

REPUBLIC OF BULGARIA

SECOND NATIONAL REPORT (2010)

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

In accordance with the **IAEA Code**, the protection of individuals, society and the environment against harmful impact of ionising radiation is the fundamental and basic principle. In compliance with the Bulgarian **Act on the Safe Use of Nuclear Energy (ASUNE)**, the highest priority over the use of nuclear energy and sources of ionising radiation is to ensure the protection of human life, health and living conditions of both present and succeeding generations, the environment and property against harmful impact of ionising radiation.

The objectives are through the development, harmonization and implementation of national policy and strategy, laws and regulations, and through the fostering of international co-operation, to:

(1) achieve and 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;

(2) 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;

(3) mitigate or minimize the radiological consequences of any accident or malicious act involving a radioactive source;

(4) promote safety culture and security culture with respect to radioactive sources.

These objectives should be achieved through the establishment of an adequate system of regulatory control of radioactive sources, applicable from the stage of initial production to their final disposal, and a system for the restoration of such control if it has been lost.

Nuclear Regulatory Agency (NRA) is the Bulgarian State Regulatory Body responsible for safe use of nuclear energy and sources of ionising radiation. The NRA has notified the IAEA for the acceptance of the obligations ensuing from the Code of Conduct on the Safety and Security of Radioactive Sources and its associated Guidance on the Import and Export of Radioactive Sources.

National Regulatory Infrastructure is established in order to ensure radiation protection, safety and security of sources of ionising radiation in the country. The National Regulatory Infrastructure comprises: legislation, regulatory body, regulatory system and resources for achievement of the objectives in accordance with the IAEA Code.

The National Regulatory Infrastructure presented in this report is based on the IAEA principles and requirements and on the European legislation related to radiation protection, safety and security of radioactive sources.

CHAPTER 1

LEGISLATIVE FRAMEWORK – LAWS, REGULATIONS, GUIDANCES

The legislative and regulatory framework in the field of radiation protection, safety and security of radioactive sources in the Republic of Bulgaria has been described in detail in the previous National Reports under the Code of Conduct.

The Bulgarian Act on the Safe Use of Nuclear Energy (ASUNE) was adopted by the Parliament on 13 June 2002 and has been in force since 2 July 2002. The act repealed and replaced the former Act on the Use of Atomic Energy for Peaceful Purposes (AUAPEPP) of 1985 (last amended in 1995) - the first law in the Republic of Bulgaria covering the use of nuclear energy and ionising radiation.

The ASUNE covers the activities associated with the State regulation of the safe use of nuclear energy and ionising radiation and with the safety of radioactive waste and spent fuel management. It specifies the rights and duties of licensees in conducting those activities, to ensure nuclear safety and radiation protection. The provisions of the Act are fully in correspondence with the principle of priority of safety over economic and other social needs, the ALARA principle, and the principle of direct and personal liability of the licensee/permit holder. The provisions of the ASUNE guarantee the regulatory independence, treating the institutional, organizational and financial aspects. There are guarantees for free economic initiative – clear conditions and terms for issuing license or permit to each person who meets the requirements, established by the ASUNE.

In the period starting from the date of entering into force of the ASUNE until the middle of 2005, there were developed and adopted the secondary legislative acts (regulations) related to its enforcement. ASUNE delegates to the Council of Ministers the power to issue regulations on strictly defined areas of its applications. The main regulations on occupational protection, public protection, medical exposure, radioactive waste and transport of radioactive material are shortly described in the attachment to this report (Appendix I).

The ASUNE and the regulations related to its enforcement establish a uniform and complete regulatory framework in accordance with the modern tendencies in the field of nuclear legislation, the good international practices (IAEA documents), practices in the EU countries in this field, as well as the experience of the leading countries in the field of nuclear safety and radiation protection.

The ASUNE and the regulations for its enforcement assign to the Chairman of the Nuclear Regulatory Agency the responsibility to implement the Act and give interpretation and guidance on fulfillment of the legal requirements. One of the possible tools for doing this is the issuance of regulatory guides. Most important guides have been drafted and have been discussed with the licensees. Some of them are already approved.

Other Acts also providing regulation of issues in this area are the Environmental Protection Act, the Act on Health and the Regulations associated with their application.

CHAPTER 2

REGULATORY BODY

2.1. RESPONSIBILITIES AND FUNCTIONS

In accordance with ASUNE the state regulation of the safe use of nuclear energy and ionising radiation, the safety of radioactive waste management and the safety of spent fuel management is implemented by the Chairman of the Nuclear Regulatory Agency (NRA). The Chairman is an independent specialised authority of the executive power and is vested with competencies, specified by the legislation.

The NRA has the authority to:

(a) establish regulations and issue guidance relating to the safety and security of radioactive sources;

(b) require those who intend to manage radioactive sources to seek an authorization, and to submit a safety assessment and a security plan or assessment as appropriate for the source and/or the facility in which the source is to be managed;

(c) obtain all relevant information from an applicant for an authorization;

(d) issue, amend, suspend or revoke, as necessary, authorizations for the management of radioactive sources;

(e) attach clear and unambiguous conditions to the authorizations issued by it, including conditions relating to:

- responsibilities;
- minimum operator competencies;
- minimum design and performance criteria, and maintenance requirements for radioactive sources and the devices in which they are incorporated;
- minimum performance criteria and maintenance requirements for equipment and systems used to ensure the safety and security of radioactive sources;
- requirements for emergency procedures and communication links;
- work procedures to be followed;
- the safe and secure management of disused sources;

(f) obtain any relevant and necessary information from a person with an authorization;

(g) require those supplying or transferring radioactive sources or devices incorporating radioactive sources to provide the recipient with all relevant technical information to permit their safe and secure management;

(h) enter premises in order to undertake inspections for the verification of compliance with regulatory requirements;

(i) enforce regulatory requirements;

(j) monitor, or request other authorized bodies to monitor, at appropriate checkpoints for the purpose of detecting orphan sources;

(k) ensure that corrective actions are taken when a radioactive source is in an unsafe or non-secure condition;

(l) provide, on a case-by-case basis, to a person with an authorization and the public any information that is deemed necessary in order to protect individuals, society and the environment;

(m) liaise and co-ordinate with other governmental bodies and with relevant non-governmental bodies in all areas relating to the safety and security of radioactive sources;

(n) liaise with regulatory bodies of other countries and with international organizations to promote co-operation and the exchange of regulatory information;

(o) ensure that radioactive sources are stored in facilities appropriate for the purpose of such storage;

(p) ensure that, where disused sources are stored for extended periods of time, the facilities in which they are stored are fit for that purpose.

The NRA establishes procedures for dealing with applications for authorization which publishes as appropriate. The NRA maintains records of persons with authorizations in respect of radioactive sources and records of the transfer and disposal of the radioactive sources on termination of the authorizations, including comprehensive information for types, activity and other characterizations of the radioactive sources authorized to use. These records and information are secured against unauthorized access or alteration.

The NRA 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 persons with authorizations;
- the areas where radioactive sources are managed are marked by users with appropriate signs to warn workers or members of the public, as applicable, of the radiation hazard;
- radioactive sources and their containers, are marked by users with an appropriate sign to warn members of the public of the radiation hazard;
- radioactive sources are identifiable and traceable, or where this is not practicable, 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, as applicable, operating experience and internationally endorsed standards and recommendations.

The NRA carries out both announced and unannounced inspections at an appropriate frequency taking into account past performance and the risks presented by the radioactive sources and takes enforcement actions, as appropriate, to ensure compliance with regulatory requirements.

