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REGULATION OF THE MINISTER OF HEALTH

of 14 October 2021

on the minimum requirements for health care units conducting activity involving exposure for medical purposes, consisting in the provision of health care services in radiotherapy and treatment using radiopharmaceutical products[1] [2]

Pursuant to Article 33p paragraph 14 of the Atomic Law Act of 29 November 2000 (Dz. U. of 2021, items 623 and 784), it is hereby decreed as follows:

§ 1. The Regulation specifies the minimum requirements for health care units conducting activity specified in Article 33p paragraph 1 of the Atomic Law Act of 29 November 2000, hereinafter referred to as the "Act", concerning the following:

1) provision of radiological and auxiliary equipment;

2) number and qualifications of the personnel taking part in specific types of radiological medical procedures.

§ 2. The minimum type of radiological and auxiliary equipment possessed by health care units that conducts the activity specified in Article 33p paragraph 1 of the Act, hereinafter referred to as the "health care unit", consisting in the provision of the following health care services:

1) teleradiotherapy, shall include the following:

   a) two megavolt treatment apparatuses that generate photon radiation, wherein the photon radiation features at least one photon beam with the nominal energy between 4 and 9 megaelectron volts (MeV), while in the case of providing health care services with the use of electron beams also generating electron radiation featuring at least three beams with minimum energy of 6 megaelectron volts (MeV); both apparatuses should enable the same irradiation techniques and mutual substitutability to ensure continuity of the provided health

[1] Within the scope of its regulation, this Regulation implements the Directive of the Council 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 (EU Official Journal L 13 of 17.01.2014, page 1, EU Official Journal L 72 of 17.03.2016, page 69, EU Official Journal L 152 of 11.06.2019, page 128 and EU Official Journal L 324 of 13.12.2019, page 80).

[2] This Regulation was presented to the European Commission on 5 July 2021 under the number 2021/422/PL pursuant to Article 4 of the Regulation of the Council of Ministers of 23 December 2002 on the functioning of the national acts and standards notification system (Dz. U. item 2039 and of 2004, item 597), which implements the provisions of the Directive of the European Parliament and of the Council (EU) 2015/1535 of 9 September 2015 r. laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codification) (EU Official Journal L 241 of 17.09.2015, page 1).

care service,

b) a system that enables conducting treatment simulation and image recording,

c) a treatment planning system integrated with a radiotherapy management system with the number of stations at least equal to the number of possessed accelerators, and if dynamic treatment plans are implemented - also a verification system for such plans,

d) a patient positioning verification system integrated with the treatment apparatus,

e) a patient immobilisation set for each treatment apparatus, CT scanner, simulator and modelling shop, adapted to the irradiation techniques used at the health care unit,

f) an analyser of beam irradiation fields used at the health care unit,

g) two equipment sets enabling the control of the dose received by the patient,

h) two sets of instruments and accessories to control the parameters of beams used at the health care unit and to control the parameters of radiation beams in the simulation system, including two dosimeters with up-to-date calibration certificates,

i) a set of equipment intended for performing operational tests on the physical parameters of radiological and auxiliary equipment;

2) stereotactic teleradiotherapy using gamma rays derived from many micro-sources, shall include the following:

a) a treatment apparatus with Co-60 micro-sources,

b) a set of collimators that enable irradiation with the geometric precision of less than 1 mm,

c) a treatment planning system,

d) two sets of instruments and accessories to control the parameters of beams used at the health care unit, including two dosimeters with up-to-date calibration certificates,

e) a set of instruments and accessories to control the parameters of radiation beams in the radiological equipment used in the treatment planning system,

f) a patient immobilisation set for each treatment apparatus and imaging equipment for treatment planning and the modelling shop, adapted to the irradiation techniques used at the health care unit;

3) stereotactic and cybernetic micro-radiotherapy, shall include the following:

a) an accelerator,

b) a treatment planning system integrated with a radiotherapy management system with the number of stations at least equal to the number of possessed accelerators, and a treatment plan verification system,

c) two sets of instruments and accessories to control the parameters of beams used at the health care unit, including two dosimeters with up-to-date calibration certificates,

d) a set of instruments and accessories to control the parameters of radiation beams in the radiological equipment used in the treatment planning system,

e) a patient immobilisation set for each treatment apparatus, CT scanner, simulator and modelling shop, adapted to the irradiation techniques used at the health care unit,

f) a system for verifying the patient's positioning during irradiation, integrated with the treatment apparatus,

g) a set of equipment intended for performing operational tests on the physical parameters of radiological and auxiliary equipment;

