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Quality control guidance for nuclear medicine equipment

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Quality control guidance for nuclear medicine equipment

1. Introduction

According to the radiation act (592/91 [1]) the responsible party shall implement planned and systematic measures to ensure that the radiation sources and accessories and associated equipment are in good condition and that the instructions and procedures concerning their use are appropriate.

More specific regulations about implementing quality assurance are provided in the Decree of the Ministry of Social Affairs and Health on the medical use of radiation (423/2000 [2]). According to the decree (18 §) quality assurance activities shall be defined in writing in a quality assurance programme. A quality assurance programme shall set out the principal tasks involved in supervising the operating condition and performance characteristics of radiological equipment (32 §). The responsibilities and instructions for measures pertaining to the supervision of individual items of equipment shall be specified separately for each item of equipment.

Guide ST 6.3 [3] gives the requirements for quality assurance of nuclear medicine. It also gives requirements for equipment, to define and control the working condition and performance characteristics, known as *technical quality control*.

2. Purpose and scope

The purpose of this guidance is to introduce standards for quality control of nuclear medicine equipment and to give recommendations for a technical quality control programme.

Chapter 3 presents the concepts and general principles of quality control. Chapter 4 introduces the standards for performance tests for gamma cameras, positron emission tomography cameras and coincidence cameras, as well as for gamma probes. Chapter 5 provides a summary of the recommended quality control tests and their frequencies for different groups of equipment and some guidance for performing the tests. Detailed guidance for performing the tests is not provided here, because equipment-specific differences for similar types of nuclear medicine equipment require differences in the way tests are performed.

In some cases recommended remedial levels for the results of quality control tests are provided. Statutory acceptability criteria are established by a decision of the Radiation and Nuclear Safety Authority. These criteria are not given in this guidance (see item 3.5). Acceptability criteria for gamma cameras and activity meters are presented in Appendix B of Guide ST 6.3 [3].

The principal purpose of this guidance is to help in establishing a quality control programme. The guidance informs responsible persons about the principles and methods for quality control and gives information to users and persons performing them about recommended tests for the various equipment groups.

Equipment specific quality control programmes can be based on this guide but the detailed content of the tests has to be considered on a case-by-case basis. In establishing a quality control programme the instructions and recommendations of the manufacturer must also be considered. The manufacturer may for instance require different testing frequencies to those established in this guidance.

Technical quality control is an important part of the quality management of a nuclear medicine department (see item 3.1). In this way it can be assured that the working order of nuclear medicine equipment is maintained within established requirements. For optimizing patient exposure during nuclear medicine examinations quality control alone is not enough. Optimization involves developing the test methods and techniques so that attention is paid continuously to patient exposure and clinical image quality (see item 3.1 and guide ST 6.3 [3]). This requires co-operation of experts in the various different areas of quality control.

3. General principals of quality control

3.1. General

The best way to implement the requirements proposed for responsible parties by radiation legislation is to use a quality system covering all operations. A quality system is a system of organizational structures, procedures, processes and resources required in *quality management* (Figure 1) (see also guide ST 1.1 [4]). The quality system is described in quality documents that are arranged to be a uniform, constantly updated entity (a quality manual or similar). One means for quality management is *quality assurance* and *technical quality control* is part of it. There are also many other components of quality assurance and the main ones are mentioned in Figure 1.

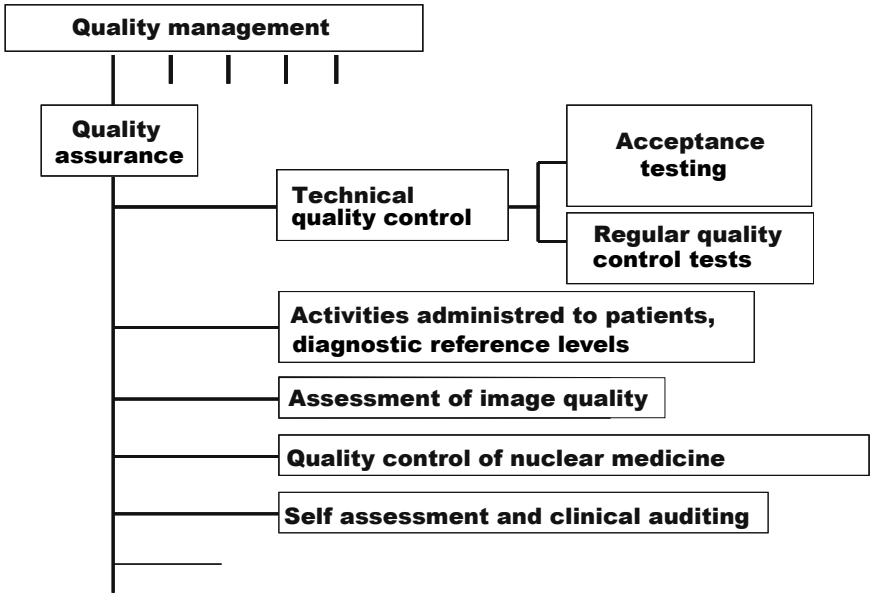

Figure 1. Contents of quality management in nuclear medicine.

Technical quality control of nuclear medicine equipment involves continuous supervision of the working order and performance characteristics of the equipment throughout its whole life cycle. It is an essential part of quality assurance in nuclear medicine and the aim is that the examinations produce the desired clinical outcome and that the patients are not exposed to an extent greater than the reliability of diagnosis requires. Technical quality control creates prerequisites for implementing the optimization principle. Technical quality control is an integral part of the use of the equipment and the necessary resources should be seen as a part of the running costs.

In optimizing the dose from nuclear medicine examinations the aim is to achieve an image quality adequate for making a diagnosis with as small a radiation exposure as possible. The precision of the diagnosis that is achieved is influenced by many issues such as: imaging

equipment, the object being imaged, the professional skills of the person performing an examination and the subjectivity of the person interpreting the image (Figure 2). Optimization requires in addition to technical quality control, an assessment of both the patient radiation exposure and diagnostic image quality.

