

# **LAW ON RADIATION AND NUCLEAR SAFETY AND SECURITY**

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## **I GENERAL PROVISIONS**

### ***Subject Matter***

#### **Article 1**

The Law on Radiation and Nuclear Safety and Security (hereinafter: the Law) regulates the measures of radiation and nuclear safety and security, conditions for conducting practices with radiation sources, response in case of planned, existing and emergency exposure to ionising radiation, and aims at ensuring proper protection of members of the public, the public and the environment from the harmful effect of ionising radiation, now and in the future.

The Law provides for the establishment of Serbian Radiation and Nuclear Safety and Security Directorate (hereinafter: the Directorate) with the aim of exercising regulatory control over the practices regulated by the Law.

### ***Scope***

#### **Article 2**

The Law shall apply to all practices involving peaceful use of nuclear energy and ionizing radiation conducted in the territory or under the jurisdiction or control of the Republic of Serbia.

The Law shall apply to any planned, existing or emergency exposure situations involving the risk of exposure to ionising radiation that cannot be disregarded from a radiation protection of a member of the public, the public and the environment point of view. The Law shall apply in particular to:

- 1) manufacture, production, processing, handling, disposal, use, storage, holding, transport, and trade of radioactive material in the Republic of Serbia;
- 2) siting, designing, construction, trial run, operation and decommissioning of nuclear facilities, and closure of radioactive waste disposal facilities;
- 3) manufacture and operation of electrical equipment emitting ionising radiation and containing components operating at a potential difference of more than 5 kilovolt (kV);
- 4) human activities involving the presence of natural radiation sources resulting in a significant increase in the exposure of workers or other members of the public, in cases of:
  - (1) the operation of aircraft, in view of the exposure of crews;
  - (2) the processing of materials with naturally-occurring radionuclides;
- 5) exposure of workers or other individuals to indoor radon, external exposure to ionizing radiation from building materials, and exposure resulting from an emergency or a past human activity;

6) preparedness for, response plan, and management in case of emergency exposure situations and nuclear and radiological emergencies that are deemed to warrant health protection measures of the workers and other members of the public.

### ***Exclusions from the Scope***

#### **Article 3**

The Law shall not apply to:

- 1) Exposure to the natural background level of radiation, such as radionuclides contained in human body and cosmic radiation prevailing at ground level;
- 2) Exposure of workers or other individuals other than aircraft crew to cosmic radiation in flight or in space;
- 3) Above ground exposure to radionuclides present in the undisturbed crust of the earth.

### ***Prohibited Activities***

#### **Article 4**

The use of nuclear energy and ionizing radiation in the Republic of Serbia other than for peaceful purposes shall be prohibited.

Practice performance without previously obtained authorization issued by the Directorate shall be prohibited.

Trade in and transport of radiation sources in the Republic of Serbia, without previously obtained authorization and permit issued by the Directorate, shall be prohibited.

All activities and practices relating to the acquisition or development of nuclear weapons, radioactive dispersal devices, or other non-peaceful uses of nuclear or other radioactive materials and related technologies that are used for the production of weapons for mass destruction as well as assisting the others in such activities shall be prohibited.

Imports of radioactive waste and spent nuclear fuel of foreign origin into the territory of the Republic of Serbia shall be prohibited.

Installation and use of radioactive lightning rods in the territory of the Republic of Serbia shall be prohibited.

Installation and use of ionising smoke detectors containing an ionising radiation source in gaseous state or an ionising radiation source whose decay products are in gaseous state shall be prohibited.

Any instance of deliberate use of radioactive substances in the production of foodstuffs, animal feeding stuffs, cosmetics, toys and personal ornaments, and the import or export of such products shall be prohibited.

Any instance of making available to the public of consumer products containing radionuclides if their intended use is not justified or does not fulfil the criteria for the exemption from mandatory notification, shall be prohibited.

Deliberate dilution of radioactive materials in order to fulfil the criteria for the release from regulatory control shall be prohibited.

The prohibited activity under paragraph 10 hereof shall not apply to the instance of mixing of such materials that takes place in the process of production where radioactivity is not a consideration.

Any activation of materials used in toys and personal ornaments, which at the time of the placing on the market or manufacturing results in an increase in activity that cannot be disregarded from a radiation protection point of view, as well as the import or export of such products or materials, shall be prohibited.

Practices involving the use of sealed radiation sources or their containers which are mechanically damaged, might be leaking or otherwise broken, shall be prohibited.

Deliberate dilution of radioactive waste in order to fulfil the criteria for the release from regulatory control shall be prohibited.

Placement of radioactivity markings on any object or location without radiation sources shall be prohibited.

Performance of all practices proscribed by other special laws shall be prohibited.

## ***Definitions***

### **Article 5**

For the purpose of this Law the following definitions shall apply:

- 1) *Activation* means a process through which a stable nuclide is transformed into a radionuclide by irradiating with particles or high-energy photons the material in which it is contained;
- 2) *Activity (A)* is the activity of an amount of a radionuclide in a particular energy state at a given time. It is the quotient of  $dN$  by  $dt$ , where  $dN$  is the expectation value of the number of nuclear transitions from that energy state in the time interval  $dt$ :  $A = \frac{dN}{dt}$   
The unit of activity is the Becquerel (Bq);
- 3) *Absorbed dose (D)* is the energy absorbed per unit mass. The unit for absorbed dose is the Gray (Gy) where one Gray is equal to one joule per kilogram;
- 4) *Security event* is any event resulting from unlawful or malicious act directed at and involving radiation sources and associated facilities and that has potential or actual implications for radiation and nuclear safety and security;
- 5) *Emergency event* means a non-routine situation or event involving a radiation source that necessitates prompt action to mitigate serious adverse consequences for human health and safety, quality of life, property or the environment, or a hazard that could give rise to such serious adverse consequences;
- 6) *Design basis accident* means accident conditions against which a nuclear installation is designed according to established design criteria, and for which the

damage to the fuel, where applicable, and the release of radioactive material are kept within authorized limits;

- 7) *High-activity sealed source* means a sealed source for which the activity of the contained radionuclide is equal to or exceeds the relevant activity value prescribed by the Directorate;
- 8) *Radiation generator* means a device capable of generating ionising radiation, such as X-rays, neutrons, electrons or other charged particles;
- 9) *Building material* means any construction product for incorporation in a permanent manner in a building or parts thereof and the performance of which has an effect on the performance of the building with regard to exposure of its occupants to ionising radiation;
- 10) *Exposure limit* means the value of the effective dose (where applicable, committed effective dose) or the equivalent dose in a specified period which shall not be exceeded for an individual;
- 11) *Decommissioning* means administrative and technical actions taken to allow the removal of some or all of the regulatory controls from a facility;
- 12) *Decontamination* is a procedure for removal or reduction of contamination, including the measures for removal of immediate risk of contamination, measures for control of further spread of contamination, isolation and safe removal of sources of contamination, as well as actions related to the assessment of risk for contamination and analysis of environmental damage due to contamination;
- 13) *Practice* means a human activity that can increase the exposure of individuals to radiation from a radiation source and is managed as a planned exposure situation;
- 14) *Diagnostic reference levels* means dose levels in medical radiodiagnostic or interventional radiology practices, or, in the case of radio-pharmaceuticals, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment;
- 15) *Event* means any unintended event caused by human errors, equipment failures, structures, systems and components failures, procedure deviation, normal operation deviation and a security event;
- 16) *Permit* means document issued by the Directorate for individual trade or transport of one or more than one radiation sources;
- 17) *Equivalent dose* is the absorbed dose, in tissue or organ weighted for the type and quality of radiation;
- 18) *Effective dose* is the sum of the weighted equivalent doses in all the tissues and organs of the body from internal and external exposure;
- 19) *Interested party* is a person or organization that can affect, be affected by, or perceive itself to be affected by, a decision or activity;
- 20) *Radioactive waste disposal facility closure* means the completion of all operations at some time after the emplacement of spent fuel or radioactive waste

in a disposal facility, including the final engineering or other work required to bring the facility to a condition that will be safe in the long term; 21) *Sealed source* means a radioactive source in which the radioactive material is permanently sealed in a capsule or incorporated in a solid form with the objective of preventing, under normal conditions of use, any dispersion of radioactive substances;

- 22) *Ionising radiation protection* means legislative, technical, engineering, building norms, rules and measures, hygienic norms, rules and measures of occupational safety and rules and measures of environmental protection guaranteeing protection of the people and environment from the harmful effect of ionising radiation;
- 23) *Health screening* means a procedure using medical radiological installations for early diagnosis in population groups at risk;
- 24) *Export* means physical transfer, sending or delivery of radiation sources from the territory of the Republic of Serbia into the territory or customs zone of another country in accordance with the custom procedures of the Republic of Serbia;
- 25) *Radiation source* means an entity that may cause exposure, such as by emitting ionising radiation or by releasing radioactive material;
- 26) *Nuclear facility construction* is the process of constructing, manufacturing and assembling the structures, systems and components of a facility which includes carrying out of civil works, the installation of components and equipment, construction of a mobile unit and the performance of associated tests;
- 27) *Exposure* means the act of exposing or condition of being exposed to ionising radiation emitted outside the body (external exposure) or within the body (internal exposure);
- 28) *Exposure to radon* means exposure to radon progeny;
- 29) *Public exposure* means exposure of individuals, excluding any occupational or medical exposure;
- 30) *Exposed worker* means a person, either self-employed or working under an employer, who is subject to exposure at work carried out within a practice and who is liable to receive doses exceeding one or other of the dose limits for public exposure;
- 31) *Integrated system of management* is a set of interconnected or inter-affected elements within an organization for establishment of policies and objectives and processes for their achievement which integrates all its elements, including safety, health, environment, quality, human-and-organizational-factor, societal and economic elements, so that safety is not compromised.
- 32) *Interventional radiology* means the use of X-ray imaging techniques to facilitate the introduction and guidance of devices in the body for diagnostic or treatment purposes;

- 33) *Disused source* means a sealed source which is no longer used or intended to be used for the practice for which authorization was granted but continues to require safe management;
- 34) *Discharge* means planned and controlled release into the environment, as a legitimate practice, within the limits authorized by the Directorate, of liquid or gaseous radioactive material that originates from regulated nuclear facilities during normal operation;
- 35) *Spent nuclear fuel reprocessing* means a process or operation, the purpose of which is to extract fissile and fertile materials from spent fuel for further use;
- 36) *Ionising radiation* means energy transferred in the form of particles or electromagnetic waves of a wavelength of 100 nanometres or less (a frequency of  $3 \times 10^{15}$  hertz or more) capable of producing ions directly or indirectly;
- 37) *Contamination* means the unintended or undesirable presence of radioactive substances on surfaces or within solids, liquids or gases or on the human body;
- 38) *Source container* means an assembly of components intended to guarantee the containment of a sealed source, where it is not an integral part of the source but is meant for shielding the source during its transport and handling;
- 39) *Quality control* means the set of operations (programming, coordinating, implementing) intended to maintain or to improve quality. It includes monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled;
- 40) *Controlled area* means an area subject to special rules for the purpose of protection against ionising radiation or preventing the spread of radioactive contamination and to which access is controlled;
- 41) *Referrer* means a medical doctor, dentist or other health professional who is entitled to refer individuals for medical radiological procedures to a practitioner, in accordance with national requirements;
- 42) *Apprentice* means a person receiving training or instruction within an undertaking with a view to exercising a specific skill;
- 43) *Radiation protection officer* means an individual who is technically competent in radiation protection matters relevant for a given type of practice to supervise or perform the implementation of the radiation protection arrangements;
- 44) *License* means permission granted in a document by the competent authority to carry out a practice in accordance with specific conditions laid down in that document;
- 45) *Nuclear facility site* means restricted area where a nuclear facility is situated, approved by the government, directly connected with the facility, including all other supplementary facilities that the licensee is primarily responsible for;
- 46) *Material out of regulatory control* refers to the absence of the direct control over material by an authorized person that is or would be mandated by regulatory control for such material. Material might therefore be designated as out of regulatory control even when some aspects of regulatory control are in place;

- 47) *Medical radiological procedure* means any procedure giving rise to medical exposure;
- 48) *Medical physicist* is an employee in clinical surroundings having at least three years of specialized education and training, competent to work independently in an area of medical radiation sources application, namely radiotherapy, nuclear medicine and diagnostic radiology;
- 49) *Medical exposure* means exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health, as well as exposure incurred by carers and comforters and by volunteers in medical or biomedical research;
- 50) *International standard* means standard by international organizations and associations in the area of radiation and nuclear safety and security;
- 51) *Protective measures* mean measures, other than remedial measures, for the purpose of avoiding or reducing doses that might otherwise be received in an emergency exposure situation or an existing exposure situation;
- 52) *Remedial measures* means the removal of a radiation source or the reduction of its magnitude (in terms of activity or amount) or the interruption of exposure pathways or the reduction of their impact for the purposes of avoiding or reducing doses that might otherwise be received in an existing exposure situation;
- 53) *Physical protection measures* mean measures, human resources, technical means and protective structures used for preventing security event;
- 54) *Mobile radioactive waste processing unit* means an on-site mobile facility for classification and processing of radioactive waste, not permanently attached to the ground or a facility that can be relocated, including a mobile unit for remedial measures;
- 55) *Potential exposure* means exposure that is not expected with certainty but may result from an event or sequence of events of a probabilistic nature, including equipment failures and operating errors;
- 56) *Environmental radioactivity monitoring* means the measurement of external dose rates due to radioactive substances in the environment or of concentrations of radionuclides in environmental media;
- 57) *Supervised area* means an area subject to supervision for the purpose of protection against ionising radiation;
- 58) *Orphan source* means a radioactive source which is neither exempted nor under regulatory control, e.g. because it has never been under regulatory control or because it has been abandoned, lost, misplaced, stolen or otherwise transferred without proper authorization;
- 59) *Carers and comforters* means individuals knowingly and willingly incurring an exposure to ionising radiation by helping, other than as part of their occupation, in the support and comfort of individuals undergoing or having undergone medical exposure;

- 60) *Non-medical imaging exposure* means any deliberate exposure of humans for imaging purposes where the primary intention of the exposure is not to bring a health benefit to the individual being exposed;
- 61) *Unintended exposure* means medical exposure that is significantly different from the medical exposure intended for a given purpose;
- 62) *Exemption level* means a value established by a competent authority or in legislation and expressed in terms of activity concentration or total activity at or below which a radiation source is not subject to notification or authorization;
- 63) *Clearance levels* mean values established by the competent authority or in national legislation, and expressed in terms of activity concentrations, at or below which materials arising from any practice subject to notification or authorization may be released from further regulatory control;
- 64) *Normal exposure* means exposure expected to occur under the normal operating conditions of a facility or activity (including maintenance, inspection, decommissioning), including minor incidents that can be kept under control, i.e. during normal operation and anticipated operational occurrences;
- 65) *Licensee* means a legal or natural person having overall responsibility for any activity or facility related to the management of spent fuel or radioactive waste as specified in a license;
- 66) *Approval holder* is a legal entity with the approval to conduct the ionising radiation protection measures;
- 67) *Authorization holder* is a legal entity or an entrepreneur who is a holder of a registration or a license;
- 68) *Registrant* is a legal entity or an entrepreneur to whom a decision on performing low-risk radiation practice has been issued;
- 69) *Nuclear or radiological emergency management system* means legislative or administrative framework serving to determine competences and preparedness for;
- 70) *Nuclear safety* means the achievement of proper operating conditions, prevention of accidents and mitigation of accident consequences, resulting in protection of workers and the general public from dangers arising from ionizing radiations from nuclear installations;
- 71) *Nuclear activities* are phases of a lifetime of nuclear facility namely: siting, design, construction, trial run or commissioning, operation, decommissioning (other than for disposal facility) or closure (other than for disposal facility) of nuclear facilities and remediation of their sites;
- 72) *Nuclear material* is a source material and special fissionable material;
- 73) *Nuclear facility* means a facility or several of nuclear facilities when they are functionally linked in the same geographically confined territory facility and managed by the same person for processing or for enrichment of nuclear materials or for production of nuclear fuel, a research reactor, a nuclear power



plant and heating plant, a facility for nuclear fuel management or radioactive waste management;

- 74) *Radioactive waste processing* means chemical or physical operations on radioactive material to benefit safety and/or economy by changing the characteristics of the waste by volume reduction, removal of radionuclides from the waste and change of composition;
- 75) *Dose constraint* means a constraint set as a prospective upper bound of individual doses, used to define the range of options considered in the process of optimization for a given radiation source in a planned exposure situation;
- 76) *Practitioner* means a medical doctor, dentist or other health professional who is entitled to take clinical responsibility for an individual medical exposure in accordance with national requirements;
- 77) *Disposal* means the emplacement of spent fuel or radioactive waste in a facility without the intention of retrieval; means the emplacement of spent fuel or radioactive waste in a facility without the intention of retrieval;
- 78) *Authorization* means the registration or licensing of a practice;
- 79) *Nuclear facility siting* means all activities taken to determine the site suitable for nuclear facility construction including preparation of relevant assessments, conceptual design, identification of possible sites and final selection of the site suitable for nuclear facility construction from the aspect of radiation and nuclear safety and security and other factors that can affect the final selection;
- 80) *Abnormal operations* means an operational process deviating from normal operation which is expected to occur at least once during the operating lifetime of a facility but which, in view of appropriate design provisions, does not cause any significant damage to items important to safety or lead to accident conditions; means an operational process deviating from normal operation which is expected to occur at least once during the operating lifetime of a facility but which, in view of appropriate design provisions, does not cause any significant damage to items important to safety or lead to accident conditions;
- 81) *Quality assurance* means all those planned and systematic actions necessary to provide adequate assurance that a structure, system, component or procedure will perform satisfactorily in compliance with agreed standards. Quality control is a part of quality assurance;
- 82) *Nuclear or radiological emergency response plan* is a document outlining all activities that need to be taken before, during and after a nuclear and radiological emergency in order to respond to the situation of emergency exposure adequately;

- 83) *Security plan* means an approved document that defines the scope, objectives and security measures for radiation sources and associated facilities based on risk assessment.
- 84) *Associated facilities* mean facilities (including associated buildings and equipment) in which nuclear material or other radioactive material is produced, processed, used, handled, stored or disposed of and for which an authorization is required. This includes nuclear facilities and any other facilities holding significant amounts of radioactive material.
- 85) *Associated activities* mean the possession, production, processing, use, handling, storage, disposal or transport of nuclear material or other radioactive material;
- 86) *Facilities mean radiation and nuclear facilities;*
- 87) *Disposal facility* means any facility or installation the primary purpose of which is radioactive waste disposal;
- 88) *Spent fuel management facility* means any facility or installation the primary purpose of which is spent fuel management;
- 89) *Radioactive waste management facility* means any facility or installation the primary purpose of which is radioactive waste management;
- 90) *Record entry certificate* is a written document issued by the Directorate to legal entities or entrepreneurs performing the practice not requiring authorization;
- 91) *Consumer product* means a device or manufactured item into which one or more radionuclides have deliberately been incorporated or produced by activation, or which generates ionising radiation, and which can be sold or made available to members of the public without special surveillance or regulatory control after sale;
- 92) *Spent nuclear fuel reprocessing* means a process or operation, the purpose of which is to extract fissile and fertile materials from spent fuel for further use;
- 93) *Radioactive material reprocessing* means chemical or physical operations on radioactive material including the source recycling, mining, conversion, enrichment of fissile or fertile nuclear material and the reprocessing of spent fuel;
- 94) *Temporary radioactive waste storing* means approved temporary placement of radioactive waste into a dedicated repository until its transfer for storage treatment and disposal;
- 95) *Notification* means submission of information to the competent authority to notify the intention to carry out a practice;
- 96) *Non-nuclear use of nuclear material* means the use of nuclear material in activities not comprising nuclear fuel cycle where nuclear material issued for the achievement of critical mass or maintenance of fission reaction;

- 97) *Naturally occurring radioactive material (NORM)* means radioactive material containing no significant amounts of radionuclides other than naturally occurring radionuclides;
- 98) *Design basis* means the range of conditions and events taken explicitly into account in the design, including upgrades, of a nuclear installation, according to established criteria, so that the installation can withstand them without exceeding authorized limits by the planned operation of safety systems;
- 99) *Trade in radiation sources* is a set of basic and supplementary business activities pertaining to import, export and transit of radiation sources;
- 100) *Occupational exposure* means exposure of workers, apprentices and students, incurred in the course of their work;
- 101) *Nuclear or radiological emergency occupational exposure* means exposure received in an emergency exposure situation by an emergency worker;
- 102) *Design basis threat* is the document determining and describing potential insider and external adversaries against nuclear material or radioactive material and associated facilities and practices, including the transport of material, and their characteristics based on which protection systems are designed and evaluated;
- 103) *Radiation and nuclear security* means prevention, detection and response to instances of theft, sabotage, unauthorized access, illegal transport, abuse or any other criminal offences that include nuclear or radioactive material and their associated facilities and practices;
- 104) *Radiation facility* means a facility where one or several radiation sources is located, whose irradiation risk is such that it may cause the occupational and public exposure above the prescribed limits;
- 105) *Radiation safety* means a set of prescribed organizational and technical-technological measures providing the optimal planned exposure and optimal risk of potential exposure to ionising radiation, which is the consequence of using radiation sources, including radiation protection measures, accident prevention measures, as well as measures for remediation of accident consequences, if any;
- 106) *Radiation risk* means hazard to human health resulting from the exposure to ionising radiation or any other risk directly stemming from exposure to ionising radiation or presence of radioactive substances;
- 107) *Radioactive substance* means any substance that contains one or more radionuclides the activity or activity concentration of which cannot be disregarded from a radiation protection point of view;
- 108) *Radioactive source* means a radiation source incorporating radioactive material for the purpose of utilizing its radioactivity;
- 109) *Radioactive material* means material incorporating radioactive substances;
- 110) *Radioactive waste* means radioactive material in gaseous, liquid or solid form for which no further use is foreseen or considered;

- 111) *Radiodiagnostic* means pertaining to in-vivo diagnostic nuclear medicine, medical diagnostic radiology using ionising radiation, and dental radiology;
- 112) *Nuclear or radiological emergency worker* means any person having a defined role in an emergency and who might be exposed to radiation while taking action in response to the emergency;
- 113) *Radon* means the radionuclide Rn-222 and its progeny, as appropriate;
- 114) *Registration* means permission granted in a document by the competent authority, or granted by national legislation, through a simplified procedure, to carry out a practice in accordance with conditions laid down in national legislation or specified by a competent authority for this type or class of practice;
- 115) *Regulatory control* means any form of control or regulation applied by the Directorate pursuant to this Law pertaining to practice performance, ionizing radiation protection, and radiation and nuclear safety and security;
- 116) *Representative person* means an individual receiving a dose that is representative of the more highly exposed individuals in the population, excluding those individuals having extreme or rare habits;
- 117) *Reference level* means in an emergency exposure situation or in an existing exposure situation, the level of effective dose or equivalent dose or activity concentration above which it is judged inappropriate to allow exposures to occur as a result of that exposure situation, even though it is not a limit that may not be exceeded;
- 118) *Sabotage* means any deliberate act directed against a nuclear facility or nuclear material in use, storage or transport which could directly or indirectly endanger the health and safety of personnel, the public or the environment by exposure to radiation or release of radioactive substances;
- 119) *Nuclear or radiological emergency management system* means legislative or administrative framework serving to determine competences and preparedness for;
- 120) *Emergency exposure situation* means any exposure resulting from nuclear or radiological emergency;
- 121) *Planned exposure situation* means an exposure situation that arises from the planned operation of a radiation source or from a human activity which alters exposure pathways, so as to cause the exposure or potential;
- 122) *Existing exposure situation* means an exposure situation that already exists when a decision on its control has to be taken and which does not call or no longer calls for urgent measures to be taken;
- 123) *Storage* is a radioactive waste, disused source or spent nuclear fuel storage facility with the intention of its retrieval for treatment, processing, disposal, release from regulatory control, export, recycling and reuse within authorized practice;

- 124) *Storing* means the holding of radioactive material, including spent fuel, a radioactive source or radioactive waste, in a facility with the intention of retrieval;
- 125) *Dosimetry service* means a body or an individual competent to calibrate, read or interpret individual monitoring devices, or to measure radioactivity in the human body or in biological samples, or to assess doses, whose capacity to act in this respect is recognized by the Directorate;
- 126) *Occupational health service* means a health professional or body competent to perform medical surveillance of exposed workers and whose capacity to act in that respect is recognized by the competent authority;
- 127) *Outside worker* means any exposed worker who is not employed by the undertaking responsible for the supervised and controlled areas, but performs activities in those areas, including, apprentices and students;
- 128) *Repository* is a facility or a room dedicated by the authorization holder and intended for temporary holding of radioactive waste, disused sources or spent nuclear fuel;
- 129) *Structures, systems and components* are all elements of a facility contributing to its safety, apart from human factors, where the structures are all passive elements, systems are sets of components assembled in a way to perform certain function, and components are individual elements within a system;
- 130) *Radiation protection expert* means an individual or, if provided for in the national legislation, a group of individuals having the knowledge, training and experience needed to give radiation protection advice in order to ensure the effective protection of individuals, and whose competence in this respect is recognized by the competent authority;
- 131) *Medical physics expert* means an individual or, if provided for in national legislation, a group of individuals, having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure, whose competence in this respect is recognized by the agency;
- 132) *Severe conditions* means conditions that are more severe than conditions related to design basis accidents; such conditions may be caused by multiple failures, such as the complete loss of all trains of a safety system, or by an extremely unlikely event;
- 133) *Transit* means carrying radiation sources through customs territory of the Republic of Serbia, in accordance with customs regulations of the Republic of Serbia;
- 134) *Import* means physical transfer, delivery or shipment of radiation sources from the territory of another state into the territory of the Republic of Serbia, in accordance with customs regulations of the Republic of Serbia;

- 135) *Spent nuclear fuel management* means all activities that relate to the handling, storage, reprocessing, or disposal of spent fuel, excluding off-site transportation;
- 136) *Radioactive waste management* means all activities that relate to handling, pre-treatment, treatment, conditioning, storage, or disposal of radioactive waste, excluding off-site transportation;
- 137) *Uranium enriched in the isotopes 235 or 233* means uranium containing the isotopes 235 or 233 or both in an amount such that the abundance ratio of the sum of these isotopes to the isotope 238 is greater than the ratio of the isotope 235 to the isotope 238 occurring in nature;
- 138) *Central storage* means a storage of radioactive waste, disused sources or spent nuclear fuel generated in the territory of the Republic of Serbia and for the need of the entire territory of the Republic of Serbia.

## II RADIATION AND NUCLEAR SAFETY AND SECURITY STRATEGIES

### ***Types of Strategies***

#### **Article 6**

In order to provide for the implementation of the policies in the area of radiation and nuclear safety and security and the policies of spent fuel and radioactive waste management in the Republic of Serbia, the following strategic documents shall be passed:

- 1) Radiation and Nuclear Safety Strategy,
- 2) Spent Fuel and Radioactive Waste Management Strategy;
- 3) Radiation and Nuclear Security Strategy;
- 4) Existing Exposure Situation Management Strategy.

The Strategies under paragraph 1 hereof determine long-term strategic direction and policies in the area of radiation and nuclear safety and security, and determine the measures to enhance spent nuclear fuel and radioactive waste management commensurate with the international standards and principles in this area as well as assumed international commitments.

The Government shall pass the Strategies under paragraph 1 hereof for the period of seven years.

The Directorate, in cooperation with the ministries responsible for environmental protection, health, science, defense, emergency situations and other interested bodies and organizations, shall prepare and propose the Strategies under paragraph 1 hereof.

The Strategies shall be published in the *Official Gazette of the Republic of Serbia*.

The Directorate shall prepare and submit to the Government, at least once a year, the report on the implementation of the Strategies.

## ***The Content of Strategies***

### **Article 7**

The Strategies under Article 6 hereof shall include:

- 1) envisioned or desired state the accomplishment of which is facilitated by the achievement of general and particular goals;
- 2) analysis and assessment of the existing state;
- 3) general and particular goals and clear timeframes for their achievement;
- 4) measures to be taken to achieve general and particular goals;
- 5) key performance indicators;
- 6) institutional framework, implementation monitoring plan and referral of the institutions responsible for strategy implementation;
- 7) action plans for strategy implementation.

### ***Action Plans***

#### **Article 8**

The integral part of the Strategies under Article 6 hereof are Action plans for the implementation thereof.

Action plans shall include measures for the achievement of general and particular goals defined by the strategy.

The Directorate shall periodically revise and propose to the Government amendments of the Action plans under paragraph 1 hereof, having regard to the developments in the area of science and engineering, as well as recommendations, experience, and lessons learned from the relevant reviews, assessments and analyses prescribed by the international conventions or other legal instruments the Republic of Serbia joined or adheres to.

The Directorate shall initiate research and development-related activities, both to implement the Action plans under paragraph 1 hereof, and acquire, maintain and further develop the required knowledge and skills.

## ***Radiation and Nuclear Safety Strategy***

### **Article 9**

The Radiation and Nuclear Safety Strategy shall be passed in order to achieve the fundamental principles of radiation and nuclear safety, as well as fundamental and particular goals of radiation and nuclear safety pursuant to this Law.

In the area of radiation safety, the Strategy defines the course of development and the focus of the activities of the relevant institutions in the area of ionizing radiation protection for the purpose of establishing, maintaining and improving ionizing radiation protection system.

This Strategy shall define the manner of implementing nuclear safety measure aimed at responsible and safe nuclear facility management.

