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Item 1959

Regulation

Of the Minister of Health[1)]

of 19 October 2021

on the information contained in the National Database of Radiological Equipment[2)]

Pursuant to Art. 33r(10) of the Act of 29 November 2000 - Atomic Law (Dz. U. of 2021, item 1941), it is ordered as follows:

§ 1. This Regulation shall specify the detailed scope of information contained in the National Database of Radiological Equipment concerning individual categories of radiological equipment.

§ 2. 1. The information contained in the National Database of Radiological Equipment shall include categories of radiological equipment used in:

1) X-ray diagnostics and interventional radiology,

2) nuclear medicine,

3) radiotherapy;

2. The radiological equipment in the National Database of Radiological Equipment shall be identified by codes, the list of which constitutes an Annex to this Regulation.

§ 3. 1. The information on X-ray diagnostics and interventional radiology equipment shall include:

1) the name of the manufacturer;

2) the name of the supplier or installer;

3) a model or type;

4) a serial number;

5) the code of the radiological equipment as given in the Annex to this Regulation;

6) a year of manufacture;

[1)] 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).

[2)] 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 ionizing 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).

7) a year of commissioning;

8) a model or type of the X-ray tube;

9) a serial number of the X-ray tube;

10) a total filtration, including the X-ray tube's own filtration;

11) the size of the focal spot or focal spots;

12) the range of nominal voltages;

13) a year of manufacture of the X-ray tube;

14) a negative result of the specialist test and corrective measures taken;

15) the number and date of the administrative decision on issuing, modifying or revoking the license to set up or use the radiological equipment together with the name of the authority issuing such license referred to in Art. 4 Section 1 Item10 of the Act of 29 November 2000 - Atomic Law, hereinafter referred to as the 'Act'.

2. If the radiological equipment referred to in Section 1)is a computed tomography (CT) scanner, information shall also be given on:

1) the minimum acquisition time;

2) the minimum thickness of layers;

3) the number of rows or layers;

4) the type of an automatic syringe.

3. Information on the purpose, equipment and generator of the diagnostic radiological equipment shall be entered according to the code list set out in the Annex to this Regulation.

§ 4. 1. Information on the radiological equipment used in nuclear medicine for:

1) a scintillation camera shall include:

a) the type of camera according to the code list set out in the Annex to this Regulation,

b) the name of the manufacturer,

c) the name of the supplier or installer,

d) a model or type,

e) a serial number,

f) the code of the radiological equipment as given in the Annex to this Regulation,

g) a year of manufacture,

h) a year of commissioning,

i) types of collimators according to the code list set out in the Annex to this Regulation,

j) the name, version and manufacturer of software used,

k) the number of data processing stations or descriptor stations,

l) the method of image recording (analogue or digital),

m) a list of phantoms,

n) a list of control sources,

o) the negative result of the specialist test and corrective measures taken,

p) the number and date of the administrative decision on issuing, modifying or revoking the license to set up or use the radiological equipment together with the name of the authority issuing such license referred to in Art. 4 Section 1 Item10of the Act;

2) a positron emission tomograph (PET) shall include:

a) a type of the PET according to the code list set out in the Annex to this Regulation,

b) the name of the manufacturer,

c) the name of the supplier or installer,

d) a model or type,

e) a serial number,

f) the code of the radiological equipment as given in the Annex to this Regulation,

g) a year of manufacture,

h) a year of commissioning,

i) the crystal size and field of view according to the code list set out in the Annex to this Regulation,

j) accessories according to the code list set out in the Annex to this Regulation,

k) a negative result of the specialist test and corrective measures taken,

l) the number and date of the administrative decision on issuing, modifying or revoking the license to set up or use the radiological equipment together with the name of the authority issuing such license referred to in Art. 4 Section 1 Item 10 of the Act.

2. If the PET:

1) is equipped with:

a) a cyclotron, the information shall include:
- the name of the manufacturer,
- the name of the supplier or installer,
- a model or type,
- a serial number,
- the code of the radiological equipment as given in the Annex to this Regulation,
- a year of manufacture,
- a year of commissioning,
- the maximum energy of particles,
- a list of produced isotopes and their activity,
- the number and date of the administrative decision on issuing, modifying or revoking the license to set up or use the radiological equipment together with the name of the authority issuing such license referred to in Art. 4(1)(10) of the Act.

b) a radiopharmaceutical synthesizer, the information shall include:
- the name of the manufacturer,
- the name of the supplier or installer,
- a model or type,
- a serial number,
- the code of the radiological equipment as given in the Annex to this Regulation,
- a year of manufacture,
- a year of commissioning,
- types of manufactured radiopharmaceutical products and their activity,

– the number and date of the administrative decision on issuing, modifying or revoking the license to set up or use the radiological equipment together with the name of the authority issuing such license referred to in Art. 4 Section 1 Item10 of the Act;

2) is not equipped with:

a) a cyclotron, information shall include names and addresses of isotope suppliers,

b) a radiopharmaceutical synthesizer, the information shall include the names and addresses of suppliers of radiopharmaceutical products.

