

## **REGULATION ON RADIATION PROTECTION DURING ACTIVITIES WITH SOURCES OF IONISING RADIATION (SIR)**

(Promulgated in “State Gazette”, No. 74, August 24<sup>th</sup>, 2004, amended and supplemented SG No. 74/08.09.2006, effective 1.01.2007, amended SG No. 46/12.06.2007, amended SG No. 5/1.01.2010, amended SG No. 7/21.01.2011, *amended State Gazette № 76/5.10.2012*)

### **Chapter One.**

#### **Section I.**

##### **Subject**

Article 1. (Amended State Gazette № 76/2012) This Regulation shall establish the requirements and rules for radiation protection of personnel and population during activities with sources of ionising radiation (SIR), the terms and conditions of keeping records and control of sources of radiation, and the categorisation of radioactive sources and the relevant activities (practices) depending on radiation risk.

Article 2. (Amended State Gazette № 76/2012) The activities with SIR shall be carried out in compliance with the requirements of this Regulation, and abiding by the principles and provisions as laid down in the Act on the safe use of nuclear energy (ASUNE) and the Regulation on the Basic Norms of Radiation Protection.

#### **Section II.**

##### **General Provisions**

Article 3. Radiation protection during activities with sources of ionising radiation shall be provided by:

1. Justified selection of the area and site for location of a site with sources of ionising radiation;
2. High quality of the design and the construction of a site with sources of ionising radiation;

3. Justified choice of the technology and technological equipment for a site with sources of ionising radiation;
4. Justified choice of equipment for radiation control and means of radiation protection at the site with sources of ionising radiation, and programme for radiation control;
5. (Amended State Gazette № 76/2012) Establishment of areas on the territory of the facility with sources of ionising radiation and around it (differentiating of controlled and supervised areas, and area of preventive protection measures and monitored area around the site);
6. Technical requirements and conditions for safe operation of the technological systems and equipment at the site with sources of ionising radiation;
7. Rational organisation of the work processes and measures for radiation protection of the personnel and population under normal operating conditions of the site with sources of ionising radiation and in case of radiation accident, including decommissioning;
8. Availability of qualified and licensed (certified) personnel at the site with sources of ionising radiation;
9. Physical protection and fire protection and emergency preparedness at the site with sources of ionising radiation;
10. Availability of procedures and authorised personnel for accounting and control of the sources of ionising radiation;

Article 4. The organisational and technical measures for radiation protection of the personnel shall include:

1. Assessment of the nature and degree of the radiation risk in the design documentation;
2. Determination of control levels within the ranges of the radiation limits, established by the currently valid norms of radiation protection;
3. Classification of workplaces in the different areas of the site with sources of ionising radiation;
4. Specialised training, instructions and control of the observation of the rules for safe work with sources of ionising radiation;
5. Use of protective barriers against the spread of radioactive substances, protective screens, devices for remote manipulation of sources of ionising radiation, as well as limiting the

time of work with sources of ionising radiation and optimisation of the distance to the sources of ionising radiation, while working;

6. Creating safe conditions for work with sources of ionising radiation in compliance with the Regulation and the current norms of radiation protection, and creation of safety culture;
7. Use of means for personal radiation protection;
8. Organisation of radiation technological and dosimetric control at the site;
9. Information about the radiation situation and the exposure from the sources of ionising radiation at the facility;
10. Measures for protection in cases of specially allowed increased exposure;
11. Use of safety factors in the design of the protection against external and internal exposure;
12. Application of controlled restrictive access of persons to work with sources of ionising radiation;
13. (New provision- State Gazette № 74/ 2006) leak tightness control of high activity sources;
14. (New provision- State Gazette № 74/ 2006) identification and designation of the radioactive sources and their containers.

Article 5. The status of the radiation protection at sites with sources of ionising radiation shall be evaluated on the basis of:

1. Analysis of the doses from external and internal exposure of the personnel, groups of the population and the whole population, received as a result of the effect of all kinds of sources of ionising radiation;
2. Analysis of the number of persons, who have received exposure beyond the limits, established by the valid norms for radiation protection;
3. Analysis of the radioactive contamination of the environment;
4. Analysis of the measures for radiation protection and the observation of the norms and regulations of radiation protection;
5. Analysis of probabilities for radiation accidents and their scale, of accidents and the implementation of the undertaken protective measures;
6. Analysis of the preparedness for cases of radiation accidents and for liquidating of their consequences.

Article 6. (Amended State Gazette № 76/2012) The technical means, which are used for radiation control at the sites with SIR shall be metrologically assured according to the Act on Measurements.

Article 6a. (New provision- State Gazette № 74/ 2006) (1) The manufacturer of high activity sources identifies each source with unique number, engraved or placed in other permanent way on the source itself when this is possible. When high activity sources are imported, the supplier shall guarantee that the imported by him sources are identified by the manufacturer with unique number.

(2) The identification number of the source is engraved or placed in other permanent way and on the container itself, in which the source is placed. When it is not possible or a container for multiple transport is used, the container is marked by a label, containing instructions about the type, the radionuclide content and the activity of the sources.

(3) The manufacturer provides a photograph of each model of source and each model of container, used by him for placing sources.

(4) Each high activity source shall be accompanied by documentation, which contains the identification number of the source, the way and place of the designation, photos of the model of source and the model of container, the activity and the radionuclide content of the source, design and other data, important for the safe use of the source.

Article 7. (1) (former text of art. 7 - State Gazette № 74/ 2006, effective 01.01.2007, amended State Gazette № 76/2012) Each natural or legal person who carries out activities with SIR is obliged to ensure:

1. Adherence to the requirements of the regulation and all the other legislative acts related to radiation protection;
2. Adherence to the terms and conditions of the issued licenses and/ or permits and the requirements, stipulated with the Regulation, by implementing instructions and other internal documents, concerning the radiation protection at activities with SIR;
3. (Amended State Gazette № 76/2012) Control of the radiation environment in workplaces, in the premises, in the area of the site with SIR, in the area of preventive protective

measures and in the monitored area, including control over the radioactive releases (liquid or aerosol) in the environment and informing the personnel;

4. (amended State Gazette № 76/2012) Control of the individual dose from external and/ or internal exposure of the personnel and informing the persons for received doses against signature;
5. Specialized training and certified employees, including carrying out initial, current and periodic instructions and inspections of the radiation protection knowledge of the personnel and its skills to perform the assigned tasks.
6. Compulsory preliminary and periodic medical examinations of the personnel which have activities with SIR;
7. (amended - State Gazette № 74/ 2006) the notification of Nuclear regulatory agency and the other competent authorities of the executive power in case of an event in an area with SIR (deviations from the normal exploitation, incident, accident).
8. (New provision- State Gazette № 76/2012) technical support of the systems and equipment providing radiation protection.

(2) (New provision- State Gazette № 74/ 2006) In case of delivery or a transaction with radioactive SIRs, the licensee or the holder of permit is obliged to ensure that the person who obtains them holds the relevant license or permit in accordance with ASUNE. Within 7 days the licensee or the holder of permit informs the Nuclear Regulatory Agency about the completed activities and provides the data about the recipient, including the identification numbers of the issued license or permit of the recipient.

Article 8. Each person of the personnel, who works with sources of ionising radiation shall be obliged to:

1. Observe the requirements of radiation protection, established in the Regulation, in the internal instructions and other documents, related to radiation protection;
2. Use means for individual protection in cases, when it is needed, and a personal dose meter in compliance with the active (valid) norms of radiation protection;
3. Obey the requirements for prevention of radiation accident and the rules for action in case of such accident;
4. Pass compulsory periodical medical examinations and follow the directives of the competent medical persons;

5. Notify the officials, responsible for the radiation protection at the site, about defects or failures of facilities and equipment, which create radiation danger for the personnel;
6. Follow the directives for radiation protection from the persons, responsible for the radiation protection at the site;
7. (repealed – State Gazette № 76/2012)

## **Chapter Two.**

### **REQUIREMENTS FOR PROVISION OF RADIATION PROTECTION FOR LOCATION OF A SITE WITH SOURCES OF IONISING RADIATION IN A SELECTED LOCATION**

Article 9. The activity related to location of a site with sources of ionising radiation at a particular location shall include site selection and preparation of the corresponding territorial diagram and plan within the meaning of the Territorial Development Act.

Article 10. (1) In the process of selection of the location of the site with sources with ionising radiation, which, in the case of radiation accident, may cause radiation impact on the population and the environment and the application of protective measures, the meteorological, hydrological, geological and seismic characteristics of the site shall be evaluated. Sites in regions with scarce population shall be the preferred, which, with their topographic, climate and hydrological and geological features, restrict in a natural way the possibility for spreading of radioactive substances across the boundaries of the site with sources of ionising radiation.

(2) Sites with sources of ionising radiation, which, in case of radiation accident, may cause radiation influence on the population and the environment and the application of protective measures, shall be located predominantly on the leeward side with respect to living areas and medical, resort and sports facilities, schools and kindergartens; taking into account the wind rose of the vicinity of the selected construction site.

Article 11. The development diagram and plan of a site with sources of ionising radiation shall be designed in compliance with the Territorial Development Act, taking into account the

prediction of the radiation situation at the site and around it and the possibility of occurrence of radiation accident.

Article 12. (1) It shall be forbidden to locate site with sources of ionising radiation in residential buildings or childcare institutions (schools and kindergartens).

(2) (Amended – State Gazette № 76/2012) The ban under para (1) may not be applied when using dental X-rays devices.

### **Chapter Three.**

#### **REQUIREMENTS FOR PROVISION OF RADIATION PROTECTION DURING THE CONSTRUCTION, INSTALLATION AND PRELIMINARY TESTS OF A SITE WITH SOURCES OF IONISING RADIATION**

Article 13. (1) The construction of site with sources of ionising radiation (including reconstruction), installation and preliminary tests shall be carried out on the basis of a technical project and measures for provision of radiation protection.

(2) The construction of a new site with sources of ionising radiation or the reconstruction of an existing one shall be done after an analysis and assessment of the nature and probability of any possible exposure and the expected doses as a result of the activities with sources of ionising radiation as planned.

Article 14. (1) The design documentation of a site with sources of ionising radiation shall contain justification of the measures for radiation protection during the construction or reconstruction, in operation and on decommissioning, including the case of radiation accident at the site.

(2) The documentation pursuant to paragraph (1) shall contain as an inseparable part “Analysis and assessment of the radiation protection”, which shall include:

1. Detailed technical description and characteristic of the site with sources of ionising radiation, accompanied by drawings, diagrams and other evidence important for the radiation protection;
2. Description and characteristics of the site;

3. Analysis and assessment of all sources of ionising radiation and possible ways of radiation impact on the personnel and the population; respectively the expected doses from internal and external exposure under normal operating conditions and in case of radiation accidents;
4. Description, analysis and assessment of the technical and organisational means for ensuring radiation protection of the personnel and population under normal conditions and in case of radiation accidents at a site with sources of ionising radiation, including the methods, technical equipment and the volume of radiation control, the layout of the rooms, technological equipment and the test and measurement equipment at the site, as well as the division into areas of the territory in and around the site with sources of ionising radiation

Article 15. The project documentation of a site with sources of ionising radiation shall include for every room, sector or territory the following:

1. In the case of operation with unsealed sources of ionising radiation: description of the type and nature of the planned activities, type, individual and total activity, physical condition, chemical form, maximal activity at the workplace, and yearly consumption of the radionuclides used, generated radioactive waste and the method of its storage, other specific characteristics and conditions, related to the radiation protection;
2. In the case of operation with sealed sources of ionising radiation: description of the type and nature of the planned work, the radionuclides used by type, individual and total activity, permissible activity at the workplace, design parameters and other specific characteristics and conditions, related to radiation protection;
3. In the case of operation with generators of ionising radiation: description of the type and nature of the planned work, type of equipment, brand, maximum anode voltage, maximum anode current, power, technical description and other limiting conditions and specific characteristics, related to radiation protection, including the maximum number of devices working together the same room (sector, territory);
4. In the case of operation of accelerators, generators of radionuclides and other sources of ionising radiation with complex radiation characteristic: description of the type and nature of the planned work, type, brand, radiation properties and characteristics of the sources of

ionising radiation used, dimensions, generated radioactive waste and the method of its storage, other specific characteristics and conditions, related to radiation protection;

Article 16. (1) In the design of protection from external exposure the design the equivalent dose rate on the surface of the protection shall be calculated by the following formula:

$$H = D/(k.h)$$

Where:

D is the yearly limit of the dose for the personnel or the population according to the valid norms of radiation protection (mSv);

k – safety coefficient;

h – duration of exposure (hours per annum).

