AND ACTIVITIES AUTHORIZED BY THE NRA

Practices involving sources of ionizing radiation shall be performed on the grounds of licences, permits, registration or notification.

Notification is required for activities:

- involving materials with an increased content of natural radionuclides;
- involving management of materials originating from objects for extraction and processing of ore containing uranium or thorium, where the exposure cannot be neglected from the point of view of radiation protection;
- in which the exposure to radon of workplaces can not be neglected from the point of view of the radiation protection;
- where the probability of damage to health is negligible.

Registration is required for following practices involving sources of ionizing radiation:

- handling of sources of ionizing radiation for the purpose of maintenance, assembly, dismantling, measurement, construction and repair work other and services for persons using or manufacturing sources of ionizing radiation;
- using of sources of ionizing radiation for non-medical imaging.

Permit is required for:

- construction, assembly and pretesting of an irradiation installation, except in the cases subject to notification;
- making changes in structures, systems and components envisaged in a design and related to radiation protection in irradiation installations;
- decommissioning of a radioactive substances installation;
- temporary storage of radioactive substances resulting from the performance of activities involving sources of ionizing radiation or associated with such activity;
- a one-time shipment of radioactive substances;
- import and export of sources of ionizing radiation;
- transit of nuclear material, nuclear waste, spent fuel or other radioactive substances;
- reclamation of sites contaminated with radioactive substances.

License is required for:

- use of sources of ionizing radiation for economic, medical, veterinary or scientific purposes or for process control, except in the cases where registration or notification is required;

- manufacture of sources of ionizing radiation;
- manufacture of consumer products, including medical devices, by adding radioactive substances;
- transport of radioactive substances;
- operation and technical liquidation of objects for extraction and processing of ore containing uranium or thorium.

By decree No. 65/30.04.2018 of the Council of Ministers amendments were made to the Regulation on the Procedure for Issuing Licenses and Permits for the Safe Use of Nuclear Energy. A graded approach was introduced depending on the radiation risk during the performance of activities with SIR.

The requirements to the licensees and permit holders related to ensuring the radiation protection, safety and security of radioactive sources, are determined in the ASUNE and the Regulation for radiation protection. The NRA keeps a public registers of licences, permits and registration certificates issued for activities involving SIR. The NRA also keeps public register of the submitted notifications for activities according art.56, a 2 of ASUNE.

In **2018**, a total number of **105** licenses (new and renewed) were issued, out of which:

- for use of SIR – 99, including 87 for medical purposes, 12 for industrial purposes;
- for transport – 6.

Pursuant to Article 21 of ASUNE, **97** effective licenses are amended, and by request of the licensees, **29** licenses are terminated.

In **2018**, a total number of **226** permits for activities with SIR were issued, as follows:

- temporary storage of radioactive substances – 12;
- construction, installation and preliminary tests – 138;
- single-time transportation of radioactive substances – 7;
- transit transport of radioactive substance – 6;
- for import and export – 63.

The permits issued by the NRA for each import or export of SIR are accompanied by certificates, required by the Regulation on the conditions and procedure for recording and permitting foreign trade deals. The main part of the imported SIR is intended for medical purposes (technetium generators for nuclear medicine). High-activity sealed sources are imported for industrial gamma radiography (^{192}Ir , ^{75}Se) and for brachytherapy.

During 2018 **51** declarations for supply of sealed SIR are certified in accordance with Regulation 1493/93/ Euratom.

Up to 31.12.2018, the total number of the licensees and permit holders registered at the NRA for activities with SIR is **1459**:

- licenses for use of SIR – 1106;
- licenses for transport of radioactive substance – 42;
- licenses for handling of sources of ionizing radiation for the purpose of maintenance, assembly, dismantling, measurement, construction and repair work other and services for persons using or manufacturing sources of ionizing radiation (after January 2018 this activities is under registration) – 115;
- licenses for manufacture of SIR – 2;
- permits for temporary storage of radioactive substance – 38;
- permits for construction, installation and preliminary tests – 138;
- permits for import or export of SIR – 19;
- permits for single-time transportation of radioactive substances - 3.

