

Pursuant to Articles 8(h) and 16(1) of the Law on Radiation and Nuclear Safety in Bosnia and Herzegovina (*Official Gazette of BiH* No 88/07) and Article 61(2) of the Law on Administration (*Official Gazette of BiH* Nos 32/02 and 102/09), the director of the State Regulatory Agency for Radiation and Nuclear Safety issues the

**REGULATION  
ON THE RADIATION PROTECTION AND MEDICAL PHYSICS SERVICE**

**PART ONE – GENERAL PROVISIONS**

Article 1  
**(Subject)**

- (1) This regulation provides for requirements for the authorization holder that carries out a practice involving radioactive sources in a medical radiological facility (hereinafter: authorization holder) and shall have a radiation protection and medical physics service (hereinafter: Service); the tasks that shall be performed by the Service; the Service organization, responsibilities, and resources; the documentation that shall be prepared and kept by the Service; the relations with other organizational units; the requirements for Service authorization; the contents of the radiation protection manual for which the Service shall be responsible, and also other important matters regarding the tasks performed by the Service in the medical radiological facility.
- (2) This regulation shall apply to the medical radiological facility that shall have an organized Service within its structure as the internal technical service in accordance with provisions of this regulation.
- (3) The authorization holder for the specific medical practices of radiotherapy, nuclear medicine, and diagnostic radiology shall have the Service within its organization as a separate organizational unit in relation to the departments for the above specific practices.
- (4) The Service shall possess or use radioactive sources to perform the tasks provided for in this regulation.
- (5) If an authorization holder carries out two of three specific medical practices involving radioactive sources referred to in paragraph (3), the Agency, taking into account the radiation risk and the complexity of practice, shall assess on a case-by-case basis whether an authorization holder will have the Service within its organization and issue a relevant legally binding document for the authorization holder.
- (6) The authorization holder that does not have the Service within its organization shall contract an appropriate external technical service that performs tasks and provides expert advice from the field of radiation protection and medical physics.

Article 2  
**(Definitions)**

The following definitions shall apply for the purpose of this regulation:

- a) 'Medical radiological facility': A medical facility (hereinafter: facility) where medical radiological procedures are performed, such as diagnostic or therapeutic procedures involving ionizing radiation; procedures in diagnostic radiology, nuclear medicine or

radiotherapy; planning procedures involving radiation; intervention procedures involving radiation by using radiation generators, devices containing sealed or unsealed radioactive sources, or by using radiopharmaceuticals administered to patients.

- b) 'Authorization holder': A legal person authorized by the State Regulatory Agency for Radiation and Nuclear Safety (hereinafter: the Agency) for carrying out a practice involving radioactive sources in the facility. The authorization holder is legally responsible for the facility.
- c) 'Optimization of radiation protection': The process of determining what level of protection and safety makes exposures and the probability of potential exposures as low as reasonably achievable, economic and social factors being taken into account (ALARA).
- d) 'Radiation protection manual': A written document prepared and updated by the Service. The main role of the manual is to ensure adequate radiation protection of exposed workers, the public, and the work environment. The manual shall ensure that radioactive sources in the facility are procured and used in accordance with applicable regulations and that the radiation exposure is kept below regulatory limits as low as reasonably achievable. The manual shall ensure adequate information from radiation protection and medical physics to the exposed workers whose tasks are associated with a risk of exposure to ionizing radiation.
- e) 'Exposed worker': A person, either self-employed or working under an employer, who is subject to exposure at work carried out within a practice in the facility and who is liable to receive doses exceeding one or other of the dose limits for public exposure.
- f) 'Radiation protection and medical physics service': An organizational unit of the authorization holder that performs radiation protection and medical physics tasks and is independent in relation to other organizational units using the sources. The Service shall have appropriate resources and be competent to perform radiation protection and medical physics tasks needed for functioning of radiological departments in the facility. The Service shall perform the tasks and provide expert advice in the field of radiation protection and medical physics in accordance with the provisions of this regulation and other applicable regulations.
- g) 'Radiological emergency event': An event that affects the facility systems, structures and components and may actually or potentially cause a risk of an increased exposure of workers and the public. It is an unintentional event that occurred during the use of radiation generators or radioactive sources, and results or may result in a radiation exposure of any individual or the environment beyond the limits that can be normally expected for a practice, including the events such as an operator's fault, an equipment failure or an operating system failure. The event warrants investigation of its cause. Radiological emergency events include medical emergency events in which the radiation is not administered to a patient as prescribed by a medical practitioner.

### Article 3

#### **(Responsibilities of the authorization holder)**

- (1) The authorization holder shall be responsible for the establishment and performance of the Service.
- (2) The responsibilities referred to in paragraph (1) refer to:
  - a) submission of application for Service authorization to the Agency;
  - b) selection and appointment of the Service manager;
  - c) specification of responsibilities, enough powers, organizational freedom, time, resources and managements options for the Service manager in writing;

- d) ensuring through the Service manager that the radiation protection and medical physics tasks are performed in accordance with the licensed practices and the regulatory requirements;
- e) developing, documenting and implementing through the Service the requirements of the radiation protection manual that corresponds to the contents of licensed practices and is adequate to ensure compliance with the provisions of applicable regulations;
- f) a periodic (at least once a year) review of the radiation protection manual, of which the records shall be made;
- g) as required, revision of the radiation protection manual in accordance with the use of ionizing radiation, the regulations and the license requirements;
- h) reviewing and approving the revision of the radiation protection manual together with the Service manager;
- i) ensuring that the personnel members to whom the revised manual applies are informed with its contents before implementing the changes;
- j) ensuring that the Service manager has education, training and experience as required in applicable regulations and specific requirements of the radiation protection manual;
- k) in cooperation with the Service, keeping records of the process of selecting and procuring all types of radioactive materials, radiation generators, nuclear materials, appropriate personal protective equipment and instruments for radiation monitoring; and
- l) allocating funds required for the Service to operate and implement requirements of the radiation protection manual.