(2) In the design of protection from external exposure the safety coefficient for the population shall be minimum 5, and for the personnel in sites with sources of ionising radiation – minimum 2,5.

(3) In the design of protection from external exposure the presence of other sources of ionising radiation at the site and the perspective of installation of new sources of ionising radiation shall be also accounted for, as well as the purpose of the respective rooms in the sites with sources of ionising radiation, the category of the exposed persons and the duration of exposure.

Article 17. (Amended – State Gazette № 76/2012) For the purpose of the design of protection against external exposure with normal duration of stay in the rooms and the adjacent territory, limits for the equivalent dose rate for the personnel and the population shall be used, which shall be obtained by the formula of Article 16, paragraph (1), taking into account the provisions of Article 16, paragraph (2) and (3):

Persons	Function of the rooms and territory	Duration of exposure (hours per annum)	Limits for the equivalent dose rate for design purposes
Personnel	Rooms with permanent presence of personnel of category A at site with sources of ionising radiation	1700 h	5 $\mu$ Sv/h
	Rooms with temporary presence of personnel of category A at site with sources of ionising radiation	850 h	10 $\mu$ Sv/h
	Rooms at site with sources of ionising radiation, where personnel of category B is staying.	2000 h	1 $\mu$ Sv/h
Population	All other rooms and territories of the country	8800 h	0,025 $\mu$ Sv/h

(\* ) The natural gamma background shall not be taken into account.

The table illustrates the equivalent dose rates from technogenic sources of ionising radiation. The conversion from the measurable equivalent dose to the effective dose shall be done using methodology, which is co-ordinated with the Ministry of Health.

Article 18. (1) (Amended – State Gazette № 76/2012) The design of site with sources of ionising radiation and the selection of technological schemes and equipment for operation with sources of ionising radiation shall ensure:

1. Compliance with the limits for the doses of external and internal exposure and optimisation of the radiation protection;

2. Minimum quantity of the generated radioactive waste and use of reliable and simple methods for its storage;
3. Minimum release of radioactive substances in the environment;
4. Automation of the technological operations with sources of ionising radiation;
5. Signalling by sound and light alerts in case of deviations from the normal operating mode; automatic locks and safeguards for prevention of the occurrence of a radiation accident at the site;
6. Automatic and visual monitoring of the course of the technological processes at the site with respect to the nature of the performed activities;
7. Conditions for fire-fighting and rescue activities in accordance with the special normative requirements for fire and accident safety.
8. (New provision – State Gazette № 76/2012) In case of design of sites with sealed and unsealed SIR the appropriate requirements for radiation protection shall be observed as per Chapter VI and Chapter VII.
9. (New provision – State Gazette № 76/2012) In case of design of facilities with SIR used for medical purposes the appropriate requirements for radiation protection set in the secondary legislation related to the Health Act shall be observed.
10. (New provision – State Gazette № 76/2012) In case of design of storage facilities for SIR the appropriate provisions of Chapter IV shall be observed.

Article 19. The design projects of site with sources of ionising radiation shall envisage organisational, technical and sanitary-hygienic measures for ensuring of radiation protection of the personnel and the population in the course of repair works.

Article 20. (1) (Amended – State Gazette № 76/2012) The activities related to installation of equipment and/or preliminary tests of sources of ionising radiation shall be carried out:

1. By persons possessing a license or permit from the Nuclear Regulatory Agency for performing such activities;
2. With proper equipment and means of measurement, required by the corresponding activity;
3. Observing the programmes and procedures for ensuring radiation protection and the quality of work.

(2) (New provision – State Gazette № 76/2012) Upon carrying out the activities set up in para (1), in the Nuclear Regulatory Agency shall be presented the reports for these activities and the results on the preliminary tests.

#### **Chapter Four.**

### **RADIATION PROTECTION REQUIREMENTS FOR THE STORAGE OF RADIOACTIVE SUBSTANCES**

Article 21. (1) The storage rooms, specially equipped for storage of radioactive substances shall be located, as a rule, on the lowest floors of the buildings at the site (basement, first floor) or in isolated parts of the buildings.

(2) Appropriate temperature shall be maintained in storage rooms for radioactive substances, so that the possibility of damage or harm to the stored sources and their packages due to overheating or freezing shall be eliminated.

(3) The equipment of the storage rooms unsealed sources of ionising radiation shall meet the requirements for operating rooms of the corresponding class but not lower than second class.

Article 22. (1) The equipment for storage of radioactive substances (niches, wells, safes) shall be of designed in such way that, when placing or removing radioactive sources, the personnel shall not be exposed to exposure by the rest of the sources in the storage facility.

(2) The doors of the separate sections of the storage facility and the containers with radioactive substances shall be designed for easy opening and with durable signs of the type of radionuclide and its activity.

(3) (Amended – State Gazette № 76/2012) The person responsible for the sources of ionising radiation at the site shall be obliged to have a scheme of the location of the sources of ionising radiation in the storage facility, including a list of SIR in every storage facility.

(4) Glass vessels, containing radioactive liquids, shall be placed in metal or plastic vessels of such volume that they shall hold all stored liquid in case the integrity of the primary container is damaged.

Article 23. Radioactive substances, which, during their storage may release radioactive gases, vapours or aerosols, shall be stored in special closed cabinets, boxes and chambers with

purifying filters, made of fire-proof materials, and the generated gases shall be lead off to an exhaust ventilation system.

Article 24. Moving of radioactive sources in rooms, buildings and around the territory of the site shall be done with the use of containers and other specialised equipment for manipulating and moving, with regard to the requirements and regulations for radiation protection, and taking into account their physical state, activity, type and intensity of the ionising radiation, the dimensions and the weight of the packaging enclosures.

Article 25. (1) The persons, who store radioactive sources, shall be obliged to ensure their physical protection, so that the possibility of losing, stealing or uncontrolled use of these sources shall be eliminated.

(2) The persons, who store radioactive sources, shall be obliged to ensure fire and accident safety of the storage facility.

Article 26. Radioactive sources, which are not in use, shall be stored in specially selected sites or storage facilities, which are equipped and designed in such a way, that the possibility of uncontrolled access by unauthorised persons is eliminated and safety storage is provided for. The activity of the stored sources is not allowed to exceed the limit values, indicated in the corresponding permit or license of the Nuclear Regulatory Agency.

Article 27. (1) (Amended – State Gazette № 76/2012) Storage of radioactive sources in temporary storage facilities outside the territory of the facility, including gamma radiography devices, logging device, humidity meters and densimeters, etc. which are used in the field shall be admitted to operation after: Co-ordination with the Ministry of Interior (MI); and receipt of permit from the Nuclear Regulatory Agency (NRA).

(2) The dose rate on the external surfaces of a temporary storage facility for radioactive sources or on its fence shall not exceed 1  $\mu\text{Gy/h}$ .

## **Chapter Five.**

### **REQUIREMENTS FOR ENSURING OF RADIATION PROTECTION USING SOURCES OF IONISING RADIATION**

Article 28. (1) Activities with sources of ionising radiation shall be permitted only in rooms specified for the purpose, in the controlled area of the site with sources of ionising radiation, which have been listed in the corresponding licenses and/or permits, issued by the Nuclear Regulatory Agency. Activities, which are not directly related to the application and servicing of the corresponding sources of ionising radiation, shall not be allowed in these rooms.

(2) The controlled area at site with sources of ionising radiation shall be designated in an adequate way, depending on the specifics of the corresponding site, and signs of radiation danger and of the function of the room shall be placed on the doors of the rooms with sources of ionising radiation.

(3) (New provision, State Gazette № 76/2012) The controlled and supervised areas in the site will be set up in accordance with the requirements of the Regulation on basic norms for radiation protection.

Article 28a. (New provision, State Gazette № 76/2012) In case of activities with SIR for medical purposes the specific requirements for radiation protection set up in the relevant secondary legislation of the Health Act.

Article 29. (1) (amended - State Gazette № 74/ 2006) The equipment, the containers, the packages, the apparatus, maintenance and replacement devices which are meant for activities with SIR and/ or contain high activity sources and where it is possible – the source itself, are compulsory marked with a sign for radiation hazard or in other appropriate way of warning.

(2) The type and the design of a standard sign indicating a radiation hazard are shown in annex № 1.

Article 30. (Amended, State Gazette № 76/2012) (1) When operating sources of ionising radiation, the persons – holders of license for use of sources of ionising radiation, shall be obliged to create, maintain and update the following documents, which are directly related with the provision of radiation protection at the respective site:

1. Instructions for safe operation of the sources of ionising radiation, including technical maintenance and repair of the facilities and equipment at the site;
2. Instructions for radiation protection of the site according to Annex 9;
3. Internal emergency plan for the site, including measures for fire and accident protection according to Annex 10;
4. Internal rules of procedure that includes:
  - a) The work organisation with SIR and the control over the access to the facility;
  - b) Responsibilities of the responsible persons as per item 6 and responsibilities of the personnel engaged in operations with SIR;
  - c) Internal regulations and/or procedures for delivery, storage, handling and accounting of SIRs at the facility;
  - d) Internal rules and procedures for collection, sorting, processing, handing over, storage and accounting of the generated radioactive waste at the facility;
  - e) Internal regulations and procedures for the way of admission to independent work with sources of ionising radiation, conduction of initial, routine, current and periodical instructions and assessment of the knowledge and skills of the personnel on radiation protection;
5. Monitoring programme of the radiation characteristics of the working environment and for individual monitoring;
6. Internal document issued by the Head of the site, appointing the personnel engaged in operations with SIR at the site and the persons responsible for radiation protection (Head of the site, radiation protection officer, person responsible for radiation monitoring, person responsible for accounting and control of the SIR and person responsible for notification in case of incidents and accidents).
7. Rules for authorisation and provision of radiation protection of outside teams summoned for the elimination and limitation of the consequences of an accident that has occurred at the facility.
  - (2) The number of the persons under para. 1, item 6 shall be set up by the relevant licensee or permit holder according to the specifics and complexity of the facility with SIR. It is

permissible to assign the functions of radiation protection officer, person responsible for accounting and control of the SIR and person responsible for notification in case of incidents and accidents to one person."

Article 31. (1) Members of the personnel at site with sources of ionising radiation, who are involved directly with handling and work with sources of ionising radiation shall meet the following requirements:

1. Over 18 years of age;
2. Passed the compulsory initial and/or periodic medical examinations and possess a positive medical statement for work with sources of ionising radiation;
3. Have obtained personal certificates issued by a person holding a license from the Nuclear Regulatory Agency for giving specialised training for activities with sources of ionising radiation.

(2) Instructions and tests of the knowledge on radiation protection of the personnel at site with sources of ionising radiation shall be carried out periodically with repetition rate and following the procedure established by the person – holder of license or permit for activities with sources of ionising radiation.

(3) In case of change of the conditions and nature of the operation with sources of ionising radiation at a given site additional training sessions for the personnel shall be held.

Article 32. When working with sources of ionising radiation, no operations, which are not envisaged by the internal regulations, rules and other documents shall be performed at the site with sources of ionising radiation. Exception from this rule is permitted only in case of radiation accidents, when actions are performed for prevention of the development of the accident or for life saving and life-protection measures in accordance with the internal emergency plan.

Article 33. (Amended, State Gazette № 76/2012) Each member of the personnel of site with sources of ionising radiation on encounter of deviations or infringements of the provisions and regulations for radiation protection shall be obliged to perform the required actions for their elimination and notify the respective authorised members of the staff at the site.

Article 34. Each member of the personnel at site with sources of ionising radiation shall be responsible for his own safety by observing the strictly established requirements and rules for radiation protection.

## **Chapter Six.**

### **ADDITIONAL REQUIREMENTS FOR PROVIDING RADIATION PROTECTION IN APPLICATIONS OF SEALED SOURCES OF IONISING RADIATION AND GENERATORS OF IONISING RADIATION**

Article 35. (1) (Amended, State Gazette № 76/2012) Sealed sources of ionising radiation and generators of ionising radiation shall be used in accordance with this Regulation, the technical documentation of the manufacturer of these sources of ionising radiation, the active (valid) standards, and other specific normative requirements to them, and the provisions of the licenses issued in compliance with Act on the Safe Use of Nuclear Energy.

(2) (New provision, State Gazette № 76/2012) The sealed SIR depending on the risk related to their application are classified in five categories according to Annex 7.

Article 36. The equipment, where sealed sources of ionising radiation are placed, shall be mechanically robust and capable of withstanding thermal, chemical and other types of impacts; they shall correspond to the type of sources, to the method and conditions of their usage and shall be designated with the sign of radiation danger.