ACCOUNTING AND CONTROL OF RADIOACTIVE SOURCES

Pursuant to the ASUNE, the holders of licenses and permits, who produce, process, use or store SIR, are obliged to:

- perform inventory and keep records of the SIR they are in charge of and shall periodically present information to the Chairman of NRA about the results;
- appoint qualified persons responsible for SIR internal control;
- inform the Chairman of NRA immediately when absence or theft of SIR is found, as well as any other incident with SIR.

The conditions and order of radioactive substances accounting (sealed and unsealed sources) and other SIR are established in the Regulation for radiation protection. In the facilities with radioactive sources, an inventory is performed annually and the availability, location and condition of the used and stored sources is checked, as the manager of each site submits to the NRA a protocol of the inspection findings, drawn-up by the inventory commission assigned. Persons responsible for radiation protection are appointed and income and expense books, accounting the movement of the radioactive sources. In accordance with the new Regulation on radiation protection since 2018, the sample forms and the instructions published on the NRA website have been revised and updated. Special forms for operational control and traceability of SIR have been introduced. In connection with this, in 2018 the NRA has requested from licensees and permit holders of the additional extraordinary inventory of available SIR.

The licensees and permit holders are obliged to submit to the Nuclear Regulatory Agency a copy of the registers kept for the purposes of accounting and control of high activity sources according to the following deadlines:

- 7 days from the establishment of the register and the acquisition of high activity sources;
- 14 days - upon change of the information in the registers;
- 14 days – in case of removal from the register of a certain source, when the enterprise undertaking no longer owns this source, indicating the name of the undertaking or a disposal or storage facility where the source has been transferred;
- 14 days - without undue delay upon the closure of the records for a specific source upon closing a register, when the undertaking no longer holds this high activity sources;
- annually, by the end of the first quarter of each subsequent calendar year.

Category 1 includes high-activity sealed sources installed in gamma irradiators. Category 2 includes high-activity sealed sources, used for non-destructive testing devices and brachytherapy. At the end of 2018 in the country there are 11 gamma irradiation facilities - 8 for medical purposes (one for the irradiation of blood plasma and 7 for telegammatherapy) and 3 for industrial and scientific purpose. Registered are 5 devices for high dose brachytherapy and 220 for gamma defectoscopy. Fore “hot cells” for technical service and maintenance of devices with high radioactive SIR are used. The number of accelerators for charged particles in the country is 44, and the medical x-ray devices for diagnostic and therapy is over 2000.

In 2018 the total number of SIR (sealed, unsealed, generators and accelerators) that are subject of the permitted activities according to the valid 1265 licenses and 38 permits for temporary storage is 4907.

In 2018 are imported 100 high radioactive SIR:

- cobalt-60- 21 for gama- irradiators;
- iridium-192- and Selen-75 – 63 for non-destructive testing devices;
- iridium- 192 – 16 for high dose brachytherapy.

The NRA submits information to MI, MH, State Agency “National Security” for facilities with radioactive sources, including copies of licenses and permits issued by the NRA.

Measures are implemented for resuming the control over any orphan sources and for enhancement of safety in the management of high-activity sources, spent sources and “historical”

RAW. Any detected orphan sources are safeguarded, transported and delivered to SERAW for safe storage. The orphan sources which are subject of investigation procedure are delivered for temporary storage in a repository, organized for such purpose and for subsequent expert opinion at the Institute for Nuclear Research and Nuclear Energy.

The control and assurance of safety and security of high-activity sources (including orphan sources) is a priority task for the NRA and MI. Control and traceability is implemented during the “life” cycle.

