JOURNAL OF LAWS
OF THE REPUBLIC OF POLAND

Warsaw, 27 December 2022

Item 2759

REGULATION OF THE MINISTER OF HEALTH[1]

of 12 December 2022

on operational tests of radiological equipment and auxiliary devices[2]

On the basis of Art. 331 sect. 16 of the Act of 29 November 2000 - the Atomic Law (Dz. U. of 2021, item 1941 and of 2022, item 974), it shall be ordered as follows:

§ 1. The Regulation shall specify the range and the frequency of operational tests, as well as tolerances for the tested physical parameters for radiological equipment and auxiliary devices.

§ 2. 1. The range and the frequency of operational tests of radiological equipment and tolerances for the tested physical parameters for such equipment and devices shall be specified in the Annex no. 1 hereto.

2. The range and the frequency of operational tests of auxiliary devices and tolerances for the tested physical parameters for such equipment and devices shall be specified in the Annex no. 2 hereto.

§3.1. The inspection of radiological equipment and auxiliary devices other than those specified respectively in the Annexes no. 1 and 2 hereto shall be performed within the range and with the frequency resulting from the current level of knowledge and practice, including validated research methods.

2. When the range and frequency of the inspection of radiological equipment and auxiliary devices mentioned in Section 1 cannot be determined on the basis of the current level of knowledge and practice, including validated research methods, this inspection shall be performed within the range and the frequency resulting from the operating manual of given radiological equipment or an auxiliary device.

§ 4. Irrespective of the operational test frequency, each repair of radiological equipment or an auxiliary device conducted to the extent that could influence diagnostic quality of obtained image or dose administered to a patient, operational tests should be retaken, at least within the range justified by the specification of a given repair.

§ 5. Within 18 months since the date of entry into force of this regulation operational tests, specific tests and basic tests may be performed by the entities mentioned in Art. 331, Sections 8 and 9 of the Act of 29 November 2000 - the Atomic Law, within the range and with the frequency specified in the Annex no. 3 hereto.

§ 6. The Regulation shall enter into force on the day following its promulgation.[3]

Minister of Health: *A. Niedzielski*

[1] Minister of Health shall manage governmental administration in the area of health, on the basis of art. 1 sect. 2 of the Regulation of the President of the Council of Minister of 27 August 2020 on the detailed scope of activities of the Minister of Health (Dz. U. of 2021, item 932).

[2] Within its regulatory scope, this Regulation shall implement the Directive of the Council no. 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 (OJEU L 13 of January 17, 2014, p. 1, OJEU L 72 of 17 March 2016, p. 69, OJEU L 152 of 11 June 2019, p. 128 and OJEU L 324 of 13 December 2019, p. 80).

[3] This Regulations was preceded by the Regulation of the Minister of Health of 18 February 2011 on safe conditions of application of ionizing radiation for all kinds of medical exposure (Dz. U. of 2017, item 884), which, within regulatory scope of this Regulation, expired on 24 September 2022 in compliance with Art. 37 Section 2 Item 2 of the Act of 13 June 2019 amending the Act - the Atomic Law and the Act on Fire Protection (Dz. U. of 2019, item 1593 and of 2020, item 284).

Annexes to the Regulation of the Minister of Health
of December 12, 2022 (Dz. U., item 2759)

Annex no. 1

THE RANGE AND THE FREQUENCY OF OPERATIONAL TESTS OF RADIOLOGICAL EQUIPMENT AND TOLERANCES FOR THE TESTED PHYSICAL PARAMETERS FOR SUCH DEVICES

I. Basic tests and specific tests of radiological equipment used in X-ray diagnostics and interventional radiology

1. Terms used in specific tests and basic tests in X-ray diagnostics and interventional radiology:

1) **CNR** –a contrast-to-noise ratio, in digital mammography, it is determined for a test object in a form of a 0.2 mm thick aluminum plate placed on a PMMA phantom (e.g. 4.5 cm), as specified in the equation below:

$$\mathrm{CNR}=\frac{x_1 - x_2}{\sqrt{\frac{\sigma_1^2 + \sigma_2^2}{2}}}$$

where:

x_1 – an average pixel value determined in ROI outside a 0.2 mm thick aluminum object image,

x_2 – an average pixel value determined in ROI inside a 0.2 mm thick aluminum object image,

σ_1 - a pixel value standard deviation determined in ROI outside a 0.2 mm thick aluminum object image,

σ_2 - a pixel value standard deviation determined in ROI inside a 0.2 mm thick aluminum object image;