Article 37. In idle state the sealed sources of ionising radiation shall be kept in protective devices and the generators of ionising radiation shall be switched off (disconnected from the power supply).

Article 38. (1) Special accessories and tools and devices for remote manipulation shall be used for taking sealed sources out of their containers. Touching by hand of sealed sources of ionising radiation, regardless of their type or activity is forbidden.

(2) Manipulators and protective screens shall be used when working with sources of ionising radiation taken out of their containers.

(3) If the dose rate exceeds 2 mGy/h at a distance of one meter from the source, the work shall be carried out with the application of special protective devices (boxes, cabinets, chambers) with remote control.

Article 39. (1) The dose rate from mobile and fixed radiography devices, equipment for therapy, and other devices, operating by using sealed sources, shall not exceed 20  $\mu\text{Gy/h}$  at a distance of one meter from the surface of the protection module with the source. In the case of equipment with sealed sources of ionising radiation, which are used for technological control in industrial enterprises, the dose rate in every accessible point of the surface of the protection module with the source shall not exceed 100  $\mu\text{Gy/h}$ , and at a distance of one meter from its surface – 3  $\mu\text{Gy/h}$  (for neutron sources – 100  $\mu\text{Sv/h}$  and 3  $\mu\text{Sv/h}$  respectively).

(2) The dose rate of devices, the operation of which is accompanied by X-ray radiation, shall not exceed 1,0  $\mu\text{Gy/h}$  at a distance of 0,1 meter from their external surface.

(3) The dose rate for mobile and fixed radiography devices and equipment for therapy is allowed to be greater than 20  $\mu\text{Gy/h}$  at a distance of one meter from the surface of the protection module with sealed source of ionising radiation, if it is known in advance, that the working time of the personnel with such equipment is less than the standard one. In this case the permissible the dose rate shall be determined by the formula introduced in Article 16.

Article 40. (1) The working part (the irradiation module) of fixed devices and equipment possessing unrestricted towards its direction, beam of ionising radiation shall be located in a separate room, a separate building or a separate section of a building. The materials and the thickness of the walls, floor and ceiling of these rooms and buildings shall provide for attenuation of the primary and the dispersed ionising radiation in the adjacent rooms and on the territory of the site to the established limits in compliance with the current norms of radiation protection, taking into account all possible real positions of the source and the direction of the beam.

(2) The control consoles of fixed devices and equipment and equipment with unrestricted towards its direction, beam of ionising radiation shall be located in a control room separated

from the sources of ionising radiation. An open door to the corresponding room shall lead to automatic prevention of the positioning of the radioactive source in working position or switching on of the accelerating voltage of a generator of ionising radiation, with the purpose of eliminating the possibility of accidental exposure of members of the personnel or visitors from the outside.

Article 41. (1) The rooms, where the fixed equipment and devices with sealed sources of ionising radiation are located, shall be equipped with an automated system for display, signalling and blocking of the position and movement of the radioactive source (the irradiation module) and an automatic system for alarm alerting in the case of increasing of the dose rate above the permissible level. Equipment for forced remote return of the radioactive source in its storage position shall be provided for the case of accidental switch of the electric power supply of the equipment or if another type of accident occurs at the site, including fire, earthquake, flood or other disaster.

(2) In the case of underwater storage of the sealed sources of ionising radiation at the site, systems for automatic control of the water level in the pool shall be provided as well as alarm systems for changes of the water level and increase of the dose rate in the working room and the control room.

Article 42. (1) No special provisions shall be complied with for the location of rooms with equipment or devices with sealed sources of ionising radiation, when the dose rate does not exceed  $1,0 \mu\text{Gy/h}$  at a distance of one meter from the accessible parts of the surface of the equipment in working position and in case of storing of the sources in protective facilities in non-operational position.

(2) When the dose rate is greater than  $1,0 \mu\text{Gy/h}$  at a distance of one meter from the accessible parts of their surface, the fixed equipment and devices shall be placed in rooms, located in a separate building or in a separate section of the building.

Article 43. (1) The operation of sealed sources of ionising radiation shall not pose special requirements to the layout of the rooms, where they are placed. The norms and standards for

construction, fire protection and hygiene, as well as other norms and standards related to manufacturing rooms in regular businesses shall be applied.

(2) The rooms, where disassembly, recharge, repair and temporary storage, as well as other specific activities, concerning the maintenance and control of sealed sources of ionising radiation, shall be equipped in accordance with the requirements for the operation of unsealed sources of ionising radiation of III class (please refer to Chapter seven).

(3) (Amended. - State Gazette № 76/2012) When using generators of ionising radiation in the facilities, a general air-exchange ventilation system shall be foreseen.

Article 44 The application of irradiation facilities with high-activity sealed sources of ionising radiation at the site, that can lead to accumulation of toxic substances above the permissible concentrations, in the air of the working rooms, shall pose the requirement of provisioning of a forced-exhaust ventilation system.

Article 45. When devices and equipment with sealed sources of ionising radiation or generators of ionising radiation are used, in case of need, in common manufacturing rooms of a given site or in the field (outside the rooms), the following requirements shall be observed:

1. The direct beam of the ionising radiation shall be pointed to the ground, if possible, or in a direction without people on its way;
2. The operated SIR shall be placed at the farthest possible distance from the service personnel or other persons present;
3. The access and stay of people from the outside in the vicinity of the sources of ionising radiation, which are used, shall be prevented, and measures for the temporary storage and physical protection of these sources of ionising radiation shall be undertaken;
4. If needed, protection screens and movable barriers shall be provided and used for reducing of the exposure;
5. Signs for radiation danger and alerting signs: “Attention! Radiation!”, visible from a distance of minimum 3 meters shall be positioned around the sources of ionising radiation;
6. The time of stay of persons close to the respective sources of ionising radiation shall be reduced to a minimum.

Article 45a. (amended - State Gazette № 74/ 2006) (1) Each licensee or holder of permit provides control on the condition of the used and stored sealed high activity sources through periodic leak tests. The chairman of the NRA assigns the frequency of the leak test of the high activity sealed sources.

(2) Apart from the cases mentioned in article 1, leak tests should be carried out in accordance with mandatory directives, issued by an inspector of the NRA .

(3) After the expiry of the term for safety operation of a high activity source stipulated in the manufacturer's documentation, its leak tightness is inspected at least once a year if it is used. A commission, appointed by the chairman, evaluates the leak tightness results. The assessment contains a conclusion about the further safe use of the source.

## **Chapter Seven.**

### **ADDITIONAL REQUIREMENTS FOR PROVISIONING OF RADIATION PROTECTION WHEN USING UNSEALED SOURCES OF IONISING RADIATION**

#### **Section I.**

##### **Requirements to the Radiation Protection in the Controlled Area**

Article 46. (1) The radionuclides, as potential sources of internal exposure, shall be divided into four groups, depending on the degree of radiation hazard (radio toxicity) for the personnel and population:

1. Radionuclides with very high toxicity (first group);
2. Radionuclides with high toxicity (second group);
3. Radionuclides with medium toxicity (third group);
4. Radionuclides with low toxicity (fourth group);

(2) The distribution of radionuclides into groups depending on their radio toxicity is presented in annex No. 2. The short-lived radionuclides with half-life less than 24 hours shall be included in the fourth group (radionuclides with low toxicity) and they are not described in this annex.

Article 47. (1) Depending on the group of radio toxicity, which the used radionuclide belongs to, and on its maximum permissible activity at the working place, the types of work with

sealed sources of ionising radiation shall be divided into three classes – I, II, and III, as laid down in annex No. 3.

(2) The requirements to the layout and equipment of the rooms, where work with unsealed sources of ionising radiation is carried out shall be defined depending on the class of this work (I, II, or III class).

Article 48. At site, where work with sealed sources of ionising radiation is carried out, the rooms for activities of a given class shall be located at one place, in one section of a particular building or in a standalone building at the site. When work of the three classes I, II, and III is carried out, the rooms shall be divided depending on the class of the performed activities.

Article 49. (1) The rooms for activities of class I with sealed sources of ionising radiation shall be located in a separate building or an isolated section of a given building with a separate entrance and access through a sanitary checkpoint. The rooms shall be equipped with chambers, boxes, and other hermetic devices.

(2) The rooms for activities of class I with sealed sources of ionising radiation shall be split, as a rule, into three areas:

1. First area (1<sup>st</sup> area) – not-attended rooms, where the technological equipment and communications shall be placed, which constitute the basic sources of ionising radiation and of radioactive contamination (chambers, boxes, etc.);
2. Second area (2<sup>nd</sup> area) – rooms which are served periodically, intended for repair of equipment and other work, related to disassembly of technological equipment, loading and unloading of radioactive materials, temporary storage of raw materials and materials, finished products, and radioactive waste;
3. Third area (3<sup>rd</sup> area) – rooms for permanent presence of the personnel in working hours (control consoles of technological processes and other workplaces).

(3) For the purpose of prevention of spread of radioactive substances, sanitary locks between the three areas – 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup> (between the not-attended and periodically serviced rooms, as well as between the periodically serviced rooms and the rooms for continuous human presence).

(4) For activities of class I with unsealed sources of ionising radiation, depending on the purpose and specifics of the site and on the type of the protective barriers used, two-zone layout of the rooms shall be acceptable, i.e. the working rooms at the site shall be divided into two areas only.

Article 50. (1) The rooms for activities of class II with unsealed sources of ionising radiation shall be located in a separate building of the corresponding site. Rooms for continuous and temporary presence of personnel shall be provided by the room layout plans. The rooms for activities with unsealed sources of ionising radiation of class II shall be equipped with a sanitary checkpoint or bathroom with a shower, and dosimetric monitoring at the exit.

(2) The rooms for activities of class II with unsealed sources of ionising radiation shall be equipped with cabinets, chimney-pieces or boxes and shall be ventilated by forced-exhaust ventilation systems. Operations with powder, evaporation of solutions, manipulations with emanating solutions and volatile substances, etc., which are related to a potential possibility of radioactive contamination of the air in the rooms, shall be carried out in chimney-pieces and boxes with exhaust ventilation. The work tables, stands, the metal and other types of cabinets, chimney-pieces and boxes shall be covered with materials with low sorption.

(3) When works of class II or class III with unsealed sources of ionising radiation are carried out at a given site, united by common technology, a common block of rooms may be assigned, which shall be equipped in compliance with the provisions for activities of class II with unsealed sources of ionising radiation.

Article 51. (1) No special requirements exist for the provision of laboratories, where activities of class III with unsealed sources of ionising radiation will be performed. Work of class III with unsealed sources of ionising radiation shall be performed in separate rooms, which shall meet the general requirements for chemical laboratories.

(2) Activities of class III with unsealed sources of ionising radiation, which are related to potential possibility for radioactive contamination of air in the corresponding rooms (operations with powders, evaporation of solutions, manipulations with emanating solutions and volatile substances) shall be carried out in cabinets with exhaust ventilation.

(3) It is recommended in the case of rooms for activities of class III with unsealed sources of ionising radiation to have available a bathroom with a shower and a separate room for storage and distribution of the radioactive solutions, which are used in these activities. It is recommended to ventilate these rooms by forced-exhaust ventilation system.

Article 52. In the case of activities with unsealed sources of ionising radiation of class I and II, the common electrical distribution boards and the controls of the common systems for heating, ventilation, water supply, gas supply and pressurised air shall be located outside the basic working rooms of the site.

Article 53 (1) For the purpose of reducing the external exposure of the personnel by unsealed sources of ionising radiation, automated systems and remote control of the technological processes as well as screening of the sources of ionising radiation and diminishing of the duration of work operations shall be used;

(2) (Amended State Gazette № 76/2012) Operations with unsealed sources of ionising radiation of class I in chambers and boxes shall be performed by remote controlled equipment or by gloves, airtight sealed to the front wall of the chambers or boxes. The placing in or taking out of the processed products or equipment shall be done without disturbing the hermetic sealing of the respective chambers or boxes. In the case of replacement or repair of the manipulators, chamber gloves and other components, temporary disturbance of the air tightness of the chambers or boxes is permissible, with the application of adequate individual means of protection of the personnel and the execution of the necessary dosimetric and radiation control.

(3) The control of the accessory equipment for supply of water, gas, and air or for creating of vacuum shall be performed from the side of the front wall of the chambers or boxes.

Article 54. (1) In the process of determination of the workplaces in operator rooms and of accessories and remote control systems, the access areas for the operators shall be taken into account and an adequate lining up of the work positions of the personnel shall be ensured, in respect of the anthropomorphic and psycho-physiological characteristics of man.