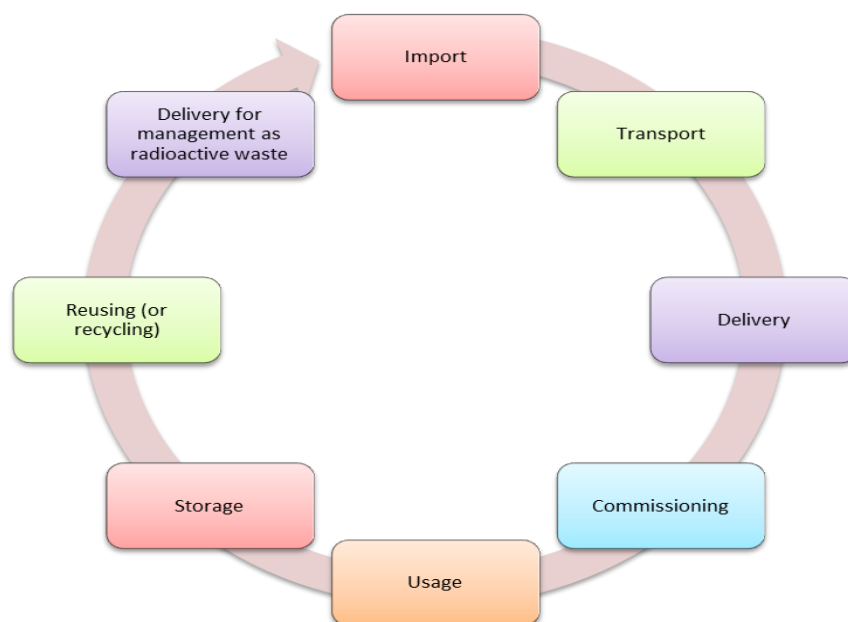


Fig 1 “Life” cycle

At border crossing points (BCP), radiation control is performed for vehicles and cargoes with the aim of preventing any illicit traffic of radioactive materials. At the main BCP automated stationary radiation monitoring systems are installed. 6 mobile accelerators for scanning of large cargoes are put into operation at BCP. General Directorate “Border Police” (MI) has additionally been supplied with portal monitors and mobile systems for radiation control.

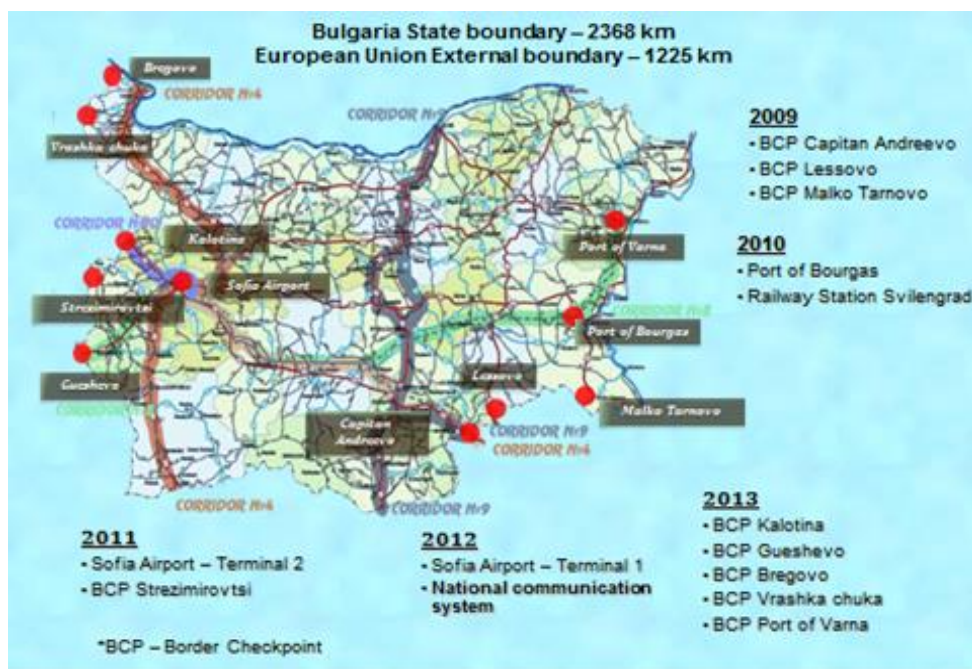


Fig 2 European Union external border – Bulgarian checkpoints

In the metallurgical factories are placed units for incoming radiological control with an alarm system for admission of metal scrap for remelting. A preventive radiological control of metal scrap is also performed with portable radiometric tools by officers of factories working with scrap and by licensed firms.

In finding illegal traffic, illegal import, export or transport of radioactive materials, the NRA notifies IAEA and competent bodies of States concerned.

REGULATORY INSPECTIONS IN FACILITIES WITH RADIOACTIVE SOURCES

In compliance with ASUNE, the NRA inspectors perform preventive, permanent and follow-up control in facilities with radioactive sources, in accordance with the annual inspection plan approved by the NRA Chairman. The scope and frequency of the inspections is determined depending on the category of SIR and the level of radiation risk while performing activities with them. The annual inspection plan for 2018 included, as a priority, sites with accelerators of charged particles and high-level sources (category 1, 2 and 3).