The Radiation and Nuclear Safety Strategy shall include:

- 1) general and particular goals of radiation and nuclear safety and clear milestones and timeframes for their achievement;
- 2) international agreements and treaties concluded with other states in the area of radiation and nuclear safety, if any;
- 3) legal, regulatory and institutional framework ensuring radiation and nuclear safety;
- 4) need and provision for human and financial resources;
- 5) research and development- related activities necessary for maintaining and enhancing the standard of radiation and nuclear safety;
- 6) social and economic elements;
- 7) adequate mechanisms for the establishment of safety culture;
- 8) improvement of the overall level of radiation protection by preserving the existing mechanisms in the area and by introducing specific activities such as dose assessment for the population of the Republic of Serbia, the assessment of the possible effects of ionising radiation, and the identification of measures necessary to optimize the radiation protection in a number of areas;
- 9) identification of potential radiation sources outside regulatory control and mechanism for their introduction into regulatory control;
- 10) better awareness of the identification, prompt establishment or re-establishment of control over orphan sources;
- 11) identification of the existing nuclear facilities in the Republic of Serbia, together with the characteristics thereof, current life-cycle phase, current and intended use and future plans;
- 12) decommissioning plans for radiation and nuclear facilities including the means necessary to preserve the knowledge on the facility in the longer run;
- 13) responsibility for the implementation of the strategy and key performance and development indicators in the implementation thereof;
- 14) manners and schedule of reporting on the strategy implementation.

### ***Spent Fuel and Radioactive Waste Management Strategy***

#### **Article 10**

Spent Fuel and Radioactive Waste Management Strategy shall be passed with the aim of planning for the implementation of the principles of responsible and safe management of spent fuel and radioactive waste, and shall include the following:

- 1) review, analysis and assessment of spent fuel and radioactive waste management conditions;
- 2) fundamental safety principles in respect of spent fuel and radioactive waste management in accordance with the law;
- 3) general statutory objectives and fundamental principles in respect of spent fuel and radioactive waste management;



- 4) significant milestones and clear timeframes for the achievement thereof in the light of over-arching national strategy objectives;
- 5) inventory of all spent fuel and radioactive waste and estimates for their future quantities, including those from decommissioning, which serve to clearly indicate the location and the amount of radioactive waste and spent fuel in accordance with the appropriate radioactive waste classification;
- 6) concepts and technical solutions for radioactive waste and spent fuel management from generation to disposal;
- 7) concepts or plans for the post-closure period of a disposal facility's lifetime, including the period during which appropriate controls and the means to be employed to preserve knowledge of that facility in the longer term are retained;
- 8) research, development and demonstration activities that are needed in order to implement solutions for the management of spent fuel and radioactive waste;
- 9) responsibility for the implementation of the national programme and the key performance indicators to monitor progress towards implementation;
- 10) assessment of the national programme costs and the underlying basis and hypotheses for that assessment, which must include a profile over time;
- 11) financing scheme and programme of the strategy;
- 12) means and measures for making necessary information available to workers and the public so as to provide their full participation in the decision-making process;
- 13) agreements concluded with other states, if any, on spent fuel and radioactive waste management, including those on the use of radioactive waste disposal facilities;
- 14) manner and schedule in respect of reporting on Strategy realization.

## ***Radiation and Nuclear Security Strategy***

### **Article 11**

Radiation and Nuclear Security Strategy shall be passed with the aim of developing the national radiation and nuclear security framework, planning and implementing the measures to prevent malicious and unlawful use of radiation sources, which can have harmful effect on the people's health, property and the environment, and with the aim of meeting the obligations imposed by the ratified international legal instruments.

The Strategy under paragraph 1 hereof shall include the following:

- 1) obligations and responsibilities of all institutions in the Republic of Serbia competent for security;
- 2) guidelines for devising plans for preventing, detecting and response in case of security event including radioactive and nuclear material;
- 3) guidelines for identifying and evaluating potential threats to radiation and nuclear security;
- 4) identification of potential targets and unacceptable radiological consequences in case of security event;

- 5) plans for continuous maintenance and development of national radiation and nuclear security framework;
- 6) plans for continuous maintenance and development of capacities to prevent, detect and respond to security event;
- 7) plans for continuous monitoring and revision of legal framework in the area of radiation and nuclear security;
- 8) plans for human resources development in the area of radiation and nuclear security;
- 9) guidelines for international cooperation in case of security event and in accordance with the applicable law and concluded international agreements.

The Strategy under paragraph 1 hereof shall be passed in compliance with the other national programmes covering the area of overall security.

### ***Existing Exposure Situation Management Strategy***

#### **Article 12**

Existing Exposure Situation Management Strategy shall define the course of action and long-term management plans and goals, commensurate with risk assessments and effective results of ionising radiation protection measures that are implemented in every situation of existing exposure.

Existing Exposure Situation Management Strategy shall imply over-arching analysis, establishment of reference levels for the exposed workers, a representative person, members of the public and the public, and the evaluation of regulatory control implementation in case of existing exposure situation.

Existing Exposure Situation Management Strategy shall include the following elements:

- 1) review, analysis and assessment of available information in order to evaluate the exposure for every recognized situation;
- 2) illustration of all parameters that can be used as special indicators of exposure of workers, a representative person, a member of the public, the public and the environment, which results from the effects of ionising radiation;
- 3) research, development and practical activities necessary to implement solutions for the existing exposure situation management;
- 4) establishment of reference levels for the exposed workers, a representative person, a member of the public and the public for every recognized situation of existing exposure;
- 5) public relations system with the aim of raising awareness of a member of the public and the public, informing local decision-making bodies, legal entities or entrepreneurs, and workers on risk elements for the recognized exposure situation;
- 6) guidelines on the manner and possible methods of measurement as well as guidelines on the implementation of remediation measures according to the situation;
- 7) assignment of institutional competences, mechanisms of inter-institutional coordination and available resources for action plan implementation;

- 8) plans and timeframes for action plan reassessment;
- 9) criteria for service certification and criteria for mandatory measurements which need to be taken during remediation activities;
- 10) financial resources to support the measurements and remediation methods in the existing exposure situations with the assessed high level of risk of the harmful effect of ionising radiation to a member of the public and the public;
- 11) long-term goals regarding mitigating the risk from the harmful effect of ionising radiation for the health of a member of the public and the public, and the protection of the environment.

### III SERBIAN RADIATION AND NUCLEAR SAFETY AND SECURITY DIRECTORATE

#### ***Establishment***

##### **Article 13**

For the purpose of providing the environment for professional and efficient regulatory control of practices regulated by the Law, Serbian Radiation and Nuclear Safety and Security Directorate shall be established by law as an independent and separate regulatory body with regulatory, expert and associated executive functions in the area of radiation and nuclear safety and security.

#### ***Position of the Directorate***

##### **Article 14**

With respect to the performance of functions within its competence, the Directorate shall be responsible to the Government of the Republic of Serbia.

The Directorate is a legal entity.

The head office of the Directorate is in Belgrade

Internal organization, remit and manner of work, manner of planning, performing activities and other issues of relevance for the Directorate shall be regulated by the Statute of the Directorate and other general legal enactments pursuant to law.

#### ***Bodies of Directorate***

##### **Article 15**

The bodies of the Directorate are the Board and the Director, appointed by the Government.

#### ***Requirements for the Appointment of Board Members and Roles of the Board***

##### **Article 16**

A person appointed as the Member of the Board of the Directorate shall:

- 1) be the citizen of the Republic of Serbia and have the residence on the territory of the Republic of Serbia;
- 2) have higher degree of education;
- 3) not have criminal record deeming him or her unworthy of such function.

The Board of the Directorate shall:

- 1) prepare drafts of Strategies stipulated by the Law;
- 2) adopt programmes and plans stipulated by the Law;
- 3) pass the Statute of the Directorate;
- 4) adopt annual work plan;
- 5) adopt financial plan;
- 6) monitor and assess radiation and nuclear safety and security and propose to the Director ways of enhancing such safety and security;
- 7) monitor developments in the areas relevant for radiation and nuclear safety and security and radioactive waste management worldwide, and stimulate transfer of knowledge;
- 8) monitor the implementation of and propose modifications in regulations governing the radiation and nuclear safety and security and radioactive waste management;
- 9) adopt the annual report on work and business operations;
- 10) participate in the preparation of annual report on the implementation of radiation and nuclear safety and security and radioactive waste management measures;
- 11) propose remediation actions in case of emergency events;
- 12) pass general enactments determined by the Statute;
- 13) pass rules on procedures;
- 14) conduct other functions in accordance with law and the Statute.

### ***Term of Board Members***

#### **Article 17**

A member of the Board shall be appointed for a five-year term and can be re-appointed for additional two terms.

A member of the Board can be removed from the office by the decision of the Government in case of malfeasance or a criminal conviction making him or her unworthy of the function of a Board member.

The function of a Board member shall cease with the termination of the term, with the act of resignation, if in case of serious illness confirmed by a competent health institution they are permanently incapable of performing the duties, and with the removal from the office.

### ***Requirements for the Appointment of the Director***

#### **Article 18**

A person appointed as the Director shall:

- 1) have higher degree in scientific or professional field in the area of natural, engineering or social sciences in Economics or Law;
- 2) have at least five years of work experience in the remit of the Directorate, or at least ten years of work experience in managerial positions;
- 3) have organizational and managerial skills;
- 4) not have any criminal convictions making him or her unworthy of the function.

### ***Term and Roles of the Director***

#### **Article 19**

The Director shall be appointed for a five-year term and can be reappointed for another two terms.

The Director can be removed from the office by the decision of the Government in case of malfeasance or a criminal conviction making him or her unworthy of the function.

The function of the Director shall cease with the termination of the term, with the act of resignation or, if in case of serious illness confirmed by a competent health institution, he or she is permanently incapable of performing the entrusted functions, and with the removal from the office.

The Director shall have the right to remuneration compensation for the period of three months as of the day of termination of the function for the amount received on the day of the termination.

The right to compensation under paragraph 4 hereof shall cease prior to the expiration of three-month period if the former Director concludes new employment contract or exercises the right to retirement.

The Director shall:

- 1) represent and act on behalf of the Directorate;
- 2) organize and manage the operations in the Directorate;
- 3) propose enactments to the Board;
- 4) execute the Board's decisions and take steps necessary for the implementation of such decisions;
- 5) ensure lawfulness in the operations and be liable for the use and allocation of finances and assets of the Directorate;
- 6) pass the rulebook on internal organization and systematization of work positions;
- 7) decide on the rights, duties and responsibilities of the staff;
- 8) pass administrative acts pursuant to this Law;
- 9) perform other functions established by law and the Statute.

### ***Human and Finance Resources***

## **Article 20**

The resources of the Directorate are provided from the budget of the Republic of Serbia, as proposed by the Directorate, the income the Directorate acquires from the activities within its remit, donations, grants and other sources pursuant to law.

The Directorate shall independently use the resources under paragraph 1 hereof, pursuant to law.

The Directorate shall take into employment the appropriate number of employees with relevant qualifications, experience and expertise.

The Directorate may also use external resources and expertise in support of its regulatory functions.

The Directorate shall ensure staff training programmes in the field of radiation and nuclear safety and security, and to ensure preparedness to respond in case of an emergency event.

All rights, duties and responsibilities of the employees of the Directorate are subject to general regulations governing employment, general acts of the Directorate and employment contract.

### ***Self-assessment of the Directorate in the area of Nuclear Safety and Security***

## **Article 21**

The Directorate shall, at least once every 10 years, arrange for periodic self-assessment of compliance of national legal, regulatory and institutional framework with the international standards in the area of radiation and nuclear safety and security and radioactive waste and spent nuclear fuel management.

The assessment of compliance under paragraph 1 hereof shall be arranged by inviting international peer review groups of relevant segments of radiation protection and nuclear safety and other fields of peaceful use of nuclear energy that the Directorate proposes to the Government.

The Directorate shall ensure the implementation of appropriate additional and follow-up measures based on relevant findings resulting from the peer review process from other states and international organizations.

The Directorate shall ensure the publication of relevant reports with regards to the peer review process under paragraph 3 hereof and the findings thereof, when available.

The Directorate shall advise the Government of the Republic of Serbia to invite relevant international peer review groups under paragraph 2 hereof without undue delay in case of a nuclear or radiological emergency requiring off-site emergency measures or protective measures for the public.

### ***Functions of the Directorate***

## **Article 22**

Functions of the Directorate are:

- 1) to prepare draft Strategies and Action plans for their implementation under Article 6 and 8 hereof;
- 2) to prepare draft regulations adopted by the Government pursuant to this Law;
- 3) to pass Rulebooks and other guides pursuant to this Law;
- 4) to pass the Environmental Radioactivity Monitoring Programme, monitor the level of radioactivity and the changes thereof, evaluate the effects of radioactivity on the public and the environment, give instructions on the implementation of the appropriate measures, monitor the implementation of such measures, and publish the annual report on the level of public exposure to ionizing radiation in the Republic of Serbia;
- 5) to prepare draft Response plan in case of nuclear and radiological emergency situation;
- 6) to lay down protective measures for a member of the public, the public and the environment from the harmful effect of ionizing radiation;
- 7) to establish requirements for protection against increased exposure of workers, members of the public and the public to naturally occurring radiation;
- 8) to bring decisions on issuing, suspending or revoking authorizations for practices, use of radiation sources, approvals to perform radiation protection, permits for trade in radiation sources and permits for the transport of dangerous goods class 7 ADR/RID/ADN (radioactive material), and for the exemption of duty to obtain authorization pursuant to the Law;
- 9) to issue, suspend or revoke certificates pursuant to the Law;
- 10) to issue certificate of entry into records and deletion from the records of radiation sources;
- 11) to lay down criteria for the exemption from the obligation of notification;
- 12) to lay down criteria for the release from regulatory control;
- 13) to verify the competence of persons responsible for the implementation of radiation protection measures;
- 14) to define the obligations, including the financial ones, of authorization holders;
- 15) to ensure continuous professional cooperation in the performance of duties by engaging consultants, preparing projects or establishing permanent and *ad hoc* advisory bodies;
- 16) to establish and keep registry of applications, issued authorization and certificates and persons responsible for the implementation of radiation protection measures, registry of radiation sources and their users, exposed workers, external workers and other data relevant for radiation protection and radiation and nuclear safety;
- 17) to establish and keep records of facilities, radiation sources and radioactive waste, as well as other data relevant for radiation and nuclear safety and security;
- 18) to establish a system of control over radiation sources and devices with such sources as their integral part to ensure their safe and secure management and protection during and at the end of their useful lives;

19) to establish categorization of radiation sources based on their possible impact and harmful effect on the health and lives of people and the environment;

20) to establish categorization of nuclear and radioactive material based on the evaluation of possible damage in case of theft or unauthorized use of certain type and amount of material, or in case of sabotage of the facility where nuclear or radioactive material is generated, processed, used, stored or disposed, and to prescribe appropriate protective measures for different categories of material;

21) to lay down the requirements for security of nuclear and radioactive material and facilities in which such material is used, including the measures of prevention, detection and response in case of unauthorized and malicious activities involving such material and facilities;

22) to participate in defining design bases and design basis accidents for the purpose of implementing radiation and nuclear safety and security measures;

23) to cooperate with other state bodies and organizations within their competences;

24) to cooperate, independently or in coordination with other competent state bodies and organizations, with the International Atomic Energy Agency and other international organizations, bodies and competent authorities of other countries with respect to the enforcement of this Law and other international obligations assumed by the Republic of Serbia;

25) to establish and implement, in cooperation with the ministries and services responsible for foreign affairs, defense, internal affairs, economy and customs, a system of control of the export and import of nuclear and other radioactive material, radiation sources, equipment, special equipment and non-nuclear material, information, and technology for the purpose of fulfilling international obligations assumed by the Republic of Serbia;

26) to cooperate with other relevant institutions of the Republic of Serbia in establishing and maintaining nuclear and radiological emergency response plan in accordance with the National Emergency Protection and Rescue Plan;

27) to give opinion at the request of competent state authorities regarding joining the international conventions and other agreements in the area of radiation and nuclear safety and security;

28) to establish appropriate mechanisms and procedures for informing the public and consulting other interested bodies and organizations in the area of radiation and nuclear safety and security;

29) to fulfil any other commitments deemed as necessary to establish protection of the public and the environment in the Republic of Serbia;

30) to initiate enhancement of the national framework in the area of radiation and nuclear safety and security, based on operational experience, insights gained in the decision-making process and technology and research related development;

31) to carry out control and inspection oversight of the implementation of radiation and nuclear safety and security measures;

32) to control the fulfilment of conditions serving as the basis for the issuance of authorizations pursuant to the Law;



- 33) to review, observe and assess the practices to verify their compliance with this Law, applicable regulations and the requirements for obtaining authorizations;
- 34) to take actions, require and monitor the implementation thereof in the event of noncompliance with the law, bylaws and other applicable regulations regarding the requirements for obtaining authorizations;
- 35) to establish and maintain the system of accountancy and control of nuclear material;
- 36) to perform other statutory duties.

### ***Rules of the General Administrative Procedure***

#### **Article 23**

In proceedings before the Directorate, provisions of the Law governing General Administrative Procedure shall be applied unless this Law states otherwise.

#### ***Judicial control***

#### **Article 24**

Decisions issued by the Directorate are final and cannot be appealed to. However, administrative dispute can be initiated within 30 days as of the day of decision delivery.

### ***Scientific and Technical Support in the Area of Radiation and Nuclear Safety and Security***

#### **Article 25**

The Directorate may engage legal and physical entities as consultants with necessary scientific and technical qualifications, expertise, specialized knowledge and skills in the field of analyzing, improving and regulating radiation and nuclear safety and security measures.

### ***Principles of Scientific and Technical Support in the Area of Radiation and Nuclear Safety and Security***

#### **Article 26**

When selecting consultants under Article 25 hereof, the Directorate shall apply the principle of impartiality.

The Directorate shall engage consultants without compromising its own independence by ensuring that there is no conflict of interest for the consultants that provide scientific and technical support to the Directorate.

The consultant shall provide the Directorate with scientific and technical support without commercial, financial or any other kind of leverage from other interested parties, and without the influence from any other organization regarding the results of their work.

The consultant shall provide the Directorate with scientific and technical support based on solely technical knowledge, analysis results and regulatory requirements.

### ***Graded approach to Regulatory Control***

#### **Article 27**

The Directorate shall exercise its regulatory control by applying graded approach commensurate with the radiation risk.

### ***Integrated System of Management***

#### **Article 28**

The Directorate shall establish, implement, continuously assess and improve an integrated system of management, which is aligned with safety goals and contributes to their achievement.

The Directorate shall implement regulatory process based on the procedures incorporated in the integrated system of management and thus ensure stable and consistent regulatory control.

In order to fulfil provisions under paragraphs 1 and 2 hereof, the management of the Directorate shall:

- 1) demonstrate leadership for and commitment to safety;
- 2) be responsible for the establishment, implementation, sustainability and continuous improvement of the integrated system of management;
- 3) establish goals, strategies and plans of the Directorate that are aligned with the safety policies of the Directorate;
- 4) ensure adequate interaction with the interested parties;
- 5) determine and ensure competences and resources necessary for safe activity performance within the Directorate.

Integrated system of management of the Directorate shall be documented, developed and applied in accordance with the principle of graded approach.

## **IV FUNDAMENTAL PRINCIPLES OF IONIZING RADIATION PROTECTION**

### ***Fundamental Principles of Ionizing Radiation Protection***

#### **Article 29**

Fundamental principles of radiation protection are:

1) *Justification*: Decisions introducing a practice shall be justified in the sense that such decisions shall be taken with the intent to ensure that the individual or societal benefit resulting from the practice outweighs the health detriment that it may cause. Decisions introducing or altering an exposure pathway for existing and emergency exposure situations shall be justified in the sense that they should do more good than harm;

2) *Optimization* - Radiation protection measures of individuals subject to public or occupational exposure shall be optimized with the aim of keeping the magnitude of individual doses, the likelihood of exposure and the number of individuals exposed as low as reasonably achievable taking into account the current state of technical knowledge and economic and societal factors. The optimization of the protection of individuals subject to medical exposure shall apply to the magnitude of individual doses and be consistent with the medical purpose of the exposure;

3) *Dose limitation* - In planned exposure situations, the sum of doses to an individual shall not exceed the dose limits laid down for occupational exposure or public exposure. Dose limits shall not apply to medical exposures.

## V EXEMPTION FROM NOTIFICATION REQUIREMENT, NOTIFICATIONS AND AUTHORIZATIONS

### ***1 Exemption from Notification***

#### **General Criteria of Exemption from Notification Article 30**

General criteria of exemption from notification are such that:

- 1) the radiation risks to individuals caused by the practice are sufficiently low, so as to be of no regulatory concern;
- 2) the type of practice has been determined to be justified; 3) the practice is inherently safe.

The Directorate shall stipulate special requirements for the exemption from notification.

### ***2 Notification***

#### **Notification of the Intention to Perform a Practice Article 31**

A legal entity or entrepreneur shall notify the Directorate on any intention to perform practices involving radiation sources, naturally occurring radioactive material leading to the exposure of workers or the public that cannot be disregarded from a radiation protection point of view, and on the use of nuclear material for non-nuclear purposes.

The Directorate shall issue a certificate of the notification of the intention to perform practices under paragraph 1 hereof.

Notification shall be made prior to the practice commencement.

Holders of the certificate under paragraph 2 hereof shall notify the Directorate on the decision to abandon the intention to perform the practice, for which the Directorate issues a certificate.

The Directorate shall specify the requirements for practice notification and the content of the certificate under paragraph 2 hereof.

### ***Exemption of Notified Practice from Obtaining Authorization*** **Article 32**

Notified practices can be exempted from obtaining authorization based on the specific requirements prescribed by the Directorate.

### **Categorization of Practices** **Article 33**

According to the health risks of exposed workers, members of the public, the public and the environment, as well as the type of practice performed, the practices can be classified as:

- 1) Low risk radiation practices
- 2) Moderate risk radiation practices
- 3) High risk radiation practices
- 4) Nuclear activities

The Directorate shall specify the requirements for the categorization of radiation practices under paragraph 1 hereof.

## ***3 Issuance of Authorizations***

### **Obligation to Obtain Authorization** **Article 34**

Performance of radiation practices under Article 33, paragraph 1 hereof require authorization issued by the Directorate.

Low risk radiation practice under Article 33, paragraph 1, point 1) hereof shall be authorized by the decision on registration.

Moderate risk radiation practice, high risk radiation practice and nuclear activity under Article 33, paragraph 1, points 2) -4) hereof shall be authorized by the decision on license issuance.

## **General Principles Governing Authorization Holder Responsibilities**

### **Article 35**

Authorization holder shall bear prime responsibility for radiation and nuclear safety and security.

Authorization holders shall be responsible for all activities conducted by legal entities, physical entities and entrepreneurs they engage, and whose practices can affect radiation and nuclear safety and security.

The responsibilities under paragraphs 1 and 2 hereof cannot be delegated.

Authorization holder shall ensure that radiation doses for exposed workers, apprentices, students and the public, as well as the impact of radiation on the environment are, in terms of social and economic factors, as low as reasonably practicable.

Authorization holder shall be responsible for the safety and security of the facility where the practice is performed even if the authorization has expired, as long as the facility, the site, and the parts thereof are not released from the regulatory control.

## **Responsibilities of the Authorization Holder**

### **Article 36**

Authorization holder shall:

- 1) apply the fundamental principles of radiation and nuclear safety;
- 2) take all necessary steps to protect people's health and the environment from the harmful effect of ionizing radiation, now and in future, by keeping the exposure level below the specified limits, and take all reasonable steps to minimize, now and in future, the harmful effect on the public;
- 3) plan and implement technical and organizational measures necessary to ensure the adequate level of radiation and nuclear safety and security;
- 4) prepare and implement the plan in case of emergency in accordance with the Law;
- 5) keep relevant records and report to the Directorate on emergency events in accordance with the Law;
- 6) ensure compliance with the prescribed dose limits and monitor the exposure of workers to ionizing radiation;
- 7) obtain adequate financial and human resources with adequate qualifications and competences necessary to conduct the prescribed radiation and nuclear safety and security measures when conducting practices;
- 8) ensure that their subcontractors, whose activities can affect radiation and nuclear safety and security, throughout the practice performance provide for required staffing with appropriate qualifications and competences necessary to carry out their activities;
- 9) provide for continuous education and training of persons participating in the practice performance;

10) provide for adequate financial resources to handle disused radiation sources, radioactive waste management, decommissioning and liability in case of radiological or nuclear damage;

11) enable the inspectors of the Directorate to carry out their work without impediment and to have access to the facilities and sites where the practice is conducted;

12) not modify the manner of the performance of the authorized practices in a way that could affect the protection of workers, the public or the environment without previously

13) notifying and obtaining the appropriate authorization from the Directorate, and;

14) provide, upon the request of the Directorate or in line with the requirements, all information regarding the practice performance that the Directorate deems necessary or relevant for radiation and nuclear safety and security.

The Directorate shall specify the requirements under paragraph 1 hereof.

### **Authorization Holder Responsibilities with respect to Records of Nuclear Material, Activities, Special Equipment and Non-nuclear Material associated with Nuclear Fuel Cycle**

#### **Article 37**

Authorization holder shall keep the records of nuclear material, activities, special equipment and non-nuclear material associated with nuclear fuel cycle in line with the ratified international agreements and this Law.

The Directorate shall specify the requirements under paragraph 1 hereof.

### **Requirements for Authorization Issuance**

#### **Article 38**

The Directorate shall issue the authorization for practices under Article 33, paragraph 1, points 1) - 4) hereof to legal entities or entrepreneurs provided they fulfil general and particular requirements pursuant to the Law.

The authorization under paragraph 1 hereof cannot be delegated.

### **General Requirements for Authorization Issuance**

#### **Article 39**

General requirements for the issuance of authorization under Article 33, paragraph 1, points 1) - 4) hereof are:

1) that the facilities, the venues and the sites where the practice is performed meet technical, safety, security and other requirements ensuring the protection of exposed workers, members of the public, the public and the environment from the harmful effect of ionising radiation;

2) that the exposed workers handling radiation sources are provided with the adequate radiation protection tools and ionising radiation measuring devices;

3) to designate a radiation protection officer or a radiation protection service;

4) depending on the type of practice, to have staff with adequate education and training in the area of radiation protection that fulfil necessary health requirements to work with radiation sources;

5) to implement the measures necessary to prevent contamination of work and living environment by the practice performance, excluding the practices using ionising radiation generators;

6) to use and trade in radiation sources in a safe and secure manner and in accordance with the relevant regulations;

7) to implement other radiation protection measures stipulated by the Law.

The Directorate shall define special requirements and necessary documentation required to obtain authorization for practice performance under Article 33, paragraph 1, points 1) – 4) hereof.

### **Authorization Issuance in case of Emergency**

#### **Article 40**

The Directorate may issue the authorization for practice performance under Article 33, paragraph 1, points 1) - 4) hereof under special procedure in the event of natural disasters, emergencies and crises, warfare, terrorism, large migrations of the population, humanitarian crises and activities in connection with health protection and rescuing, on the basis of the complexity of the circumstances and risk assessment for the practice performance.

#### *a) Registration of Practices*

#### **Article 41**

The Directorate shall bring a decision on registration of practice based on the application submitted by a legal entity or an entrepreneur.

The Directorate shall make a decision on registration under paragraph 1 hereof upon fulfilment of all requirements stipulated under Article 39 hereof, within 30 days of duly submitting the application and all necessary documentation verifying the required conditions have been met.

By issuing the decision on registration, the Directorate may prescribe additional radiation and nuclear safety and security measures.

Decision on registration is not time limited, except the decision to perform low-risk radiation practices – trade in radiation sources and transport of dangerous goods Class 7 ADR/RID/ADN (radioactive material) which has a three-year validity.

The decision under paragraph 1 hereof enters into force on the day of delivery.

A legal entity or an entrepreneur undertakes to report to the Directorate any change of data on the fulfilment of the requirements that served as the basis for obtaining the decision on registration, within 30 days of change occurrence the latest.

#### *b) Licensing of Practices*

##### **Article 42**

A legal entity or an entrepreneur shall submit to the Directorate the application for a license for moderate-risk radiation practice, high-risk radiation practice or a nuclear activity.

In addition to the application under paragraph 1 hereof, the applicant shall submit:

- 1) confirmation that the general and particular conditions under Article 39 hereof have been fulfilled, and
- 2) confirmation that radiation and nuclear safety and security measures have been implemented.

The implementation of radiation and nuclear safety and security measures shall be confirmed based on the Safety Analysis Report, Radiation Protection Programme and other documentation specified by the Directorate.

In case of high-risk radiation practice, it is necessary first to obtain the consent from the Directorate to the initial Safety Analysis Report.

The licensee shall report to the Directorate, without undue delay, and within eight days the latest, any change in data on the fulfilment of conditions that served as the basis for license issuance.

#### ***Safety Analysis Report***

##### **Article 43**

The Safety Analysis Report under Article 42, paragraph 3 shall include:

- 1) description of the practice;
- 2) description and features of the premises, facility and site, and any other location where the practice is performed;
- 3) conditions for and limitations to the performance of the practice;
- 4) safety assessment of the practice performance for normal and abnormal operations, including emergency events, and assessment of possible initial events that could lead to deviation from the intended manner of work;
- 5) evaluation of potential emergency events and measures for their prevention and mitigation as well as remediation in case of emergency.