(2) The height of the rooms for work with radioactive substances and the area, calculated per individual worker, shall be determined in compliance with the regulations and norms for design and construction of industrial enterprises.

(3) For works of I or II class with unsealed sources of ionising radiation the area per worker in a given room shall be minimum 10 square meters.

Article 55. Measures for decontamination of the production rooms and equipment shall be envisaged at the site with unsealed sources of ionising radiation.

Article 56. The technological equipment, protection devices and working facilities in the rooms at the site with unsealed sources of ionising radiation shall be with smooth surface, of simple design and with coatings with low sorption, which facilitate the removal of radioactive contamination and which can stand the effects of the working materials, substances, solutions and chemical agents used.

Article 57. (1) The floors and ceilings of the rooms for operations of II class with unsealed sources of ionising radiation and of the rooms of the 3<sup>rd</sup> area for operations of class I with unsealed sources of ionising radiation shall be coated with materials of low sorption, which are durable to cleansing means. It is recommended to paint the rooms belonging to different classes and areas of operations in different colours.

(2) The requirements, as laid down in paragraph (1) shall be valid for the ceilings of the rooms of the 1<sup>st</sup> and 2<sup>nd</sup> area for activities of class I with unsealed sources of ionising radiation, as well as for the floors of rooms for activities of class III with unsealed sources of ionising radiation.

(3) The edges of the floor coatings shall be glued to the walls, bent in advance at 10 cm height from the floor. If special sewage system is available, the floors of the rooms shall slope down to the facilities for draining of the water. The corners of the rooms shall be rounded and the doors and window frames shall be of simplified design.

(4) When tiling the rooms, the requirements for effective decontamination shall be rationally combined with prophylactic of eye fatigue. It is recommended to use light colours in the

rooms for continuous or periodic stay of the personnel, with different colours for the two types of rooms.

Article 58. In the case of operations of I and II class with unsealed sources of ionising radiation, the tools, accessories and work furniture shall be assigned to the respective rooms of a given class (area) and shall be designated in an adequate way. They shall be moved from one room to another, when the latter is of a different class (area), after performing of radiation control and changing of the signs indicating the class (area) in correspondence to the class (area) of the new room.

Article 59. (1) The quantity of unsealed sources of ionising radiation at the workplaces shall be the minimum required by the particular activity. Radioactive substances with the minimum toxicity, solutions instead of powders, and solutions with the least specific activity shall be selected.

(2) The number of operations, which may create a possibility for radioactive contamination of the rooms and the environment (transferring of powders and liquids from one container into another, sifting of powders, etc.) shall be reduced to a minimum. Manual operations with radioactive solutions shall be performed with the application of proper protective means.

Article 60. When working with unsealed sources of ionising radiation, auxiliary materials and devices for one-time use (plastic vessels and coatings, paper filters, etc.) shall be used for limiting of the radioactive contamination of surfaces, equipment and rooms. The work shall be performed on mats of materials with low sorption.

Article 61. When working with unsealed sources of ionising radiation, a separate room shall be designated at the site for the purpose of storage of the necessary decontaminating solutions, devices, materials and equipment for cleansing of the rooms as well as other means of liquidation of radioactive contamination.

Article 62. The activities at site with unsealed sources of ionising radiation shall be organised and performed in such a way, that the quantity of the released radioactive waste during the corresponding technological processes and manipulations shall be at its attainable minimum.

## **Section II.**

### **Requirements to the Ventilation Systems, Systems for Cleansing of Dust, Aerosols and Gases, Heating, Water Supply and Sewage Systems at Site with unsealed sources of Ionising Radiation**

Article 63. (1) The requirements to the design of the systems for ventilation, removal of dust, aerosols and gases, heating, water supply and sewage shall be determined by the currently valid construction norms and regulations for industrial enterprises. The operation of these systems shall be done in accordance with the regulations of this Regulation and the currently valid norms of radiation protection.

Article 64. (1) The ventilation and air cleaning systems prevent pollution of the air environment in the working rooms and of the air from the atmosphere. It is achieved by correct organisation of their operation, availability of the required equipment (boxes, chambers, cabinets, etc.), the rational layout of the rooms and equipment, observing the provisions of radiation protection, established by the respective normative documents.

(2) The workrooms, boxes, cabinets and other technological equipment shall be designed in such a way, that the air flow is directed from less polluted space to relatively more polluted space.

(3) The project documentation of ventilation of rooms at site with unsealed sources of ionising radiation shall be co-ordinated with the Ministry of Health .

Article 65. (1) The air from the ventilated rooms boxes, chambers, sealed cabinets shall be cleaned from radioactive contamination, before it is released in the atmosphere, and the activity of the released radioactive substances shall be monitored. The filters used for cleansing shall possess sufficient efficiency, which shall be justified in the project documentation of the respective sites with unsealed sources of ionising radiation. Rarefaction

of the radioactive contaminated air before passing it to through the cleansing filters shall not be allowed.

(2) (Amended State Gazette № 76/2012) The limits for the activity of aerosol releases in the atmosphere at sites with unsealed sources of ionising radiation shall be authorised by the Nuclear Regulatory Agency in co-ordination with the Ministry of Health, on the basis of the corresponding dose quotes for the population and the currently valid norms for radiation protection.

(3) At sites, where works of I and II class are being carried out with unsealed sources of ionising radiation, ventilation tubes (chimneys) for release of the air into the atmosphere shall be constructed; their height shall ensure diminishing of the volume concentration of the released radioactive substances at the point of reaching the ground to values, which, on a conservative estimation, shall not exceed the established dose quotes for the population.

Article 66. (1) The number of ventilation systems, providing service to rooms for activities with unsealed sources of ionising radiation, shall be minimal. The ventilation systems, providing service to chimney-pieces, boxes, chambers, shall be separate from the ventilation systems, servicing the rooms of the respective site with unsealed sources of ionising radiation.

(2) The entrances to chambers, chimney-pieces, boxes, which are ventilated, shall be located on the side of the rooms with continuous presence of personnel, and the currently valid norms with respect to the concentration of radioactive and toxic substances in working rooms shall be observed.

(3) In buildings, where only part of the available space is dedicated to working operations with unsealed sources of ionising radiation, separate ventilation systems shall be provided: for the rooms for operations with sources of ionising radiation , and for the rooms, where no such operations are carried out.

Article 67. (1) For the storage of sources of ionising radiation in quantities, which lead to ozone concentrations above  $0,1 \text{ mg/m}^3$ , and of nitrogen oxides above  $5 \text{ mg/m}^3$  in the air of the working rooms at sites with unsealed sources of ionising radiation, the ventilation systems shall be with continuous operational mode.

(2) For the purpose of cleansing and purification of air from radioactive and toxic substances in rooms for work activities of I and II class the application of systems for recirculation of the air and aeration of the rooms shall be permissible, adhering to the limits of the volume activities for the respective radionuclides, according to the currently valid norms of radiation protection.

Article 68. (1) The airflow rate through the working openings of the special ventilation equipment at sites with unsealed sources of ionising radiation shall be determined at the stage of their design and shall not exceed 1,5 m/s.

(2) For the preliminary calculation of exhausted air, with more than three chimney-pieces, only half of the area of the working openings (hatches) shall be taken into account.

(3) (Amended State Gazette № 76/2012) In hermetic chambers and boxes vacuum of not less than 15-mm water column shall be maintained with sealed openings. The chambers and boxes shall be equipped with gauges for monitoring of the degree of vacuum. The calculated design airflow rate in the working openings of the ventilated cabinets shall be assumed equal to 1,5 m/s.

(4) Short-time fall of the rarefaction in hermetic boxes and chambers to 10 mm water column, and reduction of the velocity of air in the working openings to 0,5 m/s, shall be permissible under the condition that the purity of the air environment in the working rooms shall be kept within the limits of the allowed average volume activity of the air for the respective radionuclides, according to the currently valid norms of radiation protection.

Article 69. The air ducts of the exhaust ventilation and the cleansing filters at the sites with unsealed sources of ionising radiation shall be designed and sized in such a way as to ensure a velocity of 1 m/s in the periodically opened boxes and chambers. In the case of special technological requirements and the presence of heat and humid emissions in the boxes and chambers, the required volume of air exchange shall be calculated taking into account the specific provisions.

Article 70. If three or more chambers or boxes are available, the total quantity of the released air from sites with unsealed sources of ionising radiation shall be determined depending on the

number of the openings, which are being opened at one and the same time during the operational process, with a safety coefficient of 2 and taking into account possible leaks in the whole system.

Article 71. (1) The fans, which service boxes, chambers and closed cabinets, shall be located in specially dedicated rooms. In rooms for working operations of class I with unsealed sources of ionising radiation the ventilation exhaust chamber shall be included in the number of rooms for periodic service (rooms of 2<sup>nd</sup> area). The ventilation systems, which provide service to rooms for work of class I with unsealed sources of ionising radiation shall be equipped with back-up (spare) units with productivity not less than 1/3 of the full design value.

(2) The start-up controls of the electric motors shall have visual signalling for indication of their state (“on”, “off”), and shall be located in rooms of continuous presence of the personnel (rooms of 3<sup>rd</sup> area). The fans shall have visual alarms for indicating halt conditions of their motors.

Article 72. (1) In the case of operations with emanating and volatile radioactive substances a continuously working exhaust ventilation system for the storage rooms, the working rooms and boxes of the sites with unsealed sources of ionising radiation shall be designed and used. The system shall be equipped with a back-up ventilation unit with productivity of no less than 1/3 of the full design value.

(2) In rooms for work operations of I and II class with unsealed sources of ionising radiation, in the case of area layout of the equipment, facilities for flexible duct connections and mobile ventilation units shall be installed to complement the exhaust ventilation systems and ensure the possibility of carrying out repair works in the respective area.

Article 73. In the process of selection, design, and operation of systems and facilities for cleansing of dust and gases at sites with unsealed sources of ionising radiation the following requirements shall be observed:

1. The number of the dust cleansing and gas cleansing systems shall be limited to a reasonable minimum;

2. The processes of technical maintenance, repair and replacement of equipment for cleansing of dust and gases shall be automated and, in case of necessity, remotely controlled;
3. Systems for control and signalling of the efficiency of the cleansing equipment and filters shall be provided and implemented (i.e. measurement of rarefaction, aerodynamic resistance, coefficient of purification, and other technical parameters).  
In the case of a multistage system for cleansing of dust and gases, automated control and signalling of the efficient work shall be performed on the whole system and on its separate parts;
4. Reliable isolation of the dust-cleansing and gas-cleansing equipment as a source of ionising radiation shall be provided, as well as radiation protection of the personnel during visual checks and technical maintenance of the respective equipment.

Article 74. The filters and equipment of the dust-cleansing and gas-cleansing systems shall be placed, if possible, in the closest proximity to the corresponding boxes, chambers, cabinets, so that to reduce to a minimum the contamination of the main air ducts at the site with unsealed sources of ionising radiation. The duration of use of the filters and equipment shall be determined depending on the reduction of the throughput for the purified air and on the degree of radiation hazard, which is a result of accumulation of radioactive substances in them.

Article 75. During the location of dust-cleansing and gas-cleansing equipment in individual rooms, sections of a building or in separate buildings, the requirements, valid for the main production rooms at sites with unsealed sources of ionising radiation shall be met. In case the dust-cleansing and gas-cleansing equipment is located in an under-roof floor of a building, this floor shall be equipped as a technical floor.

Article 76. The rooms, where dust-cleansing and gas-cleansing equipment is located, shall be isolated and not connected by air path with the main production rooms and areas of the site with unsealed sources of ionising radiation. Entry into these rooms shall be through a sanitary checkpoint and separate entrance.

Article 77. (1) Isolated hermetic rooms or hermetic ventilated sections for repair, disassembly, temporary storage of filters, devices and their components, as well as for storage of means for cleansing and decontamination shall be provided in the rooms of the systems for dust-cleansing and gas-cleansing.

(2) In the case of centralised layout of dust-cleansing and gas-cleansing equipment the sections for operations of class I with unsealed sources of ionising radiation shall be designed on the area principle as part of the common zone.

Article 78. (1) In rooms of the 1<sup>st</sup> and 2<sup>nd</sup> area for operations of class I, with unsealed sources of ionising radiation, a system for blowing air to isolating pipe-type individual means of protection of the personnel (pneumo-suits, pneumo-headpieces, hose connected gas masks) shall be provided.

