Pursuant to Article 16(1) of the Law on Radiation and Nuclear Safety in Bosnia and Herzegovina (Official Gazette of BiH 88/07) and Article 61(2) of the Law on Administration (Official Gazette of BiH 32/02 and 102/09), the director of the State Regulatory Agency for Radiation and Nuclear Safety issues:

REGULATION ON THE NOTIFICATION AND AUTHORIZATION OF PRACTICES INVOLVING IONIZING RADIATION SOURCES

PART ONE - BASIC PROVISIONS

Article 1 (Subject)

This regulation governs the procedure of notification and as well the procedure of issuing authorization for carrying out practices involving sources of ionizing radiation, which are conducted the State Regulatory Agency for Radiation and Nuclear Safety (hereinafter: Agency).

Article 2 (Definitions)

- (1) The terms and expressions, as used in this regulation, mean:
 - a) **Export** The physical transfer of the radiation source from BiH into an importing State
 - b) **Exporter** A legal person authorized for foreign trade operations with ionizing radiation sources.
 - c) Exemption level A value established by the Agency and expressed in terms of activity concentration, total activity, dose rate or radiation energy at or below which an ionizing radiation source is exempted from regulatory control without further consideration.
 - d) **Clearance level** A value established by the Agency and expressed in terms of activity concentration or total activity at or below which an ionizing radiation source is released from regulatory control.
 - e) **Approval for possession** A document issued by the Agency and confirming that the recipient has fulfilled requirements for the possesion and reception of radiation sources.
 - f) **Clearance** Removal of radioactive materials within authorized practices from any further regulatory control carried out by the Agency.
 - g) **Radiation protection officer** An individual technically competent in the field of radiation protection for a given practice, appointed by the registrant or licencee to monitor and implement the laws and other regulations from the field of radiation safety.
 - h) **Open source** All other radioactive sources that are not included in the definition of the sealed radioactive source.
 - i) **Consignor** A legal person which prepares consignment for transport and is indicated as "consignor" in the transport documentation.
 - j) **Preliminary consent for procurement** A consent issued by the Agency approving the procurement of radiation sources.
 - k) **Transport** Any planned movement of the radiation source from the consignor to the consignee.
 - 1) **Carrier –** A legal person authorized for the transport of radiation sources.
 - m) **Acceptance test** A test that the vendor of equipment must ensure to establish whether the delivered equipment meets the specification requirements.
 - n) Consignee A legal person taking delivery of a consignment and indicated as

- "consignee" in the transport documentation.
- o) Radioactive source Radioactive material that is permanently sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It also means any radioactive material released if the radioactive source is leaking or broken, but does not mean material encapsulated for disposal, or nuclear material within the nuclear fuel cycles of research and power reactors.
- p) **Transit** Physical movement of the radiation source across the territory of BiH.
- q) **Import** The physical transfer of the radiation source from an exporting State to an importing State.
- r) **Exporter –** A legal person authorized for the foreign trade operations with radiation sources.
- s) **Sealed source** Refers to the radioactive material that is either permanently sealed in a capsule or closely bonded and in a solid form.
- (2) Other terms and expressions as used in this regulation are defined in the Law on radiation and nuclear safety in Bosnia and Herzegovina.

Article 3 (Types of practices)

Within the meaning of this regulation, the practice involving sources of ionizing radiation means: manufacturing, export and import, lease, inheritance, transport, outsourcing operations with ionizing radiation sources, possession, procurement, distribution, use and termination of use, repair, maintenance, relocation, borrowing, withdrawal from service, storage of ionizing radiation sources and as well any other way of placing on the market except the practices and sources that are excluded or exempted in accordance with the provisions of this regulation.

Article 4 (Specific practices)

- (1) The term specific practices means individual practices within a group of practices.
- (2) The list of specific practices is given in Annex 1.

Article 5 (Types of sources)

The ionizing radiation sources covered by this regulation are:

- a) radioactive sources (open and sealed);
- b) radiation emitting devices;
- c) devices containing sealed sources;
- d) nuclear materials (source materials and special nuclear materials);
- e) radioactive waste generated by the use of radioactive source;
- f) any other ionizing radiation source as defined by the Agency.

Article 6 (Categorization of radioactive sources)

- (1) The categorization of radioactive sources is shown in table 1 of Annex 2, which is an integral part of this regulation.
- (2) The categorization of radiation emitting devices is shown in table 2 of Annex 2, which is an integral part of this regulation.

