

Pursuant to Article IV.4a) of the Bosnia and Herzegovina Constitution, the Parliamentary Assembly of Bosnia and Herzegovina, at the 16th session of the House of Representatives held on October 11 and 30, 2007, and at the 9th session of the House of Peoples, held on October 29, 2007, adopted the

**ACT
ON RADIATION AND NUCLEAR SAFETY IN
BOSNIA AND HERZEGOVINA**

I. BASIC PROVISIONS

**Article 1
(Subject Matter)**

- (1) The Act on Radiation and Nuclear Safety in Bosnia and Herzegovina (hereinafter referred to as: the Act), regulates the system of control over sources of ionising radiation, the protection of humans, present and future generations, as well as of the environment, from exposure or potential exposure to ionising radiation.
- (2) This Act shall be applied to all situations, which include exposure or potential exposure to ionising radiation, except for those excluded from control.
- (3) This Act shall also establish the liability for nuclear damage.

**Article 2
(Purpose)**

The purpose of this Act shall be to ensure the protection against ionising radiation – radiation and nuclear safety of the citizens of Bosnia and Herzegovina, as follows:

- a) Establish and implement a system, which enables development and use of ionising radiation sources in line with the requirements pertaining to the protection of health of humans and of safety.
- b) Establish and maintain a regulatory programme for ionising radiation sources, and thereby ensure compatibility with international standards on safety of radiation sources and for protection against ionising radiation.
- c) Establish a State regulatory body for radiation and nuclear safety with appropriate set of functions and responsibilities, and resources required for the establishment of regulatory control.

Article 3 (Definitions)

Terms and phrases used in this Act shall have the following meaning:

- a) **Emergency Event (Accident)** – shall mean an event resulting, or potentially resulting, in irradiation, i.e. radioactive contamination of working environment, persons working with sources of ionising radiation, population, or material goods, exceeding the limits set forth under the regulations.
- b) **Applicant** – legal person who applies to regulatory body filing a application to the regulatory body for the purpose of obtaining the authorisation for undertaking of specific activities.
- c) **Authorisation** – permit issued by the regulatory body to legal persons, which applied for the performance of a practice or another activity. Authorisation can be in the form of a registration or a license.
- d) **Exclusion** – exclusion of a particular category of exposure from the scope of regulatory control on the grounds of amenable to regulatory control.
- e) **Ionising radiation** – for the purpose of radiation protection , shall mean the radiation capable of producing ion pairs in biological materials.
- f) **Legal Person** – any organisation, corporation, company, firm, association, public or private institution, or other persons registered in line with the State law, which holds or hold the responsibility and the license for undertaking of any activity provided for under this Act.
- g) **Notification** – document submitted by a legal person to the regulatory body, informing the respective body on the intention of the legal person to carry out a practice described under this Act or under regulations.
- h) **Practice** – any human activity , that introduces additional sources or additional exposure pathways,or extends exposure to additional people or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of people or the number of people exposed.
- i) **Radiation protection** – protection of people from the effects of exposure to ionising radiation, and the means for achieving of this protection.
- j) **Exposure** – act or condition being subject to irradiation.
- k) **Potential exposure** – an exposure that not expected to occur with certainty but that may result from an accident at a source or owing to an event or sequence of events of a probabilistic nature, including equipment failures and operating errors.

- l) **Exemption** – determination by a regulatory body that a source or practice need not be subject to some or all aspects of regulatory control on the basis that the exposure(including potential exposure) due to the source or practice is too small to warrant the application of those aspects;
- m) **Inspection** – examination, observation, measurement, or test undertaken to assess structures, components, and materials, as well as operational activities, technical processes, organisational processes, procedures, and personnel competence.
- n) **Radioactive waste management** – all administrative and operational activities involve handling , pretreatment, treatment, conditioning, transport, storage, and disposal of radioactive waste.
- o) **Radiation safety** – set of measures with the purpose to minimise the probability of accidents involving radiation sources, and, in the event of accidents, to mitigate their consequences if they were to occur.
- p) **Regulatory Body** – organised by the State Government (authority) for regulatory purposes, for the radiation protection , radiation and nuclear safety.
- r) **Registration** – permit issued by the State regulatory agency for radiation and nuclear safety for low and moderate risk practices, for which the legal person responsible for the practice prepares and submits the safety assessment. The practice is authorised with conditions and limitations. The requirements for safety assessment and the conditions or limitations applied to the practices are less severe than those for licensing.
- s) **License** – permit issued by the State regulatory agency for radiation safety and nuclear safety to the legal person for the performance of higher or high risk practice, on the basis of safety assessment and along with the specific requirements and terms, which have to be met by the license holder.
- t) **Operator** – legal person applying for authorisation for performance of a practice (applicant, registrant and licensee).
- u) **Safety assessment** – inspection of all aspects, pertaining to design and operation of the sources, relevant for radiation protection and for radiation safety, including the analysis of safety and protection requirements established under the design and operation of the source, and analysis of risks associated with normal operation and accidental situations.
- v) **Security of radioactive and nuclear materials** – measures of prevention of unauthorised access to the source, loss, theft, or unauthorised transfer of radioactive and nuclear materials.