§ 5. 1. Information on the radiological equipment used in radiotherapy shall include:

1) for a device with a radioactive source:

a) the name of the manufacturer,

b) the name of installer,

c) a model or type,

d) a serial number,

e) the code of the radiological equipment as given in the Annex to this Regulation,

f) a year of manufacture,

g) a year of commissioning,

h) an initial source activity at the date of installation,

i) a negative result of the operational test and corrective measures taken,

j) the number and date of the administrative decision on issuing, modifying or revoking the license to set up or use the radiological equipment together with the name of the authority issuing such license referred to in Art. 4 Section 1 Item10 of the Act;

2) for an accelerator:

a) the type of accelerator according to the code list set out in the Annex to this Regulation,

b) the name of the manufacturer,

c) the name of the supplier or installer,

d) a model or type,

e) a serial number,

f) the code of the radiological equipment as given in the Annex to this Regulation,

g) a year of manufacture,

h) a year of commissioning,

i) types of beams,

j) nominal energies of photon beams,

k) nominal energies of electron beams,

l) nominal energies of proton beams,

m) the type of collimators according to the code list set out in the Annex to this Regulation,

n) a negative result of the operational test and corrective measures taken,

o) the number and date of the administrative decision on issuing, modifying or revoking the license to set up or use the radiological equipment together with the name of the authority issuing such license referred to in Art. 4 Section 1 Item10 of the Act.

2. Information on the radiological equipment used in brachytherapy shall include:

1) the type of equipment according to the code list set out in the Annex to this Regulation;

2) the name of the manufacturer;

3) the name of the supplier or installer;

4) a serial number;

5) the code of the radiological equipment as given in the Annex to this Regulation;

6) a year of manufacture;

7) a year of commissioning;

8) the method of loading the source into the applicator;

9) a radioactive isotope used;

10) a nominal source activity;

11) types of applicator according to the code list set out in the Annex to this Regulation;

12) the method of transport of the source in the applicator;

13) the method of implantation;

14) a negative result of the operational test and corrective measures taken;

15) the number and date of the administrative decision on issuing, modifying or revoking the license to set up or use the radiological equipment together with the name of the authority issuing such license referred to in Art. 4 Section 1 Item 10 of the Act.

§ 6. This Regulation shall enter into force 14 days following its promulgation.) [3]

Minister of Health: *A. Niedzielski*

[3]) This regulation was preceded by the Regulation of the Minister of Health of 27 March 2008 on the database of radiological equipment (Dz. U., item 366), which became invalid as of 24 September 2021 pursuant to Art. 37 Section 1 Item 1 of the Act of 13 June 2019 amending the Act - Atomic Law and the Act on Fire Protection (Dz. U., item 1593 and of 2020, item 284).

LIST OF CODES FOR RADIOLOGICAL EQUIPMENT USED IN X-RAY DIAGNOSTICS AND INTERVENTIONAL RADIOLOGY, NUCLEAR MEDICINE AND RADIOTHERAPY

General coding rules and the identification of boxes for X-ray diagnostics and interventional radiology, nuclear medicine and radiotherapy

The code contains 28 boxes; one digit is entered in each box according to the following rules and principles.

Group code	Basic devices															Equipment							Software				
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27

Box number:

0 Group code: 1 – X-ray diagnostics and interventional radiology,
2 – nuclear medicine,
3 – radiotherapy;

1 to 15 Basic devices

16 to 22 Equipment

23 to 27 Software

1. X-ray diagnostics and interventional radiology

Group code	Basic devices															Equipment							Software				
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
1											0											0				0	0

Box number:

A. Basic devices

1, 2 Code of device

3, 4, 5 Code and frequency of the generator (power supply)