(3) The categorization of nuclear materials is shown in table 3 of Annex 2 which is an integral part of this regulation.

PART TWO – EXCLUSION, EXEMPTION AND CLEARANCE FROM REGULATORY CONTROL

Article 7 (Exclusion)

- (1) The following exposures are excluded from the provisions of this regulation:
 - a) to natural radioactivity in the human body (K-40);
 - b) to cosmic radiation at ground level;
 - c) to unmodified concentrations of natural radionuclides in raw materials.
- (2) Exposures from any other sources that are not subject to control, as defined by the Agency, shall also be excluded from the provisions of this regulation.

Article 8 **(Exemption and clearance)**

- (1) Ionizing radiation sources and practices involving radiation sources may be exempted from the provisions of this regulation provided that their activity or activity concentration (specific activity) does not exceed the exemption levels specified in table 1 of Annex 3 which is an integral part of this regulation.
- (2) The nuclear materials that are exempted from the provisions of this regulation are listed in table 2 of Annex 3 which is an integral part of this regulation.
- (3) The radioactive materials whose total nuclide activity or their activity concentration in the material mass of 1,000 kg does not exceed the exemption levels specified in table 1 of Annex 3, which is an integral part of this regulation, shall be exempted from the provisions of this regulation.
- (4) The exemption of the above materials prohibit the production of any described product.
- (5) The apparatus containing a radioactive material whose activity or activity concentration exceeds the one referred to in paragraph (3), provided that:
 - a) it is of a type approved for use by the Agency;
 - b) it is constructed as a sealed source and, in normal operating conditions it does not cause a dose rate exceeding 1 μ Sv/h at a distance of 10 cm from any accessible surface of the apparatus nor, for any member of the public, a dose exceeding 10 μ Sv in a year.
- (6) The electric apparatus to which this regulation applies and ensures that:
 - a) it is of a type approved by the Agency for use;
 - b) in normal operating conditions it does not cause a dose rate exceeding 1 μ Sv/h at a distance of 10 cm from any accessible surface of the apparatus;
- (7) Cathode ray tubes intended for the display of visual images or other electric devices operating on a potential which does not exceed 30 kV and in normal operating

- conditions do not cause a dose rate exceeding 1 μ Sv/h at a distance of 10 cm from any accessible surface of the apparatus.
- (8) The exemption levels for radioactive materials are shown in table 3 of Annex 3 which is an integral part of this regulation.

PART THREE - REGULATORY CONTROL PROCEDURES

CHAPTER I - NOTIFICATION

Article 9

(Ionizing radiation sources subject to notification)

- (1) The following sources of ionizing radiation are subject to notification as the only requirement:
 - a) Radiation sources in mass use:
 - 1) for illumination in compasses;
 - 2) night sights;
 - 3) autoluminescent lights;
 - 4) ionizing smoke detectors;
 - 5) built-in sources in gas chromatographs, beta counters and other instruments and devices.
 - b) Radiation sources for the calibration of alpha and gamma spectrometry systems;
 - c) All other radiation sources and devices as defined by the Agency.
- (2) All other radiation sources shall be subject to the authorization procedure.

Article 10 (Notification)

- (1) Any legal person intending to start carrying out a practice involving sources of ionizing radiation or already possessing radiation sources and carrying out a practice by the time of entering of this regulation into force shall submit a notification to the Agency.
- (2) The notification shall be submitted using the Form no. 1 shown in Annex 4.

Article 11 (Information from the Agency)

- (1) Upon receiving the notification, the Agency informs the legal person possessing a radiation source about all requirements for the authorization.
- (2) As needed, the Agency informs the legal person that made the notification but does not possess a radiation source about all requirements for the procurement of radiation sources.

CHAPTER II - REGISTRATION

(Radiation sources subject to registration)

- (1) The application for registration shall be submitted for the possession and use of the following radiation sources:
 - a) RTG devices for the control of luggage and individuals;
 - b) sealed Category 4 and 5 radioactive sources;
 - c) eliminators of static charge;
 - d) lightning rods with a built-in radioactive source (Co-60 and Eu 152/154);
 - e) fluorescence with X-radiation;
 - f) the use of C-14 in nuclear medicine;
 - g) RIA test.
- (2) The application for registration shall be also submitted for all other ionizing radiation sources as defined by the Agency.