## **PART TWO – RADIATION PROTECTION AND MEDICAL PHYSICS SERVICE**

### **Article 4 (Service)**

- (1) The Service in the facility is the internal technical service for radiation protection and medical physics that performs tasks and gives appropriate advice to the authorization holder in accordance with the provisions of this regulation after the conducted authorization process.
- (2) The information about the performance of all Service tasks shall be sent to the Agency in the deadlines specified in this regulation.
- (3) An analysis of the information referred to in paragraph (3) allows the Agency to check various aspects of work operations in the facility.

## **CHAPTER I. RADIATION PROTECTION AND MEDICAL PHYSICS TASKS PERFORMED BY THE SERVICE IN THE FACILITY**

### **Article 5 (Licensing)**

The Service shall perform the following tasks for the authorization holder in the licensing process:

- a) maintains the current Service licence and collects all required documents for granting, broadening or amending the licence;
- b) prepares, updates and distributes the radiation protection manual required for licensing;
- c) participates from the perspective of radiation protection in the preparation for submitting the licensing application for the possession and use of radioactive sources in the facility;

- d) ensures that the possession, use and storage of radioactive sources are consistent with the applicable regulations, the licence requirements, the register of radioactive sources and any manufacturer's recommendation and instruction.

#### Article 6

##### **(Phases)**

- (1) The Service shall be familiar with, participate in or monitor all phases of project design, installation, operation, modification and decommissioning of the facility, particularly those related to radiological systems and devices, and to all measures of protection against ionizing radiation in the facility.
- (2) ALARA principle shall be observed in the implementation of all phases referred to in paragraph (1).
- (3) The Service shall advise the authorization holder in the planning of a new facility and acceptance into service of new or modified radioactive sources associated with any engineering control, project characteristics, source safety characteristics and warning instruments relevant for radiation protection.

#### Article 7

##### **(Procurement)**

- (1) The Service shall be actively involved from the beginning in the process of procuring all types of radioactive materials, radiation generators and nuclear materials.
- (2) The Service shall advise the authorization holder on the selection and procurement of appropriate personal protective equipment and radiation monitoring instruments.

#### Article 8

##### **(Radiological risk)**

- (1) The Service shall implement, participate in the revision or revise the assessed risk in the event of an actual or potential exposure by quantifying and calculating the doses associated with normal work and in an emergency in the facility.
- (2) The Service shall establish investigation levels for:
  - a) personal exposure;
  - b) control of radiation areas by measuring dose rate and contamination; and
  - c) bioassays (internal dosimetry).

#### Article 9

##### **(Classification and categorization)**

The Service shall perform the following classification and categorization tasks:

- a) classification of controlled and supervised areas, marking, surveillance, access restriction, and creating work conditions in accordance with the risk of exposure to ionizing radiation;
- b) categorization of exposed workers in accordance with radiological hazards and the classification of radiation areas;

- c) updating the classification and the categorization referred to in points a) and b) in accordance with the existing conditions.

Article 10  
**(Access, time spent and work)**

- (1) The Service shall establish rules for access, time spent and work in the areas with radiological risk through:
  - a) establishing access requirements for supervised and controlled areas;
  - b) access control measures for controlled areas;
  - c) criteria for issuance and use of protective clothing and respiratory equipment in the areas with risk of contamination;
  - d) determining the level of surface contamination in order to use protective clothing and radiation protection equipment again;
  - e) assessing the level of contamination of exposed workers' skin and the level for performing decontamination;
  - f) criteria for radiological control of persons and equipment for the areas outside access control areas;
  - g) specifying the tasks that are not permitted in supervised or controlled areas;
  - h) procedures, instructions and warning measures for the purpose of preventing radioactive contamination of people and minimizing external exposure, in accordance with the radiological conditions in radiation areas and the nature of the work;
  - i) establishing criteria and methodologies for the monitoring of individual doses and, where necessary, the collective dose; and
  - j) analyzing work conditions for pregnant and breastfeeding women.
  
- (2) For the purpose of adequate marking with appropriate warning signs, the Service shall:
  - a) mark the doors, premises and radiation areas;
  - b) mark protective containers, injections and injection caps; and
  - c) keep all signs visible and readable.
  
- (3) For the purpose of radiation protection during the work of exposed pregnant and breastfeeding workers, the Service shall:
  - a) review earlier occupational doses;
  - b) advise the exposed workers about dose restrictions;
  - c) discuss the status of pregnant women;
  - d) monitor monthly doses;
  - e) modify pregnant women's job so as to keep the dose to embryo/foetus below regulatory limits;
  - f) ensure radiation protection instructions for pregnant women.

Article 11  
**(Monitoring of radiation and contamination levels)**

- (1) While monitoring of levels of radiation and contamination with radioactive material in the workplace, the Service shall specify the following information:
  - a) radiation and contamination levels;
  - b) contents and frequency of the monitoring;

- c) the situations that require special monitoring;
  - d) types of detectors, main features, the way of performance of detection and measurement systems in use;
  - e) evaluation and a register of results.
- (2) For the purpose of monitoring the radiation and contamination levels, the Service shall:
- a) measure the ambient dose rate;
  - b) measure the surface contamination;
  - c) measure/calculate the concentration of radioactive particles in the air;
  - d) advise on the selection of instruments, the use of calibration, and repairs;
  - e) advise on fixed monitors, monitoring of released radioactive effluents, selection, use, calibration and repair.