(2) There shall be a separate pneumatic line or separate fans for blowing air to the line-fed means for protection, or separate fans, which deliver at the connection point the necessary pressure (500 mm water column) and the necessary air volume (15 m<sup>3</sup>/h). The connection points of the flexible pipes shall be equipped with spherical or spring automatic valves.

(3) The air conduit system for air supply by flexible pipes to the isolating individual means of protection shall be made of corrosion resistant materials.

Article 79. (Amended State Gazette № 76/2012) The air conditioning of the rooms for operations with unsealed sources of ionising radiation shall be of a type, which will not allow additional spread of dust and aerosols.

Article 80. (1) A system for hot and cold water supply and sewage system shall be available at the sites with unsealed sources of ionising radiation. Exempted from this requirement shall be only field laboratories, where class III works with unsealed sources of ionising radiation are carried out and which are situated outside towns and villages or in towns and villages without central water supply system.

(2) Storage facilities for unsealed sources of ionising radiation shall be equipped with cold water supply system and sewage system.

Article 81. In rooms for activities of class I or II with unsealed sources of ionising radiation, the water taps of the sinks shall be with hot-cold water mixing facility, which is pedal or elbow controlled or by other methods, which do not require physical contact by the personnel. Hand dryers shall be installed in the washing rooms for drying of the hands after washing. The washing of WCs shall be done by pedal control or by controls, which do not require actuation by physical contact.

Article 82. The special sewage systems shall provide the possibility for decontamination of the waste radioactive waters and their repetitive use for technological purposes. The cleansing facilities of the special sewage system shall be located in a separate room or a dedicated section of the territory of the site with unsealed sources of ionising radiation. The special sewage system shall be equipped with technical means for control and measurement of the quantities and the activities of the incoming and processed waste radioactive waters.

Article 83. The receivers of poured radioactive solutions (sinks, draining facilities, pits, etc.) of the special sewage system shall be made of corrosion-proof materials or shall be covered on their internal and external surfaces with coatings, which can be easily deactivated. The receivers of poured stuff shall be of design preventing the splashing and spilling of the poured radioactive solutions.

Article 84. The installation of air-ducts, water pipes and other communication elements of the ventilation systems, water supply and sewage systems through the walls and barriers, which serve as protection from ionising radiation at sites with unsealed sources of ionising radiation, shall be designed and implemented in such a way that the radiation protection at the locations of the pipe/duct through-holes shall not be weakened.

Article 85. Before repair and cleaning of the sewage systems, which are intended for removal and decontamination of liquid radioactive waste, the radiation situation at the respective locations shall be assessed and, if necessary, additional personal protective means shall be used.

### **Section III.**

#### **Requirements to the Maintenance and Decontamination of Rooms and Equipment**

Article 86. (1) The surface radioactive contamination of rooms, means for individual protection and equipment at sites with unsealed sources of ionising radiation shall not exceed the established limits in accordance with the currently valid norms of radiation protection.

(2) No norms shall be set for the surface radioactive contamination of internal surfaces of boxes, chambers and cabinets and of the equipment inside them. The contaminated surfaces shall not create radioactive contamination of the air in the workrooms or exposure of the personnel above the established limits in accordance with the current norms of radiation protection.

Article 87. At sites, where activities of class I with unsealed sources of ionising radiation are being performed, the equipment, tools, vessels and other items, taken out of chimney-pieces, boxes, chambers, cabinets and rooms of 1<sup>st</sup> and 2<sup>nd</sup> area, shall be deactivated on the spot to the permissible limits for the respective categories of rooms, where they will be taken to or, they shall be placed in containers and packed hermetically.

Article 88. (1) The floors and external surfaces of the equipment in the rooms of continuous stay of the personnel at sites with unsealed sources of ionising radiation shall be cleaned daily by wet methods. Full periodic cleaning with washing of the walls, floors, ceilings, doors, sinks and external surfaces of the equipment in the rooms for continuous stay of the personnel (no “dry” cleaning is permissible) shall be carried out.

(2) The items, needed for the cleaning, shall be stored at specially defined places and shall be used only for the rooms of the corresponding activities with unsealed sources of ionising radiation, for which they are intended.

Article 89. (1) At sites with unsealed sources of ionising radiation a permanent reserve of decontamination agents and cleansing preparations, selected depending on the used radionuclides and their chemical combinations, and on the type of the deactivated and cleaned substances.

(2) After completion of work the workplaces shall be cleansed and, in case of necessity, the external surfaces of the used vessels, tools and equipment shall be deactivated to the respective limits. Specially selected and trained personnel shall perform these operations.

Article 90. The effectiveness of decontamination (the extent of removal of radioactive contamination from surfaces) shall be controlled by radiometric measurements with mobile and fixed test equipment. The equipment, tools, coatings, which are sources of additional exposure for the personnel and cannot be subject to decontamination and thus become useless for further application, shall be treated as radioactive waste and shall be replaced.

Article 91. When radioactive solutions have been spilled, they shall be gathered and removed to a convenient location; on scattering of radioactive dust the ventilation systems, which may cause spread of the radioactive contamination, shall be switched off and measures shall be undertaken for collecting and removing of the spilled powder.

Article 92. At sites with unsealed sources of ionising radiation a reserve of means for liquidating of accidental radioactive contamination shall be maintained (appropriate decontamination solutions, tools and equipment for decontamination and cleansing of rooms, additional personal protection means for the personnel, etc.).

#### **Section IV.**

##### **Requirements to the Means for Individual Protection and Radiation Hygiene**

Article 93. Persons working with unsealed sources of ionising radiation, or persons visiting sites, where work is performed with unsealed sources of ionising radiation, shall be provided with means for individual protection in accordance with the type and class of work with these unsealed sources of ionising radiation.

Article 94. The surface radioactive contamination of the personnel (skin of the body, surface of the working overalls, shoes and personal protection means) shall not exceed the established limits according to the valid norms of radiation protection.

Article 95. (1) In the process of performing activities of class I with unsealed sources of ionising radiation and of some works of class II, the personnel shall be obliged to use basic and additional means of individual protection depending on the type of the unsealed sources of ionising radiation and on the level and nature of the radioactive contamination. No personal clothes shall be allowed.

(2) (Amended State Gazette № 76/2012) The means of individual protection shall include:

1. Overall or protective suit (shirt, trousers);
2. Underwear, socks, mittens;
3. Cap or helmet, special shoes, towels and handkerchiefs for one-time use;
4. Filtrating and isolating means for protection of the respiratory organs depending on the extent of radioactive contamination of air (respiratory devices, face-pieces of full and half face coverage, pneumatic helmets, pneumatic suits (overalls)).
5. (New provision- State Gazette № 76/2012) safety glasses, helmets, crash helmets;
6. (New provision- State Gazette № 76/2012) rubber or latex gloves;
7. (New provision- State Gazette № 76/2012) additional special wear made of plastic or made of polymeric covered fabric (wrappers, overalls, tunics, over sleeves, aprons, waterproofs);
8. (New provision- State Gazette № 76/2012) rubber and plastic special shoes or boots.
9. (New provision- State Gazette № 76/2012) Gas masks and autonomous breathing devices (oxygen masks, oxygen suits).

(3) (Amended-State Gazette № 76/2012) In case of operations of class II with unsealed SIR and in some operations of class III, the personnel shall be obliged to use aprons, capes, caps, glasses, latex gloves, light shoes and, if necessary, means for protection of the respiratory organs.

(4) (Repealed-State Gazette № 76/2012)

Article 96. The means of individual protection shall be made of materials, which are easily decontaminated, or disposable means shall be used.

Article 97. (1) Filtration means (respiratory devices, face-pieces - full-face or half-face) and isolating means (pneumatic suits, pneumatic helmets or, in some cases autonomous breathing devices) for individual protection of the respiratory tract shall be used for work in air

environment containing radioactive gases, vapours and/or aerosols with concentration, which exceed the permissible limits (during repair or welding of equipment, contaminated with radioactive matter, during operation in rooms, where leakage of gaseous or liquid radioactive substances is present, during manipulations with radioactive powders or liquids, during liquidation of the consequences of radiation accidents).

(2) Isolating personal protection means of the respiratory tract shall be used in all cases, when the provided filtrating means cannot ensure radiation protection of the personnel during certain types of work with unsealed sources of ionising radiation.

Article 98. (1) The personnel working with radioactive solutions and powders and the personnel cleaning rooms for operations with unsealed sources of ionising radiation shall be obliged to use supplementary means of individual protection depending on the type of the unsealed sources of ionising radiation, the level and nature of the radioactive contamination.

(2) The personnel, performing metal cutting or welding operations, of items containing radionuclides or contaminated with radionuclides, shall use special means for individual protection made of spark-resistant and easily deactivated materials.

Article 99. On passing from rooms for activities with unsealed sources of a higher class to rooms for operations of a lower class, the level of the radioactive contamination of the personal protection means shall be checked. In rooms for work of class I, on passing from 2<sup>nd</sup> to 3<sup>rd</sup> area, the additional personal protection means shall be taken off.

Article 100. Exiting rooms after finishing the particular work performed with unsealed sources, it is mandatory to:

1. Check the extent of radioactive contamination of the working garments, certain parts of the body of the worker and the personal protection means;
2. Take off the personal protection means and put them in the respective places;
3. Hand over for decontamination the means for individual protection in case of radioactive contamination in excess of the permissible limits;
4. Wash the hands and body and if necessary deactivate contaminated skin surfaces with proper means.

Article 101. (1) For activities of I and II class with unsealed sources of ionising radiation, the contaminated in excess of the permissible limits working garments shall be decontaminated in special laundry facilities. The basic working garments, including the underwear, shall be replaced periodically with new and/or washed clothing.

(2) The additional personal protection means (plastic, rubber, with polymer coating) after each case of use shall undergo preliminary decontamination in a sanitary lock or at another specially designated place. If, after the decontamination, the residual radioactive contamination exceeds the established limits, the additional personal protection means shall be handed over for decontamination in a special laundry room of the site with unsealed sources of ionising radiation.

(3) personal protection means, which cannot be deactivated below the established limits, shall be treated as radioactive waste and discarded.

Article 102. The possibility of radioactive contamination of the personal clothing and shoes at sites with unsealed sources of ionising radiation shall be excluded. In case such contamination is encountered, the personal garments and/or shoes shall be deactivated under the supervision and with the co-operation of the person responsible for the radiation protection of the respective site. If the decontamination is impossible, the individual garments and/or shoes shall be treated as radioactive waste.

Article 103. In rooms for activities with unsealed sources of ionising radiation the following shall be forbidden:

1. Stay of personnel and visitors without the required personal protection means;
2. Storage and use/consumption of food stuffs, cosmetics, toilet accessories and items, medicines, chewing gum, tobacco products, home (leisure) clothes, books, and other items and materials, which are not related to the principal activities.

Article 104. (1) At sites with unsealed sources of ionising radiation, where radioactive contamination of the personnel is possible, suitable washing means and preparations shall be used for decontamination of the body, which shall remove radioactive contamination and shall not cause penetration of radionuclides through the skin into the body.

(2) At sites, where works of class I with unsealed sources of ionising radiation are being carried out, an emergency reserve of means for individual protection and individual dosimeters shall be provided and maintained, which shall be available to the persons, taking part in the liquidation and limiting of the consequences of occurred accidents, including quantities for the outside teams, summoned for this purpose.

## **Section V.**

### **Requirements to Sanitary Checkpoints and Sanitary Locks**

Article 105 In sites where class I activities with unsealed sources are carried out, sanitary checkpoints shall be present. A sanitary checkpoint shall be located in a building, where work with unsealed sources of ionising radiation is performed, or in a separate part of the building, which shall be connected to the production section (laboratories and the rest of workrooms) with a covered corridor .

(2) The sanitary checkpoint shall include:

1. Shower room and lockers for personal clothes;
2. Lockers for working overalls, a room for control of the surface radioactive contamination of the body and of the working garments;
3. Room for storage and handing out of means for personal protection;
4. Storage rooms for new and washed working garments;
5. Separate sanitary-hygienic rooms for men and women, which shall be equipped with WCs, sinks with hot and cold water, washing preparations, hand dryers;
6. Fountains for drinking water – pedal controlled or controlled without physical contact.
7. (New provision- State Gazette № 76/2012) Emergency equipment locker;

Article 106. The layout of the sanitary checkpoints shall ensure splitting of the human lines on entry and on exiting of personnel in/from the workrooms of the site and mixing of the incoming and outgoing personnel shall be prevented.