2) $\mathrm{CTDI}_{\text{free air}}$ – a tomography dose index in free air, a dosimetric parameter used in computed tomography and corresponding to the CTDI_{100} value measured in an isocenter without a dosimetric phantom;

3) $\mathrm{CTDI}_{\mathrm{vol}}$ – a volumetric tomography dose index, a dosimetric parameter used in computed tomography and determined as follows:

$$\mathrm{CTDI}_{\mathrm{vol}} = \frac{L}{d} \cdot \left(\frac{1}{3} CTDI_{100c} + \frac{2}{3} CTDI_{100p}\right)$$

where:

L – total nominal width of active detectors,

d – a distance a table moves during one complete rotation of an X-ray tube,

CTDI_{100c} – CTDI_{100} value measured inside a dosimetric phantom,

CTDI_{100p} – an arithmetic mean of CTDI_{100} values measured at the edges of a dosimetric phantom,

CTDI_{100} – a dose profile integrating along the distance of 100 mm along a line parallel to an X-ray tube axis of rotation for a single layer, divided by the value of nominal layer thickness;

4) **reference exposure –** in analogue mammography, it is the exposure of a homogenous PMMA phantom of total thickness of 4.5 cm, performed at high voltage of 28 kV, using a molybdenum

anode and a filter and with an active exposure automatic control system and an anti-scatter grid, assuring obtained images have optical density of l.6±0.l, measured in a reference point;

5) an **image quality assessment phantom –** in basic tests in digital mammography, it is a phantom imitating a 4.2 cm thick breast with average density corresponding to 50% of glandular tissue and 50% of adipose tissue, containing:

a) fiber-imitating elements, including those with a diameter of 0.75 mm and smaller and larger diameters,

b) groups of microcalcification-imitating elements, including those with a diameter of 0.32 mm and smaller and larger diameters,

c) round solid lesion-imitating elements, including those with thickness of 0.75 mm and smaller and larger thickness;

6) a **dosimetric phantom –** a cylindrical PMMA phantom imitating a patient's head with a diameter of 16 cm or a patient's body with a diameter of 32 cm;

7) a standard patient-equivalent **phantom–** a homogenous PMMA phantom with dimensions of at least 30 x 30 cm and thickness of 15 cm PMMA, which can also be replaced by a fixed water phantom with thickness of 15 cm.; in specific tests, it is also allowed to use a vertical image tripod and, as a standard patient-equivalent phantom, a 2.5 cm Al plate, assuring coverage of the entire image recorder;

8) a **step phantom –** a phantom containing at least three elements (steps) of different thickness to assess exposure repeatability, made of the same material or different materials;

9) **G** – a coefficient of previous image remains, in digital mammography is determined as follows:

$$G = \frac{x_3 - x_2}{x_1 - x_2}$$

where:

x_1 – an average pixel value determined in ROI outside the area covered by a 4.5 cm thick PMMA phantom and outside an aluminum object,

x_2 – an average pixel value determined in ROI outside the area covered by a 4.5 cm thick PMMA phantom, inside a 0.1 mm thick aluminum object,

x_3 – an average pixel value determined in ROI in the area covered by 4.5 cm thick PMMA, inside a 0.1 mm thick aluminum object;

10) an **image detector main area –** in image detector X-ray devices, it is the area corresponding to the location of the active sensor area in the automatic exposure control (AEC) system;

11) **HVL** – a layer, thickness of specific material that, for narrow beams, reduces X-rays with certain radiant energy or radiation spectrum, so kerma, radiation exposure, absorbed dose, kerma value, radiation exposure value or absorbed dose value is halved, when compared to this value measured without the said material;

12) **MTF — a** modulation transfer function describing a system response to a sinusoidal input

signal.

In computed tomography, MTF can be determined as the ratio of an output signal modulation to an input signal modulation; then MTF for the pattern of alternating lines with different HU values can be expressed as follows:

$$\mathrm{MTF}(\nu) = \frac{\pi}{\sqrt{2}} \cdot \frac{\sqrt{M_{\text{wzór}}^2 - N_{\text{tło}}^2}}{|HU_{\text{materiał}} - HU_{\text{tło}}|}$$

where:

$M_{pattern}$ – a modulation in the alternating line pattern image, expressed as a pixel value standard deviation,

$N_{background}$ – an average background noise calculated as an arithmetic mean for pixel value standard deviations, calculated in a uniform area of the pattern and background material, for ROI containing at least 100 pixels,

$HU_{material}$ and $HU_{background}$ – HU values measured in a uniform area of the pattern and background material, for ROI with the area containing at least 100 pixels;

13) **MTF_{50}** – spatial frequency expressed in line pairs per mm or cm, corresponding to the MTF value of 50%;

