Pursuant to Article 57, paragraphs 10 and 22, point 3) of the Law on Radiation and Nuclear Safety and Security ("Official Gazette of RS", Nos. 95/18 and 10/19) and Article 15, paragraph 1, point 4) of the Statute of Serbian Radiation and Nuclear Safety and Security Directorate ("Official Gazette of RS", No.9/19), the Board of Serbian Radiation and Nuclear Safety and Security Directorate, on its session held on 14 December 2021, passes:

# THE RULEBOOK ON ISSUING APPROVALS FOR PERFORMANCE OF RADIATION PROTECTION DUTIES

## Subject Matter

## Article 1

This Rulebook shall prescribe in detail the requirements and the documentation necessary for obtaining the approval for the performance of radiation protection duties.

Radiation protection duties include:

1) radioactivity monitoring or particular testing within monitoring;
2) measurements to assess the level of exposure to ionizing radiation of the exposed workers, other members of the public and the public;
3) decontamination of workplace environment and the environment;
4) decontamination of staff;
5) removal of orphan sources;
6) preparation of Safety Analysis Report and Radiation Protection Programme;
7) training and education of the exposed workers and radiation safety officers;
8) testing of radiation sources parameters for the purpose of quality control of the radiation protection measures.

The particular testing within the monitoring under paragraph 2, point 1) of this Article include:

1) testing of the level of external radiation;
2) testing of the content of gamma-ray-emitting radionuclides;
3) testing of the total alpha and total beta activity;
4) testing of the content of strontium-90;
5) testing of the content of tritium;
6) testing of radon concentration;
7) testing of alpha-particle emitting radionuclides.

The measurements to assess the level of exposure to ionizing radiation of the exposed workers, other members of the public and the public under paragraph 2, point 2) of this Article include:

1) measurements of the ambient dose equivalent rate;
2) measurements of the ambient dose equivalent;
3) measurements of personal dose equivalents Hp (10), Hp (3) and Hp (0.07);
4) measurements of radionuclide activity in workplace samples;
5) measurements of surface contamination;
6) *in-vivo* measurements;
7) *in-vitro* measurements;
8) biodosimetry measurements of individual exposure.

The testing of radiation sources parameters for the purpose of quality control of the radiation protection measures under paragraph 2, point 8) of this Article includes the testing in the following fields:

1) x-ray diagnostics and interventional radiology;
2) radiotherapy.

**Definitions**

**Article 2**

For the purpose of this Rulebook the following definitions shall apply:

1) *in-vivo* measurement means any procedure in which direct measurements serves to determine the type, activities and the places in a body where radionuclides are present or retained;
2) *in-vitro measurement* means any procedure used to determine the type, activities and places where radionuclides are present or retained in excreta material discharged or otherwise taken form the body;
3) *radioactivity monitoring* means environmental radioactivity monitoring and monitoring of radiation sources;
4) *training of the exposed workers and radiation safety officers* means the acquisition of theoretical knowledge by persons engaged in the field of radiation protection;
5) *education of the exposed workers and radiation safety officers* means the acquisition of practical knowledge by persons engaged in the field of radiation protection;
6) *test subject* means air, fallout, foodstuffs, feeding stuff, soil, biological material, a human, a radiation source and other substances, material or objects on or in which the testing is conducted.

The remaining definitions in this Rulebook have the meaning defined in the Law on Radiation and Nuclear Safety and Security.

**Application for Approval for Performance of Radiation Protection Duties**

**Article 3**

The legal entity shall submit to Serbian Radiation and Nuclear Safety and Security Directorate (hereinafter: the Directorate) the application for the approval to perform the radiation protection duties.

The application under paragraph 1 shall be submitted in П05-01 form under Appendix 1 hereof. The Appendix 1 is a constituent part of this Rulebook.

**General Requirements for Approval Issuance**

**Article 4**

The legal entity shall supplement the documentation under Articles 3 hereof with the following:

1) the written decision on the entry into the Business Entity Register, *i.e.*, the written decision from the competent court on the entry into the Court Registry;
2) the list of persons engaged in the radiation protection duties in П05-02 form under Appendix 1 hereof;

3) the list of procedures and instructions for the performance of radiation protection duties the approval is issued for;
4) the proof of the payment of the republic administrative fee for the issuance of the written decision on approval.

**Special Requirements for Approval for Performance of Radioactivity Monitoring**

**Article 5**

For the purpose of obtaining the approval for the performance of radioactivity monitoring, a legal entity shall supplement the documentation under Articles 3 and 4 hereof with the following:

1) the proof in П05-02 form under Appendix 1 hereof of the engagement at least four persons with a higher education degree acquired in the undergraduate studies in the scientific, *i.e.* professional field of physics, physics and chemistry, chemistry, technology or electrical and computer engineering of at least four years of duration or of 240 ECTS credits awarded, and with at least three years of work experience in the radioactivity monitoring duties;
2) the description and the drawing of the premises where the preparation, examination and retention of testing samples and data processing are conducted;
3) the list of laboratory equipment, including its measurement properties, which is used for sampling, sample preparation for testing, and testing, which complies with the prescribed meteorological conditions for use and the list of reference materials in П05-03 form under Appendix 1 hereof;
4) the copy of the Certificate and the Supplement to Certificate on the accreditation of the laboratories against ISO/IEC 17025, issued by the Accreditation Body of Serbia or an international accreditation body recognized by the national accreditation body for all testing types, testing methods and test subjects listed in Table 1 under Appendix 3, which is a constituent part of this Rulebook;
5) detailed description of the radioactivity monitoring duties which particularly contains the description of the sampling procedures and the procedures of sample preparation and sample measurements.