Article 107. (1) At sites, where work of class II with unsealed sources of ionising radiation is carried out, a checkpoint for control of radioactive contamination and a shower room and rooms with separate lockers for personal items and for working garments shall be present if, on other grounds, sanitary lockers are not available.

Article 108. (1) At sites with unsealed sources of ionising radiation stationary sanitary locks shall be present between 2<sup>nd</sup> and 3<sup>rd</sup> areas of the workrooms of class I. Depending on the volume and nature of the of the performed work the sanitary lock shall include:

1. Places for changing (of clothes) and preliminary decontamination of additional means for individual protection, which shall be stored in cabinets or on shelves;
2. Facility for cleaning of working shoe soles on exit of the sanitary lock;
3. Radiation control point, equipped with test devices for measurement of the radioactive contamination;
4. Changing room for radioactive contaminated work clothing, equipped with containers for different kinds of clothing, with benches and washbasins.

The area, layout and the components of the sanitary lock may change depending on the volume, type and the specifics of the performed work.

(2) Besides fixed sanitary locks mobile sanitary locks may be used, which shall be placed at the entrances of the rooms, where repair activities are performed on radioactive contaminated equipment.

Article 109. (1) The floors, walls and ceilings of the sanitary and living rooms and the surface of the wardrobes and lockers for working overalls shall be with coatings resistant to humidity, preventing sorption of radioactive substances and facilitating cleaning and decontamination.

(2) The walls of the locker rooms, shower rooms, storage rooms and the radiation control points shall be covered to a height of minimum two meters with proper coatings, which shall be of low sorption, facilitating cleaning and resistant to acids and bases. The rest of the walls and the ceiling shall be painted in oil paint or polymer based paint. The floors of the shower rooms and of WCs shall be covered with non slippery materials of low sorption.

Article 110. (1) The sorting of the working garments shall be done according to type and extent of radioactive contamination, which shall be detected and quantified by radiometric measurement. After sorting the radioactive contaminated work clothing shall be packed and handed over from the change room to the storage room for such clothing.

(2) The places for sorting of radioactive contaminated working overalls shall be ventilated. The storage rooms for keeping the contaminated work clothing shall be situated in the proximity of a radiation control point and locker room for used work clothes.

Article 111. The number of storage positions for personal clothing and working garments shall correspond to the maximum number of the members of the personnel and additional positions shall be provided for the temporary outside personnel working at the site.

Article 112. The necessary area of the rooms at the sanitary locks, the number of showers in the shower rooms, the quantity and type of the means for individual protection shall be determined depending on the volume, nature and class of the performed work and the number of members of personnel at the sites with unsealed sources of ionising radiation in accordance with the sanitary and hygiene norms and regulations, valid for industrial enterprises.

#### **Chapter Eight.**

#### **REQUIREMENTS TO THE RADIATION MONITORING OF ACTIVITIES WITH SOURCES OF IONISING RADIATION**

Article 113. (1) The radiation monitoring shall ensure continuous observation and obtaining of the necessary information of the radiation status and the doses of exposure of the personnel and the population during the process of performing of activities with sources of ionising radiation.

(2) (Amended-State Gazette № 76/2012) At sites, where sources of ionising radiation are operated, radiation monitoring shall be performed of the basic characteristics of the working and surrounding environment for determination and assessment of the exposure of the personnel and the population in the respective areas (controlled area and supervised area at the site with sources of ionising radiation, the area for preventive protective measures and monitored area around the site with sources of ionising radiation).

(3) For each site with sources of ionising radiation a programme for radiation monitoring shall be available, which shall specify the monitored radiation parameters, the type, ranges and the accuracy of the applied radiometric and dosimetric test equipment, the test locations, and the frequency of the performed measurements.

(4) The scope and volume of the programme for radiation monitoring at sites, where works of class I with unsealed sources of ionising radiation are carried out, shall be subject to co-ordination with the supervising bodies.

Article 114. The system for radiation monitoring shall be developed at the design stage of the site with sources of ionising radiation, taking into account the expected exposure doses, and it shall include the organisation, the terms and procedure for control of the radiation status.

Article 115. The radiation control at sites with sources of ionising radiation shall be performed by a radiation protection office or by a specially appointed persons , depending on the volume, nature and complexity of the performed activities at the site. These persons shall be indicated in the documentation, which shall be an inseparable part of the licenses or permits, issued by the Nuclear Regulatory Agency for the respective activities at sites with sources of ionising radiation.

Article 116. (1) The organisational structure, functions and obligations of the office (responsible persons) for radiation protection shall be established by orders and other internal documents (regulations, codes, job instructions) at the respective sites with sources of ionising radiation.

(2) The persons who are working at the radiation protection office and are responsible for radiation protection shall have passed special training and have certificates of qualification, issued by a person – holder of a license from the Nuclear Regulatory Agency for delivering of specialised training.

Article 117. The managers of sites with sources of ionising radiation shall notify the Nuclear Regulatory Agency and the Ministry of Health about all cases of occurrence of exposure or radioactive contamination above the established normative levels.

Article 118. The radiation monitoring at the sites with sources of ionising radiation depending on the nature of the performed activities shall include:

1. (Amended-State Gazette № 76/2012) Measurement of the equivalent dose rate of X-ray, gamma, neutron and other ionising radiation and measurement of the particle fluence rate at the workplaces, in the workrooms, in the radiation protected area and in the monitored area of the site with sources of ionising radiation;
2. Measurement of the extent of surface radioactive contamination of working surfaces, equipment, transport vehicles, means for individual protection, the body and clothing of the personnel at the site with sources of ionising radiation;
3. Measurement of the volume activity of gases and aerosols at the workplaces and in the production rooms of the site with sources of ionising radiation;
4. Measurement of the activity of gas-aerosol and liquid radioactive releases in the environment;
5. (Amended-State Gazette № 76/2012) Measurement of the radioactive pollution of various components of the environment (air, water, soil, bottom residues, vegetation, agricultural produce) within the boundaries of the radiation protection area and the monitored area around the site with sources of ionising radiation;
6. Measurement of the equivalent dose rate, the specific activity, the radionuclide content, the surface radioactive contamination and other characteristics of radioactive waste during its collection, sorting, processing, transportation and storage.

Article 119. (1) At sites with sources of ionising radiation systematic monitoring of the external and internal exposure of the personnel shall be performed with the application of proper methods and technical means for individual monitoring.

(2) The individual monitoring shall include:

1. Measurement and/or evaluation of the individual effective and equivalent doses of external gamma, X-ray, neutron and other ionising radiation;
2. Determination of the nature, dynamics, and the levels of entry of radioactive substances in the organism for the purpose of evaluation of the individual effective and equivalent doses of internal exposure by direct spectrometric and radiometric measurements of the bodily activity and by taking measurements from biologic samples;
3. Radiometric control of the surface radioactive pollution of the body and the means for individual protection of the personnel;

4. Analysis, assessment and archiving of the registered doses from external and internal exposure .

Article 120. (1) The system for radiation monitoring of sites with sources of ionising radiation, which, in case of radiation accident, may cause radiation impact on the population and environment and implementation of protective measures, shall include:

1. Operational monitoring of the radiation status in the controlled area and the supervised area of the site with fixed automated technical equipment and/or by mobile and portable technical equipment;
2. (Amended-State Gazette № 76/2012) Operative monitoring of the radiation status in the radiation protected area and the monitored area around the site by mobile or portable technical equipment;
3. Laboratory analyses with stationary measurement equipment (radiometric, spectrometric and dosimetric equipment).

(2) The automated systems for continuous monitoring shall provide the functions of measurement, registration, display, acquisition, processing, transmission and archiving of the data about the radiation status at the respective sites with sources of ionising radiation.

Article 121. In rooms for operations of class I with unsealed sources of ionising radiation, when the radiation status may vary within broad ranges, it is mandatory to have available equipment for radiation monitoring for the corresponding type of exposure with local visual and sound signalling features, and the personnel shall be equipped with individual emergency dosimeters.

Article 122. (1) The results of the individual monitoring of the personnel at the sites with sources of ionising radiation shall be stored for the term, as laid down in the Regulation on the Basic Norms of Radiation Protection. Records shall be made and accounted of the effective and equivalent individual doses, the received doses for each and every year and for every five consecutive years, as well as of the accumulated dose during the whole period of professional work with sources of ionising radiation.

(2) The received individual doses shall be logged in a special logbook with subsequent input of the data in individual dosimetric cards for every member of the personnel of a given site with sources of ionising radiation. On transfer from one site to another, a copy of the individual dosimetric card of the respective member of the personnel shall be sent in due order to the new workplace, and the original shall remain at the previous workplace.

(3) Members of external personnel at a site with sources of ionising radiation shall receive copies of their filled individual dosimetric cards with the received doses during their work at this site. The data about the received doses shall be registered in their individual dosimetric cards by the enterprise where they are permanently employed.

Article 123. (1) For the purpose of the radiation control at sites with sources of ionising radiation reference control levels shall be determined for the monitored parameters, characterising the radiation situation and the exposure of the personnel.

(2) In setting the reference control levels the primary and secondary limits according to the currently valid norms for radiation protection and the principle of diminishing the exposure of the personnel and the population to a reasonable achievable level, with respect to the economic and social factors, shall be taken into account with reference also to:

1. The irregularity of the radiation impact as a function of time;
2. The necessity to keep the level of radiation impact at a given site with sources of ionising radiation below the established limits according to the valid norms of radiation protection;
3. The effectiveness of the measures for upgrading of the radiation protection at the site with sources of ionising radiation.

(3) During the determination of reference control levels for the volume and specific activity of radionuclides in the atmospheric air and water in water basins, the possible intake along the nutrition chain and the external exposure from radionuclides accumulated in the surrounding environment, shall be taken into account.

Article 124. The operational control in the case of exposure of personnel under conditions of constant concentration of radionuclides in the air of the workrooms, in the atmospheric air and in water shall be based on the established limits for the average annual volume activity of the respective radionuclides according to the valid norms of radiation protection. The repetition

rate, type and volume of the radiation control shall be determined in such a way that it would be possible to assess the yearly intake of radionuclides in the organism of the personnel and persons of the population.

Article 125. (1) The data of the radiation monitoring shall be collected, analysed, evaluated and stored during the operation of the respective site with sources of ionising radiation and after its decommissioning.

(2) The results of the radiation monitoring shall be analysed and assessed by comparison with the primary and secondary limits according to the currently valid primary norms of radiation protection, the control reference levels and the dose quotas. On exceeding these values the managers of the sites with sources of ionising radiation shall analyse every such case and notify the Ministry of Health and the Nuclear Regulatory Agency, including the causes and the undertaken corrective measures.

#### **Chapter Nine.**

### **REQUIREMENTS TO THE ACCOUNTING OF SOURCES OF IONISING RADIATION**

Article 126. (1) Every person responsible for the receipt, delivery, storage, accounting and control of the sources of ionising radiation at the respective site shall be obliged to keep and maintain the necessary documentation according to the established formats and templates pursuant to annexes No. 4, 5, and 6.

(2) (Amended - State Gazette № 74/ 2006) An office copy of annex № 4 with the initial record is submitted to the Nuclear regulatory agency.

(3) The received sources of ionising radiation shall be put on record and accounted for by the number of packages, the type and activity of the radionuclides, the types and designations, indicated in the accompanying documentation. The products containing sources of ionising radiation (devices, apparatuses, equipment) shall be put on record and accounted for by type, designation and identification numbers of the manufacturer, and for those containing radioactive substances, the activity and the type of radionuclides shall be indicated. In the case of generators of short-lived radionuclides, the activity of the “parent” radionuclide shall be indicated.

(4) The date of manufacture shall be registered for all types of sources of ionising radiation.

Article 127. (1) The transfer of the sources of ionising radiation from the place of their storage to the respective workplace at the site shall be done by the person responsible for the sources of ionising radiation after presentation of a written application of the person carrying out the work, approved by the site manager or by a person authorised by him. The written application shall be formatted according to the template laid down in annex No. 5.

(2) 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 site.

(3) The usage of radioactive substances shall be authenticated by the act according to the template form of annex No. 6, prepared by the person responsible for the sources of ionising radiation and by the worker performing the respective activity with sources of ionising radiation at the site. The act shall be endorsed by the site manager and shall serve for accounting and control of the used sources of ionising radiation.

(4) On termination of a labour contract or transfer to another job/ workplace of a person, who has worked at a site with sources of ionising radiation, the corresponding manager shall demand from this person the return of all sources of ionising radiation, which he has worked with, by a written demand form after the sample pursuant to annex No. 5.

