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 the:

REGULATION
ON REQUIREMENTS FOR THE TRANSFER AND USE OF SOURCES OF IONISING RADIATION

PART ONE – GENERAL PROVISIONS

Article 1
(Subject matter)

(1) This regulation provides for requirements for the transfer and use of sources of ionising radiation (hereinafter: radioactive sources) and establishes:

a) requirements for the premises where radioactive sources are stored or used in accordance with their purpose and the place of use;
b) technical characteristics, main requirements for radioactive sources and operating conditions the sources must meet, having in mind their aggregate condition, design, composition, physical and chemical properties;
c) conditions of ionising radiation (hereinafter: radiation) exposure of exposed workers and other persons while carrying out a practice involving the sources;
d) radiation protection measures, the type, characteristics and amount of protective equipment, and the way of its use while working with the sources;
e) other technical and organisational measures necessary to improve the safety and radiation protection for a practice involving the sources.

Article 2
(Responsibility)

The authorisation holder shall be responsible for meeting the requirements from this regulation.

Article 3
(Main terms)

(1) The terms defined in this regulation have the following meanings:

a) **Accelerator** means a device or machine that accelerates charged particles to produce radiation with energies of more than 1 MeV.
b) **Analytical X-ray device** is a device used to determine the microscopic structure or the element or chemical composition of a material (devices for X-ray diffraction, fluorescence analysis or spectroscopy).
c) **Applicator** means a device used to determine the treatment field size at a given distance from the virtual source.
d) **Safety interlock** means a device that automatically interrupts radiation emission during an unauthorised entry into a radiation area.
e) **Brachytherapy** is a radiation treatment in which a radioactive source is placed inside or in direct contact with the patient's body.
f) **Leakage radiation** means radiation emanating from a diagnostic or therapeutic source except for the useful radiation beam, and the radiation produced when exposure switches or the timer is not activated.

g) **Defectoscope** means a device containing a sealed radioactive source and used for the storage, transport, generation and use of defined radiation beams in industrial radiography.
h) **Phantom** means an object behaving similarly to tissue, with respect to scattering or absorption of ionising radiation. This requires that the effective atomic numbers, electronic densities (the number of electrons per unit of mass) and mass densities (mass per unit of volume) of the material used to construct phantoms be approximately equal to that in tissue.
i) **Beam flattening filter** means a filter used to ensure the uniform distribution of the useful X-ray beam generated in the linear accelerator at a specified depth.
j) **Electron scattering foil** is a filter used to scatter the electron beam.
k) **Security of the source** is a measure preventing unauthorised access, damage, loss, theft or unauthorised transfer of the source.
l) **Focus** is a surface on the X-ray tube anode, bombarded with accelerated electrons from the cathode, where the useful radiation beam is produced.
m) **Radiation generators** are electric devices used to generate X-ray radiation and ion, neutron or electron beams.
n) **Industrial nondestructive testing (INDT) using the radiography testing method (RT)** is a procedure of testing a material without causing damage, applied in industry by using radioactive sources built into special devices (defectoscopes) and radiation generators for the purpose of examining and detecting discontinuity and damage of the tested specimen.
o) **Quality control (QC)** is an integral part of quality assurance. It is a set of operations (programming, coordinating, implementing) intended to maintain or improve quality. It includes examination, evaluation and maintenance at required levels of all verifiable and measurable characteristics of a system or device.
p) **Controlled area** means a radiation area in which specific protective measures and compliance with the safety procedures are required in order to control the normal exposure to radiation and prevent the spread of contamination in normal work conditions, as well as to prevent and limit the potential exposure.
q) **Supervised area** is a radiation area not designated as the controlled area and not requiring special protective measures and compliance with the special safety procedures although the occupational exposure conditions are controlled.
r) **Quality assurance (QA)** means all planned and systematically implemented activities necessary to provide a high level of assurance that a system, component or process complies with the requirements laid down in relevant standards.
s) **Unsealed source** means unshielded radioactive material in liquid, gaseous, or powder form, which could give rise to the contamination of people, animals, the environment, etc.
t) **Radiotherapeutic treatment** means a procedure of the internal or external patient exposure to certain radiation doses for treatment purposes.
u) **Exposed workers** means persons working with radioactive sources or in radiation fields during the work.
v) **Transfer of radioactive sources** means the import, export, sale, acquisition, keeping or any other method of source transfer.
w) **Radiation areas** means the areas where the annual dose is likely to exceed 1 mSv.
x) **Radioactive source** means radioactive material that is permanently sealed in a capsule or closely bonded, in a solid form and 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.

y) **Radiotherapy** is a clinical specialty involving the use of radiation in treating patients with malignant neoplasms and can be used either alone or in a combination with surgery and/or chemotherapy.
z) **Dose monitoring system** means a system of devices for the detection, measurement and indication of values expressed in radiation measurement units.
aa) **Radiation generators** are electric devices capable of producing or emitting radiation while in operation.
bb) **Devices containing sealed sources** means devices containing sealed radioactive sources and used to generate and use defined radiation beams (radiographic, calibration, sterilisation, therapeutic and others), including the devices used in process measurement technology (density, thickness and level gauges, static electricity eliminators, etc.).
cc) **Sealed source** refers to radioactive material permanently sealed in a capsule the design of which prevents, under normal conditions of use, any dispersion of radioactive material into the environment.
dd) **Tube assembly** is a part of X-ray device consisting of a housing with an aperture for the passage of the useful X-ray beam and the X-ray tube inserted into the housing.

(2) Other terms and concepts used in this regulation are defined in the Law on Radiation and Nuclear Safety in Bosnia and Herzegovina.

Article 4
(General requirements for the transfer of radioactive sources)

(1) Legal persons involved in the transfer of radioactive sources shall have:

a) a radiation protection officer qualified to implement radiation protection measures;
b) suitable premises for the safe storage and keeping of the sources except if the sources are imported, i.e. acquired per order of a user and the sources are directly delivered to the user without prior storage;
c) written rules on radiation protection measures and a procedure in the event of an accident, visibly posted in the room where the sources are stored and kept.

(2) Before transferring a radiation source, the legal persons referred to in paragraph (1) of this Article shall submit to the State Regulatory Agency for Radiation and Nuclear Safety (hereinafter: Agency) the documents confirming the fulfilment of all radiation protection measures for the source transfer as specified in this regulation.

(3) The Agency authorises the legal persons that meet the requirements referred to in paragraph (1) of this Article.

(4) The Agency shall keep a register of authorised legal persons that meet the requirements referred to in paragraph (1) of this Article.

Article 5
(General requirements for the use of radioactive sources)

(1) Legal persons using radioactive sources (hereinafter: user) shall ensure:

a) suitable premises as prescribed in the applicable standard for the safe work with the sources and their safekeeping;

b) personnel that meets the requirements for work with a certain type of radioactive sources;
c) a radiation protection officer qualified to implement radiation protection measures;
d) a radiation protection program;
e) individual dosimetry control of exposed workers in the prescribed intervals;
f) medical examinations of exposed workers in the prescribed intervals;
g) protective equipment for exposed workers and patients;
h) a monitor of radiation and contamination, except for the sources in X-ray diagnostics, suitable for the source type and in compliance with the prescribed metrology requirements for the use in radiation protection.

(2) X-ray devices, accelerators and other radiation generators shall not be used for commercial or other purposes if such use could give rise to an individual or public exposure above the authorised limits.

(3) The Agency authorises the legal persons that meet the requirements referred to in paragraph (1) of this Article.

(4) The Agency shall keep a register of authorised legal persons that meet the requirements referred to in paragraph (1) of this Article.

Article 6
(Radiation protection officer)

(1) The authorisation holder shall appoint at least one radiation protection officer whose duties and obligations are clearly defined and documented.

(2) The radiation protection officer shall be authorised to stop the operations if all necessary radiation protection measures have not been taken.

(3) The radiation protection officer shall be qualified for performing radiation protection tasks.

(4) All exposed workers shall notify in writing the radiation protection officer and the immediate supervisor of all irregularities and deficiencies that could affect radiation safety.

(5) If a violation of radiation safety is established, the radiation protection officer shall promptly notify the licensee in writing. The licensee shall notify the Agency thereof within 24 hours.

(6) The radiation protection officer's duties and obligations shall include:

a) supervising the operations to the level necessary to achieve safety and compliance with the radiation protection procedures and the authorisation requirements;
b) ensuring that only trained and certified personnel conducts operations and implements procedures in emergencies;
c) preparing and reviewing written procedures to ensure compliance with the regulations and the authorisation requirements;
d) ensuring that the safety assessment and emergency plans are in place;
e) ensuring that the equipment for personnel radiation protection is operable and maintained;

f) establishing necessary protective measures and equipment to control access to the premises where radioactive sources are used;
g) organising and monitoring medical examinations and the use of individual dosimeters, and ensuring keeping records thereof;
h) ensuring an adequate workplace monitoring to prevent unnecessary exposure of personnel;
i) updating the register of radioactive sources with their main characteristics;
j) participating in inspections and along with a responsible person providing comments on the inspection record.

Article 7
(Premises)

(1) Radioactive sources may be used only in special facilities or premises constructed and equipped so that the dose rates on the external surface of the facility or premises where the sources are used do not give rise to individual exposure above the authorised limits.

(2) Radioactive sources may be used in the environment if it is ensured that their use does not give rise to a dose rate increase above the authorised limits.

(3) Before beginning operations, a legal person intending to carry out a practice involving radioactive sources shall obtain a radiation safety assessment of the facility where the sources will be used or stored, including a calculation of barrier thickness made by an authorised technical service.

(4) When the Agency receives the radiation safety assessment, it will verify whether the assessment lays down appropriate radiation protection measures in accordance with the type and purpose of radioactive sources.

(5) The radiation safety assessment referred to in paragraphs (3) and (4) of this Article shall be made again after every construction intervention or repurposing that could change the quality of radiation protection inside or outside the room.

Article 8
(Keeping of radioactive sources)

(1) Sealed and unsealed sources, and devices containing the sources shall be kept in a holding facility when not in use.

(2) The holding facility shall be constructed so that the dose rate on the external surface of the facility does not exceed the values that could give rise to an individual exposure above the authorised dose limits.

(3) The location and design of the holding facility shall fulfil all fire safety requirements and minimise the likelihood of flood.

(4) If radioactive gases, vapours and aerosols are being released during the keeping of radioactive sources, the holding facility shall have a ventilation system with appropriate filters.

