RULEBOOK

ON THE RECORDS OF IONIZING RADIATION SOURCES, PROFESSIONALLY EXPOSED PERSONS, PATIENTS EXPOSURE TO IONIZING RADIATION AND RADIOACTIVE WASTE

("Official Gazette of Republic of Serbia ", no 97/11 and 127/21)

I GENERAL PROVISIONS

Article 1

This Rulebook stipulate:

1. content and deadlines for submission of records on increase of naturally occurring radionuclides concentrations above the limits set for the environmental contamination in technical-technical-technological process of production;

2. the form and content of records on ionizing radiation sources, on professionally exposed persons, on exposure of patients to ionizing radiation and on radioactive waste.

Article 2

Certain expressions used in this Rulebook have following meanings:

1. *processor* is a legal person or entrepreneur who in technical-technological process of production faces the increase in the concentration of natural radionuclides above the limits set for the environmental contamination;

2. *significant points of the production process* are all the points in the buildings, the yard and the immediate surroundings of processors which authorized dosimetry service designate as a measuring points for the control of increase in the concentration of natural radionuclides;

3. *user* is a legal person or entrepreneur that holds the license for performing radiation practice.

II INCREASE IN THE CONCENTRATION OF NATURAL RADIONUCLIDES IN TECHNICAL-TECHNOLOGICAL PROCESS

Article 3

Processor is required to perform measurements of ambient dose rate equivalent in all significant points of the production process.

Measuring expenses from paragraph 1 of this Article shall bear processor.

Article 4

Measuring from Article 3 of this Rulebook shall be carried only by an authorized dosimetry service at the request of processors.

Authorized dosimetry service based on the measuring results of ambient equivalent dose rate may assess a minimum of additional measurements (identification of radionuclides, sampling and measurements in work areas or the immediate surroundings, etc.) necessary to determine the level of exposure of workers in technical-technological process and the exposure of the population in the surroundings of investigated objects.

Authorized dosimetry service shall submit the measuring results to the processor, along with the evaluation of exposure to ionizing radiation mentioned in paragraph 2 of this Article. **Article 5**

Processor is required to keep records of the type and quantity of material entering the technicaltechnological process, the type and quantity of final products and the measuring results of the authorised dosimetry service.

Article 6

Processor is required to submit the record under Article 5 of this Rulebook to the Serbian Radiation Protection and Nuclear Safety Agency (hereinafter referred to as - Agency) within one year from starting operation.

Processor that started operation before this Rulebook enters into force, is obliged to submit the records under Article 5 of this Rulebook no longer than one year from the day when this Rulebook enters into force.

Article 7

Upon submission of records, the Agency is required to evaluate degree of threat to human health and the environment, and to inform the processor about evaluation.

The Agency shall order the implementation of radiation protection measures if the result of the evaluation under paragraph 1 of this Article is such that the possible exposure of humans or the environment is above the prescribed limits.

Article 8

If the Agency has ordered a processor implementation of radiation protection measures for workers or the environment, processor is required to implement ordered measures sticking to requirements imposed by the Agency.

Costs of implementing protective measures under paragraph 1 of this Article shall bear processor.

III FORM AND CONTENT OF RECORDS ON IONIZING RADIATION SOURCES

Article 9

The holder of the license for nuclear activities performance is required to keep records and submit them to the Agency in the manner prescribed by bylaws on nuclear safety.

The holder of a license under paragraph 1 of this Article is obliged to keep records of ionizing radiation sources (except nuclear material and radioactive waste in storage) and persons professionally exposed to ionizing radiation, in a manner required by this Rulebook. **Article 10**

The user is obliged to keep records of the sources of ionizing radiation, professionally exposed persons, the exposure of patients to ionizing radiation and radioactive waste in written or electronic form.

The user is required to keep the records under paragraph 1 of this Article in a manner prescribed by Articles 13, 14 and 15 of this Rulebook.

Article 11

On the request by the Agency, user is obliged to submit his data, and data from the records described in Article 10 of this Rulebook.

The user is obliged to submit his data on the Form 7, which is attached in Appendix 1 of this Rulebook and is an integral part thereof.

Article 12

The Form 7 contains information about the user such as: name of the legal person or entrepreneur, headquarters, address, phone number, fax number and e-mail address of the legal person or entrepreneur; identification number and tax identification number of the legal person or entrepreneur, number and date of issuance of the license for performing radiation practice; person responsible for radiation protection (name, level of education, phone number, fax number and e-mail addresses); certification of records (which include: date and location; place for the seal; signature of authorized person).

Article 13

The content of of records maintained by the user of the devices that produce ionizing radiation includes the following information:

1. name of generator and additional devices;
2. name and address of the producer;
3. type and serial number of the generator or the x-ray tube;
4. location of the building or the room where it is used;

5. room size and ventilation shafts;
6. number and date of decision issuance of use and the license for performing radiation practice;
7. number and date of attest;
8. generator type and purpose of the generator;
9. tube types;
10. operating mode (illumination, imaging);
11. nominal high voltage X-ray tube and the anode current;
12. circuit of the generator;
13. filtration;
14. repeatability of recording time, high voltage and equivalent dose;
15. position of the reference axis;
16. type of image receiver;
17. measurements for estimation of exposure to ionizing radiation (dosimetric measurements);
18. measurements for control of the quality management system;
19. date and type of accident/incident and the method of repair;
20. changes carried out on the device (failures, repairs, services, replacing of tube);
21. name and address of the legal person that performs servicing or maintenance;
22. other reasons for cessation of use of the generator.

The user is required to include in the records those information specified in paragraph 1 of this Article, related to the type of radiation practice performed (medical application - therapy, diagnostics, industrial application, etc.).