The patient's radiation exposure is linearly comparable to the activity of the radionuclide administered. This means that in optimization an adequate image quality is produced with the smallest possible activity. The activities used have to be compared regularly to the diagnostic reference levels established by the Radiation and Nuclear Safety Authority (STUK) [3].

To make a diagnosis the intended image quality varies according to the anatomical imaging object and the indication of the examination. For this reason it is important to recognise that the assessment of physical image quality as established in this guidance is not in itself sufficient. For optimization clinical image quality also has to be assessed. Moreover, it is important to ensure appropriate performance of software used by the nuclear medicine imaging equipment (item 5.7).

Delivery and archiving of the digital imaging is becoming an electronic process. Similarly, patient histories are increasingly being transferred into electronic media and there is the possibility of a national image archive. With the adoption of these techniques attention should be paid to the consistency of expression of the images. This requires standardization of the image monitors. This can be performed using for example, a DICOM grey scale display instrument. In addition to quality control of the image monitors it should be possible to standardize the processing and saving of digital images so that images are archived with a diagnostic shade scale and so separate processing at an image work station is not needed. In addition to raw images and image slices, key images of the examination and the colour scale used in their reading should be saved to the DICOM archive. This requires optimizing the imaging instructions and image processing in collaboration with nuclear medicine physicians, medical physics experts and nursing staff. This makes it easier to read the images at those work stations without multiple image processing tools available, and makes image reading faster.

When there are gamma cameras from different manufacturers in use for the same examinations (for example, dynamic renal gamma imaging), the images taken with different cameras should be printed and key images processed using the same work station for their analysis. Otherwise differences in the equipment could result in false interpreting by physicians of different specialities in assessing the findings.

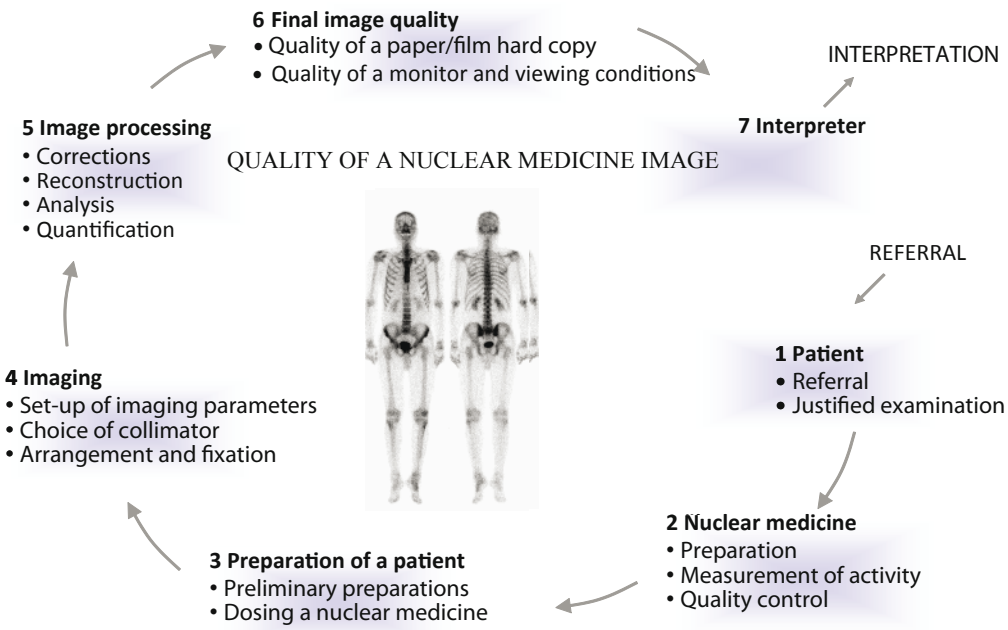

Figure 2. Factors that have influence on image quality in nuclear medicine.

3.2 Phases and content of quality control

In Figure 3, the life cycle of an item of nuclear medicine equipment is established beginning from the intention to procure and ending at the disposal of the equipment, including tests performed during the working life cycle of the equipment. Quality control tests are conducted before taking the equipment into use (acceptance testing) and during clinical use of the equipment. According to the decree of the Ministry of Social Affairs and Health on the medical use of radiation (423/2000) 32 § the functions of radiological equipment shall be tested in particular:

1) before the equipment is commissioned (acceptance testing)
2) at specified intervals according to device-specific instructions (periodic testing)
3) following significant repairs or servicing
4) when there is cause to suspect a malfunction or a change in operation of an item of equipment.

Quality control of nuclear medicine equipment includes both safety and performance tests. *Safety tests* include checks of condition and operation of radiation detectors, warning lights, radiation protection meters and the condition of radiation shielding as well as testing the mechanical operational safety (for example, alarm switches and collision stoppers). F*unctional tests* verify that the system performance is fulfilling the established requirements, especially with regard to aspects that influence the activity administered to the patient, and image quality. Functional tests are typically stability tests in which the test result achieved is acceptable if it stays within the set remedial levels (see item 3.5). It is important for the purpose of meaningful comparisons that stability tests are performed in a similar way each time, as is required during acceptance testing.

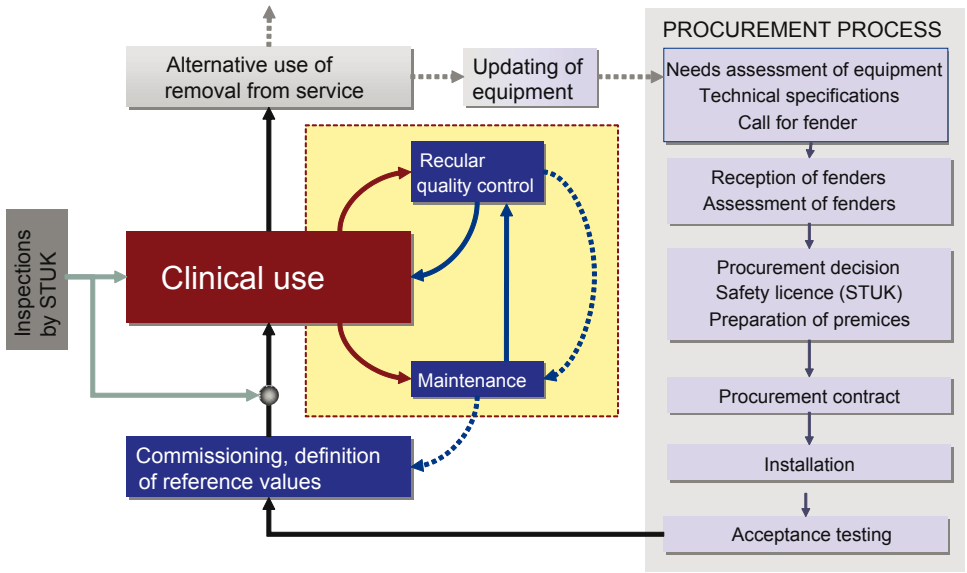

Figure 3. Life cycle and testing of nuclear medicine equipment.

