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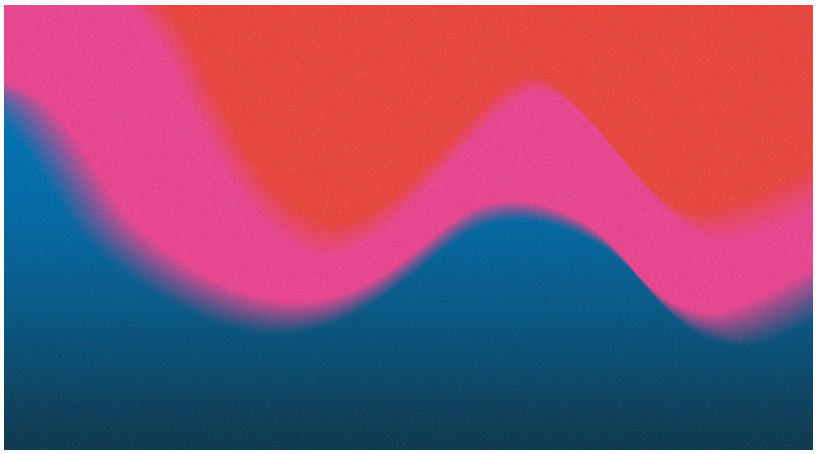

Guideline
QA of cameras in nuclear medicine
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www.bag.admin.ch/str-wegleitungen

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Quality assurance of gamma, SPECT and PET cameras

1 Objective and scope

This guideline is intended for suppliers and users of gamma cameras, single photon emission computed tomography (SPECT) scanners and positron emission tomography (PET) scanners. Its purpose is to indicate the quality assurance procedures to be followed during the commissioning, use and periodic revision of this equipment.

Quality assurance measures for organ-specific gamma cameras (e.g., those dedicated to cardiac or thyroid examinations) or PET cameras (e.g., for brain examinations), with direct application to human beings, shall in principle correspond to those defined in this guideline where relevant. The manufacturer's own methods are acceptable where necessary. In this case, the manufacturer must justify any deviations from the measures defined in this guideline.

Quality assurance measures for preclinical imaging devices, or more generally imaging devices without direct application to human beings (e.g., micro-PET/-SPECT devices, with or without CT part, for small animal imaging, or devices developed for the assessment of excised tissues) are not defined in this guideline. However, manufacturers of such systems must define appropriate quality assurance measures for these cameras. For such equipment, it is recommended to refer to other specific standards and guidelines[1], or to use this guideline as a starting point for developing an appropriate quality assurance programme. In contrast, this guideline applies analogously to clinical veterinary applications.

[1] Such as the joint EANM and ESMI guideline for quality assurance of preclinical SPECT and PET cameras [15].

Content

2 Legal provisions

Article 100 of the Radiological Protection Ordinance (RPO; SR 814.501; [1]) of 26 April 2017 specifies that nuclear medicine examination systems must be checked before being used for the first time and that they must also be regularly checked and revised. Article 62 of the Federal Department of Home Affairs' Ordinance on the Use of Radioactive Materials (UraM/OUMR/MMRa; SR 814.554; [2]) specifies that a reception test must be carried out by the supplier when these systems are put into service; that maintenance must be carried out every six months by an authorised qualified technician, with a status check at the end of this maintenance; and that regular checks must be carried out on the stability of these systems.

In principle, the system user will have the resources required to carry out the stability tests (phantoms, radioactive reference sources). These resources depend, among other things, on the type of construction of the equipment. They are generally determined by the supplier at the time of installation and during the reception test. Finally, in accordance with art. 60, para. 5 of the UraM/OUMR/MMRa, the company authorised under art. 9, let. g, RPO, to carry out quality assurance measures must notify the Federal Office of Public Health (FOPH) of the execution and results of reception tests and status checks.

In the case of hybrid PET/CT and SPECT/CT systems, the computed tomography (CT) scanner must also be checked in accordance with the FOPH directive on quality assurance for CT scanners [3].

If the parameters to be checked are established using a method other than that recommended in this guideline (for example in accordance with the standards [4,5,6,7]), the company responsible for the checks must prove and document in the technical file the equivalent quality of the method, which has to be validated by FOPH upon application and before using the device. This may be the case in particular where there are manufacturing differences from the usual design.

For certain tests, instead of using unsealed radioactive sources whose activity is measured by dose calibrator, the use of sealed sources, the activity of which is officially calibrated, may be authorised, but must be approved by FOPH. The application for approval must contain information on the manufacturing method, the activity of the source and its traceability.