- z) **Medical exposure** – exposure incurred the patients as a part of their own medical or dental diagnosis (diagnostic exposure), or treatment (therapeutic exposure); or by persons, other than those occupationally exposed, knowingly while voluntarily helping in the support and comfort of patients, and by volunteers in a programme of biomedical research involving their exposure.
- aa) **Occupational exposure** – all exposures of workers at work incurred in the course of their work, with the exception of exposures excluded from international standards, and source exposures, and practices exempted from the standards.
- bb) **Public exposure** – exposures of members of public from critical group from radiation sources, excluding any occupational or medical exposure and normal, local, natural background radiation, but including the exposure from authorized sources and practices, and from intervention situations.
- cc) **Intervention** – any action intended to reduce or avert exposure or the likelihood of exposure to sources that are not part of controlled practice or that are out of control as a consequence of an accident.
- dd) **Radioactive waste** – material, whatever its physical form, remaining from practices or interventions, which is the waste product from a practice or an intervention for which no further use is foreseen and (i) that contains or is contaminated with radioactive substances and has an activity or activity concentration higher than the level for clearance from regulatory requirements and (ii) exposure to which not excluded from regulations.
- ee) **Regulatory control** – any form of control or of regulation applied by the regulatory body to facilities or activities, for the reasons relating to radiation protection or to safety of radiation sources, or security of radioactive sources.
- ff) **Radiation source** – anything that may cause radiation exposure, which envelops radioactive material and radiation generating equipment.
- gg) **Radiation generating equipment** – devices that can produce or emit radiation during operation.
- hh) **Nuclear safety** – set of measures mitigate the consequences of nuclear accident, occurring in the countries in the region, which can affect Bosnia and Herzegovina.
- ii) **Nuclear accident** – event or series of events occurring in operations of a nuclear facility, causing one of the consequences that fall under the definition of an emergency event.
- jj) **Nuclear damage** is:
 - 1) damage due to death, physical injury, or other infringement to human health, loss or damage to property, occurring or being a consequence of

radioactive characteristics or a combination of such characteristics with poisonous, explosive or other hazardous characteristics of nuclear fuel or radioactive products or waste located in a nuclear facility, or nuclear material sent to a nuclear facility or produced in the facility or being sent out of it;

- 2) damage due to death, physical injury, or other infringement to human health, loss or damage to property, occurring or being a consequence of other ionising radiation originating from any other radiation source in a nuclear facility.

kk) **Nuclear material:** uranium and thorium of natural isotopic structure, uranium with reduced (depleted uranium), or increased contents of isotope 235, uranium of isotopic structure 233, plutonium 239 and its heavier isotopes, industrial products or products made of such substances, as well as other substances designated by the state regulatory body competent for radiation safety and nuclear safety.

ll) **Radioactive material:** material (solid, liquid, or gas), which spontaneously emit radiation, including accelerator produced material, by-product material, natural material, source and special nuclear material.

mm) **Source material** includes:

- 1) uranium containing an isotopic mixture appearing in nature,
- 2) depleted uranium in 235 isotope,
- 3) thorium,
- 4) any of the stated materials in the form of metal, alloy, chemical compound, or concentrate,
- 5) any material other substance containing one or more of the above stated elements with concentration level designated by the state regulatory body.

II. REGULATORY BODY

Article 4 (Establishment of the State Regulatory Agency)

(1) State Regulatory Agency for Radiation and Nuclear Safety (hereinafter: the Agency), shall be established with the purpose of performing administrative and professional operations in the field of ionising radiation.

(2) In line with the Act and other regulations, the Agency shall independently perform regulatory control over safety of radiation sources, radioactive waste safety, and transport safety.