3.2.1 Procurement of equipment and acceptance testing

When procuring equipment it is good practice to have a purchasing plan. In purchasing it is good practice to use a medical physics expert, a nuclear medicine physician and (due to the potential for contractual issues) specialists in procurement. Equipment manufactured after 13 June 1998 must bear the CE marking (Directive 93/42/EEC) referred to in the Act. The CE marking is a manufacturer's warranty that the apparatus meets the equipment safety requirements imposed by European Community Directives.

It is the responsibility of the supplier and installer of the equipment to verify that the

equipment operates correctly and safely after installation. This includes electrical and mechanical safety as well as radiation safety.

Safety during commissioning and use of the equipment is the responsibility of the responsible party. During acceptance testing whether this is conducted by the responsible party (who has ordered the equipment) or contracted out it must be verified that the equipment and its associated accessories are intact and in order and that all necessary documentation (especially user instructions and manuals) is in place. In addition, it must be verified that the apparatus functions in an appropriate and safe manner, so that the statutory requirements and the principal performance characteristics and safety features notified by the manufacturer are satisfied. Often, all the types of tests and measurements that are necessary before taking the equipment into use (the commissioning tests) are included into acceptance tests. Acceptance testing has to be recorded separately.

At the time of the acceptance tests (or commissioning), it is also expedient to determine the *reference values for performance characteristics* that will be required in the course of supervising the operating condition and performance characteristics of the equipment. All quality control tests that are needed during the use of the equipment will be performed for the first time during acceptance testing. At the same time, it should be decided which kind of non-conformances in the test results will require further actions or repair of the equipment (remedial level, see item 3.5).

The person who performs the acceptance test may be a representative of the operating organization, a representative of the supplier, or a third party. It is good practice to use experts in both medical physics and nuclear medicine during acceptance testing. Even if acceptance testing is conducted by members of the responsible party, it is good practice that the users of the equipment participate in performing the acceptance tests. It is usually expedient also to co-operate with the suppliers of the equipment during acceptance testing. If a person other than a representative of the operating organization performs the acceptance test, then the said organization must ensure adequate supervision of the test and must appoint a person to be responsible for this duty of supervision. Acceptance tests are described in the literature references [5].

3.2.2 Quality control during the use of equipment

There should be detailed instructions on the use, maintenance and service of the equipment to assure the continuity of operation in an acceptable way, for example when staff are changed. Staff must be trained to operate the equipment especially when new equipment is taken into use or staff are changed.

Quality control tests during the use of equipment are conducted at periodic intervals according to a written quality control programme. Testing points during the year should be planned in a way that takes account the resources that are available. A useful way to achieve this may be a system that reminds the user and assists in the control of the conduct of the tests (for example, an electronic calendar or an internet based solution). No more than a year after commissioning, and later whenever there is cause to suspect any malfunction or alteration in equipment operations, it is appropriate to verify the operating condition and performance characteristics of equipment. It is not necessary to repeat acceptance testing unless there is

cause to suspect a change in performance after repair or servicing, or due to some other reason. Quality control tests are performed after substantial repair or servicing, and whenever there is cause to suspect any malfunction or alteration in equipment operations.

Documentation for the quality control programme must also exist in respect of each item of equipment as follows:

- the inspections and measurements to be performed and the purpose thereof
- the methods of inspection and measurement
- apparatus and instruments to be used
- the intervals for performing inspections and measurements
- the action thresholds for inspection and measurement results (see item 3.5)
- the actions to be taken when action thresholds are exceeded.

The vocational group deemed competent to perform the tests, and also those with responsibility for controlling the test results must be designated, but they do not need to be named individuals. The inspection and measurement methods must be described in sufficient detail for the inspections and measurements to be repeated in compliance with the quality assurance programme in the manner intended by the person who prepared the programme.

Chronological records ("a log book") must be kept for each item of equipment specifying when the required inspections and measurements were made and by whom, and the results. Records can be in electronic form – in which case it will be easier to follow up the results and their trends. For example, small changes are most easily identified graphically. If action levels are exceeded the taken actions must also be recorded. The results obtained should be assessed periodically and used to modify the quality control protocol as necessary.

3.3. Quality control objectives and test groups

In this guide, quality control objectives of nuclear medicine equipment are divided into eight specific groups:

1. Gamma cameras
2 Coincidence cameras
3. PET cameras (PET: positron emission tomography)
4. Combined imaging devices: SPECT-CT and PET-CT (SPECT: single photon emission computed tomography; CT: computed tomography)
5. Gamma probes
6. Software of nuclear medicine equipment
7. Activity calibrators
8. Gamma counters.

In addition, it is necessary to supervise periodically the operating performance of the image monitors which are part of nuclear medicine equipment, because it is known that the image quality of these monitors deteriorates over time. The operating performance of the image monitors which are used in the tests of nuclear medicine equipment has to be verified before tests made under the quality control programme of the image monitor. More information of the

quality control of image monitors is given in the guidance STUK Informs 2/2008 (in Finnish) [6].

3.4 Test frequencies

All tests that are recommended in chapter 5 are performed for the first time during acceptance testing and after that with frequencies recommended in the tables in that chapter. The frequency given is a *recommended minimum frequency* so that the test is recommended to be performed at least as frequently. In choosing the frequency it is important to take into account that manufacturer's instructions may require more frequent testing as presented in the tables in chapter 5.