6, 7 Automation

8 Tomography or planigraphy

9 Independent or hybrid

10 Number of x-ray tubes

11 Spare

12 Image registration method

13, 14, 15 Power of amplifier

B. Equipment

16, 18, 20	Equipment code
17, 19, 21	Connection mode
22	Spare

C. Software

23	Procedure code
24, 25, 26, 27	Software code

A. Basic devices (boxes numbered 1 to 15)

A device code

Box		Description
1	2	Unused figure values are spare ones to be used as technology develops
0	1	Stand for vertical imaging
0	2	Bone table
0	3	Stand and bone table
0	4	X-ray wall
0	5	Bone table and X-ray wall
0	6	Stand, bone table and X-ray wall
0	7	Telecommand
0	8	Telecommand with video track equipped with an arm for positioning the video track at the required angle to the patient
0	9	Telecommand and stand for vertical imaging
1	0	U-shoulder X-ray device
1	2	Mobile bedside X-ray device
1	4	Mobile examination device with video track equipped with an arm enabling the video track to be positioned at the required angle to the patient.
1	6	Mammograph
1	7	Mammotomy biopsy device (mammotome)
1	8	Angiograph
2	0	Computed tomography (CT)
2	1	Therapeutic simulator
2	3	Dental device for intraoral (spot) radiographs
2	4	Pantomograph
2	5	Cone Beam Computed Tomograph (CBCT)
4	1	Large Densitometer
4	2	Small Densitometer
9	9	Other device

Code of the generator (power supply):

Box	Description
3	
1	Low frequency
	At high frequency (HF), a frequency value in [kHz] shall be entered in all boxes (3, 4 and 5).

Box		Description
4	5	
		At low frequency, number of pulses is: 1, 2, 3, 6, 12

Automation code:

Box	Description
6	
0	No automation
1	AEC (automatic exposure control)
2	AERC (automatic exposure rate control)
3	For CT in Z axis (for 20 in boxes 1 and 2)
	For CT in Z axis and in the plane of the scan (for 20 in boxes 1 and 2)
9	Other

Box	Description
7	
1	Time control
2	Time and current control
3	Time, current and voltage control
4	Time, current, voltage and anode or filtration control
5	Current control
6	Voltage control
9	Other

Code for tomography or planigraphy devices:

Box	Description
8	
0	None
1	Planigraphy (for 2, 3, 5, 6, 7, 8, 9 or 10 in boxes 1 and 2)
2	Tomosynthesis (for 2, 3, 5, 6, 7, 8, 9, 10 or 16 in boxes 1 and 2)
2	Computed tomography - helical scan (for 20 in boxes 1 and 2)
2	Angiography in two planes (for 18 in boxes 1 and 2)
3	3D angiography (for 8, 14 or 18 in boxes 1 and 2)
4	Angiography in two planes and 3D angiography (for 18 in boxes 1 and 2)
9	Other

Independent or hybrid

Box 9	Description
0	Independent
1	(for 14 in boxes 1 and 2) with lithotripter
2	(for 14 in boxes 1 and 2) with surgical table
1	(for 20 in boxes 1 and 2) with SPECT gamma camera (single photon emission computed tomography)
2	(for 20 in boxes 1 and 2) with PET gamma camera
3	(for 20 in boxes 1 and 2) with therapy planning system
1	(for 20 in boxes 1 and 2) with therapy planning system
1	(for 23 in boxes 1 and 2) with dental unit
9	Other

Number of x-ray tubes

Box 10	Description
	Number of X-ray tubes used in the set

Image recording:

Box 12	Description
0	Analogue
1	Indirect digital radiography - CR panels
2	Direct digital radiography - DR panels (DDR)
3	Digital fluoroscopy (for 4, 5, 6, 7, 8, 9, 14 or 18 in boxes 1 and 2)
4	Indirect digital radiography CR + digital fluoroscopy (for 4, 5, 6, 7, 8, 9, 14 or 18 in boxes 1 and 2)
5	Direct digital radiography DR + digital fluoroscopy (for 4, 5, 6, 7, 8, 9 14 or 18 in boxes 1 and 2)
6	Single layer CT acquisition (for 20 in boxes 1 and 2)
7	For CT in Z axis (for 20 in boxes 1 and 2)
8	Multilayer CT acquisition (for 20 in boxes 1 and 2)
9	Other

Power of amplifier

Box			Description
13	14	15	
			In radiography (01, 02, 03, 05, 06, 07, 08, 09, 10, 12 or 16 in boxes 1 and 2), give the largest dimension of the side of the image recorder. In fluoroscopy (04, 05, 06, 07, 08, 09, 14, 18 or 21 in boxes 1 and 2), give the diameter of the image amplifier or the length of the shorter (in cardiac procedures) or longer (in other procedures) side of the DR panel [cm]. In CT (20 in boxes 1 and 2 and 7 in box 12), enter the number of layers that can be reconstructed from a single scan.

