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

LAW ON RADIATION AND NUCLEAR SAFETY IN BOSNIA AND HERZEGOVINA

I. BASIC PROVISIONS

Article 1 (Subject matter)

- (1) The Law on Radiation and Nuclear Safety in Bosnia and Herzegovina (hereinafter: Law) regulates the system of control over sources of ionising radiation, the protection of the people, present and future generations, and also the environment from exposure or potential exposure to ionising radiation.
- (2) This Law applies to all situations that include exposure or potential exposure to ionising radiation except those excluded from the control.
- (3) This Law also establishes the liability for nuclear damage.

Article 2 (Objective)

The objective of this Law is ensuring protection against ionising radiation – radiation and nuclear safety of people in Bosnia and Herzegovina in the following way:

- a) by establishing and implementing a system enabling the development and use of sources of ionising radiation consistent with the requirements for human health protection and safety,
- b) by establishing and maintaining a regulatory programme for sources of ionising radiation, thus ensuring the compatibility with international safety standards for sources of ionising radiation and protection against ionising radiation,
- c) by establishing a state regulatory body for radiation and nuclear safety with an appropriate set of functions and responsibilities, and the resources necessary to establish regulatory control.

Article 3 (Definitions)

The terms and phrases used in this Law shall mean the following:

- a) **Emergency event (accident)** An event resulting or potentially resulting in irradiation, that is, radioactive contamination of the work environment, persons working with sources of ionising radiation, the public or property above the limits set out in the regulations.
- b) **Applicant** A legal person submitting application to the regulatory body for an authorisation to perform specified activities.

- c) **Authorisation** A permit issued by the regulatory body to a legal person that applied for carrying out a practice or another activity. The authorisation may have the form of registration or licence.
- d) **Exclusion** The exclusion of a particular category of exposure from the scope of regulatory control on the grounds that it is not amenable to regulatory control.
- e) **Ionising radiation** For the purpose of radiation protection, radiation capable of producing ion pairs in biological material.
- f) **Legal person** Any organisation, corporation, company, firm, association, public or private institution, or other entity registered under a national law with responsibility and permission to take any action under this Law.
- g) **Notification** A document submitted to the regulatory body by a legal person to notify an intention to carry out a practice described in this Law or 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** The protection of people from the effects of exposure to ionising radiation and the means for achieving the protection.
- j) **Exposure** The process of being subject to ionising radiation.
- k) Potential exposure Exposure that is 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.
- Exemption The 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 An examination, observation, measurement, or test undertaken to assess system 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 involved in the handling, pretreatment, treatment, conditioning, transport, storage, and final disposal of radioactive waste.
- a) Radiation safety A set of measures with a view to minimizing the likelihood of accidents involving radioactive sources and for mitigating the consequences of accidents should they occur.
- b) Regulatory body Established by the national government (authority) for regulatory purposes in connection with radiation protection, and radiation and nuclear safety.
- r) **Registration** A permit issued by the State Regulatory Agency for the purpose of radiation and nuclear safety in practices of low and moderate risk whereby the legal person responsible for the practice prepares and submits a safety

assessment. The practice is performed with conditions or limitations as appropriate. The requirements for safety assessment are less strict than those for licensing.