The NRA prepares provisions to recover and restore appropriate control over orphan sources and to deal with radiological emergencies. The NRA 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 requires prompt reporting by authorized persons of loss of control over, and of incidents in connection with radioactive sources and promotes the establishment of a safety culture and of a security culture among all individuals and in all bodies involved in the management of radioactive sources.

The NRA actively collaborates with the IAEA, EU institutions, European Union countries, neighbouring countries, USA and other countries in the field of radiation protection, safety and security of radioactive sources, emergency preparedness and response.

2.2. ORGANIZATION, RESOURCES, INDEPENDENCE

The NRA Chairman is designated by a decision of the Council of Ministers and is appointed by the Prime Minister for a period of five years and may be re-appointed for one additional term of office (mandate). Two Deputy-Chairmen assist the Chairman in the exercising of his/her authorities. The two deputies are designated by a decision of the Council of Ministers on a motion by the NRA Chairman and are appointed by the Prime Minister.

In his/her activity, the Chairman is assisted by an Administration organised in the form of a Nuclear Regulatory Agency. The Agency's structure, operation and work organisation, as well as the staffing is determined by the Statutory Rules adopted by the Council of Ministers on a motion by the NRA Chairman.

The NRA organizational structure is shown in Appendix II. The NRA organization consists of five departments:

- General Department of Safety Regulation of Nuclear Facilities;
- Department of Safety Analysis, Assessment, Research and Development;
- Department of Radiation Protection and Emergency Preparedness;
- Department of International Co-operation and European Integration;
- Department of Administrative, Legal and Financial Services.

The NRA currently employs 104 persons comprising of engineers, physicists, technical and general administration personnel. 95 % of the NRA staff have university education, master degrees. The personnel is qualified to carry out its functions and regulatory activities according to the ASUNE.

The NRA activities are financed by the national budget and by proceeds from the fees collected under the ASUNE. The NRA Chairman is a Primary Distributor of Budgetary Credits and administers the financial resources raised from the state budget, fees collected under the ASUNE, donations and any accrued interest. The NRA Chairman has the same budgetary authority as other ministers in Bulgaria to manage and to distribute the NRA budget.

The funds "Radioactive Waste Fund" and "Nuclear Facilities Decommissioning Fund" are established by the ASUNE. The legal entities and persons which perform activities resulting in the generation of radioactive waste shall make contributions to these funds.

The NRA Chairman obtains advises of two advisory bodies - Advisory Council on Nuclear Safety and Advisory Council on Radiation Protection. The NRA Chairman approves the composition of the Advisory Councils by an order. The Advisory Councils include prominent scientists and experts in the field of nuclear energy and ionising radiation, radioactive waste management and spent fuel management. The Advisory Councils adopt rules of procedure and the meetings are presided by the NRA Chairman or by an authorised person. The Advisory Councils assist the Chairman by giving expert advice on the scientific aspects of nuclear safety and radiation protection.

NRA provides to the public comprehensive and timely information on different aspects of nuclear activities. The public has the opportunity to provide their views and opinions at the organized meetings and formal hearings.

The NRA has placed all laws, regulations, guides, amendments to the legal acts, enforcement actions, emergency events and other important public information on the NRA web page. Website information is updated regularly and is maintained in Bulgarian and English.

The Act on Safe Use of Nuclear Energy guarantees the effective independence of the regulatory body from other organisations or bodies that are responsible for facilities or activities involved with nuclear energy, ionising radiation, the safety of radioactive waste management and the safety of spent fuel management. Article 12 states that “State bodies, which by financing or in another manner are engaged with promotion or use of nuclear energy or sources of ionising radiation, shall not exercise any state regulatory functions with respect to nuclear safety and radiation protection.”. A clear separation between regulatory and promotion functions is reached.

Some state bodies have particular competencies specified in the legislation. Article 13 states: “The Minister of Health, the Minister Environment and Water, the Minister of Interior, the Minister of Defence, the Minister of Agriculture and Food, the Minister of Transport, Information Technologies and Communications, and the Minister of Education, Youth and Science shall exercise specialised control in accordance with their competencies specified in the legislation.”

Functions and responsibilities of specialised control bodies, as well as terms of interaction and coordination between them are clearly and unequivocally defined in the respective legislation thus avoiding overlapping of activities and contradictions (Appendix III).

CHAPTER 3

REGULATORY SYSTEM, REGULATORY ACTIVITIES AND CONTROL OF RADIOACTIVE SOURCES

3.1. PREVENTIVE CONTROL – AUTHORIZATION

Under the ASUNE, the activities related to the use of ionising radiation can be performed only after obtaining the respective licenses and permits. The licensing regime covers all practices and sources in the country. The licenses and permits issued by BNRA contain general and special conditions. The licences issued by the BNRA may be valid not more than 5 years.

According to the ASUNE there are **four types of licenses** for practices with radioactive sources, as follows:

- use of radiation sources;
- manufacturing of radiation sources or parts thereof;
- handling of radiation sources for services;
- transport of radiation sources.

According to the ASUNE there are **five types of permits** for practices with radioactive sources, as follows:

- construction of a facility with radiation sources, assembly and preliminary tests;
- decommissioning of a facility with radiation sources;
- temporary storage of radioactive substances;
- single transport of radioactive sources;

- import and export of radioactive sources.

The requirements for issuing of permits and licenses as well as the responsibilities of the NRA Chairman, related to the issuance, amendment, renewal and withdrawal of such permits and licenses has been presented in details in the previous National Reports.

The total number of licences issued by BNRA is about 150 per year. The licensees for use of radioactive sources are about 220. (The NRSIR contains data for more than 1 300 licensees controlled by NRA.)

Radioactive sources or materials, containing radioactive substances, resulting from a licensed activity, may be used or recycled without restrictions for their origin, type and field of application on the condition that the specific activities of individual radionuclides contained in them, shall be less or equal to the **clearance levels** indicated in the Regulation on Radiation Protection in Activities Related to the Use of sources of ionising radiation. **Exemption levels** are defined in the Regulation on the Basic Radiation Protection Norms.

Note: The clearance and exemption levels mentioned above are the same as those recommended by the IAEA.

3. 2. NATIONAL REGISTER OF RADIOACTIVE SOURCES

The NRA has established a database for radioactive sources inventory (**National Register of Sources of Ionising Radiation – NRSIR**) and updates this database when granting or amending licenses and permits. The NRA manages own integrated information database system which includes authorised holders, licenses and permits issued, inspections performed, emergency events and all other official documents received or sent by the NRA.

The NRA is developed and maintain **NRSIR** according of the IEAE “**Code of conduct on the safety and security of radioactive sources**”. The **NRSIR** complies with the requirements of the IEAE **Code of conduct** (item 11) concerning the categorization of radioactive sources, security of the information, standard data format, possibilities of information exchange and tracking of the registered sources. The **NRSIR** contains data on the type, activity, radionuclide content, technical characteristics and location of the controlled radioactive sources of categories 1 through 5 as well as generators of ionising radiation, including data of the persons carrying out activities with these sources.

The NRSIR includes 14 modules as follows:

- „**Manufacturers**” – a module about the input of the data about the manufacturers of the different sources and equipment;
- „**Units**” – a module about the input of the measure units used in the Register;
- „**Radionuclides**” – the module contains specific for the nuclides data – mass, half life, daughter nuclides, probability to obtain the corresponding daughter nuclides, D –values and etc;
- „**Towns and villages**” – the module contains data about the town and villages, in accordance with the location of the town/village and the territory division of the country;
- „**Persons**” – the module contains data about some responsible persons, personal data and their positions;
- „**Companies**” – the module contains data about the companies;

- „**Transport vehicles**” – the module contains data about the used transport vehicles from the companies;
- „**Sites**” – the module contains data about the sites of the companies;
- „**Fire detectors**” – the module contains specific data about the fire detectors;
- „**Generators of X- and Roentgen rays**” – the module contains data about their manufacturer, model and technical parameters;
- „**Equipment with built-in sources**” - the module contains data about their manufacturer, model, technical parameters, number of the sources, activity of the sources;
- „**Sealed sources**” – the module contains data about their manufacturer, model, dimensions, radionuclide, activity;
- „**Unsealed sources**” – the module contains specific for these sources data;
- „**Licenses**” – a module about input of the necessary data for issuing of licenses.