14) a **deviation of the tested physical parameter from the recommended value:**

a) a deviation expressed in percentage – parameter expressed as follows:

$$odchylenie\ procentowe = \left(\frac{m}{p} - 1\right) \cdot 100\%$$

b) an absolute deviation – parameter expressed as follows:

$$absolute\ deviation = m - p$$

where:

m – a value measured for a given physical parameter,

p – a recommended value (e.g. reference value, nominal value);

15) **PMMA** — poly(methyl methacrylate);

16) a **threshold contrast –** a contrast level for the smallest difference detectable in an image between an object and a background;

17) a **reference point –** in mammography, a point located 60 mm from a table's edge from thorax and centrally in relation to table's side edges;

18) **r_{xy}** – a Pearson correlation coefficient (from a sample), covariance (from a sample) divided by a square root value for a product of respective standard deviations (from a sample):

$$\mathrm{r_{XY}} = \frac{\sum_{i=1}^{n}(X_i - X_{śr}) \cdot (Y_i - Y_{śr})}{\sqrt{\sum_{i=1}^{n}(X_i - X_{śr})^2 \cdot \sum_{i=1}^{n}(Y_i - Y_{śr})^2}}$$

where:

$\mathbf{r_{xy}}$ – a correlation coefficient,

X_i, Y_i – random variables of continuous probability distribution,

$X_{śr}$, $Y_{śr}$ – average values for X_i, Y_i samples;

19) **ROI** – in digital systems, it is a region of interest, marked in an image;

20) **low contrast resolution –** a contrast level for which a difference between an object and background can be seen;

21) **high contrast resolution –** system capability to distinguish an object in a displayed image in the case a difference in radiation attenuation between objects and background is larger when compared to noise;

22) **a fixed water phantom –** a phantom made of a material with an effective atomic number similar to water with density of (1.03±0.02) g/cm^3 and transverse dimensions of at least 30 x 30 cm;

23) **SNR** – a signal-to-noise ratio; in digital radiology basic tests, it is determined as follows:

$$SNR=\frac{x}{\sigma}$$

where:

x – an average pixel value measured in ROI,

σ - a pixel value standard deviation measured in ROI;

24) **SNR** – a signal-to-noise ratio; in digital radiology specific tests, it is determined as follows:

$$SNR=\frac{x-o}{\sigma}$$

where:

x – an average pixel value measured in ROI,

σ - a pixel value standard deviation measured in ROI,

o – a pixel value standard deviation for zero exposure;

25) an **average glandular dose –** in mammography, an average X-ray dose absorbed in the glandular tissue of uniformly compressed breast;

26) **an X-ray field center –** a geometrical X-ray field center (blackened field) marked on an X-ray image;

27) **an image recorder center –** a geometrical image recorder center;

28) **W** – X-ray tube efficiency expressed as follows:

$$W=\frac{K}{Q}$$

where:

K —a value of kerma measured in air,

Q – a current and time load.

X-ray efficiency for the focus-to-detector distance of 1 m is:

$$W = \frac{K}{Q} \cdot \left(\frac{d}{d_0}\right)^2$$

where:

d – a measured X-ray focus-to-detector distance, expressed in meters,

d_0 – an X-ray focus-to-detector distance of 1 m;

29) **a tomographic layer –** in conventional tomography, it is an imagined layer of a phantom longitudinal section;

30) **HU value** – a value used to determine average X-ray attenuation, related to each basic surface of an image obtained during computed tomography;

31) **a nominal value –** a value given by the manufacturer in technical documentation, displayed on a device or located on a device label, used for comparative purposes;

32) **a reference value –** an average parameter value expressed by a user on the basis of measurements performed on five consecutive days of operation of completely operational X-ray equipment, directly after acceptance tests and always after every significant repair; for such tests like high-contrast image resolution, threshold image contrast and image blackening repeatability, reference values can be determined on the basis of a single measurement; tests for which reference values are used should be performed within the same geometry for the same exposure conditions as the reference value measurement;

33)**a pixel value –** a discrete value representing a grey scale level assigned to a given pixel;

34) **high voltage –** difference of potentials applied to an X-ray tube anode and cathode;

35) $\mathbf{X_{śr}}$- an average value, arithmetic mean for a measurement series

$$X_{śr} = \sum_{i=1}^{n} \frac{x_i}{n}$$

where:

n – a measurement number;

36) a **range – a** difference between the maximum and the minimum value of a given feature.