Article 128 (Amended - State Gazette № 74/ 2006) (1) A commission, appointed by orders of the person, which possesses license and/or permit for activities with sources of ionizing radiation, shall check on a yearly basis, the presence, location and status of the used and stored sources of ionizing radiation at the respective facility. A copy of the audit document and of the templates in compliance with annex № 4 shall be submitted to the Nuclear Regulatory Agency not later than the end of the first quarter of every following year.

(2) In case of absence, theft or unregulated use of sources of ionising radiation, the person holding a license and/or a permit for activities with these sources of ionising radiation, shall notify immediately the Nuclear Regulation Agency and the Ministry of Interior.

#### **Chapter Ten.(Repealed-State Gazette № 76/2012)**

## **LEVELS OF EXEMPTION FROM CONTROL OF RADIOACTIVE SUBSTANCES OR MATERIALS CONTAINING RADIOACTIVE SUBSTANCES**

### **Chapter Eleven.**

#### **DECOMMISSIONING OF SITES WITH RADIOACTIVE SUBSTANCES**

Article 138. (1) Sites, where activities with radioactive substances have been carried out, shall be decommissioned after receipt of permit in compliance with the Regulation on the Procedure for the Issuance of Licenses and Permits for Safe Use of the Nuclear Energy.

(2) After decommissioning the use of the rooms, where work with radioactive substances has been carried out shall be permitted by the state control bodies pursuant to the Health Act.

Article 139. (1) Before taking the decision for decommissioning of a given site with radioactive substances a complete survey shall be carried out of the radiation and technical status of the technological systems and equipment, the building construction aspects and the surrounding territory.

(2) For the purpose of decommissioning of sites or parts of them a plan shall be developed in advance.

Article 140. The plan for decommissioning shall make provisions for ensuring safety on each stage of the decommissioning: discontinuation of operations, conservation, disassembly, repairs, liquidation, storage and burial, restoration of affected areas at and around the site.

Article 141. The plan for decommissioning shall include:

1. Preparation of the equipment needed for carrying out of the disassembly activities;
2. Methods and means of decontamination of the disassembled equipment;
3. Method and procedure of radioactive waste management;
4. Assessment of the expected individual and collective doses of exposure of the personnel and population;
5. Assessment of the impact on the environment pursuant to Article 81, paragraph (1), item 2 of the Environmental Protection Act.

## **SUPPLEMENTARY PROVISIONS**

§ 1. Within the meaning of the Regulation:

3. “Decontamination” means the removal or diminishing of radioactive contamination from a surface or environment.
4. “Removable radioactive contamination” means the presence of radioactive substances, which may be transferred by contact onto other items, and are removed by decontamination.
5. “Open source of ionising radiation” means a source of ionising radiation containing radioactive substance, which, when operated, may release radionuclides contained in it into the environment.
6. “Radiation monitoring” means the acquisition and evaluation of information on the radiation situation at sites with sources of ionising radiation, in the environment, and on the exposure of people (includes radiometric and dosimetric control).
7. “Radioactive contamination” means the presence of radioactive substances on surfaces or content of radioactive substances in materials, air, the human body and other locations, in quantities, which are higher than the levels established by the current valid norms of radiation protection.
8. “Sanitary checkpoint” means the set of rooms intended for change of clothing and shoes, for sanitary processing of the personnel, and for control of the radioactive contamination of the body, means of individual protection, special garments and personal clothing of the personnel.
9. “Sanitary lock” means the room or the place between two different areas at sites with sources of ionising radiation intended for preliminary decontamination and change of additional means of radiation protection.
10. (Amended - State Gazette № 76/2012)“Means of individual protection” means equipment for protection of the personnel from external exposure or from inhalation intake of radioactive substances in the organism and from radioactive contamination of the skin.
11. “Accelerator” means equipment (installation), which generates ionising radiation with energy above 1 MeV by accelerating particles (e.g. electrons).

12. "Fixed (irremovable) radioactive contamination" means the presence of radioactive substances, which are not transferred by contact onto other objects and cannot be removed by decontamination.
13. (Amended - State Gazette № 74/ 2006 and № 76/2012 ) "High activity source" is a sealed source that contains a radionuclide whose activity at the moment of the manufacturing (or when it is not known - at the moment of its availability for sale), is equal to or higher than the limit value of the respective radionuclide in accordance with annex № 8..
14. (Amended - State Gazette № 74/ 2006) "A manufacturer of SIR" is every natural person or legal entity that produces SIR.
15. (Amended - State Gazette № 74/ 2006) "A supplier of SIR" is every natural person or legal entity that import, delivers, sells and/ or consign in other way SIR.
16. (Amended - State Gazette № 74/ 2006)"A container for SIR" is a packing in accordance with The [Regulation on the conditions and procedure of transport of radioactive material](#). The container is not an integral part of SIR and is designed for transport, storage or manipulation with SIR.
17. (New - State Gazette № 76/2012) "Generator of ionising radiation" means a device capable of generating ionizing radiation using energy from an external energy source.

## **FINAL PROVISIONS**

§ 2. This Regulation shall repeal Regulation No. 0-35 for activities with radioactive substances and other sources of ionising radiation ("State Gazette", No. 60, 1974).

§ 3. The Regulation is adopted pursuant to Article 26, paragraph (2) of the Act on the Safe Use of Nuclear Energy.

### **Transitional and Final Provisions**

## **TO DECREE № 228 of August 30, 2006 ON THE AMENDMENT OF REGULATION FOR RADIATION PROTECTION IN ACTIVITIES WITH SOURCES OF IONIZING RADIATION**

**(Promulgated. - SG 74<sup>th</sup> of 2006, in force since 01.01.2007)**

§ 10. NRA Chairman shall issue instructions and guidelines for the implementation of the regulation.

§ 11. This Decree shall enter into force on 1 January 2007.

§ 12. Regarding SIR marketed before the entry into force of the decree, § 1, item 1, § 2, 4 and 5 (of the decree) apply after 31 December 2007

§ 13. The regulation introduces the requirements of Directive 2503/122/EVRATOM of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources.

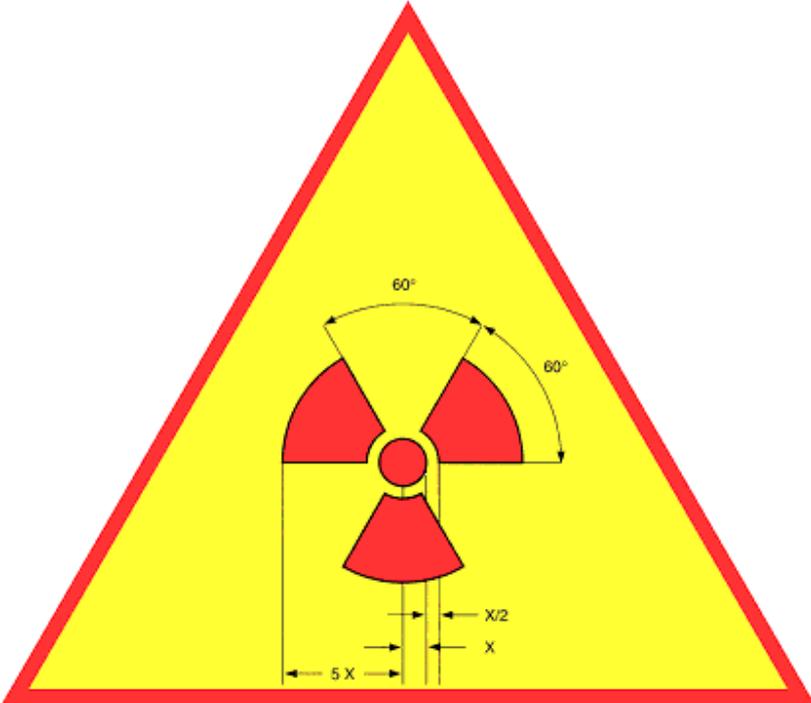
#### **FINAL PROVISIONS**

#### **TO DECREE № 123 of June 1, 2007, AMENDING REGULATORY ACTS OF THE COUNCIL OF MINISTERS**

**(Promulgated - SG. 46<sup>th</sup> of 2007, in force from 12.06.2007)**

§ 16. This Decree shall enter into force on the day of its publication in the "State Gazette".

Sign for Radiation Hazard



Note: The change of the red colour with black is permissible

**Annex No. 2 to Article 46, paragraph (2)**

**Groups of radionuclides by radiotoxicity**

Group 1: Radionuclides with very high radiotoxicity

Chemical element	Mass numbers of the radionuclides
Lead	210
Polonium	210
Radium	223, 225, 226, 228
Actinium	227
Thorium	227, 228, 229, 230
Protactinium	231
Uranium	230, 232, 233, 234
Neptunium	237
Plutonium	236, 238, 239, 240, 241, 242
Americium	241, 242m, 243
Curium	240, 242, 243, 244, 245, 246, 247, 248
Californium	248, 249, 250, 251, 252, 254
Einsteinium	254

Group 2: Radionuclides of high radiotoxicity

Chemical element	Mass numbers of the radionuclides
Sodium	22
Chlorine	36
Calcium	45
Scandium	46
Cobalt	60
Strontium	90
Yttrium	91
Zirconium	93
Niobium	94
Ruthenium	106
Silver	110m
Cadmium	115m
Indium	114m
Antimony	124, 125
Iodine	124, 125, 126, 131
Caesium/Caesium	134
Barium	140
Cerium	144
Europium	152, 154
Terbium	160
Thulium	170
Hafnium	181
Tantalum	182
Iridium	192
Thallium	204
Lead	212
Bismuth	207, 210
Astatine	211

Radium	224
Actinium	228
Thorium	232, natural thorium
Protactinium	230
Uranium	236
Plutonium	244
Americium	242
Curium	241
Berkelium	249
Californium	246, 253
Einsteinium	253, 254m
Fermium	255, 256

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Group 3: Radionuclides of medium radiotoxicity

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Chemical element	Mass numbers of the radionuclides
Beryllium	7
Carbon	14
Fluorine	18
Sodium	24
Silicon	31
Phosphorus	32, 35
Sulphur	35
Chlorine	38
Argon	41
Potassium	42, 43
Calcium	47
Scandium	47, 48
Vanadium	48
Chromium	51
Manganese	52, 54
Iron	52, 55, 59
Cobalt	55, 56, 57, 58
Nickel	63, 65
Copper	65
Zinc	65, 69m
Gallium	72
Arsenic	73, 74, 76, 77
Selenium	75
Bromine	82
Krypton	74, 77, 87, 88
Rubidium	86
Strontium	83, 85, 89, 91, 92
Yttrium	90, 92, 93
Zirconium	86, 88, 89, 95, 97
Niobium	90, 93m, 95, 96
Molybdenum	90, 93, 99
Technetium	96, 97, 97m, 99
Ruthenium	97, 103, 105
Rhodium	105
Palladium	103, 109
Silver	105, 111
Cadmium	109, 115

Indium	115m
Tin	113, 125
Antimony	122
Tellurium	121, 121m, 123m, 125m, 127m, 129m, 131, 131m, 132, 133m, 134
Iodine	120, 123, 130, 132m, 133, 135
Xenon	135
Caesium/Caesium	132, 136, 137
Barium	131
Lanthanum	140
Cerium	134, 135, 137m, 139, 141, 143
Praseodymium	142, 143
Neodymium	147, 149
Promethium	147, 149
Samarium	151, 153
Europium	152m, 155
Gadolinium	153, 159
Dysprosium	165, 166
Holmium	166
Erbium	169, 171
Thulium	171
Ytterbium	175
Lutetium	177
Tungsten	181, 185, 187
Rhenium	183, 186, 188
Osmium	18, 191, 193
Iridium	190, 194
Platinum	191, 193, 197
Gold	196, 198, 199
Mercury	197, 197m, 203
Thallium	200, 201, 202
Lead	203
Bismuth	206, 212
Radon	220, 222
Thorium	226, 231, 234
Protactinium	233
Uranium	231, 237, 240
Neptunium	239, 240
Plutonium	234, 237, 245
Americium	238, 240, 244m, 244
Curium	238
Berkelium	250
Californium	244
Fermium	254

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Group 4: Radionuclides of low toxicity

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Chemical element	Mass numbers of the radionuclides
Hydrogen (Tritium)	3
Oxygen	15
Argon	37
Manganese	51, 52m, 53, 56

Cobalt	58m, 60m, 61, 62m
Nickel	59
Zinc	69
Germanium	71
Krypton	76, 79, 81, 83m, 85, 85m
Strontium	80, 81, 85m, 87m
Yttrium	91m
Niobium	38, 89, 97, 98
Molybdenum	93m, 101
Technetium	96m, 99 m
Rhodium	103m
Indium	113m
Tellurium	116, 123, 127, 129, 133
Iodine	120m, 121, 128, 129, 134
Xenon	131m, 133
Caesium/Cesium	125, 127, 129, 130, 131, 134m, 135, 135m, 138
Cerium	137
Osmium	191m
Platinum	193m, 197m
Polonium	203, 205, 207
Radium	227
Uranium	235, 238, 239, natural uranium
Plutonium	235, 243
Americium	237, 239, 245, 246m, 246
Curium	249

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Note: Natural thorium with activity 1 Bq corresponds to 0,5 Bq thorium-232 and 0,5 Bq thorium-228. Natural uranium is a mixture of three radionuclides: uranium-234 (0,006 %), uranium-235 (0,712 %), and uranium-238 (99,282 %).