At the end of 2009 the total number of the facilities with radioactive sources and generators registered in the NRSIR is **1757**, that are distributed as follows:

- for industrial applications - **169** facilities;
- for medical applications - **1214** facilities;
- for science, research, education and agriculture purposes – **130** facilities;
- for control and other purposes – **107** facilities;
- facilities with smoke detection devices (SDD) – **68**.

The total number of sealed radioactive sources is **3768 from category 1 to 5** (without SDD). The number of radioactive sources build in the SDD is more than **15 000** used and stored in 68 facilities registered by the NRA.

The total number of the persons authorised by the NRA to use and store radioactive sources (holders) is about 220.

There are a total of 34 gamma irradiators (**category 1**). 20 gamma irradiation facilities have a license for use (10 for medical use, 10 for other purposes). 14 gamma irradiators are stored in the Novi Han repository.

To **category 2** pertain activities and radioactive sources for industrial radiography (in use – 109 devices, in storage – 123 devices).

To **category 3** pertain the radioactive sources used in the technological control gages (total number - 474 devices with 542 sources - moisture-density gages, level gages etc.).

To **category 4** pertain the static electricity eliminators pertain (total number – 61 devices).

The smoke detection devices (SDD) pertain to **category 5** (above 15 000 sources).

There are other types sealed radioactive sources used in laboratories and installations for metrology, for radiation measurment and control purposes which pertain to **category 3, 4 or 5** (according to the activity of the sources and the type of work).

The NRSIR contains data for unsealed radioactive sources used in 90 facilities for scientific, research and medical purposes (nuclear diagnostics, metabolic radiotherapy, medico-baillogical research etc.).

There are totally 3228 generators of ionising radiation registered in the NRSIR (2 757 X-ray devices used in medicine, 3 accelerators, 141 X-ray industrial radiography devices etc.).

The NRA has a plan to upgrade the NRSIR which includes:

- Development of new functional modules in the system and extending the existing ones for improvement of the traceability of the radioactive sources;
- Development of new “Import/Export Module” for more effective control of the import and export of radioactive sources;
- Development of a public system web interface to provide the interested organizations and agencies with partial access and to allow enquiries in the NRA register database;
- Extension of the interface and functionality of the information system.
- Further Optimization of the Data Base for Operation with Large Data Arrays.

The functional block-scheme of the NRSIR is shown in Appendix IV.

3.3. PREVENTION OF EMERGENCY EVENTS AND RESPONSE IN CASE OF INCIDENTS OR ACCIDENTS WITH RADIOACTIVE SOURCES

The ASUNE, the Act on Crisis Management, the Disaster Protection Act, the Act on Health and the respective regulations determine the principles, criteria, order and conditions for maintaining emergency preparedness and response in case of incidents and accidents with possible radiological consequences. The infrastructure for emergency preparedness and emergency response corresponds to the requirements and criteria given in the IAEA documents and European legislation in this field.

In accordance with the ASUNE licensees performing activities with radioactive sources are obliged to create organisation and to foreseen measures for emergency preparedness and response. The licence for performing activities with radioactive sources is issued only after submitting by the applicant the on-site emergency plan.

The human, technical and material resources for emergency response and ensuring radiation protection of the population in case of radiation accident is ensured at a national, institutional and local level. A communication information system is maintained for informing the population. Organization is established and the necessary technical means and equipment are provided for notification and early warning, radiation monitoring, radiation protection for the population and the emergency teams, performing engineering restoration works and urgent medical help in case of a radiation accident. Emergency centres and a National situational centre exist for management of emergency events in the country.

Training and exercises are organized periodically at institutional, national and international level for action and response in case of emergency events.

The NRA and specialised control bodies undertake co-ordinate measures for prevention of events with orphan sources and illicit trafficking of radioactive materials. The NRA, “Civil Protection” and “Border police” (MI) apply standard procedures for acting in case of discovering of materials with increased radiation. The preventive border control for discovery of goods and materials with increased radiation and developed system for co-operation between the specialised control authorities contributes for the prevention of illicit trafficking and radiation incidents with orphan sources. A special procedure has been developed for actions in case of discovering of orphan sources, which is part of the National emergency plan. The NRA emergency plan is part of the National emergency plan.

The NRA maintains a database on the registered in the country incidents and accidents with radioactive sources. The NRA publishes at its web page information on the incidents with radioactive sources in the country.

The distribution by years of registered events with radioactive sources that have occurred over the period 1998 – 2009 (a total of 229 events) is shown on the **figure № 1**. The distribution of the events according to their characteristics is shown on the **figure № 2**. About **80 %** of the cases (a total of 178) pertain to **scrap metal** where materials with increased radioactivity have been found. These are usually (142 cases) appliances or parts covered with luminous fluorescent paint /containing radium-226/. 17 incidents with radioactive sources have been registered in 2009, 14 of which are related to scrap metal.

Emergency teams, organized according to the specific case by employees from the competent state bodies (NRA, MN, MI, SERAW) are formed for the liquidation of incidents or accidents. Approved response procedures for events involving radioactive sources and materials are being applied for that purpose. The actions of the Emergency Response Team comprise: detection of contaminated material (radioactive substances); removing and localisation of the contaminated material in appropriate place for temporary storage; monitoring of the dose-rate, doses and contamination including in situ gamma-spectrometry; transportation of the founded sources to the permanent repository or for special investigation; police investigation for the origin of the material; notification and reporting.

All orphan sources or radioactive contaminated materials that were found were collected and isolated for temporary storage on proper location and after that were transported and delivered for safe storage at the SERAW (in Novi Han repository).

Consequences for the population and the environment have not been registered during considered 12 years period.

3.4. REGULATORY APPROACH UPON EXPIRATION OF RADIOACTIVE SOURCE LIFE TIME

According to the definition of „radioactive waste” given in the ASUNE, each radioactive source whose term of safe use is expired according to his production documentation should be proclaimed and treated as radioactive waste. But the operational term of the radioactive sources given by their producers can not be leading and final for their integrity and safety, respectively must not exclude the possibility for their reuse or recycling in the cases of non-violation of the requirements of the radiation protection and safety. The declaring of a radioactive source as radwaste on „operational life time” criteria basis determined by the producer is not substantiated and pragmatic.

The NRA encourages the reuse or recycling of radioactive sources, when practicable and is consistent with considerations of safety and security. According to the Regulation for Radiation Protection During Activities with Sources of Ionising Radiation there is a possibility for extension of the term of safe use of radioactive sources after the expiration deadline shown in the producer documentation .

Each licensee shall provide control over the condition of used and stored radioactive sources by periodical tests for source integrity. The Chairman of NRA defines the test frequency. Furthermore additional integrity tests may be prescribed by the NRA Inspector.

After the termination of the operational term, given in the producer documentation, the integrity of the used radioactive sources shall be checked not less than once per year. Commission, appointed by the NRA Chairman shall access the results from the performed tests.

This Commission gives conclusion for the further safe use of the source after the termination of term of operation, shown in the producer's documentation and then the NRA may issue permit for use or does not allow its further use).

The disused (spent) radioactive sources declared as radwaste are liable to conditioning, storage and final disposal. In certain cases radioactive sources can be returned for reuse or recycling to the country-producer.