**Special Requirements for Approval for Performance of Particular Testing within Radioactivity Monitoring**

**Article 6**

For the purpose of obtaining the approval for the performance of particular testing within radioactivity monitoring, a legal entity shall supplement the documentation under Articles 3 and 4 hereof with the following:

1) the proof in П05-02 form under Appendix 1 hereof of the engagement at least four persons with a higher education degree acquired in the undergraduate studies in the scientific, *i.e.* professional field of physics, physics and chemistry, chemistry, technology or electrical and computer engineering of at least four years of duration or of 240 ECTS credits awarded, and with at least three years of work experience in performing particular testing within radioactivity monitoring for which the approval is applied for, namely:
    (1) at least one person if the application is submitted for particular testing comprising the maximum of two types of testing and one test subject or one type of testing notwithstanding the number of test subjects;

(2) at least two persons if the application is submitted for particular testing comprising the maximum of two types of testing notwithstanding the number of test subjects;
(3) at least three persons if the application is submitted for particular testing comprising the maximum of three types of testing notwithstanding the number of test subjects;
(4) at least four persons if the application is submitted for particular testing comprising four or more than four types of testing notwithstanding the number of test subjects;

2) the description and the drawing of the premises where the preparation, examination and retention of testing samples and data processing are conducted;
3) the list of laboratory equipment, including its measurement properties, which is used for sampling, sample preparation for testing, and testing, which complies with the prescribed meteorological conditions for use and the list of reference materials in П05-03 form under Appendix 1 hereof;
4) the copy of the Certificate and the Supplement to Certificate on the accreditation of laboratories against ISO/IEC 17025, issued by the Accreditation Body of Serbia or an international accreditation body recognized by the national accreditation body for the testing type, testing method and test subject the approval is applied for;
5) detailed description of the particular testing within radioactivity monitoring which particularly contains the description of sampling, sample preparation sample measurement procedures.

The list of the types and methods of testing within particular radioactivity monitoring testing is given in Table 2 under Appendix 3 hereof.

**Special Requirements for Approval for Measurements to Assess Level of Exposure to Ionizing Radiation of Exposed Workers, Other Members of Public and Public**

**Article 7**

For the purpose of obtaining the approval for the performance of the measurements to assess the level of exposure to ionizing radiation of the exposed workers, other members of the public and the public, a legal entity shall supplement the documentation under Articles 3 and 4 hereof with the following:

1) the proof in П05-02 form under Appendix 1 hereof of the engagement of persons with a higher education degree acquired in the undergraduate studies in the scientific, *i.e.* professional field of physics, physics and chemistry, chemistry, technology or electrical and computer engineering of at least four years of duration or of 240 ECTS credits awarded, with at least three years of work experience in the measurements under Article 1, paragraph 4 hereof, for which the approval is applied for, namely:
(1) at least one person if the application is submitted for the maximum of two instances of particular testing;
(2) at least two persons if the application is submitted for the maximum of four instances of particular testing;
(3) at least three persons if the application is submitted for the maximum of five or more than five instances of particular testing;
2) filled-out П05-04 form under Appendix 1 hereof containing the data on the exposed workers including the data on their health fitness to work in the ionizing radiation zone, as well as their training and education necessary to implement radiation safety measures;
3) the proof of the provision of the individual monitoring for the exposed workers;
4) the proof in П05-05 form under Appendix 1 hereof of the appointment of a radiation protection officer whose duties include those prescribed by Article 104, paragraph 3, points

5) to 12) and 14) of the Law on Radiation Protection and Nuclear Safety and Security, with a higher education degree in the undergraduate studies in a scientific, *i.e*., professional field of physics, chemistry, physics and chemistry, technology or electrical and computer engineering of at least four years of duration or of 240 ECTS credits awarded, with at least three years of work experience in the field of radiation and nuclear safety, and prerequisite education for a radiation safety officer;

5) the Description of the radiation protection measures ;
6) the description and the drawing of the premises where the preparation, examination and retention of testing samples and data processing are conducted;
7) the list of laboratory equipment, including its measurement properties, which is used for sampling, sample preparation for testing, and testing, which complies with the prescribed meteorological conditions for use and the list of reference materials in П05-03 form under Appendix 1 hereof;
8) the copy of the Certificate and the Supplement to Certificate on the accreditation of laboratories against ISO/IEC 17025, issued by the Accreditation Body of Serbia or an international accreditation body recognized by the national accreditation body for the measurements to assess the level of exposure to ionizing radiation of the exposed workers, other members of the public and the public the approval is applied for;
9) the description of the methodology for the assessment of the level of exposure to ionizing radiation of the exposed workers and other members of the public and the public;
10) detailed description of the duties comprising the measurements to assess the level of exposure to ionizing radiation of the exposed workers and other members of the public and the public, which particularly contains the purpose of the measurements and the description of the measurement procedure.

For the purpose of obtaining the approval for the measurements under Article 1, paragraph 4, point 8) hereof, a legal entity may submit the Certificate of the accreditation against ISO 15189 instead of ISO/IEC 17025.

The content of the Description of the radiation protection measures under paragraph 1, point 5) is given under Appendix 2 hereof. Appendix 2 is a constituent part of this Rulebook.

The holder of the approval for radiation protection duties shall review the Description of the radiation protection measures under paragraph 1, point 5) at least once every five years, and imperatively prior to any change in the operational conditions or procedures.

**Special Requirements for Approval for Decontamination of Workplace Environment and Environment**

**Article 8**

For the purpose of obtaining the approval for decontamination of workplace environment and the environment, a legal entity shall supplement the documentation under Articles 3 and 4 hereof with the following:

1) the proof in П05-02 form in Appendix 1 hereof of the engagement at least one person with a higher education degree acquired in the undergraduate studies in the scientific, *i.e.* professional field of physics, physics and chemistry, chemistry, technology or electrical and computer engineering of at least four years of duration or of 240 ECTS credits awarded, with at least three years of work experience in the field of decontamination of workplace

environment and the environment including the data on the training and education for the implementation of radiation safety measures;

