



# JOURNAL OF LAWS OF THE REPUBLIC OF POLAND

Warsaw, 20<sup>th</sup> of September 2021

Item 1725

## REGULATION OF THE MINISTER OF HEALTH<sup>1</sup>

of 13 September 2021

### **on the minimum requirements for health care units conducting medical exposure activities involving the provision of X-ray diagnostics, interventional radiology or diagnostics involving the administration of radiopharmaceutical products to patients<sup>2,3</sup>**

Pursuant to Article 33q(13) of the Act of 29 November 2000 on the Atomic Law (Dz. U. of 2021, item 623 and 784), it is ordered as follows:

§ 1. 1. This Regulation specifies the minimum requirements for health care units carrying out the activities referred to in Article 33q(1) of the Act of 29 November 2000 on the Atomic Law, hereinafter referred to as the "Act", concerning the following:

- 1) radiological equipment and auxiliary equipment,
- 2) number and qualifications of personnel taking part in the performance of particular types of medical radiological procedures.

2. Whenever the provisions of this Regulation refer to an electroradiology technician, it shall be understood as a person holding a professional title of an electroradiology technician or a diploma of higher education in fields of training in electroradiology and a bachelor's or master's degree.

§ 2. 1. The minimum equipment with radiological devices of a health care unit carrying out activities referred to in Article 33q(1) of the Act, hereinafter referred to as "health care unit", consisting in the provision of health care services in the field of:

- 1) X-ray diagnostics, including mammography, shall be a permanently installed X-ray apparatus for taking pictures or X-rays, or pictures and X-rays, intended for the diagnosis of anatomical areas resulting from medical radiological procedures;

<sup>1</sup> The Minister of Health heads the department of government administration - health, pursuant to § 1(2) of the Regulation of the Prime Minister of 27 August 2020 on the detailed scope of activities of the Minister of Health (Dz. U. of 2021, item 932).

<sup>2</sup> This Regulation implements within its scope the Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ EU L 13, 17.1.2014, p. 1, OJ EU L 72, 17.3.2016, p. 69, OJ EU L 152, 11.6.2019, p. 128 and OJ EU L 324, 13.12.2019, p. 80).

<sup>3</sup> This Regulation was notified to the European Commission on 31 May 2021 under number 2021/314/PL, pursuant to § 4 of the Regulation of the Council of Ministers of 23 December 2002 on the manner of operation of the national system of notification of standards and legal acts (Dz. U., item 2039, and of 2004, item. 597), which implements the provisions of the Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codification) (OJ EU L 241, 17.9.2015, p. 1).

- 2) dental radiology, excluding exposure-related activities referred to in Article 33q(14) of the Act, shall be an X-ray machine or a computed tomography scanner intended for the diagnosis of anatomical areas resulting from the medical radiological procedures performed;
- 3) computed tomography shall be a multidetector-row computed tomography scanner and, in the case of medical radiological procedures for cardiac examinations, at least a 64-detector computed tomography scanner;
- 4) interventional radiology constitutes:
  - a) an X-ray machine with a video track equipped with an arm enabling the video track to be positioned at the required angle to the patient,
  - b) for vascular procedures, an angiographic apparatus with equipment and software resulting from the medical radiological procedures performed;
- 5) diagnostics related to the administration of radiopharmaceutical products to patients constitutes:
  - a) in the case of diagnostic imaging, a scintillation camera,
  - b) an activity meter to measure directly the radioactivity of the radiopharmaceutical before administration to the patient.

2. The health care unit shall be equipped with shielding against ionising radiation for the patient and staff and other necessary ancillary equipment for:

- 1) presentation and archiving of diagnostic images; digital images are stored and archived using the DICOM (Digital Imaging and Communication in Medicine) format;
- 2) perform basic tests for the control of the physical parameters of the radiological equipment and ancillary equipment.