If the technical specifications of the device allow it, and if both the manufacturer and the user agree, lower activity levels than those specified in Annexes 2 through 5 may be applied.

The responsibility for carrying out the various quality checks and their frequency are summarised in the following Table:

	Reception tests	**Status checks**	**Stability tests**
Executing body	Licensed company	Licensed company	User
Periodicity	At reception and after major modifications†, always before commissioning	Half-yearly	Regularly‡

† Examples of major modifications: move of the device to another room (except for small, mobile cameras), or addition of a ring of detectors. For large cameras installed on trucks, the possible requirement for new reception tests following the relocation of the truck is specified individually in the relevant FOPH license.

‡ See annexes 3 and 5 for the frequency of each test.

Participation of SSRMP certified medical physicists in the execution of the quality assurance tests, in coordination with the radiographers and nuclear medicine physicians, is encouraged in the following way:

- Being involved in an efficient information exchange with the supplier or licensed company in the frame of the reception tests and half-yearly status checks (in particular for the communication of the test results); being involved during the handing-over of the device from the supplier to the user.
- Direct involvement in the stability tests performed by the user.

The present guideline enters into force on March 1st, 2025, with a one-year transition period, during which quality assurance checks may be carried out in accordance with the requirements of the previous version of this guideline, Revision 1, dated March 7th, 2018.[2]

3 Technical file and control records

During installation and reception testing carried out by the supplier, a technical file is drawn up for each gamma camera, SPECT camera and PET camera. This contains the documents and reports described in Annex 1 of this guideline. The results of reception tests and status checks must be recorded in a report and filed in the technical file, in paper or electronic form. Due to their volume, the stability tests carried out by the user may be saved electronically or documented in a separate file. However, the technical file must contain at least the reference values established at the time of the last status check or reception test carried out by the licensed company and which serve as a reference for the stability tests.

For reception tests and status checks, the target values and tolerance intervals, if not specified in the Annexes to this guideline, must correspond to the manufacturer's specifications and must be documented and passed on to the users.

4 Reception tests and status checks for gamma, SPECT and PET cameras

The **licensed company** (supplier or manufacturer) performs the reception test and documents it in a report, after installation of the gamma camera, SPECT camera or PET camera and before its commissioning, or following major modifications (see the Table of §2 for examples of major modifications). The status checks are also performed and documented in a report by the qualified personnel of a **licensed company**, in the frame of the half-yearly maintenance. During the reception test or the status checks, some reference values for the stability tests (see next §5) are established.

Although the responsibility for the reception tests and the status checks lies with the licensed company, the preparation of phantoms and the handling of open radioactive sources can be delegated to the user, in agreement with the latter.

The parameters to be checked, their periodicity (at reception or during the status checks), and the reference of the procedures and measurements to be followed (mainly the latest[3] NEMA NU-1 2018 [8] and NEMA NU-2 2018 [9] standards) are given in Annex 2 for the gamma cameras and SPECT cameras and in Annex 4 for the PET cameras. The target values and tolerance intervals, if not specified in Annexes 2 and 4, are given by the manufacturer's specifications and must be documented and made available to the user.

The companies possessing a BAG license must perform preventive, manufacturer-specific maintenance checks in addition to the tests performed in the frame of the half-yearly status checks mentioned in Annexes 2 and 4.

The user's dose calibrator employed during the reception tests and the status checks must be the same as the one usually used for the applications of radiopharmaceuticals to the patients.

[2] In well justified cases, an extension of the one-year transition period can be requested from FOPH.

[3] The updated NEMA NU-1 2023 standard has been published at the end of the revision process of this guideline and does not contain any significant changes compared with the 2018 version.

Certain tests listed in Annex 2 are only required for SPECT devices using absolute quantification in clinical examinations (see column "Devices concerned"). The nuclear medicine physician, serving as radiation protection expert (medical expertise) on the device license, is responsible for deciding whether absolute quantification will be used in clinical examinations. In addition, if a user begins using a SPECT camera without absolute quantification for clinical examinations, and later decides to use this functionality, the corresponding reception tests must be conducted at that time.

5 Stability tests for gamma, SPECT and PET cameras

The user is responsible for performing and documenting in reports the stability tests. In particular, in order to ensure the independence of these measurements, the user cannot mandate the licensed company to perform the stability tests.