2) filled-out П05-04 form under Appendix 1 hereof containing the data on the exposed workers including the data on their health fitness to work in the ionizing radiation zone, as well as thier training and education necessary to implement radiation safety measures;
3) the proof of the provision of the individual monitoring for the exposed workers;
4) the proof in П05-05 form under Appendix 1 hereof of the appointment of a radiation protection officer whose duties include those prescribed under Article 104, paragraph 3, points 5) to 12) and 14) of the Law on Radiation Protection and Nuclear Safety and Security, with a higher education acquired in the undergraduate studies in the scientific, *i.e.* professional field of physics, chemistry, physics and chemistry, technology or electrical and computer engineering of at least four years of duration or of 240 ECTS credits awarded, with at least three years of work experience in the field of radiation and nuclear safety and the education necessary for a radiation safety measures officer;
5) the Description of the radiation protection measures;
6) the list of the equipment and tools for decontamination including their properties;
7) the list of measurement equipment, including its properties, which complies with the prescribed meteorological conditions for use and the list of reference materials in П05-03 form under Appendix 1 hereof;
8) the copy of the Certificate and the Supplement to Certificate on the accreditation of laboratories against ISO/IEC 17025, issued by the Accreditation Body of Serbia or an international accreditation body recognized by the national accreditation body for the measurement of surface decontamination and ambient dose equivalent rate;
9) the data from the authorization for the transport of dangerous goods Class 7 *ADR/RID/AND* (radioactive material) or the copy of the contract with the legal entity or the entrepreneur holding the authorization for the transport of dangerous goods Class 7 *ADR/RID/AND* (radioactive material);
10) detailed description of the duties comprising the decontamination of the workplace environment and the environment including in particular the description of the decontamination procedures, the description of the tools and equipment used during decontamination, the procedure of radioactive material transport and the radiological characterization procedures serving to determine the presence of contamination, and the measurements serving to determine decontamination efficiency, as well as the training and re-training procedures for the persons engaged in decontamination;
11) the copy of the contract with the licensee for the operation of the central radioactive waste storage;
12) the procedure for radioactive waste management until its handover to the central storage or its release from the regulatory control which shall contain in particular:
    (1) the manner in which radioactive waste is collected (collection and segregation of radioactive waste):
    (2) assumed categories and classes of radioactive waste;
    (3) technical, organizational and other measures to control radioactive waste generation (measures implemented with the aim of reducing the volume of the generated radioactive waste);
    (4) the conditions for handover of radioactive waste to the licensee for the operation of the central radioactive waste storage (data on containers, central storage acceptance criteria and organization of transport);

(5) the requirements for the environmental discharges (proof of the fulfilment of the requirements for a discharge into the environment, the manner of discharging, the process of obtaining the consent from the Directorate);
(6) the manner of maintaining the radioactive waste records.

The content of the Description of radiation protection measures under paragraph 1, point 5) of this Article is given under Appendix 2 hereof.

The holder of the approval for radiation protection duties shall review the Description of the radiation protection measures under paragraph 1, point 5) of this Article at least once every five years, and imperatively prior to any change in the operational conditions or procedures.

**Special Conditions for Approval for Staff Decontamination**

**Article 9**

For the purpose of obtaining the approval for the performance of staff decontamination, a legal entity shall supplement the documentation under Articles 3 and 4 hereof with the following:

1) the proof in П05-02 form under Appendix 1 hereof of the engagement of at least one medical doctor or a person with higher education degree acquired in the undergraduate studies in the scientific, *i.e.* professional field of physics, physics and chemistry, chemistry, technology or electrical and computer engineering of at least four years of duration or of 240 ECTS credits awarded, including the data on the training and education for the implementation of radiation protection measures;
2) filled-out П05-04 form under Appendix 1 hereof containing the data on the exposed workers including the data on their health fitness to work in the ionizing radiation zone, as well as their training and education necessary to implement radiation safety measures;
3) the proof of the provision of the individual monitoring for the exposed workers;
4) the proof in П05-05 form under Appendix 1 hereof of the appointment of a radiation protection officer whose duties include those prescribed by Article 104, paragraph 3, points 5) to 12) and 14) of the Law on Radiation Protection and Nuclear Safety and Security, with a higher education degree acquired in the undergraduate studies in the scientific, *i.e.* professional field of physics, chemistry, physics and chemistry, technology or electrical and computer engineering for at least four years or of 240 ECTS credits awarded, with at least three years of work experience in the field of radiation and nuclear safety and the education necessary for a radiation safety officer;
5) the Description of the radiation protection measures;
6) the description and drawing of the premises where staff decontamination is performed;
7) the list of measurement equipment, including its properties, which complies with the prescribed meteorological conditions for use and the list of reference materials in П05-03 form under Appendix 1 hereof;
8) the list of equipment and tools used for staff decontamination with their properties;
9) the copy of the Certificate and the Supplement to Certificate on the accreditation of laboratories against ISO/IEC 17025, issued by the Accreditation Body of Serbia or an international accreditation body recognized by the national accreditation body for the measurement of surface decontamination and ambient dose equivalent rate;
10) detailed description of the duties comprising staff decontamination including in particular the description of the staff decontamination procedures, the description of the tools and equipment used for staff decontamination, and the radiological characterization procedures

serving to determine the presence of contamination, and the measurements serving to determine staff decontamination efficiency, as well as the training and re-training procedures for the persons engaged in decontamination;

11) the data from the authorization for the transport of dangerous goods Class 7 *ADR/RID/AND* (radioactive material) or the copy of the contract with the legal entity or the entrepreneur holding the authorization for the transport of dangerous goods Class 7 *ADR/RID/AND* (radioactive material);
12) the copy of the contract with the licensee for the operation of the central radioactive waste storage;
13) the procedure for radioactive waste management until its handover to the central storage or its release from the regulatory control, which shall contain in particular:
    (1) the manner in which radioactive waste is collected (collection and segregation of radioactive waste):
    (2) assumed categories and classes of radioactive waste;
    (3) technical, organizational and other measures to control radioactive waste generation (measures applied with the aim of reducing generated radioactive waste);
    (4) the conditions for handover of radioactive waste to the licensee for the operation of the centralized radioactive waste storage (data on containers, centralised storage acceptance criteria and organization of transport);
    (5) the requirements for the environmental discharges (proof of the fulfilment of the requirements for a discharge into the environment, the manner of discharging, the process of obtaining the consent from the Directorate);
    (6) the manner of maintaining the radioactive waste records.

The content of the Description of radiation protection measures under paragraph 1, point 5) of this Article is given under Appendix 2 hereof.

The holder of the approval for radiation protection duties shall review the Description of the radiation protection measures under paragraph 1, point 5) of this Article at least once every five years, and imperatively prior to any change in the operational conditions or procedures.