Article 14

The content of the records maintained by the user of sealed sources of ionizing radiation include the following information:

1. name and purpose of ionizing radiation sources;
2. name and address of the producer;
3. date of manufacture, delivery, beginning and cessation of use;

4. activity of the radiation source at the time of production, procurement, beginning and cessation of use;
5. location of building or the room where it is used;
6. room size and ventilation shafts;
7. number and date of decision issuance of use and the license for performing radiation practice;
8. type and serial number of the monitor;
9. date of calibration or verification of the monitor;
10. measurements for estimation of exposure to ionizing radiation (dosimetric measurements);
11. measurements for control of the quality management system;
12. date and type of accident/incident and the repair;
13. name and address of the legal person that performs servicing or maintenance; 14. date and place of storage.

Article 15

The content of the records maintained by the user of open sources of ionizing radiation includes the following information:

1.name and purpose of ionizing radiation sources;

2. name of radioisotopes in radiopharmaceutical (only for use in medical purposes);
3. name and address of the producer;
4. date of manufacture, delivery, beginning and cessation of use;
5. activity of the radiation source at the time of production, procurement, beginning and cessation of use;
6. location of buildings or the room where it is used;
7. room size and ventilation shafts;
8. number and date of decision issuance of use and the license for performing radiation practice;
9. type and serial number of the radiation monitor;
10. date of calibration or verification of the monitor;

11. measurements for estimation of exposure to ionizing radiation (dosimetric measurements);

12. measurements for control of the quality management system;

13. date and type of accident/incident and the repair method; 14. date and place of storage.

Article 16

The user of high activity sources is obliged to keep a separate record of an individual highactivity source on Form 7 which is given in Appendix 2 of this Rulebook and is an integral part

thereof.

Form 7 contains the following information: source identification number; license holder information; information on where the source is located; source registration data; licensing data; regular control dates; source characteristics; data of source admission; data of source transfer; additional information.

Article 17

User that applies ionizing radiation sources for medical purposes is obliged to keep records of patients' exposure to ionizing radiation, which can serve as a source of information for assessment of the dose received by the patient depending on the type of medical procedure.

Records of patients exposure to ionizing radiation includes the following information:

1. patients name and surname;
2. gender: M or F;
3. patients unique identification number;
4. address and place of residence;
5. contact phone number and email address;
6. date of ionizing radiation source application;
7. name of conducted diagnostic procedure with the use of ionizing radiation source;
8. parameters of ionizing radiation (type of radiation, beam energy, dose equivalent for tumor treated tissue; applied activity with isotopes type; high voltage and a product of time and current intensity - mAs - in diagnostic procedures);
9. name and surname of the person who approved the procedure of application of ionizing radiation source;
10. side effects; 11. accidents / incidents; 12. remarks.

Article 18

User is obliged to keep records of professionally exposed persons. Records of professionally exposed persons includes the following information:

1. name;
2. surname;
3. gender: M F;
4. date of birth;
5. patients unique identification number;
6. education;
7. workplace;
8. person categorisation: A or B;
9. work experience in the ionizing radiation zone;
10. name and type of ionizing radiation source to which a person is exposed;
11. individual report of an authorized dosimetry service on measurements for estimation of exposure to ionizing radiation;
12. estimated annual effective dose;
13. estimated cumulative effective dose for the five-year period, with the fifth year running in the specified period;
14. work prohibition in the radiation zone;
15. medical examination dates and health ability evaluation.

Article 19 - DELETED

Article 20 - DELETED

Article 21

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

Appendix 1

Form 7

USERS DATA FROM RECORDS ON IONIZING RADIATION SOURCES

<table>
<tr><td colspan="2">Name of the legal person or entrepreneur:</td><td>ID number</td></tr>
<tr><td colspan="2" rowspan="2"></td><td>VAT:</td></tr>
<tr><td>City:</td><td colspan="2">Address and no:</td></tr>
<tr><td>Telephone:</td><td>Fax:</td><td>E-mail:</td></tr>
<tr><td colspan="3">License for performing radiation practice (number and date of issue)</td></tr>
<tr><td colspan="3">Person responsible for radiation protection:</td></tr>
<tr><td>Telephone:</td><td>Fax:</td><td>E-mail:</td></tr>
</table>

Verification of records

Place and date:	For legal person or entrepreneur: Seal Signature of authorised person

Appendix 2

Form 8

DATA ON HIGH-ACTIVITY SOURCE

1. High activity source ID number	2. License holder information Name: Address: Country: Producer: □ Deliverer: □ User: □	3. Sealed source is located (used or stored): if not the same as no. 2 Name: Address: Fixed: □ Stored (mobile): □
4. Source registration Date of first registration: Date of data transfer to the archive:	5. License Number: Date of issue: Date of expiry:	6. Regular controls of highly active sources
		Date:
		Date:
		Date:
		Date:
7. Characteristics of highly active source Radionuclide: Activity on the day oof production or placing on the market:	8. Admission of highly active source Admission date:	Date:
		Date:
		Date:
		Date:

Date of production: Producer:	Received from: Name: Address: Country: Producer: □ Deliverer: □ Other user: □	Date:
		Date:
Name:		Date:
Address:		Date:
Country:		Date:
Physical and chemical characteristics:	9. Transfer of high-activity source	10. Additional information:
		Lost: □ Date of loss:
Type of source:	Date of transmission:	Stolen: □ Date of stealing:
Type of capsule:	Transfered to:	YES: □ NO: □
ISO classification:	Name: Address: Country: Producer: □ Deliverer: □ Other user: □ Approved placing of source:	Found: Date:
ANSI classification:		Place:
Specific forms of certificate:		Other information: