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Pursuant to Article 22, point 3), Article 23 and Article 196, paragraph 5 of the Law on Radiation and Nuclear Safety and Security (“Official Gazette of RS”, Nos. 95/18 and 10/19) and Article 15, 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 26 December 2019 passes:

RULEBOOK on Conditions for Categorization of Radiation Practises

“Official Gazette of RS”, Nos. 94 of 27 December 2019,
133 of 31 December 2021 and 30 of 4 March 2022.

(consolidated text)

Subject Matter

Article 1

This Rulebook prescribes in detail the conditions for the categorization of radiation practises.

The conditions for the categorization of radiation practises under paragraph 1 of this Article are determined in accordance with the risk assessment criteria and pertain to the impact of a radiation practise on the health of the exposed workers and staff, the public, the environment, as well as to the type of practise.

Risk Assessment Criteria

Article 2

The criteria serving to assess the risk of a radiation practise are in particular:

- 1) information on the radiation sources and the premises in which they are used, as well as the manner in which the sources are managed;
- 2) available dosimetry measurements and the information on the exposure;
- 3) exposure of the workers, the public and the environment;
- 4) level of medical exposure (radiation practises in medicine);
- 5) complexity of the practise;
- 6) technical requirements for the radiation sources and the ancillary equipment;
- 7) protection measures for the exposed workers, the public and the environment;
- 8) exposure pathways arising from the practise performance during normal and abnormal operations;
- 9) effluent discharge;
- 10) radioactive waste generation;
- 11) recorded emergency events and radiological emergencies;
- 12) exposure assessment during normal operations and in case of an emergency event;
- 13) physical protection and other security measures for radiation sources;
- 14) transport of radiation sources;
- 15) lessons learned in radiation practise performance.

The Directorate shall apply the criteria for a radiation practise risk assessment depending on the type of practise the authorization had been applied for.

Categories of Radiation Practises

Article 3

Radiation practises are categorized based on the criteria under Article 2 hereof as low-risk radiation practises, moderate-risk radiation practises and high-risk radiation practises.

The list of radiation practises under paragraph 1, including their categories, which had been authorized until the day of entry into force of this Rulebook, is given in Table 1 under Appendix 1 of this Rulebook which makes its constituent part.

The Directorate may, in cases when radiation and nuclear safety and security measures require so, classify a justified radiation practise into a higher radiation risk category with regard to the risk categories in Table 1 under Appendix 1 hereof, on which it brings a written decision.

If justified radiation practises are not listed in Table 1 under Appendix 2 hereof, the Directorate shall, at the request of a legal entity or entrepreneur categorize such practises based on the risk assessment criteria under Article 2 hereof, on which it brings a written decision.

Transitional and Final Provisions

Article 4

On the day of entry of this Rulebook into force, the Information on Categorization of Practises of 22 March 2019 shall cease to exist.

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

The Chairperson of the Board

Maja Gojkovic, sgd.

PUBLISHER'S NOTE: Based on the decision on the amendments to the Rulebook on Conditions for Categorization of Radiation Practises (“Official Gazette of RS”, No. 30/2022) Table 1 is replaced by a new table (refer to point 1 of the Decision – 30/2022-111).

APPENDIX 1

TABLE 1. Categorization of Radiation Practises

FIELD OF USE	RADIATION PRACTISE		CATEGORY
			Risk
MEDICINE			
1. Diagnostics in medicine	Use of x-ray machines	for imaging and/or illumination	Moderate
		for mammography	Moderate
		for computed tomography	High
		for osteodensitometry	Low
	Use of x-ray machines for <i>in vitro</i> testing of tissue samples		Low
	Use of unsealed sources in a radioimmunology laboratory		Low
	Use of unsealed sources in nuclear medicine		High
2. Therapy in medicine	Use of x-ray machines	orthovoltage x-ray therapy machine	High
	Use of linear accelerators		High
	Use of sealed sources	Co-60	High
		Medium-dose-rate brachytherapy (MDR)	High
		High-dose-rate brachytherapy (HDR)	High
	Use of unsealed sources in nuclear medicine		High
3. Interventional procedures in medicine	Use of x-ray machines		High
4. Irradiation of blood products	Use of sealed sources		High
DENTISTRY			
5. Diagnostics in dentistry	Use of x-ray machines	In intraoral imaging	Low
		in orthopantomography imaging	Low