Independent of the specified frequency, tests must always be performed when needed, that is when there is cause to suspect that performance characteristics has changed (for example, after repair, servicing or modification). After a repair or modification it may even be necessary to change a reference value for constancy testing.

3.5 Action levels

If quality control test results do not meet the criteria that are set in the quality control programme, then measures must be taken to repair the equipment and restore its performance to an acceptable level. There are two kinds of action levels: *acceptance levels* and *remedial levels*, depending on the actions that are required to be taken.

Acceptability criteria are set by the regulatory body and the level denotes the minimum requirements for device performance. If the apparatus does not meet these criteria, then measures must be taken to repair the apparatus and restore its performance to an acceptable level, or the appliance must be removed from use. An exceedance of the acceptability criteria may be limited so that it is not necessary to remove the whole apparatus from use. It is not possible to set acceptability criteria for all essential characteristics of the apparatus, because in different clinical examinations different performance characteristics are needed and it may be dependent on different imaging indications. Acceptability criteria are established by a decision of STUK

Remedial levels are usually tighter than acceptability criteria and are based on how much the results are allowed to deviate from the reference values for the performance characteristics at acceptance testing, or from data of its performance characteristics which the apparatus has when it is within specification. In the event that remedial levels are exceeded then remedial actions must be taken. Actions to be taken and their urgency are dependent on the estimated influence of the detriment to the performance characteristics for quality and safety in use. A timetable for repair must be established and any necessary restrictions for the use of the apparatus before repair must be set. If repair is delayed the need to accelerate follow up of the performance characteristics has to be assessed. Before repair is undertaken, it is essential to find out the reason for the detriment in the performance characteristics and this may require other quality control tests and fundamental measurements. All actions taken must be documented together with the quality control results.

A responsible body may establish remedial levels, but they can not exceed the acceptability criteria set by the regulatory body.

If an action level is exceeded in quality control testing, the performance of the test equipment should be checked first and then that the measurement has been carried out properly. Moreover, it is often necessary to verify the result by repeating the measurement before the necessary actions are taken.

3.6 Measurement uncertainties

Quality control of nuclear medicine equipment includes measurements in which there is always uncertainty. Many factors influence the measurement uncertainty such as the measurement method, the characteristics of the measurement equipment, measurement conditions and even the person undertaking the measurements. Defining and understanding the measurement uncertainty is important to make a reliable statement either of the acceptability of performance or about exceedance of the established action levels by the measured result.

In radiation measurements, uncertainty is dependent on energy and dose rate dependence, repeatability and response of the meter and in addition but not limited to the measurement distance and the quality of the radiation. These sources of uncertainty usually result in at least a 10% error in dose measurements. It is worthwhile to document measurement geometry precisely in the quality control programme and to use images so that the measurement is easier to repeat.

Measurement of image quality visually is usually based on a test phantom in which there is a series of reducing or diminishing test objects from which the observer assesses the faintest visible object. Despite its apparent easiness, these measurements are demanding and it is difficult to get a precise result. The measurement requires that the criteria for the visibility of the test pattern can be kept the same from one measurement to another and that all measurers use the same criteria. Usually this is not achievable, but the results differ from one measurer and measurement time to another: For example the uncertainty of the contrast threshold is typically tens of percent (deviation of the measurement result is 20–30%). Because of this it is possible to observe reliably only considerable changes of image quality. It is possible to slightly improve the situation by using several observers to assess the visibility of the details in the image and to use the average of the observations. However, the change of image quality may be more easily and reliably observed when the test image and the previous reference image are compared to each other side by side.

The factors that influence the measurement results have to be assessed carefully beforehand. The requirements for measurement accuracy are dealt in the Guide ST 1.9 [7].

4. Standards for performance characteristics of nuclear medicine equipment

This guidance for quality control is based on the standards published by the National Electrical Manufacturers Association (NEMA) for nuclear medicine equipment [8–10], as described briefly in the following section. NEMA standards include basic knowledge of technical quality control of the equipment. They are revised and updated every five years if needed according to NEMA principals.

Quality control of nuclear medicine equipment is also discussed in the standards of the International Electric Commission (IEC). Standard IEC 61675-1 [11] considers PET cameras; Standard IEC 61675-2 [12] is about SPECT equipment and Standard IEC 61675-3 [13] is about whole body imaging cameras. Standards IEC 611145 [14] and IEC 61303 [15] are for activity meters and Standard IEC 61508 [16] is about software for nuclear medicine equipment. There are also recommendations for the quality control of nuclear medicine equipment in publications of the European Association of Nuclear Medicine [27,28], in publications of the International Atomic Energy Association (IAEA) [25] and in some other publications [18–24].

4.1 Gamma cameras: NEMA NU 1

The latest NEMA standard for gamma cameras is NU 1-2007, which is updated from the previous Standard NEMA NU 1-2001. A major change in the latest revision is the loss of the division into primary and secondary tests.

Quality control tests for gamma cameras based on the Standard NU 1-2007 are presented in Tables 1a–1d.

Table 1a. Quality control tests and result parameters for gamma cameras in accordance with Standard NEMA NU 1-2007: *Tests for detectors of a gamma camera.*

Test	Result parameters[1]
Intrinsic spatial resolution	FWHM UFOV (mm) FWTM UFOV (mm) FWHM CFOV (mm) FWTM CFOV (mm)
Intrinsic spatial linearity	Differential UFOV (mm) Differential CFOV (mm) Absolute UFOV (mm) Absolute CFOV (mm)
Intrinsic energy resolution	UFOV (%)
Intrinsic flood field uniformity	Integral UFOV (%) Differential UFOV (%) Integral CFOV (%) Differential CFOV (%)
Multiple window spatial registration	Maximal spatial difference with different energy windows either in X or Y directions (mm)
Intrinsic count rate performance in air	Maximal observed count rate at count loss 20 %
Intrinsic spatial resolution at 75 kcps	FWHM UFOV (mm) FWTM UFOV (mm) FWHM CFOV (mm) FWTM CFOV (mm)
Intrinsic flood field uniformity at 75 kcps	Integral UFOV (%) Differential UFOV (%) Integral CFOV (%) Differential CFOV (%)

[1] FWHM: full width at half maximum, FWTM: full width at tenth maximum, UFOV: useful field of view, CFOV: central field of view.