B. Equipment (boxes numbered 16 to 22)

Box	Description - name
16, 18 or 20	Different devices (boxes 1 and 2) may have different sets of equipment
1	Automatic syringe
2	ECG gating
3	Breath gating
4	Stereotaxis
5	Additional console for processing results
6	Paediatric equipment
9	Other
For the value 24 in boxes 1 and 2	
8	Cephalometry
Box 17, 19 or 21	Description - way of connecting to the master unit
0	Off-line
1	On-line

C. Software (boxes numbered 23 to 27)

Box 23	Description - Scope of procedures
0	General radiography
1	Angiography
2	Interventional radiology
3	Computed tomography
4	Mammography
5	Stomatology
9	Other

Box	Description
24, 25, 26 or 27	In procedures with different scopes (box 23), software with different scopes may be used
For a value of 0 in box 23	
1	Tomosynthesis
For a value of 1 in box 23	
1	Peripheral vascular
2	Neuroradiology or neurology
3	Cardiology
For a value of 2 in box 23	
1	Orthopaedics
2	Urology
3	Surgery
4	Endoscopy
For a value of 3 in box 23	
1	Cardiology
2	3D reconstruction
3	Virtual endoscopy
4	Densimetry - quantitative computed tomography (QCT)
5	CAD (computer-aided diagnosis) - chest nodes
For a value of 4 in box 23	
1	Tomosynthesis
2	CAD (computer-aided diagnosis) - detection of microcalcifications
3	CAD (computer-aided diagnosis) - tumour detection
For a value of 5 in box 23	
1	Colourful presentation
2	3D reconstruction
For any value in box 23	
7	RIS (Radiology Information System)
8	RIS (Radiology Information System) or PACS (Picture Archiving and Communication System)

2. Nuclear medicine

Group code	Basic devices															Equipment							Software				
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
2										0												0					

Box number:

	A. Basic devices
1	Gamma camera code
2	Acquisition type
3, 4, 5	Parallel collimators
6, 7, 8	Non-parallel collimators
9	Independent or hybrid
10	Number of heads
11	Spare
12, 13	Crystal size along the patient axis and field of view
14, 15	Crystal size across the patient axis and field of view
	B. Equipment
16, 18, 20	Equipment code
17, 19, 21	Connection mode
22	Spare
	C. Software
23	Procedure code
24, 25, 26, 27	Software code

A. Basic devices (boxes numbered 1 to 15)

A device code – a type of camera:

Box	Description
1	Unused figure values are spare ones to be used as technology develops
1	Rotational
2	Stationary
3	Mobile
9	Other

Acquisition type

Box	Description
2	
0	Planar
1	SPECT (single photon emission tomography)
2	PET
9	Other

Parallel collimators:

Box	Description - name
3, 4 or 5	Different devices (box 1) can have different sets of collimators
1	Low-energy (up to 150 keV), high-resolution
2	Low-energy general purpose
3	Medium energy (> 150-400 keV)
4	High-energy (> 400 keV)
9	Other

Non-parallel collimators:

Box	Description - name
5, 7 or 8	Different devices (field 1) can have different sets of collimators
1	Converging
2	Diverging
3	PinHole
9	Other

Independent or hybrid

Box	Description
9	
0	Independent
1	With CT scanner
2	(only for value 2 in box 2) with isotope generating unit (e.g., cyclotron)
3	(only for value 2 in box 2) with isotope generating unit (e.g., cyclotron) and CT scanner
4	With magnetic resonance
9	Other

Number of heads

Box	Description
10	
	Number of heads in set
11	Other

Crystal size and field of view:

Box		Description
12	13	
		Crystal size (width and thickness of active surface) along the patient's long axis in [cm] and field of view
Box		Description
14	15	
		Crystal size (width and thickness of active surface) across the patient's long axis in [cm] and field of view

B. Equipment (boxes numbered 16 to 22)

Box	Description - name
16, 18 or 20	Different devices (boxes 1 and 2) may have different sets of equipment
1	Automatic syringe
2	ECG gating
3	Breath gating
4	Other
9	Other
Box	Description - way of connecting to the master unit
17, 19 or 21	
0	Off-line
1	On-line

C. Test execution protocols (boxes numbered 23 to 27)

Box	Description - Scope of procedures
23	
0	Full-body examination
1	Planar examination
2	SPECT examination (single photon emission tomography)
3	SPECT (single photon emission tomography) ECG gating
4	PET
5	Dynamic examination
9	Other
Box	Description
24, 25, 26 or 27	In procedures with different scopes (box 23), software with different scopes may be used
For all scopes	
1	Dynamic kidney studies (renograms, deconvolution)
2	Software tools (sum, subtraction of images, operations on constants)