The inspections are performed according to the approved Procedure for Conducting Inspections at Sites with SIR, by examining:

- the compliance with the conditions of licences and permits issued and the requirements for radiation protection during activities with SIR, implementation of prescriptions;
- housekeeping, organization of the radiation monitoring and individual dosimetry control, record keeping;
- the radiation situation at the facility, the availability of means for radiation protection and preparedness to respond to a radiological emergency;
- staff competency and qualification.

The scope and frequency of inspections depend on the category of the relevant radioactive sources and radiation risk. Facilities with high-activity sources (categories 1 and 2) are included with priority. The inspections are carried out in accordance with the approved “Instruction for inspections in facilities with sources of ionizing radiation”.

Table 1 **Inspections during the period 2007– 2018**

Year	Planned inspections	Unplanned inspections	Acceptance commissions	Total number of inspections	Prescriptions	Acts for violations
2007	76	69	35	180	14	3
2008	98	134	82	314	79	4
2009	90	13	80	183	28	0
2010	56	22	79	157	11	1
2011	56	27	47	130	13	5
2012	58	137	97	195	12	3
2013	41	129	103	170	8	1
2014	54	102	88	156	0	3
2015	40	164	137	204	3	2
2016	57	5	127	189	-	-
2017	71	1	120	192	-	2
2018	51	20	44	115	-	1

Depending on the character, type, and severity of the deviations found, inspectors can issued instructions/recommendations for corrective action, prescriptions or acts for violation.

The inspection methods used by the NRA consist of monitoring and walk-down of the facilities, review of procedures, records and documentation, discussions and interview with personnel, tests and measurements. Inspections are planned (periodic), reactive, and pre-authorization inspections for commissioning of new facilities with high-active sources, unsealed sources and facilities with accelerators. Depending on their scope inspections may be comprehensive, covering the entire range of issues related to the safe use of ionizing radiation, or thematic that cover only selected areas in the inspection process. The inspectors keep records in protocols of findings.

In the case of non-compliance, the NRA inspectors have the authority to issue written prescriptions or to apply administrative enforcement measures based on the ASUNE.

Individual dose monitoring and a medical surveillance for the personnel are performed according with the regulatory requirements. The total number of individuals being covered by the system for control and assessment of occupational exposure and under medical surveillance is about 10 000.

The results from the occupational radiation exposure control show that the average annual individual effective dose is about 30 times lower than the dose limit 20 mSv for the personnel category A. About 98% of them received individual annual effective doses below 1mSv.

ENERGENSY RESPONSE AND EVENTS WITH RADIOACTIVE SOURCES

The NRA maintains a database of registered events with radioactive sources and regularly publishes information on its website. The analysis of the past 20-year period shows that about 80% of the events (327 in number) are related to radioactive metal scrap, most frequent of them (184 cases) are appliances or parts with luminous coating with radium-226 content. The remaining 20% of the events are related to orphan sources, theft of radioactive sources, illicit trafficking or other incidents with radioactive sources. There have been no radiological consequences for the population and the environment in any of the cases throughout the 20-year period being reviewed.