#### Article 12

##### **(Monitoring of radioactive effluents and waste)**

- (1) The Service shall conduct radiological monitoring of radioactive effluents and waste, and ensure at least the following:
- a) a possibility to monitor devices and systems for treatment of solid, liquid or gaseous waste, and for ventilation and filtration of effluents;
  - b) radiation monitoring of treatment and storage of solid, liquid or gaseous radioactive waste;
  - c) compliance with the limits for discharging liquid and gaseous effluents, as approved by the Agency;
  - d) classification, storage, disposal or removal of solid, liquid and gaseous radioactive waste in cooperation with an authorized technical service; and
  - e) keeping the total released activity, whether in liquid or gaseous form, and also the resulting activity concentration as low as reasonably achievable and always below the levels specified by the Agency for each individual case.
- (2) The Service shall perform tasks of radioactive waste storage and disposal in accordance with applicable regulations.

#### Article 13

##### **(Dosimetric monitoring)**

- (1) The dosimetric monitoring conducted by the Service shall achieve the following goals:
- a) monitoring and control of individual dosimetry of external irradiation of exposed workers;
  - b) monitoring and control of internal contamination;
  - c) updating and archiving the data on individual monitoring and workplace dosimetry;
  - d) assessment of individual and collective risk in the facility.
- (2) Regarding the individual monitoring of exposed workers, the Service shall:
- a) establish a system ensuring that individual dosimeters are worn and timely returned for reading;
  - b) suggest who and when must wear a personal dosimeter;
  - c) suggest where and how to wear a personal dosimeter;
  - d) ensure proper wearing of personal dosimeters;
  - e) establish a bioassay programme;

- f) interpret the results of individual monitoring;
  - g) advise the personnel on the results of individual monitoring;
  - h) in cooperation with the Agency Inspectorate, investigate the causes of exceeding doses;
  - i) provide reports on personal doses.
- (3) The Service shall ensure that the authorization holder must use the services of an authorized technical service for individual monitoring of exposed workers.

Article 14  
**(Medical surveillance)**

- (1) The Service shall ensure that Category A exposed workers are subject to regular health examinations in accordance with applicable regulations.
- (2) The Service shall ensure that the exposed workers referred to in paragraph (1) maintain health status confirmed by an authorized technical service for medical surveillance of exposed workers.
- (3) In order to conduct medical surveillance, the Service shall provide information on the radiological risk of the exposed workers' job in the facility to the authorized technical service for individual monitoring of exposed workers.

Article 15  
**(Radiological impact)**

- (1) The Service shall be familiar and analyze radiological impact of the work operations in standard work conditions.
- (2) The Service shall participate in the preparation of a plan for radiological emergency events that must include standard operating procedures for prevention, preparation and response to radiological emergency events.
- (3) In the event of a radiological emergency, the Service shall:
- a) serve as a response team in the facility;
  - b) investigate, analyse and evaluate consequences of the radiological emergency event and take necessary steps to prevent new occurrence of such an event.

Article 16  
**(Training)**

- (1) The Service shall conduct radiation protection training of the personnel in the facility to which it organizationally belongs.
- (2) The training referred to in paragraph (1) shall be conducted in accordance with applicable regulations.
- (3) The authorization holder shall provide appropriate premises, equipment and procedures needed to conduct the training referred to in the above provisions of this Article.

Article 17  
**(Optimization of radiation protection)**

For the purpose of optimizing radiation protection in the facility, the Service shall:

- a) advise on and recommends programmes and activities to the authorization holder in order to keep the doses as low as reasonably achievable;
- b) develop and implement the exposure monitoring and control program for exposed workers in order to meet the objective referred to in point a) both for individual and collective doses;
- c) identify locations, operations and work conditions that may cause a significant exposure;
- d) review and advise on changes in the work procedures and techniques from the perspective of ALARA principle;
- e) participate in revising the design of the facility modifications that may affect exposure of the personnel;
- f) participate in the development of a training programme for exposed workers in radiation areas;
- g) coordinate the application of ALARA principle with other organizational units in the facility;
- h) investigate the causes of deviation from ALARA principle and implement changes;
- i) establish appropriate dose restrictions.

Article 18  
**(Packages)**

For the purpose of ordering, receiving and transporting packages containing radioactive material for the needs of the facility, the Service shall:

- a) perform all tasks regarding the approved orders;
- b) receive, monitor, test and process the packages in accordance with applicable regulations and licence requirements;
- c) transport and distribute packages containing radioactive material within the facility in accordance with applicable regulations,
- d) advise the internal security service in the facility on the tasks referred to points a), b) and c).

Article 19  
**(Security)**

The Service shall advise the internal security service in the facility in order to ensure that:

- a) all premises/radiation areas with stored radioactive materials are actively secured;
- b) the radioactive materials that are not stored are under control and constant surveillance;
- c) all radioactive sources in the facility are secured in accordance with the applicable regulation.