(5) Radioactive sources shall not be kept in the premises with other hazardous materials.

Article 9
(Rules in the holding facility)

(1) While moving radioactive sources in and out of the holding facility, arrangements shall be made to ensure minimised radiation exposure from other radioactive sources.

(2) The access and stay in the holding facility shall be allowed only to the exposed workers designated by the user and trained for implementing radiation protection measures.

(3) The total activity of radioactive sources in the holding facility shall not exceed the activity indicated in the licence for the use of sources.

Article 10
(Packaging)

(1) The holding facility, the containers, glass and other containers for storing radioactive sources shall be easily opened and closed.

(2) Containers with easily flammable and volatile radioactive substances shall be opened with special precaution measures.

(3) Glass containers with liquid radioactive solutions shall be placed in metal or plastic containers the volume of which is sufficient to receive the entire amount of liquid in the event that the glass container breaks.

Article 11
(Warning signs)

(1) The basic radiation hazard sign is a triangle with black borders and the black trefoil radiation symbol on yellow background, as shown in Annex 1 that is an integral part of this regulation.

(2) A warning plaque reading 'Caution: ionising radiation' shall be posted below the radiation hazard sign.

(3) Every radioactive source shall be labelled with the radiation hazard sign referred to in paragraph (1) of this Article.

(4) The premises where radioactive sources are used shall be labelled in accordance with the provisions of paragraphs (1) and (2) of this Article.

(5) A warning or radiation hazard sign shall be visibly posted, or visible or audible signalling devices shall be installed at the boundary of radiation areas during the use of a device in an open area, or another boundary identifier (tapes, ropes, etc.) shall be used to warn and prevent unauthorised persons who might enter the controlled area and be exposed to radiation.

(6) Radiation hazard signs shall not be used for other purposes except for labelling radioactive sources and areas with elevated radiation levels.

(7) The user shall ensure that visible and legible warning and hazard signs are posted.

Article 12
(Radiation areas)

(1) The user shall designate and label controlled and supervised areas in accordance with the personnel exposure risk.

(2) The dose limit on the boundary of the controlled area shall not exceed 3 μSv/h averaged over eight working hours a day.

(3) Radiation areas for an X-ray device, a low-energy accelerator or another radiation generator shall exist only for the time when the mains is switched on and when the device is to be connected to the electrical network.

(4) Because of the activation of the air and the material on the photon beam path, the radiation area shall exist for the devices at least one hour after the last treatment session ends when a device generating photon beams of energies of 15 MV and more (high-energy accelerator) is used, regardless whether the mains is switched on or not.

Article 13
(Training for underage persons)

(1) An approval for training in the controlled area may be issued for the training of persons aged 16–18 in work with radioactive sources.

(2) Training of persons aged 16–18 in work with radioactive sources may be organised only if the conditions that guarantee the application of dose limits for trainees and university students are ensured.

(3) The training shall be supervised by a responsible person.

Article 14
(Other persons)

(1) Visitors may enter a controlled area only if escorted by a responsible person.

(2) Visitors' entry into the supervised and controlled areas shall be approved by a radiation protection officer.

Article 15
(Transfer and transport)

Radioactive sources shall be transferred and transported within and out of the authorisation holder's premises only in the containers that lower radiation intensity to the authorised level and prevent the release from (dispersion, evaporation, etc.) or a loss of the source.

Article 16
(Written instructions)

(1) The user shall have a written instruction for the safe handling of radioactive sources and an instruction for emergency action in accordance with an assessment of protection and exposure of exposed workers.

(2) The written instructions shall be in the language understandable to exposed workers and contain a description of the sequence of actions and the safety measures for exposed workers working with radioactive sources.

(3) The instructions shall be available at the workplace and exposed workers shall act in accordance with them.

(4) As for mobile and fixed radioactive sources in categories 1, 2 and 3, the written instructions shall include the measures to prevent unauthorised access to the source, a loss or theft of the source or its damage in the event of fire.

(5) The written instructions referred to in this Article shall indicate the organisations or bodies that must be notified and consulted in emergencies.

(6) The written instructions shall be regularly reviewed and updated in the light of facts and principles of good practices for the safe work with radioactive sources.

Article 17
(Termination of using radioactive source and nuclear material)

(1) The user of radioactive sources or nuclear material that does not intend to use them any longer shall notify the Agency thereof.

(2) The user may keep the radioactive source and nuclear material referred to in paragraph (1) of this Article in an own holding facility not more than one year.

(3) As deemed necessary, the Agency may extend the deadline referred to in paragraph (2) of this Article.

Article 18
(Radiation protection program)

(1) Every user shall have a radiation protection program in writing.

(2) If the authorisation requirements change, the user shall evaluate, and as needed, revise the radiation protection program, its contents and implementation.

Article 19
(Contents of the radiation protection program)

(1) The radiation protection program shall contain the following elements:

a) Plan of organisational structure;
b) Workplace monitoring program;
c) Quality assurance programme;
d) Work and safety procedures;
e) Emergency plan;
f) Data record keeping system.

(2) During the process of authorising a practice involving radioactive sources, the Agency approves the radiation protection program.

Article 20
(Plan of organisational structure)

(1) The plan of the organisational structure shall contain:

a) a description of the organisation and its management, including the distribution of responsibilities relating to radiation safety and particularly: personnel, equipment selection, personnel training and records retention;
b) the names of persons working with radioactive sources and the radiation protection officer, their training, qualifications and experience.

Article 21
(Workplace monitoring program)

(1) The user's workplace monitoring program shall contain:

a) radiation measurement quantities;
b) measurement locations and intervals;
c) measurement methods and procedures;
d) reference levels and the actions to be taken in the event that they are exceeded.

(2) The workplace monitoring shall be conducted by an authorised technical service periodically and in special cases.

a) Periodically:

1) every year for radioactive sources used in medicine, dental medicine and veterinary science;
2) every year for radioactive sources used in industry;
3) every two years for other sources.

b) In special cases:

1) before the new device is put into use and every time when any of the existing radioactive sources is replaced;
2) every time when the shielding of the room with a radioactive source changes so as to possibly affect radiation levels in surrounding rooms;
3) after every repair or intervention on a radioactive source that could give rise to a radiation increase.

Article 22
(Report on workplace monitoring)

(1) The legal person shall have a report on the first workplace monitoring, created by an authorised technical service before the beginning of work.

(2) The monitoring report shall contain the following:

a) Floor plan of the room with the material type and thickness of the walls, floor, ceiling and doors, and the position of radioactive sources:

1) Layout of every adjacent room (including those above and below);
2) Primary radiation beam directions;
3) Measurement points and measurement results;
4) Layout of radiation areas.

b) Annual dose assessment for exposed workers and the public, and an adequacy assessment of every protective barrier:

1) Name of the person who conducted the control;
2) Date of control;
3) Measuring instrument used (manufacturer, model and serial number, date of the last calibration).

(3) As for radiation techniques for patient imaging, a phantom placed in the patient's position shall be used to measure the level of scattered radiation, using the standard radiological techniques.

(4) Radiation levels in the adjacent premises shall be measured when the workload is at maximum and when the radiation beam orientation is the least optimal.

Article 23
(Quality assurance program)

(1) Every authorisation holder shall have a quality assurance program.

(2) If the authorisation requirements change, the authorisation holder shall revise the quality assurance program, its contents and implementation.

(3) The quality assurance program for the use of radioactive sources shall contain the following:

a) adequate assurance that the specified requirements relating to radiation protection and radiation safety are met;
b) quality control mechanisms and procedures for the control and assessment of the overall effectiveness of the safety and protective measures.

Article 24
(Procedures in medicine)

(1) Written work and safety procedures shall be available to all persons working with radioactive sources.

(2) In medical applications, the procedures shall contain the following:

a) Procedures for using personal protective equipment (for personnel and patients);
b) Individual monitoring procedures;
c) Procedures for the protection of pregnant and breastfeeding women (patients);
d) Procedures for patient holding and operator's protection;
e) Procedures for training new personnel;
f) Record keeping procedures;
g) Security procedures for radioactive sources.

Article 25
(Procedures in industry)

(1) Written work and safety procedures shall be available to all operators.

(2) The procedures in industrial use shall contain the following:

a) Methods for controlling radioactive sources;

b) Individual monitoring procedures;
c) Methods for controlled access to radiation areas;
d) Procedures for training new personnel;
e) Record keeping procedures;
f) Security procedures for radioactive sources.

Article 26
(Emergency plan)

(1) The emergency plan shall contain the following:

a) Predictable incidents and accidents and actions to be taken;
b) Names of the persons responsible for taking actions, including all information and individual responsibilities in the event of an emergency;
c) Equipment for implementing the procedures established for emergencies;
d) Training and periodic check;
e) Record keeping and reporting system;
f) Plan of urgent actions in order to avoid unnecessary doses or overdoses to patients, personnel and the public.

Article 27
(Records)

(1) The record keeping system shall contain the following information:

a) Receipt, transfer, use and disposal of all radioactive sources;
b) Models and serial numbers of all radioactive sources and control panels;
c) Individual dosimetry results;
d) Workplace monitoring;
e) Results of the quality control of radioactive sources;
f) Personnel training;
g) Tests, calibrations, maintenance and modifications of devices;
h) Tests of safety devices;
i) Calibration of measuring instruments.

PART TWO – SPECIAL REQUIREMENTS FOR MEDICINE

CHAPTER I – RADIOTHERAPY

Section A. Premises

Article 28
(Location)

The radiotherapeutic department shall be in a separate part of the hospital grounds in order to facilitate the fulfilment of the safety and security requirements for radioactive sources.

Article 29
(Premises)

(1) Sealed sources used in teletherapy and brachytherapy shall be prepared and applied only in the premises purposely built for these tasks.

(2) The teletherapy department shall consist of a treatment room, a control room, a simulator room, a mould room (workshop), a room with an area for planning and an area for evaluation of radiotherapy planning, depending on the device types in use.

(3) The brachytherapy department shall consist of a treatment room, a control room with an area for planning and preparation and a storage room where radioactive sources shall be kept when not in use, depending on the device types in use.

(4) The radiotherapy device and the simulation device shall be placed in at least two separate rooms, in which the radiation generator will be in one of the rooms and the control panel in another.

(5) The provisions of paragraph (4) of this Article shall not apply to X-ray therapy devices with the highest voltage of 50 kV, in which case one room is sufficient and the person who initialises radiation shall be shielded by a protective cabin or screen.

(6) Rooms for radiotherapy devices shall be designated as controlled area while all other rooms fall into supervised areas.