**Annex No. 3 to Article 47, paragraph (1)**

**Classes of work with unsealed sources of ionising radiation (radioactive substances)**

<b>Radionuclide groups by radiotoxicity</b>	<b>Activity at the workplace</b>		
	Activities of class I	Activities of class II	Activities of class III
Very high	Above 0,1 GBq	From 0,1 MBq to 0,1 GBq	Below 0,1 MBq
High	Above 1 GBq	From 1 MBq to 1GBq	Below 1 MBq
Medium	Above 10 GBq	From 10 MBq to 10 GBq	Below 10 MBq
Low	Above 100 GBq	From 100 MBq to 100 GBq	Below 100 MBq

7. In the case of uncomplicated operations with liquids (i.e. operations without evaporation, barbotage, destination) it is admissible for the activity at the work position to be ten times greater than the maximum activity for the corresponding class of work.
8. In case of complicated operations with liquids, creating risk of spilling and radioactive contamination, the activity at the workplace shall be ten times less than the maximum activity for the corresponding class of work.
9. During storage of open sources of ionising radiation (radioactive substances in different physical state) it is admissible for the activity at the workplace to be 100 times greater than the maximum activity for the corresponding class of work.
10. In case of operations with open sources of ionising radiation, leading to risk of radioactive contamination of the air and the rooms (“dry” operations with dust release), the activity at the workplace for the corresponding class shall be 100 times less than the maximum activity for the corresponding class.
- 11.** In case of operations for creation and packaging of generators of short-lived radionuclides for medical purposes, it shall be permissible the activity at the workplace to be 20 times greater than the maximum activity for the corresponding class of work.

**Annex No. 4 to Article 126, paragraph (2)**

(Amended- SG 74 of 2006 and SG 76 of 2012)

**Logbook accounting and control of sealed and unsealed sources of ionising radiation**

STANDARD TABLE OF INFORMATION FOR SEALED SIR

1. Source identification number	3. Licensee / permit holder: Name:	4. Source location (use or storage), if not the same as in point 3 Name:
2. Source certificate (No, date)	Address: Country: Manufacturer <input type="checkbox"/> Supplier <input type="checkbox"/> End user <input type="checkbox"/>	Address: Stationary use: <input type="checkbox"/> Storage (portable): <input type="checkbox"/>
5. Registration:	6. License / Permit	7. Source operational control
Registration date:	Number:	Date:
Date of registration removal:	Date issued: Validity date:	Date:
8. Source characteristic Radionuclide: Activity at manufacture or market date:: Manufacture date: Manufacturer/Supplier: Name Address Country:	9. Source receipt Receipt date: Received from: Name: Address: Country: Manufacturer <input type="checkbox"/> Supplier <input type="checkbox"/> Other <input type="checkbox"/>	Date: Date: Date: Date: Date: Date: Date: Date: Date:
Physical and chemical properties: Information about source type: Information about source capsule: ISO classification: ANSI classification:	10. Source transfer Transfer date: Transferred to: Name: Address: Country: Manufacturer <input type="checkbox"/> Supplier <input type="checkbox"/> Other <input type="checkbox"/> Licensed device/installation/system:	11. Additional information: Source loss: <input type="checkbox"/> Loss date:  Date:  Place:  Other information:

STANDARD TABLE FOR UNEALED SOURCES														
№	INCOMING							SPENT				RESIDUE		NOTE
	Supplier name	No and date of delivery document	Name of the source/device/aparatus/installation	SOURCE				Transferred to	No and date of request	Quantity	Activity at the delivery date	Quantity	Activity at date delivered to storage facility	Return, inventory and disposal, pointing to proof documents
				Certificate number and date	Quantity and specific activity	Activity according to certificate	Source control							
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15

Note. The tables shall be filled for each source individually. Tables filled with data shall be collected and archived in the logbook at the site.

**Annex No. 5 to Article 127, paragraph (1)**

Approved:

(signature of the manager of the organisation)

**Request for issuance of sources of ionising radiation**

This is a request for the issuance for the purpose of the following activity:

.....  
.....

(the particular work is described)

Of the following sources of ionising radiation:

Applied for			Actual supply			
Names of the sources of ionising radiation	Quantity	Total activity	Quantity	Activity		No. and date of the passport No. of the source Batch No.
				On the passport	On the day of handover of the source of ionising radiation	
1	2	3	4	5	6	7

Person issuing the application:

.....

.....

..

(name, surname, family name)

.....

..

(laboratory, department, workshop, etc.)

Date:

.....

Receiver:

(signature)

.....

..

(name, surname, family name)

Person issuing the source: The person responsible for the sources of ionising radiation at the site

.....

..

(name, surname, family name)

.....

(name of the organisation)

(signature)

Note: The application shall be compiled in two copies. The first one shall be kept by the person responsible for the sources of ionising radiation at the respective site and the second one – by the person, who has received the radioactive substance.

**Annex No. 6 to Article 127, paragraph (3)**

Approved:.....

(signature of the manager of the organisation)

**Act on spending of radioactive substances**.....  
(name of the organisation)

The act has been prepared by: .....

(name, surname, family name of the respective members of the staff)

And the supervisor of the activity .....

(name, surname, family name)

In confirmation that with application No. .... /date .....

The source of ionising radiation: .....

(name, No. of the source or batch No., number and date of the passport)

In quantity ..... with specific activity .....

And total activity .....

Measured on date ..... hour ..... minutes .....

Has been used (spent) for: .....

(brief description of the work done)

The work has been performed by: .....

(names, surnames, family names of the respective members of the personnel)

In the work process .....

(brief description of the way of using of the corresponding source of ionising radiation)

Waste in the form of: .....

Has been handed over for storage with document No. .... date .....

The remaining part of the used source of ionising radiation ..... in quantity .....

With total activity ..... has been returned to the storage facility on date .....

Work manager: .....

(signature)

Members of the staff: 1. .... 2. .... 3. ....

(signatures)

Person responsible for SIR at the facility: .....

(name, surname, family name)

Date: .....  
.....

(signature)

## Annex No 7 to Article 35, Paragraph 2

Categorisation of radioactive sources depending on the risk related to the corresponding activities

Category	Sources of ionising radiation or activities with them	A/D
1	Teletherapy units Gamma irradiators for industrial or scientific applications Radioactive thermoelectric generators Others	$A/D \geq 1000$
2	Gamma radiography devices for industrial radiography Brachytherapy installations Others	$1000 > A/D \geq 10$
3	Fixed industrial gauges (level gauges , etc.) Logging moisture gauges Others	$10 > A/D \geq 1$
4	Fixed and portable industrial gauges (thickness, level, moisture, density gauges, etc) Low dose brachytherapy installations Static eliminators Bone densitometers Others	$1 > A/D \geq 0,01$
5	X-ray fluorescent devices Fire alarms Mosbauer spectrometry units Tritium targets Others	$0,01 > A/D$

Note. The values of D, and the methods of calculation are given in the regulation under Art. 123 ASUNE.

Activity values for specific radionuclides, above which sealed sources are classified as high activity sources

Radionuclide	Activity (TBq)
Am-241	$6 \times 10^{(-2)}$
Am-241/Be	$6 \times 10^{(-2)}$
Cf-252	$2 \times 10^{(-2)}$
Cm-244	$5 \times 10^{(-2)}$
Co-60	$3 \times 10^{(-2)}$
Cs-137	$1 \times 10^{(-1)}$
Gd-153	$1 \times 10^{(0)}$
Ir-192	$8 \times 10^{(-2)}$
Pm-147	$4 \times 10^{(1)}$
Pu-238	$6 \times 10^{(-2)}$
Pu-239/Be	$6 \times 10^{(-2)}$
Ra-226	$4 \times 10^{(-2)}$
Se-75	$2 \times 10^{(-1)}$
Sr-90 (Y-90)	$1 \times 10^{(0)}$
Tm-170	$2 \times 10^{(1)}$
Yb-169	$3 \times 10^{(-1)}$

Notes:

1. For radionuclides not listed in the table, the activities are equal to the quantity D defined in Annex № 1 to the Regulation on emergency planning and emergency preparedness for nuclear and radiological emergency, approved by Decree № 313 of the Council of Ministers in 2011 (SG. 94 of 2011).
2. For neutron sources and Pu-239/Be Am-241/Be the values refers to the activity for the alpha emitter.

**Example content of instruction on radiation protection in facilities with SIR**

1. General (purpose and scope of these instructions).
2. Allocation of responsibilities for radiation protection at the object with SIR.
3. Main features and characteristics of used and stored SIR:
  - a) for sites with sealed sources:
    - Categorization of sources and the corresponding activities;
    - Type and number of sources, single and total activity of contained radionuclides;
  - b) sites with unsealed sources:
    - Type and number of sources, single and total activity of radionuclides, maximum working activity, annual consumption;
    - Type and class work with unsealed sources;
  - c) sites with radiation generators:
    - Type and number of generators of ionizing radiation;
    - Voltage and anode current (maximum values and work), radiation rate of X-ray tubes.
4. Determination of the controlled area and supervised area (serviced, semi-serviced and non-serviced areas and location scheme).
5. Determination of dose quotas and control levels.
6. Determination of specific technical and organizational means for radiation protection at the site.
7. Personal protective means when working with SIR (type, number, function, internal rules for their use).
8. Record keeping and control of sealed and unsealed sources and providing physical protection;
9. Accounting and control of radioactive waste generated when working with unsealed sources.
10. Internal administrative control over compliance with the requirements and rules for radiation protection at the facility, specialized training and medical surveillance of staff.

Note: The instruction for radiation protection shall be approved by the enterprise manager and shall be periodically updated. The enterprise manager shall notify NRA when the instruction is amended.

## Annex No 10 to Article 30, Paragraph (1), point 3

**Example content of an internal emergency plan for facilities with SIR**

1. General (purpose and scope of the emergency plan).
  2. Risk category of the site with SIR (according to the Regulation on emergency planning and emergency preparedness in case of nuclear and radiological emergency, approved by Decree № 313 of the Council of Ministers in 2011 (SG. 94 of 2011):
    - a) sites for use or storage of gamma irradiators or other radioactive sources of category 1, belong to the risk category III;
    - b) sites for use or storage of gamma radiography devices, industrial gauges with built in sources or other radioactive sources in Categories 2 or 3 fall into the risk category IV;
    - c) transportation of radioactive material belongs to the risk category IV;
    - d) sites and activities that are not directly related to radioactive sources, such as border crossings, airports, ports and enterprises for scrap metal processing and melting fall into a risk category V;
    - e) facilities and activities with radiation generators are assigned to risk category V.
  3. Description of possible scenarios for the occurrence and development of an emergency involving radioactive sources.
  4. Criteria for the invocation of the emergency plan into action and termination of its execution.
  5. Emergency team staff, duties and responsibilities of the, means for radiation monitoring personal dosimetry, personal protection and communication means provided in case of emergency or other extraordinary event in the site with SIR.
  6. Procedures for notifying and responding to an incident or accident involving SIR, industrial accidents, fire, explosion, natural disaster or other extraordinary events related to the safety of the site.
  7. Procedures for recording and reporting of extraordinary events and for requesting external assistance for the liquidation of the radiological consequences.
  8. Maintaining emergency preparedness and training and exercise of staff to implement the emergency plan, updated phone numbers and addresses to notify the NRA, other specialized control bodies and other agencies in case of extraordinary events.
- Note: For sites of risk category V emergency plan should contain items 1-4 as well as:
- a) responsible for notification of an accident or other emergency event at the site;
  - b) updated phone numbers and addresses to notify the NRA, other specialized control bodies and other agencies in case of extraordinary events;
  - c) procedures for response and request for external assistance in case of emergency or other extraordinary event at the site.