However, the use of equipment owned by the licensed company (e.g., phantoms) for stability tests is permitted, in agreement with the licensed company. Furthermore, it is acceptable that stability tests KG1 to KG3 and KP1 to KP4 be automated. If required by the user, the licensed company must explain to the user how these automated tests are implemented in the device and carried out, and what are the test tolerances. Finally, for the KG4, KP5 and KP6 stability tests, if software tools are available from the manufacturer and accessible to the user, these tools can be used by the user, provided that an independent verification of the test values be performed at least once by the user to verify that comparable values are obtained.

The parameters to be checked, their periodicity, and the procedures and measurements to be followed for the tests are given in Annex 3 for the gamma cameras and SPECT cameras, and in Annex 5 for the PET cameras. The target values and tolerance intervals, if not specified in Annexes 3 and 5, must be given by the manufacturer's specifications and must be documented and made available to the user.

If a stability test fails, the user has to contact the responsible medical physicist. Appropriate actions must be implemented, by the medical physicist or the licensed company, before the machine can be used clinically. The license holder is responsible for the clearance for clinical use.

The user's dose calibrator employed during the stability tests must be the same as the one usually used for the applications of radiopharmaceuticals to the patients.

Certain tests listed in Annex 3 are only required for SPECT devices using absolute quantification in clinical examinations (see column "Devices concerned"). The nuclear medicine physician, serving as radiation protection expert (medical expertise) on the device license, is responsible for deciding whether absolute quantification will be used in clinical examinations.

6 References

1. Radiological Protection Ordinance (RPO, SR 814.501) of 26 April 2017
2. Ordinance of the FDHA on the Use of Radioactive Materials (UraM/OUMR/MMRa, SR 814.554) of 26 April 2017
3. Guideline R-08-08 of the FOPH: "Quality assurance for computed tomography (CT) scanners"; www.bag.admin.ch/str-wegleitungen
4. IEC 61675-1:2022, Radionuclide imaging devices – Characteristics and test conditions – Part 1: Positron emission tomographs
5. IEC 61675-2:2015, Radionuclide imaging devices – Characteristics and test conditions – Part 2: Gamma cameras for planar, wholebody, and SPECT imaging
6. IEC TR 61948-2:2019, Nuclear medicine instrumentation – Routine tests – Part 2: Scintillation cameras and single photon emission computed tomography imaging
7. IEC TR 61948-3:2018, Nuclear medicine instrumentation – Routine tests – Part 3: Positron emission tomographs
8. NEMA Standards Publication NU 1-2018, Performance Measurements of Gamma Cameras
9. NEMA Standards Publication NU 2-2018, Performance Measurements of Positron Emission Tomographs (PET)
10. Medical Devices Ordinance (MedDO, SR 812.213) of 1 July 2020
11. Guideline of the FOPH: "Radiation protection measures relating to the construction of PET facilities"; www.bag.admin.ch/str-wegleitungen
12. IAEA Human Health Series No.6, Quality Assurance for SPECT Systems
13. American association of physicists in medicine, Report No.117, Research Needs of Radiation Protection
14. American association of physicists in medicine, Report No.126, PET/CT Acceptance Testing and Quality Assurance
15. Vanhove, C., Koole, M., Fragoso Costa, P. et al. Preclinical SPECT and PET: Joint EANM and ESMI procedure guideline for implementing an efficient quality control programme. Eur J Nucl Med Mol Imaging (2024), https://doi.org/10.1007/s00259-024-06824-5

7 Legal status

This guideline is an enforcement aid issued by the FOPH in its capacity as the supervisory authority in the field of radiation protection. It is aimed primarily at license holders and experts, as well as other bodies and individuals who may be affected by ionising radiation. It specifies the requirements of radiation protection legislation and reflects the current state of the art in science and technology. If the licence holders, experts or other persons concerned comply with this guidance, they can be sure that they are implementing the radiation protection legislation in a legally compliant manner.