2. If possible and justified, non-processed image analyses should be performed in basic and specific tests.

3. In basic and specific tests of radiological equipment used in X-ray diagnostics and interventional radiology, quantities of kerma and absorbed dose in air shall be treated as equivalent parameters.

4. Tested physical parameters should be checked using clinical functions of radiological equipment available for users.

I.1. BASIC TESTS

DEVICES USED IN GENERAL ANALOGUE RADIOGRAPHY				
No.	Test name	Scope		Frequency
		test description	criterion	
1.	**Geometry**	**1.1. Congruence of X-ray field and light field** Sum of the distances between respective edges of the light field and the X-ray field (separately alongside each of two perpendicular axes of symmetry of the X-ray field) in reference to the distance between the tube focus and light field surface is max.	3%	every month
		1.2. Congruence of X-ray field and light field Sum of the distances specified in Section. 1.1 in reference to the distance between the focus and the image recorder is max.	4%	
2.	**Exposure repeatability**	Attention: Perform one of the following tests: 2.1. or 2.2. Use a test kit for the test 2.2		
		2.1. For exposure with the use of a standard patient-equivalent phantom, performed with the application of clinically used exposure parameters, deviation of a kerma value measured in air from a reference value is within a range of	±20%	every month
		2.2. For an image obtained with the use of a step phantom and clinically applied exposure parameters, a deviation of an optical density value measured at the step phantom image criterion field from	±0.20	

		a reference value is within a range of		
3.	**High and low contrast resolution**	Attention: Use a test kit to perform the test		
		At the image of a test object, containing patterns for resolution assessment and obtained with the use of clinically applied exposure parameters, high and low contrast resolution is visually not worse than a reference value	—	every 6 months
4.	**Anti-scatter grid**	Attention: Perform the anti-scatter grid test for all distances between the tube focus and the image recorder, applied clinically, using the largest clinically used test kit with a uniform screen magnifier		
		4.1. For exposure of a movable grid created during the shortest clinically applied exposure period and corresponding high voltage and amperage ensuring that optical density in a grid image center is within 0.9-1.4 (including background), grid lines are not visible in an image	—	every 3 months
		4.2. For exposure of a fixed grid created for the nearest possible high voltage value to 50 kV and amperage ensuring that optical density in a grid image center is within 0.9-1.4 (including background), significant artifacts are not visible in an image	—	
		4.3. For the direction perpendicular to anti-scatter grid sticks, deviation of optical density at image edges from optical density at image center is within a range of	±30%	
5.	**Automatic exposure**	Attention: Use a test kit to perform the test. Average optical		

	control system	density in obtained image is within the range of 0.9-1.4 (including background). The 5.1-5.3. tests should be performed with the use of a chamber or a group of chambers, that is the most often clinically applied one		
		5.1. AEC system assessment at a high voltage variation A deviation of optical density values measured at the center of images of a standard patient-equivalent phantom, obtained for the lowest and the highest value of high voltage within a clinically applied range, from an average value is within a range of	±0.15	6 months after each specific tests
		5.2. AEC system assessment at a phantom thickness variation A deviation of optical density values measured at the center of images of a standard patient-equivalent phantom and a phantom of other thickness made of the same material as a standard patient-equivalent phantom, obtained for the same most often clinically applied value of high voltage, from a reference value is within a range of	±0.30	
		5.3. AEC system assessment during an amperage variation A deviation of optical density values measured at the center of images of a standard patient-equivalent phantom, obtained for identical AEC system settings, for the lowest and the highest value of exposure period within a clinically applied range, from an average value is within	±0.15	

		a range of		
		5.4. AEC system chamber sensitivity assessment A deviation of optical density values measured at the center of images of a standard patient-equivalent phantom, obtained for each AEC system chamber, from an average value is within a range of	±0.30	
DEVICES USED IN GENERAL DIGITAL RADIOGRAPHY				
No.	Test name	Scope		Frequency
		test description	criterion	
L	**Geometry**	**1.1. Congruence of X-ray field with light field** Sum of the distances between respective edges of the light field and the X-ray field (separately alongside each of two perpendicular axes of symmetry of the X-ray field) in reference to the distance between the tube focus and light field surface is max.	3%	each month

II. Basic and specific tests of radiological equipment used in nuclear medicine

Terms used in specific and basic tests in nuclear medicine:

1) **CFOV** – central field of view; an area equal to 75% of linear dimension of the useful field of view (UFOV);

2) **system sensibility –** a fraction of photons emitted by a radionuclide of known activity, in the form of a flat source of specific dimensions, located centrally in an axis collimator and horizontally to a collimator, recorded by a camera gamma detector with a collimator, determined for each collimator and expressed in the following units: number of counts/sec./MBq;