Article 20  
**(Medical physics)**

(1) The Service shall perform the following medical physics tasks in accordance with applicable regulations:

- a) physical measurements to assess the dose to patient and other individuals subject to medical exposure;
- b) advising the authorization holder on medical radiological equipment;

- c) optimization of radiation protection for patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels;
  - d) preparation of a quality assurance programme and implementation of quality assurance for medical radiological equipment;
  - e) participation in acceptance testing of medical radiological equipment;
  - f) preparation of technical specifications for medical radiological equipment;
  - g) analysing radiological emergency events;
  - h) all tasks of the medical physics specialist in accordance with applicable regulations.
- (2) For the purpose of radiation protection of the patient, the Service shall perform the following tasks:
- a) Patient dose assessment:
    - 1) establishing and implementing calibration procedures and quality control procedures,
    - 2) assessing the patient dose and keeping records thereof.
  - b) Radiation protection of pregnant patients:
    - 1) establishing pregnancy notification procedures for female patients,
    - 2) assessing/measuring the foetal dose.
  - c) Radiation protection of breastfeeding women:
    - 1) providing radiation protection instructions.
  - d) Releasing patients:
    - 1) developing a protocol for releasing patients,
    - 2) providing radiation protection instructions,
    - 3) making specific calculations of the patient dose,
    - 4) calculating/measuring the remaining activity in the patient.
- (3) In medical emergency events, the Service shall:
- a) develop, implement and update written procedures to prevent medical emergency events;
  - b) investigate and identify the causes of medical emergency events, and take timely, appropriate corrective actions,
  - c) send reports to the authorization holder and the Agency about medical emergency events in accordance with applicable regulations;
  - d) cooperate with the Commission for Quality Assurance in Radiotherapy.

## **CHAPTER II. ORGANIZATION, RESOURCES, AND THE SERVICE MANAGER**

### **Section A: Organization and resources**

#### Article 21 **(Organization)**

Internal organization of the facility shall clearly show that the Service is a separate organizational unit that is independent in relation to other organizational units using radioactive sources (radiotherapy, nuclear medicine and diagnostic radiology).

Article 22  
**(Resources)**

The qualified personnel, premises and equipment at disposal of the Service shall correspond to the description of the tasks performed by the Service.

Article 23  
**(Qualified personnel)**

- (1) The Service shall employ at least three personnel members if the authorization holder is authorized for the three specific practices referred to in Article (1) of this regulation:
  - a) radiation protection expert in medical practices (one personnel member);
  - b) medical physics specialist or an individual that can perform tasks of the medical physics specialist (two personnel members)
- (2) The Service shall employ least two personnel members if the authorization holder is authorized for two of three specific practices referred to in Article (1) of this regulation:
  - a) radiation protection expert in medical practices (one personnel member);
  - b) medical physics specialist or an individual that can perform tasks of the medical physics specialist (one personnel member)

**Section B: Premises and equipment**

Article 24  
**(Premises)**

The general manager shall provide the Service with appropriate premises for:

- a) the work of the Service personnel;
- b) deployment of the Service own equipment;
- c) conducting training; and
- d) documentation and archive.

Article 25  
**(Equipment)**

- (1) The Service shall have own equipment for performing radiation protection tasks and which is required for the practice of external technical service for radiation safety in accordance with applicable regulations.
- (2) The Service shall have own equipment for performing medical physics tasks and which is required for the practice of external technical service for medical physics in accordance with applicable regulations.
- (3) Regarding the measurement and control of surface contamination, response curves shall be checked depending on the efficiency and energy.
- (4) All measurement systems used by the Service shall be maintained and calibrated by an authorized technical service for calibration of measuring instruments and/or individual monitoring equipment in accordance with applicable regulations.

## **Section C: Service manager**

### **Article 26 (Service manager)**

- (1) The general manager shall appoint the Service manager.
- (2) The Service manager shall directly report on the work of the Service to the general manager.
- (3) The Service manager shall be a radiation protection expert in specific medical practices and is appointed from among the qualified personnel referred to in Article 23.
- (4) The authorization holder shall appoint the Service manager as the radiation protection officer in the facility.
- (5) The Service manager shall give a written statement on acceptance of the duties of radiation protection officer.
- (6) The content of the statement is given in Annex I, which is an integral part of this regulation.
- (7) The Service manager shall be authorized and responsible for implementation of the radiation protection manual.

### **Article 27 (Authorities of the Service manager)**

The responsible person in the legal person shall authorize the Service manager to:

- a) manage the Service and ensure implementation of the provisions of this regulation and other applicable regulations;
- b) implement the radiation protection manual;
- c) identify radiation protection issues;
- d) initiate, recommend or ensure corrective actions;
- e) stop unsafe operations; and
- f) verify implementation of corrective actions.

### **Article 28 (Responsibilities of the Service manager)**

- (1) The Service manager shall be responsible for:
  - a) ensuring that all licensed practices involving radioactive sources in the facility are carried out in compliance with the licence requirements and all applicable regulations;
  - b) implementing and supervising operational aspects of the radiation protection manual;
  - c) ensuring for the authorization holder that the radiation protection tasks are implemented in accordance with approved procedures and regulatory requirements;
  - d) supervising and authorizing, together with the authorization holder, amendments to the radiation protection manual before their implementation;
  - e) assisting in identifying and investigating radiation protection problems;
  - f) initiating, recommending or ensuring corrective actions for the identified radiation protection problems;

- g) verifying the implementation of corrective actions;
- h) stopping the operations that are identified as unsafe;
- i) informing the authorization holder of radiation protection problems, unsafe operations and corrective actions;
- j) ensuring contact between the authorization holder and the Agency, and inform the authorization holder thereof;
- k) ensuring his or her role of contact person for the facility personnel in the matters of radiation protection and medical physics regulations, and also for the licence requirements;
- l) training or retraining the exposed workers employed in the Service in accordance with applicable training regulations;
- m) ensuring through the training in accordance with applicable regulations that the facility personnel has appropriate knowledge about the radiological risk associated with the performance of their tasks;
- n) if needed, ensuring a contract with relevant external experts for the purpose of educating and training the Service personnel in accordance with the associated radiation risk during the work in the controlled area and an intervention;
- o) signing the documents prepared and issued by the Service; and
- p) keeping the documents for inspection monitoring by the Agency.