Annex 1
Content of the technical file

Content	Remarks
FOPH license	License to operate a radiology system for medical use for SPECT/CT and PET/CT. License to use unsealed radioactive sources for independent gamma cameras (without CT).
Reception tests reports	Includes records of reception tests and records of handover of the installation to the user. Target values and tolerance intervals, if not specified in the Annexes to this guideline, must correspond to the manufacturer's specifications and must be documented and passed on to users. If a test does not apply to a given camera, the reason must be documented in the technical file of the device.
Status checks reports	Includes records of status checks. The target values and tolerance intervals, if not specified in the Annexes to this guideline, must correspond to the manufacturer's specifications and must be documented and passed on to users. If a test does not apply to a given camera, the reason must be documented in the technical file of the device.
Revision checklists (maintenance) and periodicity	According to the manufacturer's data.
Procedures and reference values for the stability tests	Filing of reference values and procedures to be followed for the stability tests; the reports of the stability tests are filed separately in electronic form or on paper.
Indication of the version and storage location of the instructions for use	The instructions for use must be available at all times in the language used in the unit.
EU Declaration of Conformity	In accordance with the Medical Devices Ordinance (MedDO; SR 812.213; [10]).
Indication of ambient dose rates in the room where the camera is installed and in adjacent rooms	The maximum permitted ambient dose rates must be respected in all rooms (UraM/OUMR/MMRa, annex 2). For PET equipment, the radiation protection plans and calculation tables in accordance with the guideline "Radiation protection measures relating to the construction of PET installations" [11] must be available.

Annex 2

Reception tests and status checks for gamma and SPECT cameras: parameters to be checked, periodicities, references and methodologies

Executing body: licensed company

RT = reception test; SC = status check (half yearly if not specified otherwise)

N°	Parameter	Periodicity	Reference and method	Devices concerned	Nuclides, activities and phantoms
G1	**Intrinsic Flood Field Uniformity**	RT and SC	NEMA NU 1-2018, part 2.4 The intrinsic uniformity of the system is measured, i.e., the response of the system without a collimator to a uniform flux of radiation from a point source	All, except those ones for which the collimators cannot be removed	Contrarily to what is requested by NEMA, it is sufficient to measure this parameter for two nuclides, Tc-99m and another one with photons of higher energy (if Tc-99m is the only nuclide used at the centre, the test is executed with Tc-99m only).
G2	**System Image Homogeneity & Collimator Check**	RT and SC	Both the status/condition of the collimators and the images produced with the collimators (homogeneity) shall be checked visually.	All	RT: check of all the collimators. SC: check of the mostly used collimator.
G3	**Intrinsic Energy Resolution**	RT and SC	NEMA NU 1-2018, part 2.3 The ratio of the photopeak FWHM[4] to the photopeak centre energy shall be calculated	All	Use of Tc-99m and/or Co-57 if the latter is used for daily quality assurance.
G4	**Intrinsic Spatial Resolution**	RT, and SC if the SC G5 fails (System Spatial Resolution without Scatter)	NEMA NU 1-2018, part 2.1 The FWHM and FWTM[5] shall be determined.	All, except direct conversion detectors, such as CZT[6] detectors	Use of Tc-99m.
G5	**System Spatial Resolution without Scatter**	RT and yearly SC	NEMA NU 1-2018, part 3.1 The FWHM and FWTM of the line spread function shall be measured.	All	The test has to be performed for all collimators. Use of two capillary tubes[7].

[4] FWHM = *Full width at half maximum*

[5] FWTM = *Full width at tenth maximum*

[6] CZT = *Cadmium zinc telluride* (CdZnTe).

[7] As an alternative to the method described in the NEMA standard, see the IAEA Human Health Series No.6 [12] for the methodology to create a system spatial resolution phantom with four capillary tubes.

N°	Parameter	Periodicity	Reference and method	Devices concerned	Nuclides, activities and phantoms
G6	**System Planar Sensitivity and Collimator Penetration and Scatter**	RT and SC	NEMA NU 1-2018, part 3.3 The ratio of collimated counts to the known activity of a planar source shall be determined.	All	RT: all the collimators. SC: with the mostly used one only. The activity has to be injected into Petri dishes (as requested by NEMA), but the use of traceable sources is allowed.
	System Volume Sensitivity	RT and yearly SC	NEMA NU 1-2018, part 4.4 Measurement of the total system sensitivity to a uniform concentration of activity, and determination of the average volume sensitivity per axial centimetre.	Only for SPECT devices using absolute quantification in clinical examinations	Use of Tc-99m only. Use of a fillable cylindrical phantom
G7	**System Count Rate Performance with Scatter**	RT	NEMA NU 1-2018, part 3.5 or AAPM report 117 The maximum observed count rate and the observed count rate for a 20% count loss shall be measured, and a curve of observed count rate with scatter versus input count rate shall be made. As an alternative to the NEMA methodology, the use of one of the methods mentioned in the AAPM report 117 [13] is allowed.	All	Use of Tc-99m and of a cylindrical phantom.
G8	**Intrinsic Spatial Linearity**	RT	NEMA NU 1-2018, part 2.2 The goal of the test is to identify potential distortions in the images. The intrinsic spatial differential and absolute linearity has to be reported.	All, except direct conversion detectors, such as CZT detectors	Use of Tc-99m and a lead mask with parallel slits.
	System Linearity	RT and yearly SC	In addition, a visual check for linearity and absence of distortions shall be performed.	All	Use of the data from G5 (System Spatial Resolution without Scatter).