Table 1b. Quality control tests and result parameters for gamma cameras in accordance with Standard NEMA NU 1-2007: *Tests for detectors of a gamma camera with collimators.*

Test	Result parameters
System spatial resolution without scatter	FWHM CFOV (mm) FWTM CFOV (mm)
System spatial resolution with scatter	FWHM CFOV (mm) FWTM CFOV (mm)
System planar sensitivity and penetration	System sensitivity S_{TOT} ((puls/sec)/MBq) and penetration PF (%)
Detector shielding	Maximal L_i (not i=0), LF_i and LS_i for all radionuclides in use[1]
System count rate performance with scatter	Maximal observed count rate at count loss 20%

[1] Leakage of the shield under the camera (L_i), in front of the camera (LF_i) and beside the camera (LS_i)

Table 1c. Quality control tests and result parameters for gamma cameras in accordance with Standard NEMA NU 1-2007: *Tests for performance characteristics of a gamma camera in SPECT imaging.*

Test	Result parameters
System alignment	Radial alignment of the central point (δ_{COR}) and axial alignment (δ_{AXIAL}) for a camera and a pair of cameras (mm)
SPECT reconstructed spatial resolution without scatter	Spatial resolution: Transaxial central (X+Y)/2 (mm) Central axial (Z) (mm) Radial lateral (X) (mm) Tangential lateral(Y) (mm) Axial lateral (Z) (mm)
SPECT reconstructed spatial resolution with scatter	$FWHM_{central}$ (mm) $FWHM_{lateral,\ radial}$ (mm) $FWHM_{lateral,\ tangential}$ (mm)
System volume sensitivity	System volume sensitivity per axial distance (cm) ((pulses/second) /(MBq/cm^3)) for all used radioactive nuclides and collimator types
Detector-detector sensitivity variation	Maximal detector-detector sensitivity variation (%)

Table 1d. Quality control tests and result parameters for gamma cameras in accordance with Standard NEMA NU 1-2007: *Tests for performance characteristics of a gamma camera in whole body imaging.*

Test	Result parameters
Whole body system spatial resolution without scatter	Longitudinal FWHM (mm) Longitudinal FWTM (mm) Transversal FWHM (mm) Transversal FWTM (mm)

4.2 PET- and coincidence gamma cameras: NEMA NU 2-2007

NEMA published Standard NEMA NU 2-1994 for PET performance measurements. It was later updated in Standard NEMA NU 2-2001 so as to apply additionally to coincidence cameras. This standard was further updated in Standard NEMA NU 2-2007 which is the latest standard for performance measurements of PET and coincidence imaging equipment. The latest revision was considered necessary because of the internal radioactivity of the crystal material of the PET cameras; this has been taken into account in defining measurement parameters especially count losses, random counts and sensitivity.

The measurements presented in the earlier NEMA standard were broadened to consider also 3D and reconstruction modes in Standard NEMA NU 2-2001. Once the standard included coincidence imaging equipment a larger, 70 cm long test phantom was defined. The axial field of view of a gamma camera (30–40 cm) is larger than in the oldest standard which assumed a less than 17 cm field of view. Measurements in Standard NEMA NU 2-2001 better represented whole body measurements than in the older standard, because the radiation from outside of the field of view was included. Measurements were performed using ^{18}F. These modifications have been remained in the latest Standard NEMA NU 2-2007.

The biggest reform in NEMA NU 2-2001 was the test for image quality, which has been sustained in the latest Standard NEMA NU 2-2007. The purpose of the test is to imitate a whole body imaging by using ^{18}F in which active spheres represent tumours among a low background radiation. In the image quality tests phantoms imitate radioactivity distribution in the body.

Quality control tests in accordance with Standard NEMA NU 2-2007 are presented in Table 2.

Table 2. Recommended quality control tests and result parameters for PET and coincidence imaging equipment in accordance with Standard NEMA NU 2-2007.

Test	Result parameters
Spatial resolution	FWHM and FWTM Measurement points: • one point in one centimetre radial distance (transversal and axial) and two points in 10 centimetre radial distance from central axis (tangential, radial and axial) • corresponding three points ¼ FOV lateral axially from the centre of the field of view
Scatter fraction, count losses and randoms measurement	Systemic • True event rate • Random rate • Scatter event rate • Noise equivalent count rate • Total event rate in function of activity concentration • Scatter fraction In addition from graphs • Peak true event rate • Peak noise equivalent count rate • Activity concentrations in which the previous were achieved
Sensitivity	Systemic • Sensitivity (cps/MBq) • Sensitivity profile
Accuracy: corrections for count losses and randoms	Systemic • Relative count rate error, $\Delta r_{i,j}$ for each slice • Average effective activity concentration, $a_{eff,j}$ In addition • A graph of minimums and maximums • Maximum $\lvert\Delta r_{i,j}\rvert$

Test	Result parameters
Image quality, accuracy of attenuation and scatter corrections	The following parameters must be recorded: • Concentrations and the targeted concentration • Imaging parameters – Axial imaging distance – Computational imaging time – Real total imaging time – Reconstruction parameters (reconstruction algorithm, filter, matrix size, pixel size) Following parameters are defined: • Contrast relationship (%) for cold and hot spheres with two relative concentrations • Procent variability (standard deviation/average) of background areas of interest that are used instrumental in counting the contrast relations (60 with each size of spheres) • Relative error at the area of lung insert ($\Delta C_{lung,\ i}$) for each slice. The average of these is also reported. • An image of a transversal slice at the central line of spheres and a coronal slice at the central line of the 17 mm sphere with both concentrations.

4.3 Gamma probes: NEMA NU 3-2004

Standard NEMA NU 3-2004 is for non-imaging intraoperative gamma probes. The standard applies for probes equipped with both scintillation detectors (CsI, NaI) and semiconductor detectors (CdTe, CZT). The standard does not apply for equipment that is designed for detecting beta particles.

Quality control measurements according to the NEMA NU 3-2004 are presented in Table 3.