3.5. REGULATORY CONTROL AND ARRANGEMENTS FOR IMPORT AND EXPORT OF RADIOACTIVE SOURCES

According to ASUNE the import and export of sources of ionising radiation are subject of permission regime. The NRA issues permits for import of radioactive sources taking into account the following requirements:

- the person who will use the imported radioactive sources must have a license for use or a permit for storage of radioactive sources;
- the person who will transport the imported radioactive sources must have a license or permit for transport of radioactive materials.

A confirmation for import/export of goods according to the form required by the Regulation for the conditions and the order for registration and permission of foreign trade deals is inseparable part of the issued by the NRA permissions for every import or export of sources of ionising radiation.

The NRA implements "COUNCIL REGULATION (EUROATOM) № 1493/93 of 6 June 1993 on shipments of radioactive substances between Member States" related to the import and export of radioactive sources. A holder of sealed sources who intends to carry out a shipment of such sources, or to arrange for such a shipment to be carried out, shall obtain a prior written declaration by the consignee of the radioactive substances to the effect that the consignee has complied with relevant national requirements for safe storage, use or disposal of that class of source. The declaration shall be made by means of the standard documents set out in Annexes I to this EU Regulation. The declaration referred shall be sent by the consignee to the competent authority of the Member State to which the shipment is to be made. The competent authority shall confirm with its stamp on the document that it has taken note of the declaration and the declaration shall then be sent by the consignee to the holder.

A holder of sealed sources and other relevant sources who has carried out a shipment of such sources, or arranged for such a shipment to be carried out, shall, within 21 days of the end of each calendar quarter, provide the competent authorities in the Member State of destination with the following information in respect of deliveries during the quarter:

- names and addresses of the consignees;
- the total activity per radionuclide delivered to each consignee and the number of such deliveries made;
- the highest single quantity of each radionuclide delivered to each consignee;
- the type of substance: sealed source and other relevant source.

The NRA takes appropriate steps to ensure that transfers of radioactive sources are undertaken in a manner consistent with the provisions of the IAEA Code of Conduct and Guidance on the Import and Export of Radioactive Sources. The transfers of radioactive sources in Categories 1 and 2 take place only with the prior notification by the exporting State and, as

appropriate, consent by the importing State in accordance with their respective laws and regulations.

According to the ASUNE the NRA is a competent body for issuing of licenses for transport of radioactive material (radioactive sources and others) and permissions for single transport of radioactive material. The requirements for safe transport of radioactive materials are defined in the Regulation on the conditions and procedures for transport of radioactive material. The local carrier have to be authorized by the NRA to be able to transport radioactive materials in accordance with the Regulation on the procedure for issuing license and permits for safe use of nuclear energy.

Episodically through the country territory transit transports of radioactive sources are realized. Transit of radioactive substances (radioactive sources) through the territory of Bulgaria is possible after permission given by the NRA Chairman. The practice shows good collaboration in this field and good co-ordination between the NRA and the regulatory bodies of other countries.

According to the ASUNE the import of radioactive waste is prohibited except:

- (a) re-import of used sealed sources manufactured in Bulgaria;
- (b) where the radioactive waste is generated as a result of the processing of materials performed as a service to Bulgaria or a Bulgarian legal entity.

Bulgaria does not produce and export radioactive sources.

The NRA is the point of contact for the purpose of facilitating the export and/or import of radioactive sources.

3.6. INSPECTION ACTIVITIES AT FACILITIES WITH RADIOACTIVE SOURCES

In accordance with the ASUNE, the NRA performs:

- Preventive control in the process of issuing licenses and permits;
- Routine control on the compliance with the terms of the issued licenses and permits;
- Follow-up control on the compliance with the recommendations or improvement notices given by the controlling authorities.

The planned inspections at the facilities with SIR are carried out under an established annual plan. The scope and intervals of inspections are differentially determined according to the category of the respective SIR and the level of radiation risk of the performed activities. The facilities with SIR of category 1 are inspected on an annual basis.

The inspections are carried out according to the adopted “Instruction on carrying out inspections in facilities with SIR” the following being examined:

- Compliance with the conditions of the issued licenses and permits, and the requirements for radiation protection in activities with SIR, fulfilment of improvement notices;
- House-keeping, organization of the radiation monitoring and the individual dose control, management of documentation;
- Radiation situation at the facility, availability of means for radiation protection and preparedness for response in case of a radiation incident or accident;
- Qualification and certification of the staff.

In accordance with the ASUNE the NRA implements enforcement actions in case of violations of the requirements for radiation protection, safety and security of radioactive sources (prescriptions, penalty acts etc.).

The NRA inspectors perform about 300 inspections annually (routine and follow-up control, extraordinary inspections).

CHAPTER 4

REGULATORY CONTROL AND ARRANGEMENTS FOR SAFETY AND SECURITY OF RADIOACTIVE SOURCES

The national legislative and regulatory system of control over the management and protection of radioactive sources includes requirements and preventive measures directed to:

- minimize the likelihood of a loss of control and deter, detect and delay the unauthorized access to, or the theft, loss or unauthorized use or removal of radioactive sources during all stages of management;
- reduce the likelihood of malicious acts, including sabotage;
- develop strategy for gaining or regaining control over orphan sources;
- provide for rapid response for the purpose of regaining control over orphan sources;
- foster ongoing communication between the NRA, specialised control bodies and users;
- mitigate or minimize the radiological consequences of accidents or malicious acts involving radioactive sources;
- protect individuals, society and the environment from the deleterious effects of ionising radiation from radioactive sources;
- verify the safety and security of radioactive sources, through safety and security assessments, monitoring and verification of compliance, and the maintenance of appropriate records;
- ensure the capacity to take appropriate enforcement actions.

According to the ASUNE the prime responsibility for the safe management of, and the security of, radioactive sources is placed on the persons being granted the relevant authorizations. Any person or organisation, that manufactures, processes, stores or uses nuclear material, radioactive substances and other sources of ionising radiation, is obligated to:

- make inventory and keep records of the sources of ionising radiation;
- provide periodic information on the records to the NRA Chairman;
- appoint competent personnel to take charge of the internal control over the sources of ionising radiation (data concerning this personnel must be provided to the NRA);
- report immediately any accidental loss or theft of nuclear material, radioactive substances and other sources of ionising radiation to the NRA Chairman, MI and MH;
- report to the NRA Chairman any incident involving an actual or potential breach of the integrity of the nuclear material or radioactive source;

Anyone who loses or finds any source of ionising radiation is obligated immediately to notify the NRA Chairman, specialised state body for civil protection or specialised authorities of the MI. Any radioactive source, whose owner is not known, is a state property. The NRA Chairman designates the person to whom such orphan sources shall be provided and designates the terms and conditions for this activity.

The terms and procedure for accounting and control of the sources of ionising radiation are established by the Regulation for Radiation Protection during Activities with Sources of Ionising Radiation. The radioactive sources received at the facility shall be placed on account in the logbook of receive-transfer operations. The hand over and return of sources of ionising radiation used in the working process shall be registered in the logbook of receive-transfer operations of the facility.

A commission, appointed by the order of the manager in charge, which possesses license and/or permit for activities with sources of ionising radiation, checks on a yearly basis, the presence, location and status of the used and stored sources of ionising radiation at the respective facility. A copy of the audit document should be submitted to the NRA not later than the end of the first quarter of every following year. In case of establishing an absence or unregulated use of sources of ionising radiation, the person holding a license and/or a permit for activities with sources of ionising radiation, is obliged to notify immediately the NRA and MI.