N°	Parameter	Periodicity	Reference and method	Devices concerned	Nuclides, activities and phantoms
G9	**Whole-Body System Spatial Resolution without Scatter**	RT	NEMA NU 1-2018, part 5.1 The system spatial resolution without scatter shall be measured parallel and perpendicular to the direction of continuous motion and expressed as FWHM or FWTM of the line spread function.	All, except step-and-shoot whole-body planar acquisition devices	Use of two capillary tubes[8] of Tc-99m. The camera shall be equipped with a collimator
G10	**System Alignment**	RT and SC	NEMA NU 1-2018, part 4.1, or according to the manufacturer The transaxial alignment of acquired images with the system's mechanical center of rotation shall be measured. Likewise, for multi-head SPECT imaging systems, the axial alignment of images from the individual heads shall be measured.	SPECT devices only	If the NEMA method is used, three Tc-99m or Co-57 point sources shall be used.
G11	**Detector-Detector Sensitivity Variation**	RT, and yearly SC if the yearly SC G6 fails (System Volume Sensitivity)	NEMA NU 1-2018, part 4.5 Assessment of the relative difference in sensitivity of the individual detectors. All the projection images collected using each detector shall be summed up. The difference between the largest and the smallest of these quantities shall be computed.	Only for SPECT devices using absolute quantification in clinical examinations, with the exception of devices on the which the test cannot be performed[9]	Use of the data from the second part of G6 (System Volume Sensitivity). The use of one collimator is enough.

[8] As an alternative to the method described in the NEMA standard, see the IAEA Human Health Series No.6 [12] for the methodology to create a system s.patial resolution phantom with four capillary tubes.

[9] E. g., full-ring SPECT devices.

N°	Parameter	Periodicity	Reference and method	Devices concerned	Nuclides, activities and phantoms
G12	**Tomographic Contrast and Absolute Quantification Accuracy**	RT and SC The half-yearly SC concerns the Tomographic Contrast part of the test only	NEMA NU 1-2018, part 6 Images simulating those obtained in a total body imaging study with hot and cold lesions of different diameters are produced. Measurement of the contrast of cold and hot spheres in a warm background, of the variability of the background regions, and of the deviation of the large, cold reconstructed lung region without activity. For centres using absolute quantification (image output in Bq/ml), the absolute activity concentration shall also be measured and compared to the injected activity concentration.	SPECT devices only	Use of the NEMA/IEC image quality phantom (same phantom as for the PET reception test P5)[10]. Use of Tc-99m. Background activity shall be 20 kBq/ml. The sphere-to-background activity concentration shall be 8:1. The licensed company shall involve the user in the half-yearly SC (Tomographic Contrast part of the test) by ensuring an efficient information exchange when communicating the test results.
G13	**Image Homogeneity and Precision of Quantification**	RT	Verification of the background activity. The mean coefficient of variation (Image Homogeneity) and mean background activity concentration (Precision of Quantification) shall be computed according to the paragraph "Analysis" of Annex 6. The corresponding stability test is KG4.	Image Homogeneity: all SPECT devices. Precision of Quantification: only for SPECT devices using absolute quantification in clinical examinations.	Use of the data from the second part of G6 (System Volume Sensitivity). If the latter test is not performed during the reception test, use of the data from G12 (Tomographic Contrast and Absolute Quantification Accuracy) taken in the background part of the phantom. Use of Tc-99m only. Tolerance interval: see paragraph "Tolerance" of Annex 6.

[10] Or an equivalent phantom, such as the PET ACR phantom described in the AAPM report n° 126 [14], or the Jaszczak phantom.

N°	Parameter	Periodicity	Reference and method	Devices concerned	Nuclides, activities and phantoms
G14	**SPECT/CT Co-Registration Accuracy**	RT and SC	Preferably NEMA NU-1 2018, part 7, or according to the manufacturer NEMA NU-1 2018 method: The alignment accuracy between SPECT and CT image volumes shall be measured, by using data acquired with SPECT and CT fiducial markers at six locations.	SPECT/CT only	Radionuclide for the SPECT portion of the fiducial markers: Tc-99m. It is allowed not to use the weights prescribed by NEMA NU-1 2018.
G15	**Pixel Size**	RT and SC	According to the manufacturer. The goal of the test is to make sure that the system determines distances correctly, by comparing a known length (typically 30 cm) with the length measured by the system.	All	According to the manufacturer.