4) brachytherapy, shall include the following:

a) equipment for remote radioactive source introduction, including a set of standard applicators - does not apply to ocular brachytherapy and brachytherapy including isotopic source implantation,

b) an imaging system intended to verify the positioning of applicators, radioactive sources and to take location pictures - does not apply to ocular therapy,

c) a treatment planning system - does not apply to ocular therapy,

d) a system for monitoring of dose during irradiation,

e) two sets of instruments and accessories intended for dosimetric control of radiation sources - does not apply to ocular brachytherapy;

5) surface radiation therapy, shall include the following:

a) treatment apparatus for surface radiation therapy,

b) a set for the preparation of individual covers for organs not being treated,

c) two sets of instruments and accessories to control the irradiation parameters, including two dosimeters with up-to-date calibration certificates,

d) a set of equipment intended for performing operational tests on the physical parameters of radiological and auxiliary equipment;

6) proton therapy, shall include the following:

a) a proton accelerator with the minimum proton energy of 200 MeV, and at least 55 MeV in the case of eye tumour treatment,

b) a treatment planning system integrated with a radiotherapy management system with the number of stations at least equal to the number of possessed accelerators, and a treatment plan verification system,

c) a system that enables conducting treatment simulation and image recording,

d) a set for patient positioning and immobilisation in the range required to conduct target volume irradiation for each irradiation station, CT scanner, simulator and modelling shop, adapted to the irradiation techniques used at the health care unit,

e) two sets of instruments and accessories to control the parameters of beams used at the health care unit, including two dosimeters with up-to-date calibration certificates,

f) a set of equipment intended for performing operational tests on the physical parameters of radiological and

auxiliary equipment;

7) treatment using radiopharmaceutical products, shall include the following:

a) a planar or rotating scintillation camera,

b) a meter to measure a radiopharmaceutical's activity prior to its administration,

c) personal covers against ionising radiation - if required for the personnel's radiation protection,

d) gamma and beta radiation absorbing syringe covers, if such syringes are used.

§ 3. In order to perform the radiological medical procedures when providing health care services in the scope specified in § 2, a health care unit provides the following at the minimum:

1) point 1:

a) three physicians, including two specialists in radiotherapy and radiation oncology, who after receiving the title of specialist as part of continuous professional development, specified in Article 3 paragraph 1b points 1c and 2 of the Act on the professions of physicians and dentists of 5 December 1996 (Dz. U. of 2021, items 790 and 1559), gained the skills to provide health care services related to the performance of such procedures, confirmed in a manner and following the rules specified in the Act on the professions of physicians and dentists - per each 500 patients treated with radiation in a calendar year, and above this number of patients - one additional physician per each 200 subsequent patients treated with radiation in a calendar year,

b) two persons with the professional title of electroradiology technician or a university diploma in fields providing education in electroradiology and the Bachelor's or Master's degree, hereinafter referred to as "electroradiology technicians", to operate one treatment apparatus,

c) two electroradiology technicians to operate the simulation system,

d) three physicists, including two specialists in medical physics within the meaning of Article 3 point 44a of the Act - per 1000 patients treated with radiation in a calendar year;

2) point 2:

a) a physician specialised in radiotherapy or radiation oncology,

b) a physician specialised in neurosurgery or neurosurgery and neurotraumatology, who after receiving the title of specialist as part of continuous professional development, specified in Article 3 paragraph 1b points 1c and 2 of the Act on the professions of physicians and dentists of 5 December 1996, gained the skills to provide health care services related to the performance of such procedures, confirmed in a manner and following the rules specified in the Act on the professions of physicians and dentists,

c) a radiology technician to operate a single treatment apparatus,

d) a specialist in medical physics within the meaning of Article 3 point 44a of the Act;

3) point 3:

a) three physicians, including two specialists in radiotherapy or radiation oncology, who after receiving the

title of specialist as part of continuous professional development, specified in Article 3 paragraph 1b points 1c and 2 of the Act on the professions of physicians and dentists of 5 December 1996, gained the skills to provide health care services related to the performance of such procedures, confirmed in a manner and following the rules specified in the Act on the professions of physicians and dentists,

b) two electroradiology technicians to operate a single accelerator,

c) a specialist in medical physics within the meaning of Article 3 point 44a of the Act - per 1000 patients treated with radiation in a calendar year;