§ 3. The health care unit shall provide, at least, for the purpose of performing medical radiological procedures in the provision of health care services within the scope referred to in § 2(1):

- 1) point 1:
  - a) one physician specialised in radiology and diagnostic imaging,
  - b) one electroradiology technician;
- 2) point 2:
  - a) one physician specialised in radiology and image diagnostics, or
  - b) one dental practitioner who, within the framework of continuing professional development referred to in Article 3, paragraph 1b, point 1, letters b and c, and point 2 of the Act of 5 December 1996 on professions of physicians and dentists (Dz. U. of 2021, item 790 and 1559), has acquired skills in the provision of health services related to the performance of such procedures, confirmed in the manner and according to the principles specified in those provisions, or
  - c) one electroradiology technician;
- 3) point 3:
  - a) one physician specialised in radiology and diagnostic imaging,
  - b) one electroradiology technician,
  - c) one specialist in medical physics or one person approved by the head of the health care unit to perform the tasks, in the field of X-ray diagnostics or surgical radiology, referred to in Article 33h (9) and (10) of the Act - for 15,000 medical radiological procedures of computed tomography performed annually at the health care unit,
  - d) one nurse in the case of procedures in which the administration of a contrast medium is necessary and the personnel indicated in (a-c) are not qualified to do it;

- 4) point 4:

a) one physician specialised in the field of:

- radiology and diagnostic imaging, who, after obtaining the title of specialist, within the framework of continuing professional development referred to in Article 3, paragraph 1b, point 1, letter c, and point 2 of the Act of 5 December 1996 on professions of physicians and dentists, has acquired skills in the provision of health services related to the implementation of such procedures, confirmed in the manner and according to the principles set out in these provisions, or
- medicine corresponding to the type of medical radiological procedures performed, who, within the framework of the specialisation programme, participated in training in the performance of such procedures and performed such procedures in the number established by the specialisation programme, who, after obtaining the title of specialist, within the framework of continuous professional development referred to in Article 3, paragraph 1b, point 1, letter c and point 2 of the Act of 5 December 1996 on professions of physicians and dentists, has acquired skills in the provision of health care services related to the implementation of such procedures, confirmed in the manner and according to the principles set out in these provision.

b) one electroradiology technician,

c) one specialist in medical physics or one person approved by the head of the health care unit to perform the tasks, in the field of X-ray diagnostics or surgical radiology, referred to in Article 33h (9) and (10) of the Act - for 20,000 medical radiological procedures of computed tomography performed annually at the health care unit,

d) one nurse in the case of procedures in which the administration of a contrast medium is necessary and the personnel indicated in (a-c) are not qualified to do it;

5) point 5:

a) one physician specialised in nuclear medicine,

b) one electroradiology technician,

c) one specialist in medical physics or one person authorised by the head of a health care unit to perform tasks, in the field of nuclear medicine, referred to in Article 33h (7) and (8) of the Act,

d) one nurse in the case of procedures in which the administration of a contrast medium is necessary and the personnel indicated in (a-c) are not qualified to do it.

**§ 4.** In cases for granting the consent referred to in Article 33q(1) of the Act, initiated and not concluded before the date of entry into force of this Regulation, with regard to the minimum requirements for radiological and auxiliary equipment and the qualification of personnel of health care units, the previous provisions shall apply.

**§ 5.** Health care units shall adapt their activities to the requirements set out in this Regulation within 6 months of its entry into force.

**§ 6.** This Regulation shall enter into force on the day following its promulgation.<sup>4</sup>

Minister of Health: A. Niedzielski

<sup>4</sup> This Regulation was preceded by the Regulation of the Minister of Health of 27 March 2008 on the minimum requirements for health care units providing health care services in the field of X-ray diagnostics, interventional radiology and diagnosis and radioisotope therapy of non-cancerous diseases (Dz. U., item 365, and of 2011, item 253), which shall be repealed as of the date of entry into force of this Regulation, pursuant to Article 37 (1) (1) of the Act of 13 June 2019 amending the Act on the Atomic Law and the Act on Fire Protection (Dz. U., item 1593, and of 2020, item 284).