Annex 3

Stability tests for gamma and SPECT cameras: parameters to be checked, periodicities, references and methodologies

Executing body: user

N°	Parameter	Periodicity	Reference and method	Devices concerned	Nuclides, activities and phantoms	Tolerances
KG1	**Background Count Rate**	Every working day	Perform a blank scan of 2.5 to 3 minutes. A given number of counts (manufacturer-specific) should not be exceeded to make sure that no radioactive contamination is present in the system. In case of contamination, measures have to be taken.	All	--	According to the manufacturer
KG2	**Check of the Energy Window**	**Qualitatively**: ideally before each exam, but at least once a day **Quantitatively:** once a week	Check of the correct position of the Tc-99m peak. A visual check shall be performed, with the injected patient himself (no additional source needed). Once a week, a quantitative measure shall be performed and documented, in order to follow any shift in the energy window.	All	Qualitative tests: use of Tc-99m. Quantitative tests: use of Tc-99m or of Co-57 phantoms.	According to the manufacturer
KG3	**Homogeneity**	Weekly	Methodology (with or without collimator, maximal number of counts, point source or flat source) according to the manufacturer.	All	See column "Reference and method".	According to the manufacturer
KG4	**Image Homogeneity and Precision of Quantification**	Half-yearly	See Annex 6 for detailed instructions and tolerance intervals. Verification of the background activity. The mean coefficient of variation (Image Homogeneity) and mean background activity concentration (Precision of Quantification) are measured and compared with given tolerance intervals.	Only for SPECT devices using absolute quantification in clinical examinations	Radionuclide: use of Tc-99m only, with 10–20 MBq/kg. Use of a cylindrical fillable phantom (same as for P7 and KP5).	Mean background-activity concentration within ±10% of true activity concentration; mean coefficient of variation < 15%

Annex 4

Reception tests and status checks for PET cameras: parameters to be checked, periodicities, references and methodologies

Executing body: licensed company
RT = reception test; SC = status check (half yearly if not specified otherwise)

N°	Parameter	Periodicity	Reference and method	Devices concerned	Nuclides, activities and phantoms
P1	**Spatial Resolution**	RT	NEMA NU 2-2018, part 3 Imaging point sources in air and then reconstructing images by a linear reconstruction method, such as filtered back projection, with no smoothing or apodization. The FWHM and FWTM of the image point spread function are measured.	All	Use of F-18 or Na-22.
P2	**Scatter Fraction, Count Losses, and Randoms**	RT	NEMA NU 2-2018, part 4 The relative system sensitivity to scattered radiation, the effects of system dead time and the generation of random events are measured.	All	Use of a dedicated phantom (solid right circular cylinder with a hole drilled parallel to the central axis of the cylinder) with approximately 500 MBq of F-18 (or another activity according to the manufacturer).
P3	**Sensitivity**	RT	NEMA NU 2-2018, part 5 The sensitivity of the system (rate in counts per second that true coincidence events are detected for a given source strength) is measured.	All	Use of F-18 with approximately 10 MBq activity. Use of the NEMA sensitivity phantom (five sleeves of different diameters). The use of a cylinder with Ge-68 sources (according to the former NEMA NU 2-1994) is not allowed[11].
P4	**Accuracy: Corrections for Count Losses and Randoms**	RT	NEMA NU 2-2018, part 6 The accuracy of corrections for dead time losses and random event counts is measured.	All	Test performed with the measurement data from P2 (Scatter Fraction, Count Losses, and Randoms).

[11] Among other arguments because in 3D mode acquisition, the scatter is not negligible and the test is more precise with the sleeves foreseen by the NEMA norm.