Article 30
(Treatment room)

(1) The treatment room shall be large enough to allow for unobstructed movement around the treatment table in all directions.

(2) The treatment room with devices containing radioactive sources shall have an autonomous device for radiation monitoring and continuous dose rate measurement connected to an alarm for exposed workers warning them that the device is activated or on standby.

(3) The rooms with radiotherapy devices shall have a ventilation device or a complete air-conditioning device. The device capacity shall be determined by the type of therapy device (photon beams of 15 MV and more require 10 air changes per hour while those below 15 MV require 4).

(4) Radiotherapy devices with a maximum 50 kV voltage need not have a ventilation device.

(5) Only one radiation generator shall be placed in one treatment room but as an exception, two radiotherapy devices may be placed in one room provided that the electric connection is such that precludes the possibility of using both devices.

(6) The rooms for radiotherapy devices exceeding 1 MV shall have a maze.

(7) The maze shall be constructed so as to be as long as possible and with the least possible cross section.

(8) The minimum maze width shall be determined by the dimensions of the treatment unit that will be used and the possibility to access the hospital bed.

Article 31
(Safety systems)

(1) For devices using radioactive sources, the treatment room shall have a lock with an interior safety interlock at the entrance of the maze or the room while for other radiotherapy devices, if there is no door due to the length of the maze, a photocell-based system for interrupting radiation shall be installed in the event of an unauthorised entry.

(2) The door shall have a possibility of manual opening in the event of power failure or danger.

(3) The door shall have a switch preventing the radiotherapeutic treatment if the door is open or opening the door if the treatment is in progress.

(4) The entrance door to the treatment room or the maze and in the radiotherapy treatment room shall have a colour coded light sensor indicating whether the treatment is in progress, in which the warning lights shall have two stages: one (green light) indicates that the source is in the shielded position and that there is no irradiation, while the second (red light) indicates that irradiation is in progress and that the entry to the treatment room is prohibited.

(5) The rooms with radiotherapy devices shall be under the constant personnel supervision during the work hours and then be locked with the key left in a designated place. An additional security in the form of an alarm shall exist for devices containing radioactive sources.

Article 32
(Controlling the device operation)

(1) The control panel shall be placed in the control room.

(2) The control panel shall have installed switches preventing the device operation if any of the entrance doors to the room is open, and also a safety switch to terminate the radiation immediately.

(3) The control panel and the radiation area shall have the indicators of irradiation beginning, course and end.

(4) Monitoring the area around the radioactive source and the patient treatment shall be ensured via surveillance cameras.

(5) Radiotherapy devices using radioactive sources and X-ray therapy devices without built-in dose measurement systems shall have a dual system for measuring the treatment time and stopping the treatment after the preset time has expired.

(6) Radiotherapy devices with measuring systems for stopping the treatment shall have two autonomous systems functioning in a way that the second measuring system activates and stops the treatment in the event that the primary measuring system fails. There shall also be an additional time switch to ensure the interruption of radiation in case the first two fail.

(7) In order to ensure that the requirements referred to in paragraphs (5) and (6) of this Article are met, all devices used in radiotherapeutic treatment shall have a CE marking or a certificate of compliance with the relevant IEC standards (for the

devices), i.e. ISO standards (for radioactive sources).

(8) In addition to the safety systems listed in paragraph (5) of this Article, rooms with radiotherapy devices shall have safety interlocks and safety switches arranged so that it is possible to stop the radiation at any time regardless whether the operator is in the control or treatment room.

Section B. Radioactive sources

Article 33
(Radioactive sources in teletherapy)

(1) Devices used in teletherapy are:

a) X-ray therapy devices;
b) supervoltage radiotherapy devices (linear electronic accelerator, accelerator for heavy-charged particles).

(2) Radioisotopic teletherapy devices (telecobalt device, teleisotopic device for radiosurgery – gamma knife).

Article 34
(Devices and accessories for simulation in teletherapy)

(1) To plan and perform teletherapy, the following devices and accessories are used:

a) X-ray radiotherapy simulator (conventional);
b) CT radiotherapy simulators;
c) accessories for patient mobility;
d) accessories for the design and modification of radiation fields and the beam;
e) accessories for patient contouring.

Article 35
(X-ray teletherapy devices)

X-ray therapy devices are classified into surface radiotherapy devices (maximum tube voltage of 50–150 kV) and orthovoltage devices (maximum tube voltage of 300 kV).

Article 36
(Additional filters)

(1) X-ray therapy devices shall have additional visibly labelled filters so that their composition and thickness are visible from the position of the device operator who monitors the course of irradiation.

(2) There shall be a safety system ensuring that the therapy cannot be delivered if an appropriate filter is not placed in a designated place.

Article 37
(Supervoltage radiotherapy devices)

(1) Supervoltage devices are devices generating radiation beams of energies greater than 1 MeV.

(2) Linear electronic accelerators (hereinafter: accelerators) producing photon beams in the energy range of 4–25 MV and monochromatic electronic radiation of energy (4–25 MV) and accelerators of protons and heavy ions (60–350 MeV) are used in radiotherapy.

Article 38
(Telecobalt device)

(1) The initial activity of a sealed source Co-60 shall be between 222 TBq and 370 TBq.

(2) The source in the telecobalt device shall be replaced with a new one before the dose rate in the isocentre for the field size of 10 cm x 10 cm becomes 100 cGy/min.

(3) The dose rate at 1 m from any point on the device main frame shall not exceed 20 μGy/h.

Article 39
(Simulation devices)

(1) X-ray devices operate in the diagnostic X-ray regime of up to 150 kV and serve to simulate treatment fields, position the patient in relation to the beam and determine entry points of treatment fields on the patient's skin, which is the main precondition for the proper application of high therapeutic doses to the target – tumour.

(2) Radiotherapy simulators can be designed as conventional X-ray devices capable of radiography and fluoroscopy or as modern CT radiotherapy simulators that must be capable for virtual simulation (a software enabling the simulation of treatment fields on a ‘patient ‘, i.e. 3D reconstruction of the CT layers).

Article 40
(Radioactive sources in brachytherapy)

(1) The following radioactive isotopes are used in brachytherapy: Co-60, Cs-137, Ir-192, Au-198, I-125, Sr-90, Am-241, La-145, Yb-168 and Pd-103.

(2) The isotopes are gamma, beta and alpha emitters and used as sealed sources with the only exception of the colloidal Au-198 isotope.

Article 41
(Sealed source properties and application in brachytherapy)

(1) Radioactive isotopes are stored in capsules, needles or tubes made of different material (steel, aluminium, alloys of noble metals, titanium, platinum, glass and plastic), depending on the source type, strength and therapeutic purpose.

(2) Various devices and various techniques of radioisotope application are used in brachytherapy, taking into account the place of application and the radiation dose:

a) surface brachytherapy, intracavitary brachytherapy, interstitial brachytherapy, intraluminal brachytherapy;
b) low dose rate brachytherapy (LDR), medium-dose rate brachytherapy (MDR), high dose rate brachytherapy (HDR), pulsed dose rate brachytherapy (PDR).

Section C. Procedure

Article 42
(Methods of applying and positioning brachytherapy sources)

(1) Brachytherapy sources shall be applied in three ways: using external applicators, interstitial applicators (temporary) and permanent intracavitary applicators adjusted and shaped to follow the cavity.

(2) Brachytherapy sources may be applied manually, afterloaded, manually and remotely afterloaded using special devices.

Article 43
(Use of sealed sources)

(1) Devices containing sealed sources shall be used in accordance with the manufacturer's technical instructions and needed documentation.

(2) It shall be forbidden to use sealed sources without the manufacturer's technical documentation and the sources damaged in any way or leaking excess radiation.

(3) When not in use, the sources applied manually shall be placed in a separate container and stored in a proper place. Taking a source from and returning it into the container and applying it shall be logged.

Article 44
(Relocation or replacement of radioactive sources)

(1) Written procedures shall be in place for the relocation or replacement of radioactive sources in a radiation device. A radiation protection officer shall be present during the source replacement or relocation.

(2) Personnel replacing the source shall wear individual dosimeters and detectors with a sound signal warning of an exceeded dose.

(3) The source replacement procedure shall be carried out only by the persons licensed for the procedure and in the presence of a radiation protection officer.

Article 45
(Security of radioactive sources)

The authorisation holder shall make a security plan for radioactive sources with enhanced security measures, and a security plan for the sources in the event of an internal transfer, relocation and servicing.

CHAPTER II – NUCLEAR MEDICINE

Section A. Premises

Article 46
(General notes)

(1) Radiation protection during the transfer and use of unsealed sources means protection from external and internal exposure, and radioactive contamination of the

premises, air and people.

(2) While working with unsealed sources, it shall be mandatory to prevent the spread of radioactive substances into the environment from the place of source use and to maintain a high level of cleanliness at the workplace.

(3) The provisions of this chapter apply to:

a) unsealed sources administered to the patient (*in vivo*) or used in the research of diagnostic techniques;
b) unsealed sources used for *in vitro* tests in medicine;
c) unsealed sources used for radiotherapeutic purposes.

Article 47
(Premises)

(1) While designing and constructing the premises intended for the use of unsealed sources, arrangements shall be made for appropriate protective measures, a sufficient number and arrangement of rooms, equipment in the room, technological work procedures with the optimal organisation of workplaces and measures for maintaining personal hygiene of the personnel, an appropriate ventilation system, and an organised and safe system of collecting and managing the radioactive waste generated during the work.

(2) Waiting rooms for the patients waiting for an examination or radionuclide administration shall be separated from the waiting rooms for the patients who have been administered radionuclides.

(3) The premises where unsealed sources are used shall be constructed of a chemically, heat resistant and non-hygroscopic material.

(4) The floors shall be constructed as a single whole, without cracks and be unbroken for the purpose of the easiest possible maintenance.

(5) If the release of radioactive aerosols during the preparation and handling of unsealed sources is anticipated, the devices specially designed for that purpose shall be used. If radioactive iodine is used, special coal filters shall be installed.

Article 48
(Premises)

(1) The diagnostics premises shall consist of a preparation room, an application room, a waiting room for active patients, a waiting room for patients waiting for examination or radionuclide administration, a storage room, a room with gamma cameras, SPECT/CT and PET/CT devices.

(2) The therapy premises shall consist of a preparation room, an application room, a waiting room for patients waiting for an examination or radionuclide administration, a storage room and a room for patients.