(3) The Agency shall define the set of measures to mitigate the consequences of a nuclear accident, occurring in the countries in the region, which can affect Bosnia and

Herzegovina. The set of measures entails plans of evacuation and accommodation of population, decontamination, and other measures of intervention.

Article 5
(Agency Status)

- (1) The Agency shall be an independent administrative organisation.
- (2) The Agency shall execute its authorisations under direct supervision of the Council of Ministers of Bosnia and Herzegovina.
- (3) The Agency is independent from other governmental and nongovernmental agencies and legal persons involved in promotion of radiation technologies.
- (4) The Seat of the Agency shall be in Sarajevo.
- (5) As a part of the Agency, regional offices shall be established in the Republic of Srpska Entity, with the Seat in Banja Luka, in the Federation of Bosnia and Herzegovina Entity, with the Seat in Mostar.

Article 6
(Agency Financing)

- (1) The Agency shall be financed from the Budget of Bosnia and Herzegovina institutions and the international obligations of Bosnia and Herzegovina, and from independent sources.
- (2) Financing shall be executed directly to the Agency and shall not depend on the amount of fee collected from authorisations, inspection, or from fines.
- (3) The Agency Director shall propose annual budget based on the needs for realisation of the regulatory programme.

Article 7
(Agency Director)

- (1) The Agency shall be managed by the Director appointed by the Council of Ministers of Bosnia and Herzegovina, in line with the Act on Civil Service in the Institutions of Bosnia and Herzegovina.
- (2) The Agency Director shall have two deputies.
- (3) Rights and duties of the Director and his/her deputies shall be established under the law and the Rulebook on Internal Organisation of the Agency.

Article 8
(Agency Functions and Competences)

The Agency shall have the authority to:

- a) define the policy in the field of radiation and nuclear safety, the principles of safety, and appropriate criteria as the basis for its regulatory actions;
- b) prepare and issue regulations and guides, which constitute the basis for its regulatory action;
- c) define radiation exposures excluded from the scope of regulations, based on the fact of those amenable to regulatory control;
- d) define and implement procedures for notification, authorisation, inspection, enforcement of regulatory requirements;
- e) require from each operator to perform safety assessment;
- f) enter the premises or the facility, at any time, in order to perform state inspection of safety of radiation sources;
- g) issue, amend, suspend or revoke, and set the conditions for authorisations for import, export, production, purchase, receipt, possession, storage, usage, transit, transportation, maintenance, recycling and final disposal, as well as any other activity related to the sources of ionising radiation;
- h) issue, amend, suspend or revoke approvals to technical services for radiation protection;
- i) define exclusions and exemptions with regards to possession and usage of sources of radiation, and issue an adequate document for the purpose;
- j) undertake appropriate measures in the case of emergency event or nuclear accident;
- k) establish and maintain the State Register of sources of ionising radiation and persons exposed to ionising radiation, as well as of issued permits;
- l) cooperate with other administrative bodies and other institutions with respect to the scope of work of the Agency;
- m) define appropriate methods to disseminate public information on the issues pertaining to ionising radiation;
- n) define the proposal of the amount of fees for the issuing of the authorisation, i.e. approval; shall not be concerned with the collection;
- o) liaise with regulatory bodies of other countries and the International Atomic Energy Agency (IAEA), and with other relevant international organisations;
- p) it is the State partner to the International Atomic Energy Agency;
- r) represent Bosnia and Herzegovina at the international level with respect to the issues in the field of radiation safety and nuclear safety;
- s) in cooperation with relevant state agencies, undertake required measures pertaining to the security of radioactive and nuclear materials; and to ask from other competent bodies to perform monitoring inside the country and in required inspection locations, with the purpose of revealing the source, which are not under regulatory inspection;
- t) to be prepared to assist in emergency situations and react in line with the state action plan for emergency situations;

- u) define official arrangements with other relevant agencies involved in the regulatory process;
- v) provide opinions and recommendations with respect to accession to international conventions, as well as recommendations for adoption of other international documents in the field of radiation safety and nuclear safety;
- z) implement obligations assumed by Bosnia and Herzegovina in line with the international conventions and bilateral agreements pertaining to radiation safety and nuclear safety, and application of protection measures for the purpose of non-proliferation of nuclear weapons.

Article 9
(Surveillance and Reporting)

- (1) The Agency shall answer to the Council of Ministers of Bosnia and Herzegovina with respect to lawful, complete, effective, and professional realisation of functions and competences referred to in Article 8 of this Act.
- (2) The Agency shall, at least once a year, submit a report on the status of radiation safety and nuclear safety to the Parliamentary Assembly of Bosnia and Herzegovina.