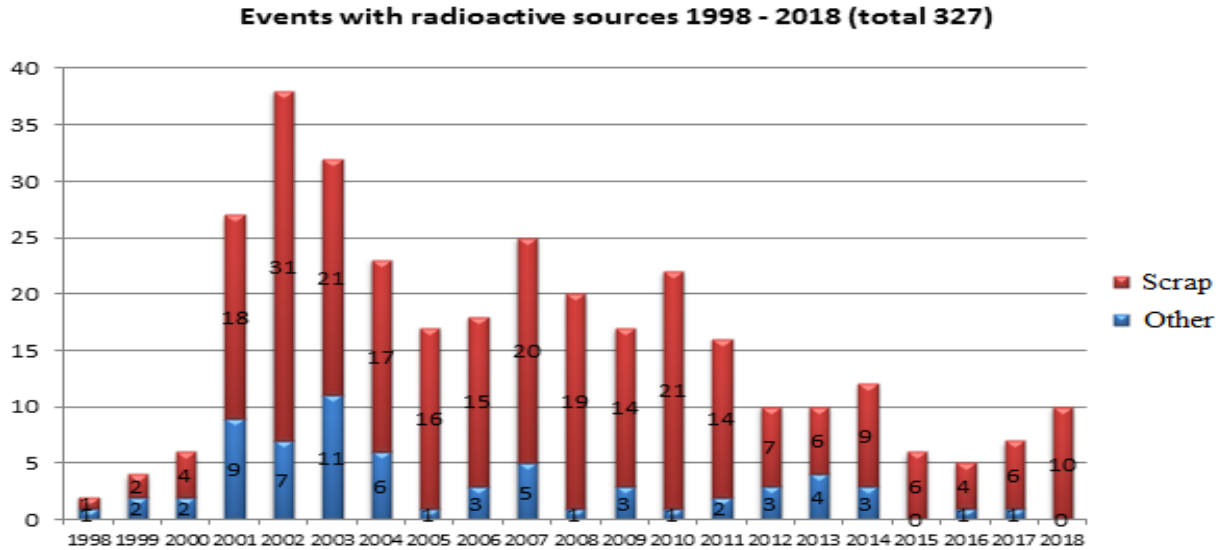


Fig 3

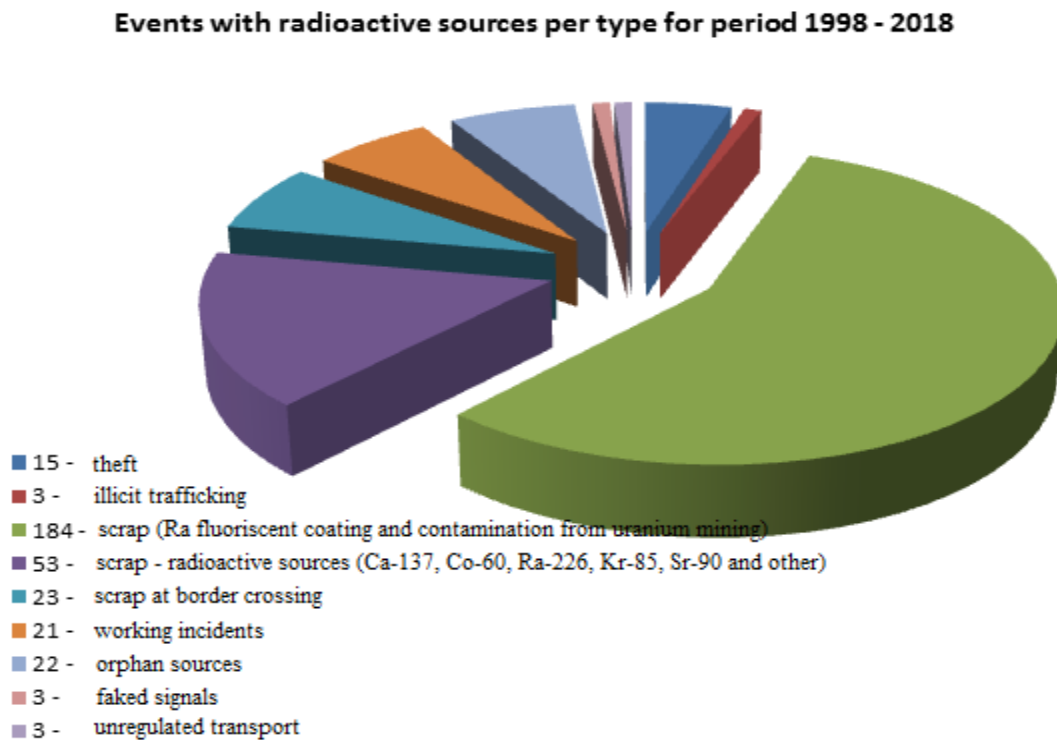


Fig 4

On-site inspections were conducted by interdepartmental emergency teams, formed from employees of the NRA, MH, MI, SERAW, with respect to these events. The radioactive sources and materials found was isolated, transported and delivered for safe storage at the SE RAW. There have been no radiological consequences for the population and the environment in any of the events throughout the period 1998-2018.

CONCLUSION

The system for regulatory control and the national infrastructure for safety and security of radioactive sources are established in compliance with the provisions and principles laid down in the Code of Conduct on the Safety and Security of Radioactive Sources.

The Bulgarian nuclear regulatory authority fulfils all obligations for ensuring the safety and security of radioactive sources, in accordance with Code of Conduct and it's supplementary guidances.