(3) The rooms for preparation, application, storage, accommodation of patients for therapy, diagnostics and the waiting room for active patients shall be designated as controlled areas.

(4) All other premises shall be designated as supervised areas.

Article 49
(Equipment for premises)

(1) Lavatories and sinks shall be placed near the entrance door in every room where unsealed sources are used.

(2) In the laboratories or units classified in the medium- or high-risk category, the faucet shall be operable without having to use hands (e.g., by pressing the foot pedal under the lavatory or using the elbow), while warm air hand dryers or disposable absorbent towels shall be used for drying hands.

(3) In the laboratories classified in the medium- or high-risk category, a separate drainage system shall be installed with special chambers for the ageing of liquid radioactive waste before discharging into sewerage.

(4) If unsealed sources with a long half-life are used, such drains shall be separately labelled with the radiation warning sign in order to warn the maintenance and repair personnel.

(5) Work surfaces or table-tops shall be smooth, unbroken, resistant to chemical substances and physical damage and easily maintained.

(6) Work surfaces classified in the medium- or high-risk category shall have radiation protection shielding for exposed workers handling unsealed sources and for other exposed workers in the room.

(7) The table-top shall ensure an appropriate shielding of exposed workers for the body parts below the belt, depending on the radionuclide type and the highest activity on the table-top, with a shielding effect weakening the dose rate under the table at least 1,000 times in relation to the dose rate from the table-top.

(8) The medium- or high-risk category laboratories shall contain a radiation measuring instrument and an instrument for measuring surface radioactive contamination.

Article 50
(Holding of sources)

(1) Unsealed sources may be kept in the premises where they are used (a special container, safe, cooler, etc.), but if they leak radioactive gases, evaporations or aerosols, the storage room must have a ventilation device.

(2) The container or safe referred to in paragraph (2) of this Article shall be divided into compartments clearly labelled with the radionuclide type and activity.

Article 51
(Ventilation system)

(1) The rooms used for the preparation of unsealed sources shall have installed an autonomous artificial ventilation system.

(2) The ventilation system shall be designed so that the air from the rooms where radionuclides are used will not be recirculated or the system is not needed in the rooms where such substances are not used.

(3) If radionuclides of various activities are used in multiple rooms, the ventilation system shall ensure the air flow direction from the rooms with lower activity towards the rooms with higher activity.

Section B. Procedures

Article 52
(Basic remarks)

(1) The rooms where unsealed sources are prepared for use or kept before the use shall be designated as controlled areas.

(2) Only the persons whose presence is necessary due to the nature of work shall enter the controlled area.

(3) In the area of exposure, exposed workers shall not eat, drink, smoke and use any cosmetic and body products that, when used, come into direct contact with the skin and the mucous membrane.

(4) Exposed workers shall not enter the area of exposure if they have an open skin wound. Before entering the area, open wounds have to be protected with a waterproof cover. If an exposed worker injures the skin while working with unsealed sources, the wound shall be promptly cleaned, followed by checking for radioactive contamination and decontamination as needed.

Article 53
(Receipt of sources)

(1) Upon receipt of a container with unsealed sources from a carrier or vendor, the accompanying documents on the container contents shall be checked and compared with the order form that must be in accordance with the permit for the procurement of radioactive sources.

(2) Unpacking shall be done by using gloves and inspecting each individual piece of the shipment.

(3) The received radionuclides and their activity shall be promptly entered into records, followed by the storage in a holding facility.

Article 54
(Records)

(1) Regular and accurate records shall be kept on the unsealed sources received from the vendors.

(2) The use, spending and storage of unsealed sources shall be accompanied with accurate entries in the radionuclides accounting record.

Article 55
(Application)

(1) In order to protect exposed workers, the syringe used to administer radiopharmaceuticals to the patient shall be first placed into a special protective cover made of tungsten, lead, lead glass or other similar materials whenever the application procedure permits so.

(2) While administering radiopharmaceuticals, an absorbing pad shall be placed below the body part where radiopharmaceuticals are to be administered to prevent radioactive contamination in the event that a smaller amount of radioactive material spills during the administration.

(3) After the use, the syringes and needles shall be placed in a separate container for radioactive waste.

Article 56
(Contamination protection)

(1) Due to the contamination hazard during pharmaceutical administration to a patient, exposed workers shall wear gloves and protective work clothing.

(2) After the work done, the exposed worker shall place the gloves in a separate container for radioactive waste.

(3) Before beginning with any other work, the exposed worker shall carefully wash hands and measure the contamination using a device for measuring the contamination of hands, feet and clothing.

(4) If the exposed worker discovers or determines a contamination trace on the hands, body or clothing, the worker must stay in the area, notify a responsible person and then take further necessary actions to remove radioactive contamination.

Article 57
(Hazard groups)

(1) Protection from unsealed sources depends on:

a) radiotoxicity;
b) weighing factor in relation to the activity;
c) weighing factor in relation to the type of radiation.

(2) Based on their radiotoxicity, unsealed sources can be classified into:

a) Class A. Very high: Am-241, Cf-252;
b) Class B. High: Na-22, Ca-45, Mn-54, Co-60, Sr-89, I-125, I-131, Yb-169, Gd-153;
c) Class C. Medium: C-14, F-18, P-32, Cr-51, Co-57, Ga-67, Se-75, Mo-99, In-111, I-123, Au-198, Tl-201, Re-186, Re-188, Sc-47, Sn-117m, Ga-68, Y-90, Sm-153, Lu-177;
d) Class D. Low: C-11, N-13, O-15, Tc-99m, Xe-133.

(3) Depending on the activity, unsealed sources can be classified into the following groups:

a) Low risk: activity less than 50 MBq;
b) Medium risk: activity greater than 50 MBq and less than 50 GBq;
c) High risk: activity greater than 50 GBq.

(4) Depending on the type of radiation, unsealed sources are classified into the following classes:

a) A – weighing factor 100;

b) B – weighing factor 1;
c) C – weighing factor 0.1.

Article 58
(Contamination control)

(1) In the rooms where unsealed sources are used, the contamination of the room surfaces, work areas, exposed workers' clothing and skin shall not exceed the limits laid down in Annex 2 of this regulation that makes its integral part.

(2) Contamination shall be occasionally checked by using a special device for measuring surface contamination or by wipe sampling from the relevant surfaces and later measurements to determine radionuclide presence and their content in the samples.

(3) The contamination measurement of exposed workers' clothing or skin shall be done on the most appropriate body surface part of 100 cm^2. If the radioactive contamination of the walls, floor or ceiling is to be determined, an area of up to 1000 cm^2 shall be chosen while for other surfaces an area of 300 cm^2 will suffice.

Article 59
(Removal of radioactive waste)

(1) Solid and liquid radioactive waste shall be promptly removed from the work areas.

(2) Solid waste shall be separated in containers by the types of radionuclides.

(3) Solid waste containers shall be strong enough to prevent leakage, thus causing environmental contamination.

(4) Before transferring to the storage facility, all vessels and bags with solid radioactive waste shall be sealed and labelled with a tag indicating the content (radionuclides), the date of disposal and the surface dose rate indicated in mSv/h.

(5) If the transfer is carried out outside the area of exposure, additional measures shall be taken to prevent environmental contamination.

(6) Liquid radioactive waste shall be discharged through drains into a special pools for temporary holding or directly into the sewerage with plenty flushing with running water for the purpose of dilution.

(7) The method of discharge and the amounts of radioactive waste shall comply with the limits in accordance with a particular regulation.

Article 60
(Therapy)

(1) The patients who have received an I-131 activity greater than 800 MBq during the therapy shall be hospitalised.

(2) The patients who have received an I-131 activity greater than 1100 MBq during the therapy shall be accommodated in a single-bed patient room equipped with a sanitary facility.

(3) The patients who have received an I-131 activity greater than 800 MBq and less 1100 MBq during the therapy may be accommodated in a two-bed room provided that a shielding barrier is placed between the patients to ensure that the patient dose due to the presence of the second patient is below dose limits for the members of the public.

(4) The hospitalised patients treated with I-131 may be discharged from the hospital when the radionuclide activity in the body falls below 800 MBq.

(5) During the radionuclide therapy with P-32, Y-90, Re-186, Sm-153 and Sr-89 emitting beta radiation and with an activity of less than 200 MBq, a patient may be discharged from the hospital without any restriction measures.

Article 61
(General requirements for hospital discharge)

(1) A patient may be discharged from the hospital if it is ensured that:

a) Any member of the public does not receive an effective dose greater than 0,3 mSv a year;
b) A patient's household member does not receive an effective dose greater than 1 mSv a year;
c) Except for pregnant women, a household member who voluntarily provide care to the patient after the hospital discharge does not receive an effective dose greater than 5 mSv a year.

(2) The dose estimate referred to in the preceding paragraph of this Article shall be carried out by a radiation protection officer.

(3) Before leaving the hospital, patients treated with radionuclides shall be given written instructions and warnings they must follow to reduce the risk of external exposure or radioactive contamination of other persons.

Article 62
(Procedures during the patient therapy)

(1) Immediately after the radionuclide administration, only the necessary care shall be provided to the patient with as short as possible stay near the patient and from the farthest possible distance.

(2) Access to the patient shall be allowed only to the persons that provide care and treatment, in which the patient must have restricted mobility.

(3) The patients referred to in the preceding paragraph of this Article shall not leave the hospital room without an approval of the medical personnel responsible for the therapy, in which a record on possible leaving the room shall be kept.

(4) The personnel interacting with the patient who has been administered radionuclides shall wear gloves and shoe covers to protect against contamination.

(5) If an appropriate device has confirmed that all objects in direct contact with the patient are contaminated, they must be placed in a separate radioactive waste container after their use.

(6) If an obvious room contamination has occurred because of spilling body secretions from a patient who has been administered radionuclides, the patient shall be promptly relocated to another area and decontaminated.

(7) The hospital room and all objects used by the patient who has been administered radionuclides shall be checked for radioactive contamination before their reuse, and as needed, cleaned up from the remaining radioactivity, followed by keeping a written record thereof.

Article 63
(Post-mortem examination)

Post-mortem examination and cremation of the deceased persons who were administered therapeutic radionuclides with the remaining activity greater than 800 MBq shall be carried out with all radiation protection measures the purpose of which is to avert external exposure and radioactive contamination.

CHAPTER III – DIAGNOSTIC AND INTERVENTION RADIOLOGY

Section A. Premises

Article 64
(Premises)

(1) Radiological, diagnostic and intervention examinations shall be performed in the specially designed and designated premises for these examinations except the interventions during surgeries in operating rooms and in the case of immobile patients when mobile X-ray devices are used, and in dental offices.