Article 13 (Registration requirements)

- (1) The application for registration shall be submitted using the Form no. 3 shown in Annex 4.
- (2) Along with the application referred to in paragraph (1), the applicant shall attach the following documentation:
 - a) For the legal person:
 - 1) a proof of registration of the legal person with the competent authority;
 - 2) a proof of administrative tax payment;
 - 3) approval for the possession of ionizing radiation sources (for new sources).
 - b) For the ionizing radiation source:
 - 1) procedures for ensuring radiation protection measures;
 - 2) a certificate from an authorized technical service of the compliance with the fulfillment of radiation protection measures for the premises and the source;
 - 3) emergency instructions.
 - c) For the radiation protection officer: a proof of appointment of radiation protection officer or a contract with an authorized technical service for radiation protection matters.
- (2) For new sealed sources referred to in Article 12, in addition to the documentation specified in paragraph (2), it is necessary to submit an insurance policy for the source management or a copy of a contract with the clause on returning the source to the manufacturer after its disuse.
- (3) For lightning rods with a built-in radioactive source, in addition to the application for registration referred to in paragraph (1), it is necessary to meet the requirements referred to in paragraph (2)(a) and paragraph (2)(b) indent 2).
- (4) If it deems necessary, the Agency may request the applicant to attach additional documentation in addition to that specified in paras (1), (2), (3) and (4).

Article 14 (Procedural decision on registration)

(1) The Agency issues the procedural decision on the registration of radiation source

under the Law on Administrative Procedure.

(2) The procedural decision is issued for a period of up to 5 (five) years.

CHAPTER III - LICENCING

Article 15 (Types of licences)

The Agency issues licences for performance of the following practices involving sources of ionizing radiation:

- a) possession and use of radiation sources;
- b) transport of radioactive sources;
- c) import and export of radioactive sources;
- d) technical services;
- e) procurement and distribution of ionizing radiation sources;
- f) manufacturing of radiation sources.

Article 16 (Radiation sources requiring the licence)

The radiation sources requiring the licence for carrying out a practice are:

- a) all radiation sources not listed in Articles 9 and 12;
- b) nuclear materials (source materials and special nuclear materials);
- c) all radiation emitting device that are not listed in Articles 9 and 12;
- d) all other ionizing radiation sources as defined by the Agency.

Article 17 (Application for licence)

- (1) It is necessary to file a licence application to perform the practice involving sources of ionizing radiation referred to in Article 16.
- (2) The licence application shall be submitted using the Form no. 2 shown in Annex 4.

Article 18 (Required documentation)

- (1) Along with the application referred to in Article 17 and depending on a specific practice, the following documentation shall be submitted:
 - a) For the legal person:
 - 1) a proof of registration of the legal person with the competent authority;
 - 2) approval for the possession of ionizing radiation sources (for new radiation sources);
 - 3) a certificate from an authorized technical service of the compliance with the fulfillment of radiation protection measures for the premises and the source;
 - 4) a proof of administrative tax payment.
 - b) For the radiation protection officer:
 - 1) a document on appointment of radiation protection officer;
 - 2) a proof of ensured personal dosimetry control;

- 3) a proof of performed medical surveillance.
- c) For individuals working with the sources of ionizing radiation:
 - 1) a list of the personnel who carry out activities involving radiation sources;
 - 2) proofs on their qualifications and proficiency to carry out radiation protection measures in the activities that involve or could involve occupational exposure;
 - 3) a proof of ensured personal dosimetry control;
 - 4) a proof of performed medical surveillance.
- d) For the ionizing radiation source:
 - 1) acceptance test (for new sources of ionizing radiation);
 - 2) a radiation protection program;
 - 3) technical characteristics of the source;
 - 4) a copy of the contract on maintenance of the equipment with a relevant service for sources of ionizing radiation in radiotherapy;
 - 5) a plan for the safety of radiation sources (for Category 1, 2 and 3 radioactive sources).
- (2) For Category 1, 2 and 3 radioactive sources, it is necessary to submit an insurance policy for the source management or a copy of a contract with the clause on returning the source to the manufacturer after its disuse.
- (3) The Agency may conduct an on-site check for the purpose of verifying validity of the submitted documentation before issuing the license.
- (4) If it deems necessary, the Agency may request the applicant to attach additional documentation in addition to that specified in paras (1) and (2).
- (5) Along with the application referred to in Article 17, the legal person shall also submit to the Agency a statement confirming its fulfillment of requirements from applicable regulations on the radiation and nuclear safety.