The Regulation for the provision of physical protection of nuclear facilities, nuclear material and radioactive substances determines the requirements related to physical protection during use, storage and transport of nuclear materials and radioactive substances. It is taken into consideration the existence of different kinds of facilities, nuclear materials and radioactive substances, which include different levels of physical protection, depending on the category of nuclear materials and radioactive substances and the degree of risk.

According to the Regulation on Emergency Planning and Emergency Preparedness in Case of Nuclear or Radiation Emergency the waste and scrap metal storage and processing facilities, as well as the national border check points of the country, are classified in 5th threat category, which require available emergency plan for action in case of discovering of radioactive sources or increase of the radioactivity.

The competent bodies undertake measures for prevention of events with orphan sources and illicit trafficking of radioactive materials. The NRA and Border police (MI) apply standard procedures for acting in case of discovering of materials with increased radiation. A special procedure is developed for actions in case of discovering of orphan sources, which is part of the National emergency plan.

The monitoring of the movement of radioactive materials at the Bulgarian borders is performed continuously and comprises the national border points. There are automatic radiation monitoring systems for 7 border points. The staff of the checkpoints is equipped with handheld radiation monitors and pagers.

There are automatic radiation monitoring systems in the main Bulgarian "scrap" metal processing facilities (Kremikovcy company, Stomana Industry company, KCM –Plovdiv, Sofia MED). There are in use also mobile radiation devices for control of scrap metal. On-site emergency plan for performing actions in case of determination of increased radioactivity in scrap metal was developed. Documentation for the origin of the scrap is required for the scrap metal received for smelting. Special places are identified for isolation and unloading of the transport vehicles in case of discovering radioactive contaminated scrap metal. The NRA is issuing licenses to the organisations and companies specialised in the performing radiation monitoring of the scrap. The licensees are obliged to notify immediately the NRA in case of discovering of radioactive contamination.

The NRA published Guidance for control of the scrap metal and emergency response in a case of incidents with radioactive scrap metal.

Appropriate facilities and services for radiation protection, safety and security are available to, and used by, the persons who are authorized to manage radioactive sources. Such facilities and services are needed for:

- searching for missing sources and securing found sources;
- intervention in the event of an accident or malicious act involving a radioactive source;
- personal dosimetry and environmental monitoring;
- the calibration of radiation monitoring equipment.

Arrangements are performed for the appropriate training of the staff of the state control bodies, users of radioactive sources and emergency teams. The NRA co-ordinates and organises the participation of Bulgarian experts in international training courses and seminars connected with the radiation and physical protection of the facility using sources of ionising radiation, emergency planning and illicit trafficking of radioactive materials.

With the finance and expert assistance of the IAEA, EU and USA in the period 2005 – 2009 a significant progress has been achieved in relation to:

- Safety management of high activity sources, including disused sources;
- Prevention of incidents with orphan sources;
- Prevention of illicit trafficking of nuclear and radiation substances.

The following results are achieved based of the successfully implementation of the international projects:

- harmonisation of the legislation with the EU Directive 122/2003;
- decommissioning and transferring for long-term safe storage at Novi Han repository of 5 gamma-irradiators from practices in the past;
- decommissioning and transferring for long-term safe storage at Novi Han repository of disused radioactive sources from facilities in liquidation;
- delivery of radiation monitoring equipment for the needs of NRA, MH and SERAW (including mobile laboratory for the NRA);
- improvement of the physical protection in 13 medical and industrial facilities with high activity sources Category 1 (special security equipment have been installed);
- delivery of equipment for radiation monitoring of the transit commodities and materials at the border checkpoints.

For the period 2006-2008 Action Plan for Implementation of the European Union Legislation in the Field of Radiation Protection was adopted by the NRA and MH and is implemented.

In accordance with the Strategy for Management of Spent Nuclear Fuel and Radioactive Waste approved by the Council of Ministries, all disused sources from previous practices should be collected and stored in the Novi Han repository at the end of 2010. The SERAW implements Special Program for collecting and transfer in the the Novi Han repository of disused (spent) sources from previous practices.

Two projects in the field of radiation protection, safety and security of radioactive sources, are finished in 2009, namely:

- Project BG 2006/018-411.01.03 - Improvement of the regulatory infrastructure in the field of radiation protection and application of good European practice for safe management of highly radioactive sources;
- Project BG 2006/018-411.01.02- Improvement of the regulatory infrastructure in the field of transport of radioactive materials including prevention of illicit trafficking

CHAPTER 5

ONGOING ACTIVITIES AND FUTURE PLANS

5.1. MAIN AMENDMENTS AND SUPPLEMENTS OF THE ASUNE

In applying the policy of NRA for periodical review of the legislation in the field of nuclear safety and radiation protection, in 2008 a decision was taken to prepare amendments and supplement to the Act. The draft Act on amendment and supplement of the ASUNE was prepared for discussion with the competent state authorities, licensees and the public at the end of 2008. According to Statutory Rules of Council of Ministers and its administration at the beginning of 2009 coordination procedure was carried out.

With Council of Ministers Decision № 304/24.04.2009 the draft Act on amendment and supplement of the ASUNE (**DAAS ASUNE**) was approved. DAAS ASUNE was submitted to the 40-th National Assembly on 28 April 2009. After the elections and constitution of the 41-th National Assembly DAAS ASUNE was sent back to BNRA for new coordination procedure.

On 25 June 2009 entered into force Directive 2009/71/EURATOM establishing a Community framework for the nuclear safety of nuclear installations. Working group on the amendment and supplement of the ASUNE made additional proposals, which aim was full and strict Directive 2009/71/EURATOM transposition.

Draft Act on amendment and supplement of the ASUNE is under consideration in the Bulgarian National Assembly. It is expected that the Act will be adopted in June 2010.

The changes are based on the gained experience in applying the law, implementing the new EU directives in the field of radiation protection, transport of radioactive substances and nuclear material, nuclear safety as well as the changes in the Convention on the Physical Protection of the Nuclear Material (CPPNM). The main amendments and supplements proposed in the draft are in the following fields, namely:

- **Basic IAEA principles**

DAAS ASUNE introduces basic principles for safety and radiation protection(Art.3) according to the principles given in IAEA SF-1 “Safety Fundamentals”.

- **Physical Protection of the Nuclear Material**

Taking into consideration the changes in CPPMN.

- **Early exchange of information in the event of radiological emergency (Ecurie)**

The “Agreement between the European Atomic Energy Community (Euratom) and non-member States of the European Union on the participation of the latter in the Community arrangements for the early exchange of information in the event of radiological emergency (Ecurie)” is ratified by a law by the National Assembly in 2005 (State Gazette № 34/19.04.2005). By DAAS ASUNE for the implementation of this Agreement the NRA Chairman is designated to be a competent authority and point of contact (Art. 5).

- **Nuclear safety of nuclear installations** (harmonization with Council Directive 2009/71/EURATOM)

Most of the directives requirements already exist in ASUNE as principles or specific regulations. Nevertheless, with the aim of complete transposition, certain provisions were additionally reviewed and amended, while in other cases new provisions were created.

- **Radiation protection**

In the field of SIR use a detailed analysis of the existing authorisation regime was made with the aim to facilitate, to the fullest possible extent, the facilities and activities which present insignificant risk to the health and the environment. DAAS ASUNE stipulates a number of measures to ease the authorization regime, such as:

- The Act provides a legal possibility for removing the licensing regime for certain categories of SIR, which have a low radiological risk and are employed in medicine and industry, such as dental X-ray devices with digital sensors, some smoke detectors (SDT) using radioactive substances etc. This category of SIR remain under the regulatory control, but only under a notification regime.;

- Authorisation regime is completely removed for the parts of SIR, such as x-ray tube stands, cables, image intensifiers etc. which do not present a radiological risk;

- The maximum term of validity of the licence for use of sources of ionising radiation for economic, medical, scientific or process control purposes is extended from 5 to 10 years;

DAAS ASUNE introduces the principle of return of certain categories of radioactive sources to the manufacturer. For the issuing of a permit for import of certain categories of sealed sources the DAAS ASUNE introduces the requirement for ensuring the return of the highly active radioactive sources to the manufacturer after the expiration of their lifetime resource. The expected effect is the decrease of the number of orphan sources, as well as diminishing of the number of sources disposed on the territory of Republic of Bulgaria as radioactive waste (RAW).