### **CHAPTER III. SERVICE DOCUMENTATION AND RELATIONS WITH OTHER ORGANIZATIONAL UNITS**

#### **Section A: Documentation**

##### Article 29 **(Radiation protection manual)**

- (1) The authorization holder shall have a radiation protection manual that is developed, kept and updated by the Service.
- (2) The radiation protection manual shall correspond to the contents of the activities carried out in the facility and the hazards associated with the use of radioactive sources, and adequately protect patients, exposed workers and the public from radiation protection.
- (3) The authorization holder, the Service and all exposed workers using radioactive sources in the facility shall participate in the establishment and implementation of the radiation protection manual, which applies ALARA principle.
- (4) The radiation protection manual shall consist of two parts, as follows:
  - a) general part; and
  - b) specific part.
- (5) The specific part shall consist of three parts:
  - a) Radiation protection programme in radiotherapy;
  - b) Radiation protection programme in nuclear medicine; and
  - c) Radiation protection programme in diagnostic radiology.
- (6) The radiation protection manual shall be developed in accordance with the contents of the radiation protection manual shown in Annex II, which is an integral part of this regulation.

- (7) The Agency shall approve the contents and implementation of the radiation protection manual in the process of authorizing the Service.
- (8) The legal person incorporating the Service need not have a radiation protection programme as defined in Article 18 of the "Regulation on requirements for transfer and use of sources of ionizing radiation" (*Official Gazette of BiH* No 66/10).

Article 30  
**(Instruction)**

- (1) The Service shall develop an instruction for use of personal dosimeters.
- (2) The instruction referred to in paragraph (1) shall be prepared in accordance with the Agency's guide on use of personal dosimeters.
- (3) The guide referred to in paragraph (2) shall be published on the Agency's official web page.

Article 31  
**(Form)**

- (1) The Service shall create a personal dosimeter issuance form.
- (2) The contents of the form referred to in paragraph (1) is presented in Annex III, which is an integral part of this regulation.

Article 32  
**(Exposed workers)**

- (1) The Service shall give the following documents to every newly employed exposed worker before beginning of their work in the facility:
  - a) Radiation protection manual;
  - b) Instruction on use of personal dosimeters;
  - c) Personal dosimeter issuance form.
- (2) Within 30 days from the entering of this regulation into force, the Service shall give the following documents to every exposed worker in the facility:
  - a) Radiation protection manual;
  - b) Instruction on use of personal dosimeters.
- (3) The Service shall ensure that all exposed workers using radioactive sources in the facility comply with the procedures that include the use of radioactive sources and the ALARA principle.
- (4) Exposed workers shall immediately inform the Service manager of the events listed in Annex IV, which is an integral part of this regulation.

Article 33  
**(Documentation on measurements)**

- (1) After every measurement of activity on the source and in surrounding premises, the Service shall create an appropriate report in accordance with applicable regulations.

- (2) For measurements performed in six-month and longer periods, the Service shall issue an appropriate certificate of radiation safety and medical physics in accordance with applicable regulations.
- (3) The Service shall post the certificate on a visible spot in the room with the radioactive source within seven days after the measurement.
- (4) The Service shall keep the certificate visible and legible.

Article 34  
**(Revisions and reviews)**

- (1) The Service shall conduct the following revisions and reviews, and keep records on:
  - a) in cooperation with the general manager, a review of the radiation protection manual and its implementation;
  - b) revisions of the radiation protection manual, the reports of which shall be sent to the general manager;
  - c) review of occupational doses and the summary report, including the individuals who received doses greater than the investigation level and the regulatory limits;
  - d) review of the results of dose rate measurement, contamination control and the summary report;
  - e) revision of the adequacy of procedures for prevention of a medical emergency event;
  - f) analysis of accidents involving ionizing radiation, including the data on the procedure of investigating causes and measures taken.
- (2) The documents created in the process of revisions and reviews shall be kept in the Service in accordance with applicable regulations.

Article 35  
**(Work reports)**

- (1) The Service shall make and send reports on its work to the authorization holder and the Agency.
- (2) The contents of the reports, the recipients and the reporting deadlines are given in Annex V, which is an integral part of this regulation.
- (3) The documentation on reports shall be kept in the Service in accordance with applicable regulations.

Article 36  
**(Other documentation)**

- (1) In addition to the documentation referred to in the Articles of this chapter, the Service shall keep and retain the documents:
  - a) about the licensing procedure for a practice involving radioactive sources:
    - 1) copies of all issued licences for practices involving sources of ionizing radiation in the facility, including for diagnostic radiology, radiotherapy, nuclear medicine and the Service,
    - 2) copies of all submitted applications to grant, broaden or amend licenses,
    - 3) the general manager' approval for initiating authorization,

4) applicable radiation protection regulations published in the *Official Gazette of BiH*.

b) for the radiation protection officer:

- 1) a copy of powers and responsibilities,
- 2) a signed copy of the statement on acceptance of the duties of radiation protection officer,
- 3) the applicable version of the radiation protection manual, approved by the general manager and the Service manager,
- 4) revisions and other reviews of the contents and implementation of the radiation protection manual.

c) a list of a radiological departments;

d) a list of all personnel in radiological departments;

e) a list of exposed workers;

f) a list of individuals subject to individual monitoring;

g) a register of all radioactive sources;

h) a list of used radioactive material, indicating the amounts approved by the Agency and the annual used amounts;

i) an inventory of generated radioactive waste, including information about radionuclides, physical condition, waste holding facility, storage, waste management, and annual amounts of generated waste;

j) documents on the way of waste disposal;

k) plans for radiological emergency events in the facility;

l) rules of work for all radiological departments;

m) optimization methods (quality control and radiation protection plans);

n) for patients:

1) about the doses applied in medicine,

2) about calibration of the instruments for measuring the activity of sealed and unsealed sources,

3) about discharge of the patients containing radioactive material or implants containing radioactive material.

o) methods to monitor the work environment (protocols);

p) quarterly and annual reports on individual dosimetry of exposed workers;

q) reports on control in radiological departments:

1) control of ambient dose,

2) control of fixed and removable contamination,

3) control after implantation and removal of the source,

4) control of therapy treatment unit,

5) calibration of measuring instruments.

r) documents on installation, maintenance, adjustments and repairs of radiological equipment;

s) reports on radiological emergency events in the facility.