3) **large number of counts –** in a camera gamma detector uniformity test it is ca. 10,000 counts in a pixel (i.e. 30-40 min counts for a 64 x 64 image matrix or more than 100 min counts for a 128 x 128 image matrix);

4) **FOV** – field of view; an area limited by a collimator;

5) **FWHM –** full width of a drawn profile in a location at half maximum of height of this profile; for spatial resolution measurements, an image profile for a point or linear source is drawn, for a single gamma rays emitting radionuclide;

6) $\mathbf{J_c}$ – integrating spatial uniformity; variability factor for a number of counts recorded by a detector for its defined area and for the uniform stream of gamma rays falling at camera UFOV, expressed as follows:

$$J_c = \left(\frac{max - min}{max + min}\right) \cdot 100\ \%$$

where:

max – maximum number of counts, recorded by a detector within a defined area,

min – minimum number of counts, recorded by a detector within a defined area;

7) $\mathbf{J_r}$ – differential spatial uniformity; variability factor for a number of counts recorded by a detector for defined distance and for the uniform stream of gamma rays falling at camera UFOV, expressed as follows:

$$J_r = \left(\frac{max - min}{max + min}\right) \cdot 100\ \%$$

where:

max – a maximum number of counts, recorded by a detector alongside a defined distance (5 consecutive pixels in an image),

min – a minimum number of counts, recorded by a detector alongside a defined distance (5 consecutive pixels in an image);

8) **external spatial uniformity – a** variability factor for a number of counts recorded by a detector with a collimator;

9) **internal spatial uniformity – a** variability factor for a number of counts recorded by a detector without a collimator;

10) **NU** – non-uniformity; a parameter determined as follows:

$$\mathrm{NU_{vol}} = \mathrm{MAX}\left(\frac{max_j - ave_j}{ave_j}, \frac{ave_j - min_j}{ave_j}\right) \cdot 100\ \%$$

where:

max_j – a maximum number of counts in all images for all sections,

min_j – a minimum number of counts in all images for all sections,

ave – an average number of counts in all images for all sections;

11) an **energy window –** the amount of energy of gamma rays that will be recorded and processed; the window can be presented as an energy amount or a percentage value of an expected energy peak; when a window is presented as a percentage value, an energy peak must be determined and a window is always symmetrical when compared to this peak;

12) **repeatability – the** ratio of a measurement result standard deviation to an average value of these results;

13) **a reference radioactive source –** radioactive source (Co-57, Cs-137 or Ba-133) with a calibration certificate by national meteorological institutions or designated institutes, acting as depositaries of state-issued calibration certificates;

14) $\mathbf{R_E}$ – energy resolution; energy resolution capacity; a system ability to distinguish photons of various energy, determined as follows:

$$\mathrm{R_E} = \frac{FWHM}{E_0} \cdot 100\%$$

where:

FWHM – full width at half maximum, expressed in energy units,

E_0 - energy of monoenergetic radiation emitted by a source;

15) **spatial resolution –** FWHM of a function profile of detector response to a linear source, drawn perpendicularly to a vertical axis of this source;

16) **UFOV** – useful field of view; a detector area used for imaging;

17) **a reference value –** in basic tests, it is a parameter average value determined by a user for measurements performed on five consecutive days of operation of fully operational radiological equipment and a monitor, directly after acceptance tests and after each significant repair, using measurement methods designed for basic tests with specified measurement conditions and geometry; for such tests like energy resolution and spatial resolution, reference values can be determined on the basis of measurements performed on the same day.

II.1. BASIC TESTS

ABSOLUTE ACTIVITY GAUGES				
No.	Test name	Scope		Frequency
		test description	criterion	
1.	**Background measurement**	Attention: Perform the test with settings applicable for the radionuclide used on a given day, with a holder placed in the gauge		
		Background fluctuations are within two standard deviations from the reference value	—	at the beginning of each day, the gauge is going to be used on
2.	**Consistency of readings**	Attention: Perform the test using the reference radioactive source. Count number measurement should be performed with settings applicable for a given radionuclide and for all radionuclides to be used on a given day. Measurement conditions and geometry are in compliance with those specified during determination of a reference value		
		Measurement deviation from the reference value (after considering radionuclide decay) is within a range of	±5%	every day
3.	**Count accuracy**	Attention: Perform the test using the reference radioactive source		
		Measurement result repeatability calculated for at least 30 measurements is max.	5%	every 6 months
4.	**Linearity of readings**	Attention: Perform the test for the most often clinically used radionuclide (e.g. ^{99m}Tc, ^{131}I) in the entire scope of applied activities. Select activity measurement points, so they evenly cover the entire scope of applied activities. Determine expected activity values on the basis of the radioactive decay law		
		A deviation of the measured activity value from the expected activity value for each measurement point is	±5%	every 12 months