Through DAAS ASUNE, on a legislative level, the term “qualified expert of radiation protection” is introduced. These experts act as consultants, whose qualification is approved by the competent authorities. DAAS ASUNE creates a new legislative mechanism for acknowledging the qualification of such experts. At present the term “qualified expert of radiation protection” is introduced in the “Regulation for basic norms for radiation protection”.

By DAAS ASUNE the provision on prohibited activities is specified.

Article 17 in the ASUNE (“The following activities are prohibited: The addition of radioactive substances with aim of increasing the level of activity in foodstuffs and other products or by activation, except as provided for by a specialised law, as well as importing and exporting such commodities and products”) is changed. The new provision prohibits the addition of radioactive substances during the production of foodstuffs, toys, jewelry and cosmetics, as well as import and export of such commodities.

The control of conditions and procedures for activities with materials with enhanced content of natural radionuclides, which can not be neglected from the radiation protection point of view, is reviewed and specified in detail, which guarantees the personnel and population safety.

- **Transport of radioactive substances and nuclear material**

Harmonization with Directive 2006/117/EURATOM of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel. The Council Directive 2006 /117/ Euratom is transposed in December 2008 by an order of NRA Chairman and the EU

was notified for its implementation. The DAAS ASUNE regulates the established procedures for the transboundary transport of SF and RAW. The Directive introduces an unified regime concerning the shipments of RAW and SF within the Union and to and from third countries, as well as the application of the Standard Document for supervision and control of shipments of radioactive waste and spent nuclear fuel.

The DAAS ASUNE does not foresee addition or revoking of the permission regimes. The shipment through the territory of Republic of Bulgaria is carried out on the basis of NRA Chairmans written consent.

- **Decommissioning of nuclear facilities**

According to the ASUNE in force the NRA Chairman issues to the licensee a separate permit for each stage of the decommissioning of a nuclear facility. The DAAS ASUNE introduces issuing of a license for decommissioning. In this way the issuing of permits for decommissioning is eliminated and the dual permission regime is avoided. In addition, the responsibility of the licensee, concerning the safety of the facility is retained for the entire decommissioning period, which may last decades. The license for decommissioning shall have validity of 10 years. The new regime avoids the necessity that the entity decommissioning the facility to be the same as the one operating the nuclear facility.

The decommissioning includes dismantling of clean and contaminated equipment, demolishing of buildings and installations etc. During the implementation of the decommissioning activities at different stages, a vast amount of waste is generated, which have a various level of radioactive contamination. Not all of the waste present a risk for the population and the environment, that is why it is necessary to introduce a mechanism for its release from regulatory control ("clearance"). According to the DAAS ASUNE, the clearance will not follow a separate permission regime since each concrete "clearance" shall be approved by an order of a NRA Chairman. The requirements for clearance shall be established by Council of Ministers Regulation. The clearance is accomplished following clear and exact rules after performance of independent investigations and measurements. Introduction of this regime corresponds to the internationally accepted practices and the requirements of Directive 96/29 Euratom.

- **Specialised training**

DAAS ASUNE gives a legal possibility for qualification certificate amendment. This will ease the procedure for the renewal of the certificate and the financial burden of the concerned licensees.

- **Funds**

In accordance with the EU Commission Recommendation of 24 October 2006 on management of financial resources for decommissioning of nuclear facilities, spent fuel and radioactive waste (2006/851/EURATOM) by DAAS ASUNE some provisions on activities of a Nuclear Facilities Decommissioning Fund and a Radioactive Waste Fund are amended. Internationally accepted principle for licensee responsibility "contaminator pays" is introduced.

- **Cancellation of fees exemption**

According to ASUNE (in force) legal entities financed through the national budget do not pay fees under this Act. In fulfilling the equality principle between all entities, the legal entities financed through the national budget shall pay the required fees under the amended ASUNE.

5.2. OTHER ACTIVITIES PLANNED FOR THE NEXT YEARS

- Review, recast and consolidation of the Bulgarian Radiation Protection Legislation taking into account ICRP publication № 103 (2007), the new EURATOM Basic Safety Standards (EBSS) and the new the IAEA Basic Safety Standards (IBSS) which should be published in 2011;
- Upgrading of the regulatory control system (graded approach, harmonization of exemption and clearance concepts etc.) and improvement of the regulatory mechanisms for effective control on radioactive sources in compliance with the new IBSS and new EBSS;
- Establishment and Development of a National Long Term Strategy for safe management and strengthening control of the radioactive sources (including disused sources and orphan sources) based on the IAEA TECDOC 1388 and the EU legislation in this area;
- Development and fulfilment of the Action Plan for implementation of the National Long Term Strategy mentioned above;
- Upgrading of the National Register of Sources of Ionising Radiation (NRSIR);
- Implementation of the relevant suggestions for improvement of the national infrastructure based on the above mentioned Project BG 2006/018-411.01.03 and Project BG 2006/018-411.01.02, taking into account the good European practices;
- Development and application of guidances in the field of radiation protection and safe management of radioactive sources Category 1, 2 and 3.

CONCLUSION

Republic of Bulgaria adheres to the basic principles and requirements underlined in the IAEA Code of Conduct on the Safety and Security of Radioactive Sources. The regulating and the legislative system for control and management of the radioactive sources and provisions of their safety and security are in compliance with the IAEA recommendations. The National Regulatory Infrastructure is adequate.

Activities and measures are planned in order to improve and strengthen the control of radioactive sources and to enhance their safety and security.

Appendix I

The main regulations on occupational protection, public protection, medical exposure, radioactive waste and transport of radioactive material:

•**Regulation on the procedure of issuing licenses and permits for safe use of nuclear energy** (adopted 2004). This regulation covers all matters related to the procedures for issuing, changing, renewing, canceling, revoking and controlling the licenses and permits stipulated by the ASUNE and takes into consideration the types of facilities, activities and sites with sources of ionising radiation. The scope and contents of the required documents is specified taking into account the necessary measures for providing the nuclear safety, radiation protection and physical protection. For activities with certain types of ionizing radiation sources, based on the lower risk for the population and the environment, alleviation of the required documents is provided.

•**Regulation on the Basic Norms of Radiation Protection** projects the requirements for radiation protection contained in the key EU Directives in this field, namely Directive 96/29, Directive 97/43 and Directive 90/641.

•**Regulation on Radiation Protection During Activities with Sources of Ionising Radiation** is based on Directive 96/29 and Directive 122/2003. The legal framework in this field is the foundation on which the national regulatory infrastructure is developed for ensuring radiation protection of the population and protection of the environment against harmful effects of ionising radiation. Regulation covers the requirements and norms for occupational radiation protection (dose limits for external and internal exposure, individual monitoring, workplace monitoring, exposure to sources of natural radiation) and public radiation protection (dose limits for external and internal exposure, control of exposure to radon-222 and other natural sources, control of environmental radiation levels, control of discharges), as well as for registration of the results obtained.