(2) Other documentation shall be kept in the Service in accordance with applicable regulations.

## **Section B: Relations with other organizational units**

### **Article 37 (Relations)**

Relations of the Service with other organizational units in the facility shall be such that the information Service provides to the units ensures that the units are familiar, from the perspective of prevention and radiation protection, with procedures and protection measures associated with the system operations involving the use of radiation in the facility.

### **Article 38 (Procedures)**

The procedures in other organizational units in the facility that affect the Service performance shall be approved in writing by the Service manager and the general manager.

## **PART THREE: AUTHORIZATION OF THE RADIATION PROTECTION AND MEDICAL PHYSICS SERVICE**

### **Article 39 (Authorization)**

- (1) The authorization holder incorporating the Service shall submit the application for Service authorization to the Agency.
- (2) The authorization holder's application shall be signed by the general manager and contain:
  - a) documents describing the tasks performed by the Service;
  - b) proofs of:
    - 1) Service's own premises,
    - 2) qualified personnel employed in the Service, and
    - 3) Service's own equipment.
  - c) a radiation protection manual made in accordance with the provisions of this regulation;
  - d) the name of the Service manager and a certified copy of the certificate of radiation protection officer;
  - e) the statement on the acceptance of the duties of radiation protection officer, signed by the appointed Service manager;
  - f) the documentation on the Service personnel regarding:
    - 1) conducted medical examinations for the current year,
    - 2) individual monitoring, and
    - 3) categorization of exposed workers (A or B).
  - g) procedures for monitoring, assessment and way of dose registration for the personnel in the facility and dose limits for exposed workers.
- (3) The Service shall be authorized by licensing.
- (4) After the conducted procedure and verifying that all prescribed requirements are met, the Agency shall issue a procedural decision on authorization and a licence.

Article 40  
**(Establishment of committee)**

- (1) The Agency director shall establish an expert committee to verify whether the Service meets the performance requirements referred to in this regulation within seven days after receiving the application for Service authorization.
- (1) The committee members shall be competent to assess the fulfilment of requirements for Service authorization.
- (2) The committee shall consist of three members.
- (3) One of the committee members shall be a radiation protection expert in medical practices, appointed by the Agency director from the list of qualified experts.
- (4) The radiation protection expert in medical practices referred to in paragraph (4) of this Article shall not be employed with the applicant for Service authorization.
- (5) Administrative tasks relating to the Committee work shall be performed by the committee secretary appointed from among the Agency personnel under a procedural decision issued by the Agency director.

Article 41  
**(Work of the committee)**

- (1) The committee shall work and make decisions at sessions at which all its members shall be present.
- (2) Within 21 days after its establishment, the committee shall find facts on the spot, in the applicant's premises.
- (3) The committee shall make an assessment record on the fulfilment of requirements for Service authorization, make a proposal of the decision on the fulfilment of requirements within three days from the fact-finding and immediately submit it to the Agency director.
- (4) The Agency director shall issue a procedural decision on granting or refusing the Service authorization within seven days from receiving the committee's proposal of the decision.

Article 42  
**(Complaint)**

- (1) The authorization holder whose application for Service authorization is rejected has the right to complain.
- (2) The complaint procedure shall be conducted in accordance with administrative procedure principles.

Article 43  
**(Sanctions)**

The authorization holder that does not comply with the provisions of this regulation shall be sanctioned under the laws and regulations.

## **PART FOUR: TRANSITIONAL AND FINAL PROVISIONS**

### **Article 44 (Harmonization of regulations)**

- (1) Upon entering into force, this regulation shall supersede the provision of Article 3(hhh) and Article 33 of the "Regulation on radiation protection in occupational exposure and in public protection (Official Gazette of BiH 102/11)
- (2) Upon entering into force, this regulation shall supersede the provision of Article 3(1)z) and Article 20 of the "Regulation on radiation protection in medical exposure" (Official Gazette of BiH 13/11).
- (3) Upon entering into force, this regulation shall amend Article 86(3) of the "Regulation on radiation protection in medical exposure" (Official Gazette of BiH 13/11) so as to insert the words "for radiation protection and" after the word "service".
- (4) The authorization holder incorporating the Service shall harmonize its operations with the provisions of this regulation within six months from its effective date.

### **Article 45 (Entry into force)**

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

No.: \_\_\_\_\_/  
Date:

**DIRECTOR**  
Emir Dizdarević

**A N N E X E S**

**ANNEX I: Statement on the acceptance of duties**

**STATEMENT  
ON THE ACCEPTANCE OF DUTIES OF THE  
RADIATION PROTECTION OFFICER**

Date: / / (year)

Address of the medical radiological facility:

Manager of the Radiation Protection and Medical Physics Service:

As the manager of the Radiation Protection and Medical Physics Service, I hereby declare that I accept the job position of radiation protection officer, and I fully understand the position responsibilities.

Please make a copy of this document and leave the original with the Office of the Director.