**Special Requirements for Approval for Removal of Orphan Sources**

**Article 10**

For the purpose of obtaining the approval for the removal of orphan sources, a legal entity shall supplement the documentation under Articles 3 and 4 hereof with the following:

1) the proof in П05-02 form under Appendix 1 hereof of the engagement at least one person with a higher education degree acquired in the undergraduate studies in the scientific, *i.e.* professional field of physics, physics and chemistry, chemistry, technology or electrical and computer engineering of at least four years of duration or of 240 ECTS credits awarded, with at least three years of work experience in the operations with orphan sources, including the data on the training and education for the implementation of radiation protection measures;
2) filled-out П05-04 form under Appendix 1 hereof containing the data on the exposed workers including the data on their health fitness to work in the ionizing radiation zone, as well as their training and education necessary to implement radiation safety measures;
3) the proof of the provision of the individual monitoring of the exposed workers;
4) the proof in П05-05 form under Appendix 1 hereof of the appointment of a radiation protection officer whose duties include those prescribed by Article 104, paragraph 3, points

5) to 12) and 14) of the Law on Radiation Protection and Nuclear Safety and Security, who has acquired a higher education degree acquired in the undergraduate studies in the scientific, *i.e.* professional field of physics, chemistry, physics and chemistry, technology or electrical and computer engineering of at least four years of duration or of 240 ECTS credits awarded, with at least three years of work experience in the field of radiation and nuclear safety and the education necessary for a radiation safety measures officer;

5) the Description of the radiation protection measures;
6) the list of equipment used for the removal of orphan sources, orphan sources transport and retention containers including properties, and decontamination equipment in П05-06 form under Appendix 1 hereof ;
7) the list of measurement equipment, including its properties, which complies with the prescribed meteorological conditions for use in П05-03 form under Appendix 1 hereof;
8) the copy of the Certificate and the Supplement to Certificate on the accreditation of laboratories against ISO/IEC 17025, issued by the Accreditation Body of Serbia or an international accreditation body recognized by the national accreditation body for the measurement of surface decontamination and ambient dose equivalent rate;
9) the data on the license for the operations with sealed radiation sources, especially on the installation and dismantling of sealed sources of categories I, II, III in the devices with incorporated radiation sources, or a copy of the contract with the legal entity or entrepreneur holding such license;
10) the data from the authorization for the transport of dangerous goods Class 7 *ADR/RID/AND* (radioactive material) or the copy of the contract with the legal entity or the entrepreneur holding the authorization for the transport of dangerous goods Class 7 *ADR/RID/AND* (radioactive material);
11) detailed description of the duties comprising the removal of orphan sources including in particular the description of the contamination detection and orphan sources removal procedures, decontamination procedure, the description of the procedure for the removal of and care for the contaminated material and the orphan sources, the procedure of radioactive material transport, the description of the tools and the equipment for the orphan sources removal and decontamination, and radiological characterization procedures serving to determine the presence of orphan sources and contamination, and the measurements serving to determine decontamination efficiency, as well as the training and re-training procedures for the persons engaged in the orphan sources removal procedures;
12) the copy of the contract with the licensee for the operation of the central radioactive waste storage;
13) the procedure for the radioactive waste management until its handover to the central storage or its release from the regulatory control which shall contain in particular:
    (1) the manner in which radioactive waste is collected (collection and segregation of radioactive waste):
    (2) assumed categories and classes of radioactive waste;
    (3) technical, organizational and other measures to control radioactive waste generation (measures applied with the aim of reducing generated radioactive waste);
    (4) the conditions for handover of radioactive waste to the licensee for the operation of the centralized radioactive waste storage (data on containers, centralised storage acceptance criteria and organization of transport);
    (5) the requirements for the environmental discharges (proof of the fulfilment of the requirements for a discharge into the environment, the manner of discharging, the process of obtaining the consent from the Directorate);

(6) the manner of maintaining the radioactive waste records.

The content of the Description of radiation protection measures under paragraph 1, point 5) of this Article is given under Appendix 2 hereof.

The holder of the approval for radiation protection duties shall review the Description of the radiation protection measures under paragraph 1, point 5) of this Article at least once every five years, and imperatively prior to any change in the operational conditions or procedures.

**Special Requirements for Approval for Preparation of Safety Analysis Report and Radiation Protection Programme**

**Article 11**

For the purpose of obtaining the approval for the preparation of the Safety Analysis Report and Radiation Protection Programme, a legal entity or entrepreneur shall supplement the documentation under Articles 3 and 4 hereof with the following:

1) the proof in П05-02 form under Appendix 1 hereof of the engagement at least one person with a higher education degree acquired in the undergraduate studies in the scientific, *i.e.* professional field of physics, physics and chemistry, chemistry, technology or electrical and computer engineering of at least four years of duration or of 240 ECTS credits awarded, with at least three years of work experience in the preparation of Safety Analysis Report and Radiation Protection Programme;
2) the description of the methodology used for the safety assessment and design of protection barriers, including the reference documents.

**Special Requirements for Approval for Training and Education of Exposed Workers and Radiation Safety Officers**

**Article 12**

For the purpose of obtaining the approval for training and education of the exposed workers and radiation safety officers, a legal entity or entrepreneur shall supplement the documentation under Articles 3 and 4 hereof with the following:

1) the list of training and education programmes in accordance with the regulation governing the training and education in the field of radiation protection for which the approval is applied for in П05-07 form under Appendix 1 hereof, which includes:
   (1) the name of the training and education programme;
   (2) the list of engaged lecturers for each training and education programme;
   (3) the list of teachers in practical exercises for each training and education programme;
   (4) the list of teaching resources and education equipment for each training and education programme;
   (5) the information on the authorization holder for the performance of radiation practises or nuclear activities where the education programme is conducted;
2) the proof that the persons under point 1) subpoint (2) have acquired a higher education degree in the undergraduate studies or specialized vocational studies in the scientific, *i.e.* professional field of medicine, veterinary medicine, stomatology, physics, physics and chemistry, chemistry, machine engineering, geology, technology or electrical and computer engineering of at least 3 years of duration and of 180 ECTS credits awarded, with at least three years of work experience in the field of radiation protection;

3) the proof that the persons under point 1) subpoint (3) engaged by the authorization holder have at least three years of work experience in the relevant practise;
4) the copy of the contract with the authorization holders for the relevant radiation practises or nuclear activities where the education programme is conducted. The contract with the authorization holder for the relevant radiation practise or nuclear activity shall contain in particular: the name of the programme for which the contract is entered into, the name of a radiation practise or a nuclear activity, and the names of the persons engaged by the authorization holder conducting the education programme;
5) the syllabus and the curriculum for each education programme in accordance with the regulations governing the education and training in the field of radiation protection;
6) the Description of the applied radiation protection measures during the implementation of the education programme.