Article 10
(Cooperation with other bodies and organisations)

- (1) At the request of the Agency, executive, administrative and other bodies in Entities and Cantons and in Brcko District of Bosnia and Herzegovina, shall be obliged to submit data, reports, and other documentation pertaining to the scope of work and responsibilities of the Agency.
- (2) Entity Ministries of Health can demand from the Agency, or via respective Entity offices, the submission of data pertaining to the scope of work thereof.

Article 11

The Agency can establish, ad hoc, independent bodies and committees for the purpose of resolving of professional issues pertaining to its respective competences.

Article 12
(Engagement of consultants)

- (1) The Agency can use individual professional consultants, who satisfy the requirements from specific fields, with the purpose of providing for the implementation of this Act.
- (2) The request from Paragraph (1) of this Article (technical or academic), consultant's independency, conflict of interest, and such like, shall be defined under a special act issued by the Agency Director.

III. CONDITIONS FOR PERFORMANCE OF OPERATIONS

Article 13
(Contents of the authorisation system)

- (1) No activity shall be introduced, implemented, ceased or stopped, and no source shall be designed, produced, built or assembled, purchased, imported or exported, distributed, sold, borrowed or leased, possessed, located, put in operation, used or operational, maintained or repaired, transferred or decommissioned, disassembled, stored or finally disposed, except in line with relevant regulations on safety of radiation sources and/or other requirements established by the Agency.
- (2) Obligation referred to in Paragraph (1) of this Article shall be in effect until radiation exposure from such an operation or source is excluded from the contents of the relevant regulation, or until the Agency excludes such an operation or source from the regulatory control, including notification and authorisation requests.

Article 14
(Approval Request)

- (1) It is forbidden to possess a radiation source and perform a practice involving the source without an approval from the competent state body.
- (2) Every legal person with the intention to perform a practice or to possess the radiation source shall be obliged to file to the Agency, in the Seat or via Entity offices, an approval request, which has to be in the form of a registration or a license.
- (3) Approval referred to in Paragraph (1) of this article shall be issued for a designated period of time, from one to five years, depending on the type of source of ionising radiation and the request for the use thereof.

- (4) The Agency shall issue preliminary consent for the purpose of obtaining the radiation source.

Article 15
(Primary Liability)

- (1) License holder and registrant shall bear the primary liability for the safety of the radiation source. In line with that, license holder and registrant shall be responsible for the adherence to legal and all bylaw acts regulating radiation safety and nuclear safety.
- (2) License holder shall be liable for safe management of radioactive waste resulting from the practice involving the radioactive source.
- (3) License holder or registrant shall, at the request of the Agency or at their own initiative, submit the information pertaining to the ionising radiation source activities.

Article 16
(Radiation safety and nuclear safety regulations)

- (1) The Agency Director shall issue the regulations on the safety of ionising sources, including the requests on occupational, medical, and public exposure, as well as the requests for emergency situations pertaining to the implementation of this Act.
- (2) The Agency Director shall issue the regulations on the safety of nuclear materials, sales, records, and control, as well as the security of nuclear materials..
- (3) The Agency Director shall issue the regulations on nuclear safety.

Article 17
(Regulations on radioactive waste management)

- (1) The Agency Director shall issue the regulations on radioactive waste management in line with the international standards.

Article 18
(Regulations on safe transport of radioactive materials)

- (1) Transport of radioactive substances shall be performed in line with the law and regulations on transport of radioactive materials issued by the agency.

IV. EMERGENCY EVENTS, NUCLEAR ACCIDENTS, AND NUCLEAR DAMAGE

Article 19 (Emergency situations)

- (1) At the proposal of the Agency, the Council of Ministers of Bosnia and Herzegovina shall issue the state action plan for emergency cases for protection of population against ionising radiation in the case of emergency event, nuclear accident, or occurrence of nuclear damage.
- (2) State action plan referred to in Paragraph (1) of this Article shall be reviewed and updated as needed, relative to the realisation of plan pertaining to the field of protection against ionising radiation in line with the international conventions.
- (3) In line with the international conventions, including the Vienna Convention on Civil Liability for Nuclear Damage, the Agency shall be obliged to develop the state nuclear safety plan in the event of accidents in nuclear facilities in other countries, which can affect nuclear safety status in Bosnia and Herzegovina.
- (4) The state action plan referred to in Paragraph (1) of this Article shall be adopted by the Parliamentary Assembly of Bosnia and Herzegovina, at the proposal from the Council of Ministers of Bosnia and Herzegovina.