- s) Licence A permit issued by the State Regulatory Agency for Radiation and Nuclear Safety to a legal person for carrying out a practice of a higher or high risk, based on a safety assessment and accompanied by specific requirements and conditions to be complied with by the licensee.
- t) **Operator** A legal person applying for the authorisation to carry out a practice (applicant, registrant or licensee).
- u) Safety assessment A review of all aspects of the source design and operation that are relevant for radiation protection and radiation safety, including an analysis of the safety and protection requirements established for the source design and operation, and an analysis of risks associated with normal operations and accidental situations.
- v) **Safety of radioactive and nuclear material** Measures to prevent unauthorised access to the source and loss, theft or unauthorised transfer of radioactive and nuclear material.
- z) Medical exposure Exposure incurred by patients as part of their own medical or dental diagnostics (diagnostic exposure) or treatment (therapeutic exposure); by persons, other than those occupationally exposed, who voluntarily help the patients, and by volunteers in a programme of biomedical research involving their exposure.
- aa) **Occupational exposure** All exposures of workers incurred in the course of their work with the exception of exposures excluded from international standards and exposures from sources and practices exempted from the standards.
- bb)**Public exposure** Exposures of members of the critical group, excluding any occupational or medical exposure and the normal local natural background radiation, but including exposure from authorised sources and practices and from intervention situations.
- cc) **Intervention** Any action intended to reduce or avert 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 in any physical form that remains from practices or interventions and for which no further use is foreseen, and: (i) contains or is contaminated with radioactive substances at an activity or activity concentration greater than levels for clearance from regulatory requirements and (ii) gives rise to exposure not excluded from regulations.
- ee) **Regulatory control** Any form of control or regulation applied to facilities or activities by a regulatory body for reasons relating to radiation protection, safety of radiation sources or radioactive sources.
- ff) **Radioactive source** Anything that can give rise to exposure to radiation, including radioactive material and radiation generating equipment.
- gg)**Radiation generating equipment** Devices that can produce or emit radiation during operation.

- hh)**Nuclear safety** A set of measures to mitigate the consequences of a nuclear accident in a country of the region that can affect Bosnia and Herzegovina.
- Nuclear incident Any occurrence or series of occurrences during the operation of a nuclear facility, causing one of the consequences that fall under the definition of emergency event.

jj) Nuclear damage is:

- damage due to death or a physical injury or other damage to the human health, or loss of or damage to property that arises out of or results from radioactive properties or a combination of such properties with toxic, explosive or other hazardous properties of nuclear fuel or radioactive products or waste located in a nuclear facility, or nuclear material sent to, originating in or coming from a nuclear installation,
- damage due to death or a physical injury, or other damage to the human health, or loss of or damage to property that arises out of or results from other ionising radiation emitted by any radioactive source in a nuclear installation.
- kk) **Nuclear materials**: Uranium and thorium in the isotope composition occurring in nature, uranium with reduced (depleted uranium) or increased content of the isotope 235, uranium-233, plutonium-239 and its heavier isotopes, industrial products or products made of these materials, as well as other materials as determined by the state regulatory body competent for radiation and nuclear safety.
- II) **Radioactive materials**: Material (solid, liquid or gaseous) emitting radiation spontaneously including accelerator-produced material, by-product material, natural material, source material and special nuclear material.

mm)Source material includes:

- 1) uranium containing the mixture of isotopes occurring in nature,
- 2) uranium depleted in the isotope 235,
- 3) thorium,
- 4) any of the above materials in the form of metal, alloy, chemical compound or concentrate,
- 5) any other material containing one or more of the above elements in such concentration level as the state regulatory body determines.

II. REGULATORY BODY

Article 4 (Establishment of the State Regulatory Agency)

(1) The State Regulatory Agency for Radiation and Nuclear Safety (hereinafter: Agency) is hereby established with a view to performing administrative and professional operations in the field of ionising radiation.

- (2) Under the Law and other regulations, the Agency shall independently perform regulatory control of the safety of radioactive sources, the safety of radioactive waste and the transport safety.
- (3) The Agency shall define a set of measures to mitigate the consequences of a nuclear accident in a country in the region that can affect Bosnia and Herzegovina. The set of measures implies plans for evacuating and accommodating citizens, decontamination and other intervention measures.

Article 5 (Status of the Agency)

- (1) The Agency shall be established as an independent administrative organisation.
- (2) The Agency shall exercise its powers under direct supervision of the Council of Ministers of Bosnia and Herzegovina.
- (3) The Agency shall be independent from other governmental and non-governmental agencies and legal persons involved in promotion of radiation technologies.
- (4) The headquarters of the Agency shall be in Sarajevo.
- (5) Regional offices within the Agency shall be established in the entity of the Republic of Srpska, with the seat in Banja Luka, and in the entity of the Federation of Bosnia and Herzegovina, with the seat in Mostar.