Manager  
Radiation Protection and Medical Physics Service

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Name

---

Signature

## **ANNEX II: Contents of the radiation protection manual**

### **RADIATION PROTECTION MANUAL**

#### **A. GENERAL PART**

##### **1. Introduction**

- 1.1. Goal
- 1.2. Contents
- 1.3. Availability
- 1.4. Revision of the manual
- 1.5. References

##### **2. Main radiation protection principles**

- 2.1. Radiation quantities and units
- 2.2. Radiation risk
  - 2.2.1. Risk of radioactive contamination
- 2.3. Biological effects of ionizing radiation
- 2.4. Main principles
- 2.5. Dose limits
- 2.6. Classification of exposed workers–personnel
- 2.7. The public
- 2.8. Pregnancy and breastfeeding
- 2.9. Classification of work areas
  - 2.9.1. Signs (warning signs)
  - 2.9.2. Criteria for upgrading the area

##### **3. Detection of ionizing radiation**

- 3.1. Types of detectors
  - 3.1.1. Fixed detectors
  - 3.1.2. Portable detectors

##### **4. Monitoring of exposed workers**

- 4.1. Individual dosimetric control
  - 4.1.1. Category A workers
  - 4.1.2. Category B workers
  - 4.1.3. Significant radiation levels
- 4.2. Dosimetry of areas
- 4.3. Dosimetric control of internal and external contamination
- 4.4. History and dosimetric data
- 4.5. Estimate of special doses
- 4.6. Dose estimate in radiological emergency events
- 4.7. Exceeding the dose limits
- 4.8. Medical surveillance of exposed workers

##### **5. Organization and dependence of the Service**

- 5.1. Human resources
- 5.2. Technical assets
- 5.3. Position location
- 5.4. Organization and dependence
- 5.5. Relation with other organizational units

**6. Functions and responsibilities**

- 6.1. Service functions
- 6.2. Responsibilities
  - 6.2.1. General manager
  - 6.2.2. Managers of organizational units
  - 6.2.3. Service manager
  - 6.2.4. Joint responsibilities
- 6.3. Personnel using radioactive sources
- 6.4. Authorized technical service for medical surveillance of exposed workers
- 6.5. Authorized technical service for individual monitoring of exposed workers
- 6.6. Administration
- 6.7. General services in the facility
- 6.8. Responsibility for maintenance of equipment in the facility
- 6.9. Outside workers

**7. Continuous training of the personnel employed by the authorization holder that has the Service within its structure**

**8. Archiving of the documentation**

**9. Service's own equipment**

- 9.1. Measurement of ambient dose or radiation beam
- 9.2. Surface contamination
- 9.3. Computerized systems of X-ray control
- 9.4. Accessory systems
- 9.5. Physical dosimetry:
  - o Electrometers
  - o Ionization chamber
  - o Semiconductor detectors
  - o Phantoms
  - o Source stability
  - o Accessory equipment
  - o Dosimetric equipment for inpatients

Use Table 9.1. to enter the data from 9.1. to 9.5.

*Table 9.1*

Device	Manufacturer	Model	Type	Serial number	Date of first use

9.6. Calibration of equipment

Use Table 9.2. to enter the equipment calibration data.

Table 9.2

Type	Purpose	Calibration laboratory	Calibration date

### 9.7. Radioactive sources

Use Table 9.3. to enter the data on radioactive sources.

Table 9.3

Radionuclide	Activity (Bq)	Date of manufacture

## 10. Definitions of terms and concepts used in the General Part

### B. SPECIAL PART

#### *B1: Radiation protection programme in radiotherapy*

#### 1. Description of the department

- 1.1. General aspects
- 1.2. Linear electronic accelerator
  - 1.2.1. Characteristics
- 1.3. Simulator
- 1.4. Cobalt-60

#### 2. Access

#### 3. Work rules

- 3.1. Introduction. Responsible persons in the radiotherapy department.
- 3.2. Functions and responsibilities
  - 3.2.1. Operators
- 3.3. Classification of personnel
- 3.4. Work rules
  - 3.4.1. General
  - 3.4.2. Access rules for treatment rooms
  - 3.4.3. Access situations and requirements
  - 3.4.4. Irradiation rules
  - 3.4.5. Simulator
  - 3.4.6. Special work rules for maintenance personnel

3.4.7. Training rules for personnel

**4. Information flow for radiation safety**

- 4.1. Normal condition
- 4.2. Minor failure
- 4.3. Major failure

**5. Periodic checks**

- 5.1. Linear accelerators
- 5.2. Simulator
- 5.3. Cobalt-60

**6. Plan for radiological emergency events**

- 6.1. Linear accelerator
- 6.2. Cobalt-60
- 6.3. Information gathered about a radiological emergency event

**7. Quality assurance programme in radiotherapy**

**8. Ground plan (drawing) of the radiotherapy department**

***B2: Radiation protection programme in nuclear medicine***

**1. Description of the department**

- 1.1. Handling and storage premises
- 1.2. Waste storage
- 1.3. Movable shields
- 1.4. Equipment in the nuclear medicine department
- 1.5. Classification of radiological areas and personnel
  - 1.5.1. Radioactive waste management
  - 1.5.2. Solid waste
  - 1.5.3. Liquid waste

**2. Work rules**

- 2.1. Introduction – responsible persons in the nuclear medicine department
- 2.2. Classification of radiological personnel
- 2.3. Functions and responsibilities
  - 2.3.1. Operators
  - 2.3.2. Service
- 2.4. Work rules – general
  - 2.4.1. General
  - 2.4.2. Work rules
  - 2.4.3. Radiation protection rules for patients
  - 2.4.4. Rules for radioactive waste
  - 2.4.5. Receipt of radioactive material
  - 2.4.6. Cleaning
  - 2.4.7. Applications of rules to patients outside the facility
  - 2.4.8. Rules for work with patients hospitalized at the nuclear medicine department
  - 2.4.9. Rules for implementing techniques