•**Regulation on the conditions and procedure for establishing of zones with special status around nuclear facilities and sites with sources of ionising radiation** (adopted in 2004) sets requirements for the activities of licensees and holders of permits in the zones with special status, including provision of radiation monitoring of the environment and the population. The criteria for determining the size and boundaries of these zones, the procedure for creating the zones and for control of the competent state authorities are established.

•**Regulation on physical protection of nuclear facilities, nuclear material and radioactive substances insurance** (adopted in 2004) determines the requirements related to physical protection of nuclear facilities and during use, storage and transportation of nuclear materials and radioactive substances.

•**Regulation on emergency planning and emergency preparedness in case of nuclear and radiological emergencies** (adopted in 2004) defines the conditions and procedure for developing emergency plans and the obligations of the responsible persons who apply them. The actions and measures for limitation and liquidation of the consequences of nuclear or radiation accident are also defined as well as the criteria for decision making for their activation and the methods for informing the public. The regulation sets requirements for the maintenance and control of emergency preparedness and the interaction between the competent state authorities and the licensees or holders of permits.

• **Regulation on the terms and procedure for notification of the NRA about events in nuclear facilities and sites with sources of ionising radiation** (adopted in 2004) defines the obligations of the licensee or the holder of a permit for collecting, registration, investigation, analysis and evaluation of events and determination of corrective measures. The regulation sets requirements for use of the information about events, as well as the procedure and terms for providing information to the public for events of different level.

• **Regulation on safety of radioactive waste management** (adopted in 2004) defines the requirements and rules for safety during site selection, design, construction, commissioning and operation of facilities for radioactive waste management as well as the obligations of the entities carrying out radioactive waste management activities.

• **Regulation on the conditions and procedure for transfer of radioactive waste to the State enterprise “Radioactive waste”**

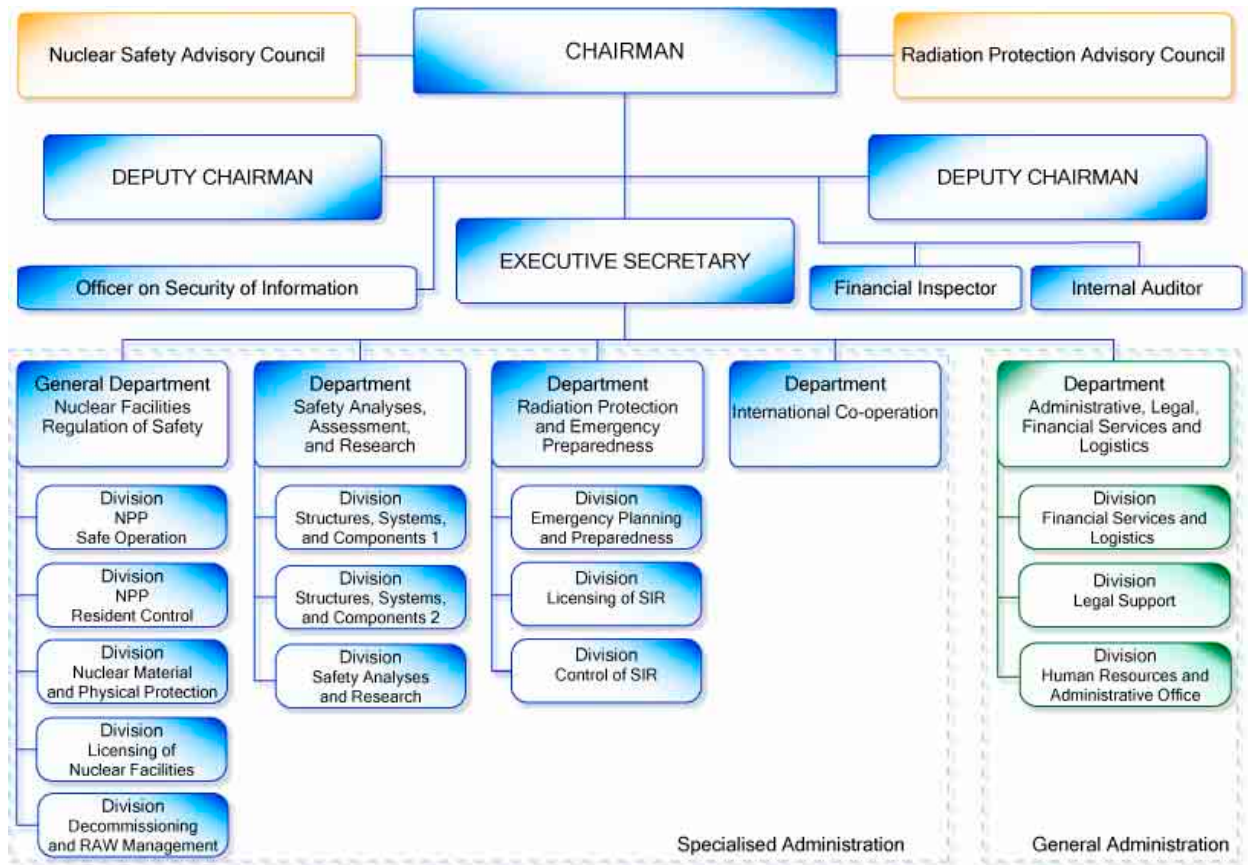
• **Regulation on safe transport of radioactive materials** (adopted in 2005) is based on IAEA Safety Requirements TS-R-1 (2003).

• **Regulation № 1 on radiation protection norms about rehabilitation of the territories affected by uranium mining and milling** (adopted in 1999.

• **Regulation on individual monitoring of occupational exposure during activities with sources of ionizing radiation** (adopted in 2006).