The content of the Description of the radiation protection measures under paragraph 1, point 6) of this Article is given under Appendix 2 hereof.

The holder of the approval for the radiation protection duties shall review the Description of the radiation protection measures under paragraph 1, point 6) of this Article at least once every year, and imperatively prior to every change in operational conditions and procedures.

**Special Requirements for Approval for Testing of Radiation Sources Parameters for Quality Control of Radiation Protection Measures**

**Article 13**

For the purpose of obtaining the approval for testing of radiation sources parameters for the purpose of quality control of the radiation protection measures, a legal entity shall supplement the documentation under Articles 3 and 4 hereof with the following:

1) the proof in П05-02 form in Appendix 1 hereof of the engagement at least one person with a higher education degree acquired in the basic academic studies in the scientific, *i.e.* specialized field of physics, physics and chemistry, chemistry, technology or electrical and computer engineering of at least four years of duration or of 240 ECTS credits awarded, with at least three years of work experience in the operations of testing of radiation sources parameters for the purpose of quality control of the radiation protection measures;
2) filled-out П05-04 form in Appendix 1 hereof containing the data on the exposed workers to confirm their health fitness to work in the ionizing radiation zone, as well as their training and education necessary to implement radiation safety measures;
3) the proof of the provision of the individual monitoring of the exposed workers;
4) the proof in П05-05 form in Appendix 1 hereof of the appointment of a radiation protection officer whose duties include those prescribed by Article 104, paragraph 3, points 5) to 12) and 14) of the Law on Radiation Protection and Nuclear Safety and Security, who has acquired a higher education degree in the undergraduate studies in the scientific, *i.e.* professional field of physics, chemistry, physics and chemistry, technology or electrical and computer engineering of at least four years of duration or of 240 ECTS credits awarded, with at least three years of work experience in the field of radiation and nuclear safety and the education necessary for a radiation safety measures officer;
5) the Description of radiation protection measures;
6) the list of measuring equipment with its properties, which fulfils the prescribed meteorological conditions in П05-03 form in Appendix 1 hereof;

7) the copy of the Certificate and the Supplement to Certificate on the accreditation of laboratories against SRPS ISO/IEC 17025, or a copy of the certificate issued by an international accreditation body recognized by the national accreditation body for the measurement of all parameters prescribed by a special Rulebook regulating the use of radiation sources in medicine and aiming at the quality control of radiation sources protection measures under Appendix 4, which is a constituent part of this Rulebook, and which is subject to a special application;
8) detailed description of the testing of radiation sources parameters for the purpose of quality control of the radiation protection measures, which particularly contains the description of the procedures of radiation sources parameters testing for the quality control of the radiation protection measures for each device, including the list of measuring equipment being used.

The content of the Description of the radiation protection measures under paragraph 1, point 6) of this Article is given in Appendix 2 hereof.

The holder of the approval for the radiation protection duties shall revise the Description of radiation protection measures under paragraph 1, point 6) of this Article at least once every year, and imperatively prior to every change in operational conditions and procedures.

**Maintaining Records**

**Article 14**

The approval holder shall maintain the records on the conducted radiation protection duties.

The content of the report on the conducted duties under paragraph 1 of this Article is given under Appendix 5, which is a constituent part of this Rulebook.

The approval holder shall retain the reports on the conducted work for the following periods:

1) radioactivity monitoring or particular testing within the monitoring – 10 years;
2) measurements to assess the level of exposure to ionizing radiation of the exposed workers, other members of the public and the public – until their reaching of the age of 75 years or not shorter than 3 years after the end of exposure;
3) decontamination of the workplace environment and the environment – 10 years;
4) decontamination of staff – 30 years;
5) removal of orphan sources – 5 years;
6) preparation of the Safety Analysis Report and Radiation Protection Programme – 5 years;
7) training and education of the exposed workers and radiation safety officers – 10 years;
8) testing of radiation sources parameters for the purpose of quality control of the radiation protection measures – 5 years.

**Reporting**

**Article 15**

The approval holder shall deliver to the Directorate the records of the conducted radiation protection duties prior to 31 March of the current year for the previous year.

The records under paragraph 1 shall be submitted electronically commensurate with the contents of П05-08 in Appendix 1 hereof.

The approval holder under Article 1, paragraph 2, points 1) and 2) shall, in addition to the report under paragraph 1 of this Article, deliver to the Directorate the risk-informed analysis of the conducted

measurement results if they point at a possible exposure of the exposed workers, other members of the public and the public and the environment above the prescribed limits or reference levels as early as reasonably achievable, and within five days at the latest of conducting the measurement which confirms the non-compliance.

**Article 16**

The applicant shall deliver to the Directorate all data required by the forms electronically in the format the Directorate publishes on its official website.

**Transitional and Final Provisions**

**Article 17**

The procedures for obtaining the approvals from the Directorate which had not been finalized until the day of the entry of this Rulebook into force shall be finalized in accordance with the provisions of the regulations applicable at the time of the procedure commencement.

**Article 18**

The holders of the approvals issued in accordance with the provisions in force prior to entry into force of this Rulebook, shall comply their work and operations with the provisions of this Rulebook, within two years as of the entry into force of this Rulebook.

**Article 19**

On the day of entry of this Rulebook into force, the Rulebook on Conditions for Obtaining Approval for Radiation Protection Duties ("Official Gazette of RS", No.101/16) and the Rulebook on Records of Conducted Radiation Protection Duties ("Official Gazette of RS", No. 17/11) shall cease to exist.

**Entry into Force**

**Article 20**

This Rulebook shall enter into force on the eighth day of its publication in "the Official Gazette of the Republic of Serbia".