(2) Not more than one intervention shall be performed in one room unless the room is designated for several simultaneous interventions. In that case, the patient dose due to other interventions in the room shall not exceed the authorised dose limits for the members of the public.

(3) Controlled area means an area with a radioactive source (X-ray tube).

(4) Supervised area means all other premises at the diagnostics department.

Article 65
(Requirements for the premises)

(1) Operator's workplace requirements:

a) The area shall have the dimensions allowing for flexibility in work, in which the distance from the wall to the control panel shall not be less than 1 m.
b) The access to the control panel shall be unobstructed.
c) The shielded area shall be located so that the direct attenuated beam does not reach the operator's position.
d) The area shall have a ventilation device or an air-conditioner.

(2) Building requirements:

a) The walls used for the purpose of radiation protection shall not be less than 2.1 m high.

b) The doors not immediately under the operator's supervision shall be constructed so that the entrance to the diagnostic area is prevented during a radiological examination.

(3) Control panel position:

a) The control panel shall be placed in a fixed position in the cabin.
b) If the cabin does not have a door leading to the room with an X-ray device, then the control panel shall be at least 1 m away from the passage to the room.
c) The control panel shall be placed so as to enable an unobstructed view through the window.

(4) Monitoring system requirements:

a) The operator shall have a possibility to see the patient during any exposure, the position of other persons in the room and the entrance door.
b) The material of which the window is made shall be of an appropriate lead equivalent.
c) If the monitoring system consists of mirrors, the mirrors must be placed so as to meet all the requirements referred to in paragraph (4) point a);
d) If the monitoring system is electronic, the camera must be placed so as to meet the requirement referred to in paragraph (4) point a) and an alternative monitoring system shall be in place.

Article 66
(Dental imaging)

An intraoral X-ray device may be used in the premises not specifically designated for X-ray diagnostics, provided that an adequate protection is ensured for adjacent rooms and that the operator has enough space to move to a safe distance from the device in the opposite direction from the useful radiation beam.

Section B. Radioactive sources

Article 67
(Devices)

The devices used in diagnostic and intervention radiology are considered fixed and mobile imaging or fluoroscopy X-ray devices, combined X-ray devices (X-ray devices capable of both imaging and fluoroscopy), devices for conventional and computerised tomography, mammography, dental X-ray devices and other devices for diagnostics and interventions in medicine by using X-radiation.

Article 68
(Device requirements)

(1) All diagnostic X-ray devices shall meet the following requirements:

a) The transmitted radiation from the casing measured at 1 m in any direction from the source shall not exceed 1 mGy/h when the X-ray tube is operating under maximum conditions used for clinical purposes.
b) The required minimum half-value layer of the useful beam shall include the contribution to the filtration of all materials permanently positioned between the source and the patient, and the inherent tube filtration.

c) If two or more tubes are controlled by a single switch, the selected tube(s) shall be clearly indicated before the initiation of exposure.
d) The mechanical tube holder shall be adjusted so that the tube housing remains stable during exposure.
e) On battery-powered X-radiation generators, visual means shall be ensured on the control panel to indicate when the battery is being charged for the relevant operation.

Article 69
(Maximum voltage)

(1) The maximum possible tube voltage of the X-ray device used in medical diagnostics shall not exceed 150 kV.

(2) The X-ray tube housing shall have an aperture only for the passage of the useful X-ray beam directed towards the patient.

Article 70
(Serial number)

(1) A clearly legible X-ray tube housing number, the focal spot sign and the serial number of X-ray tube shall be clearly indicated on a visible spot on the housing.

(2) The X-ray tube housing shall have a label confirming that the control of the source has been performed by a licensed technical service for the current year.

Article 71
(Filters)

(1) The X-radiation shall be filtered before it enters the patients' body.

(2) The filters shall be installed as permanent and additional, in which the latter ones may be installed or removed as needed.

(3) The filter composition and thickness shall be indicated on the X-ray tube housing.

(4) The filter thickness includes the inherent filtration of the X-ray tube housing and the filtration of permanent and additional filters expressed in the values of aluminium or copper thickness.

Article 72
(Grid)

(1) If grids are used between the patient and the image receptor to decrease scatter, the grid must:

a) be positioned properly, i.e., tube side facing the correct direction and the grid centred to the central ray;
b) if the grid is focused, be at the proper distance for the SIDs being used.

Article 73
(Device indicators)

(1) The X-ray device control panel shall have visibly labelled function of every control.

(2) The control panel shall have a light indicator that undoubtedly indicates that the panel is connected to electrical network.

(3) The control panel shall have a light indicator that, when switched on, indicates the duration of exposure to X-radiation.

(4) Except for dental X-ray devices, the control panel shall have a switch for immediate interruption of power supply.

Section C. Procedures

Article 74
(Protective measures)

(1) Except for immovable patients, only the personnel required for the medical procedure shall be in the room during the radiographic exposure.

(2) The following requirements shall be met:

a) All individuals shall be positioned so that the useful beam will strike no part of their body unless protected by at least 0.5 mm lead-equivalent material.
b) The operator and other professional personnel shall be protected from the scattered radiation by protective aprons or whole body protective barriers of not less than 0.25 mm lead-equivalent material.
c) Immovable patients shall be protected from the scattered radiation by whole body protective barriers of not less than 0.25 mm lead-equivalent material or be positioned so that the nearest portion of the body is at least 2 m from both the tube and the nearest edge of the image receptor.
d) Gonad shielding of not less than 0.5 mm lead-equivalent material shall be used for the patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the direct beam, except for cases in which gonad shielding would interfere with the diagnostic procedure.
e) When a patient or film must be supported during an exposure, mechanical holding devices shall be used when the technique permits and no individual shall be used routinely to hold film or patients.
f) The written safety procedures shall indicate the requirements for selecting a holder of the patient and the procedure that the holder shall follow.
g) The holder of the patient shall receive instructions on personal protection and use personal protection equipment.

Article 75
(Other X-ray devices)

(1) The X-ray devices used in education or demonstration shall be exempt from the quality control requirements.

(2) The quality control for bone densitometry devices shall be carried out in accordance with the manufacturer's recommendation.

(3) The quality control for the devices used in veterinary science shall be identical to that for radiography devices in medicine.

(4) Cephalometric and panoramic X-ray devices are considered as medical X-ray devices and shall be subject to the requirements for X-ray devices in medical radiography.

(5) The users of digital X-ray systems shall observe the quality control protocol for image processing provided by the manufacturer.

Section D. Special device requirements

Article 76
(X-ray devices in radiography and tomography)

(1) The focus-skin distance for imaging X-ray devices shall not be less than 30 cm and not less than 60 cm for the imaging of chest organs.

(2) The imaging X-ray device shall have a built-in aperture for limiting the size of the X-ray field and a light indicator of the field size.

(3) The time switch for turning on the X-ray imaging device shall be constructed so as to reliably ensure that the tube stops operating after the time selected for imaging has expired.

(4) The reliability of the time switch shall be ensured by an additional alternative way of switching the tube off that is activated if that the procedure has failed.

(5) The time switch shall not be capable of turning the X-ray tube radiation on again until the previous exposure has not been fully completed.

Article 77
(X-ray devices in diascopy)

(1) A diascopic X-ray device may be used only if it has an electronic image intensifier and a display monitor.

(2) The X-ray tube housing, the aperture window for limiting the useful radiation beam and the electronic image intensifier shall be connected so that the beam does not go beyond the entrance surface of the electronic intensifier.

(3) The housing and the holder of the electronic intensifier shall ensure radiation protection of not less than 2 mm lead equivalent effect for the tube voltage of up to 100 kV and an increased protection of 0.01 mm lead equivalent effect per every KV for the voltages between 100 and 150 kV.

(4) The absorbed dose rate shall not exceed 1 mGy/h in the point where the centre of the useful radiation beam enters the patient's body.

(5) For stationary diascopic X-ray devices, the focus-skin distance shall not be less than 30 cm.

(6) The diascopic X-ray devices shall have a safety interlock for automatic turning the X-ray tube off after a preset time of maximum 10 minutes has expired. The expiry of that interval shall be indicated by a sound signal that the turning off will begin.

(7) The switch for turning diascopy on shall be constantly pressed throughout an examination. Diascopy shall immediately turn off when the switch is released. The switch may be pressed by hand or foot, depending on the device type and purpose.

(8) The X-ray device used for diascopy of an upright patient shall have protective aprons under the electronic image intensifier and to its left, on the holder.

(9) The protective apron under the electronic image intensifier shall be of the same width or wider that the enhancer's holder and not less than 40 cm long. The apron shall be made of least three parts in which the adjacent parts shall overlap not less than 1 cm.

(10) If an X-ray device is used for diascopy of a lying patient, the protective apron shall also be placed on the side where the examiner is.

(11) The shielding effect of the aprons referred to in the preceding three paragraphs of this Article shall have 0.5 mm lead equivalent effect.

(12) The provisions of this Article shall not apply to remote operating diascopic X-ray devices and mobile diascopic X-ray devices in operating rooms.

Article 78
(Interventional radiology and cardiology)

(1) During the use of a diascopic X-ray device for special procedures (interventional radiology, interventional cardiology), the persons beside the patient shall use other protective equipment, including special shields, screens and curtains to reduce their exposure to ionising radiation scattered from the patient and the device parts, in which the shielding effect of the protective equipment shall not be less than 0.25 mm lead equivalent.

(2) During the use of a diascopic X-ray device for special procedures (interventional radiology, interventional cardiology), the persons beside the patient shall use wrap-around apron covering the front and back parts of the body, in which the shielding effect shall not be less than 0.5 mm lead equivalent.

(3) The warning light shall be installed on all entrance doors to the premises.

Article 79
(Mammography X-ray devices)

(1) For breast imaging (mammography), only the special X-ray devices intended for that purpose shall be used.

(2) The mammography X-ray device shall have a breast compression device and a grid in the cassette holder.

(3) The focus size shall be less than 0.6 mm. The focus-cassette distance shall be greater than 50 cm.

Article 80
(X-ray devices for computerised tomography-CT)

(1) The warning light shall be installed on the entrance doors to the rooms where CT devices are used.

(2) The warning light shall have the capability to turn on whenever the X-ray tube is in preparation mode before or during exposure. The light shall remain on during exposure.