Table 3. Quality control tests and result parameters for gamma probes in accordance with Standard NEMA NU 3-2004.

Test	Result parameters
Sensitivity in air	Pulse rate/activity (cps/MBq) with distances for example 10, 30 and 50 mm with selected nuclides and an energy window.
Sensitivity in a scatter medium	Pulse rate/activity (cps/MBq) with distances for example 10, 30 and 50 mm with selected nuclides and an energy window.
Sensitivity	A number indicating sensitivity.
Sensitivity through side shielding in air	Pulse rate/activity (cps/MBq) with a certain lateral distance in air (for example 50 mm), with selected nuclides and an energy window.
Sensitivity to scatter	Pulse rate/activity (cps/MBq) with a certain lateral distance in water (for example 50 mm), with selected nuclides and an energy window. It is documented if the result is corrected for the effect from the sensitivity through side shielding in air (see previous).
Spatial resolution in a scatter medium	FWHM and FWTM (mm) in 30 mm source-detector-distance in water, with a selected nuclide and an energy window.
Volume sensitivity to distributed activity in a scatter medium	Pulse rate/activity (cps/MBq).
Short-term sensitivity stability	An averaged value for 20 sequential measurements (pulses/selected time), observed and expected standard deviance and chi-square-value. Intrinsic sensitivity stability is reported for open energy window and sensitivity stability for an energy window of a certain nuclide.
Count rate capability in a scatter medium	Source activity and pulse rate, with which a count loss of 20% is achieved and the pulse rates less than that which deviate more than 20% from the computational value.
Angular resolution in a scatter medium	FWHM and FWTM (degrees) with 30 mm source-detector distance in water, with a selected nuclide and an energy window.
Energy resolution	Either absolute or relative energy resolution: Energy resolution (keV) = $keV_{Channel\ B}$ - $keV_{Channel\ A}$ Energy resolution (%)=(Channel B-Channel A)/$Channel_{PEAK}$
Side and back shielding	Relative efficacy of shielding or relative leakage sensitivity.
Visual and physical inspection	Damages in cables, detectors or collimators that can be seen visually.
Power source – for internally-powered systems	As recommended in the manufacturer's manual.

5. Recommended quality control programmes for different groups of equipment

5.1 General

To test the operation of nuclear medicine equipment, variable measurements of performance parameters are needed. The importance of the parameters and frequencies of the tests are essentially dependent on the purpose of the imaging and how often the equipment is used. In static imaging, a decision is needed in each examination about what is adequate resolution and sensitivity. In dynamic examinations it is important to have a good count rate performance. If the gamma camera is used for SPECT examinations then the field uniformity is a crucial parameter.

Safety tests are included in both acceptance testing and in quality control, (see 3.1). The following recommendations do not include these but instead are concentrated on performance measurements of the equipment that is being performance tested.

Recommended performance tests are based on NEMA standards, but the conduct of the tests does not need to be totally identical with that given in NEMA standards. The aim is to ensure the performance of nuclear medicine imaging system in use so it is most important that the tests also show possible changes in the performance of the system.

This guidance only includes tests that directly concern nuclear medicine equipment. Temperature and humidity in the environment in which nuclear medicine equipment is used have to be followed up because the stability of the equipment requires usually unchanged environmental conditions.

5.2 Gamma camera

In *acceptance testing* of a gamma camera (see item 3.2.1) all tests in Standard NEMA NU 1-2007 are recommended (Tables 1a–1d, item 4.1). After a significant repair of a gamma camera it is recommended that applicable tests of Standard NEMA NU 1-2007 are conducted, taking into consideration possible effects of the repair to the performance of the equipment.

In *quality control* testing of a gamma camera during use, the tests in Table 4 are minimum recommendations.

Table 4. Recommended tests for periodic quality control of a gamma camera.

Test	Recommended minimum frequency	Comments
Visual check of the condition of an equipment	1 d	Fast check to reveal mechanical damage or other visible failures.
Background radiation and contamination check	1 d	To detect for example radioactive contamination of the equipment.
Energy window check	1 d	To check the correct energy setting is used (is a photo peak in the centre of the energy window).
Uniformity of the field	1–3 d	To find out if the camera produces a uniform image from a uniform source. The test can be conducted using a point source without a collimator or using a plane source with a collimator. If the measurement is performed routinely without a collimator it is a good practice to repeat periodically a measurement with a plane source to check the condition of collimators.
Energy resolution (FWHM)	1 y	
Correspondence between positions of several energy windows	1 y	The test is appropriate if the camera is used for dual nuclide examinations or nuclides used have several energies (for example ^{67}Ga, ^{111}In)
Spatial resolution	1 y	To assess the spatial resolution of a camera (with different collimators). It is possible to use arrangements described in the NEMA standards or for example a plane source and a lead slit phantom. In the latter it is essential that the image from acceptance testing is available as a reference.
Sensitivity	1 y	To explore the camera's ability to detect (with a specific collimator) pulses from a known source (pulses/second)/MBq). Alternatively, corresponding information can be gained from uniformity measurements by recording the activity of a source and calculating the pulse rate/activity (cps/MBq).
Centre of rotation	1 mo	To find out if the computational centre of the image and the mechanical centre of the rotation match. The test should be done using all collimators that are used in SPECT examinations and with all the detector-detector angles used.
Spatial resolution in whole body imaging	1 y	To assess the resolution both along the imaging direction and orthogonally. It is useful to do testing both in the centre of the imaged area and at its ends.
SPECT –performance (not a NEMA measurement)	1 y	To assess the performance characteristics of the camera in SPECT imaging. A suitable cylindrical phantom (like Jaszczak) is used for assessing the uniformity of the flat area and the visibility of different sized hot and cold objects. It is essential that the reference data from acceptance testing is available.

5.3 Coincidence camera

Similar detectors are used in coincidence imaging and in gamma imaging so that quality control operations for both acceptance testing and quality control (Table 4) are the basis of a quality control programme for a coincidence camera.

In *acceptance testing* of a new coincidence gamma camera (see item 3.2.1) it is recommended to perform the tests that are best applicable for the intended use of the equipment. For example, tests for spatial resolution, sensitivity measurement and image quality measurement are recommended. After repair of an operational coincidence gamma camera the same tests are recommended taking into consideration the possible effect of the repair on the performance characteristics of the equipment.