Article 6 (Funding of the Agency)

- (1) The Agency shall be funded from the budget of institutions of Bosnia and Herzegovina and international obligations of Bosnia and Herzegovina, and from independent sources.
- (2) The funding shall be directly provided to the Agency and shall not depend on the amount of administrative taxes collected from authorisations, inspection or fines.
- (3) The director of the Agency shall propose the annual budget based on the needs to implement the regulatory programme.

Article 7 (Director of the Agency)

- (1) The Agency shall be managed by the director appointed by the Council of Ministers of Bosnia and Herzegovina under the 'Law on civil service in the institutions of Bosnia and Herzegovina'.
- (2) The director of the Agency shall have two deputies.
- (3) The rights and duties of the director and the deputies shall be established under the Law and the 'Rulebook on the internal organisation of the Agency'.

Article 8 (Functions and authority of the Agency)

The Agency shall have the following powers:

- a) defining the policy in the field of radiation and nuclear safety, the principles of safety and appropriate criteria as the basis for its regulatory action;
- b) preparing and issuing regulations and instructions constituting the basis for its regulatory action;
- c) determining the exposures to radiation to be excluded from the scope of regulations on the grounds that they are not amenable to regulatory control;
- d) establishing and implementing procedures for notification, authorisation, inspection and the enforcement of regulatory requirements;
- e) requiring each operator to conduct a safety assessment;
- f) entering the premises or the facility at any time to conduct the state inspection of the safety of radioactive sources;
- g) issuing, amending, suspending, revoking, and imposing authorisation requirements for import, export, production, acquisition, receipt, possession, storage, use, transit, transport, maintenance, recycling and final disposal, as well as for any other activity relating to sources of ionising radiation;
- h) issuing, amending, suspending or revoking approvals granted to technical services for radiation protection;
- i) determining exclusions and exemptions relating to the possession and use of radioactive sources, and issuing a relevant document thereof;
- j) taking appropriate measures in the event of a radiological emergency or nuclear accident;
- k) establishing and maintaining the national register of sources of ionising radiation, persons exposed to ionising radiation, and also of the granted permits;
- cooperating with other administrative bodies and other institutions regarding the scope of the Agency's work;
- m) determining appropriate methods for disseminating public information about the matters relating to ionising radiation;
- n) determining the proposed amount of administrative taxes for granting authorisations, that is, approvals, and ensuring the collection of taxes;
- cooperating with other countries, the International Atomic Energy Agency (IAEA) and other relevant international organisations;
- p) acting as the country partner to the International Atomic Energy Agency;
- r) representing Bosnia and Herzegovina internationally in the matters of radiation and nuclear safety;
- s) in cooperation with the relevant state agencies, taking necessary safety measures for radioactive and nuclear material and requesting other competent bodies to perform monitoring in the country and at the necessary control locations with a view to discovering radioactive sources out of regulatory control;

- t) preparing itself to assist in emergency situations and respond in accordance with the national action plan for emergency situations;
- u) establishing official arrangements with other relevant agencies involved in the regulatory process;
- v) providing opinions and recommendations for accession to international conventions, as well as recommendations for adoption of other international instruments in the field of radiation and nuclear safety;
- z) implementing the obligations assumed by Bosnia and Herzegovina under the international conventions and bilateral agreements relating to radiation and nuclear safety and the application of safeguards for the purpose of nonproliferation of nuclear weapons.

Article 9 (Monitoring and reporting)

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

Article 10 (Cooperation with other bodies and organisations)

- (1) At the request of the Agency, the executive, administrative and other bodies in the entities, cantons and the Brcko District of Bosnia and Herzegovina shall submit data, reports and other documentation relevant for the scope of work and responsibilities of the Agency.
- (2) Entity ministries of health may request the Agency or its relevant entity office to submit the data from within the Agency's scope of work.

Article 11

The Agency may establish ad hoc independent bodies and committees for the purpose of resolving professional issues from within its authority.