• **Guidance for prevention of incidents with radioactive scrap metal (2008)**

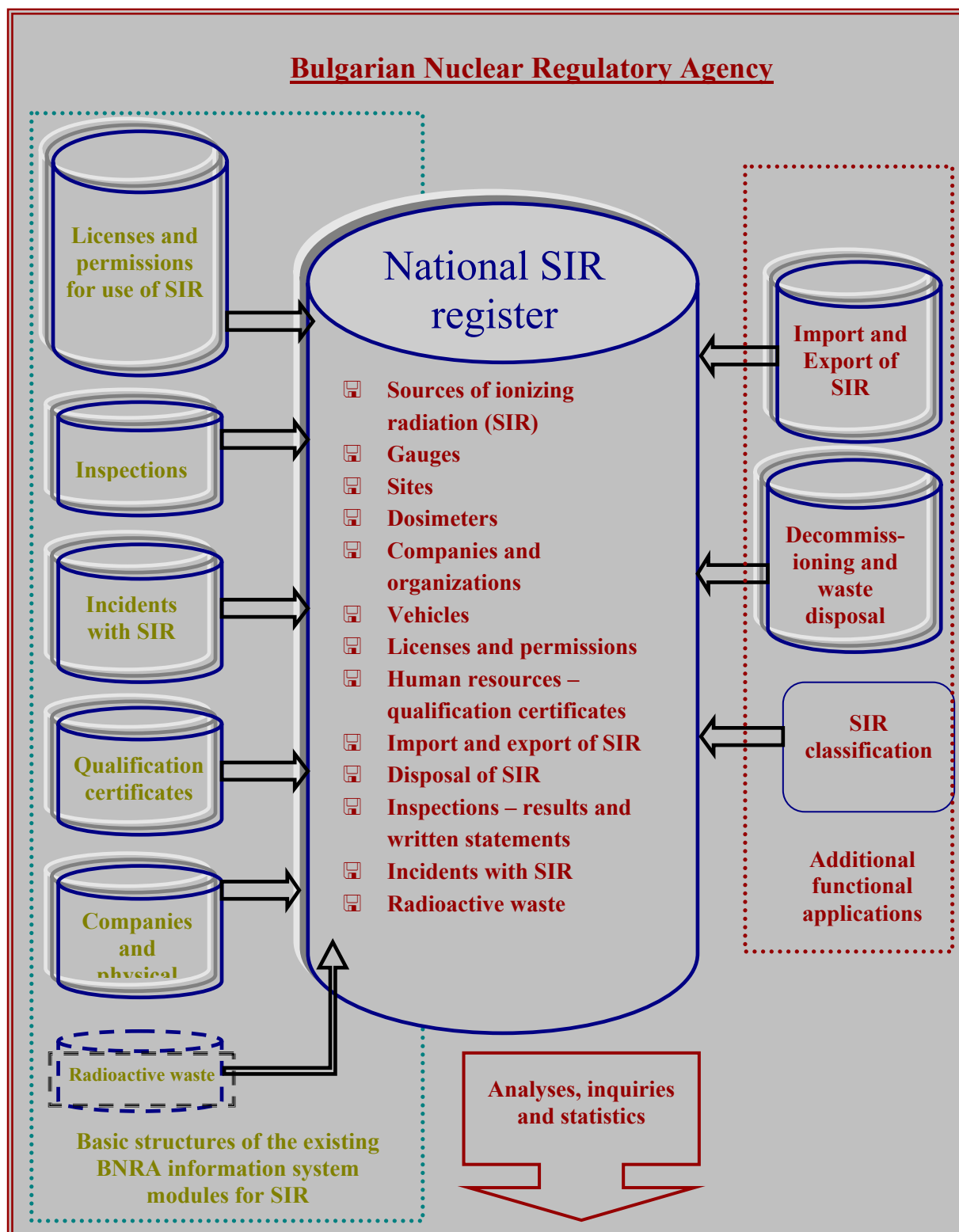
Appendix II



Appendix III

Main functions of specialised control bodies:

- **Ministry of Health** performs the specialised control of professional exposure and the exposure of the population, carries out medical surveillance of the personnel and monitoring of the workspace and its quality;
- **Ministry of Environment and Water** manages the National system for control of the environment and performs radio ecological control;
- **Ministry of Interior** manages the specialised control over the physical protection of nuclear facilities and facilities with SIR and storage of radioactive sources; DG Civil protection manages activities connected with emergency planning, emergency response and maintains emergency preparedness for protection of the population in case of radiological emergency, disasters and accidents;
- **Ministry of Agriculture and Food** manages the specialised control of the radioactivity content of the agricultural products;
- **State Agency for Metrology and Technical Control** manages activities connected with the metrological control of devices dedicated to measurement of ionising radiation.



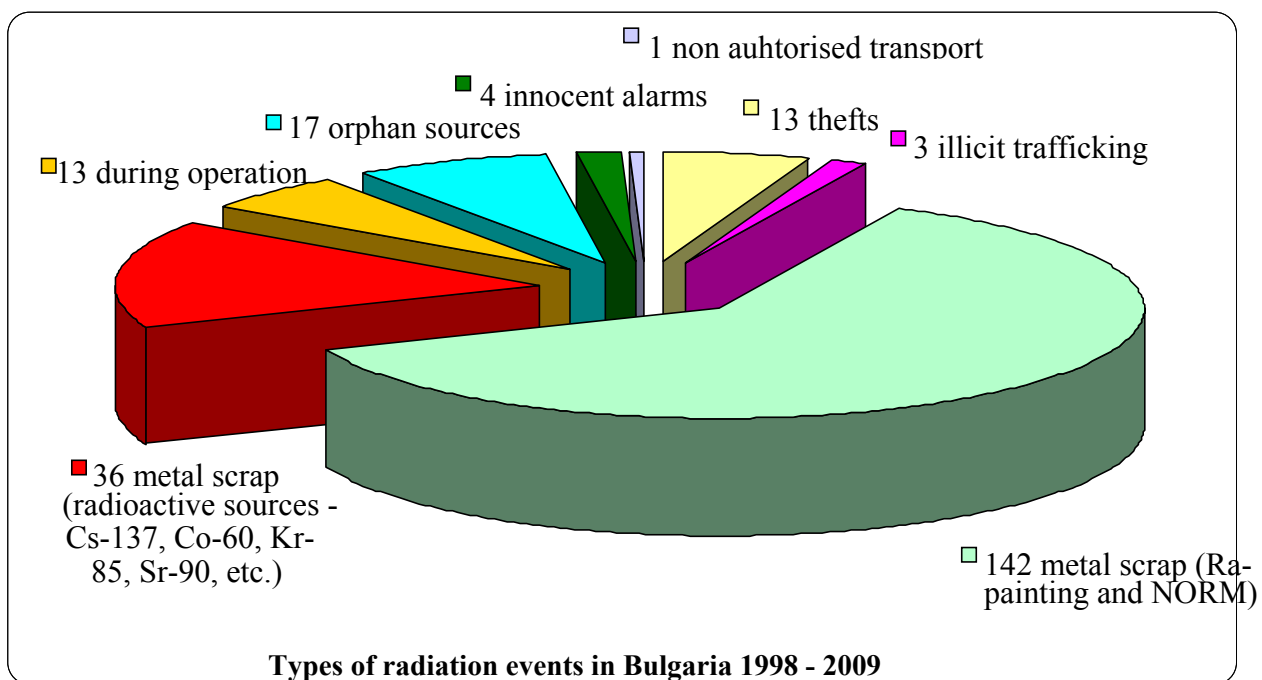


fig.1.

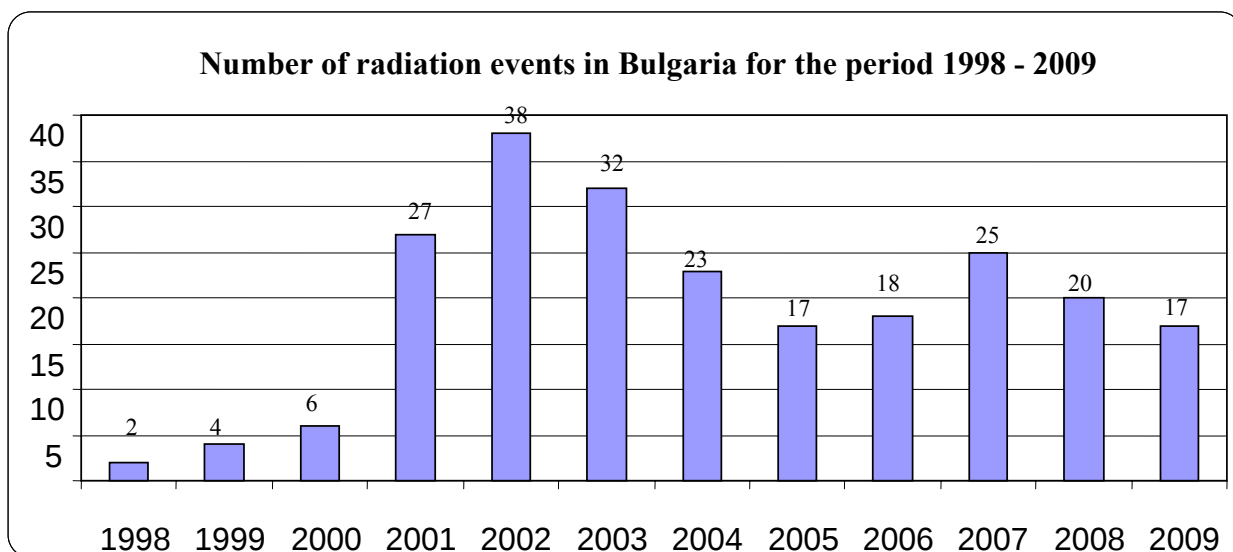


fig.2