**Belgrade, 14 December, 2021**

**Ref. No. 110-00-20/2021-02**

**BOARD OF THE DIRECTORATE**

**CHAIRPERSON**

**Maja Gojkovic, LLB**

**APPENDIX 1**

**П05-01 Form**

**Application for the approval for the performance of radiation protection duties**

I Data on the legal entity

| | | | | | |
|---|---|---|---|---|---|
| Business name | | | Registration number | | |
| | | | TIN | | |
| Place | | Postal code | | Municipality | |
| Address | | Telephone | | e-mail | |
| Radiation protection officer (optional) | | | | | |
| Contact person | | | | | |

II Data on the type of radiation protection duties the approval is issued for

Radiation protection duties the approval is issued for:
(Fill out a separate application for each practise under Article 1. of the Rulebook on Conditions for Obtaining Approval for Radiation Protection Duties. List the types od duties the applied is applied for, if applicable.)

**Particular testing within monitoring**

☐ testing of the level of external radiation;
☐ testing of the content of gamma-ray-emitting radionuclides;
☐ testing of the content of strontium-90;
☐ testing of the total alpha and total beta activity;
☐ testing of the content of tritium;
☐ testing of radon concentration;
☐ testing of alpha-particle emitting radionuclides.

☐ **Radioactivity monitoring**

**The measurements to assess the level of exposure to ionizing radiation of the exposed workers, other members of the public and the public**

☐ measurements of the ambient dose equivalent rate;
☐ measurements of the ambient dose equivalent;
☐ measurements of personal dose equivalents Hp (10), Hp (3) and Hp (0.07);
☐ measurements of radionuclide activity in workplace samples;
☐ measurements of surface contamination;
☐ in-vivo measurements;
☐ in-vitro measurements;
☐ biodosimetry measurements of individual exposure.

☐ **Decontamination of workplace environment and the environment**

☐ **Decontamination of staff**

☐ **Removal of orphan sources**

☐ **Preparation of the Safety Analysis Report and the Radiation Protection Programme**

**Training and education of the exposed workers and radiation safety officers**

- ☐ Training and education of the exposed workers;
- ☐ Training and education of the radiation safety officers

**Testing of radiation sources parameters for the purpose of quality control of the radiation protection measures**

X-ray diagnostics and interventional radiology

- ☐ x-ray imaging machine;
- ☐ x-ray illuminator;
- ☐ x-ray mammography machine ;
- ☐ x-ray CET machine;
- ☐ x-ray ostedensitometry machine;
- ☐ x-ray intraoral machine;
- ☐ x-ray orthopantomography machine;
- ☐ x-ray dental cone beam computed tomography (CBCT).

Radiotherapy

- ☐ Linear accelerator;
- ☐ x-ray CET machine – simulator;
- ☐ sealed radiation source Co-60 machine;
- ☐ kilovoltage x-ray therapy machine;
- ☐ brachytherapy machine.

III Confirmation by the legal entity

Under full substantive and criminal liability we hereby confirm the following data as accurate.

| | | | |
|---|---|---|---|
| Place | | Name of the approved person | |
| Date | | Signature | |

**П05-02 Form**

**The list of engaged persons**

**I Data on the legal entity**

| | | | |
|---|---|---|---|
| Business name | | Registration number | |
| | | TIN | |

II Data on the engaged persons

| No. | 1. | 2. | 3. | 4. | 5. | 6. | 7. | 8. | 9. | 10. |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |

1. Name and surname;
2. Profession;
3. Qualifications;
4. Job title;
5. Date of entry into a fixed-term employment contract;
6. Duration of the fixed-term employment contract;
7. Work experience in radiation protection duties the approval is applied for;
8. Date of issuing the certificate on the training and education for radiation safety duties, not older than five years;
9. The name of the training and education programme for radiation protection duties;
10. Business name of the approval holder issuing the certificate on the training and education programme for radiation safety duties.

III Confirmation by the legal entity

Under full substantive and criminal liability we hereby confirm the following data as accurate.

| | | | |
|---|---|---|---|
| Place | | Name of the approved person | |
| Date | | Signature | |

**П05-03 Form**

**List of measuring and laboratory equipment**

I Data on the legal entity

| | | | |
|---|---|---|---|
| Business name | | Registration number | |
| | | TIN | |

II Data on the equipment

| No. | Name | Type and characteristics | Calibration valid to: |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

III List of reference material

| No. | Name | Radionuclides | Maximum activity |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

IV List of software

| No. | Name | Field of use |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

V Confirmation by the legal entity

Under full substantive and criminal liability we hereby confirm the following data as accurate.

| | | | |
|---|---|---|---|
| Place | | Name of the approved person | |
| Date | | Signature | |

**П05-04 Form**

**List of exposed workers**

I Data on the legal entity

| | | | |
|---|---|---|---|
| Business name | | Registration number | |
| | | TIN | |

II Data on the exposed workers

| No. | 1. | 2. | 3. | 4. | 5. | 6. | 7. | 8. | 9. | 10. | 11. | 12. | 13. | 14. | 15. |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |

1. Name and surname;
2. Personal identity number;
3. Occupation;
4. Qualifications;
5. Date of acquiring qualifications;
6. Job title;
7. Date of entry into a fixed-term employment contract;
8. Duration of the fixed-term employment contract;
9. Date of starting work in radiation zone;
10. Category of the exposed worker A/B;
11. Date of issuing the health certificate not older than one year containing the confirmation the person is fit to work in the radiation zone;
12. Date of issuing the certificate on training and education for radiation safety duties not older than five years;
13. Name of the training and education programme for radiation safety measures;
14. Business name of the approval holder issuing the certificate on training and education for radiation safety duties;

15. Date of cessation of work in the radiation zone.

III Confirmation by the legal entity

Under full substantive and criminal liability we hereby confirm the following data as accurate.

| | Name and surname | Date | Signature |
|---|---|---|---|
| Radiation protection officer | | | |
| Approved person with the legal entity | | | |

**П05-05 Form**

**Form intended for radiation protection officer**

I Data on the legal entity

| | | | |
|---|---|---|---|
| Business name | | Registration number | |
| | | TIN | |

II Data on the radiation protection officer

| No. | 1. | 2. | 3. | 4. | 5. | 6. | 7. | 8. | 9. | 10. | 11. | 12. | 13. | 14. | 15. |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |

1. Name and surname;
2. Personal identity number;
3. Occupation;
4. Qualifications;
5. Date of acquiring qualifications;
6. Name of the institution issuing the acquired degree of qualifications;
7. Job title;
8. Date of entry into a fixed-term employment contract;
9. Duration of the fixed-term employment contract;
10. Date of starting work in radiation zone;
11. Date of appointment;
12. Date of issuing the certificate on training and education for radiation safety duties of a radiation protection officer, not older than five years;
13. Name of the training and education programme for radiation safety duties of a radiation protection officer;
14. Business name of the approval holder issuing he certificate on the training and education programme of radiation safety duties;
15. Date of cessation of work of the radiation protection officer.