The licensee undertakes to modify and supplement the Safety Analysis Report commensurate with the changes occurring as the practice is conducted so that the report would always reflect the current status of the practice performance.

Safety Analysis Report can be prepared by the applicant or another person empowered to do so.

The Directorate shall specify the scope and the content of the Safety Analysis Report for each practice the license is issued for.

### **Revision of Safety Analysis Report**

#### **Article 44**

The licensee shall perform systematic and periodic revisions of Safety Analysis Report under Article 43 hereof on which they shall submit the report to the Directorate.

Revision under paragraph 1 hereof shall entail review, verification and improvement of radiation and nuclear safety measures, emergency event prevention measures and emergency event remediation measures, if necessary.

If the circumstances justify so, the Directorate may require the licensee to conduct extraordinary revision of the Safety Analysis Report and submit the report on it to the Directorate.

The Directorate shall specify the content and schedule of the revision of Safety Analysis Report and subsequent submission of the report to the Directorate.

### **Initial Safety Analysis Report**

#### **Article 45**

In the process of obtaining the decision on issuing the license for high-risk radiation practice, a legal entity or an entrepreneur shall first submit to the Directorate the application for the consent to the Initial Safety Analysis Report.

The Directorate shall issue a decision on the consent under paragraph 1 hereof within 90 days of duly submitted application.

The legal entity or entrepreneur shall, without undue delay and within eight days the latest, report to the Directorate on any changes in the conditions that served as the basis for issuing the consent under paragraph 1 hereof as well as in case of abandoning the intended practice. The Directorate shall specify the scope and the content of the Initial Safety Analysis Report and the documentation supplementing the application for issuing the consent to the Initial Safety Analysis Report.

### **Ionising Radiation Protection Programme**

#### **Article 46**

The Radiation Protection Programme under Article 42, paragraph 3, shall particularly include:

- 1) assignment of responsibilities to all management levels in case of occupational exposure to ionizing radiation, which in case of external workers can also include appropriate organizational cooperation and the allocation of responsibilities between external workers and legal entities or entrepreneurs as authorization holders;
- 2) designation of controlled and supervised areas;
- 3) establishment of rules for workers to follow and supervision of their work;
- 4) arrangements for individual monitoring of exposed workers and the workplace, including the acquisition and maintenance of radiation protection instruments;
- 5) system of recording and reporting of all relevant information related to the control of ionizing radiation exposure, decisions on measures of radiation protection, and individual monitoring of exposed workers;
- 6) education and training programme on the nature of hazards, radiation protection measures and radiation and nuclear safety measures;
- 7) methods and schedule for periodically reviewing and auditing the performance of the Radiation Protection Programme;
- 8) plans to be implemented in case of emergency events;
- 9) health surveillance programme;
- 10) requirements for the implementation and assurance of quality control.

The Directorate shall specify the scope and content of the Radiation Protection Programme under paragraph 1 hereof.

## **License for Moderate-risk Radiation Practice**

### **Article 47**

The Directorate shall bring a decision on issuing the license for moderate-risk radiation practice performance after affirming that all requirements under Article 42 hereof have been fulfilled.

The Directorate shall issue the decision under paragraph 1 hereof within 60 days of duly submitted application.

In addition to the license to perform a moderate-risk radiation practice, the Directorate shall issue a decision on the use of radiation sources.

The license for a moderate-risk radiation practice shall be issued for the period of ten years except the license for a moderate-risk radiation practice – trade in radiation sources and transport of dangerous goods Class 7 ADR/RID/ADN (radioactive material) which is issued for the period of three years.

The license under paragraph 1 hereof shall enter into force on the day of delivery.

The licensee under paragraph 1 hereof, 60 days prior to the termination of the license at the latest, shall submit to the Directorate the application for its extension.

### **License for High-risk Radiation Practice** **Article 48**

The Directorate shall bring a decision on issuing the license for a high-risk radiation practice performance after affirming that all requirements stipulated by Article 42 hereof have been fulfilled.

The applicant for the performance of a high-risk radiation practice shall establish, maintain and implement the integrated system of management.

In addition to verifying that the requirements under paragraphs 1 and 2 hereof have been met, a legal entity or an entrepreneur shall submit the consent from the Ministry of Interior to the Security Plan, pursuant to this Law.

Provisions under paragraph 3 hereof shall not pertain to the applicants for the license for practices associated with radiation source generators.

The Directorate shall issue a decision under paragraph 1 hereof within 90 days of the day of duly submitting the application.

The license for the performance of a high-risk radiation practice shall be issued for the period of 5 years, except the license for high-risk radiation practices of trade in radiation sources and transport of dangerous goods Class 7 ADR/RID/ADN (radioactive material) which is issued for the period of 3 years.

The license under paragraph 1 hereof enters into force on the day of delivery.

In addition to the license to perform a high-risk radiation practice, the Directorate shall issue the decision on the use of a radiation sources.

The decision to issue the license for the performance of a high-risk radiation practice shall be published in *the Official Gazette of the Republic of Serbia*.

The licensee for the performance of a high-risk radiation practice shall submit to the Directorate the application for the extension of the license within 90 days prior to its termination at the latest.

The license for the performance of a high-risk radiation practice with unsealed sources and sources of categories I and II shall expire, *inter alia*, on the day of issuing the license for a radiation facility decommission.

### **License for Nuclear Activity** **Article 49**

The Directorate shall bring a decision on issuing the license for the performance of a nuclear activity after affirming that all requirements under Article 42 hereof have been fulfilled.

The applicant for nuclear activity performance shall establish, maintain and implement the integrated system of management.

In addition to verifying that the requirements under paragraph 1 and 2 hereof have been met, a legal entity or an entrepreneur, pursuant to this Law, shall submit the consent from the Ministry of Interior to the Security Plan.

The decision under paragraph 1 hereof shall be issued within 180 days of duly submitted application.

In addition to the application for the license for a nuclear activity, the applicant shall submit the consent to the assessment of the environmental effect of the project from the Ministry responsible for the environmental protection pursuant to a special law.

The decision that serves as the basis for issuing the license for a nuclear activity shall be published in *the Official Gazette of the Republic of Serbia*.

The license for a nuclear activity performance shall be issued for the period of 10 years except the license for the nuclear activity – trial run of a nuclear facility that shall be issued for the period of 2 years.

The license under paragraph 1 hereof enters into force on the day of delivery.

The licensee for a nuclear activity performance shall submit to the Directorate the application for the extension of the license within 180 days prior to its termination at the latest.

### **Self-assessment of the Licensee**

#### **Article 50**

The licensee for a nuclear activity performance shall assess the compliance of the applied measures of radiation and nuclear safety and security with the Law and the international standards in the area of radiation and nuclear safety and security and radioactive waste and spent nuclear fuel management.

The Directorate shall specify the schedule of the compliance assessment under paragraph 1 hereof.

### **4 Modifications of Authorizations**

#### **Article 51**

The Directorate may modify the decision on registration or license issuance at the request of the authorization holder or based on the inspection findings.

### **5 Suspension of Authorization**

#### **Article 52**

The Directorate may suspend the decision on issuing a registration or license.

The suspension under paragraph 1 hereof shall be conducted if:

1) the authorization holder temporarily ceases to fulfil any of the conditions established by the decision on authorization issuance;

2) the inspection oversight determines that the authorization holder has failed to take radiation and nuclear safety and security measures or has failed to implement them in the schedule prescribed by the Directorate;

3) the inspector issues a decision to prohibit radiation practice or nuclear activity performance;

4) the authorization holder fails to provide the Directorate with all the data serving to affirm the fulfilment of radiation and nuclear safety and security measures;

The decision under paragraph 2 hereof shall be issued within seven days of the day of reception of information under paragraph 2, points 1) - 4) hereof.

By suspending the authorization, the Directorate orders the authorization holder to remedy all detected deficiencies, and establishes the schedule for the authorization holder to do so.

The suspension under paragraph 3 hereof shall be for the period of 12 months the longest as of the day of delivery of the suspension decision to the applicant.

The decision on the suspension enters into force on the day of delivery.

During suspension, the authorization holder cannot perform the practice the suspension was issued for.

If authorization holders act contrary to the decision on suspension, they shall be liable for all damage incurred.

The suspension of the authorization shall terminate on the day of delivery of the decision on revoking the suspension on condition that the authorization holder has remedied all detected deficiencies.

The decision on the suspension cannot be extended.

## ***6 Revocation of Authorization***

### **Article 53**

The Directorate shall revoke the decision on registration or license issuance if the authorization holder:

1) ceases to fulfil some of the requirements serving as the basis for license issuance;

2) fails to report to the Directorate an emergency event during practice performance;

3) following suspension, fails to timely meet the requirements arising from the suspension;

4) fails to conduct the prescribed measurement, withholds or reports inaccurate data in connection with the implementation of radiation and nuclear safety and security measures;

5) submits the application for the termination of the registration or license.

The Directorate shall revoke the decision on license issuance if the licensee, in addition to the points under paragraph 1 hereof:

1) fails to review and audit the Safety Analysis Report or fails timely to submit to the Directorate the report on the review and audit of the Safety Analysis Report; 2) fails timely to submit the application for the license extension.

The decision on the license revocation enters into force on the day delivery.

If the licensees act against the decision on license revocation under paragraph 3 hereof, they shall be liable for the damage incurred.

## ***7 Extension of the License***

### **Article 54**

The Directorate shall issue a decision on license extension at the request of the licensee.

The Directorate shall issue the decision under paragraph 1 hereof when it has been affirmed that all conditions serving as the basis for issuing the license and all radiation and nuclear safety and security measures have been met.

Fulfilment of radiation and nuclear safety and security measures shall be affirmed based on the report on periodic review and audit of the Safety Analysis Report and based on all reported changes in the data on the fulfilment of conditions serving as the basis for license issuance.

The decision on the license extension under paragraph 2 hereof shall be issued for the same period as the decision on the license issuance.

The Directorate shall issue the decision on license extension within 60 days of the duly submitted application for the license extension in case of a moderate-risk radiation practice performance, and within 90 days of duly submitted application for the extension of the license for the performance a high-risk radiation practice and the license for a nuclear activity.

## ***8 Termination of License***

### **Article 55**

The decision on the license issuance shall be terminated:

- 1) if the validity of the license expires and the licensee does not apply for the extension within the prescribed schedule;
- 2) in case of bankruptcy or liquidation of the licensee;
- 3) if the proceedings have been abated in the event of the owner's demise and the rights, duties and legal interests cannot be transferred to the successors;
- 4) in case of revocation of the license, and
- 5) in instances stipulated by this Law

The Directorate shall specify all obligations for legal entities and entrepreneurs whose license has expired regarding the protection of the public and the environment.

## ***9 Performance of Ionizing Radiation Protection Duties***

## **Ionizing Radiation Protection Duties**

### **Article 56**

Radiation protection duties shall entail:

- 1) radioactivity monitoring or individual testing therein;
- 2) measurements conducted to assess the level of exposure to ionizing radiation of exposed workers, other members of the public and the public;
- 3) decontamination of work and living environment;
- 4) decontamination of individuals;
- 5) removal of orphan sources;
- 6) preparation of Safety Analysis Report and Radiation Protection Programme;
- 7) training and education of exposed workers and radiation safety officers;
- 8) testing of radiation sources parameters for the purpose of radiation protection measures quality assurance.

The Directorate shall specify the types and methods of the testing under paragraph 1, point 1) hereof.

## **Approval for Radiation Protection Duties**

### **Article 57**

The Directorate shall issue the decision to give approval to legal entities to perform radiation protection duties based on the provisions prescribed by the Law.

The decision under paragraph 1 hereof shall be issued within 60 days of duly submitted application and documentation affirming the fulfilment of the requirements.

The decision under paragraph 1 hereof shall be issued for the period of five years and cannot be delegated.

The decision under paragraph 1 hereof shall enter into force on the day of delivery.

The decision under paragraph 1 hereof for the performance of duties under Article 56, paragraph 1, point 3), 4) and 5) hereof serves to establish the requirements for activities with radioactive waste and radiation sources.

Approval holder shall, without undue delay, within eight days the latest, report to the Directorate any change of information serving as the basis for issuing the decision under paragraph 1 hereof.

Approval holder shall, 60 days prior to the termination of the decision, submit to the Directorate the application for its extension.

Approval extension shall be issued for the same period and under the same conditions as in case of the issuance of the decision.

The Directorate shall keep record of the issued decisions.

The Directorate shall specify the requirements and necessary documentation for obtaining the decision under paragraph 1 hereof.

## ***Modification, Suspension and Revocation of the Approval***

### **Article 58**

The Directorate may modify, suspend or revoke the approval under Article 57 hereof.

The Directorate shall issue a decision to modify, suspend or revoke the approval under paragraph 1 hereof.

#### *a) Modification of the Approval*

### **Article 59**

The Directorate shall issue the decision to modify the approval under Article 57 hereof at the request of the approval holder.

#### *b) Suspension of the Approval*

### **Article 60**

The Directorate shall suspend the approval under Article 57 hereof if:

- 1) the approval holder temporarily ceases to fulfil any of the requirements serving to issue the approval;
- 2) the inspection oversight determines that the approval holder fails to conduct radiation and nuclear safety measures within the timeframe prescribed by the inspector;
- 3) the inspector issues the decision to ban the activities in the area of radiation protection until all detected deficiencies have been remedied, i.e. all requirements met;
- 4) the approval holder fails to submit to the Directorate all information necessary to affirm the fulfilment of radiation and nuclear safety measures.

The Directorate shall issue the decision on the suspension within seven days of the day of receiving the information under paragraph 4 hereof.

The decision on the suspension serves the Directorate to order the approval holder to remedy all detected irregularities.

The decision on the suspension enters into force on the day of the delivery.

The suspension can be issued for the period of 12 months the longest as of the day of serving the approval holder with the decision.

During the suspension, the approval holder cannot conduct any of the radiation protection activities the approval suspension was issued for.

The approval holders shall be held liable for all the damage incurred if they act against the approval suspension decision.

Approval suspension shall be terminated by the decision to revoke the suspension on condition that the approval holder has remedied all detected irregularities before the period of suspension has expired.

Suspension decision cannot be extended.



*c) Revocation of the Approval*

**Article 61**

The Directorate shall revoke the approval under Article 57 hereof if the approval holder:

- 1) before the suspension period has expired, fails to fulfil the requirements imposed by the suspension.
- 2) permanently ceases to fulfil one or more than one requirement serving as the basis for the approval issuance;
- 3) fails to report to the Directorate an emergency event in the course of radiation protection duties;
- 4) fails to remedy operational deficiencies and irregularities within the specified period;
- 5) fails to conduct the prescribed measurements, intentionally withholds or delivers inaccurate information relevant for radiation protection measures implementation;
- 6) submits the application for the termination of the decision on the approval for radiation protection duties.

Approval revocation shall enter into force on the day of delivery.

Approval holders shall be held liable for all damage incurred if they act against the decision revoking the approval.

***10 Release of Material, Facilities, Sites and the Parts thereof from Regulatory Control***

**Release of Material from Regulatory Control**

**Article 62**

The Directorate shall issue a decision to release materials from regulatory control at the request of a legal entity or entrepreneur, and keep records of the decisions issued on the release of materials from regulatory control.

Material can be released from regulatory control provided that the specific activity does not exceed the clearance level set out by the Directorate.

The Directorate shall specify the clearance levels and requirements for the release of material from regulatory control.

**Release of Facilities, Sites and the Parts thereof from Regulatory Control Article 63**

The Directorate shall issue a decision to release a facility, site or the parts thereof at the request of a legal entity or an entrepreneur and keep records of all decisions issued on the release from regulatory control.

Facility, site or the parts thereof subject to regulatory control, including the facilities and sites containing naturally occurring radioactive material shall be released from regulatory control once the radiation sources, radioactive waste and contaminated structures, systems and components have been removed.

The Directorate shall issue the decision to release a facility, site or the parts thereof from regulatory control.

Prior to the issuance of the decision to release a facility, site or the parts thereof from regulatory control, the Directorate shall conduct review, control and supervision of the facility, the site or the parts thereof to verify that:

- 1) all responsibilities covered by the license have been satisfactorily discharged by the licensee and that there is no reasonable expectation that the licensee will have further responsibilities with respect to the facility, site or the parts thereof;
- 2) all active and passive control measures, including environmental radioactivity monitoring, are in place;
- 3) the final radiological status of the facility, site or the parts thereof is fully documented;
- 4) the radiological history of the exposed workers is fully documented;
- 5) the documentation is made publicly available, unless protected by law from disclosure.

The decision under paragraph 3 hereof serves the Directorate to specify limitations of use and access to the facility, site or the parts thereof.

The legal entity or entrepreneur under paragraph 1 hereof shall implement the measures to limit the use and access to the facility, site or the parts thereof and such obligation cannot be delegated.

If the licensee applies for the release of only a part of the facility or site from regulatory control, the remaining part of the facility or site continues to be under regulatory control in accordance with the law.

The license for a practice performance shall be terminated, *inter alia*, on the day of delivery of the decision on the release of the facility, site or the parts thereof from regulatory control.

The Directorate shall specify the criteria, specific requirements and documentation necessary for the release of the facility, site or the parts thereof from regulatory control.

**Report on Final Radiological Survey**  
**Article 64**

In addition to the application for the facility, site or the parts thereof to be released from regulatory control, the legal entity or entrepreneur shall submit the final report on radiological survey of the facility, site or the parts thereof.

The decision on release of the facility, site or the parts thereof from regulatory control under Article 62 hereof shall be issued based on the assessment of the report on final radiological survey under paragraph 1 hereof, which serves to affirm that the requirements for release from the regulatory control have been met, and based on the conducted review, control and supervision.

An authorized contractor independent of the applicant hereof shall prepare the report under paragraph 1.

The cost of the report under paragraph 1 hereof shall be borne by the applicant.

***11 Content and Official Form of License and Certificate***  
**Article 65**

Licenses and certificates issued by the Directorate pursuant to the Law shall have specific form and content.

The Directorate shall specify the form and the content of licenses and certificates under paragraph 1 hereof.

**VI RADIATION AND NUCLEAR SAFETY**

**Fundamental Principles of Radiation and Nuclear Safety**  
**Article 66**

Fundamental principles of radiation and nuclear safety are:

- 1) prime responsibility for radiation and nuclear safety must rest with the legal entity or entrepreneur responsible for practices and facilities that give rise to elevated radiation risk;
- 2) establishment and maintenance of effective legal and institutional framework for radiation and nuclear safety, including the establishment of an independent regulatory body in the field of radiation and nuclear safety.
- 3) establishment and maintenance of effective management system of radiation and nuclear safety by the legal entities or entrepreneurs whose practices give rise to the elevated risk of radiation exposure;
- 4) practices that give rise to elevated risk of radiation exposure must yield an overall benefit;

- 5) radiation protection must be optimized to provide the highest level of radiation and nuclear safety that can reasonably be achieved;
- 6) measures of radiation risk control must ensure that no individual bears an unacceptable risk of harm from exposure to ionizing radiation;
- 7) protection of the public and the environment from radiation risk, now and in the future;
- 8) all practical efforts must be made to prevent and mitigate the impact of nuclear or radiation emergencies;
- 9) arrangements for emergency preparedness and response in case of nuclear or radiation emergencies;
- 10) protective actions to reduce the existing or unregulated radiation exposure risks must be justified and optimized.

## ***1 Radiation Safety***

### **Dose Constraints for Occupational Exposure, Public Exposure and Medical Exposure**

#### **Article 67**

Authorization holder shall specify the dose constraint for occupational exposure, as well as the exposure of outside workers.

Dose constraint in case of public exposure is determined for a single dose that a member of the public receives in the event of planned exposure.

Dose constraint in case of medical exposure shall pertain only regarding the protection of carers and comforters, and volunteers taking part in medical and biomedical research.

Dose constraints under paragraphs 1, 2 and 3 hereof shall be established only in terms of an individual effective or equivalent dose during the specified period.

The Directorate shall specify the manner of determining and constraining the doses under paragraphs 1, 2 and 3 hereof.

### **Exposure Prohibitions and Constraints**

#### **Article 68**

Effective and equivalent dose received by occupationally exposed persons and a member of the public shall not exceed the prescribed exposure limits.

Effective dose received by students younger than 18 years of age, except students and apprentices older than 18 years of age that undergo regular training and education for the purpose of performing radiation protection duties shall not exceed the prescribed limits for the public exposure.

The Directorate shall stipulate the exposure limits for occupationally exposed persons, the public and students.

Authorization holder shall provide such radiation protection level so as to prevent the exposure of the employed women during pregnancy above the limits stipulated for the public.

Breastfeeding women shall not occupy a work post with a likelihood of internal or external contamination.

### **Exposure for Non-medical Imaging Purposes** **Article 69**

Individual exposure for non-medical imaging purposes shall be conducted only with the previously obtained consent form the Directorate.

The Directorate shall evaluate the justification of the exposure for non-medical imaging purposes based on the submitted application.

The Directorate shall specify, together with the Ministry responsible for health, the criteria for non-medical imaging exposure and the list of justified practices.

All practices involving deliberate exposure of people for non-medical imaging must be justified from the radiation protection point of view prior to the practice authorization.

Each individually authorized practice under paragraph 1 hereof is subject to review by the Directorate.

If the Directorate verifies the use of medical equipment in the practice of non-medical imaging exposure as justified, such practice shall be subject to authorization issuance.

### **Justification of Practices** **Article 70**

Preliminary to the introduction of a new class of radiation practice, the Directorate shall give consent to the use thereof in terms of exposure to ionizing radiation as justified based on the information submitted by the legal entity or entrepreneur.

Regarding the information under paragraph 1 hereof, the legal entity or entrepreneur shall submit the assessment of the intended practice as justified in terms of the overall societal and individual benefit, compared with a radiation risk.

The legal entity or entrepreneur, when verifying the justification under paragraph 2 hereof, shall take into account the following:

- 1) the benefit and the harm of the practice for a member of the public and the society;
- 2) financial and human resources necessary to perform the practice.

The Directorate shall establish a commission as an expert body to confirm the justification of a new class of radiation practice.

Preliminary to the introduction of new techniques and technologies into the existing radiation practices, the authorization holder shall re-examine their use as justified in terms of exposure to ionizing radiation and report on it to the Directorate, which shall give its consent to the introduction of new techniques and technologies within the existing radiation practice.

### **Training, Education and Exchange of Information in the field of Radiation Protection**

## **Article 71**

In order to provide for the education of persons whose jobs require special competences in the field of radiation and nuclear safety, the Directorate shall specify the training, education and exchange of information programmes, timeframes for periodic retraining and the method of testing and verifying the acquired knowledge.

The Directorate shall specify the type of jobs that require special competences in the field of radiation and nuclear safety.

## ***2 Professional Exposure***

### **Classification of Workplaces**

#### **Article 72**

Workplaces shall be classified as controlled areas and supervised areas.

Classification under paragraph 1 hereof shall be made with regard to the expected annual doses and the probability and magnitude of potential exposures.

The authorization holder shall classify the workplaces in accordance with paragraphs 1 and 2 hereof.

The Directorate shall specify the conditions of the classification under paragraph 1 hereof.

### **Categorization of Exposed Workers**

#### **Article 73**

For the purposes of radiation exposure monitoring, a distinction shall be made between two categories of exposed workers, category A and B.

The authorization holder shall categorize all exposed workers in line with paragraph 1 hereof.

The Directorate shall specify the requirements of categorization of the exposed workers under paragraph 1 hereof.

### **Medical Surveillance of Exposed Workers**

#### **Article 74**

Medical surveillance of the exposed workers shall be based on the principles governing the health protection.

Medical examination of the exposed workers shall be performed prior to employment, during the employment, following an emergency, and, if necessary, after cessation of work.

The authorization holder shall conduct medical surveillance of the exposed workers in accordance with paragraphs 1 and 2 hereof.

Ministries responsible for health and labour shall specify the scope and the schedule of the medical surveillance under paragraph 2 hereof.

## **Medical Records of Exposed Workers**

### **Article 75**

Medical records of the exposed workers shall be opened, kept and updated in line with the regulations governing record keeping in the field of health protection and include:

- 1) employment information;
- 2) results of medical examinations prior to employment;
- 3) results of periodic health screening;
- 4) results of the individual monitoring pursuant to the Law.

Medical records of the exposed workers are kept so long as the worker remains exposed and retained until the individual has or would have attained the age of 75 years, but in any case not less than 30 years after termination of the work involving exposure to ionizing radiation.

## **Individual monitoring of Exposed Workers**

### **Article 76**

The purpose of individual monitoring of the exposed workers under Article 73, paragraph 1 is to observe the exposure to ionizing radiation.

Authorization holder shall arrange individual monitoring of all engaged exposed workers including the external workers as well.

Authorization holder shall make the results of individual monitoring available to the Directorate and services competent for occupational health protection so as to gain better insight into the possible impact on the health of the exposed workers.

The Directorate shall specify the manner of conduct and requirements of individual monitoring of the exposed workers under Article 73, paragraph 1 hereof.

## **Monitoring of Workplace**

### **Article 77**

Workplace monitoring shall comprise the measurement of external dose rates, the measurement of radionuclide specific activity concentration in air and surface density of contaminating radionuclides.

The Directorate shall specify the requirements and the method of conducting the workplace monitoring under paragraph 1 hereof.

## **Responsibilities of Authorization Holder**

### **Article 78**

In the course of practice, the authorization holder shall provide for the exposed workers, persons engaged in emergency response, persons engaged in remediation activities, students and apprentices, and workers exposed to radon at their workplace, the following:

- 1) prior evaluation to identify ionizing radiation risk;
- 2) optimization of radiation protection in all working conditions, including occupational exposures as a consequence of practices involving medical exposures;
- 3) classification of exposed workers into different categories;
- 4) monitoring relating to the different areas and working conditions, including, where necessary, individual monitoring;
- 5) medical surveillance;
- 6) education and training;
- 7) the undertaking to inform the exposed workers on:
  - (1) the radiation health risks involved in their work;
  - (2) the general radiation protection procedures and precautions to be taken;
  - (3) the radiation protection procedures and precautions connected with the operational and working conditions of both the practice in general and each type of workstation or work to which they may be assigned;
  - (4) the relevant parts of the emergency response plans and procedures;
  - (5) the importance of complying with the technical, medical and administrative requirements;
  - (6) the obligation timely to inform the employer on pregnancy or breastfeeding; availability of the results of the individual monitoring.

Responsibilities of the authorization holder under paragraph 1 hereof are duly applied to the protection of volunteers as well.

## **Protection of Outside Workers**

### **Article 79**

The authorization holder shall be responsible for the ionizing radiation protection of the outside workers, hired either directly or through contractual agreements with their employer to carry out certain work.

The authorization holder shall ensure that the system for individual radiological monitoring affords the outside workers equivalent protection to that for the exposed workers employed on a permanent basis.

The outside workers shall make their own contributions to adhere to all radiation protection measures the authorization holder requires.



## **Specially Authorized Exposures**

### **Article 80**

The Directorate may decide, in exceptional circumstances, evaluated case by case, excluding emergencies, and where a specific operation so requires, to authorize individual occupational exposures of identified workers exceeding the dose limits.

The exposures under paragraph 1 hereof are limited in time, confined to certain working areas and within the maximum exposure levels that the Directorate defines for a particular case.

The Directorate shall specify the requirements for the permission of the exposures under paragraph 1 hereof.

## ***3 Medical Exposure***

### **Justification of Medical Exposure**

#### **Article 81**

Medical exposure shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct benefits to health of an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionizing radiation.

The justification of medical exposure under paragraph 1 hereof shall entail that:

- 1) new types of practices involving medical exposure are justified in advance before being authorized;
- 2) all individual medical exposures are justified in advance taking into account the specific objectives of the exposure and the characteristics of the individual involved;
- 3) if a type of practice involving medical exposure is not justified in general, a specific individual exposure of this type can be justified, where appropriate, in special circumstances, to be evaluated on a case-by-case basis and documented;
- 4) the referrer and the practitioner, where practicable, obtain previous diagnostic information or medical records relevant to the planned exposure and consider these data to avoid unnecessary exposure;
- 5) the Ministry responsible for health shall assess the justification of medical exposure for the purpose of medical or biomedical research;
- 6) the specific medical radiological procedures to be performed as part of a health screening programme are justified and consented by the Directorate and the Ministry responsible for health;
- 7) the exposure of carers and comforters show a sufficient net benefit, taking into account the direct health benefits to a patient, the possible benefits to the carer / comforter and the detriment that the exposure might cause;

8) any medical radiological procedure on an asymptomatic individual, to be performed for the early detection of disease, is part of a health screening programme, or requires specific documented justification for that individual by the practitioner, in consultation with the referrer, following guidelines from the Ministry responsible for health.

### **Optimization of Medical Exposure**

#### **Article 82**

Medical exposure shall be such that all doses are kept as low as reasonably achievable consistent with the required medical information, taking into account economic and societal factors.

Medical exposure shall be optimized by means of diagnostic reference levels that are regularly kept up to date.

Each medical or biomedical research project involving medical exposure shall comply with the following requirements:

- 1) that the individuals concerned participate voluntarily;
- 2) that these individuals are informed about the risks of exposure;
- 3) that a dose constraint is established for individuals for whom no direct medical benefit is expected from exposure;
- 4) that in case of patients who voluntarily accept to undergo an experimental medical practice and who are expected to receive a diagnostic or therapeutic benefit from this practice, the dose levels concerned shall be considered on an individual basis by the practitioner and/or referrer prior to the exposure taking place.

The Directorate shall specify and regularly review the diagnostic reference levels under paragraph 2 hereof.