		within a range		
THYROID IODINE UPTAKE MEASUREMENT KIT				
No.	Test name	Scope		Frequency
		test desciption	criterion	
1.	**Energy calibration**	Check of energy window setting accuracy at photopeak. Make a correction, when energy window is not photopeak-centered	—	on the day preceding the day of tests in which the device is going to be used (multi-channel probes) or every month (single-channel probes)
2.	**Background measurement**	Background fluctuations are within two standard deviations from the reference value	—	at the beginning of each day in which the device is going to be used
3.	**Consistency of readings**	Attention: Perform the test using the reference radioactive source. Measurement conditions and geometry are in compliance with those specified during determination of a reference value		
		Measurement deviation from the reference value (after considering radionuclide decay) is within a range of	±10%	on the day preceding the day of tests in which the device is going to be used
4.	**Count accuracy**	Attention: Perform the test using the reference radioactive source		
		Using a chi-squared test check whether the count variance is within the limits anticipated for the Poisson distribution. Set the confidence interval at 95%.	—	every 6 months
SCINTILLATION COUNTERS FOR IN VITRO GAMMA X-RAY MEASUREMENT				
No.	Test name	Scope		Frequency
		test description	criterion	
1.	**Energy calibration**	Attention: Perform the test for the used radionuclides with		

		energy values selected, so they cover the entire applied scope. If one radionuclide is used, perform the test for this radionuclide		
		Check of energy window setting accuracy at photopeak. Make a correction, when energy window is not photopeak-centered	—	every 6 months, if the device is used less often, perform the test before its operation
2.	**Background measurement**	Attention: Perform the test for the most often clinically applied energy and window		
		Background fluctuations are within two standard deviations from the reference value	—	on the day preceding the day of tests in which the device is going to be used
3.	**Consistency of readings**	Attention: Perform the test using the reference radioactive source. Measurement conditions and geometry are in compliance with those specified during determination of a reference value		
		Measurement deviation from the reference value (after considering radionuclide decay) is within a range of	±10%	on the day preceding the day of tests in which the device is going to be used
4.	**Count accuracy**	Attention: Perform the test using the reference radioactive source		
		Using a chi-squared test check whether the count variance is within the limits anticipated for the Poisson distribution. Set the confidence interval at 95%.	—	every 6 months
OPERATING MEASUREMENT PROBES				
No.	Test name	Scope		Frequency
		Test description	Criterion	
1.	**Energy calibration**	Check of energy window setting accuracy at photopeak. Make	—	every 6 months, if the device is used less often, perform

		a correction, when an energy window is not photopeak-centered		the test before its operation
2.	**Background measurement beyond operating field**	Attention: Perform the test for all collimators used on a given day		
		Background fluctuations are within two standard deviations from the reference value.		on the day preceding the day of tests in which the device is going to be used on
3.	**Consistency of readings**	Attention: Perform the test using the reference radioactive source for all used energy windows and collimators. Measurement conditions and geometry are in concordance with those specified during determination of a reference value		
		Measurement deviation from the reference value (after considering radionuclide decay) is within a range of	±10%	on the day preceding the day of tests in which the device is going to be used
PLANAR SCINTILLATION CAMERAS				
No.	Test name	Scope		Frequency
		test description	Criterion	
1.	**Background measurement**	Attention: Perform the test for the most often used low energy window		
		Counts are evenly distributed in the image within a visual assessment	—	every day
2.	**Check of an energy window position at photopeak**	Attention: Perform the test for all radionuclide or approximate energy values that are going to be used on a given day		
		Correct the energy analyser window location, if it is different from the reference value or it exceeds the limit value provided by the manufacturer	—	on the day preceding the day of tests in which given radionuclides are going to be used on
3.	**Visual collimator inspection**	No visible external collimator damage during a visual inspection	—	every day