For a value of 2 in box 23	
1	Reconstruction of SPECT (single photon emission tomography) images - organ studies - heart
2	Reconstruction of SPECT (single photon emission tomography) images - organ studies - lung
3	Reconstruction of SPECT (single photon emission tomography) images - organ studies - general examinations

3. Radiotherapy

Group code	Basic devices															Equipment							Software					
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
3																						0					

Box number:

	A. Basic devices
1	Type of radiotherapy
2	Type of device
3	Isotope or type of emitted radiation
4, 5, 6	Maximum isotope activity or energy of accelerated particles
7, 8, 9	Activity or collimation
10	Number of channels or wedges
11, 12, 13	Possibilities for positioning or positioning control
14, 15	Recording and supervision over the procedure
	B. Equipment
16, 18, 20	Equipment code
17, 19, 21	Connection mode
22	Spare
	C. Software
23	Procedure code
24, 25, 26, 27	Software code

a. Basic devices (boxes numbered 1 to 15)

Type of radiotherapy:

Box 1	Description
1	Brachytherapy
2	Teleradiotherapy
9	Other

Type of device

Box 2	Description
For a value of 1 in box 1	
1	LDR (low dose rate)
2	PDR (pulse dose rate) therapy
3	MDR (medium dose rate)
4	HDR (high dose rate)
9	Other
For a value of 2 in box 1	
1	Device with isotope source
2	Monoenergetic linear accelerator
3	Multi-energetic linear accelerator
4	Intra-operative accelerator
5	Cyclotron
6	GammaKnife
7	CyberKnife
9	Other

Isotope or type of emitted radiation:

Box 3	Description
For a value of 1 in box 1	
1	Iridium 192
2	Caesium 137
3	Cobalt 60
4	Tantalum 182
5	Radium 226
6	Yttrium 90
9	Other
For a value of 2 in box 1	
1	Photons from an isotope source
2	Photons
3	Electrons
4	Photons + electrons
5	Protons
9	Other

Maximum activity of the isotope (for a value of 1 in box 1) or maximum energy of accelerated particles or radiation emitted from the isotopic source (for a value of 2 in box 1):

Box			Description
4	5	6	
			Activity [GBq] or energy [MeV]

Applicators code (for value of 1 in box 1) or collimation (for value of 2 in box 1):

Box	Description
7, 8 or 9	
For a value of 1 in box 1	
1	Applicators for gynaecological brachytherapy
2	Applicators for intracameral brachytherapy
3	Applicators for intra-tissue brachytherapy
4	Microapplicators for brachytherapy
5	Applicators for contact brachytherapy
6	Individual applicators
9	Other
For a value of 2 in box 1	
0	Symmetrical rectangular collimator only
1	Asymmetrical rectangular collimator
2	Static multileaf collimator
3	Dynamic multileaf collimator
4	Multileaf collimator for stereotaxy
5	Electron applicators
6	Electron tubes
9	Other

Number of available channels (for a value of 1 in box 1) or wedges (for a value of 2 in box 1):

Box	Description
10	
For a value of 1 in box 1	
	Number of source guideways that can be used simultaneously
For a value of 2 in box 1	
0	None
1	Physical wedges
2	Dynamic wedges
9	Other

Possibilities for positioning or positioning control

Box 11, 12 or 13	Description
For a value of 1 in box 1	
1	Applicators for brachytherapy adapted to x-ray imaging
2	Applicators for brachytherapy adapted for tomographic imaging
9	Other
For a value of 2 in box 1	
1	Portal system
1	Positioning using an infrared camera system
2	Positioning using an X-ray system
3	Positioning using ultrasound system
4	Positioning using a tomographic system
9	Other

Recording and supervision over the procedure:

Box 14 or 15	Description
1	Portal dosimetry system
2	Record and Verify System
3	In vivo dosimetry
9	Other

B. Equipment (boxes numbered 16 to 22)

Box	Description - name
16, 18 or 20	Different devices (boxes 1 and 2) may have different sets of equipment
1	Breathing control system
9	Other
Box 17, 19 or 21	Description - way of connecting to the master unit
0	Off-line
1	On-line

C. Software (boxes numbered 23 to 27)

Box 23	Description - Scope of procedures
1	Therapy planning
9	Other
Box	Description
24, 25, 26 or 27	In different devices (boxes 1 and 2) and in procedures with different scopes (box 23), software with different scopes may be used

For a value of 1 in box 1 and a value of 1 in box 23	
1	2D treatment planning system
2	3D treatment planning system
3	Real-time treatment planning system
For a value of 2 in box 1 and a value of 1 in box 23	
1	