### **Responsibilities for Performing Medical Exposure**

#### **Article 83**

Any medical exposure shall take place under the clinical responsibility of a practitioner competent for medical exposure.

The practitioner competent for medical exposure, the medical physics expert and those entitled to carry out practical aspects of medical radiological procedures are involved in and responsible for the optimization process of medical exposure.

The referrer and the practitioner competent for conducting medical exposure are involved in the justification process of individual medical exposures, within their competences.

The practitioner competent for conducting medical exposure and the referrer shall ensure that the patients undergoing medical exposure, including carers and comforters, are provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure.

## **Medical physicist**

### **Article 84**

Engagement of medical physicist is required for the performance of high-risk practices in medicine.

Medical physicist shall:

- 1) ensure that measuring devices have been calibrated and verified;
- 2) ensure technical surveillance of devices and their maintenance;
- 3) ensure data and device documentation keeping;
- 4) observe investigation and development of new techniques in the field of medical physics;
- 5) perform acceptance testing of devices;
- 6) perform dosimetry of radiation sources and dosimetry of patients;
- 7) optimize physical aspects of diagnostic and therapeutical activities;
- 8) provide for radiation protection of patients, staff and other individuals;
- 9) perform surveillance of protocols of quality assurance and quality control;
- 10) carry out, develop and enhance the protocols for safe and secure use of radiation sources.

In the process of the intended introduction of new classes of devices or techniques within a high-risk practice in medicine, the legal entity or entrepreneur shall provide for participation of a medical physicist with regard to drafting spatial documentation and technical specification.

## **Protection Measures for Radiation Practices in Medicine**

### **Article 85**

In terms of medical practices and pursuant to the fundamental principles of radiation protection under Article 29 hereof, the Directorate shall specify the following:

- 1) protection measures for persons using radiation sources in medicine;
- 2) protection measures for patients including justification and optimization of exposure;
- 3) the type and the scope of procedures necessary to perform a radiation practice in medicine;
- 4) training and education of persons taking part in medical exposure
- 5) criteria for technical specifications and functionality of radiation generators or devices with integrated radioactive sources;
- 6) protection measures for particularly important groups
- 7) measures relating to accidental and unintended medical exposures;
- 8) method of evaluating the level of medical exposure;
- 9) radiation safety and security measures in medicine;
- 10) special measures necessary for medical radiation practice performance.

## **4 Public Exposures**

### **Operational Protection of Members of the Public**

#### **Article 86**

In order to ensure the protection of individuals from the harmful effects of ionizing radiation, the licensee shall, in the facilities where the practices are performed, implement radiation and nuclear safety and security measures with particular regard to:

- 1) Examination and approval of the proposed siting and design of the facility from a radiation protection point of view, taking into account relevant demographic, meteorological, geological, hydrological and ecological conditions, as well as environmental protection conditions;
- 2) Acceptance into service of the facility subject to the requirement of adequate protection against radiation exposure or radioactive contamination;
- 3) Examination and approval of plans for the discharge of radioactive effluents; 4) Measures to control the access of members of the public to the facility.

The Directorate shall specify the conditions under paragraph 1 hereof.

In case of practices subject to registration, the Directorate shall specify the requirements for health protection of the members of the public under normal circumstances.

### **Estimation of doses for a Representative Person**

#### **Article 87**

Prior to obtaining relevant authorization, a legal entity or entrepreneur shall ensure that in the course of practice performance and commensurate with radiation exposure risk all arrangements are made for the estimation of doses for a representative person and a member of the public.

The Directorate shall specify, proportionately to the risk involved, the practices requiring the evaluation of doses under paragraph 1 hereof and the manner of evaluating the dose.

### **Radioactive Discharges**

#### **Article 88**

The authorization holder shall obtain the consent from the Directorate for every instance of deliberate discharge of radioactive effluents into the environment.

Prior to authorization issuance, the Directorate shall approve of the dose limits and requirements for discharging radioactive effluents as effective annual doses for a representative person taking into account good practice of handling the same or similar facilities.

The Directorate shall specify the criteria and requirements for discharging radioactive effluents into the environment, the issuance of the consent under paragraph 1 hereof, and for approving of the limits under paragraph 2 hereof.

The Directorate shall authorize discharge of radioactive effluents at the request of a licensee, and based on the fulfilment of requirements for health protection of a member of the public, the public and the environment.

### **Monitoring of Radioactive Discharges**

#### **Article 89**

The authorization holder shall undertake to monitor permitted discharges of radioactive effluents and to report regularly the results of such monitoring to the Directorate.

The Directorate shall specify the manner of and the requirements for the monitoring, and the schedule of reporting the results to the Directorate under paragraph 1 hereof.

### **Responsibilities of Authorization Holders in Terms of Radiation Protection**

#### **Article 90**

In the course of practice performance and for the purpose of ensuring the control of the exposure of the members of the public and the public, the authorization holder shall carry out the following tasks:

- 1) achieve and maintain an optimal level of protection of members of the public;
- 2) accept into service the adequate equipment and procedures for measuring and assessing the exposure of the members of the public and radioactive contamination of the environment;
- 3) regularly check the efficiency and maintenance of the equipment under point 2) and ensure regular calibration of measuring instruments;
- 4) seek advice from a radiation protection expert in the performance of the tasks under points 1), 2) and 3), if necessary.

The Directorate shall specify the authorization holder's tasks in terms of ionizing radiation protection for the public.

### **Environmental Radioactivity Monitoring**

#### **Article 91**

The purpose of environmental radioactivity monitoring is to determine the presence of radionuclides in the environment and to assess the levels of exposure of the public to ionising radiation in normal circumstances, in case of a suspicion of an emergency, and during a nuclear or radiological emergency.

The environmental radioactivity monitoring under paragraph 1 hereof shall be implemented in accordance with the Environmental Radioactivity Monitoring Programme, which is passed by the Directorate.

Environmental Radioactivity Monitoring Programme serves to establish the locations, time intervals and the manner of control of radioactivity in the environment.

Only a person with the approval to carry out the tasks of radiation protection, that is radioactivity monitoring or individual monitoring tests can conduct environmental radioactivity monitoring.

The Directorate shall specify the manner of conducting radioactivity monitoring under paragraph 1 hereof, the content and the schedule of adopting the Environmental Radioactivity Monitoring Programme, as well as the requirements for its modification.

### **Environmental Radioactivity Monitoring Report Article 92**

The approved radiation protection officer conducting the environmental radioactivity monitoring shall submit the Environmental Radioactivity Monitoring Report to the Directorate not later than 31 March of the current year for the previous year, or immediately in case of a nuclear or radiological emergency, or at the request of the Directorate.

Environmental radioactivity monitoring results serve the Directorate to observe the level of public exposure to ionizing radiation, to assess the doses received by the public and, in case of increased radioactivity, to make arrangements for and order urgent and other protection measures to be taken.

The Directorate shall publish the annual report on the levels of public exposure to ionizing radiation in the Republic of Serbia not later than 31 May of the current year for the previous year.

Financial arrangements for the environmental radioactivity monitoring and the assessment of the public exposure level shall be provided from the budget of the Republic of Serbia.

### **Existing Exposure Situations Article 93**

The Directorate shall specify the requirements for identifying the existing exposure situations based on the evidence of exposure caused by:

- 1) residual contamination resulting from the past practices or emergency situation which cannot be disregarded from a radiation protection point of view;
- 2) increased radioactivity resulting from the presence of naturally occurring radiation sources;

3) use of consumer products incorporating naturally occurring ionizing radiation sources. Depending on the risk assessment, existing exposure situations can also be regarded as planned exposure situations.

The Directorate shall specify protective measures for the exposed workers and members of the public from the harmful effect of ionizing radiation in case of existing exposure situations.

### **Contaminated Areas**

#### **Article 94**

The Directorate shall specify the requirements for the management of areas with residual contamination resulting from past practices or an emergency that cannot be disregarded from a radiation protection point of view.

### **Building Material**

#### **Article 95**

The Directorate shall specify the reference level of indoor external exposure to gamma-ray radiation emitted by building material in order to protect the members of the public from gamma-ray radiation from building material.

### **Indoor Exposure to Radon**

#### **Article 96**

The Directorate shall specify reference levels of indoor radon concentration in dwellings, closed space at work, appropriate protection measures, radon concentration-reducing measures in the existing facilities, as well as means of preventing radon from penetrating into new facilities.

The Directorate shall specify workplaces that require radon concentration measurements in order to evaluate the level of staff exposure to ionizing radiation and requirements for performing activities in such workplaces that are outside the scope of practices prescribed by this Law.

### **Radionuclide Control**

#### **Article 97**

Products and other goods intended for the public, animals or intended for the use in work or living environment shall not be made available to the public if the content of radionuclides is such that their usual or recommended use can lead to the public exposure above the prescribed limits.

The Directorate shall specify the manner of control of radionuclide content for the products under paragraph 1 hereof.

**Naturally-occurring Radioactive Material**  
**Article 98**

The Directorate shall specify the requirements necessary to identify the types of activities outside the scope of practices provided by this Law that make use of materials containing naturally occurring radionuclides leading to the exposure of workers or members of the public that cannot be disregarded from a radiation protection point of view.

The Directorate shall specify the requirements for conducting the activities under paragraph 1 hereof.

***5 Services and Experts***

**Occupational Health Services**  
**Article 99**

Occupational health service shall perform medical surveillance of the exposed workers with regard to their exposure to ionizing radiation and their fitness to perform the assigned tasks involving activities with radiation sources in accordance with the health protection requirements.

**Dosimetry Service**  
**Article 100**

Dosimetry service shall control and read measuring equipment for individual exposure and interpret the results of measurements, measure radioactivity level in human body or biological samples and evaluate the dose.

The legal entity with the authorization to perform ionizing radiation protection tasks under Article 56, paragraph 1, point 2) is, in view of this Law, considered as a dosimetry service.

**Radiation Protection Expert**  
**Article 101**

The Directorate shall issue a certificate for the activities of radiation protection expert based on the submitted application and supplementary documentation prescribed by the Directorate.

The certificate under paragraph 1 hereof shall be issued for an individual or several fields of radiation protection for the period of five years as of the day of decision.

The radiation protection expert shall give competent advice to legal entities or entrepreneurs on matters relating to compliance with applicable legal requirements, in respect of occupational and public exposure.



The advice of the radiation protection expert shall cover, where relevant, but not be limited to, the following:

- 1) optimization and establishment of appropriate dose constraints;
- 2) plans for new facilities and the acceptance into service of new or modified radiation sources in relation to any engineering controls, design features, safety features and warning devices relevant to radiation protection;
- 3) categorization of workplaces as controlled and supervised areas;
- 4) classification of workers;
- 5) workplace and individual radiation monitoring programmes;
- 6) appropriate radiation monitoring instrumentation;
- 7) quality assurance;
- 8) environmental monitoring programme;
- 9) arrangements for radioactive waste management;
- 10) arrangements for prevention of emergencies;
- 11) preparedness and response in emergency exposure situations;
- 12) training and retraining programmes for exposed workers;
- 13) investigation and analysis of emergency events and appropriate remedial actions;
- 14) employment conditions for pregnant and breastfeeding workers;
- 15) preparation of appropriate documentation such as prior risk assessments and written procedures.

The radiation protection expert shall, where appropriate, liaise with the medical physics expert.

The radiation protection expert may be assigned the tasks of radiation protection of workers, members of the public and the public.

The Directorate shall specify the areas of ionizing radiation protection the certificate is issued for, detailed requirements for obtaining, extending and revoking the certificate for a radiation protection expert as well as the relevant certificate fees.

### **Consultations with a Radiation Protection Expert**

#### **Article 102**

The Directorate shall specify the authorization holders' responsibilities with regard to consultations with a radiation protection expert.

### **Medical Physics Expert**

#### **Article 103**

Medical physics expert is a person having the required knowledge, education and experience to participate in or give specialist advice on, as appropriate, the matters relating to the use of ionizing radiation in the course of medical exposure.

The Directorate shall issue the certificate for the activities of a medical physics expert.

The certificate under paragraph 2 hereof shall be issued for an individual or several areas of ionizing radiation use during medical exposure, for the period of 5 years.

Medical physics expert shall have the following tasks:

- 1) optimization of the radiation protection of patients and other individuals subject to medical exposure, including the application and the use of diagnostic reference levels;
- 2) the definition and quality assurance of the medical radiological equipment;
- 3) acceptance testing of medical radiological equipment;
- 4) the preparation of technical specifications for medical radiological equipment and installation method;
- 5) the surveillance of the medical radiological facilities;
- 6) the analysis of events involving, or potentially involving, accidental or unintended medical exposures;
- 7) the selection of equipment required to perform radiation protection measurements;
- 8) the training of practitioners responsible for medical exposure and other staff in relevant aspects of radiation protection.

The medical physics expert shall, where appropriate, liaise with the radiation protection expert.

The Directorate shall specify the areas of ionising radiation use in the course of medical exposure that require certificate, detailed requirements for obtaining, extending and revoking the certificate for the activities of a medical physics expert as well as the relevant certificate fees.

## **Radiation Protection Officer and Radiation Protection Service**

### **Article 104**

Radiation protection measures can be implemented by a radiation protection officer or a radiation protection service.

The Directorate shall specify the practices which call for the establishment of a radiation protection service for the implementation of the measures under paragraph 1 hereof, as well as requirements which need to be fulfilled in order to have such service established.

Radiation protection officer and a radiation protection service shall:

- 1) ensure that work with radiation is carried out in accordance with the requirements of any specified procedures or local rules;
- 2) supervise implementation of the workplace monitoring programme;
- 3) maintain adequate records of all radiation sources;
- 4) carry out periodic assessments of the condition of the relevant safety and warning systems;
- 5) supervise implementation of the personal monitoring programme;
- 6) supervise implementation of the health surveillance programme;

- 7) provide new workers with an appropriate introduction to local rules and procedures;
- 8) give advice and comments on work plans;
- 9) establish procedures for implementing radiation protection;
- 10) provide reports on the implementation of radiation protection;
- 11) participate in the arrangements for prevention of, preparedness for and response to emergency exposure situations;
- 12) ensure information and training of exposed workers;
- 13) liaise with the radiation protection expert;
- 14) conduct all the other activities connected with the radiation protection.

The Directorate shall specify the type and the degree of vocational education as well as the training and education necessary for the implementation of radiation protection measures by a radiation protection officer and persons engaged in radiation protection service.

## **6 *Radioactive Sources***

### **Classification of Radioactive Sources**

#### **Article 105**

Radioactive sources are classified into categories I, II, III, IV and V.

The Directorate shall specify the criteria for categorization of radioactive sources based on their likelihood to cause harm to a member of the public, the public and the environment if they are not managed in a safe and secure manner.

### **Control of Radioactive Sources**

#### **Article 106**

The authorization holder shall ensure that arrangements are made for keeping control of unsealed and sealed radioactive sources and devices with incorporated radioactive sources so as to guarantee their safe and secure management during their useful lives, and, when no longer required, their recycling or disposal.

The authorization holder shall keep records of sources and devices under paragraph 1 hereof.

The Directorate shall specify the measures and the content of records under paragraph 1 and 2 hereof.

The authorization holder shall promptly report to the Directorate and other competent authorities about any loss, theft, sabotage, significant leakage, unauthorized use or unauthorized release of radioactive material into the environment.

The authorization holder shall promptly report to the Directorate any transfer of high activity sealed sources and other sealed sources on whose change of location the Directorate must be notified.

## **Control of High Activity Sealed Sources**

### **Article 107**

A legal entity or entrepreneur, together with the application for the authorization for practices involving a high-activity sealed source, shall submit to the Directorate verification that:

- 1) adequate arrangements have been made for the safe management and control of high activity sealed sources, including when they become disused sources, for the purpose the authorization application has been submitted;
- 2) adequate provision, by way of a financial security or any other equivalent means appropriate for the source in question, has been made for the safe management of sources when they become disused sources, for the purpose the authorization is applied for, including the case where a legal entity or entrepreneur becomes insolvent or ceases activities.

The Directorate shall specify the requirements for the control of high-activity sealed sources.

The authorization holder or source supplier shall ensure that high-activity sealed sources and containers comply with the requirements for their identification and marking.

The Directorate shall specify the manner of identification of high-activity sealed sources and the containers thereof.

## **Record-keeping of Radioactive Sources**

### **Article 108**

The Directorate shall establish and regularly update the records of radioactive sources and the legal entities and entrepreneurs that perform practices with radioactive sources. The Directorate shall specify the content of the records under paragraph 1 hereof.

## **Disused sources**

### **Article 109**

The authorization holder for the performance of practices involving sealed radiation sources shall formally declare a sealed source to be disused.

The authorization holder under paragraph 1 hereof shall take all required measures to return the source to its supplier after it had been declared to be disused.

Provided that reshipment to supplier is not possible, a disused source can be recycled, its ownership transferred to another licensee, or declared to be radioactive waste.

The declaration under paragraph 1 hereof shall contain the intended handling of disused sources.

The authorization holder under paragraph 1 hereof shall submit the declaration to the Directorate within eight days of the day of the issuance.

The authorization holder under paragraph 1 hereof shall report to the Directorate all relevant information within eight days of the reshipment of a source to the supplier, its sending

for recycling, transfer of ownership over the source to another licensee or its sending to a centralized storage.

The Directorate shall specify the content of the declaration under paragraph 1 hereof.

The authorization holder under paragraph 1 hereof can keep a disused source in their own repository, but not longer than one year when they are obliged to transfer it to the centralized storage.

The Directorate shall specify the requirements concerning disused sources management.

## **Orphan Sources**

### **Article 110**

The legal entities or entrepreneurs performing activities outside the scope of practices covered by this Law, which are likely to cause threat to human lives, health and the environment from ionizing radiation resulting from the presence of orphan sources, shall:

- 1) obtain the appropriate equipment meeting the required meteorological conditions for radioactivity measurement;
- 2) hire staff adequately trained for radioactivity measurement;
- 3) perform regular measurements of radioactivity in order to recover orphan sources;
- 4) keep record on recovered orphan radiation sources;
- 5) report to the Directorate the recovered orphan radiation sources; 6) act in accordance with the requirements.

The practices under paragraph 1 hereof *inter alia* include:

- 1) activities in metal scrap storage facilities;
- 2) activities in metal scrap recycling facilities;
- 3) activities in ironworks and foundries using metal scrap;
- 4) nodal transit points such as traffic, post, border and administrative check points.

The Directorate shall plan for financial arrangements covering the costs of recovering orphan radiation sources.

Only the holder of the authorization for removal of orphan radiation sources can remove an orphan source from its location and transfer it to the centralized storage without undue delay.

The owner of an orphan source, if known, shall bear the costs of subsequent establishment of regulatory control over the orphan source.

Financial means necessary to cover the costs of subsequent establishment of regulatory control over orphan sources are provided from the budget of the Republic of Serbia if the owner of the orphan source is unknown.

The Directorate shall specify the practices and requirements for legal entities or entrepreneurs for taking action in case of recovery of orphan sources, the type of equipment, educational programme for staff responsible for radioactivity measurements of orphan sources, as well as the manner of conducting measurement, record-keeping and reporting under paragraph 1 hereof.

## **Decommissioning of a Radiation Facility**

### **Article 111**

The licensee for a radiation practice shall decommission the facility where the practice has been performed.

The Directorate shall stipulate the radiation practices requiring decommissioning.

The provisions of the Law pertaining to nuclear facility decommissioning shall duly apply to a radiation facility decommissioning under paragraph 1 hereof.

Radiation facility decommissioning under paragraph 1 hereof does not require the decision by the Government on the final status of decommissioning.

The licensee for a radiation practice under paragraph 1 hereof shall prepare and regularly review the initial decommissioning plan for a radiation facility.

## ***2 Nuclear Safety***

### **Management of Nuclear Facilities**

#### **Article 112**

Nuclear facility management is a practice of general interest in the Republic of Serbia.

The practice under paragraph 1 hereof shall include the management of centralized storage for radioactive waste, disused sources and spent nuclear fuel.

The public company whose founder is the Republic of Serbia shall perform the practices under paragraphs 1 and 2 hereof.

### **Prevention of Emergency Event**

#### **Article 113**

The authorization holder shall perform all nuclear activities in such a manner to prevent emergency occurrence and, in case of emergency event, to mitigate and avoid the consequences of:

- 1) early discharge of radioactivity that would require off-site action measures in case of nuclear or radiological emergency when there is insufficient time for their implementation;
- 2) substantial discharge of radioactivity requiring protection measures that could not be limited in terms of space and time.

In order to prevent the emergency event under paragraph 1 hereof, the authorization holder shall ensure:

- 1) that the impact of extreme outside natural elements and dangers unintentionally caused by human actions is as low as reasonably achievable;

- 2) prevention of abnormal operation and occurrence of failures;
- 3) control of abnormal operation and detection of failures;
- 4) control of design basis accidents;
- 5) control of severe conditions, including the prevention of emergency escalation and mitigation of emergency event consequences;
- 6) establishment of organizational structure for action in case of emergency event.

The Directorate shall specify the requirements for nuclear activity performance in terms of prevention of emergency events.

### **Radiation Protection Service**

#### **Article 114**

Licensee for a nuclear activity, except licensees for siting, design and construction of a nuclear facility, shall establish the radiation protection service under Article 104 hereof.

### **Integrated System of Management**

#### **Article 115**

The licensee for a nuclear activity shall implement and maintain integrated system of management.

The licensee for a nuclear activity performance shall take measures to improve and develop nuclear safety and nuclear security culture by implementing the integrated system of management.

The Directorate shall specify the measures and requirements for the establishment of the integrated system of management.

### **a) Construction of Nuclear Facility**

#### *Consent for the Intention to Construct a Nuclear Facility*

#### **Article 116**

The Government of the Republic of Serbia shall give its consent for the intention to construct a nuclear facility and the intention to acquire a mobile radioactive waste processing unit.

The Government of the Republic of Serbia shall give its consent for the intention to change the purpose of the existing facility into a nuclear facility.

The Government of the Republic of Serbia shall give the consents under paragraph 1 and 2 hereof based on the submitted application and justification to construct a nuclear facility, acquire mobile radioactive waste processing unit or change the purpose of the existing facility from a radiation and nuclear safety and security and the environmental impact point of view.

*License for Nuclear Facility Siting*

**Article 117**

The legal entity that has obtained the Government consent for the intention to construct a nuclear facility under Article 116 hereof, prior to the commencement of nuclear facility siting activities, shall obtain the license for a nuclear facility siting pursuant to Article 42 hereof.

The license under paragraph 1 hereof shall cease to be valid *inter alia* on the day of the issuance of the license for a nuclear facility design.

*Selection of Nuclear Facility Site*

**Article 118**

The aim of a nuclear facility site selection is to determine the most appropriate site for the construction of a nuclear facility and includes the analysis of:

- 1) all relevant factors in connection with the site, particularly the effects of external events occurring in the region of a particular site, either of natural origin or human induced;
- 2) the characteristics of the site and its environment that could influence the transfer of radioactive material that has been released to the public and the environment;
- 3) the population density and population distribution and other characteristics of the external zone in so far as they may affect the possibility of implementing emergency measures and the need to evaluate the risks to the population and the environment.
- 4) the impact of the proposed nuclear facility on the safety of the public and the environment.

The Directorate shall specify the requirements for a nuclear facility site selection.

*Report on a Nuclear Facility Site Selection*

**Article 119**

The licensee for performing a nuclear facility siting shall obtain the consent from the Directorate on the report on the nuclear facility site selection after conducting the analyses under Article 118, paragraph 1 hereof.

The Directorate shall issue the consent under paragraph 1 hereof within 60 days of the day of the duly submitted application.

The report on a nuclear facility site selection shall contain particularly the following elements:

- 1) the analysis of potential sites for the construction of a nuclear facility with regards to the social and economic factors;
- 2) the data on the most appropriate site for the construction of a nuclear facility and the results of initial radiological testing;
- 3) the design concept of a nuclear facility;



4) the analysis of the impact of the most appropriate site on the safety of the nuclear facility design concept;

5) financial and other guarantees for a nuclear facility construction.

The Directorate shall draw up special requirements for the issuance of the consent under paragraph 2 hereof, and the scope and the content of the report on a nuclear facility site selection.

The Directorate may prescribe additional measures of radiation and nuclear safety and security for the selected site.

The Directorate shall reject the application for the issuance of the consent under paragraph 1 hereof if the established requirements of radiation and nuclear safety and security have not been fulfilled.

### *License for Nuclear Facility Design*

#### **Article 120**

The licensee for a nuclear facility siting, prior to a nuclear facility design, shall obtain the license for a nuclear facility design pursuant to Article 42 hereof.

The legal entity intending to build a mobile radioactive waste processing unit shall also obtain the license for nuclear facility design after obtaining the consent from the Government under Article 116 hereof.

The legal entity intending to change the purpose of the existing facility into a nuclear facility, prior to facility conversion, shall conduct the analysis of the site pursuant to Article 118 hereof, report the results of the analyses to the Directorate and obtain the license for a nuclear facility design pursuant to Article 42 hereof.

The license under paragraph 1 hereof shall expire, *inter alia*, on the day of the issuance of the license for a nuclear facility construction.

### *Design of Nuclear Facility*

#### **Article 121**

Design of a nuclear facility, except mobile radioactive waste processing unit, shall be performed only with the previously obtained consent from the Directorate to the report on the nuclear facility site selection under Article 119, paragraph 2 hereof.

Nuclear facility design should be such that radiation and nuclear safety and security requirements can be met in accordance with the features of the selected site and design basis. A nuclear facility design shall ensure that:

1) the nuclear facility and associated structures, systems and components relevant for the safety and security have the appropriate characteristics to allow for the safety and security functions performance with necessary reliability;

- 2) the facility can be operated safely within the operational limits and conditions for its entire lifetime and in case of failures;
- 3) the nuclear facility can be decommissioned in a safe and secure manner;
- 4) the harmful effect on people and the environment is as low as reasonably achievable.

The licensee for a nuclear facility design shall draft the initial decommissioning plan during the design stage for all nuclear facilities, i.e. the initial closure plan for radioactive waste disposal facilities pursuant to this Law.

Design of a nuclear facility, except a mobile radioactive waste processing unit, shall be in line with the regulations governing planning and construction of facilities.

The Directorate shall specify the requirements for a nuclear facility design, and the scope and the content of a nuclear facility design.

### *Report on a Nuclear Facility Design*

#### **Article 122**

The licensee for a nuclear facility design shall prepare and submit to the Directorate for consent the report on a nuclear facility design and the design of a nuclear facility.

The Directorate shall issue the consent under paragraph 1 hereof within 60 days of the day of duly submitted application.

The report on a nuclear facility design under paragraph 1 hereof shall include the following elements in particular:

- 1) nuclear facility design basis assessment;
- 2) nuclear facility site boundaries
- 3) protection against external and internal hazards that can lead to an emergency event;
- 4) ionizing radiation protection measures;
- 5) safety and reliability analysis of the associated structures, systems and components relevant for the safety and security of a nuclear facility;
- 6) routine radioactive discharges from the nuclear facility;
- 7) evidence of learning from operating experience in designing a nuclear facility;
- 8) evaluation of human and organizational resources necessary for the safety and security of the nuclear facility.

The Directorate shall specify the scope and the content of the report on a nuclear facility design.

The Directorate may prescribe additional radiation and nuclear safety and security measures for a nuclear facility design.

The Directorate shall reject the application for the consent to the report under paragraph 1 hereof if the established radiation and nuclear safety and security requirements have not been fulfilled.

### *Nuclear Facility Site*

#### **Article 123**

Nuclear facility design serves to establish the boundaries of a nuclear facility site.

The Directorate shall specify the criteria for establishing the boundaries of a nuclear facility site.

The Government, as proposed by the Directorate, shall declare the nuclear facility site based on the approved report on nuclear facility design under Article 122 hereof.

### *Decision on Nuclear Facility Construction*

#### **Article 124**

The Government, based on previously obtained consent from the National Assembly shall decide on the construction of a nuclear facility, except a mobile radioactive waste processing unit.

The applicant for the decision on a nuclear facility construction shall obtain, and submit to the Government, together with the application, the following:

- 1) consent to the intention to construct a nuclear facility under Article 116 hereof;
- 2) license for a nuclear facility design under Article 120 hereof;
- 3) consent for the reports on a nuclear facility site selection and a nuclear facility design under Articles 119 and 122 hereof.

### *License for a Nuclear Facility Construction*

#### **Article 125**

The licensee for a nuclear facility design shall, before the construction of a nuclear facility or reconstruction of the existing facility obtain the license for a nuclear facility construction pursuant to Article 42 hereof.

The license for a nuclear facility construction shall be issued for the construction of a nuclear facility with previously obtained:

- 1) consent to the report on a nuclear facility design under Article 122, paragraph 2 hereof;
- 2) construction permit in accordance with the regulations governing planning and construction;
- 3) the decision by the Government of the Republic of Serbia on the construction of a nuclear facility pursuant to this Law.

Provisions under paragraph 2, points 2) and 3) shall not pertain to a mobile radioactive waste processing unit.

In addition to requirements under Article 42 hereof, the applicant shall ensure:

- 1) the integrated system of management has been established;
- 2) that all subcontractors have also established the integrated system of management;

3) organizational and financial arrangements for decommissioning and radioactive waste and spent nuclear fuel management.

The license under paragraph 1 hereof shall expire, *inter alia*, on the day of the issuance of the license for trial run of a nuclear facility.