Article 19 (Licence for the possession and use)

To obtain the licence for the possession and use of ionizing radiation sources, the legal person shall submit:

- a) the application referred to in Article 17;
- b) the documentation referred to in Article 18.

Article 20 (Licence for the transport)

To obtain the licence for the practice of transport of radioactive sources, the legal person shall submit:

- a) the application referred to in Article 17;
- b) the documentation referred to in Article 18(1)(a) indents 1) and 4), paragraph (1) subparagraphs b) and c), and paragraph (3);
- c) ADR certificate of approval, driver training certificate, and an escort training certificate for the transport of radioactive material (ADR);
- d) a proof of the possession of an appropriate portable radiation measuring instrument;
- e) emergency action plan.

Article 21 (Licence for the import and export)

To obtain the licence for the practice of import and export of radioactive sources, the legal person shall submit:

- a) the application referred to in Article 17;
- b) the documentation referred to in Article 18(1)(a) indents 1) and 4), and paragraph (3);
- c) own licence for the transport of radioactive sources or a contract with a legal person licenced for the transport of radioactive sources.

Article 22 (Licence for technical services)

- (1) The legal person intended to carry out the practice of technical service shall obtain a licence from the Agency.
- (2) The Agency issues the licences referred to in paragraph (1) for the following practices of technical services:
 - a) individual monitoring of the occupationally exposed workers;
 - b) radiation monitoring of the workplace;
 - c) radiation monitoring of the environment;
 - d) quality control of ionizing radiation sources in the fields of diagnostic radiology, nuclear medicine, radiotherapy, and industrial radiography;
 - e) control of radionuclide activity in samples of biological material;
 - f) biodosimetric measurements of individual exposure to ionizing radiation;
 - g) radiation safety assessment and design of radiation protection measures;
 - h) safety control of ionizing radiation sources, except for jobs specified in subparagraphs b) and d);
 - i) medical surveillance of exposed workers;
 - j) calibration of measuring instruments;
 - k) education and training;
 - I) radioactive waste management;
 - m) testing the concentration of radon and radon daughters;
 - n) installation, servicing and maintenance of equipment;
 - o) consultations in the field of radiation and nuclear safety.
- (3) To obtain the licence referred to in paragraph (1), the legal person shall submit:
 - a) the application referred to in Article 17;
 - b) the documentation referred to in Article 18(1)(a) indents 1) and 4), and paras (3) and (4);
 - c) filled Form no. 4, which is an integral part of this regulation.

Article 23

(Licence for the procurement and distribution of ionizing radiation sources)

(1) The legal person shall submit the following documentation for the licence for

procurement and distribution of ionizing radiation sources:

- a) the application referred to in Article 17;
- b) the documentation referred to in Article 18(1)(a) indents 1) and 4), and paragraph (3).

Article 24

(Licence for the manufacturing of ionizing radiation sources)

- (1) The legal person shall submit the following documentation for the licence for the practice of manufacturing ionizing radiation sources:
 - a) the application referred to in Article 17;
 - b) the documentation referred to in Article 18.

Article 25

(Licencing of foreign legal persons)

- (1) The foreign legal persons shall be subject to the authorization by the Agency for a temporary use of ionizing radiation sources in special circumstances in the territory of Bosnia and Herzegovina.
- (2) Along with the application referred to in Article 17, the legal person shall submit:
 - a) a licence from the state of origin;
 - b) a proof of administrative tax payment.
- (3) The Agency may request the applicant to attach additional documentation in addition to that specified in paragraph (2).

Article 26 (Issuing the licence)

- (1) The licence is an integral part of a procedural decision issued by the Agency under the Law on Administrative Procedure.
- (2) The licence for the practice involving sources of ionizing radiation contains the following information:
 - a) the number of licence;
 - b) the date of issue;
 - c) the type of licenced practice;
 - d) the specific practice;
 - e) types of ionizing radiation sources;
 - f) signature;
 - q) stamp;
 - h) the licence expiration date.
- (3) The licence shall be issued using the form shown in Annex 5 and it makes its integral part.
- (4) The licence is issued for a time period of up to 5 (five) years.
- (5) In addition to the information referred to in paragraph (2), the procedural decision on issuance of the licence also contains conditions and limitations for performing the practice and as well the name of radiation protection officer.