III Confirmation by the legal entity

Under full substantive and criminal liability we hereby confirm the following data as accurate.

| | | | |
|---|---|---|---|
| Place | | Name of the approved person | |
| Date | | Signature | |

**П05-06 Form**

**List of equipment used for the removal of orphan sources, orphan sources transport and retention containers, and decontamination equipment**

I Data on the legal entity

| | | | |
|---|---|---|---|
| Business name | | Registration number | |
| | | TIN | |

II Data on the equipment and containers

| No. | Name | Characteristics |
|---|---|---|
| | | |
| | | |
| | | |

III Confirmation by the legal entity

Under full substantive and criminal liability we hereby confirm the following data as accurate.

| | Name and surname | Date | Signature |
|---|---|---|---|
| Radiation protection officer | | | |
| Approved person with the legal entity | | | |

**П05–07 Form**

**List of training and education programmes for radiation safety duties**

I Data on the legal entity

| | | | |
|---|---|---|---|
| Business name | | Registration number | |
| | | TIN | |

II Data on the programme

| No. | Programme title | List of engaged lecturers | List of trainers * | List of teaching tools and equipment | Data on the authorization holder* |
|---|---|---|---|---|---|
| 1. | | 1 …<br>2. …<br>. | 1 …<br>2. …<br>. | 1 …<br>2. …<br>. | 1 …<br>2. …<br>. |
| 2. | | 1 …<br>2. …<br>. | 1 …<br>2. …<br>. | 1 …<br>2. … | 1 …<br>2. …<br>. |

* only for the programmes including practical exercises

III Confirmation by the legal entity

Under full substantive and criminal liability we hereby confirm the following data as accurate.

| | | | |
|---|---|---|---|
| Place | | Name of the approved person | |
| Date | | Signature | |

**П05-08 Form**

**Records of conducted radiation protection duties**

I Data on the approved legal entity

| | | | | | |
|---|---|---|---|---|---|
| Business name | | | Registration number | | |
| | | | TIN | | |
| Place | | Postal code | | Municipality | |
| Address | | Telephone | | e-mail | |
| Title of Approval | | | | | |
| Approval number | | Date of issuance | | Contact person | |

II Record of conducted duties

| No. | 1. | 2. | 3. | 4. | 5. | 6. | 7. | 8. |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |
| | | | | | | | | |

1. Business name of a legal entity/entrepreneur where the duties have been conducted;
2. Registration number;
3. Legal entity/entrepreenur address;
4. Name of practise;
5. Type of duty;
6. Number of conducted duties;
7. List of radiation sources or a list of samples and the type of measurement not complying with the regulations, including the list of non-compliances;

8. Note

III Analysis of the conducted measurement results including the exposure assessment

Relevant only for the approvals under Article 1, paragraph 2, points 1) and 2)

IV Confirmation by the legal entity

Under full substantive and criminal liability we hereby confirm the following data as accurate.

| | | | |
|---|---|---|---|
| Place | | Name of the approved person | |
| Date | | Signature | |

**APPENDIX 2**

**CONTENT OF DESCRIPTION OF RADIATION MEASURES**

The document shall imperatively include the following information:

1. Title;
2. Review number;
3. Name and signature of radiation protection officer reviewing and approving the document;
4. Data on the legal entity
    1) Business name;
    2) Address;
    3) Reference number of entry into the Business Registry Agency, *i.e.* written decision by the competent court;
    4) Business number;
    5) TIN;
    6) Telephone;
    7) Web address;
    8) Contact person;
    9) e-mail address.
5. Data on the radiation protection duties

The document shall contain at least the following sections:

**1. Introduction**

The purpose and the scope of the document;

**2. Requirements and limitations**

The requirements and limitations for the performance of radiation protection duties;

**3. Organizational structure and allocation of responsibilities**

The allocation of responsibilities in all management during the occupational exposure to ionizing radiation;

**4. Safety assessment**

The safety assessment for the performance of radiation protection duties in normal circumstances and in abnormal circumstances including emergency events, as well as the analysis of the reasonably foreseeable initiating events likely to lead to inadequate work;

**5. Conduct in case of an emergency event**

The evaluation of the possible emergency events and related measures of prevention, mitigation and rehabilitation in case of an emergency event;

**6. Protection of exposed workers**

The establishment of rules of conduct for the engaged persons and/or the exposed workers and control of their work, the establishment of individual monitoring for the exposed workers and the environmental monitoring;

**7. Conduct with radioactive waste**

The procedures related to radioactive waste management, the description of a repository and the data on the contract with the operator of the central radioactive waste storage;

**8. Recording and informing**

The system of recording and informing on all required information relating to the control of radiation exposure, decisions on the implementation of radiation protection measures and individual monitoring of the exposed workers.

**APPENDIX 3**

**Table 1: Types of testing, methods of testing and test subjects within radioactivity monitoring**

| Type | Method | Subject |
|---|---|---|
| Testing of the level of external radiation | Measurement of the ambient dose equivalent from gamma-ray spectra | – air |
| | Measurement of the ambient dose equivalent from gamma-ray spectra in air by passive dosimeters | |
| Testing of the content of gamma-emitting radionuclides | Gamma-spectrometry analysis | – aerosols<br>– solid and liquid fallout<br>– drinking water<br>– surface waters<br>– river sediment<br>– foodstuffs and feeding stuff<br>– bioindicators<br>– soil |
| Testing of total alpha and total beta activity | Measurement of total alpha and total beta activity obtained with proportional counter | – drinking water<br>– surface waters |
| Testing of the content of strontium – 90 | Measurement beta activity obtained with a proportional counter or measurement of beta activity obtained with scintillation detectors | – drinking water<br>– surface waters<br>– river sediment<br>– foodstuffs and feeding stuff<br>– soil |
| Testing of the tritium content | Measurement of beta activity obtained with scintillation detectors | – surface waters<br>– drinking water<br>– river sediment |
| Testing of radon concentration | Gamma-spectrometry analysis after the absorption in activated charcoal filters<br>or<br>Measurement of radon concentration with trace detectors | – air |