(3) There shall be no persons in the room with a CT device during the preparation period after connecting the device to electrical network while the warming up and self-

adjustment of the X-ray tube that emits radiation is in progress.

(4) The personnel member responsible for monitoring the CT device during the preparation period after the device is turned on shall not leave the place by the control panel until the entire preparation procedure has been completed.

(5) There shall be a two-way aural communication between the patient and the control panel operator.

(6) A visual indication shall be ensured whenever X-rays are generated.

(7) Emergency switches shall be clearly marked.

(8) Every series of scans shall be initiated by the operator.

(9) A CT device shall be designed so that the technical imaging parameters (conditions) are known before the imaging begins.

(10) Every manufacturer of CT systems shall provide the user with the following:

a) A phantom for verifying the image noise, the thickness of tomographic section, the low and high contrast resolution and the value of CT number for water or other reference materials;
b) Instructions for using the phantom and a data storage method;
c) Demonstration phantom images on the film or in a digital form.

Article 81
(Dental imaging devices)

(1) Only the patient and the person turning on the time switch, provided that the latter is shielded by an appropriate protective screen, shall be in the room with an X-ray dental imaging device during the X-ray tube operation. The operator shall have a view of the patient during the entire procedure.

(2) The shielding effect of the screen referred to in paragraph (1) of this Article shall not be less than 1 mm lead equivalent.

(3) The user shall have a protective apron and a thyroid shield made of 0.25 mm lead equivalent material. In panoramic radiography, the user shall have a wrap-around protective apron covering the front and back parts of the body.

(4) The primary radiation beam from the dental imaging device shall not be directed under any circumstances towards the person that turns on the time switch.

(5) The shielded open applicator shall be used so that the transmitted radiation at 1 m from the source in any direction of X-radiation shall not exceed 0.25 mGy/h for intraoral devices and 1 mGy/h for other devices.

(6) The housing shall have an indication of the focus position.

(7) X-ray dental imaging devices with nominal fixed kVp values less than 50 kVp shall not be used.

(8) The X-radiation of the dental imaging device shall be filtered by using filters.

(9) The filter composition and equivalent thickness shall be indicated on the X-ray tube housing.

(10) X-ray dental imaging devices shall have a light indicator for electrical network.

(11) X-ray dental imaging devices shall have a light indicator that is turned on during the X-ray tube operation and turned off after the preset imaging time has expired.

Article 82
(Bone densitometry X-ray devices)

(1) All design and administrative requirements shall be met for bone densitometry X-ray devices.

(2) The bone densitometry system shall be placed in a controlled area.

(3) The operator, the ancillary staff and members of the public shall be positioned not less than 2 m from the patient and the densitometry system during the examination.

(4) The operator shall inform the patient before the examination that X-radiation is used in bone densitometry.

Article 83
(X-ray devices in education)

(1) The manager of the educational institution shall appoint an instructor responsible for the possession and use of X-ray devices.

(2) The responsible instructor shall:

a) keep records of the purchase and transfer of X-ray equipment;
b) prepare rules for using X-ray devices;
c) familiarise the persons in training in work with radioactive sources with the applicable rules and regulations;
d) as necessary, perform measurements from the field of radiation protection;
e) ensure that the dose limits for the persons in training in work with radioactive sources do not be exceeded.

(3) X-ray devices shall be used only under the supervision of the responsible instructor.

(4) X-ray devices shall be protected from unauthorised use.

(5) An X-ray device shall have a device that automatically and clearly indicates when X-radiation is generated.

(6) The dose rate shall not exceed 5 μGy/h at any point at 5 cm from the exterior surface.

(7) The room where an X-ray device is used shall have two internal safety interlocks that can turn off the device from the power supply.

Section E. X-ray diagnostics in veterinary science

Article 84
(General requirements)

An X-ray device used for diagnostics in veterinary medicine shall meet the requirements laid down in this regulation for the X-ray devices of the same type used in diagnostic radiology.

Article 85
(Special requirements)

(1) The person holding the patient (animal) subject to examination shall wear a protective apron, protective gloves, and as needed, other protective equipment.

(2) The shielding effect of the equipment above shall be 0.5 mm lead equivalent.

(3) Not any part of the person holding the animal during the examination shall be exposed to the primary radiation beam.

(4) Pregnant women, likely pregnant women and persons under 18 years of age shall not hold animals examined with X-ray devices.

(5) Whenever possible, the animal should be put to sleep or immobilised during the X-ray examination.

PART THREE – SPECIAL REQUIREMENTS FOR INDUSTRY

CHAPTER I – INDUSTRIAL RADIOGRAPHY

Section A. Premises

Article 86
(Irradiation area)

(1) Radiation generators and devices containing radioactive sources used for radiographic material testing shall be placed in at least two rooms.

(2) The X-ray tube or a device containing a radioactive source, and the material subject to testing shall be placed in one room while the device control panel or a time switch used only to turn radiation on shall be placed in another room.

(3) As an exception, X-ray devices and devices containing radioactive sources for radiographic tests may be used at a construction site, i.e. outside specially equipped rooms-bunkers provided that the tests are performed on the basis of a written procedure for work and radiation protection, and in accordance with the specified requirements of this regulation.

(4) Controlled area means an area where a radioactive source (X-ray tube, device containing a radioactive source-defectoscope) is placed.

(5) Supervised area means all other rooms within the department for material testing.

Article 87
(Storage facility)

(1) A permanent and purposely designed storage facility for radioactive sources shall be established in the authorisation holder's premises, and as needed a suitable temporary storage facility at the construction site may be established as well.

(2) The storage facility shall meet the following requirements:

a) Capable of being locked in order to prevent unauthorised taking radioactive sources out or bringing them in;
b) Capable of protecting the equipment from mechanical damages and extreme weather conditions;
c) Capable of ensuring fire protection;
d) Radioactive sources shall not be stored or located near flammable or corrosive materials or explosives;
e) Capable of providing exposed workers with an adequate protection from ionising radiation;
f) The storage entrance door shall be clearly and permanently labelled with the radiation warning sign and written warnings, and if the facility is located at the construction site – temporary storage facility – in addition, the name, address and phone number of the person responsible for radiation protection to be contacted in the event of an emergency.

Section B. Radioactive sources

Article 88
(Device description)

(1) Sealed sources used in radiographic material testing shall be kept and transferred to the location of use in a device that is at the same time the work device-defectoscope.

(2) The work device shall be equipped with a safety lock that must be always locked when the radioactive source is not in use.

(3) The device with a locked source for radiographic material testing and serving at the same time as work and portable device shall comply with the relevant technical standards.

(4) The absorbed dose rate in the air on any accessible point on the surface of the portable device-defectoscope shall not exceed 2 mGy/h or 0.02 mGy/h at 1 m from any point on the surface of the shielding container.

Article 89
(Device labelling)

(1) In addition to the radiation warning sign, the surface of the device containing a sealed source used for radiographic material testing shall be labelled with the chemical symbol of the radioactive element for which the device is intended and the maximum permitted activity that the device may contain.

(2) The accurate information about the sealed source activity at the time of its use shall be provided for the work device containing a sealed source used for radiographic material testing.

Article 90
(Measuring instruments)

(1) The authorisation holder shall provide at least one radiation measuring instrument for every radioactive source. The instrument shall be used:

a) to delineate the boundaries of the controlled area and the supervised area;
b) before and after every source exposure in order to determine that the source is in its fully shielded position within the device containing a radioactive source-defectoscope;
c) when the sources are taken from and returned to a storage facility;
d) when a source is transferred from one to another device-defectoscope;
e) in emergencies.

Article 91
(Irradiation equipment)

(1) Radiographic tests shall be carried out in a purposely designed room-bunker that must ensure personnel protection in routine and accident situations except when this is not possible.

(2) The following safety systems and warning systems shall be installed in the rooms where fixed sealed sources, X-ray devices or accelerators for industrial radiography are used:

a) Switches enabling turning the device on only when the door is closed and terminating exposure if the door opens. This safety system shall be adjusted so as not to initiate exposure by closing the door;
b) The control panel shall have a master key without which the tube assembly cannot be turned on;
c) The control panel shall have a light indicator that must flash during exposure and turn off after the irradiation has stopped;
d) Emergency switches enabling a person accidentally found themselves in the room to turn the device off;
e) A sound signal inside and outside the room, warning that the door is open while exposure is in progress;
f) A light signal (rotating-blinking light) inside and outside the room, warning that exposure is in progress;
g) If a sealed source is used, a radiation monitor shall be placed inside the exposure room to ensure a visible indication that the preset radiation level is exceeded;
h) Visibly posted radiation warning symbols and written warnings in all relevant places of access to the exposure room and also inside the room, including explanations of the meanings of different warning systems.

Section C. Procedures

Article 92
(Professional qualifications)

(1) All persons performing industrial non-destructive tests (NDT) using the radiographic testing (RT) method shall be trained and certified in accordance with BAS EN 473 or SNT-TC-1A standard.

(2) The authorisation holder shall have at least two permanently employed certified persons, one of which must have the RT Level II certificate. If not permanently employed, the RT Level II certified person may be engaged as needed.

(3) The authorisation holder shall also provide specific training in radiation protection and radiation safety for all personnel performing NDT using the RT method.

(4) The persons performing NDT using the RT method shall be responsible for the safe daily work with radioactive sources, in which they must implement personal protection measures, pay attention to the safety of co-workers and other exposed workers not directly related to the radioactive sources, and members of the public.

Article 93
(Dosimetry)

(1) In addition to passive individual dosimeters, persons who perform radiographic tests shall wear electronic individual dosimeters emitting a sound alarm when exposure exceeds the preset dose rate.

(2) All persons tasked with keeping dosimeters shall be familiarised with the written procedures on the method of dosimeter use and keeping.

Article 94
(Modification)

(1) Any modification of a sealed source, a device containing the source-defectoscope, a radiation generator and other equipment used for radiographic testing shall be forbidden.

(2) The equipment referred to in paragraph (1) of this Article shall not be used in the conditions or environment for which it is not intended.

Article 95
(Protection)

(1) The authorisation holder shall establish physical protection and a written procedure to prevent the damage, theft, loss or unauthorised removal of radioactive sources.

(2) Also, the entry of unauthorised persons to a storage facility for radioactive sources, a purposely designed premises-bunker and a controlled area during the work at the construction site in the open shall be prevented.

Article 96
(Device handover)

(1) Only an authorised exposed worker with a work order for performing a certain task may remove a device containing a sealed source for radiographic testing-defectoscope from the storage facility, provided that the worker signs the record of sealed source utilisation.