V. REGULATORY INSPECTION

Article 20 (Inspection)

- (1) All areas pertaining to regulatory liability under this Act shall fall under the competence of the Agency, which incorporates the Radiation Safety and Nuclear Safety Inspection, which shall perform the affairs within its respective competences, respectively through the Seat of the Agency and respective Entity offices.
- (2) The Agency must define a planned and systematic inspection programme.
- (3) The contents of inspection performed in a regulatory process shall depend on the potential size or nature of danger pertaining to the practice, which is subject to control.
- (4) Inspection carried out by the Agency, announced or unannounced, must constitute a continuous activity.

Article 21
(Radiation safety and nuclear safety inspectors)

- (1) The radiation safety and nuclear safety control shall be performed by the state inspectors for radiation safety and nuclear safety.
- (2) Radiation safety and nuclear safety inspectors shall be the individuals with special authorisations. Conditions for the selection of inspectors and the contents of their respective authorities shall be defined through bylaw.
- (3) In the event of immediate harm to the life and health of people, an inspector can order temporary measures. An appeal to the decision document on temporary measures shall not postpone the enforcement thereof.

VI. PENAL PROVISIONS

Article 22
(Minor Offences and Penalties)

In the event of a minor offence referred to in Article 10 of this Act – failure to submit data at the request of the Agency – a legal person shall be subject to a fine in the amount of 10.000 KM.

Article 23

- (1) In the event of a minor offence referred to in Article 14 of this Act, a legal person shall be subject to a fine in the amount ranging from 10.000 to 30.000 KM, if:
 - a) it commences to perform a practice with radiation source without the Agency's approval;
 - b) continues with the practice after the expiry of the period of the approval for the use of ionising radiation source;
 - c) the practice performed is not in line with the terms of the granted approval.
- (2) For minor offence referred to in Paragraph (1) of this Article, and in addition to a fine, a prohibition measure pertaining to the performance of the practice can be stated to the legal person, for the period from one to three years.
- (3) For minor offence referred to in Paragraph (1) of this article, a responsible individual in the legal person shall be fined in the amount from 2.000 to 6.000 KM. A measure of prohibition to perform the practice involving ionising radiation

sources, for the period from one to three years, can be stated against the legal person in the event of damage due to illegal operation.

Article 24

Regulation issued on the grounds of an act pertaining to radiation safety and nuclear safety, radioactive waste management, safe transportation of radioactive waste, as well as other bylaws, shall set forth the liability pertaining to the minor offence related to non-adherence to terms established under the respective regulation.

Article 25

Authorised individual in the Agency shall be obliged to file criminal charges against the responsible individual who has, through illegal actions, caused or could have caused danger from an accident.

VII. TRANSITIONAL AND FINAL PROVISIONS

Article 26 (Issuing of regulations)

Within six months after this Act enters into force, the Agency shall issue the regulations on radiation safety and nuclear safety, radioactive waste management, and on safe transportation of radioactive substances.

Article 27 (Harmonisation of legal regulations)

- (1) All approvals issued for the use of radiation sources shall be deemed temporary for the period of one year, until which time an approval is to be obtained from the Agency in line with this Act.
- (2) Within the six months period, the Council of Ministers of Bosnia and Herzegovina and Entity Governments shall, through a special agreement, resolve the issue of equipment, inventory, working means, archives and documentation, official premises, and employees in regulatory bodies in the Entities and in inspectorates.
- (3) Entity regulations pertaining to radiation safety shall cease to apply within six months after this Act enters into force.

Article 28
(Appointment of the Agency Director)

- (1) The Agency shall commence to work as of the day of appointment of the Agency Director.
- (2) Within 30 days after this Act enters into force, the Council of Ministers of Bosnia and Herzegovina shall appoint the acting Director of the Agency.
- (3) The Agency Director shall issue internal regulations with regards to organisation and functioning of the Agency, within three months following the appointment, and with the consent form the Council of Ministers of Bosnia and Herzegovina.

Article 29
(Entering into Force)

This Act shall enter into force eight days following the day of the publishing thereof in the "Official Gazette of BiH".

PABIH no. 127/07
October 30, 2007
Sarajevo

Chairmen of the
House of Representatives
of BiH Parliamentary Assembly
Dr. Milorad Zivkovic, s.r.

Chairman of the
House of Peoples
of BiH Parliamentary Assembly
Ilija Filipovic, s.r.