N°	Parameter	Periodicity	Reference and method	Devices concerned	Nuclides, activities and phantoms
P5	**Image Quality, Accuracy of Corrections**	RT	NEMA NU 2-2018, part 7 Images simulating those obtained in a total body imaging study with hot lesions of different diameters are produced, with activity also present outside the region of interest of the scanner to reproduce the clinical routine. Image contrast and background variability ratios for hot spheres are used as measures of image quality. The accuracy of corrections is determined from the uniform background and cold lung insert regions.	All	Use of the NEMA/IEC image quality phantom[12] (body phantom). Radionuclide to be used: F-18 with an activity concentration[13] of 5.3 MBq/kg. Use as well of the solid right circular cylinder (scatter phantom, same as for P2 (Scatter Fraction, Count Losses, and Randoms)) with same activity concentration. Fill the spheres with a unique activity ratio of 4:1.).
P6	**Qualitative Contrast Test**	RT	Qualitative determination of the contrast by counting and reporting the number of visible lesions in images simulating those obtained in a total body imaging study with hot lesions of different diameters. The size of the smallest visible lesion detected during RT will be the reference value for the later stability tests KP6 and has to be reported.	All	Use of the NEMA/IEC image quality phantom[12] prepared for P5 (Image Quality, Accuracy of Corrections) one hour after P5 has been performed[14]. The test has to be performed without the scatter phantom and with the clinically recommended algorithm. For the centres undergoing accreditation tests for quantitative measurements (e.g., EARL), if an additional concentration ratio is used at reception (in addition to the 4:1 ratio specified by NEMA for P5), this additional concentration ratio can be used for P6 (reception test) and KP6 (stability tests). Similarly, the background activity concentration used for the accreditation tests can also be used for P6 and KP6. The activity concentrations used for the test must be documented. The same phantom must be used for P6 and KP6.

[12] Or an equivalent phantom, such as the PET ACR phantom described in the AAPM report n° 126 [14], or the Jaszczak phantom.

[13] Corresponding to 370 MBq for a mass of 70 kg.

[14] To have an activity concentration of 3.5 MBq/kg of F-18, corresponding to the diagnostic reference level (DRW/NRD).

N°	Parameter	Periodicity	Reference and method	Devices concerned	Nuclides, activities and phantoms
P7	**Image Homogeneity and Precision of Quantification**	RT	See Annex 6 for detailed instructions and tolerance intervals. Verification of the background activity. The mean coefficient of variation (Image Homogeneity) and mean background activity concentration (Precision of Quantification) are measured and compared with given tolerance intervals. The corresponding stability test is KP5.	All	Radionuclide: F-18 with 30–100 MBq. Use of a cylindrical fillable phantom covering the axial field of view (diameter at least 20 cm).
P8	**PET/CT Co-registration Accuracy**	RT and SC	PET/CT devices: preferably NEMA NU-2 2018, part 9, or according to the manufacturer. PET/MR devices: according to the manufacturer. NEMA NU-2 2018: The co-registration error between PET and CT data is determined by using data acquired with PET and CT fiducial markers at six locations within the PET and CT field of view.	For PET/CT and PET/MR devices only	Radionuclide for the PET portion of the fiducial markers: F-18 or Na-22 as prescribed by NEMA NU-2 2018, or another radionuclide according to the manufacturer. It is allowed not to use the weights prescribed by NEMA NU-2 2018.
P9	**Time-of-Flight Resolution**	RT	NEMA NU-2 2018, part 8, has to be followed for devices sold after this Guideline enters into force and for devices that underwent a major upgrade. For the older devices, the test has to be performed with the datasheet of the system provided by the supplier. The time-of-flight resolution (uncertainty in detecting the arrival time-difference of two photons in a coincidence event) is assessed by measuring the FWHM of the detector response.	For devices with	If NEMA NU-2 2018 is followed: use of the measurement data from P2 (Scatter Fraction, Count Losses, and Randoms).

Annex 5

Stability tests for PET cameras: parameters to be checked, periodicities, references and methodologies

Executing body: user

N°	Parameter	Periodicity	Reference and method	Devices concerned	Nuclides, activities and phantoms	Tolerances
KP1	**PM Check**	Every working day	Check of the amplification factor (gain), offset PM, and homogeneity.	All	Use of an external positron source, except for those devices equipped with an appropriate internal radioactive source (for example lutetium sources).	According to the manufacturer
KP2	**Control of the Energy Window**	Every working day	Check of the setting and FWHM resolution.	All	Use of an external positron source, except for those devices equipped with an appropriate internal radioactive source (for example lutetium sources).	According to the manufacturer
KP3	**Visual Verification of the System**	Every working day	Comparison of the sinograms.	All	Use of an external positron source, except for those devices equipped with an appropriate internal radioactive source (for example lutetium sources).	According to the manufacturer
KP4	**Coincidence Timing**	Every working day for the PM devices Weekly for the semiconductor devices	The parameter to be checked is as defined by the manufacturer.	All	Use of an external positron source.	According to the manufacturer
KP5	**Image Homogeneity and Precision of Quantification**	Half-yearly	See Annex 6 for detailed instructions. Verification of the background activity. The mean coefficient of variation (Image Homogeneity) and mean background activity concentration (Precision of Quantification) are measured and compared with given tolerance intervals.	All	Radionuclide: F-18 with 30–100 MBq. Use of a cylindrical fillable phantom (same as for P7 (Image Homogeneity and Precision of Quantification)). For the centres undergoing accreditation tests for quantitative measurements (e.g., EARL), this test can be skipped. The results of the accreditation tests and the activity concentrations used shall instead be filed in the stability tests file.	Mean background activity concentration within ±10% of true activity concentration; mean coefficient of variation < 15%