Article 12 (Engagement of consultants)

- (1) The Agency may use individual professional consultants who satisfy requirements in specific fields with a view to ensuring implementation of this Law.
- (2) The request (technical or academic) referred to in paragraph (1) of this Article, the consultant's independency, the conflict of interest etc. shall be defined under a separate bylaw issued by the director of the Agency.

III. REQUIREMENTS FOR CARRYING OUT A PRACTICE

Article 13 (Contents of the authorisation system)

- (1) It is prohibited to introduce, implement, interrupt or stop a practice or to design, produce, manufacture, assemble, acquire, import, export, distribute, sell, borrow, lease, possess, place, accept into service, use, make operational, maintain, repair, transfer, take out of service, disassemble, store or finally dispose a source unless as provided in the relevant regulations on the safety of radioactive sources and/or other requirements established by the Agency.
- (2) The obligation referred to in paragraph (1) of this Article shall be in effect until the exposure to radiation resulting from a practice or source is excluded under the relevant regulation, or until the Agency excludes such practice or source from the regulatory control, including the requirements for notification and authorisation.

Article 14 (Application for approval)

- (1) It is forbidden to possess a radioactive source and carry out a practice involving the source without an approval from the competent national body.
- (2) Any legal person intending to carry out a practice or possess a radioactive source shall file to the seat of the Agency or its relevant entity office the application for approval which shall be in the form of a registration or licence.
- (3) The approval referred to in paragraph (1) of this Article shall be granted for a definite period of time, which is from one to five years, depending on the type of source of ionising radiation and the application for its use.
- (4) The Agency shall issue a preliminary consent for the acquisition of radioactive sources.

Article 15 (Prime responsibility)

- (1) The prime responsibility for the safety of radioactive sources shall rest with the licensee or the registrant. Accordingly, the licensee and the registrant shall be responsible for the compliance with the laws and regulations governing radiation safety and nuclear safety.
- (2) The licensee shall be liable for the safe management of radioactive waste generated from a practice involving radioactive sources.
- (3) At the request of the Agency or at their own initiative, the licensee and the registrant shall submit the information regarding the activities with sources of ionising radiation.

Article 16 (Regulations on radiation safety and nuclear safety)

(1) The director of the Agency shall issue regulations on the safety of radioactive sources, including the requirements for occupational, medical and public exposures, and the requirements for emergency situations pertaining to the implementation of this Law.

- (2) The director of the Agency shall issue regulations on the safety of nuclear material, transfer, records, and control, as well as the safety of nuclear material.
- (3) The director of the Agency shall issue regulations on nuclear safety.

Article 17 (Regulations on radioactive waste management)

The director of the Agency shall issue regulations on radioactive waste management in accordance with international standards.

Article 18 (Regulations on the safe transport of radioactive material)

The transport of radioactive material shall be performed under the law and the regulations on the transport of radioactive material issued by the Agency.

IV. EMERGENCY EVENTS, NUCLEAR INCIDENTS AND NUCLEAR DAMAGE

Article 19 (Emergency situations)

- (1) At the proposal of the Agency, the Council of Ministers of Bosnia and Herzegovina shall approve a national action plan for emergency cases of public protection against ionising radiation in the event of an emergency, a nuclear accident or the occurrence of nuclear damage.
- (2) The national action plan referred to in paragraph (1) of this Article shall be revised and updated as needed in relation to the realization of plan in the field of protection against ionising radiation in accordance with international conventions.
- (3) In accordance with international conventions, including the Vienna Convention on Civil Liability for Nuclear Damage, the Agency shall develop a national nuclear safety plan in case of an accident in nuclear facilities in other countries that can affect the status of nuclear safety in Bosnia and Herzegovina.
- (4) The national action plan referred to in paragraph (1) of this Article shall be adopted by the Parliamentary Assembly of Bosnia and Herzegovina at the proposal of the Council of Ministers of Bosnia and Herzegovina.