4.	**Detector spatial uniformity**	Attention: Perform the uniformity test for all radionuclides used on a given day. If the manufacturer guarantees keeping of uniformity on the basis of a correction map calculation for ^{99m}Tc, performance of this test for other nuclides can be abandoned. Assess external or internal spatial uniformity		
		Count distribution is homogeneous within a visual inspection and no clear local maxima, minima and gradients are visible	—	on the day preceding the day the camera is going to be used
5.	**External spatial uniformity for a large number of counts**	Attention: Perform the test using the ^{99m}Tc or ^{57}Co source (or other radionuclide, if it is clinically used more often, e.g. ^{131}I). Calculate the integral and the differential measure of uniformity for a large number of counts		
		Integral uniformity determined for UFOV and CFOV is max.	7%	every month
6.	**Spatial resolution and detector linearity**	Attention: Perform the test using a collimator and the phantom consisting of 4 sectors of lines with different width, adjusted to camera resolution. Perform the test 4 times, turning the phantom by 90 degrees after each acquisition.		
		6.1. During a visual inspection line layout in an image does not deviate from straight lines	—	every 6 months
		6.2. During a visual inspection line distinguishability is identical as in the reference image	—	
SPECT and SPECT/CT CAMERAS				
Attention: Perform all tests planned for scintillation cameras, excluding the test no. 5, and the tests specified below				
No.	Test name	Scope		Frequency
		test description	criterion	
1.	**Rotation centre location**	Attention: Perform the test for all collimators used in a workshop and for all angles of detector settings having impact on each other		
		Rotation centre shift in	As per	every 3 months

		relation to the image matrix is max.	recommendations of the manufacturer	
2.	**External detector spatial uniformity for a large number of counts**	Attention: Perform the test using the ^{99m}Tc or ^{57}Co source (or other radionuclide, if it is clinically used more often, e.g. ^{131}I). Calculate the integral and the differential measure of uniformity for a large number of counts		
		Integral uniformity determined for UFOV and CFOV is max.	5%	every month
3.	**Adjustment of tomography cuts obtained by means of the SPECT and CT techniques**	Attention: Perform the test using the dedicated phantom with spatially distributed point or linear sources		
		No perceptible shifts among the SPECT and CT images in a visual inspection	—	every 6 months
4.	**Comprehensive operations of the imaging system**	Attention: Perform the test using the phantom designed to assess comprehensive operation of SPECT camera, i.e. a cylindrical PMMA phantom filled with a radioisotope solution, containing bars for resolution assessment, spheres for contrast assessment and the uniformed section		
		4.1. Bar resolution in a visual inspection is in concordance with the reference value	—	every 12 months
		4.2. Number of cold foci in a visual inspection is in concordance with the reference value		every 12 months
5.	**CT module test**	Attention: For SPECT/CT cameras in which the CT module is used for diagnostic purposes, perform all tests planned for computed tomography machines. When the CT module is used to locate transformations visible in a SPECT test and to correct radiation absorption, perform tests for computed tomography machines in terms of basic tests, specified at the following points: artifacts, HU value, image uniformity, noise level, geometrical image correctness, locating lights, table movement		

PET IPET/CT SCANNERS

No.	Test name	Scope		Frequency
		test description	criterion	

1.	**PET detector stability**	Perform using the source specified by the manufacturer in concordance with recommended methods	as per recommendations of the manufacturer	on the day preceding the day the scanner was used
2.	**Normalisation**	Attention: Perform using the phantom or the source specified by the manufacturer in concordance with recommended methods		
		Sinograms in a visual inspection are correct	—	as per recommendations of the manufacturer
3.	**Reconstructed image uniformity**	Attention: Perform using a uniformed source (e.g. a cylinder filled with the F-18 solution or the cylindrical Ge-68/Ga-68 source). Reconstruction should be performed with the use of all corrections (i.e. normalisation, dead time, decay, sensitivity, accidental coincidences, dispersion and attenuation) and clinically applied parameters		
		3.1. Artifacts in a visual inspection are not visible at the reconstructed image, and in transaxial and sagittal sections	—	every 3 months
		3.2. Deviation of calculated non-uniformity from the reference value in a quantitative assessment is max.	5%	every 3 months
4.	**Activity concentration calibration**	Perform using the phantom specified by the manufacturer in concordance with recommended methods, for two or three dimensions	as per recommendations of the manufacturer	every 3 months
5.	**Image quality**	Attention: Perform using a cylindrical phantom containing elements to assess spatial resolution, contrast (spheres of various diameters from 10 to 40 mm) and uniformed layer		
		5.1. Bar resolution in a visual inspection is in concordance with the reference value	—	every 6 months
		5.2. Image uniformity in	—	every 6 months