**Table 2 Types and methods of particular testing within radioactivity monitoring**

| Type | Method |
|---|---|
| Testing of external radiation level | Measurement of the ambient dose equivalent from gamma-ray spectra |
| | Measurement of the ambient dose equivalent from gamma-ray spectra in air by passive dosimeters |
| Testing of the content of gamma-emitting radionuclides | Gamma-spectrometry analysis |
| Testing of total alpha and total beta activity | Measurement of total alpha and total beta activity obtained with proportional counter |
| Testing of the content of strontium – 90 | Measurement of beta activity obtained with proportional detectors |
| | Measurement of beta activity obtained with scintillation detectors |
| Testing of the tritium content | Measurement of beta activity obtained with scintillation detectors |
| Testing of radon concentration | Gamma-spectrometry analysis after the absorption in activated charcoal filters |
| | Measurement of radon concentration with alpha trace detectors |
| | Alpha spectrometry analysis |
| Testing of alpha-particle emitting radionuclides | Alpha spectrometry analysis |
| | Measurement of alpha activity with proportional counters |

**APPENDIX 4**

**Radiation sources whose parameters are tested for the purpose of quality control of the radiation protection measures**

| Scope | Subject |
|---|---|
| X-ray diagnostics and interventional radiology | X-ray imaging machine |
| | X-ray illumination machine |
| | X-ray mammography machine |
| | X-ray computed tomography machine |
| | X-ray ostedensitometry machine |
| | X-ray intraoral machine |
| | X-ray orthopantomography machine |
| | X-ray dental cone beam computed tomography (CBCT) |
| Radiotherapy | Linear accelerator |
| | X-ray computed tomography machine – simulator |
| | Sealed radiation source Co-60 machine |
| | Kilovoltage x-ray therapy machine |
| | Brachytherapy machine |

**APPENDIX 5**

**The content of the report on the conducted radiation protection duties**

I General information on the conducted duties:

1) Business name of the legal entity/entrepreneur where the duty has been conducted;
2) Registration number;
3) Address of the legal entity/entrepreneur;
4) Type of duty;
5) Number of conducted duties;
6) Note

II Data according to the type of duty (if applicable)

1) Radioactivity monitoring or particular testing within monitoring:
   (1) methods used and the data on sample collection;
   (2) methods used and the data on sample preparation;
   (3) measurement methods used and (time of sample measurement, sample measurement geometry, etc.);
   (4) geographic coordinates of the sampling location or measurements in case of external radiation level measurement;
   (5) measurement results including measuring uncertainties;
   (6) assessed effective dose for the public.
2) Measurements to assess the level of exposure to ionizing radiation of the exposed workers, other members of the public and the public:
   (1) measurement of ambient dose equivalent rate, measurement of ambient dose equivalent, measurements of radionuclide activity in workplace samples and measurements of surface decontamination:

      1. methods used and data on sample collection;
      2. methods used and the data on sample preparation;
      3. measurement methods used (time of sample measurement, sample measurement geometry, etc.);
      4. geographic coordinates of the sampling location or measurements in case of external radiation level measurement;
      5. measurement results including measuring uncertainties;
      6. assessed effective dose.

   (2) measurements of personal dose equivalents Hp (10), Hp (3) and Hp (0.07):
      1. Name of the exposed worker;
      2. Personal identification number;
      3. Sex;
      4. Date of birth;
      5. Citizenship;
      6. Job title;
      7. Position;
      8. Business name, address and employer's registration number;
      9. Category (a or b);
      10. Date of individual monitoring commencement;

11. Date of individual monitoring cessation (if applicable);
12. Assessed effective dose (if applicable);
13. Dose equivalent for eye lens (if applicable);
14. Dose equivalent for skin (if applicable);
15. Dose equivalent for extremities (if applicable);
16. Assessed effective dose in case of an emergency event.

(3) *in-vivo* measurements, *in-vitro* measurements and biodosimetry measurements of individual exposure:

1. Name of the exposed worker;
2. Personal identification number;
3. Sex;
4. Date of birth;
5. Citizenship;
6. Job title;
7. Position;
8. Business name, address and employer's registration number;
9. Category (a or b);

3) Decontamination of workplace environment and the environment
   (1) decontamination location;
   (2) decontamination date;
   (3) radionuclides;
   (4) applied decontamination techniques;
   (5) dose rate on the site following decontamination;
   (6) radionuclide activity on the site following decontamination;
   (7) data on the exposure of the exposed workers in case of an emergency event.
4) Staff decontamination
   (1) name and surname;
   (2) decontamination date;
   (3) radionuclides;
   (4) applied decontamination techniques.
5) Removal of orphan sources
   (1) device name;
   (2) type and model;
   (3) producer;
   (4) serial number;
   (5) producer of radioactive source;
   (6) serial number of a radioactive source;
   (7) radionuclide;
   (8) maximum source activity;
   (9) dose rate in contact;
   (10) dose rate on 1-meter distance from the source;
   (11) date of handover to the centralized storage;
   (12) data on the exposure of the exposed workers in case of an emergency event.

NOTE: the data under points (1) to (8) shall be delivered if determinable.

6) Training and education
   (1) programme name;
   (2) duration;
   (3) location;
   (4) number of candidates;
   (5) number of candidates successfully passing the exam.
7) Testing of radiation sources parameters for the purpose of quality control of the radiation protection measures:
   (1) in the field of x-ray diagnostics and interventional radiology;
      1. Name of x-ray machine (test subject);
      2. Producer of an x-ray machine;
      3. Type and model of an x-ray machine;
      4. Serial number of an x-ray machine;
      5. Generator producer;
      6. Serial number of a generator;
      7. Producer of an x-ray tube;
      8. Serial number of an x-ray tube;
      9. Radionuclide;
      10. Producer of a radioactive source;
      11. Number of radioactive sources;
      12. Serial number of radioactive sources;
      13. Operation regime;
      14. Maximum electron energy and maximum photon energy;
      15. Maximum voltage of an x-ray tube and anode current;
      16. Maximum activity of a radiation source and date of production;
      17. Activity on the day of testing;
      18. Date and reason of discontinuance in the test subject use.