In *quality control* of a coincidence gamma camera it is recommended to perform at least the tests that are presented in Table 5.

Table 5. Recommended tests for periodic quality control of a coincidence gamma camera.

Test	Recommended minimum frequency	Comments
An energy window check using a nuclide (for example ^{18}F) that is used in coincidence mode	Always before imaging a patient	To check the energy setting is correct (the photo peak in the centre of the energy window)
Blank scan	1 mo	If attenuation correction sources are used
Image quality	1 y	As in Standard NEMA NU 2-2007
Performance check of the coincidence electronics	1 y	In accordance with the manufacturer's maintenance
Other acceptance tests (Tests from Table 2 that are applicable for the use of the equipment)	When needed	As in Standard NEMA NU 2-2007

5.4 PET camera

During *acceptance testing* of a new PET camera (item 3.2.1) it is recommended to perform applicable tests from those introduced in item 4.2 (Table 2) that are best suited to the intended use of the equipment. One test recommended in Standard NEMA NU 2-2007 is the resolution at distances of r = 10 mm and r = 100 mm in whole body imaging equipment, measured from the centre of the imaging area. Scatter fraction and the performance of the scatter correction, sensitivity of the camera and correction of pulse losses and random coincidences are also recommended to be checked as in Standard NEMA NU 2-2007.

For *quality control* of a PET camera in use, tests that are primarily recommended are those recommended by the manufacturer, using radiation sources recommended by the manufacturer, and at least the tests shown in Table 6.

During use of a PET camera it is essential to follow the manufacturer's instructions for the tuning of the equipment, like: repeated adjustment of the amplification factors of photon multiplier tubes or calibration coincidence times of detectors and normalizing the equipment. If there are inner radiation sources in the equipment their location has to be observed to verify that it corresponds to the indications of the computer or the console.

The electronics of a PET camera should be checked daily using radiation sources that are used in the attenuation correction measurements (a so called "blank scan") or radiation sources purchased for quality control purposes. Due to the relative long half life of the radiation source (^{68}Ge T1/2 = 270,8 d; ^{137}Cs T1/2 = 30,2 y; ^{22}Na T1/2 = 2,6 y) it is easily possible to perform long term follow up of the camera during the same measurement. It is recommended that a number of real incidences are recorded daily. Statistical criteria are set in the software for analyzing the measurements, because there is deviation between single detectors that is tolerable within certain limits. If the counts deviate more than is expected (knowing the half life of the nuclide and within statistical limits), the performance of the camera has to be checked more carefully. Modern PET cameras are equipped with automatic quality control software that reports condition results for the camera daily. The user has to interpret the printout of the results.

In a quantitative check of PET images with a ROI method (Region of Interest), it is recommended to image using a cylindrical ^{68}Ge source or a similar source with a long half life for which the concentration is known and the diameter is at least 170 mm and the length is more than the axial field of view of the camera. The purpose of the measurement is to show that image reconstruction and image processing perform correctly. If the result deviates from the previous measurement (reference value) by more than 5% (remedial level) the cause of the deviation should be clarified. If the deviation from the reference value is more than 10% (acceptability criteria) the method cannot be used for quantitative examinations before the performance characteristics is improved.

Table 6. Recommended tests for periodic quality control of a PET camera.

Test	Recommended minimum frequency	Comments
Performance test using the equipment specific quality control programme. For example: • blank scan • real incidences with a known source • interpreting a sinogram	Before imaging a patient	Performed using a point or a rod source without attenuating object at the imaging area. Tuning photo multiplier tubes or an energy window may be necessary due to the measurement.
Quantitative check of PET images	3 mo	To check that ROI values in the PET images correspond to the radioactive concentration in the imaged phantom.
Calibration of the camera with a known activity	6 mo	Always performed after normalizing the equipment. Calibration is based on the measurement of a known phantom filled with a radioisotope.
Image quality	1 y	As in Standard NEMA NU 2-2007.
Other tests performed during acceptance testing. (Appropriate tests for the use of the equipment from Table 2)	When necessary	As in Standard NEMA NU 2-2007.

5.5 Hybrid imaging equipment SPECT-CT and PET-CT

Hybrid imaging equipment SPECT-CT and PET-CT are nuclear medicine equipment in which one patient table integrates SPECT camera (gamma camera) system or a PET camera and a computed tomography (CT) system so that two types of image are obtained. The CT image is used in nuclear medicine imaging for attenuation corrections and to produce an anatomical image. Fusing an isotope image and a CT image gives more information than a normal SPECT or PET image alone.

Recommended tests for acceptance testing of SPECT-CT and PET-CT equipment and periodic quality control are the same tests as above in Tables 4 and 6. For CT equipment it is recommended to perform the same tests as are recommended for other tomography equipment. Quality control of CT equipment is discussed in the guidance STUK Informs 2/2008 (in Finnish). A manufacturer's recommendation is a good basis for daily quality control of CT equipment. In addition, the geometrical alignment of nuclear medicine equipment and CT equipment of hybrid SPECT-CT and PET-CT equipment must be checked periodically (for example monthly) [25–28].

The performance of an attenuation correction has to be checked during the commissioning of the equipment and annually and after any repair that may influence image quality. A vessel

filled with radioactive liquid is enough for a basic check. An inhomogeneous image quality phantom is used for testing accuracy of the attenuation correction.

Despite quality control, attenuation correction may not work correctly with all patients or in every imaging. Uncorrected images must be available during reading of patient images.

5.6 Gamma probes

In acceptance testing of a gamma probe (a detector used in surgery for localizing a tumour) it is recommended to perform tests presented in Standard NEMA NU 3-2004 (Table 3, item 4.3) and in periodic quality control, tests that are introduced in Table 7.

Table 7. Recommended tests for periodic quality control of gamma probes.