(2) From the time of taking over a device containing a sealed source until its return to the storage facility, the exposed worker shall be responsible for the source and the implementation of protective actions during the source transfer, transport and use.

Article 97
(Device key)

The keys for the device containing a sealed source-defectoscope and the keys to the storage facility shall be in possession of only the persons authorised for the monitoring and keeping records of sealed sources.

Article 98
(Irradiation requirements)

(1) Irradiation during radiographic material testing shall be performed by not less than two persons who meet the requirements for work with radioactive sources and who must be present all the time during the work with the source.

(2) After the device containing a sealed source-defectoscope is turned off, a radiation measuring instrument shall be used to verify whether the source is in the defectoscope, followed by locking the source.

Article 99
(Irradiation procedure)

(1) The sealed source used for radiographic material testing shall be brought into the working position for irradiation only by using a special remote control device.

(2) The use of a device containing a sealed source shall be forbidden if the source can be brought into the working position without the possibility of remote control.

Article 100
(Additional equipment)

For the purpose of additional protection, additional equipment for narrowing a beam-collimator shall be used whenever possible and justified from the perspective of radiographic technique.

Article 101
(Source transfer)

A sealed source from one device-defectoscope to another shall be transferred only in the presence of a radiation protection officer and using special tools and device intended for such replacement, in which the replacement must be performed only by the persons trained for this job.

Article 102
(Inspection of the device containing a sealed source)

(1) Every time before using a device containing a sealed source, persons performing radiographic testing shall inspect at least the following:

a) Proper functioning of the source locking mechanism;
b) Functioning and possible mechanical damage of the security mechanism for remote control that moves the source into the working position;
c) Proper connection of the security mechanism for remote control with the exposure device-defectoscope;
d) Whether the radiation levels are within the authorised limits.

(2) Periodically, in prescribed intervals for inspecting devices containing sealed source-defectoscopes and other equipment by trained persons and at least once a year by a licensed technical service, the following shall be inspected:

a) The points referred to in paragraph (1) of this Article;
b) The security of the mechanism for attaching the source to its needle holder;
c) Leakage test;
d) Mobility of the unlocked source;
e) The functionality after the source is installed;
f) The device compactness and possible mechanical damages.

Article 103
(Inspection of radiation generators)

(1) The daily inspection of radiation generators carried out by the person that performs radiographic tests shall consist of the following:

a) Establishing that there are no visible mechanical damages on the device, cables and other equipment;
b) Establishing that there are no visible traces of oil leaks in the cooling system;
c) Establishing whether the safety systems function properly;
d) Establishing whether all warning indicators (sound and light) function properly.

(2) Periodically, in prescribed intervals of inspecting devices and other equipment by trained persons and at least once a year by a licensed technical service, the following shall be inspected:

a) The procedures referred to in paragraph (1) of this Article shall be carried out;
b) Electrical installation for security, including the grounding;
c) The tube housing for X-ray leakage (leakage test); maximum 100 μGy/h at 1 m from the X-ray tube anode;
d) The proper functioning of the control panel (contact key, time switch for controlling the duration of radiation, signal lights, etc.).

Article 104
(Protection measures in the open)

(1) While working with radioactive sources on a site outside the specially equipped premises, at least the following shall be ensured:

a) Clear establishment, marking and constant supervision of the access to the controlled area;
b) The use of warning signs (written, sound, light, etc.);
c) The use of existing barriers and mobile screens around the workplace and the use of radiation collimators to reduce the irradiation of exposed workers to the lowest possible level and certainly below the authorised levels;
d) The dose rate on the area boundaries shall not exceed the authorised levels;
e) The safe storage of radioactive sources;
f) The use of individual dosimeters and radiation measuring instruments.

Article 105
(Prohibition)

No persons shall be present in a controlled area when the radioactive source is in use.

Article 106
(Emergency involving a radioactive source)

(1) If it is not possible to remotely return a sealed source to a defectoscope, it is necessary to:

a) mark the work area and prohibit all persons to access the vicinity of the work place;
b) place physical barriers at the site where the dose rate is maximum 7,5 μSv/h;
c) notify the radiation protection officer of the emergency;
d) take all radiation protection measures in accordance with the plan for the elimination of consequences, which the legal person must possess, and promptly notify the Agency thereof.

Article 107
(Decommissioning)

(1) At the end of the lifetime of a sealed source, a radiation generator or purposely designed facility for radiographic testing, the legal person shall notify the Agency and ensure the decommissioning process.

(2) No radiological risk shall remain after the decommissioning.

CHAPTER II – DEVICES CONTAINING SEALED SOURCES

Article 108
(Basic remarks)

(1) Devices containing sealed sources are used during the production process or the automated management of production.

(2) The devices referred to in paragraph (1) of this Article are used for measuring thickness, height, level, flow, density or humidity.

Article 109
(Special requirements)

(1) Devices containing sealed sources shall be resistant to mechanical, thermal and other effects, and be compliant with the technical conditions of use.

(2) Devices containing sealed sources shall be used in the conditions provided for in the technical documentation.

(3) Devices containing sealed sources shall not be used if they are mechanically damaged or likely to leak radiation.

(4) Devices containing sealed sources shall have a security mechanism that enables the source movement from working to secured position.

(5) The container with a sealed source shall have a lock and a shutter that can be closed, thus interrupting the useful radiation beam.

(6) The container and the control panel shall have clear indicators whether the shutter is open.

Article 110
(Stationary devices)

(1) The equivalent dose rate on the external surfaces of stationary devices containing sealed sources shall not exceed 1 mSv/h, and 0.02 mSv/h at 1 m.

(2) The area around a device containing a sealed source in the place of use shall be labelled with the radiation warning sign in accordance with Article 11 of this regulation.

Article 111
(Process measurement technique)

(1) Devices containing sealed sources used in process measurement technique and control engineering shall be constructed so as to resist all environmental effects and maintain their integrity in all conditions of use.

(2) The source position in the device, the device position in a technological process and the implemented radiation protection measures shall ensure that the absorbed dose on the surfaces of the device parts does not exceed 0.1 mGy/h, and 0.02 mGy/h at 1 m.

(3) The area around the device containing a sealed source referred to in paragraph (1) of this Article shall be labelled in accordance with Article 11 of this regulation.

Article 112
(Outdoor use)

(1) The following protective measures shall be taken while using a device containing a sealed source outside the specially designated premises:

a) Prohibiting access to persons not working with radioactive sources near the sources where the radiation level could give rise to an exceeded authorised effective dose limit for the public;
b) Placing the warning signs: 'Radiation hazard' and sound and light radiation warning devices;
c) The use of movable and other barriers;
d) The use of sources in the conditions of the farthest possible source distance from the individual handling the device and other people;
e) Directing the radiation beam toward the floor or away where there are no people.

Article 113
(Leakage test)

(1) Sealed sources shall be tested for radiation leakage when the source damage is suspected and also in other circumstances provided for in this regulation or within the deadlines specified in the technical documentation.

(2) The test shall be performed on the accessible areas on the shielding container under applicable international standards.

(3) If the activity of the taken wipe sample is less than 200 Bq, the sealed source is considered as properly leaktight.

(4) If the activity is greater than 200 Bq, the use of the source shall be promptly terminated and actions shall be taken to remove the possible contamination and replace the device.

Article 114
(Device repair)

(1) Devices containing sealed sources used in the process measurement technique and control engineering shall be repaired in a designated room only by the persons professionally trained for this job.

(2) No other persons shall be present during the device repair except the responsible person.

CHAPTER III – X-RAY INSPECTION DEVICES

Article 115
(Special requirements)

(1) X-ray inspection devices for goods, mail, parcels, baggage and personal belongings (hereinafter: X-ray inspection devices) located in public places shall have a protective casing.

(2) No equivalent dose rate greater than 1 μSv/h should be registered at 10 cm from any point on the exterior casing surface if the X-ray emission is in the continuous regime or 1 nSv/imp in the impulse regime.

(3) If the protective casing has an access port through which the inspected objects are placed, the port shall have microswitches that prevent turning on the high voltage of the X-ray tube as long as the port is open.

(4) If the requirements referred to in paragraph (3) of this Article are not met, X-ray inspection devices shall be placed in a separate room with the 'Radiation hazard' sign on the door, while the equivalent dose rate on the surface of exterior walls of the room shall not exceed the authorised effective dose for the public.

(5) The equivalent dose rate on the device exterior surface shall not exceed the value of the authorised effective dose for the public.

(6) The personnel whose workplaces are near the casing of the X-ray devices referred to in paragraph (1) of this Article shall have prescribed individual dosimeters unless the measurements undoubtedly prove that the personnel spends most of the time outside the monitored area in all conditions of the dosimeter use.

Article 116
(Portable devices)

(1) Portable X-ray inspection devices without a protective cabinet may be used if the prescribed technical requirements are met and appropriate radiation protection measures laid down for sealed sources are taken.

(2) A portable X-ray inspection device shall be turned on and off in a way that the operator must not be exposed to higher doses than those authorised for exposed workers.

(3) The users of portable X-ray inspection devices for goods shall have an appropriate, functioning and verified radiation monitor.

Article 117
(Portable devices)

(1) X-ray inspection devices mounted on a vehicle or movable trailer shall not generate the equivalent dose rate greater 1 μSv/h at 10 cm from any point on the external surface of the vehicle or trailer if the irradiation is performed in the continuous regime or 1 nSv/imp in the impulse regime.

(2) If the requirements referred to in paragraph (1) of this Article are not met, the protective measures prescribed for portable X-ray devices must be taken.

(3) If the vehicle or trailer has an access door through which the inspected objects are placed, the door must have microswitches that prevent turning on the high voltage of the X-ray tube as long as the door is open.

(4) If the vehicle or trailer has a separate operator's cabin, the operator shall not be exposed during the work to the radiation doses greater than those authorised for exposed workers.

Article 118
(Inspection of mobile devices)

(1) The inspection of vehicles, containers and other objects by means of X-ray tubes and accelerators may be performed in the facilities built for this purpose, in accordance with the prescribed technical requirements.

(2) The full inspection installation shall be placed in at least two rooms. The control panel and systems necessary for inspection shall be placed in separate rooms.

(3) Protective doors with protective switches that prevent turning X-radiation on as long as the door is open shall be installed at the entrance and exit points of inspection.

(4) The effective dose rate limit authorised for the public should not be exceeded on the surface of the exterior walls of the rooms where the devices referred to in paragraph (1) of this Article are placed.