#### *Design Modifications during Construction*

##### **Article 126**

Based on the decision under Article 124, paragraph 1 hereof, the Government can empower the Directorate to authorize design modifications occurring in the course of construction on condition that the proposed changes either have no effect or have beneficial effect on radiation and nuclear safety and security, but prior to their realization, on which the Directorate informs the Government.

Where there is need to modify the authorized design during nuclear facility construction, the Directorate shall particularly review and assess the following:

- 1) acceptability of the proposed nuclear facility design changes from a radiation and nuclear safety and security point of view;
- 2) acceptability of changes at the authorized nuclear facility site, except mobile radioactive waste processing unit, from a radiation and nuclear safety and security point of view;
- 3) results of research and development activities relating to demonstration of design acceptability.

The Directorate shall reject the proposed design modifications under paragraph 1 hereof if it determines these have harmful effect on radiation and nuclear safety and security.

#### *Nuclear facility construction*

##### **Article 127**

Nuclear facility, except mobile radioactive waste processing unit, can be constructed only on the site with a spatial and urbanistic plan, issued construction permit and other documentation pursuant to the laws governing urban planning and construction, and the assessment of the environmental effect.

Nuclear facility has to be constructed in a manner so that its decommissioning can be conducted in a safe and secure manner.

The licensee for nuclear facility construction shall ensure that all structures, systems and components are constructed, installed, reviewed and tested in accordance with the applicable standards and regulations throughout all stages of construction.

The Directorate shall specify the requirements for a nuclear facility construction.

## **b) Nuclear Facility Operation**

### *License for a Nuclear Facility Trial Run*

#### **Article 128**

The licensee for a nuclear facility construction, prior to the nuclear facility commissioning, shall obtain the license for trial run of a nuclear facility in accordance with Article 42 hereof.

The applicant for the license for trial run of a nuclear facility shall submit to the Directorate, together with the application, the Nuclear Facility Trial Run Programme.

The Directorate shall specify the scope of Nuclear Facility Trial Run Programme.

The license for a nuclear facility trial run shall be terminated, *inter alia*, with the issuance of the license for a nuclear facility operation.

### *Trial Run of a Nuclear Facility*

#### **Article 129**

Trial run of a nuclear facility consist of two stages:

- 1) non-nuclear testing (before the introduction of nuclear or certain types of radioactive material) and
- 2) nuclear testing (after the introduction of nuclear or certain types of radioactive material).

The licensee for a nuclear facility trial run shall make use of the trial run period to confirm the quality of completed and installed systems, structures and components relevant for the safety and security.

The Directorate can be present during certain types of testing performed during nuclear facility trial run.

The legal entity or entrepreneur shall perform trial run of a mobile radioactive waste processing unit each time its location has been changed.

The licensee for a nuclear facility trial run shall establish and maintain safety and physical protection measures in the facility during the nuclear testing stage.

The Directorate shall specify the requirements for a trial run of a nuclear facility.

### *Non-nuclear Testing Stage*

#### **Article 130**

Non-nuclear testing, before the introduction of nuclear or certain types of radioactive material, shall be conducted to ensure, to the extent possible, that the nuclear facility and installed structures, systems and components are in accordance with the nuclear facility design, regulations and applicable international standards.

After the non-nuclear testing stage, the licensee for a nuclear facility trial run shall submit to the Directorate the report on the abovementioned stage, which shall include all deviations

from the design specifications and all changes in the documentation submitted for the issuance of the license that resulted from the tests conducted in this stage.

The Directorate shall give consent to the report under paragraph 2 hereof.

### *Nuclear Testing stage*

#### **Article 131**

Nuclear testing, after the introduction of nuclear or certain types of radioactive material shall be conducted to ensure, to the extent possible, that the nuclear facility, prior to operation, fulfils all radiation and nuclear safety and security requirements.

Primary to the nuclear testing stage, the Directorate shall conduct review, control and supervision over the fulfilment of the prescribed radiation and nuclear safety and security measures.

Before the nuclear testing of the facility, the licensee for a nuclear facility trial run shall submit to the Directorate radioactive waste management plan, initial decommissioning plan for all nuclear facilities except for the radioactive waste disposal facility which requires the initial closure plan pursuant to this Law.

After the nuclear testing stage, the licensee for a nuclear facility trial run shall submit to the Directorate the report on the aforementioned stage incorporating all deviations from the design specifications and all changes in the documentation submitted for obtaining the license, and which have resulted from the tests conducted during this stage.

The Directorate shall give consent to the report under paragraph 4 hereof.

### *Commissioning of Nuclear Facility after Cessation*

#### **Article 132**

Nuclear facilities which are recommissioned after cessation or reconstructions and modifications due to changes in operational technology are subject to Articles 128, 129, 130 and 131 hereof.

### *License for Nuclear Facility Operation*

#### **Article 133**

The licensee for a nuclear facility trial run shall obtain the license for a nuclear facility operation pursuant to Article 42 hereof.

Before nuclear facility operation is licensed, the Directorate shall carry out the inspection, review and assessment of:

- 1) implementation of radiation and nuclear safety and security measures; 2) results of trial run tests;
- 3) operational conditions and limits;
- 4) operating instructions and procedures;

- 5) human resources ensuring safe and secure performance of the activities;
- 6) arrangements for emergency preparedness and response.

The license for nuclear facility operation shall be terminated, *inter alia*, on the day of the issuance of the license for nuclear facility decommissioning.

### *Nuclear Facility Operation*

#### **Article 134**

The licensee for a nuclear facility operation shall ensure that:

- 1) nuclear facility is operated within the operational limits and conditions established by the Safety Analysis Report;
- 2) in-service inspection, surveillance and testing of structures, systems and components relevant for safe operation of the facility are established and implemented;
- 3) the maintenance programme for the structures, systems and components relevant for safe operation of the facility is established and implemented;
- 4) review and analysis of any changes in the procedures and the integrated system of management, and changes in the structures, systems and components important for the safety of the facility are implemented before submitting the application for modification of the decision on the issuance of the license to the Directorate and pursuant to this Law;
- 5) the adequate number of duly competent and trained staff have been engaged and the training programme has been in place;
- 6) the safety and physical protection measures have been implemented and maintained during nuclear facility operation.

The licensee for nuclear facility operation shall, during the operation of a nuclear facility, periodically review and update the radioactive waste management plan, the initial decommissioning plan for all nuclear facilities except for the radioactive waste disposal facility, i.e., the initial closure plan for a radioactive waste disposal facility in accordance with the Law.

Mobile radioactive waste processing unit shall be operated only on the site that meets all requirements for safe and secure practice performance, which are determined by the analysis under Article 118, paragraph 1 hereof.

The Directorate shall specify the requirements for nuclear facility operation.

### *Temporary Shut-down of a Nuclear Facility*

#### **Article 135**

Nuclear facility, except mobile radioactive waste processing unit, can be temporarily shut down due to any justified reason that was not devised by the Safety Analysis Report for a nuclear facility operation.

The licensee shall ensure safe and secure management of a nuclear facility during temporary shut-down, particularly in terms of radioactive waste, spent fuel and radiation sources management, and fire protection and suppression.

Pursuant to the Law, the Directorate may require the licensee to submit the application for the license for a nuclear facility trial run after its temporary shut-down.

The Directorate shall specify the requirements for a temporary shut-down of a nuclear facility.

If the nuclear facility has been permanently shut down and the legal entity that had managed it is no longer available, the Government of the Republic of Serbia shall make a decision on further management of such nuclear facility.

#### *Consent to Nuclear Facility Temporary Shut-down*

##### **Article 136**

The licensee for a nuclear facility operation shall obtain from the Directorate a consent to the nuclear facility temporary shut-down.

In addition to the application, the licensee under paragraph 1 hereof shall submit to the Directorate the Programme of temporary shut-down.

The Directorate shall specify the scope and content of the Programme under paragraph 2 hereof.

#### **c) Decommissioning**

#### *Decision on the End State of a Nuclear Facility Decommissioning*

##### **Article 137**

The Government shall make the decision on the end state of a nuclear facility decommissioning, except in case of a mobile radioactive waste processing unit at the request of the licensee for a nuclear facility decommissioning.

In addition to the application, the applicant under paragraph 1 hereof shall submit to the Government a document verifying the selected end state of decommissioning as justified, and the license for a nuclear facility decommissioning.

The end state of the facility can be:

- 1) use of the nuclear facility, site and the parts thereof without limitations;
- 2) limited use of the nuclear facility, site and the parts thereof;
- 3) limited access to the nuclear facility, site and the parts thereof.

#### *License for Nuclear Facility Decommissioning*

##### **Article 138**

Pursuant to Article 42 hereof, the licensee for nuclear facility operation shall obtain the license for nuclear facility decommissioning for all facilities except for the radioactive waste disposal facility.



Pursuant to the Law, the applicant for the issuance of the license for nuclear facility decommissioning shall also submit to the Directorate a decommissioning plan, a remediation plan and radioactive waste management plan.

The license for a nuclear facility decommissioning shall cease to be valid, *inter alia*, on the day of the issuance of the decision on the license termination.

### *Nuclear Facility Decommissioning*

#### **Article 139**

Nuclear facility decommissioning serves to reduce radiation risk and to release the nuclear facility or a part thereof from regulatory control.

Nuclear facility decommissioning consists of the preparation stage and actual decommissioning activities.

The Directorate shall specify the requirements for a nuclear facility decommissioning.

### *Decommissioning Preparation Stage*

#### **Article 140**

Preparation stage for nuclear facility decommissioning shall imply facility maintenance, the instance of obtaining the decision from the Government of the Republic of Serbia on the end state of a nuclear facility decommissioning, and the updated decommissioning plan commensurate with the decision by the Government on the end state of a nuclear facility decommissioning.

After completing the preparation stage, the licensee for a nuclear facility decommissioning shall submit to the Directorate the updated version of decommissioning plan commensurate with the decision of the Government of the Republic of Serbia on the end state of a nuclear facility decommissioning, and other updated documentation that served as a basis for issuing the license for a nuclear facility decommissioning.

The Directorate shall give its consent to the documentation under paragraph 2 hereof within 90 days of the reception of the relevant documentation.

The provision of paragraph 1 hereof does not pertain to a mobile radioactive waste processing unit.

### *Actual Decommissioning Activities*

#### **Article 141**

Actual decommissioning activities shall imply decontamination, dismantling and demolishing of nuclear facility structures, systems and components, management of the resulting radioactive waste and demonstration that the nuclear facility decommissioning end state has been achieved.

The licensee for a nuclear facility decommissioning can initiate actual decommissioning activities only after obtaining the consent under Article 140 hereof from the Directorate.

During this stage the licensee for a nuclear facility decommissioning shall:

- 1) prepare and implement procedures ensuring radiation and nuclear safety and security;
- 2) apply good engineering practice;
- 3) ensure that staff are properly trained, qualified and have necessary competences; 4) keep the required records;
- 5) choose decontamination and dismantling techniques so that the protection of workers, the public and the environment is optimized and the generation of waste as low as reasonably achievable;
- 6) establish arrangements for action in case of emergency;
- 7) establish and maintain physical protection measures for the facility during decommissioning;
- 8) ensure safe and secure management of radioactive waste arising from decommissioning activities until its disposal.

Once the decommission has been completed, the licensee for a nuclear facility decommissioning shall prepare the Decommissioning Report demonstrating that decommissioning end state has been achieved commensurate with the Decommissioning Plan, and the report on final radiological survey of the facility and the site, which are submitted to the Directorate.

The Directorate shall give its consent to the reports under paragraph 4 hereof within 90 days of the reception of the relevant documentation.

#### *Initial Decommissioning Plan*

##### **Article 142**

The licensee for design, construction, trial run and operation of a nuclear facility shall prepare, periodically update, and review the initial decommissioning plan for all nuclear facilities except for a radioactive waste disposal facility.

The initial decommissioning plan under paragraph 1 hereof shall include available decommissioning strategies, their feasibility analysis, assessment of financial arrangements for the implementation of decommissioning and their provision, category identification and quantity evaluation of radioactive and other waste that can be generated during decommissioning, as well as the manners of radioactive and other waste management.

The Directorate shall specify the scope and the content of the initial decommissioning plan under paragraph 1 hereof.

#### *Decommissioning plan*

##### **Article 143**

The licensee for nuclear facility decommissioning shall prepare, and periodically update and review the nuclear facility decommissioning plan.

The final nuclear facility decommissioning plan shall include in particular: 1)

- selected decommissioning strategy;
- 2) schedule, type and sequence of decommissioning actions;
- 3) radioactive waste management strategy applied including release from regulatory control;
- 4) proposed end state and the manner in which the licensee will demonstrate that the end state has been achieved;
- 5) timeframe for decommissioning;
- 6) financial arrangements for the completion of decommissioning.

The Directorate shall specify the scope and the content of the decommissioning plan under paragraph 1 hereof.

### *Review and Revision of Decommissioning Plan*

#### **Article 144**

The decommissioning plan under Articles 142 and 143 hereof shall be reviewed and revised in the light of operational experience gained, available information on decommissioning of identical or similar facilities, new or revised safety and security requirements and technological developments relevant to the actual decommissioning activities.

The licensee for nuclear facility decommissioning shall submit to the Directorate the report on the review and revision of the decommissioning plan under paragraph 1 hereof.

The licensee for nuclear facility decommissioning shall submit to the Directorate the report on review and revision of the decommissioning plan under paragraph 1 hereof after any unplanned event with consequences relevant for decommissioning of the facility.

The Directorate shall specify the schedule of review and revision of decommissioning plans under paragraph 1 hereof and the schedule of submitting the befitting reports to the Directorate.

The Directorate may require the licensee for nuclear facility decommissioning to perform an extraordinary review and revision of decommissioning plan under paragraph 1 hereof and to submit to the Directorate the report on it.

### *Termination of Decommissioning License*

#### **Article 145**

The licensee for nuclear facility decommissioning shall submit the application for the termination of the decommissioning license following the completion of all activities intended by the decommissioning plan under Article 143 hereof.

In addition to the application under paragraph 1 hereof, the licensee for nuclear facility decommissioning shall submit to the Directorate the decommissioning report and the report on the final radiological survey of the facility and the site.

Prior to the issuance of the decision on the termination of the license, the Directorate shall review, control and supervise the nuclear facility and the site in order to confirm that the end state intended by the decommissioning plan has been achieved and that all requirements within the license have been met.

The Directorate shall issue a decision on the termination of the decommissioning license based on the assessment of the decommissioning report and the report on the final radiological survey.

The decision to terminate the license for nuclear facility decommissioning can serve the Directorate to prescribe additional radiation and nuclear safety and security measures that the legal entity or entrepreneur shall apply in the facility, the site and the parts thereof until they have been released from regulatory control.

#### *License for Closure of Radioactive Waste Disposal Facility*

##### **Article 146**

The licensee for the operation of radioactive waste disposal facility shall obtain the license for radioactive waste disposal facility closure, pursuant to Article 42 hereof.

The applicant for the license for radioactive waste disposal facility closure, together with the application, shall submit to the Directorate the plan for radioactive waste disposal facility closure.

The license under paragraph 1 hereof shall, *inter alia*, cease to be valid on the day of issuing the decision to terminate the license for radioactive waste disposal facility closure, in accordance with the Law.

#### *Closure of Radioactive Waste Disposal Facility*

##### **Article 147**

Closure of radioactive waste disposal facility shall include the activities of decontamination, disassembling and demolishing of structures, systems and components and bringing the facility in a state that ensures long-term safety of disposed radioactive waste.

The licensee for the closure of radioactive waste disposal facility shall establish and implement measures of control at the site of closed radioactive waste disposal facility.

The measures of control particularly include:

- 1) the prevention of unauthorized use of the site and human intrusion into the disposal facility after closure;
- 2) environmental radioactivity monitoring and surveillance of the closed disposal facility site;
- 3) maintenance and remedial actions, if necessary;
- 4) the mechanism of transfer of knowledge to future generations

The Directorate shall specify requirements for the closure of radioactive waste disposal facility, and measures of control at the site.

*Initial Plan for Radioactive Waste Disposal Facility Closure*

**Article 148**

The licensee for design, construction, trial run and operation of a radioactive waste disposal facility shall prepare and periodically update the initial plan for radioactive waste disposal facility closure.

The initial plan under paragraph 1 hereof shall particularly include:

- 1) available options for the closure of radioactive waste disposal facility;
- 2) feasibility analysis for the closure of radioactive waste disposal facility;
- 3) assessment of financial arrangements and manners of their provision;
- 4) description and types of disposed radioactive waste;
- 5) timeframe for radioactive waste disposal;
- 6) annual estimates of radioactive waste volumes;
- 7) the location of radioactive waste within the facility;
- 8) plans for phased interim closure of individual disposal units.

The Directorate shall specify the scope and the content of the initial plan for radioactive waste disposal facility closure.

*Plan for Radioactive Waste Disposal Facility Closure*

**Article 149**

The licensee for radioactive waste disposal facility closure shall prepare, periodically review, and update the plan for radioactive waste disposal facility closure.

The plan under paragraph 1 hereof shall particularly include:

- 1) manner of closing the radioactive waste disposal facility;
- 2) description and types of radioactive waste disposed and its location within the facility;
- 3) description and sequence of the activities for radioactive waste facility closure;
- 4) active and passive measures of control;
- 5) timing of radioactive waste disposal facility closure actions;
- 6) assessment of financial arrangements for the facility closure.
- 7) description of the final engineered barriers and site markers preventing discharges into the environment;
- 8) type of site markers used after the closure; 9) tools used for communication with the public.

The Directorate shall specify the scope and the content of the plan for radioactive waste disposal facility closure.

*Review and Revision of Plan for Radioactive Waste Disposal Facility Closure*

**Article 150**

Review and revision of the plan for radioactive waste disposal facility closure under Articles 148 and 149 hereof shall be conducted based on the experience gained, available data on the closure of the identical or similar facilities, new or modified safety and security requirements and technology development applied during closure activities.

Review and revision of the plan for radioactive waste disposal facility closure under paragraph 1 hereof shall also be performed after every unplanned event that can affect the radioactive waste disposal facility closure.

The licensee shall submit to the Directorate the report on review and revision of the plan for radioactive waste disposal facility closure under paragraphs 1 and 2 hereof.

The Directorate shall specify the schedule of review and revision of the plan for radioactive waste disposal facility closure under paragraph 1 hereof and the schedule in which the report under paragraph 3 hereof shall be submitted to the Directorate.

The Directorate may require the licensee for radioactive waste disposal facility closure to perform an extraordinary review and revision of the plan for radioactive waste disposal facility closure under Articles 148 and 149 hereof and to submit to the Directorate a report on it.

*Termination of License for Radioactive Waste Disposal Facility Closure*

**Article 151**

The licensee for the closure of radioactive material disposal facility shall submit the application for the license termination upon the completion of all activities prescribed by the plan for radioactive waste disposal facility closure under Article 148 hereof.

The licensee for the closure of radioactive material disposal facility, together with the application under paragraph 1 hereof, shall submit to the Directorate the report on the radioactive waste disposal facility closure and the report on the completion of the final radiological survey of the facility and the site.

Prior to the decision on license termination, the Directorate shall review, control and supervise the facility and the site in order to verify that the requirements stipulated by the plan for radioactive waste disposal facility closure have been fulfilled.

The Directorate shall issue a decision to terminate the license for radioactive waste disposal facility closure based on the evaluation of the report on radioactive waste disposal facility closure, the report on the completion of the final radiological survey, the results of the review, control and supervision, and verification that the facility has been closed in a safe and secure manner.

The decision to terminate the license for radioactive waste disposal facility closure can serve the Directorate to establish additional radiation and nuclear safety and security measures that a legal entity or an entrepreneur shall apply in the facility, the site and the parts thereof until they are released from regulatory control.

*Financial Arrangements for Decommissioning and Disposal Facility Closure*

**Article 152**

The licensee for a nuclear activity, pursuant to the Law and prior to the commencement of a nuclear facility construction, shall provide for financial arrangements that will be available for decommissioning, including the management of radioactive waste arising from decommissioning activities, and for the closure of a disposal facility.

In case of the existing nuclear facilities, the Government shall provide for financial means to cover decommissioning costs, including the management of the resulting radioactive waste.

*Environmental Radioactivity Monitoring in the Vicinity of Nuclear Facility*

**Article 153**

The licensee for a nuclear activity shall perform environmental radioactivity monitoring in the vicinity of the nuclear facility that the Directorate consents to.

The Directorate shall specify the manner and the requirements for environmental radioactivity monitoring under paragraph 1 hereof.

The licensee for a nuclear activity shall provide for the financial arrangements for the radioactivity monitoring under paragraph 1 hereof.

*Records by Licensees for Nuclear Activities*

**Article 154**

The licensee for a nuclear activity shall keep the records and all data on the facility and the site thereof, radioactive waste, nuclear and other radioactive material management, and complete documentation necessary to determine the civil liability in accordance with the international convention on civil liability for nuclear damage.

The Directorate shall specify the requirements and the timeframe of record and data keeping under paragraph 1 hereof.

**3. Remediation**

**Site Remediation**

**Article 155**

The legal entity or entrepreneur shall conduct site remediation with contamination resulting from the planned activities, existing exposure situation or emergency event that cannot be disregarded from a radiation protection point of view

Remediation shall be performed with the aim of achieving the conditions that allow the site to be used without restrictions.

If the conditions under paragraph 2 hereof are not attainable, the restriction can be imposed in terms of the use of the entire site or the parts thereof, and the access to the site.

The Directorate shall prescribe the control measures for the site if its use is restricted in accordance with paragraph 3 hereof.

Following the completion of the site remediation activities, the legal entity or an entrepreneur shall carry out soil remediation pursuant to the law governing soil protection.

## **Restoration of Contaminated Facilities**

### **Article 156**

The legal entity or entrepreneur shall perform restoration of contaminated facilities with contamination arising from an existing exposure situation or an emergency event that cannot be disregarded from a radiation protection point of view.

Restoration of a contaminated facility shall be conducted to achieve the conditions that allow the facility to be used without restrictions.

If the conditions under paragraph 2 hereof are not attainable, the restriction can be imposed in terms of the use of the entire site or the parts thereof, and the access to the site.

The Directorate shall prescribe the control measures for the site if its use is restricted in accordance with paragraph 3 hereof.

Restoration of contaminated facilities under paragraph 1 hereof shall not pertain to the facilities that are in the process of obtaining the license for decommissioning.

## **Site Remediation Plan and Contaminated Facilities Restoration Plan**

### **Article 157**

The remediation plan for the site and the restoration plan for contaminated facilities shall include in particular:

- 1) remediation objectives;
- 2) reference levels;
- 3) type, scope and duration of the remediation activities that are required;
- 4) radioactive waste management measures;
- 5) restricted use of the site, i.e. contaminated facilities;
- 6) monitoring and control schemes, and active and passive measures of control for the remediated site, i.e. restored contaminated facility.

The Directorate shall specify the scope and the content of the plans under paragraph 1 hereof.

The licensee for nuclear facility decommissioning and a legal entity holding the consent to perform remediation pursuant to the Law shall periodically update the remediation plan.

A legal entity or an entrepreneur holding the consent to perform restoration of contaminated facilities shall periodically update the restoration plan.



## **Consent for Site Remediation and Contaminated Facilities Restoration Article 158**

The legal entity or entrepreneur shall obtain the consent from the Directorate for site remediation, i.e. contaminated facilities restoration.

Together with the application for the consent under paragraph 1 hereof, the legal entity or entrepreneur shall, submit:

- 1) Remediation, i.e. restoration plan;
- 2) Radioactive waste management plan.

The legal entity or entrepreneur shall conduct site remediation, i.e. contaminated facilities restoration in accordance with the plan under Article 157 hereof.

Following the completion of site remediation, i.e. contaminated facilities restoration, a legal entity or an entrepreneur shall submit to the Directorate a report verifying that the end state of the site, i.e. contaminated facility from the relevant plan has been achieved, and a report on final radiological survey.

Site remediation and facility restoration can be performed by an approval holder for decontamination of work and living environment.

The Directorate can release the site and the facility from regulatory control pursuant to Article 63 hereof.

The legal entity or entrepreneur shall keep the records and data on the site, facility, radiation sources and radioactive waste management.

The Directorate shall specify the requirements for the site and facility remediation, as well as the conditions and timeframe for the record and data keeping under paragraph 7 hereof.

## **4 Safety of Radioactive Waste and Spent Nuclear Fuel Management**

### **General Safety Principles of Radioactive Waste and Spent Fuel Management Article 159**

General principles governing safe management of radioactive waste and spent nuclear fuel in the Republic of Serbia are:

- 1) the generation of radioactive waste shall be kept to the minimum which is reasonably practicable, both in terms of activity and volume, by means of appropriate design measures and of operating and decommissioning practices, including the recycling and reuse of materials;
- 2) the interdependencies between all steps in spent fuel and radioactive waste generation and management shall be taken into account;
- 3) radioactive waste and spent nuclear fuel shall be safely managed, including in the long term with passive safety features;
- 4) implementation of radiation and nuclear safety and security measures shall follow a graded approach;

5) the costs for the management of spent fuel and radioactive waste shall be borne by those who generated such materials;

6) an evidence-based and documented decision-making process shall be applied with regard to all stages of the management of spent fuel and radioactive waste.

The Republic of Serbia shall provide for safe and secure storing of radioactive waste, disused radiation sources and spent nuclear fuel in the centralized storage.

The Republic of Serbia shall make arrangements for the safe and secure disposal of radioactive waste, disused radiation sources and spent nuclear fuel.

### **Declaration of Radioactive Material and Spent Nuclear Fuel as Radioactive Waste Article 160**

The authorization holder shall proclaim, by means of declaration, radioactive material and spent nuclear fuel not intended for further use as radioactive waste.

The authorization holder shall deliver the declaration under paragraph 1 hereof to the Directorate within eight days as of the day of proclaiming at the latest.

The Directorate shall issue a certificate on the declaration under paragraph 1 hereof.

The Directorate shall specify the content of the declaration under paragraph 1 hereof.

### **Radioactive Waste and Spent Nuclear Fuel Management Article 161**

The authorization holder whose practices give rise to radioactive waste or spent nuclear fuel shall bear prime responsibility for safe and secure radioactive waste and spent nuclear fuel management until its delivery to the centralized storage, processing or reprocessing facility, or radioactive waste or spent nuclear fuel disposal facility.

The licensee for the operation of facility for storage, processing or reprocessing and disposal of radioactive waste and spent nuclear fuel shall bear prime responsibility for the safe and secure management of stored, processed, reprocessed and disposed radioactive waste or spent nuclear fuel.

### **Stages of Radioactive Waste and Spent Nuclear Fuel Management Article 162**

Stages of radioactive waste and spent nuclear fuel management are as follows:

- 1) generation and collection;
- 2) characterization;
- 3) keeping;
- 4) radioactive waste processing or spent nuclear fuel reprocessing;
- 5) storing; 6) disposing.

Spent nuclear fuel can be considered as usable resource or declared as radioactive waste.

If spent nuclear fuel is regarded as radioactive waste, it shall be subject to provisions of this Law which pertain to radioactive waste management.

The Directorate shall specify the requirements for radioactive waste and spent nuclear fuel management, the type of packaging and markings.

### **Responsibilities of Authorization Holder in terms of Radioactive Waste and Spent Nuclear Fuel Management**

#### **Article 163**

The authorization holder shall:

- 1) collect, record and keep radioactive waste and spent nuclear fuel in an appropriate way and in accordance with the requirements, and deliver it to the licensee for the operation of the nuclear facility for processing or reprocessing, storage or disposal of radioactive waste and spent nuclear fuel;
- 2) ensure that the facilities and premises where the radioactive waste and spent nuclear fuel is collected, recorded and kept fulfil all technical requirements, and radiation and nuclear safety and security measures;
- 3) implement the measures to prevent the radioactive waste and spent nuclear fuel from contaminating the environment.

### **Generation and Collection of Radioactive Waste and Spent Nuclear Fuel**

#### **Article 164**

Generation and collection of radioactive waste and spent nuclear fuel shall be controlled and recorded as the practices are being performed.

The measures to control the generation of radioactive waste that are applied by the authorization holder are in particular:

- 1) reduction of radioactive waste generation;
- 2) reuse of radioactive waste;
- 3) radioactive waste recycling.

The Directorate shall specify the conditions for collecting, recording and controlling the radioactive waste and spent nuclear fuel.

### **Temporary Keeping of Radioactive Waste and Spent Nuclear Fuel**

#### **Article 165**

The authorization holder can temporarily keep radioactive waste and spent nuclear fuel generated in the course of practice in its own repository until it is delivered to the licensee for

the operation of nuclear facility for processing or reprocessing, storage and disposal of radioactive waste and spent nuclear fuel, or until it is released from the regulatory control.

The authorization holder can place radioactive waste or spent nuclear fuel in a repository in accordance with the authorization requirements for the practice that gives rise to the aforementioned radioactive waste and spent nuclear fuel generation.

The Directorate shall specify the manner and timeframe for keeping radioactive waste and spent nuclear fuel in a temporary repository.

## **Characterization of Radioactive Waste and Spent Nuclear Fuel**

### **Article 166**

The authorization holder shall conduct characterization of the radioactive waste and spent nuclear fuel generated during the practice performance.

Radioactive waste and spent nuclear fuel characterization serves to obtain data on its physical, mechanical, chemical, radiological and biological properties with a view of its safe and secure management.

The Directorate shall specify the conditions for characterization of radioactive waste and spent nuclear fuel.

## **Classification of Radioactive Waste**

### **Article 167**

Radioactive waste shall be classified pursuant to data under Article 166, paragraph 2 hereof.