V. REGULATORY INSPECTION

Article 20 (Inspection)

- (1) All areas of regulatory responsibility under this Law shall fall under the authority of the Agency that incorporates the inspection of radiation safety and nuclear safety, which shall perform the duties within its authority through the seat of the Agency and the entity offices.
- (2) The Agency shall develop a planned and systematic programme of inspection.
- (3) The inspection programme implemented in the regulatory process depends on the potential size or nature of danger relating to the practice subject to inspection.

(4) The inspection conducted by the Agency, either announced or unannounced, shall be a continuous activity.

Article 21 (Inspectors for radiation and nuclear safety)

- (1) Radiation and nuclear safety shall be controlled by the state inspectors for radiation and nuclear safety.
- (2) Inspectors for radiation and nuclear safety shall be individuals with special powers. The requirements for the selection of inspectors and the contents of their powers shall be defined in a regulation.
- (3) In the event of immediate danger to the life and health of people, the inspector may impose temporary measures. A complaint against the procedural decision on temporary measures shall not postpone their enforcement.

VI. PENAL PROVISIONS

Article 22 (Minor offences and fines)

For the minor offence referred to in Article 10 of this Law – failure to submit data at the request of the Agency – the legal person shall be fined up to BAM 10,000.

Article 23

- (1) For the minor offence referred to in Article 14 of this Law, the legal person shall be fined between BAM 10,000 and BAM 30,000 if:
 - a) it begins to carry out a practice involving radioactive sources without the Agency's approval;
 - b) continues with the practice after expiry of the approval period for the use of sources of ionising radiation;
 - c) the performed practice is not in accordance with the terms of the granted approval.
- (2) In addition to a fine for the minor offence referred to in paragraph (1) of this Article, the measure prohibiting a legal person to carry out the practice may be imposed for the period from one to three years.
- (3) For the minor offence referred to in paragraph (1) of this Article, the designated responsible person in the legal person shall be fined between BAM 2,000 and BAM 6,000. The measure prohibiting the person responsible within the legal person to carry out the practice involving radioactive sources for the period from one to three years may be imposed if a damage occurs due to illegal operation.

Article 24

Regulations on radiation and nuclear safety, radioactive waste management, the safe transport of radioactive waste and other regulations issued under this Law shall each provide for the responsibility for a minor offence resulting from non-compliance with the requirements in that regulation.

Article 25

The authorised person in the Agency shall file a criminal report against the responsible individual who has illegally caused or could have caused danger due to an accident.

VII. TRANSITIONAL AND FINAL PROVISIONS

Article 26 (Issuance of regulations)

Within six months after the entering of this Law into force, the Agency shall issue regulations on radiation and nuclear safety, radioactive waste management and the safe transport of radioactive material.

Article 27 (Harmonization of legislation)

- (1) All granted approvals for the use of radioactive sources shall be deemed temporary for a one-year period, until when an approval must be obtained from the Agency under this Law.
- (2) Within six months, the Council of Ministers of Bosnia and Herzegovina and the entity governments shall resolve through a separate agreement the matters of equipment, inventory, assets, archives, documentation, official premises, and employees in the regulatory bodies in the entities and inspectorates.
- (3) The entity legislation on radiation safety shall cease to apply within six months after entering of this Law into force.

Article 28 (Appointment of the director of the Agency)

- (1) The Agency shall begin to operate as of the date of appointing the director of the Agency.
- (2) Within 30 days from entering of this Law into force, the Council of Ministers of Bosnia and Herzegovina shall appoint the acting director of the Agency.
- (3) The director of the Agency shall issue internal regulations on the organisation and functioning of the Agency within three months from the appointment date and with consent by the Council of Ministers of Bosnia and Herzegovina.

Article 29 (Entering into force)

This Law shall enter into force on the eight day following that of its publication in the Official Gazette of BiH.

PA BIH, number 127/07 30 October 2007 Sarajevo

Speaker of the House of Representatives Dr Milorad Živković

Speaker of the House of Peoples of the Parliamentary Assembly of BiH of the Parliamentary Assembly of BiH Ilija Filipović