CHAPTER IV - APPROVALS

Article 27 (Approval for possession)

- (1) The Agency issues approval for the possession of ionizing radiation sources.
- (2) The legal person shall submit approval application for the possession of ionizing radiation sources using the form shown in Annex 6.
- (3) Along with the application referred to in paragraph (2), the legal person shall submit the following documentation:
 - a) a proof of registration of the legal person;
 - b) a description of the type of specific practice involving sources of ionizing radiation;
 - c) technical characteristics of the ionizing radiation sources;
 - d) information about the radiation protection officer including a proof on his proficiency in radiation protection;
 - e) a radiation safety assessment for the facility in which an ionizing radiation source will be located or stored;
 - f) a proof of administrative tax payment.
- (4) The legal persons licenced for the practice involving sources of ionizing radiation are not obligated to obtain approval for the possession of ionizing radiation sources if the conditions indicated in the licence have not changed during the source procurement.

Article 28

(Import and export of Category 1 and 2 radioactive sources)

- (1) Category 1 and 2 radioactive sources shall be imported and exported in accordance with the "Guidance on the Import and Export of Radioactive Sources," published by the International Atomic Energy Agency.
- (2) The Agency shall appoint a contact person for the purpose of regulating the import and export of Category 1 and 2 radioactive sources in accordance with the guidance referred to in paragraph (1).
- (3) The Agency issues a preliminary consent for the procurement, thus confirming the recipient's fulfillment of requirements for the possession and receipt of radioactive sources in accordance with requirements from the guidance referred to in paragraph (1).
- (4) Preliminary consent for the procurement serves as a proof for the State exporting radioactive sources that the recipient has fulfilled requirements for the receipt and possession of radioactive sources.
- (5) The consent referred to in paragraph (1) is issued upon a request of the user or the regulatory body of the exporting State based on approval for the possession of ionizing radiation sources.
- (6) For the export of Category 1 and 2 radioactive sources, the contact person referred to in paragraph (2) contacts the regulatory body of the importing State and requests a preliminary consent that the consignee has fulfilled requirements for the possession and receipt of radioactive sources.

Article 29 (Approval for import)

- (1) The Agency issues an approval for the import of radioactive sources.
- (2) The application for import approval shall be submitted by the importer using the form shown in Annex 7.
- (3) Along with the application for import approval, it shall be necessary to submit the approval for the possession of ionizing radiation sources or the licence for the possession and use, and a proof of administrative tax payment.
- (4) The import approval may be issued for a definite time period of maximum 1 (one) year with a possibility of multiple import.
- (5) Having completed the import, the importer shall send to the Agency a record on the completed import.

Article 30 (Approval for export)

- (1) The Agency shall issue an approval for the export of radioactive sources.
- (2) The application for export approval shall be submitted by the exporter using the form shown in Annex 7.
- (3) Along with the application for export approval, it shall be necessary to submit a copy of the user's licence and a proof of administrative tax payment.
- (4) The export approval may be issued for a definite time period of maximum 1 (one) year with a possibility of multiple export.

Article 31 (Approval for transit)

- (1) The Agency shall issue an approval for the transit of radioactive sources.
- (2) The application for transit approval shall be submitted by the exporter or the importer using the form shown in Annex 7.
- (3) Along with the application for transit approval, it shall be necessary to submit the following:
 - a) a document proving that the consignor will take the consignment back in case there was no transit;
 - b) a copy of the exporter's licence from the country of registration;
 - c) a copy of the carrier's licence from the country of registration;
 - d) information about the recipient;
 - e) a proof of administrative tax payment.
- (4) The transit approval may be issued for a time period of maximum 6 (six) months.

Article 32 (Approval for import, export or transit of nuclear materials)

(1) In addition to the documentation referred to in Articles 29, 30 and 31, it shall be necessary to submit the following documentation for the import, export or transit of

nuclear materials:

- a) In case of import, it shall be necessary to submit:
 - 1) the user's statement on the intended use, including the obligation to apply protection measures for nuclear materials and provide physical protection in accordance with requirements laid down in the treaties, agreements and conventions signed by BiH;
 - 2) approval for possession, and preliminary consent for the procurement of nuclear materials from the user.
- b) In case of export, it shall be necessary to submit a guarantee from the State importing nuclear materials in accordance with requirements laid down in the treaties, agreements and conventions signed by BiH.
- c) In case of transit of nuclear materials, it shall be necessary to submit a document proving that the consignor will take the consignment back if there was no transit, and as well a document on fulfillment of the requirements referred to in subparagraph b).
- d) a proof of administrative tax payment.
- (2) The approval for import, export or transit of nuclear materials is issued for a definite time period of maximum 6 (six) months.
- (3) The approval for import, export or transit of nuclear materials is issued only for single cases of import, export or transit.