		a visual inspection is in concordance with reference image uniformity		
		5.3. In a visual inspection distinguishability of cold spheres in an image is in concordance with distinguishability in a reference image	—	every 6 months
6.	**Tomography spatial resolution in air**	Attention: Perform the test using three-point or linear sources located in air in the following places: on Y axis 1 cm from rotation centre (representing the FOV centre); on Y axis 10 cm from a rotation centre and on X axis 10 cm from a rotation centre		
		Deviation of the determined tomography resolution value from the reference value is max.	5%	every 6 months
7.	**Adjustment of tomography cuts obtained by means of the PET and CT techniques**	Attention: Perform the test using the dedicated phantom with spatially distributed point or linear sources, for the most often used reconstruction methods and post-reconstruction filter parameters determined by a user		
		No perceptible shifts in a visual inspection of accuracy of 3D overlapping for PET and CT images	—	every 6 months
8.	**CT module test**	Attention: For PET/CT cameras in which the CT module is used for diagnostic purposes, perform all the tests planned for computed tomography machines. When the CT module is not used for diagnostic purposes, perform tests for computed tomography machines in terms of basic tests, specified at the following points: artifacts, HU value, image uniformity, noise level, geometrical image correctness, locating lights, table movement		

II.2. SPECIFIC TESTS

ABSOLUTE ACTIVITY GAUGES **Frequency:** Specific tests are performed at least once per 12 months			
No.	Test name	Scope	
		test description	criterion
1.	**Measurement**	Attention: Perform the test when an activity gauge is not calibrated	

	accuracy	once per year in a laboratory accredited as specified in the PN-EN ISO/IEC 17025 standard	
		1.1. For gamma radiation sources with energy exceeding 100 keV gauge accuracy is max.	5%
		1.2. For beta and gamma radiation sources with energy not exceeding 100 keV gauge accuracy is max.	10%
SCINTILLATION CAMERAS			
Frequency: Specific tests are performed at least once per 12 months			
No.	Test name	Scope	
		test decription	criterion
1.	**Pixel size**	**1.1.** Deviation of pixel size values measured alongside the X and Y axes is within a range of	±5%
		1.2. Deviation of the pixel size from the value specified by the manufacturer is within a range of	±10%
2.	**System sensitivity**	Attention: Perform the test using ^{99m}Tc for the most often used collimator	
		For a given collimator deviation of system sensitivity from the reference value is max.	10%
SPECT and SPECT/CT CAMERAS **Frequency:** Specific tests are performed at least once per 12 months			
Attention: For each transducer perform all tests planned for scintillation cameras, followed by:			
No.	Test name	Scope	
		test description	criterion
1.	**Tomography spatial resolution in air**	Attention: Perform the test using a point source located max. 1 cm from the detector rotation axis, near the centre of the detector field of view. For reconstruction use filtered backprojection, if possible, using only the ramp filter. If the system requires application of a structural filter, use the less smoothing filter, i.e. with the highest limit frequency and of the largest magnitude	
		1.1. Deviation of tomography resolution, specified by profile FWHM for reconstructed image of the point source drawn alongside the X and Y axes, from spatial resolution specified by profile FWHM for the image of this point source obtained during planar	10% or 2 mm

		acquisition, drawn alongside the X axis, is max.	
		1.2. Deviation of tomography resolution, specified by profile FWHM for reconstructed image of the point source drawn alongside the Z axis, from tomography resolution specified by profile FWHM for reconstructed image of the point source, drawn alongside the X and Y axes, is within	±10%
2.	**System tomography uniformity**	Attention: Perform the test using the phantom designed for the assessment of comprehensive operation of SPECT cameras, e.g. Jaszczak phantom. If possible, for reconstruction, use filtered backprojection, only with the ramp filter; if the system requires application ofa structural filter, use the less smoothing filter, i.e. with the highest limit frequency and of the largest magnitude. Use Chang method of absorption correction with the attenuation factor p = 0.11 cm^{-1}. For the SPECT/CT camera apply absorption correction with use of a CT module and image reconstruction	
		2.1. Contrast between any circular artifact and uniformed background is max.	10%
		2.2. Deviation of pixel centered value and edge value for the phantom uniformed layer	±10%
3.	**CT module test**	Attention: For SPECT/CT cameras in which the CT module is used for diagnostic purposes, perform all specific tests planned for computed tomography machines. When the CT module is used to locate transformations visible in a SPECT test and to correct radiation absorption, perform tests for computed tomography machines in terms of high voltage and the volumetric tomography dose index ($CTDI_{vol}$)	
PET/CT CAMERAS **Frequency:** Specific tests are performed at least once per 12 months			
1.	**CT module test**	Attention: For PET/CT cameras in which the CT module is used for diagnostic purposes, perform all specific tests planned for computed tomography machines. When the CT module is used to locate transformations visible in a PET test and to correct radiation absorption, perform tests for computed tomography machines in terms of high voltage and the volumetric tomography dose index ($CTDI_{vol}$)	