The Directorate shall specify radioactive waste categories and criteria for radioactive waste classification.

## **Processing of Radioactive Waste**

### **Article 168**

Radioactive waste processing shall be conducted with a view of producing a waste form that meets the criteria for its safe and secure transport, storage or disposal, and with a view of reducing the radioactive waste volumes by its reuse and recycling.

Radioactive waste processing consists of pre-treatment, treatment and conditioning of radioactive waste.

Once processed, radioactive waste has to be rendered into a safe and passive form so as to be kept within the package during the planned activities and emergency events that can occur during its transport, storage or disposal.

The Directorate shall specify the requirements for radioactive waste processing.

## **Reprocessing of Spent Nuclear Fuel**

### **Article 169**

Spent nuclear fuel reprocessing shall be conducted in a nuclear facility for used for reprocessing of spent nuclear.

The Directorate shall specify all requirements regarding spent nuclear fuel reprocessing.

## **Storage of Radioactive Waste and Spent Nuclear Fuel**

### **Article 170**

Storage of radioactive waste and spent nuclear fuel shall be conducted with the aim of providing the appropriate measures of isolation and monitoring of radioactive waste and spent nuclear fuel throughout all stages of management before its disposal.

The licensee for the operation of radioactive waste and spent nuclear fuel storage facility shall provide for such conditions and implement such measures so as to enable the inspection of storing conditions, prevention of critical values, transfer of radioactive waste for processing or spent nuclear fuel for reprocessing and disposal or release from regulatory control, and to enable preservation of radioactive waste and spent nuclear fuel packages in a form suitable for processing, reprocessing or disposal .

The licensee for the operation of radioactive waste and spent nuclear fuel storage facility shall keep and submit to Directorate the record of stored radioactive waste and spent nuclear fuel according to the schedule and manner prescribed by the Directorate.

The Directorate shall specify the requirements for radioactive waste and spent nuclear fuel storage.

## **Disposal of Radioactive Waste or Spent Nuclear Fuel**

### **Article 171**

Disposal of radioactive waste or spent nuclear fuel shall be conducted with a view of isolating radioactive waste and spent nuclear fuel from the people and the environment.

Nuclear facility for radioactive waste and spent nuclear fuel disposal, during design, construction, trial run, operation and closure, has to meet such conditions so as to ensure passive safety to the fullest extent possible and the minimum need for actions to be taken after the closure of the facility.

Host environment, design of engineered barriers and the operation of a nuclear facility for radioactive waste and spent nuclear fuel disposal shall ensure multiple radiation and nuclear safety and security protection measures and subcritical configuration.

Engineered barriers, structures, systems and components, including waste and spent nuclear fuel packaging, shall be designed, and the host environment shall be selected, so as to:

- 1) provide containment of the radionuclides associated with the waste until radioactive decay has significantly reduced the hazard posed by the waste and spent nuclear fuel;

- 2) prevent critical values;
- 3) provide transfer of heat in case of disposal of radioactive waste or spent nuclear fuel that generate heat.

The licensee for the operation of radioactive waste and spent nuclear fuel disposal facility shall have in place, and implement measures to preserve and protect the passive safety features.

The Directorate shall specify the requirements for radioactive waste disposal.

## **Radioactive Waste and Spent Nuclear Fuel Acceptance Criteria**

### **Article 172**

The licensee for the operation of nuclear facility for processing, storage or disposal of radioactive waste, i.e. operation of nuclear facility for reprocessing, storage or disposal of spent nuclear fuel shall establish the acceptance criteria for radioactive waste and spent nuclear fuel.

Radioactive waste that is accepted into the nuclear facility for processing, storage or disposal shall conform to the radioactive waste acceptance criteria.

Spent nuclear fuel that is accepted into a nuclear facility for reprocessing, storage or disposal of spent nuclear fuel shall conform to the spent nuclear fuel acceptance criteria.

The criteria for the acceptance of radioactive waste and spent nuclear fuel shall be established with regard to radiological, mechanical, physical, chemical and biological features of radioactive waste and spent nuclear fuel.

The Directorate shall specify the requirements to determine the criteria for the acceptance of radioactive waste and spent nuclear fuel.

## **Release of Radioactive Waste from Regulatory Control**

### **Article 173**

Radioactive waste can be released from regulatory control only with the previously obtained consent from the Directorate in accordance with Article 62 hereof.

Radioactive waste can be released from regulatory control after it has been processed or after the period of being kept and stored.

## **Radioactive Waste and Spent Nuclear Fuel Management Plan**

### **Article 174**

Radioactive waste and spent nuclear fuel management plan shall include in particular:

- 1) organizational structure for radioactive waste and spent nuclear fuel management by the authorization holder whose practices generate radioactive waste and spent nuclear fuel;

- 2) list of written procedures and other documents necessary for radioactive waste and spent nuclear fuel management;
- 3) description of manner in which radioactive waste and spent nuclear fuel were generated, categories and expected annual amounts of generated radioactive waste and spent nuclear fuel;
- 4) description of radioactive waste and spent nuclear fuel management;
- 5) technical, organizational and other measures to reduce radioactive waste and spent nuclear fuel generation;
- 6) requirements to be met in order to hand over radioactive waste and spent nuclear fuel to the licensee for the operation of nuclear facility for processing, storage and disposal of radioactive waste, i.e. the licensee for the operation of nuclear facility for reprocessing, storage and disposal of spent nuclear fuel;
- 7) description of the manner of record keeping of radioactive waste and spent nuclear fuel that has been either generated or kept in a repository, processed or reprocessed, stored or disposed.

The Directorate shall specify the scope and the content of radioactive waste and spent nuclear fuel management plan.

## **Financial Arrangements for Radioactive Waste and Spent Nuclear Fuel Management**

### **Article 175**

The legal entity or an entrepreneur whose practices give rise to radioactive waste or spent nuclear fuel shall bear the costs of radioactive waste or spent nuclear fuel management.

Where the legal entity or entrepreneur under paragraph 1 hereof is not known or no longer exists, the Republic of Serbia shall assume the responsibility for radioactive waste or spent nuclear fuel management.

Where the legal entity or entrepreneur giving rise to radioactive waste and spent nuclear fuel is subsequently determined, he or she shall reimburse the costs of radioactive waste and spent nuclear fuel management.

## **Record Keeping of Radioactive Waste and Spent Nuclear Fuel**

### **Article 176**

The authorization holder shall keep the record of radioactive waste that has been generated and placed into the repository that has been processed, stored, disposed or released from regulatory control.

The authorization holder shall keep the record of spent nuclear fuel that has been generated, placed in the repository that has been reprocessed, stored or disposed.

The authorization holder shall submit the records under paragraph 1 and 2 hereof to the Directorate.

The Directorate shall specify the requirements, the manner and timeframe for record keeping under paragraphs 1 and 2 hereof, and its delivery to the Directorate.

## ***5 Control of Transboundary Shipments of Radioactive Waste and Spent Nuclear Fuel***

### **Transboundary Shipments of Radioactive Waste and Spent Nuclear Fuel Article 177**

The Directorate shall specify the system of supervision and control over the import of radioactive waste generated during radioactive waste processing or spent nuclear fuel reprocessing in another country whose origin is in the Republic of Serbia, as well as the system of supervision and control over the export and transit of radioactive waste and spent nuclear fuel shipments.

### **Export of Radioactive Waste and Spent Nuclear Fuel Article 178**

The Directorate shall issue the permit for the export of radioactive waste and spent nuclear fuel generated in the territory of the Republic of Serbia.

Radioactive waste or spent nuclear fuel under paragraph 1 hereof may be exported only with the previously obtained permit from the Directorate and the consent of the competent authority of the importing state.

The Directorate shall issue the permit for radioactive waste and spent nuclear fuel export under paragraph 1 hereof if:

- 1) the country where the radioactive waste and spent nuclear fuel is exported to has been notified about the export prior to its arrival and if the relevant country has consented thereto;
- 2) the country where the radioactive waste and spent nuclear fuel is exported to is a signatory of the Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management;
- 3) the export of radioactive material is in line with the relevant international obligations in all transit countries;
- 4) the country where radioactive waste and spent nuclear fuel is exported to has commissioned a relevant storage before sending the shipment and has regulatory infrastructure and administrative and technical capacities necessary for certain



radioactive waste and spent nuclear fuel management in a way that preserves its safety and security in line with international standards.

The Directorate shall not issue the permit for the export of radioactive waste and spent nuclear fuel intended for storage and disposal if:

- 1) the export destination is south of latitude 60 degrees south;
- 2) it deems that the importing country does not have administrative or technical capacities necessary for safe management of radioactive waste and spent nuclear fuel.

### **Radioactive Waste Exported for Processing and Spent Nuclear Fuel Exported for Reprocessing**

#### **Article 179**

The Republic of Serbia shall remain responsible for safe disposal of radioactive waste exported for processing, spent nuclear fuel exported for reprocessing, and any radioactive waste by-product resulting from processing or reprocessing.

### **Import of Radioactive Waste and Spent Nuclear Fuel**

#### **Article 180**

The Directorate shall issue the permit for the import of radioactive waste resulting from radioactive waste processing or spent nuclear fuel reprocessing occurring in another country whose origin is in the Republic of Serbia.

The Directorate shall issue the permit for reshipment of radioactive waste and spent nuclear fuel if the export has not been completed.

### **Transit of Radioactive Waste and Spent Nuclear Fuel Shipments through the Republic of Serbia**

#### **Article 181**

At the request of a consignor from another country, the Directorate shall issue the permit for transit of radioactive waste and spent nuclear fuel shipments through the Republic of Serbia.

The application under paragraph 1 hereof shall contain verification that the consignor from another country has entered into contract with a consignee in the third country, that it has been authorized by competent authorities in both countries, and that it obliges the consignor to reaccept the radioactive waste and spent nuclear fuel if the shipment cannot be fully completed.

## VII RECORDS AND CONTROL OF NUCLEAR MATERIAL, ACTIVITIES, SPECIAL EQUIPMENT AND NON-NUCLEAR MATERIAL ASSOCIATED WITH NUCLEAR FUEL CYCLE

### ***Notification of Nuclear Material, Activities, Special Equipment and Non-nuclear Material associated with Nuclear Fuel Cycle***

#### **Article 182**

A legal entity or entrepreneur having in possession nuclear material for nuclear or nonnuclear purposes shall notify the Directorate of the possession of such material in accordance with the ratified international agreements and this Law.

A legal entity or entrepreneur shall notify the Directorate of the activities, special equipment and non-nuclear material associated with nuclear fuel cycle in accordance with the ratified international agreements and this Law.

The Directorate shall issue a certificate on notification of nuclear material under paragraph 1 hereof and the activities, special equipment and non-nuclear material under paragraph 2 hereof.

The Directorate shall keep a centralized record of nuclear material, activities, special equipment and non-nuclear material associated with a nuclear fuel cycle.

The Directorate shall specify the requirements and the schedule for the notification of the nuclear material under paragraph 1 and the activities, special equipment and non-nuclear material under paragraph 2 hereof.

### ***Record Keeping and Control of Nuclear Material, Activities, Special Equipment and Non-nuclear Material associated with Nuclear Fuel Cycle***

#### **Article 183**

The Directorate shall ensure effective implementation of the safeguards in the Republic of Serbia in compliance with the ratified international agreements on safeguard implementation, and establish and maintain system of the accountancy and control of nuclear material.

The legal entity or entrepreneur under Article 182, paragraph 1 shall keep the records of nuclear material, activities, special equipment and non-nuclear material associated with nuclear fuel cycle in accordance with the ratified international agreements and this Law.

The legal entity or entrepreneur shall submit the records under paragraph 2 hereof to the Directorate within specified schedule.

The Directorate shall exercise control over the records under paragraph 2 hereof.

The Directorate shall specify the establishment and maintenance of the system of accountancy and control of the nuclear material.

The Directorate shall specify the manner of keeping and the schedule for submitting the records under paragraph 2 hereof.

### ***Control and Supervision by International Atomic Energy Agency***

#### **Article 184**

A legal entity or entrepreneur, in accordance with the ratified international agreements, shall enable the International Atomic Energy Agency inspectors to conduct control and supervision over nuclear material, activities, special equipment and non-nuclear material associated with a nuclear fuel cycle, and other activities stipulated by the ratified international agreements and protocols.

## **VII RADIATION NAD NUCLEAR SECURITY**

### ***Security Measures for Radiation Sources and Associated Facilities***

#### **Article 185**

Security measures for radiation sources and associated facilities shall be taken to prevent malicious and unlawful actions towards the radiation sources and associated facilities and activities.

Security measures under paragraph 1 hereof shall be taken pursuant to other relevant laws, bylaws, possible threats as determined by Design Basis Threat (DBT) pursuant to this Law, radioactive source classification, and nuclear material categorization in accordance with the ratified international conventions and risk assessment of the harmful effect on individuals, assets, society and the environment that can result from a security event.

The security measures under paragraph 1 hereof shall particularly include:

- 1) detection of potential security event,
- 2) establishment of response actions to promptly and efficiently locate the missing radiation sources and their subsequent bringing under control;
- 3) deterrence of potential effects of sabotage or other malicious uses of radiation sources.

The Government, at the proposal of the Directorate, shall stipulate and monitor the implementation of radiation and nuclear security measures for radiation sources, associated facilities, and transport of radiation sources.

The Government, at the proposal of the Directorate, shall establish the Commission for radiation and nuclear security in order to coordinate and observe the activities in the field of radiation and nuclear security.

## **Design Basis Threat**

### **Article 186**

Security measures over radioactive and nuclear material and associated facilities shall be determined based on the Design Basis Threat.

Security measures during transport of radioactive and nuclear material shall be determined based on the Design Basis Threat for each transport individually.

The Government shall establish Commission to prepare Design Basis Threat.

The Commission under paragraph 3 hereof shall make threat assessment of radioactive and nuclear material and associated facilities including transport based on the available information from the security services in the Republic of Serbia, the Ministry responsible for internal affairs, the Ministry responsible for foreign affairs, the authorization holder, and the Directorate.

At the proposal of the Directorate, the Government shall prescribe the requirements for the establishment and the activities of the Commission under paragraph 3 hereof, as well as the manner and the requirements necessary to prepare, review and revise the Design Basis Threat.

### ***Responsibilities of Registrant***

#### **Article 187**

A registrant shall ensure and maintain physical protection system and other security measures depending on the type, category and the purpose of a radiation source throughout the practice performance, with the aim of preventing theft, sabotage, loss and unauthorized access thereto.

The provision under paragraph 1 hereof shall not apply to the registrant performing practices with radiation sources generators.

### ***Responsibilities of Licensee***

#### **Article 188**

A licensee shall ensure the implementation of and maintain physical protection system together with the other security measures over the radiation sources and associated facilities including transport.

A licensee shall take all prescribed measures within their competences and capacities in accordance with the Design Basis Threat, in order to prevent theft, sabotage or loss of radiation sources, and in order to reduce the resulting consequences.

Where there has been a theft, sabotage or loss of nuclear or other radioactive material, the licensee shall:

- 1) notify the Directorate and other relevant state authorities without undue delay of the incident and circumstances thereof;

- 2) provide the Directorate and other relevant state authorities with a detailed written report as soon as practicable, but not longer than 72 hours following the notification under point 1) hereof;
- 3) provide the Directorate and other relevant state authorities with any additional information when requested.

Where the attributes and characteristics of the threat exceed the limits of the Design Basis Threat, measures provided by the national security instruments shall be applied.

A licensee shall establish and maintain efficient cooperation with the state authorities responsible for security.

The provisions hereof shall not apply to the licensee performing practices with radiation sources generators.

## ***Security Plan***

### **Article 189**

Before submitting the application for the license, the legal entity or entrepreneur shall prepare Security Plan that gives detailed account of radiation and nuclear security measures.

The Security plan is a confidential document pursuant to the law governing classified information protection.

The legal entity or entrepreneur under paragraph 1 hereof shall obtain from the Ministry of the Interior the consent to the Security Plan. Security Plan shall contain in particular:

- 1) detailed account of security measures;
- 2) physical protection system design;
- 3) description of the area, facility, other premises in the area, and the material under protection supplemented by the categorization of the material;
- 4) list of internal documents regarding security;
- 5) persons responsible for security;
- 6) response plan in case of security event;
- 7) manner and plan of assessing the efficiency of the security plan

The Government of the Republic of Serbia shall specify the content of the Security Plan.

The licensee shall regularly and continuously develop the plan under paragraph 1 hereof commensurate with all the changes so that the plan can always reflect the current state of the facility and the practice.

The licensee shall ensure the compliance of the Security Plan with the Design Basis Threat.

In case of changes in the threat assessment, the licensee, as soon as reasonably achievable, shall update the system of physical protection and Security Plan in accordance with the recommendations and with the consent from the competent security authorities.

The provisions of this Article shall not apply to the licensee performing practices with radiation sources generators.

### ***International Cooperation and Assistance***

#### **Article 190**

In case of a security event involving radiation sources, the Directorate shall promptly take all necessary steps to inform the relevant state and international authorities and organizations about the event and its possible consequences, in accordance with the ratified international legal acts

### ***Protection of Classified Information***

#### **Article 191**

No person shall disclose or use any information in connection with radiation sources and facilities where the level of secrecy is determined in accordance with the provisions of the national legislation and the ratified international legal acts.

In cooperation with other relevant state authorities and organizations, the Directorate shall establish the guidelines that govern assigning the level of secrecy for the information about radiation sources and practice performance in the areas regulated by the Law pursuant to the regulations on the protection of classified information.

## **IX PREPAREDNESS AND RESPONSE IN CASE OF NUCLEAR OR RADIOLOGICAL EMERGENCY**

### ***Notification and Recording of Emergency Events***

#### **Article 192**

The authorization holder shall keep, as appropriate, a recording and analysis system of emergency events involving or potentially involving accidental or unintended exposures.

The authorization holder shall promptly notify the Directorate of the occurrence of any significant event in connection with the performed practice and immediately take all necessary actions to eliminate or mitigate the consequences, including the initial assessment of circumstances and the effects of an emergency event, and the assistance that can be provided during the implementation of protection measures.

The Directorate shall specify the requirements for the system of record keeping and analysis under paragraph 1 hereof.

### ***Response Plan in case of Nuclear or Radiological or Emergency***

#### **Article 193**

The Government of the Republic of Serbia shall adopt the Response Plan in case of a nuclear or radiological emergency inside or outside the territory of the Republic of Serbia with the objective of protecting the lives and health of the people and the environment.

The Directorate, in cooperation with other competent state authorities and organizations, shall prepare the draft of Response Plan in case of a nuclear or radiological emergency.

The Response Plan in case of a nuclear or radiological emergency shall particularly include:

- 1) objectives of response in case of nuclear or radiological emergency;
- 2) assessment of threats resulting from nuclear or radiological emergency situations;
- 3) clear allocation of competences and responsibilities of the participants in response arrangements for a nuclear or radiological emergency situation, and response to a nuclear or radiological emergency situation;
- 4) response action plans in possible nuclear or radiological emergency situations, as well as operational programme for the implementation of the Plan;
- 5) coordination and communication between nuclear or radiological emergency response participants;
- 6) reference levels for the exposure of workers and people;
- 7) protection measures for workers in a radiological emergency situation;
- 8) protection measures for the public and the environment in case of nuclear or radiological emergency situations, and the criteria for their implementation;
- 9) arrangements for radioactivity monitoring in a nuclear or radiological emergency situation;
- 10) assessment of situation and efficient implementation of protection measures throughout nuclear or radiological emergency situation;
- 11) type of warning system and manner of giving instructions to the public;
- 12) system of coordination and communication at international level;
- 13) criteria for the transition from an emergency exposure to an existing or planned exposure situation;
- 14) management system for radioactive waste resulting from a nuclear or radiological emergency situation;
- 15) expert and material resources available in the response to a nuclear or radiological emergency;
- 16) schedule and timeframes for response plan to be reviewed and revised;
- 17) arrangements for exercises and training, and record keeping thereof.

The decision to declare emergency in one part or entire territory of the Republic of Serbia, which results from a nuclear or radiological emergency situation, shall be made in accordance with the regulations governing emergency situations.

Radiological or nuclear emergency management is conducted in accordance with the law governing emergency situations.

Response participants under paragraph 3 point 4) hereof shall prepare action plans in case of nuclear or radiological emergency situation under paragraph 1 hereof.

The Directorate shall specify categorization of facilities, practices and activities with radiation sources based on threat assessment and possible consequences resulting from the practices and activities performed at these facilities including transport, loss or theft, discovery of sources outside regulatory control, radioactive contamination of unknown origin etc. The Directorate shall specify the content of the plans under paragraph 6 hereof.

### ***Contingency Plan of the Authorization Holder in case of Emergency***

#### **Article 194**

The authorization holder shall prepare a contingency plan in case of an emergency for facilities where radiation practices and nuclear activities are performed and the sites thereof.

The plan under paragraph 1 hereof shall be prepared in line with the Response Plan in case of a nuclear or radiological emergency situation, and supplementary instructions and procedures prescribed by the Directorate.

The Directorate shall specify the content of the plan under paragraph 1 hereof.

### ***Transboundary Nuclear and Radiological Emergencies and International Cooperation***

#### **Article 195**

In compliance with the ratified international conventions and agreements, the Directorate shall inform the International Atomic Energy Agency and the competent authorities in other countries in case of a nuclear or radiological emergency that poses a risk of radioactive contamination spreading beyond the borders of the Republic of Serbia, as well as in case of theft, sabotage, loss or discovery of radiation sources that could have adverse effect on the other countries.

The Government shall bring a decision on seeking assistance from other countries or the International Atomic Energy Agency, and on providing assistance to other countries in case of a nuclear and radiological emergency.

## **X TRADE IN RADIATION SOURCES**

### ***Authorization for Trade in Radiation Sources***

#### **Article 196**

Trade in radiation sources is a radiation practice of low, moderate or high risk.

The legal entity or entrepreneur shall submit to the Directorate the application for authorization for every individual category of trade in radiation sources under paragraph 1 hereof.

The Directorate shall issue the decision on registration, i.e. the decision on license for the practice of trade in radiation sources based on verification that the requirements under Articles 39 and 42 hereof have been fulfilled.



The practice of trade in radiation sources under paragraph 1 hereof can be performed with or without storage.

The Directorate shall specify the requirements for classification of practices of trade in radiation sources under paragraph 2 hereof.

The authorization holder under paragraph 3 hereof shall keep the records of trade in radiation sources.

The authorization for trade in radiation sources shall be issued for the period of 3 years.

The authorization holder for trade in radiation sources shall, 60 days before the expiration of the authorization, submit to the Directorate the application for its extension.

The authorization for trade in radiation sources shall be extended for the same period that the authorization was issued for.

The Directorate shall specify the manner and requirements for trade in radiation sources and the record keeping under paragraph 6 hereof.

### ***Permit for Import, Export and Trade of Radiation Sources***

#### **Article 197**

The authorization holder for trade in radiation sources can perform import, export or transit of radiation sources only with the previously obtained permit for import, export or transit of radiation sources, which is issued by the Directorate.

The permit under paragraph 1 hereof shall be issued for each individual practice of trade in radiation sources.

Further to the application under paragraph 1 hereof, the authorization holder for practices of trade in radiation sources shall submit the documentation stipulated by the Directorate.

The Directorate shall issue the permit under paragraph 1 hereof provided that all the measures prescribed by the Law and other applicable legislation have been implemented and provided that such trade is performed in accordance with the ratified international conventions and agreements.

The customs authority may custom clear radiation sources only with the permit under paragraph 1 hereof.

The Directorate shall specify the requirements and the documentation necessary for the issuance of permit under paragraph 1 hereof.

### ***Permit for Import of Radiation Sources***

#### **Article 198**

The Directorate shall issue the permit for individual import of radiation sources to the authorization holder for trade in radiation sources with or without storage.

The Directorate shall issue the permit for individual import of radiation sources to the authorization holder under paragraph 1 hereof only if the import is conducted for the end user with the certificate for notification of the intention to perform the practice, the application for the authorization to perform the practice, or the authorization to perform a practice.

The import of radiation sources shall be performed in accordance with the international standards and ratified international conventions and agreements.

The authorization holder for trade in radiation sources that obtains the permit under paragraphs 1 and 2 hereof shall inform the Directorate on the expected arrival of the shipment 48 hours prior to the arrival of the shipment to the border crossing at the latest.

Provisions of paragraphs 1, 2 and 3 hereof shall apply to the import of radiation sources to the free zones of the Republic of Serbia.

### ***Permit for Export of Radiation Sources***

#### **Article 199**

The Directorate shall issue the permit for individual export of radiation sources, only if the export is performed for the end user having the permit for import issued by the competent authorities of the importing state.

If the authorization holder for trade in radiation sources having the permit under paragraph 1 hereof is obliged to return the source to the Republic of Serbia at the request from the competent authorities of the importing state, the Directorate shall issue the permit for import.

In the event under paragraph 2 hereof, the authorization holder shall inform the Directorate 72 hours before the arrival of the shipment to the border crossing at the latest.

The authorization holder having the permit for trade in radiation sources under paragraph 1 hereof shall provide the Directorate with all necessary information on the end use and the end user of the radiation source being exported, which serve to confirm their peaceful and safe use.

### ***Permit for Transit of Radiation Sources***

#### **Article 200**

The Directorate shall issue the permit for transit of radiation sources only with the previously obtained consent from the competent institution in the originating country, the country of final destination and all transit countries.

The authorization holder for the transit of radiation sources that possesses the permit for the transit of radiation sources shall inform the Directorate on the arrival of shipment 72 hours before its expected arrival to the border crossing at the latest.

***Radioactivity Control of Goods in case of Import, Export and Transit***  
**Article 201**

The Directorate shall specify the type of goods requiring radioactivity control upon import, export and transit, based on available information, risk assessment for the period of three years, and in case of nuclear and radiological emergencies outside the territory of the Republic of Serbia.

The Directorate shall review and supplement the list of goods under paragraph 1 hereof.

The Directorate shall specify the manner and methods of radioactivity control of the goods under paragraph 1 hereof.

Sampling of goods under paragraph 1 hereof can be conducted by the authorization holder for radioactivity monitoring or certain monitoring tests under Article 56, paragraph 1, point 1) hereof.

Radioactivity control of goods under paragraph 1 hereof that are imported can be conducted by the authorization holder for radioactivity monitoring or certain monitoring tests under Article 56, paragraph 1, point 1) hereof.

The importer, that is, the owner of the goods under paragraphs 1 and 2 hereof shall cover the costs of radioactivity control of such goods.

Custom authority cannot take any actions implied by the appropriate custom procedure if radioactivity control of goods determines that the goods do not comply with the prescribed requirements for placing on the market.

The goods under paragraph 1 hereof that are imported and under the jurisdiction of sanitary, phytosanitary or veterinary inspectors can be imported and made available to the public only based on the verification that they meet the prescribed market requirements, based on the submitted report from the competent legal entity on radioactivity control of the goods, pursuant to the law governing the rights and the duties of the aforementioned inspectors.

If radioactivity measurements of goods subject to import do not fulfil the prescribed market requirements, sanitary, phytosanitary and veterinary inspectors, based on the report from the authorized legal entity on the radioactivity control of goods, shall ban the import of the goods and order their reshipment to the consignor.

The sanitary, phytosanitary and veterinary inspectors shall submit to the importer, custom officers and the Directorate the decision on the ban of import and on its reshipment to the consignor.

The goods under paragraph 1 hereof that is imported and not under jurisdiction of sanitary, phytosanitary and veterinary inspectors, shall be handled by the inspector for radiation and nuclear safety and security.

The goods imported into the free zones or placed into storages in the Republic of Serbia are subject to the provisions of paragraphs 4 - 11 hereof.

The export of secondary raw materials with increased level of radioactivity or contamination shall be prohibited.

Transit of secondary raw materials with increased level of radioactivity or contamination over the territory of the Republic of Serbia shall be prohibited.

### ***Detection and Prevention of Unauthorized Trade in Radioactive and Nuclear Materials***

#### **Article 202**

Customs Administration and Border police shall be responsible for measures of detection and prevention of unauthorized trade in radioactive and nuclear materials at the border crossings.

In order to detect and prevent unauthorized trade in radioactive and nuclear materials, the border crossings in the Republic of Serbia shall be equipped with stationary radiation monitors and handheld radiation detectors.

The Directorate shall specify the procedure for the use of stationary radiation monitors and handheld radiation detectors, and the intervention procedure in case of unauthorized trade in radioactive and nuclear materials across the border of the Republic of Serbia.

Customs Administration and Border police shall be responsible for the accuracy and well-functioning of the stationary monitors and handheld detectors under paragraph 2 hereof.

Procurement, installation, use and maintenance of the stationary monitors and handheld detectors under paragraph 2 hereof shall be provided for from the budget of the Republic of Serbia.

## **XI TRANSPORT OF DANGEROUS GOODS CLASS 7 ADR/RID/ADN (RADIOACTIVE MATERIAL)**

#### **Article 203**

The transport of dangerous goods class 7 ADR/RID/ADN (radioactive material) in the Republic of Serbia shall be conducted in accordance with the Law, the regulations governing the transport of dangerous goods, and ratified international conventions and agreements.

### ***Authorization for Transport of Dangerous Goods Class 7 ADR/RID/ADN (Radioactive Material)***

#### **Article 204**

Transport of dangerous goods class 7 ADR/RID/ADN (radioactive material) is a radiation practice of low, moderate or high risk.

Legal entity or entrepreneur shall submit to the Directorate the application for the authorization for each category of transport under paragraph 1 hereof individually.