Article 33

(Approval for import, export or transit of dual-purpose ionizing radiation sources)

- (1) The import, export or transit of dual-purpose ionizing radiation sources are done in accordance with the "Law on the control of foreign trade transfer of goods and services of strategic importance for the security of Bosnia and Herzegovina."
- (2) The Agency issues a preliminary consent for the Ministry of Foreign Trade and Economic Relations of BiH for the import, export or transit of dual-purpose ionizing radiation sources under the law referred to in paragraph (1).
- (3) If it deems necessary from the viewpoint of nuclear security, the Agency may request the user through the Ministry of Foreign Trade and Economic Relations of BiH to submit the following documentation:
 - a) For import, a user's statement on the intended use of sources, including the obligation to apply protection measures for nuclear material and provide physical protection in accordance with requirements laid down in the treaties, agreements and conventions signed by BiH,
 - b) For export, a guarantee from the State importing ionizing radiation sources in accordance with requirements laid down in the treaties, agreements and conventions signed by BiH,
 - c) For transit of dual-purpose ionizing radiation sources, a guarantee from the State importing such sources in accordance with requirements laid down in the treaties, agreements and conventions signed by BiH and as well a document proving that the consignor will take the consignment back if there was no transit.

Article 34

(Import or export of radioactive sources in exceptional

circumstances)

- (1) The Agency may issue an approval for the import or export of radioactive sources in exceptional circumstances, that is, when a user has not met all requirements laid down by the Agency for regular import or export.
- (2) The exceptional circumstances in which the Agency may issue an approval are:
 - a) cases of urgent health or medical needs;
 - b) cases of negligent radiation hazard;
 - c) cases of specific practices, in which the exporter maintains control of the radioactive source throughout the period of using the source outside of the exporting State, and returns the source to the exporting State after the conclusion of this period;
 - d) other circumstances as determined by the Agency.
- (3) The application for approval in exceptional circumstances shall contain the same information as for the case of regular import or export referred to in Annex 7.

Article 35 (Approval for transport)

- (1) The Agency shall issue an approval for the transport of radioactive sources and nuclear materials.
- (2) The carrier of radioactive sources and nuclear materials shall submit the application for approval referred to in Annex 7.
- (3) The transport approval may be issued for a definite time period of maximum 1 (one) year with a possibility of multiple transport.
- (4) In addition to the information referred to in paragraph (2), it shall be necessary to submit:
 - a) a copy of the approval for import, export or transit of radioactive sources and nuclear materials, except in case of inland transport;
 - b) for the foreign legal person carrying out the transport, a copy of the license issued by a competent regulatory body from the state of origin;
 - c) a proof of administrative tax payment.
- (5) After the transport, the carrier shall deliver a record on the completed transport to the Agency within 3 (three) days.
- (6) The transport of radioactive sources and nuclear materials is carried out in accordance with applicable regulations on the transport of dangerous goods.

Article 36 (Approval for import/export and transport)

If both exporter/importer and carrier are a single legal person with the licence for import or export and transport, the Agency may issue a single approval for the import or export and transport of radioactive sources and nuclear materials.

Article 37 (Approval for storage)

(1) The Agency issues an approval for the storage of radioactive sources and nuclear materials.

- (2) The application for storage approval shall be submitted by the user of radioactive sources and nuclear materials.
- (3) The user shall submit the following documentation for the storage approval:
 - a) approval application;
 - b) a proof of completed notification or authorization of radioactive sources and nuclear materials;
 - c) a contract on the service provision with a licenced technical service;
 - d) a proof of administrative tax payment.

Article 38 (Notice)

- (1) The legal person possessing the approval for import, export, transit or transport of radioactive sources and nuclear materials shall notify the Agency about any import, export, transit or transport at least 3 (three) working days in advance.
- (2) The notice about import, export, transit or transport shall contain the following information:
 - a) the name of the consignee;
 - b) the exact date of import, export, transit or transport;
 - c) the type of radionuclide;
 - d) the activity;
 - e) the number of approval for import, export, transit or transport;
 - f) the border crossing point of import or export;
 - g) the itinerary.