N°	Parameter	Periodicity	Reference and method	Devices concerned	Nuclides, activities and phantoms	Tolerances
KP6	**Qualitative Contrast Test**	Yearly	Qualitative determination of the contrast by counting and reporting the number of visible lesions in images simulating those obtained in a total body imaging study with hot lesions of different diameters.	All	Prepare the NEMA/IEC image quality phantom[15] with a background activity concentration of 3.5 MBq/kg of F-18 and fill the spheres with a single activity ratio of 4:1. The test has to be performed without the scatter phantom and with the clinically recommended algorithm. For the centres undergoing accreditation tests for quantitative measurements (e.g., EARL), if an additional concentration ratio is used at reception (in addition to the 4:1 ratio specified by NEMA for P5 (Image Quality, Accuracy of Corrections)), this additional concentration ratio can be used for P6 (reception test) and KP6 (stability tests). Similarly, the background activity concentration used for the accreditation tests can also be used for P6 and KP6. The activity concentrations used for the test must be documented. The same phantom must be used for P6 and KP6.	Minimal sphere size has to be the same (at least) as the one observed during reception test P6.

[15] Or an equivalent phantom, such as the PET ACR phantom described in the AAPM report n° 126 [14], or the Jaszczak phantom.

Annex 6

Detailed instructions for reception tests G13 and P7 and stability tests KG4 and KP5: Image Homogeneity and Precision of Quantification

Purpose

To verify the accuracy of image quantification and image homogeneity.

Materials

Cylindrical phantom which should cover[16] the axial FOV filled with 18F or Tc-99m. Diameter of the phantom should be at least 20 cm.

Procedure

1. Prepare a syringe with about[17] 30–100 MBq of F-18, or with a Tc-99m activity corresponding to an activity concentration of 10–20 MBq/kg
2. Accurately measure the activity in the same dose calibrator used for clinical routine, writing value of activity and time of assay. The clocks used for recording the time assay should be checked against the scanner.
3. Put the activity in the phantom, mixing with water solution thoroughly to get a uniform radioactivity distribution.
4. Measure the residual activity in the syringe and evaluate the net activity put into the phantom.
5. Add water until the phantom is completely filled.
6. Place the phantom on the phantom holder provided by the manufacturer and move the phantom at the beginning of the CT FOV, making sure that the phantom is centered in the FOV also with respect to the height. In case of no phantom holder, simply place it on the patient's table.

The acquisition should be performed by using the protocol provided by the manufacturer (same protocol for the reception test G13/P7 and the later stability tests KG4/KP5). In case no acquisition protocol is provided, the standard protocol used for clinical routine should be used (e.g., body, head, …).

Make sure that a low dose CT for attenuation and scatter correction purposes is included in the procedure. Attention should be paid when inserting data regarding activity assayed by the dose calibrator, time of assay and weight of the volume of the solution used to fill the phantom. Acquisition stop condition should be set for 100 million counts.

Analysis

For the acquired images, draw one circular ROI with a diameter greater than 5 cm, at least 2 cm from the phantom edge on the reconstructed central slice and on ± 5-6 adjacent slices (total of 12 ROIs). Measure the mean and standard deviation activity concentration for each ROI and calculate the coefficient of variation (COV) for each slice:

$$\text{COV}\ (\%) = \frac{\text{standard deviation}}{\text{mean}} \times 100$$

The mean COV and mean background activity concentration can then be calculated among the different ROIs.

Tolerance

The mean background activity concentration shall be within ±10% of the true activity concentration and the mean coefficient of variation should be < 15%.

[16] Phantoms covering the whole FOV might not be commercially available for long-axial FOV PET/CTs. In such a case, the user can either use several small phantoms, or move the same phantom to different bed positions. The adopted method shall allow checking the whole FOV.

[17] With this activity range, the user can choose to comply with the requirements of the EANM Research GmbH (EARL) initiative.