The Directorate shall issue the decision on registration, i.e., license for the practice of transport of dangerous goods class 7 ADR/RID/ADN (radioactive material) upon confirmation that all prescribed conditions under Articles 39 and 42 hereof have been fulfilled.

The authorization holder under paragraph 3 hereof shall keep the records of transport of dangerous goods class 7 ADR/RID/ADN (radioactive material).

The authorization under paragraph 1 hereof shall be issued for the period of three years.

The authorization holder under paragraph 1 hereof shall submit to the Directorate, 60 days prior to the termination of the authorization, the application for the authorization extension.

The extension of the authorization under paragraph 1 hereof shall be for the same period as the authorization was issued for.

The Directorate shall specify the requirements and manner of transport of dangerous goods under paragraph 1 hereof.

The Directorate shall specify the requirements and the manner of record keeping under paragraph 4 hereof.

### ***Permit for Transport of Dangerous Goods Class 7 ADR/RID/ADN (Radioactive Material)***

#### **Article 205**

Transport of dangerous goods class 7 ADR/RID/ADN (radioactive material) in the Republic of Serbia shall be conducted with the previously obtained permit for transport that is issued by the Directorate.

The permit for transport of dangerous goods under paragraph 1 hereof shall be issued for a single or multiple transport.

The Directorate shall issue the permit for transport of dangerous goods under paragraph 1 hereof at the request of the consignor or the consignee, i.e. the organizer of the transport having the authorization for the transport of dangerous goods under Article 204, paragraph 3 hereof.

Further to the application under paragraph 3 hereof, the authorization holder for the transport of dangerous goods shall submit to the Directorate all prescribed documentation as well.

The Directorate shall issue the permit for transport under paragraph 2 hereof, based on fulfilment of the requirements and in accordance with the provisions of ratified international agreements.

The permit under paragraph 5 hereof shall contain:

- 1) Information on the manufacturer, consignor, carrier and consignee;
- 2) UN number of dangerous goods, data and certificates prescribed by ADR/RID/ADN;
- 3) Information on the type, volume, chemical and physical features of dangerous goods, as well as the type of packaging, portable pressure vessels or tanks for the transport of dangerous goods;
- 4) Tachograph;
- 5) Point of upload and unload of goods;

- 6) Point of start and anticipated end of transport;
- 7) Information about the vehicle and the driver of dangerous goods in road transport; 8) Time and place intended for rest;
- 9) Authorization from the competent authority in the neighbouring country allowing import or transit;
- 10) The name of exit and entry border crossings.

If the application is submitted for multiple transport permits, it is not necessary to provide data under paragraph 6, points 9) and 10) hereof.

The Directorate shall specify the documentation required for the issuance of the permit under paragraph 6 hereof.

## XII PUBLIC INFORMATION AND TRANSPARENCY

### *Availability of Public information*

#### **Article 206**

The Directorate shall establish procedures ensuring that:

- 1) the public, local authorities, population and other interested parties in close proximity of a nuclear facility have accurate and timely information about the safety of the nuclear facility;
- 2) the public including interested parties in the process of licensing and all stages of a nuclear facility life cycle are informed and consulted;
- 3) every issued authorization and all requirements for the issuance thereof, apart from security sensitive and classified data, are made public.

The Directorate shall cooperate with the competent regulatory bodies in other countries in the area of radiation and nuclear safety and security by exchanging and/or sharing information.

The Directorate, within its remit and pursuant to the Law, shall inform the public on any unauthorized use of radiation sources or any breach of prescribed procedures in facilities that can result in an emergency event.

## XIII LIABILITY OF A LICENSEE FOR NUCLEAR DAMAGE

#### **Article 207**

In accordance with The Law on Ratification of Vienna Convention on Civil Liability for Nuclear Damage (the Law on Vienna Convention) and in accordance with this Law, the

licensee for a nuclear activity performance shall be liable for nuclear damage arising from a nuclear emergency event, based on the evidence that such damage occurred in the nuclear facility of the licensee.

Liability of the licensee under paragraph 1 hereof shall be limited to the amount of 5 million US dollars for each nuclear accident and shall not include interests or expenses awarded by the court in nuclear damage liability lawsuits.

Liability for nuclear damage caused by nuclear material that has been stolen, lost, jettisoned or abandoned shall rest on the licensee that last exercised the control of such material.

### ***Insurance Coverage for Nuclear Damage***

#### **Article 208**

The licensee for nuclear activity performance shall enter into and maintain insurance coverage for the liability for nuclear damage.

The insurer cannot stop or cancel the insurance without previously informing the licensee for a nuclear activity in writing not longer than 6 months before discontinuing, i.e. cancelling the insurance policy.

### ***Nuclear Damage Compensation Period***

#### **Article 209**

The right to compensation for nuclear damage shall cease following the ten-year period as of the day of a nuclear emergency event.

In cases when nuclear damage was caused by a nuclear emergency event in connection with nuclear material, which, at the time of the accident was stolen, lost, jettisoned or abandoned, the period under paragraph 1 hereof shall start on the day of the accident and last for 20 years as of the day the material was stolen, lost, jettisoned or abandoned.

### ***Claim for Nuclear Damages and Court Jurisdiction***

#### **Article 210**

Claims for nuclear damages may be lodged within three years as of the day when the legal entity or an entrepreneur that suffered nuclear damage discovered or should have discovered about the nuclear damage and the licensee for nuclear activity that is held accountable for it, but not later than the expiration of the prescribed periods under Article 208 hereof.

The decision on nuclear damages shall be subject to the territorial jurisdiction of the court that the nuclear facility belongs to.

If nuclear damage occurs during transport of nuclear material, it shall be subject to the territorial jurisdiction of the court where the nuclear emergency event occurred.

All persons entitled to nuclear damages in accordance with the Vienna Convention and this Law can lodge their claims against the licensee or directly against the insurer or any other person providing financial resources for the nuclear damage compensation.

## **XIV INSPECTION OVERSIGHT**

### **Article 211**

Inspection oversight over the implementation of provisions of the Law and pertaining subsidiary legislation shall be performed by the Directorate through the inspector for radiation and nuclear safety and security (hereinafter: the inspector), within the remit established by the Law.

Unless this Law states otherwise, inspection oversight is subject to a special law governing inspectional supervision.

Inspection oversight is conducted according to the Annual Inspection Oversight Plan that shall be published on the website of the Directorate until 31 December of the current year for the following year.

### **Radiation and Nuclear Safety and Security Inspectors**

#### **Article 212**

The tasks of an inspector may be performed solely by persons having university qualifications in natural, technical and technological sciences or in the area of environmental or labour protection, and having at least three years of work experience in the field of radiation and nuclear safety and security, or at least 7 years of experience in the area of inspectional supervision.

The inspector shall also have the office outside the Directorate head office. The inspector is an exposed worker.

The inspectors conducting tasks within the scope of the Law shall be provided with personal protection means, personal radiation detectors and health examinations prescribed for the exposed workers.

The inspectors shall be qualified to perform radioactivity measurements by means of radiation monitors.

The inspectors conducting tasks within the scope of the Law shall be provided with regular trainings and other forms of professional development.

The work and duties of the inspectors shall be considered as the work performed under special working conditions.

### ***Official Identification Card and Badge***

#### **Article 213**



The inspector shall have and carry official identification card and badge, which serve to affirm official duty and identity.

The Directorate shall specify the form and the content of the official identification card, the shape and the content of the official badge, as well as the rules on record keeping on the issued official identification cards and badges under paragraph 1 hereof.

### ***Rights and Duties of the Inspectors***

#### **Article 214**

In performing inspection oversight over the implementation of radiation safety and security measures, the inspector has the right and duty to establish:

- 1) Whether the requirements for a radiation practice performance have been met;
- 2) Whether the requirements for the activities of ionizing radiation protection have been met;
- 3) Whether the required ionizing radiation protection measures for the exposed workers, the public and the environment have been implemented;
- 4) Whether the prescribed radiation safety and security measures have been implemented;
- 5) Whether other measures prescribed by the Law have been implemented;

In performing inspection oversight over the implementation of nuclear safety and security, the inspector has the right and duty to determine:

- 1) Whether the requirements for nuclear activity performance have been met;
- 2) Whether the prescribed measures of ionising radiation protection for the exposed workers, the public and the environment have been implemented;
- 3) Whether the prescribed measures of nuclear safety and security have been implemented;
- 4) Whether the records of nuclear material and other records as prescribed by the Law and the applicable international agreements have been duly kept;
- 5) Whether other measures prescribed by this Law have been implemented.

### ***Powers of the Inspector***

#### **Article 215**

In performing inspectional supervision, the inspector shall be empowered to:

- 1) inspect the work premises, facilities, plants and sites that are in connection with the radiation practice performance;
- 2) inspect the sites, buildings and facilities that are in connection with the nuclear practice performance;
- 3) gain insight into the technical specification of the equipment;

- 4) gain insight into the employment documentation of the exposed workers;
- 5) gain insight into the documentation on vocational qualifications and fulfilment of health requirements for the exposed workers;
- 6) gain insight into the documentation on education and training of the exposed workers;
- 7) gain insight into ledgers, records, official documents, electronic documents and other documentation in connection with the practice;
- 8) scan and copy ledgers, records, official documents and electronic documents subject to inspectional supervision;
- 9) identify the exposed workers, ionizing radiation protection officers and other individuals found at locations where the inspection oversight is performed by inspecting their personal photographic identification documents or other public photographic identification instruments;
- 10) extract written and oral statements from the persons performing the practice, i.e. witnesses and officials, and instruct such persons to make statements on matters of significance for inspectional supervision;
- 11) take photographs and make video recordings of locations where inspection oversight is performed, as well as the ionizing radiation sources, radioactive and nuclear material or other points subject to inspectional supervision;
- 12) collect data and information that are of relevance for the inspectional supervision;
- 13) request a court warrant to search the residential or work premises if in possession of information that such premises are being used for illicit or non-compliant practices;
- 14) request the assistance and presence of the police, i.e. community police, if reasonably deemed as necessary by the circumstances of a particular case;
- 15) perform radioactivity measurements by means of radiation monitors;
- 16) attend reference sampling, measurements and decontamination of persons, work and living environment;
- 17) temporarily impound the goods subject to inspectional supervision, as well as the documentation and other points to ascertain the facts of a particular case and secure evidence, and issue a certificate of temporary impounding;
- 18) engage authorized legal entities to implement urgent measures, perform radioactivity measurements and give expert opinion in the area of radiation and nuclear safety and security;
- 19) engage experts in the area of radiation and nuclear safety and security;
- 20) engage court expert witnesses in the area of radiation and nuclear safety and security;
- 21) take other measures in accordance with the law.

The premises under paragraph 1, point 1) shall also mean the apartment, supplementary rooms or other types of residential areas registered as the head office or the place where the practice is performed in accordance with the regulations governing business registry.

The Directorate shall provide financial resources from the budget of the Republic of Serbia to cover the costs of engaging authorized legal entities, experts and court expert witnesses under paragraph 1, point 18), 19) and 20) hereof.

### ***Measures of the Inspector***

#### **Article 216**

The inspector shall be empowered to order radiation safety and security measures given as follows:

- 1) order the faults in practice performance to be remedied;
- 2) suspend the work with radiation sources in practice performance until the requirements have been met;
- 3) forbid the practice performance until the requirements have been met;
- 4) forbid the work of exposed workers not meeting the prescribed professional and health conditions, or not having the required training and education;
- 5) order the required measurement for assessing the level of exposure of the exposed workers, the public and the patients;
- 6) order the control of radioactive sources;
- 7) order the control of sealed high activity sources;
- 8) order decommissioning of a radiation facility;
- 9) order the exposed worker to have prescribed health examination in accordance with the applicable standards of the occupational medicine;
- 10) order professionals in the field of medical physics to be engaged;
- 11) order the exposed worker to have periodic retraining and acquire the required skills and knowledge to implement radiation protection measures;
- 12) order the appointment of a radiation protection officer meeting the prescribed conditions;
- 13) order the establishment of radiation protection service with staff meeting the prescribed conditions;
- 14) order the detected faults to be remedied and require legal entities and entrepreneurs performing radiation protection practices to fulfil the prescribed conditions;
- 15) forbid the authorized legal entity or entrepreneur to perform radiation protection practice until detected faults have been remedied, i.e. until the prescribed conditions have been met;
- 16) forbid the trade, import, export and transit of radiation sources over the border of the Republic of Serbia until the prescribed conditions have been met;
- 17) forbid the transport of dangerous goods class 7 ADR/RID/ADN (radioactive material) until the prescribed conditions have been met□

18) forbid the authorized legal entity or entrepreneur to perform radioactivity control in import, export and transit of goods;

19) forbid the export, import and transit of goods subject to inspection oversight that contain radionuclides above the prescribed limits and order their reshipment to a consignor;

20) order decontamination of individuals, work and living environment;

21) order the removal of radiation sources from radioactive lightning rods and ionising detectors with radiation sources in gaseous state or radiation source whose decay products are in gaseous state;

22) order appropriate record to be kept□

23) order appropriate handling of radioactive waste and disused radiation sources;

24) order the authorization holder for radiation protection and environmental radioactivity monitoring to submit the report on Environmental Radioactivity Monitoring by 31 March of the current year for the previous year;

25) order the implementation of radiation protection measures for the exposed workers and members of the public from the harmful radiation effects in the situations of existing exposure;

26) order the steps for management of areas contaminated from previous practices or an emergency event that cannot be disregarded from a radiation protection point of view;

27) order the steps for the activities outside the scope of this Law which imply the use of materials with naturally occurring radionuclides resulting in the exposure of workers or members of public that cannot be disregarded from a radiation protection point of view;

28) order mandatory radon concentration measurements in order to assess the level of ionizing radiation exposure of employees, and the requirements in such workplaces for activity performance outside the scope of this Law;

29) order the authorized legal entity or entrepreneur performing the activities outside the scope of this law measures to be taken when handling orphan sources;

30) order the measures to be taken following the discovery of orphan sources , radioactive and nuclear material out of regulatory control;

31) order the measures to be taken in order to prevent unauthorized trade in radioactive and nuclear materials;

32) order the measures to be taken in case of radiological emergency;

33) order the requirements to be fulfilled and the faults that can lead to harmful effect for the health, work and living environment to be remedied;

34) order the implementation of radiation protection programme;

35) order the protection measures to be taken in radiation practices in medicine;

36) order the prescribed radiation security measures to be taken;

37) order the records of nuclear material, activities, special equipment and nonnuclear material associated with nuclear fuel cycle to be kept in accordance with the provisions of this Law and the ratified international agreements on safeguard implementation;

38) order other radiation safety and security measures.

The inspector shall be empowered to order nuclear safety and security measures to be taken given as follows:

- 1) forbid a nuclear activity unless all requirements have been met;
- 2) forbid the trade in nuclear materials unless all requirements have been met;
- 3) forbid the work of exposed workers in the nuclear facility not meeting the prescribed professional or health conditions, or not having the required training and education;
- 4) order the exposed worker to have the appropriate health examination in accordance with the regulations governing occupational medicine;
- 5) order the exposed worker to have periodic retraining and acquire the required skills and knowledge to implement radiation protection measures;
- 6) order the establishment of radiation protection service, except in case of the license for a nuclear facility siting, design and construction;
- 7) order the establishment and implementation of the integrated management system;
- 8) order the requirements to be met and the detected faults that can have harmful effect on the health of people, work and living environment to be remedied;
- 9) order the faults in connection with the radioactive waste management to be remedied;
- 10) order the faults in connection with spent nuclear fuel management to be remedied;
- 11) order the faults in physical protection and a nuclear facility security to be remedied;
- 12) order the prescribed measures in case of nuclear emergency to be implemented;
- 13) order environmental radioactivity monitoring in the vicinity of the facility;
- 14) order record keeping of data on a nuclear facility and the site thereof, management of radioactive waste, nuclear and other material, and the entire documentation necessary to establish civil liability in accordance with the international convention on the civil liability for nuclear damage;
- 15) order decommissioning of a nuclear facility;
- 16) order the site and soil remediation;
- 17) order record keeping and control of nuclear material;
- 18) order the prescribed nuclear security to be implemented;
- 19) order other measures of nuclear safety and security;

The cost of implementation of the prescribed measures of radiation and nuclear safety and security under paragraph 1 and 2 hereof shall be borne by the supervised person.

### ***Activation of Inspection oversight***

#### **Article 217**

According to the *ratio legis* of this Law, the inspection oversight is an *ex officio* duty that is initiated by the first action of the inspector in the course of inspectional supervision.

The inspector shall take into account information, petitions, reports, briefs and applications by the legal entity or entrepreneur, submitted to initiate the inspection oversight within his or her competence.

With regards to the documents under paragraph 2 hereof, the inspector shall inform the entrepreneur, physical or legal entity on the activities and measures taken within 15 days as of the conclusion of the administrative procedure.

### ***Types and Modes of Inspection Oversight***

#### **Article 218**

Inspection oversight may take the form of scheduled oversight, emergency oversight, follow-up oversight, and supplementary oversight.

Scheduled inspection oversight shall be performed according to a pre-established inspection oversight plan.

Emergency inspection oversight shall be performed:

- 1) where urgent action is necessary to prevent or remove any direct hazard to human life and health; property; rights and interests of employees; the economy; the environment; plant and animal life;
- 2) where there are information and data that the radiation practice or nuclear activity is performed without the previously obtained authorization from the Directorate;
- 3) where, following the adoption of an annual inspection oversight plan, the hazard posed by the entity subject to supervision is assessed as high or critical, or where circumstances have altered in the meantime;
- 4) where action is taken pursuant to petitions, reports, briefs, application and requests.

Follow-up inspection oversight shall be performed to assess compliance with measures recommended to or imposed against an entity subject to supervision in the course of either scheduled or emergency supervision.

Supplementary inspection oversight shall be performed either *ex officio* or at the request of an entity subject to supervision in order to establish facts of relevance for the inspection oversight that have not been established in the course of scheduled, emergency, or follow-up supervision. Only one instance of supplementary inspection oversight may be performed within not more than 30 days following the completion of scheduled, emergency, or follow-up inspectional supervision.

By mode, inspection oversight may take the form of either field or desk supervision. Field inspection oversight shall be performed on location outside of the premises of a particular inspection body and shall consist of direct inspection of land, buildings, facilities, equipment, premises, motor vehicles and other means of transportation, objects, goods and other points, and enactments and other documents of the entity subject to supervision. Desk inspection oversight shall be performed on the premises of a particular inspection body and shall consist of inspection of enactments, data, and documents of the entity subject to supervision.

### ***Inspection Oversight Warrant and Notice***

## **Article 219**

Inspection Chief Officer in the Directorate shall issue a warrant in writing for the inspectional supervision.

Scheduled and supplementary inspection oversight shall be conducted based on the warrant issued by the chief of inspection in the Directorate, which shall primarily contain data about the inspector, the legal entity or entrepreneur subject to supervision, the time, i.e. the period of supervision, the type of practice and the subject of the supervision.

The inspector shall duly send notice in writing to the legal entity or entrepreneur subject to supervision on the impending scheduled and supplementary inspection oversight at the latest three working days prior to the commencement of the supervision.

Emergency and follow-up inspection oversight shall be performed without sending the notice to the legal entity or entrepreneur subject to supervision on the impending supervision and without any warrant for the supervision.

### ***Timing of Inspection oversight***

## **Article 220**

The inspector shall conduct the inspection oversight within regular working hours of the legal entity or entrepreneur subject to supervision.

Exceptionally, inspection oversight can be conducted outside the working hours if:

- 1) it is necessary to take urgent action to prevent or remove direct hazard to human life or health and the environment;
- 2) the level of risk appraised is high or critical, or in case of a nuclear activity;
- 3) there is need to conduct decontamination of people and work or living premises;
- 4) there is need to implement the prescribed measures following the emergency event;
- 5) there are reasons to act without delay.

### ***Minutes of Inspection Oversight***

## **Article 221**

The acting inspector shall draw up minutes of the inspectional supervision.

The inspector shall enter into the minutes all the elements and actions of inspection oversight relevant for establishing the factual situation.

The minutes shall be clear and legible and either in written or electronic form.

Statements of the subjects of inspection oversight together with the objections to the content of the minutes shall be entered into the minutes or a separate document, which is signed by a person making the statement or the record.

A responsible officer of an entity subject to supervision may refuse to endorse or take possession of the minutes, which shall be noted in writing by the inspector, along with the reasons why endorsement or taking possession were refused.

The legal entity or entrepreneur subject to supervision shall be provided with a copy of the minutes immediately after the completion of inspectional supervision. If this is not possible, a copy of the minutes shall be delivered within eight working days of the completion of the instance of inspectional supervision.

The legal entity or entrepreneur subject to supervision may file objections to the minutes of inspection oversight in writing within five working days of taking possession of such minutes.

### ***Measures in Inspection oversight***

#### **Article 222**

Measures in the inspection oversight ordered by the inspector shall be taken based on the decision.

The inspector's decision can be contested by a formal complaint to the Directorate. The decision by the Directorate under paragraph 2 hereof shall be final.

The decision of the Directorate under paragraph 2 hereof shall be subject to administrative dispute.

Complaint against the decision cannot delay its enforcement.

### ***Urgent Procedure***

#### **Article 223**

The inspector can order radiation and nuclear safety and security measures to be taken by issuing a verbal order when there is need to act without delay if:

- 1) practices are performed without previously obtained authorization from the Directorate;
- 2) there is need to eliminate the immediate danger for the lives and health of people and the environment caused by the harmful effect of ionizing radiation;
- 3) there is danger or suspicion of danger for human lives and health which requires certain prescribed activities to be taken immediately and without undue delay;
- 4) there is risk or suspicion of withholding, doctoring or destroying evidence unless certain prescribed measures are taken immediately and without undue delay;
- 5) the prescribed conditions have not been met or cannot be met to perform the practice; 6) there are significant flaws in the practice performance.

In case of verbal order, the inspector shall promptly make an official annotation on the pronounced measures.

In case of verbal order, a written warrant may be issued commensurate with the principles and rules governing the general administrative proceedings.

### ***Sealing of Facility, Offices and Equipment***



## **Article 224**

Where conditions have been met to enforce the decision by direct lawful compulsion, the inspector may secure and seal the facilities, offices and equipment (hereinafter: scheduled assets) in accordance with the law.

The inspector who conducts the sealing has to be properly equipped with sealing kit, i.e. with the official metal stamp, red sealing wax (or security seal furnished with identification mark) and sealing tape.

The procedure for securing and sealing assets shall entail displaying or posting the conclusion allowing enforcement, or procedural decision imposing a ban on doing business or performance of activity, where an appeal against such enactment does not delay enforcement, in a visible location; physically securing the scheduled asset; and stamping the seal onto heated red sealing wax so as to include the sealing tape and thus preventing entry into, or use of, the scheduled asset.

The seal must be placed in such a manner as to prevent any tampering with the assets secured and sealed without the seal being violated.

The inspector shall notify the legal entity or entrepreneur that the act of removing or violating the seal is regarded as a criminal offence and is a part of the record on the enforcement of the written decision.

In case of sealing the facility, offices or equipment used for radiation practices in medicine, the inspector shall immediately and appropriately notify the Ministry responsible for health.

## ***Impounding of Goods, Documentation and Other Items subject to Supervision to Secure Evidence***

### **Article 225**

The inspector acting in the inspection oversight proceedings shall impound documents, goods, and any other items, or the appropriate portions thereof for the purposes of securing evidence in criminal proceedings or proceedings for economic crime or misdemeanour, or in other appropriate legal proceedings, in the event that there are reasonable grounds to suspect that particular evidence will become unavailable or difficult to secure, provided that the nature of the items is such that they must be impounded to serve as evidence.

Impounding of items under paragraph 1 hereof which are radiation sources shall be conducted by the inspector with technical assistance of the authorization holder for such practice who shall duly keep such items until the final decision of the competent authority. The inspector shall make a video or photographic record of the impounded documentation, goods and items.

The inspector shall issue to the legal entity, entrepreneur or physical entity a certificate on impounding of documentation, goods and items that shall contain: data about the legal entity, entrepreneur or physical entity; the time and place the documentation, goods and items were impounded; statutory grounds for impounding; list of items with clear definition of their

respective types, quantities, and other characteristics of relevance for their identification; signature of the responsible officer of the entity subject to supervision, or note to the effect that such responsible officer has refused to sign the certificate; and name, surname, and signature of the acting inspector.

The Directorate shall provide for the safekeeping of impounded documentation, goods and items, except the items under paragraph 2 hereof.

The Directorate cannot dispose of the impounded documentation, goods and items. If the expense associated with safekeeping of impounded documentation, goods and items deemed as radiation sources is substantial, the Directorate may order their sale, provided that they meet the required conditions of being put into the market, and notify the body empowered to pursue appropriate proceedings.

The proceeds of sale shall be deposited until the final decision by the competent authority. The items under paragraph 7 hereof that cannot be sold, i.e. put into the market or used for health, safety or other reasons as stipulated by the law shall be destroyed under supervision or stored as provided for by law.

Expenses of destroying or storing such items shall be borne by the legal entity, entrepreneur or physical entity as the rightful owner of such items, and where the owner is unknown or unavailable, the expenses of destruction or storing of these items shall be borne by the Directorate.

Expenses of safekeeping of impounded documentation goods and items under paragraphs 1 and 2 hereof shall be borne by the legal entity, entrepreneur or physical entity as their rightful owner, and where the owner is unknown or unavailable, by the Directorate.

The Directorate may recover such costs from the legal entity, entrepreneur or physical entity as the owner of the goods and items under paragraphs 10 and 11 hereof once they are determined or become available.

The inspector, within eight work days of the day of impounding of documentation, goods and items under paragraphs 1 and 2 hereof, shall lodge a misdemeanor proceedings, economic proceedings or criminal complaint with the competent authority and hand over the subject documentation, goods and items, except radiation sources to the competent authority.

***Criminal Charges, Economic Offence Charges, Misdemeanor Charges, Misdemeanor Orders, and Other Actions and Measures Inspectors May Impose***

**Article 226**

In the event the inspector uncovers an instance of non-compliance by an entity subject to oversight that is punishable under law or other regulation, such inspector shall bring criminal charges, economic offence charges, or misdemeanor charges, or file misdemeanor orders, with the competent judicial body.

The judicial body before which the inspection body had brought misdemeanor charges, economic offence charges, or criminal charges, shall report *ex officio* to the inspection body of the outcome of its actions.

## ***Rights and Duties of Entities Subject to Supervision***

### **Article 227**

Legal entities, entrepreneurs and physical entities subject to supervision shall allow the inspector to perform inspection oversight without hindrance.

Legal entities, entrepreneurs and physical entities under paragraph 1 hereof shall allow access to information and business documentation that is of importance for the performance of inspection oversight and possible additional procedures within the schedule set by the inspector.

Legal entities, entrepreneurs and physical entities under paragraph 1 hereof shall temporarily cease with the activities during the supervision at the inspector's request provided that the inspector cannot otherwise perform supervision and determine the factual situation.

The licensee shall without unduly delay enable the inspector to conduct inspectional supervision, to gain insight into the documentation, to perform work without hindrance and to have all the data and material that is of importance for the performance of inspection oversight at disposal.

Any act of removing or withholding the evidence on the unlawful action is strictly forbidden. Legal entities, entrepreneurs and physical entities subject to supervision shall be required to respect the integrity and official capacity of the inspector.

## ***Operational Independence of the inspector***

### **Article 228**

The inspector shall enjoy operational independence while performing duties within the limits of the powers established by the legislation and other regulations, and shall be held personally accountable for the duties performed.

No person is allowed to use professional position or powers, overstep the powers, deliberately fail to perform the duties or in any other way in order to prevent or impede the inspector in conducting inspection oversight and undertaking measures and actions within their competence.

## ***Special Liabilities of the Inspector***

### **Article 229**

The inspector for inspection oversight shall be particularly liable where:

- 1) In the course of inspection oversight the inspector or civil servant fails to take, propose, or impose any measures from within his or her remit;
- 2) In the course of inspection oversight the inspector or civil servant fails to propose or initiate any required proceedings provided for under this Law;

3) In the course of inspection oversight the inspector or civil servant exceeds the bounds of his authority;

4) Such inspector or civil servant engages in a business or other activity on his own behalf or on behalf of another employer in the area in which he or she performs inspectional supervision; takes part in working groups or bodies of entities or individuals subject to supervision; or holds other positions or performs tasks or activities that are incompatible with the position and role of the inspector and jeopardize his professional independence. Any violations of duty referred to under paragraph 1 hereof shall be deemed major violations of duty.

### ***Records of Inspection oversight***

#### **Article 230**

Each inspector shall keep a record of inspectional supervision.

The record of inspection oversight shall contain, in particular:

1) Identification of the type and form of the instance of the inspection oversight performed;

2) Information on the inspector, i.e. the inspectors performing the instance of the inspectional supervision;

3) Information on the legal entity, entrepreneur or physical entity, i.e. their statutory representatives or responsible officers;

4) Information on the type of practice;

5) Information on the assessed radiation risk;

6) Statutory grounds for the instance of the inspectional supervision;

7) Description of the subject-matter and purpose of the instance of the inspectional supervision;

8) Duration of the instance of inspection oversight(start and end dates of the instance of inspectional supervision);

9) Description of actions taken in the course of the instance of the inspectional supervision;

10) Information on the minutes of inspection oversight and objections to such minutes;

11) Information on the measures imposed, or note to the effect that no measures were ordered, with an indication of whether there were no grounds or need to order any measures;

12) Information on criminal charges, economic offence charges, and misdemeanor charges brought and misdemeanor orders issued;

13) Information on the outcomes of actions by judicial bodies with regard to misdemeanor charges, economic offence charges and criminal charges brought by the inspection body and outcomes of misdemeanor orders issued by the inspection body. Personal data and data on the radiation sources for practice performance referred to in

paragraph 2, points 3) and 4) hereof shall be deemed confidential and may not be used for purposes other than those envisaged under the law.