PART FOUR - RESPONSIBILITIES OF THE AUTHORIZATION HOLDER

Article 39

(Responsibilities of the authorization holder)

- (1) The authorization holder shall be responsible for all prescribed radiation protection measures and fulfillment of the prescribed radiation protection requirements.
- (2) The legal person authorized by the Agency for a practice involving sources of ionizing radiation shall:
 - a) adhere to basic principles of radiation safety, nuclear security, safe management of radioactive waste and safe transport of radioactive material;
 - b) use the radiation sources in accordance with instruction manuals;
 - c) keep the documentation 5 (five) years from the date of termination of the practice;
 - d) promptly inform the Agency about any changes in the requirements from the authorization;
 - e) inform the Agency about termination of the practice within 5 (five) days from the termination date;
 - f) promptly inform the Agency about the intention to procure a new or sell an existing ionizing radiation sources to another legal person already registered for a practice;
 - g) ensure safe termination of the practice;
 - h) ensure management of ionizing radiation sources after their disuse in accordance

with the requirements laid down by the Agency.

Article 40

(Responsibility of the technical service for installation, servicing and maintenance)

- (1) The technical service possessing the licence for installation, servicing and maintenance of ionizing radiation sources shall send the following information to the Agency within 7 (seven) days from the date of installation:
 - a) information about the installation location of the radiation source (user's name, address, telephone, fax, the name of a responsible person and of the director);
 - b) information about the installed ionizing radiation source (manufacturer, source type, serial number, radionuclide, activity, numbers of control panel and tube of X-ray generating devices);
 - c) the date of installing the radiation source.
- (2) The technical service for installation may not perform the installation of ionizing radiation sources with the users unauthorized for the possession of ionizing radiation sources.
- (3) The technical service may not service ionizing radiation sources of the non-licenced user.

Article 41

(Responsibility of the licencee for the procurement and distribution)

- (1) The licencee for the procurement and distribution of ionizing radiation sources shall send to the Agency the following information within 7 (seven) days from the date of selling a radiation source:
 - a) information about the buyer;
 - b) information about the sold radiation source (manufacturer, source type, serial number, and for X-ray generating devices also the numbers of control panel and tube);
 - c) the date of sale.
- (2) The licencee for the procurement and distribution of ionizing radiation sources may sell a radiation source only to a legal person with the approval for the possession of ionizing radiation sources.
- (3) The legal person dealing with the procurement and distribution of ionizing radiation sources shall inform the Agency about the procurement of radiation sources within 7 (seven) days from the procurement date.

PART FIVE - MEASURES TAKEN BY THE AGENCY

Article 42

(Suspension of authorization)

- (1) The Agency shall suspend the authorization if the holder:
 - a) violates the principles of radiation safety, nuclear safety, safe management of radioactive waste and safe transport of radioactive material;
 - b) fails to inform the Agency about an emergency during performing of a practice involving sources of ionizing radiation;
 - c) fails to perform a practice involving ionizing radiation sources as specified in the

authorization, that is, fails to correct operational deficiencies and irregularities in the specified period, as established by an inspection surveillance.

Article 43 (Revocation of authorization)

- (1) The Agency shall revoke the authorization if:
 - a) the authorization holder has terminated a practice involving sources of ionizing radiation and has informed the Agency thereof;
 - b) the authorization was suspended because of non-compliance with requirements, and the authorization holder fails to correct deficiencies in the specified period;
 - c) the authorization holder ceases to exist as a legal entity;
 - d) the authorization holder has not renewed the authorization in compliance with the provisions of this regulation.

Article 44 (Renewal of authorization)

Renewal of the authorization is done in the same way as the first obtaining of the authorization, in accordance with the provisions of this regulation.

PART SIX - TRANSITIONAL AND FINAL PROVISIONS

Article 45 (Harmonization of regulations)

- (1) Legal persons carrying out a practice involving sources of ionizing radiation involving shall harmonize their operations with the provisions of this regulation within one year from the date of entering this regulation into force.
- (2) The legal person that is responsible for carrying out a practice involving sources of ionizing radiation shall submit a notification to the Agency within 6 (six) months from the date of entering this regulation into force.

Article 46 (Entering into force)

This regulation enters into force on the eight day following its publication in the "Official Gazette of BiH."

No.: 01-02-2-560-1/10 23 July 2010 Sarajevo Director **Enes Čengić, M.Sc.**