4) point 4:

a) two physicians specialised in radiotherapy or radiation oncology, and in the case of ocular brachytherapy two physicians specialised in ophthalmology, who after receiving the title of specialist as part of continuous professional development, specified in Article 3 paragraph 1b points 1c and 2 of the Act on the professions of physicians and dentists of 5 December 1996, gained the skills to provide health care services related to the performance of such procedures, confirmed in a manner and following the rules specified in the Act on the professions of physicians and dentists,

b) two electroradiology technicians, and in the case of using equipment intended for remote radioactive source introduction two electroradiology technicians to operate each of the devices; this requirement does not apply to ocular brachytherapy,

c) a specialist in medical physics within the meaning of Article 3 point 44a of the Act, and in the case of using equipment intended for remote radioactive source introduction one specialist in medical physics within the meaning of Article 3 point 44a of the Act - per 600 patients treated with radiation in a calendar year;

5) point 5:

a) a physician specialised in radiotherapy or radiation oncology, who after receiving the title of specialist as part of continuous professional development, specified in Article 3 paragraph 1b points 1c and 2 of the Act on the professions of physicians and dentists of 5 December 1996, gained the skills to provide health care services related to the performance of such procedures, confirmed in a manner and following the rules specified in the Act on the professions of physicians and dentists - per 500 patients treated with radiation in a calendar year,

b) an electroradiology technician to operate a single treatment apparatus,

c) a specialist in medical physics within the meaning of Article 3 point 44a of the Act - per 1000 patients treated with radiation in a calendar year;

6) point 6:

a) three physicians, including two specialists in radiotherapy and radiation oncology, who after receiving the title of specialist as part of continuous professional development, specified in Article 3 paragraph 1b points 1c and 2 of the Act on the professions of physicians and dentists of 5 December 1996, gained the skills to provide health care services related to the performance of such procedures, confirmed in a manner and following the rules specified in the Act on the professions of physicians and dentists - per each 500 patients

treated with radiation in a calendar year, and above this number of patients - one additional physician per each 200 subsequent patients treated with radiation in a calendar year,

b) two electroradiology technicians to operate each treatment station,

c) two electroradiology technicians to operate the simulation system,

d) three physicists, including two specialists in medical physics within the meaning of Article 3 point 44a of the Act - per 600 patients treated with radiation in a calendar year;

7) point 7:

a) a physician specialised in nuclear medicine, who after receiving the title of specialist as part of continuous professional development, specified in Article 3 paragraph 1b points 1c and 2 of the Act on the professions of physicians and dentists of 5 December 1996, gained the skills to provide health care services related to the performance of such procedures, confirmed in a manner and following the rules specified in the Act on the professions of physicians and dentists - per 500 patients treated using radiopharmaceutical products in a calendar year,

b) an electroradiology technician,

c) a nurse, whenever justified by the manner of the radiopharmaceutical's administration,

c) a specialist in medical physics within the meaning of Article 3 point 44a of the Act or a medical physicist in nuclear medicine specified in Article 33h paragraph 7 of the Act - per 1000 patients treated using radiopharmaceutical products in a calendar year.

§ 4. The regulations in force prior to 24 September 2021 apply to matters of approval specified in Article 33p paragraph 1 of the Act in terms of the minimum requirements concerning the radiological and auxiliary equipment as well as the number and qualifications of the health care unit's personnel, commenced and not concluded prior to this Regulation's entry into force.

§ 5. Health care units shall adapt their activity to the requirements specified in this Regulation within 6 months from its entry into force.

§ 6. The Regulation enters into force on the day following the date of its publication.[3]

Minister of Health: *A. Niedzielski*

[3] This Regulation was preceded by the Regulation of the Minister of Health of 7 April 2006 on the on the minimum requirements for health care facilities applying for approval to conduct activity involving exposure to ionising radiation for medical purposes, consisting in the provision of medical services in radiation oncology (Dz. U. of 2013, item 874), which expired on 24 September 2021 pursuant to Article 37 paragraph 1 point 1 the Act of 13 June 2019 amending the Atomic Law Act and the Fire Protection Act (Dz. U. item 1593 and of 2020, item. 284).