The Directorate shall prescribe the template of the record of inspection oversight and the manner of keeping such record.

### ***Digitalization of the Documentation***

#### **Article 231**

The documentation of the inspection oversight and certain documents (the minutes, statements, copies of documentation subject to supervision etc.) can be filed as electronic documents in accordance with the law regulating electronic documents.

### ***Actions by the Inspector Falling Under the Remits of Different Inspections***

#### **Article 232**

In the event the inspector finds the entity subject to supervision has infringed upon a law or other regulation under the remit of a different inspection body, such inspector shall draw up a record of the facts of the case and provide such record duly and without delay to the inspection body that has jurisdiction over the business operations or performance of activity by the entity subject to supervision.

## **XV CRIMINAL PROVISIONS**

### ***Economic Offences***

#### **Article 233**

The fine amounting from RSD 1,500,000 to 3,000,000 shall be levied for an economic offence on a legal entity if such legal entity:

- 1) performs practices without previously obtained authorization issued by the Directorate (Article 4 paragraph 2);
- 2) performs trade in and transport of radiation sources in the Republic of Serbia without the authorization or permit issued by the Directorate (Article 4, paragraph 3);
- 3) installs and uses radioactive lightning rods on the territory of the Republic of Serbia (Article 4, paragraph 6);
- 4) installs and uses ionizing smoke detectors with ionizing radiation sources in gaseous state or with decay radioactive products in gaseous state (Article 4, paragraph 7);
- 5) deliberately dilutes radioactive material so as to fulfil the requirements for the release from regulatory control (Article 4, paragraph 10);
- 6) uses sealed radiation sources or their containers which are mechanically damaged or suspected to be leaking or are otherwise broken (Article 4, paragraph 13);

7) deliberately dilutes radioactive material for the purpose of its release from regulatory control (Article 4, paragraph 14);

8) fails to implement general principles of radiation and nuclear safety and security (Article 35);

9) the authorization holder continues to perform the suspended practice during the suspension (Article 52, paragraph 7);

10) commences to perform radiation protection duties without previously obtained decision from the Directorate (Article 57, paragraph 1);

11) the approval holder during suspension performs radiation protection duties subject to the decision on the approval suspension (Article 60, paragraph 6);

12) puts into the market products and other goods intended for the public, animals, and products and other goods intended to be used work or living environment containing such amount of radionuclides that the use of such products in regular and recommended manner can lead to the exposure of the public above the prescribed limits (Article 97, paragraph 1);

13) fails to perform decommissioning of a radiation facility where moderate risk radiation practice with unsealed radiation sources and high risk radiation practice with unsealed radiation sources of category I and II is performed, and fails to prepare and periodically review and revise the initial decommissioning plan (Article 111, paragraphs 1 and 5);

14) fails to perform nuclear activities in a way to prevent emergency event (Article 113, paragraph 1);

15) fails to prevent a nuclear emergency event while performing nuclear activities (Article 113, paragraph 2);

16) fails to establish a radiation protection service for nuclear activities except in case of a license for nuclear facility siting, design and operation (Article 114);

17) fails to establish and employ an integrated system of management and fails to take action to improve and enhance nuclear safety and security culture by implementing the integrated system of management (Article 115, paragraphs 1 and 2);

18) does not obtain a license for nuclear facility siting (Article 117, paragraph 1);

19) does not obtain the consent from the Directorate for the report on a nuclear facility siting (Article 119, paragraph 1);

20) does not obtain a license for a nuclear facility design (Article 120, paragraph 1);

21) fails to prepare an initial decommissioning plan for all nuclear facilities, i.e. an initial closure plan for radioactive waste disposal facilities (Article 121, paragraph 4);

22) does not obtain the consent from the Directorate for the report on a nuclear facility siting and nuclear facility design (Article 122, paragraphs 1 and 2);

23) does not obtain a license for a nuclear facility construction (Article 125, paragraph 1);

24) fails to ensure that all structures, systems, components and equipment are manufactured, installed, reviewed and tested in accordance with the applicable standards and regulations throughout all stages of a nuclear facility construction (Article 127, paragraph 3);

- 25) does not obtain a license for a nuclear facility trial run (Article 128, paragraph 1);
- 26) fails to conduct trial run of a mobile radioactive waste processing unit upon each change of location of such unit (Article 129, paragraph 4);
- 27) fails to obtain the consent from the Directorate for the report on the final nonnuclear testing stage of a facility (Article 130, paragraphs 2 and 3);
- 28) fails to obtain the consent from the Directorate for the report on the final nuclear testing stage of a facility (Article 131, paragraphs 4 and 5);
- 29) does not obtain a license for a nuclear facility operation (Article 133, paragraph 1);
- 30) fails to ensure prerequisites necessary for a nuclear facility or mobile radioactive waste processing unit operation (Article 134, paragraph 1, 2 and 3);
- 31) fails to ensure safe and secure management of a temporarily shutdown of a nuclear facility (Article 135, paragraph 2);
- 32) fails to obtain the consent from the Directorate for a temporary shutdown of a nuclear facility (Article 136, paragraph 1);
- 33) does not obtain a license for a nuclear facility decommissioning for all facilities except for a nuclear facility for a radioactive waste disposal (Article 138, paragraph 1);
- 34) fails to obtain the consent from the Directorate for the updated decommissioning plan commensurate with the Government decision on the end state of a nuclear facility decommissioning, and other updated documentation serving as the basis for the issuance of a license for a nuclear facility decommissioning (Article 140, paragraphs 2 and 3);
- 35) commences decommissioning activities without previously obtained consent from the Directorate, fails to duly perform decommissioning activities and fails to obtain the consent from the Directorate for the report on decommissioning serving to verify that the decommissioning end state, commensurate with the Decommissioning Plan has been achieved, and the consent for the Report on final radiological survey of the facility and the site thereof (Article 141, paragraphs 2, 3, 4 and 5);
- 36) fails to prepare and periodically review and revise the initial decommissioning plan for a nuclear facility (Article 142, paragraph 1);
- 37) fails to prepare and periodically review and revise the decommissioning plan for a nuclear facility (Article 143, paragraph 1);
- 38) fails to submit to the Directorate the report on the review and revision of Decommissioning Plan and fails to submit such report on each unplanned event that can have impact on the nuclear facility decommissioning (Article 144, paragraphs 2 and 3);
- 39) does not obtain a license for a radioactive waste disposal facility closure (Article 146, paragraph 1);
- 40) fails to implement environmental radioactivity monitoring in the vicinity of a nuclear facility (Article 153, paragraph 1);
- 41) fails to keep the records and data on the nuclear facility and the site thereof, on the management of radioactive waste, nuclear and other radioactive material, and the entire documentation necessary to establish civil liability pursuant to the international convention on civil liability for nuclear damage (Article 154, paragraph 1);

42) fails to perform site remediation with contamination resulting from an existing exposure situation or an emergency event that cannot be disregarded from a radiation protection point of view (Article 155, paragraph 1);

43) fails to conduct soil remediation pursuant to the law governing soil protection (Article 155, paragraph 5);

44) fails to conduct restoration of contaminated facilities with contamination resulting from an existing exposure situation or an emergency event that cannot be disregarded from a radiation protection point of view (Article 156, paragraph 1);

45) fails to periodically update the remediation and restoration plans (Article 157, paragraphs 3 and 4);

46) fails to obtain from the Directorate the consent for site remediation, i.e. the consent for contaminated facility restoration (Article 158, paragraph 1);

47) fails to submit to the Directorate the report on remediation completion, i.e. restoration completion serving to confirm the end state of the site, i.e. the facility in accordance with the plan, and the report on final radiological survey (Article 158, paragraph 4);

48) fails to declare radioactive material and spent nuclear fuel not intended for further use to be radioactive waste (Article 160, paragraph 1);

49) fails to manage radioactive waste and spent nuclear fuel in a safe and secure manner (Article 161);

50) fails to meet obligations pertaining radioactive waste and spent nuclear fuel (Article 163);

51) fails to control and keep records of generated and collected radioactive waste and spent nuclear fuel (Article 164);

52) fails to implement due measures for temporary keeping of radioactive waste and spent nuclear fuel (Article 165);

53) fails to perform categorization of radioactive waste and spent nuclear fuel generated during practice performance (Article 166, paragraph 1);

54) fails to duly keep and submit to the Directorate the records of stored radioactive waste and spent nuclear fuel in timely manner (Article 170, paragraph 3);

55) fails to provide prescribed conditions for radioactive waste and spent nuclear fuel disposal, and fails to implement passive safety measures (Article 171);

56) fails to establish criteria for radioactive waste and spent nuclear fuel acceptance in the facilities for processing, storing or disposing of radioactive waste, i.e. the facilities for reprocessing, storing or disposing of spent nuclear fuel (Article 172, paragraph 1)

57) fails to keep the records of generated radioactive waste which is kept in a repository, processed, stored, disposed or released from regulatory control and submit these records to the Directorate, fails to keep the records of spent nuclear fuel which is kept in a repository, reprocessed, stored or disposed and submit these records to the Directorate (Article 176, paragraphs 1, 2 and 3);

58) fails to report to the Directorate the possession of nuclear material for nuclear or non-nuclear purposes in accordance with the ratified international agreements and this Law (Article 182, paragraph 1);



59) fails to notify the Directorate on the activities, special equipment and nonnuclear material associated with nuclear fuel cycle in accordance with the ratified international agreements and this Law (Article 182, paragraph 2);

60) fails to keep the records of the nuclear material, activities, special equipment and non-nuclear material associated with nuclear fuel cycle in accordance with the ratified international agreements and this Law (Article 181, paragraph 1);

61) fails to submit to the Directorate in timely manner the records of the nuclear material, activities, special equipment and non-nuclear material associated with nuclear fuel cycle in accordance with the ratified international agreements and this Law (Article 183, paragraph 3);

62) fails to enable the inspectors from the International Atomic Energy Agency to carry out control and supervision of the nuclear material, activities, special equipment and nonnuclear material associated with nuclear fuel cycle, and other activities in accordance with the ratified international conventions and agreements (Article 184);

63) fails to provide and maintain physical protection and other security measures depending on the type, category and purpose of a radiation source during practice performance and with the aim of preventing theft, sabotage, loss or unauthorized access (Article 187, paragraph 1);

64) fails to provide and maintain physical protection and other security measures for radiation sources and associated facilities including transport (Article 188, paragraph 1);

65) fails periodically and continuously to enhance the Security Plan serving to describe radiation and nuclear security measures commensurate with all the changes so that the Security Plan could always reflect the current state of the practice and the facility (Article 189, paragraph 6);

66) fails to ensure compliance of the Security Plan with Design Basis Threat (Article 189, paragraph 7);

67) fails promptly to modify physical protection system and the Security Plan in line with the recommendations from the competent security authorities and with their consent, in the event of a change in Design Basis Threat (Article 189, paragraph 8);

68) fails to prepare Response plan in case of emergency event in the facilities for radiation practices and nuclear activities and the sites thereof (Article 194, paragraph 1);

69) performs the practice of trade in and transport of radiation sources without previously obtained decision from the Directorate on registration, i.e. license issuance (Article 196, paragraph 3);

70) fails to enter into and maintain the insurance coverage for its nuclear damage liability (Article 208, paragraph 1).

For the economic offence under paragraph 1 hereof, a fine may be levied in proportion to the amount of damage, non-performance of obligation or value of goods or other item subject to the economic offence, but up to twenty times the amount of the damage, nonperformance or value of goods or other item subject to the economic offence.

For the economic offence under paragraph 1 hereof, the responsible person of the legal entity shall be also fined the amount from RSD 200,000 to 500,000.

## **Article 234**

A fine amounting from RSD 1,000,000 to 2,000,000 shall be levied for an economic offence on the legal entity – the licensee for a nuclear activity performance if they fail to conclude and maintain the insurance coverage for its nuclear damage liability.

For the economic offence under paragraph 1 hereof, the responsible person of the legal entity - the licensee for a nuclear activity performance shall be also fined the amount from RSD 100,000 to RSD 200,000.

## ***Misdemeanors***

### **Article 235**

The fine amounting from RSD 500,000 to 1,000,000 shall be imposed in case of misdemeanor on a legal entity if such legal entity:

- 1) places radioactivity markings on any items or locations where there are no radiation sources (Article 4, paragraph 15);
- 2) fails to notify the Directorate on the intention to perform a practice with radiation sources, naturally occurring radioactive material resulting in the exposure of workers or the public that cannot be disregarded from a radiation protection point of view, and on the use of nuclear material for non-nuclear purposes (Article 31, paragraph 1);
- 3) fails to conduct notification before the commencement of the practice (Article 31, paragraph 3);
- 4) fails to notify the Directorate on abandoning the intention to perform a practice (Article 31, paragraph 4);
- 5) fails to fulfil the prescribed obligations (Article 36, paragraph 1);
- 6) fails to keep the records of nuclear material, activities, special equipment and nonnuclear material associated with nuclear fuel cycle in accordance with the ratified international agreements and this Law (Article 37, paragraph 1);
- 7) fails to notify the Directorate on any change of data on the fulfilment of requirements that served as the basis for issuing the decision on registration, within 30 days as of the day of the change at the latest (Article 41, paragraph 6);
- 8) fails to notify the Directorate on any change of data on the fulfilment of requirements that served as the basis for issuing the decision on license, within eight days as of the day of the change at the latest (Article 42, paragraph 5);
- 9) fails to review and update the Safety Report commensurate with the changes occurring during practice performance so that the report can always reflect the current status of the practice performance (Article 43, paragraph 2);
- 10) fails to revise the Safety Report under Article 43 hereof and fails to submit the report thereof to the Directorate (Article 44, paragraph 1);

- 11) does not obtain the decision from the Directorate on the consent for the Initial Safety Report (Article 45, paragraph 1);
- 12) fails to report to the Directorate, without undue delay, the changes in the requirements serving as the basis for issuing the consent for the Initial Safety Report, and decision to abandon the intended practice performance, within eight days as of the change occurrence, i.e. decision to abandon at the latest (Article 45, paragraph 3);
- 13) fails to submit to the Directorate the application for the extension of the license for low-risk radiation practice performance within 60 days prior to the license termination at the latest (Article 47, paragraph 6);
- 14) fails to establish, maintain and employ the integrated system of management for a high-risk radiation practice performance (Article 48, paragraph 2);
- 15) fails to submit to the Directorate the application for the extension of the license for a high-risk radiation practice within 90 days prior to the license termination at the latest (Article 48, paragraph 10);
- 16) fails to establish, maintain and employ the integrated system of management for a nuclear activity performance (Article 49, paragraph 2);
- 17) fails to submit to the Directorate the application for the extension of the license for a nuclear activity performance within 180 days prior to the license termination at the latest (Article 49, paragraph 9);
- 18) fails timely to evaluate the compliance of the applied radiation and nuclear safety and security measures with this Law and the international standards in the area of radiation and nuclear safety and security and radioactive waste and spent nuclear fuel management (Article 50);
- 19) fails to report to the Directorate on any change of data that served as the basis for issuing the decision for ionizing radiation protection duties, within eight days at the latest (Article 57, paragraph 6);
- 20) fails to submit to the Directorate the application for the extension of the decision on radiation protection duties within 60 days prior to the decision termination at the latest (Article 57, paragraph 7);
- 21) does not obtain the decision from the Directorate on the release of material from regulatory control (Article 62, paragraph 1);
- 22) does not obtain the decision from the Directorate on the release of facilities, sites and the parts thereof from regulatory control (Article 63, paragraph 1);
- 23) fails to implement the measures of restriction on the use or access to the facility, the site or the parts thereof (Article 63, paragraph 6);
- 24) fails to prepare the report on the final radiological survey of the facility, the site and the parts thereof (Article 64);
- 25) fails to forbid or restrict the exposure of individuals (Article 68);
- 26) exposes individuals for non-medical imaging purposes without previously obtained consent from the Directorate (Article 69, paragraph 1);
- 27) fails to obtain the consent from the Directorate for the introduction of a new radiation practice (Article 70, paragraph 1);

- 28) fails to obtain the consent from the Directorate for the introduction of new methods and technologies within the existing radiation practice (Article 70, paragraph 5);
- 29) fails to classify the work premises (Article 72, paragraph 3);
- 30) fails to categorize the exposed workers (Article 73, paragraph 2);
- 31) fails to conduct health surveillance of the exposed workers (Article 74, paragraph 3);
- 32) fails to keep health records of the exposed workers (Article 75);
- 33) fails to provide individual monitoring for all engaged exposed workers including outside workers (Article 76, paragraph 2);
- 34) fails to provide the Directorate and occupational medicine services with the results of individual monitoring so as to evaluate possible consequences on the health of the exposed workers (Article 76, paragraph 3);
- 35) fails to provide the prescribed conditions for the exposed workers in the course of practice performance, persons involved in the response to an emergency event, persons engaged in the remediation activities, apprentices, students and workers exposed to radon at their workplaces (Article 78);
- 36) fails to conduct individual monitoring of the outside workers in the same manner as in case of permanent employees (Article 79, paragraph 2);
- 37) carries out a high-risk practice in medicine without engaging a medical physician (Article 84, paragraph 1);
- 38) fails to engage a medical physician to participate in drafting spatial documentation and technical specifications during intended introduction of a new type of device or a method within a high-risk practice in medicine (Article 84, paragraph 3);
- 39) fails to implement radiation and nuclear safety and security measures for the facilities where practices are performed so as to ensure the protection of a member of the public from the harmful effect of ionizing radiation (Article 86, paragraph 1);
- 40) fails to conduct dose assessment for a representative person and a member of the public (Article 87, paragraph 1);
- 41) fails to obtain the consent from the Directorate for each intended discharge of radioactive effluents into the environment (Article 88, paragraph 1);
- 42) fails to conduct monitoring of permitted discharges of radioactive effluents into the environment and regularly to report on such monitoring to the Directorate (Article 89, paragraph 1);
- 43) fails to meet obligations in terms of ionizing radiation protection for a member of the public and the public during practice performance (Article 90, paragraph 1);
- 44) fails to submit to the Directorate the report on radioactive monitoring by 31 March of the current year for the following year at the latest, or immediately in case of nuclear or radiological nuclear event, or at the request of the Directorate (Article 92, paragraph 1);
- 45) fails to take control measures for unsealed and sealed radioactive sources and devices with integrated radioactive sources so as to ensure their safe and secure management during their useful lifecycle and later, and during the process of their recycling and disposal (Article 106, paragraph 1);

- 46) fails to keep the records of sources and devices (Article 106, paragraph 2);
- 47) fails to inform the Directorate and other competent bodies and organizations on loss, theft, sabotage, significant spill, unauthorized use or unauthorized discharge of radioactive material into the environment (Article 106, paragraph 4);
- 48) fails to inform the Directorate on any change of location of highly active and other types of sealed sources (Article 106, paragraph 5);
- 49) fails to apply due markings on a highly active source and the container thereof (Article 107, paragraph 3);
- 50) fails to take all necessary measures to reship a source to a consignor once the sealed source has been declared to be disused (Article 109, paragraph 2);
- 51) fails to submit the declaration of a sealed source as disused to the Directorate within eight days as of the day of declaring (Article 109, paragraph 5);
- 52) fails to inform the Directorate within eight days on the instance of source reshipment to the consignor, intended recycling, transfer of ownership to another licensee or delivery to the central storage (Article 109, paragraph 6);
- 53) keeps a disused source in its own repository longer than one year (Article 109, paragraph 8);
- 54) if, during activity performance not incorporated in the practices prescribed by the Law, likely to endanger the lives and the health of people and the environment due to harmful effect of ionizing radiation from orphan sources, they act contrary to the prescribed requirements (Article 110, paragraph 1 and 3);
- 55) fails to apply for the termination of the license for decommissioning after the completion of the activities intended by the decommissioning plan under Article 143 hereof (Article 145, paragraph 1);
- 56) fails to submit to the Directorate Decommissioning report and the report on final radiological survey of the facility and the site thereof (Article 145, paragraph 2);
- 57) fails to establish and implement measures of control on the site of a closed radioactive waste disposal facility (Article 147, paragraph 2);
- 58) fails to prepare and regularly review and revise the initial plan for the closure of radioactive waste disposal facility (Article 148, paragraph 1);
- 59) fails to prepare and regularly review and revise the plan for the closure of the radioactive waste disposal facility (Article 149, paragraph 1);
- 60) fails to submit to the Directorate the report on the review and revision of the plan for the closure of radioactive waste disposal facility (Article 150, paragraph 3);
- 61) fails to apply for the termination of the license following the completion of all activities intended by the plan for the closure of radioactive waste disposal facility under Article 148 hereof (Article 151, paragraph 1);
- 62) fails to submit to the Directorate the report on the closure of a radioactive waste disposal facility and the report on finalized radiological survey of the facility and the site thereof (Article 151, paragraph 2);
- 63) fails to retain the records and the data on the site, facility, radiation sources and radioactive waste management (Article 158, paragraph 7);

64) fails to keep the records and conduct the analysis of emergency events including, but not limited to, the emergency or unintended exposure (Article 192, paragraph 1);

65) fails promptly to inform the Directorate on any emergency event associated with the practice being performed and fails promptly to take all necessary measures to eliminate or mitigate the consequences, including the initial assessment of the circumstances and consequences of an emergency event and provision of assistance in the course of protection measures implementation (Article 192, paragraph 2);

66) fails to keep the records on the trade in radiation sources (Article 196, paragraph 6);

67) fails to submit to the Directorate the application for the authorization extension for the practice of trade in radiation sources 60 days prior to the authorization termination (Article 196, paragraph 8);

68) fails to obtain the permit for the import, export or transit of radiation sources, which is issued by the Directorate (Article 197, paragraph 1);

69) fails to inform the Directorate on the expected shipment arrival 48 hours at the latest before its arrival at the border crossing during radiation source import (Article 198, paragraph 4);

70) fails to inform the Directorate 72 hours at the latest before the expected shipment arrival to the border crossing in the Republic of Serbia in case of reshipment of a radiation source (Article 199, paragraph 3);

71) fails to provide the Directorate with the information on the end use and the end user of the radiation sources being exported, which serves to confirm their justified peaceful and safe use (Article 199, paragraph 4);

72) fails to inform the Directorate 72 hours at the latest before the expected shipment arrival to the border crossing in the course of transit of a radiation source (Article 200, paragraph 2);

73) conducts the practice of transport of dangerous goods class 7 ADR/RID/ADN (radioactive material) without the decision from the Directorate on registration, i.e. decision on the license issuance (Article 204, paragraph 3);

74) fails to keep the record of the transport of dangerous goods class 7 ADR/RID/ADN (radioactive material) (Article 204, paragraph 4);

75) fails to submit to the Directorate the application for the extension of the issued authorization for transport of dangerous goods class 7 ADR/RID/ADN (radioactive material) 60 days prior to the authorization termination (Article 204, paragraph 6);

76) fails to act upon the decision from the inspector (Article 222, paragraph 1);

77) fails to act upon the verbal order from the inspector in case of urgent actions (Article 223, paragraph 1);

78) fails to enable the inspector to seal the facilities, premises and equipment (Article 224, paragraph 1);

79) fails to enable the inspector to temporarily impound the goods, documentation and other items subject to supervision for the purpose of securing evidence (Article 225, paragraph 1);

80) fails to enable the inspector to perform inspection oversight without impediment, fails to submit information and business documentation necessary for the inspection oversight and additional procedures within the schedule defined by the inspector, fails to suspend the activities during inspection oversight provided that this is the only way for the inspector to conduct the supervision and determine factual situation, fails to enable inspection oversight without undue delay, insight into documentation, undisturbed work and to provide the inspector with the data and material necessary for the inspectional supervision, removes or conceals evidence and fails to show due respect for the integrity and official capacity of the inspector (Article 227).

For the violation under paragraph 1 hereof, a fine may be levied proportional to the amount of damage, non-performance, value of goods or other item subject to the violation, but up to twenty times the amount of the values.

For the violation under paragraph 1 hereof, the responsible person of the legal entity shall be also fined at the amount from RSD 50,000 to 100,000.

### **Article 236**

The fine amounting from RSD 250,000 to 500,000 shall be levied for a violation on an entrepreneur in case of violations under Article 233, paragraph 1, points 1)-9), point 12) points 42) – 54) and points 57) – 69), and Article 235, paragraph 1, points 1)-15), point 18), points 21) – 43), points 45) – 54) and points – 63) – 80) hereof.

## **XVI TRANSITIONAL AND FINAL PROVISIONS**

### ***Harmonization with the EU Acquis***

#### **Article 237**

This Law transposes into Serbian legislation the following: Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against dangers arising from exposure to ionising radiation, and repealing the following Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L 13, 17.1.2014, p. 1), then Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations (OJ L 172, 2.7.2009, p. 18), Council Directive 2014/87/Euratom of 8 July 2014 amending Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations (OJ L 219, 25.6.2014, p. 42), Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste (OJ L 119, 2.8.2011, p. 48) and Council Directive

2006/117/Euratom of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel (OJ L 337, 5.12.2006, p. 21).

#### **Article 238**

On the date of entry into force of this Law, the Law on Radiation Protection and Nuclear Safety (*Official Gazette of the Republic of Serbia* No. 36/09 and 93/12) shall cease to have effect.

On the date of entry into force of this Law, provisions of the Law on Transport of Dangerous Goods (*Official Gazette of the Republic of Serbia* No. 104/16 and 83/18) governing the transport of dangerous goods class 7 ADR/RID/ADN (radioactive material) shall cease to have effect.

#### **Article 239**

On the date of entry into force of this Law, the public company *Nuclear Facilities of Serbia* shall continue its operations in accordance with this Law.

#### **Article 240**

All regulations passed based on the Law on Radiation Protection and Nuclear Safety shall be implemented until the regulations based on this Law have been passed.

#### **Article 241**

Proceedings commenced before Serbian Radiation Protection and Nuclear Safety Agency where the final decision has not been arrived at until the day of entry into force of this Law, shall be concluded according to the provisions of this Law.

#### **Article 242**

On the day of entry into force of this Law, Serbian Radiation Protection and Nuclear Safety Agency, established by the Decision of the Government, shall continue its functions as the Directorate.

The employees of Serbian Radiation Protection and Nuclear Safety Agency shall continue with their current employment with equal rights and obligations until conclusion of new employment contracts.

On the day of entry into force of this Law, the Directorate shall assume all employees, as well as rights, duties, cases, tools, equipment and archives from Serbian Radiation Protection and Nuclear Safety Agency, which are necessary to carry out the functions of the Directorate.



On the day of entry into force of this Law, the Directorate shall assume from the Ministry of Environmental Protection the employees engaged in inspection oversight in the field of ionizing radiation protection, together with the objects, tools, equipment and archive necessary to carry out the functions of the inspectional supervision.

The employees under paragraph 4 hereof shall keep their remuneration under the existing regulations until the conclusion of new employment contracts.

#### **Article 243**

The Statute, Employee Handbook and Rulebook on Internal Organization and Systematization of Work in the Directorate shall be passed within 60 days of the day of the entry into force of this Law.

The existing enactments remain valid until the enactments under paragraph 1 hereof have been passed.

#### **Article 244**

The Director and the Management Board of Serbian Radiation Protection and Nuclear Safety Agency shall continue with their functions until the termination of their terms, when new bodies of the Directorate shall be appointed pursuant to the provisions of this Law and the Statute.

#### **Article 245**

Approval holders shall continue with their activities pursuant to the Law on Radiation Protection and on Nuclear Safety until approval termination but not later than 31 December 2021.

#### **Article 246**

Licensees shall continue with their activities pursuant to the Law on Radiation Protection and on Nuclear Safety until license termination but not later than 31 December 2021.

The legal entity under Article 239 hereof, entrusted with the management of nuclear facilities in the Republic of Serbia as the practice of general interest that on the day of entry into force of this Law does not obtain the license for the performance of nuclear activities under Articles 117, 120, 125, 128, 133, 138 and 146 hereof shall, within six months as of the day of entry into force of this Law, submit to the Directorate the application for the issuance of the relevant license.

#### **Article 247**

The diagnostic reference levels established by the European Commission shall be implemented until the establishment of the national ones.

#### **Article 248**

For existing nuclear and radiation facilities where there is no initial decommissioning plan on the day of entry into force of this Law, such plan shall be prepared by the legal entity or entrepreneur within 6 months as of the day of entry into force of this Law.

#### **Article 249**

The owners of cadastral plots and facilities with radioactive lightning rods shall undertake to remove them.

The removal of radioactive lightning rods can be conducted by the licensee at the request of the owners of the cadastral plots and facilities under paragraph 1 hereof.

The owners of the cadastral plots and facilities under paragraph 2 hereof shall cover the cost of the radioactive lightning rods removal.

The means and resources for the removal of the radioactive lightning rods from the cadastral plots and facilities where the owners are not known or have ceased to exist shall be provided from the budget of local self-governments in the area where such radioactive lightning rods have been discovered.

The Directorate shall specify the requirements for the issuance of the license under paragraph 2 hereof.

#### **Article 250**

This Law shall come into force on the day following its publication in the *Official Gazette of the Republic of Serbia*.