Test	Recommended minimum frequency	Comments
Visual and physical check for the condition of an equipment	Before patient examination	Fast check of the detector, meter or cables to reveal mechanical damage or other visible damage.
Background radiation	1 d	The pulse rate due to background radiation is checked when there is no other radioactivity present.
Stability of sensitivity and repeatability of measurement results	6 mo	Using a suitable radiation source, which has a long half life, and in a fixed geometry the stability of sensitivity can be followed up. Repeatability of results is defined by repeating the measurements. The test is performed using all energy settings and collimators that are in clinical use.
Condition of power supply (for detectors with batteries)	1 d 6 mo	The condition of a power supply (adequate voltage) is checked one day prior to use. Operational time of a power supply (time that a fully charged power supply produces adequate voltage)
Energy resolution	6 mo	Detector response is checked with all energies that may possibly be used.

If ^{99m}Tc labelled medicine is used in the surgery, the gamma probe's sensitivity can be measured using a ^{57}Co source. During sensitivity measurements the following data should be recorded: date, radionuclide used and its activity on a reference date, source to detector distance and the measurement result or sensitivity, that is measured pulse rate (cps or 1/s) divided by the decay corrected activity (Bq).

5.7 Software of nuclear medicine equipment

5.7.1 General

Computer software in nuclear medicine equipment should give reliable, consistent and repeatable information. In order to operate reliably analytical software, whether this is commercial or self made, various verifications and validations are required:

- performance of the physiological-mathematical model
- performance and correctness of the programme code
- clinical usability (best assessed using test objects)
- instructions and training to use the software.

It is difficult to verify the validity of physiological parameters (model, programme code, use). Often manufacturers of the software only take care of the technical performance of the software, however sometimes software is validated by the manufacturer. Responsibility for the accuracy of the results is on the user. *Self made unvalidated programmes are not recommended.* Often, widely used software is more reliable than non-mainstream software. Each software package has to be locally validated during commissioning (for example, with respect to collecting parameters, filtering, delineating etc). It is good practice to verify the performance of software by an independent method (phantom measurements, comparison to other software or method). Visual inspection of images and graphs should always be used to support parametrical data whenever possible.

All phases should be documented. A good summary for programmers is represented in IPEM publication [18].

5.7.2 Reconstruction and filtering practice

The most important issue in processing tomography data is to choose a reconstruction and filtering practice and its consistent use. A good basis for the choice is the manufacturer's recommendation. It has been shown in practice that definitions of filters are different in different software and even in different versions. A good and simple follow up method is to save a reference raw data file and reconstructed slices. After a workstation is changed this method may not be enough and phantom measurements may be needed.

5.7.3 Image printing

A number of factors need to be taken into account with respect to image printing as follows:

- in printing images on film or on paper, care has to be taken with stability of colours and shades; this requires quality control of printers if the image reading is based on a print
- windowing practice has to be based on the similar, generally written, principles independent of an operator
- adequate notes should be taken to ensure consistency of both image and computational documents.

5.7.4 Recommendations for quality control of software

The following actions are needed to produce reliable information about the examination (summary in Table 8):

- documentation about the software version
- standardization of the use of the software for diminishing variation in and between units (delineating regions of interest, filtering etc)
- training, self assessment
- participating in national and international quality comparisons
- documenting of all phases.

Table 8. Quality control of software in nuclear medicine equipment.

Software quality factor	Notice
Documenting	Software version number, notes
Commissioning and use	Validation, training, reference prints
Validation	Software and other phantoms, comparison to other software or method, quality
Physiological-mathematical model	Literature, co-operation
Programme code	Testing, clarity, limits for input data, documented special cases, changes of parameters
Reconstruction and filtering practice	See item 5.7.2
Image printing	See item 5.7.3
Documenting/record keeping?	On all levels, including a quality system

5.8 Activity meters

In acceptance testing of an activity meter (a dose calibrator) and in periodic quality control the tests presented in Table 9 are recommended.

Table 9. Recommended tests for acceptance testing and periodic quality control of an activity meter.

Test	Recommended minimum frequency	Comments
High voltage	1 d	To check that the high voltage to the activity meter is correct.
Timer	1 d	To check the timer's accuracy.
Zero adjustment	1 d	To check that the display is at zero when there are no radiation sources near the activity meter.
Background	1 d	To check background at settings for a specified radionuclide. The test will reveal any potential contamination.
Reproducibility	1 d 1 y	The reproducibility of the activity meter is checked by using test sources: • with settings for the radionuclide used in a test source (1 d) • with settings for all radionuclides used (1 y).
Repeatability, precision	3 mo	Repeatability is defined from ten sequential measurements. The variation in sequential measurement results is checked using a chi-square test to verify that it is only due to the decay characteristics.
Accuracy	1 y	To define the deviation between the activity meter's display and the nominal activity.
Linearity	6 mo/1 y	To verify that with a certain radionuclide the activity meter displays the correct activity across the whole scale from the largest activity (GBq) to the smallest activity (MBq) used.
Geometry		To define the response of the activity meter at different heights from a radioactive source.
Calibration factors in different geometries and different volumes for variable radio nuclides		To define calibration factors for activity measurements in different geometries (syringe, ampoule or other) and volumes.

5.9 Gamma counters

A gamma counter is used mainly in measurement of blood samples (for example GFR measurement by ^{51}Cr-EDTA). The equipment may be of manual or automatic.

The tests shown in Table 10 are recommended for acceptance testing and periodic quality control of gamma counters

During acceptance testing the shielding of the scintillation detector should be checked for both background radiation and for other sample tubes. The location of equipment in the department should be such that the background radiation does not vary significantly. If background radiation is not shielded adequately the background measurement has to be made in connection to each patient measurement.

Periodic quality control is performed by carrying out reproducibility tests. By that it is verified that the position of an energy peak has not changed and that a number of detected pulses in the measurement window obeys a correct value (relative to decaying). Test sources have a long half life, for example ^{129}I, ^{68}Ge or ^{137}Cs.

Table 10. Recommended tests for acceptance testing and periodic quality control of gamma counters.

Test	Recommended maximum frequency	Comments
Energy window	1 wk	For all radionuclides in use
Background	1 wk or in connection to each patient measurement	Verifying the unchanged background
Sensitivity	1 wk	Number of detected counts in the measurement window by a test source.
Stability	1 wk	Repeatability and accuracy of the equipment are verified.

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