### **3. Plan for radiological emergency events**

#### **3.1. Predictable radiological emergency events**

- 3.1.1. Surface contamination
- 3.1.2. Contamination of personnel
- 3.1.3. Fire

#### **3.2. Procedures for contamination**

- 3.2.1. Human contamination
- 3.2.2. Surface contamination of the equipment

### **4. Periodic checks**

- 4.1. Waste disposal
- 4.2. Receipt of radioactive material
- 4.3. Surface contamination
- 4.4. Contamination of the work environment
- 4.5. Internal contamination of the personnel

### **5. Quality assurance programme in nuclear medicine**

### **6. Ground plan (drawing) of the nuclear medicine department**

### ***B3: Radiation protection programme in diagnostic radiology***

#### **1. Description of the department**

- 1.1. General characteristics and the location of equipment

#### **2. Work rules**

- 2.1. Classification of areas
- 2.2. Classification of exposed workers
- 2.3. Work standards listed in the relevant regulation

#### **3. Plan for radiological emergency events**

- 3.1. Predictable radiological emergency events

#### **4. Periodic checks**

#### **5. Quality assurance programme in diagnostic radiology**

#### **6. Ground plan (drawing) of the diagnostic radiology department**

**ANNEX III: Form for issuing a personal dosimeter and required documents**

- 1) The Service has issued a personal termoluminescent dosimeter (TLD) to the following individual – exposed worker:

First name		
Last name		
Legal person		
Exposed worker's organizational unit		
Category: A B		
Position		
Type of TL dosimeter	Whole body	Extremities
Wearing period: 1 month / 3 months		
Work start date		
Exposed worker's contact address		
Exposed worker's email		

- 2) The Service issued the following documents to the individual above:

- (a) Radiation protection manual,
- (b) Instruction on use of personal dosimeter,
- (c) Characteristics of the workplace,
- (d) Work standards.

- 3) The individual above is informed about the following:

- (a) Proper wearing and exchange of dosimeters shall be the sole responsibility of the exposed workers themselves.
- (b) Before using the dosimeter, the user shall be informed about the work rules and the plan for radiological emergency events.
- (c) The users not confident about their knowledge shall approach the manager of the Radiation Protection and Medical Physics Service within at least three (3) days before starting to work with a radioactive source.

Exposed worker

Exposed worker's signature

\_\_\_\_\_

\_\_\_\_\_

Manager of the Radiation Protection and Medical Physics Service

\_\_\_\_\_

Signature of the manager of the Radiation Protection and Medical Physics Service

\_\_\_\_\_

Place:

Date: / / (year)

#### **ANNEX IV: List of events**

Exposed workers shall immediately notify the Service manager about the following events:

- 1) If a patient cannot be released because he or she had to receive urgent medical assistance or died, the personnel caring for the patient shall notify the Service manager.
- 2) In the following cases:
  - (a) radiological equipment does not function as it should;
  - (b) unsafe work conditions;
  - (c) spillage of radioactive material;
  - (d) observed damage of a package containing radioactive materials;
  - (e) observed damage of a container containing a radioactive source.
- 3) If a patient who had received a therapeutical amount of radionuclides had to be urgently operated and injured during the operation with a possibility of radioactive material entering the wound, the personnel shall notify the Service manager about the possible radiation hazards.
- 4) For the purpose of autopsy on a patient who received a therapeutical amount of radionuclides, the personnel shall notify the Service manager immediately after the patient has died.
- 5) In the event of any radiological emergency event involving a source of ionizing radiation.

## ANNEX V: Service reports – recipients, deadlines and contents

*Table 1: Individual reports – within seven days from the control*

Report	Sent to
Radiation protection control in the workplace – annual	Agency
Quality control – annually	Agency

*Table 2: Monthly reports – within seven days in the following month*

Report	Sent to
Individual doses	Exposed workers
Excessive doses or significant doses	Head of Clinic
Mistakes in exchange of dosimeters	Head of Clinic
Radiation protection control of clinics	Heads of clinics
Quality control in diagnostic radiology	Head of Clinic
Complete dosimetry information	Outside workers
Report on radiological emergency event, including investigated causes and measures taken	Agency and general manager

*Table 3: Quarterly reports – within seven days in the following month*

Report	Sent to
Mistakes in exchange of personal dosimeters	Head of Clinic/Institute/Department and general manager
Evaluation of the received dose for every exposed worker at the clinic	Head of Clinic/Institute/Department and general manager
Radiation protection control of clinics	Head of Clinic/Institute/Department
Complete dosimetry information	Outside workers
Quality control in radiotherapy	Head of Clinic/Institute/Department
Quality control in nuclear medicine	Head of Clinic/Institute/Department

Quality control in diagnostic radiology	Head of Clinic/Institute/Department
Summary report on occupational doses, including individuals who exceeded the investigation level and the regulatory limits	Head of Clinic/Institute/Department
Summary report on dose rate measurements and contamination control	Head of Clinic/Institute/Department

*Table 4: Semi-annual reports – within 15 days in the following month*

Assessment of radiation protection manual	General manager
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*Table 5: Annual reports – deadline 31 January the following year*

<b>Report</b>	<b>Sent to</b>
Summary report on the radiation protection control of in the medical radiological facility	Agency and heads of clinics/institutes/departments and general manager
Annual information about monthly doses (email)	Exposed workers
Summary information about annual individual doses	Heads of clinics/institutes/departments and general manager
Summary report on mistakes in exchange of personal dosimeters	Heads of clinics/institutes/departments and general manager
Assessment of adequacy of procedures for preventing medical emergency events	General manager
Elaborate study on radiological emergency events	Agency and general manager