CHAPTER IV – RADIOLUMINUOUS PAINT

Article 119
(Basic remarks)

Only tritium H-3 and promethium Pm-141 shall be used as components in radioluminuous paint, in which they must be bonded chemically or in another way so as to compose insoluble or poorly soluble material.

Article 120
(Activity)

The total activity of the radioluminuous paint coated on the dials and hands of timepieces and instruments shall not exceed the values specified in the table in Annex 3.

Article 121
(Special requirements)

(1) Radioluminuous paint on coated surfaces shall stick during the normal conditions of use so that the paint does not fall off during the shocks or temperature changes.

(2) Timepieces and other instruments the parts of which are coated with radioluminuous paint shall be placed in boxes with a translucent lid. The box and the lid have to be shock and impact resistant during the normal conditions of use and minor accidents.

(3) Special timepieces and instruments containing radioluminuous paint shall have the radioactivity sign on the dial to warn the user or service person about radionuclides.

Article 122
(Storage of radioluminuous paint)

(1) Radioluminuous paint shall be stored in a closed storage facility before use. The facility shall have a sign clearly indicating the content and the activity.

(2) The waste generated during the use of radioluminuous paint shall be collected in a separate container or plastic bag and later be treated in accordance with the regulations on radioactive waste.

Article 123
(Protective measures)

(1) During the work with radioluminuous paint, the same protective measures shall be applied as during the work with unsealed sources.

(2) The workplace at which radioluminuous paint is handled shall have a good lighting and ventilation.

(3) Exposed workers shall have a special protective clothing they will put on before the work. A separate changing room and a sanitary facility shall be ensured for them.

(4) After leaving the workplace, exposed workers shall always wash their hands well in order to remove possible radioactive contamination from the hands and then use an appropriate measuring instrument to check for contamination of the clothing and the body.

CHAPTER V – IRRADIATORS FOR STERILISING FOODSTUFFS
AND ITEMS OF GENERAL USE

Article 124
(Basic remarks)

(1) Irradiators for sterilising foodstuffs and items of general use using a high-activity sealed source (irradiation facilities) shall be placed in a separate building that meets the protection requirements for exposed workers, other persons and the environment, in which the construction method must ensure that the work premises and the environment will not be threatened during the use of sealed sources.

(2) A possibility of an accident shall be reduced to the lowest possible level through the use of automated and redundant operation systems.

(3) A possibility of an accident shall be additionally prevented through the automation of detailed established technological procedures that cannot be changed arbitrarily and are settled into routine and tested through exercises conducted by exposed workers.

(4) Written instructions for exposed workers shall exist for all operations.

Article 125
(Requirements for the premises)

(1) No person shall be present in the irradiation room while the irradiation facility is in operation.

(2) For a panoramic irradiation facility, the entrance for exposed workers shall be protected by a door or by both a door and a maze.

(3) The entrance door shall bear a radiation hazard sign or a warning indicating the presence of radioactive sources.

(4) The sealed source shall be in the shielded position if the door is open, i.e. opening the door shall be prevented if the source is in the working position.

(5) The door of the room with a sealed source shall have the capability of opening from the inside at any time.

Article 126
(Panoramic irradiation)

(1) The room where a sealed source is used for panoramic irradiation shall have a radiation measuring instrument installed not in the direct beam but interlocked with the entrance door for exposed workers and indicating whether the source is in the shielded or unshielded position by measuring the radiation level in the irradiation room.

(2) The radiation measuring instrument shall be connected to light and sound signals.

(3) The dose rate shall neither exceed 20 μGy/h at 1 m from any point of the surface of the container with the sealed source in the shielded position nor 200 μGy/h at 5 cm from any point of the container surface.

Article 127
(Operation system)

(1) The sealed source shall be operated remotely.

(2) Before the irradiation begins and the sealed source is moved from the shielded position, light and sound signals shall be turned on and last long enough so that all persons in the irradiation room can leave.

(3) The control panel shall have light indicators that are colour coded to indicate the sealed source position in the irradiation room.

(4) The irradiation room shall have installed safety switches simple for turning on so that the person in the room can return the source to the shielded position independently of the control panel.

(5) The sealed source shall have the capability of automatic returning to the shielded position in the event of longer than 10 seconds electrical power failure in the irradiator facility, in which case the entry to the irradiation room will be permitted only with a radiation measuring instrument.

Article 128
(Preparation procedures)

(1) The irradiation room shall have a safety delay timer that must be actuated on to initialize irradiation from the control panel.

(2) Before switching on the mains on the control panel, an authorised exposed worker shall enter and inspect the room, turn on the delay timer, leave the room, close the entrance door and initiate the irradiation procedure using the master key.

(3) The delay timer referred to in paragraph (1) of this Article shall be interlocked with the main control panel so as to prevent using the control panel to move the sealed source from the shielded position until the entire procedure referred to in paragraphs (1) and (2) of this Article has been conducted.

(4) The master key on the control panel shall be the only key in use while a spare key shall be separately kept in the manager's office or a safe and may be used only in accordance with special instructions.

(5) It shall be prevented to remove the master key from the control panel unless the sealed source is in the shielded position. The master key is used to open the entrance door to irradiation room. The master key shall be attached to a portable radiation measuring instrument so that the exposed worker who opens the entrance door to the irradiation room has to carry both the instrument and the key that the worker must never leave unattended.

(6) The irradiation facility shall not be in operation unless at least two exposed workers are present at the same time in the control area.

Article 129
(Protection requirements for the water pool)

(1) If the sealed source is shielded in a water pool when it is not in use, the access to the pool shall be prevented by physical barriers and locked, in which only authorised exposed workers shall have the keys. The key shall be used only if special circumstances warrant so and upon the manager's authorisation for the purpose of surveillance, repair or maintenance.

(2) The level of pool water shall be controlled and maintained, and every loss of water shall be automatically replenished.

(3) The conductivity shall not exceed 10 msiemens/cm.

Article 130
(Pool drain)

(1) A radiation measuring instrument controlling the contamination of the pool water shall be installed at the drain of the pool used for demineralisation or cleaning.

(2) If the radioactive contamination of the water exceeds the authorised limit, the drain shall have the capability of automatic closing.

(3) If the device referred to in paragraph (1) of this Article sounds off, the water shall be tested for radioactive contamination to check for the reason of alarm activation.

(4) Before beginning to use the pool, it shall be necessary to check its impermeability and the quality of design that shall be maintained and verified by a special certificate.

Article 131
(Dose rate)

The absorbed dose rate shall not exceed 20 μGy/h at 30 cm from any point on the pool water surface when the source is in the shielded position.

Article 132.
(The package conveyor system)

(1) If the irradiation packages are conveyed to the radiation room by an automatic system with a perpetual conveyor belt, a radiation measuring instrument shall be installed at the product exit port to ensure that the sealed source has not been dislodged from the rack and carried out of the room.

(2) Physical barriers (fences) between the sealed source and the belt conveying the irradiated products shall be placed to prevent the contact with the source even in accident circumstances.

PART FOUR – SPECIAL REQUIREMENTS FOR RADIOACTIVE SOURCES IN MASS USE

CHAPTER I – IONISING SMOKE DETECTORS

Article 133
(General remarks)

(1) Ionising smoke detectors may have built-in radioactive sources with activity less than 185 kBq and established to have not more than 0.5% of the total source activity in a single wipe sample of radioactive material from the holder.

(2) Radioactive sources in gaseous condition or whose progeny is in gaseous condition shall not be built-in or used in ionising smoke detectors.

(3) The equivalent dose rate measured at 10 cm from any point on the external surface of the smoke detector insert shall not exceed 1 μSv/h.

Article 134
(Maintenance)

(1) Cleaning and maintenance of the radioactive sources used in ionising smoke detectors shall be done in the way and with the methods prescribed in the technical documentation.

(2) Ionising smoke detectors not in use shall be kept locked with radiation protection measures in place.

(3) The person responsible for implementing radiation protection measures shall be also responsible for the storage and keeping of ionising smoke detectors.

Article 135
(Obligations)

In the event of disappearance of a source, fire or other natural disasters, the user of ionising smoke detectors shall notify the Agency.

CHAPTER II – LIGHTNING RODS

Article 136
(General notes)

(1) The installation of new radioactive lightning rods in Bosnia and Herzegovina shall be forbidden.

(2) Removal of the radioactive lightning rods shall be performed only by a licensed technical service.

(3) After the removal of a radioactive lightning rod, the licensed technical service referred to in paragraph (2) of this Article shall issue a user certificate confirming that the radioactive source has been properly stored and notify the Agency and the licensed technical service that conducted the source dosimetry control.

(4) Radioactive lightning rods shall be transported in a special vehicle, and the radioactive sources shall be placed in a transport container during the transport.

PART FIVE – TRANSITIONAL AND FINAL PROVISIONS

Article 137
(Harmonisation of regulations)

Legal persons carrying out practices with radioactive sources shall harmonise their operations with the provisions of this regulation within one year from the date of entry of this regulation into force.

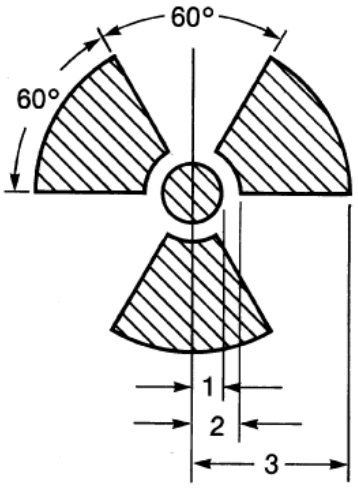
Article 138
(Entry into force)

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

No: 01-02-2-561-1/10
23 July 2010
Sarajevo

Director
Enes Čengić, MS

Annex 1 – International ionising radiation symbol, ISO 361



1 = Radius of central circle
2 = 1.5 radii of the central circle
3 = 5 radii of the central circle

Annex 2

Surface	Radionuclide class		
	A	B	C
	Bq cm-2		
Surfaces and equipment in the controlled area	30	300	3000
Human body surface	3 (0.3)	30	300
Areas of monitoring and public places, personnel clothing and hospital bed sheets	3	30	300

Annex 3

Timepiece type	Radionuclide	Total activity
Wrist and pocket	^{3}H ^{147}Pm	0.30 GBq 0.60 MBq
Wall	^{3}H ^{147}Pm	0.40 GBq 7.40 MBq
Special	^{3}H ^{147}Pm	0.90 GBq 18.50 MBq