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FIELD OF USE	RADIATION PRACTISE		CATEGORY
			Risk
		in orthopantomography and <i>CBCT</i> imaging	Moderate
VETERINARY MEDICINE			
6. Diagnostics in veterinary medicine	Use of x-ray machines	for imaging and/or illumination	Low
INDUSTRY			
7. Analysis of material content and items	Use of x-ray machines, namely: <i>XRF</i> , <i>EDXRF</i> , <i>XRD</i>		Low
	Use of sealed radioactive sources		Commensurate with Table 2
8. Industrial radiography	Use of x-ray machines		High
	Use of sealed radioactive sources		High
9. Quality control, control of products and processes (determination of thickness, moisture, level, density, static electricity elimination, etc.)	Use of x-ray machines		Low
	Use of sealed radioactive sources		Commensurate with Table 2
10. Production of radiation sources	Production of radiation-emitting electronic products		Moderate
	Production of radiopharmaceuticals		High
	Production, re-packing and recycling of sealed radiation sources	Cat. IV and V	Moderate
		Cat. I, II and III	High
11. Operations with radiation sources	Installation and removal of sealed radiation sources in devices with integrated radiation sources	Cat. IV and V	Moderate
		Cat. I, II and III	High
	Removal of radioactive lightning rods		Moderate
12. Borehole logging operations	Use of neutron generator		High
	Use of sealed radioactive sources		Commensurate with Table 2
13. Sterilization and conservation of foodstuffs and general use goods, medical tools, pharmaceutical raw material and finished goods	Use of sealed radioactive sources		Commensurate with Table 2
	Servicing and repair of radiation generators		Moderate

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FIELD OF USE	RADIATION PRACTISE		CATEGORY
			Risk
14. Servicing and repair of devices with incorporated radiation sources	Service and repair of devices with incorporated sealed sources		Commensurate with Table 2
15. Processing of materials and products	Use of an electron beam obtained by accelerator		High
EDUCATION, SCIENCE AND RESEARCH			
16. Scientific research	Use of x-ray machines, namely: <i>XRF, EDXRF, XRD</i>		Low
	Use of sealed radioactive sources		Commensurate with Table 2
	Use of unsealed radiation sources		Commensurate with Table 2
	Use of ion/electron sources		Low
17. Education	Use of x-ray machines		Commensurate with the practise the education programme is intended for
	Use of sealed radioactive sources		Commensurate with Table 2
	Use of unsealed radiation sources		Commensurate with Table 2
TRADE AND TRANSPORT			
18. Trade	Radiation generators	including storage	Low
		without storage	Low
	Radioactive sources without storage		Low
	Radioactive sources including storage	Cat. III, IV, V	Moderate
		Cat. I and II	High
19. Transport of dangerous goods Class 7 <i>ADR/RID/ADN</i> (radioactive material)	Type-A transport container UN2915, UN3327, UN3332, UN3333		Low
	LSA UN3324, LSA UN3325		Low
	SCO UN3326		Low
	UN2913		Low
	<i>HASS</i> and packed fissile material UN2916, UN3328, UN2917, UN3329, UN3323, UN3330,		High

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FIELD OF USE	RADIATION PRACTISE	CATEGORY
		Risk
	Based on the fulfilment of special conditions in packages UN2919, UN3331; UF6 in packages UN2977, UN2978 and UN3507	High
OTHER		
20. Calibration and examination of instruments and devices	Use of x-ray machines	Moderate
	Use of sealed radioactive sources	Commensurate with Table 2
	Use of unsealed radiation sources	Commensurate with Table 2
21. Control of goods and shipments	Examination of the content of luggage, hand-luggage, parcels and shipments by means of x-ray machines	Low
	Examination of vehicles and cargo by means of accelerators	Moderate
22. Decontamination of radiation facilities		High

TABLE 2 Categorization of radiation practises based on the type of radioactive source

TYPE OF SOURCE		CATEGORY
		Risk
Sealed source	Category I and II sources and highly-active sealed source (HASS)	High
	Category III source	Moderate
	Category IV and V source	Low
Unsealed source	Class I tasks	High
	Class II and III tasks	Moderate