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GUIDELINES

Acceptance testing for nuclear medicine instrumentation

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Introduction

These recommendations cover acceptance and reference tests that should be performed for acceptance testing of instrumentation used within a nuclear medicine department. These tests must be performed after installation and before the instrument is put into clinical use, and before final payment for the device. These recommendations must be considered in the light of any national guidelines and legislation, which must be followed. The recommendations cover the types of test to be performed, but they do not specify the procedures to be followed, which are available from other reference sources quoted.

Acceptance testing is extremely important, as it can affect the whole life performance of a system. The requirement that acceptance testing be performed should be included in the purchase agreement of an instrument. This agreement should specify responsibilities regarding who does acceptance testing, the procedure to be followed when unsatisfactory results are obtained, and who supplies the required phantoms and software. A specific time slot must be allocated for performing acceptance tests.

Acceptance and reference tests

Acceptance tests are performed to verify that the instrument performs according to its specifications. Each instrument is supplied with a set of basic specifications. These have been produced by the manufacturer according to standard test procedures, which should be traceable to standard protocols, such as the NEMA and IEC performance standards [1–4, 11, 30, 37]. By following the standard procedures in the clinical setting, with support from the vendor supplying the special phantoms and software where necessary, specifications can be verified. Some acceptance tests are essential performance tests that should be repeated on either a routine or a periodic basis, and these acceptance tests provide reference data that the user can refer to during the whole life of the system. In addition to acceptance tests that verify specifications, additional tests are usually required at acceptance in order to more thoroughly test individual components of an instrument, and these are referred to here as reference tests. Reference tests may reveal a problem with performance that needs to be corrected by the manufacturer before the system is accepted. Some reference tests are simpler versions of the acceptance tests, using phantoms or devices available within the department. The results of all tests made at acceptance form the baseline reference data for all future quality control tests.

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Test performance, follow-up and documentation

Acceptance and reference tests must be performed by the medical physics expert in nuclear medicine or other experienced nuclear medicine physicist who is competent in applying the appropriate test procedures. Tests performed at acceptance may be carried out either completely by the installing vendor, or together with the vendor, but the evaluation of the results must be made by the medical physicist or medical physics expert acting on behalf of the purchaser. Any test results not meeting specifications must be questioned and repeated, and appropriate action taken. The instrument should not be accepted until tests prove that the instrument performs as required. Because the equipment has a guarantee period, this is the time to ensure that the components of the equipment that have been purchased perform within specifications and give the best possible quality.

It is acknowledged that there is often pressure to begin to use a system as soon as the company installation has ended, but adequate time must be allowed to perform the tests and to investigate issues. Additional days at this stage may save many days of dealing with ongoing issues in the future.

All test methods and results must be recorded carefully and archived, so that all future quality control tests can be accurately compared with the test data acquired at acceptance. These data form the start of a log-book or digital record for the instrument.

Acceptance and reference test recommendations

Details of the tests that cover the main performance characteristics that should be tested in a given instrument are presented in Tables 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11. Acceptance tests must be performed as closely as possible to standard procedures so that the results can be compared with the manufacturer's specifications. Reference tests are acceptance tests and additional performance tests that do not have a related manufacturer's specification. The results provide baseline data that will become the reference for future repeated periodic and routine quality control tests. These tests are not intended to supersede national guidelines or national regulations, which should always be followed. It is strongly recommended that the physicist responsible for acceptance testing is in close communication with the installing engineer, and has regular conversations with the engineer during installation to see and become familiar with the system and any issues that arise during installation. For multidetector systems, each detector must be tested individually. Some tests should be repeated with all detectors operating simultaneously. There is also a note in the legend to each table giving the general type of technology that the recommendations apply to. Specific systems may employ technologies that need other checks, as specified by the manufacturer. Optional tests are intended to measure more subtle performance or parameters that are less important for modern systems. They are not essential for the functioning of an instrument and therefore should be performed when special working conditions are expected (e.g. high count rate) or if a particularly thorough performance check is intended.

Software

Tests of the DICOM functions can be performed to check against the specification and the DICOM conformance statement, and the user's specification for the storage to and recall of data from a PACS. It is important to check the correct geometric orientation of the images transferred to other systems, the correctness of numerical pixel values, and the correctness of the total number of images transferred and their sequence.

Software for clinical applications may be tested during acceptance, but such tests are rarely performed since they are not standardized due to the wide range of software applications.

Note: All clocks within the department and within all instruments and computers must be synchronized. This is an essential requirement for accurate activity administration and for quantitative data analysis.

Procedures and references

Test procedures are not included in this document, but can be found by reference to standard descriptions, and by reference to other literature and national and international protocols. Any manufacturer-supplied test procedures, test phantoms and software should also be taken into account. Some essential literature references are given. They should be consulted for detailed generic test procedures and advice regarding test evaluation, action thresholds and follow-up. It is recommended that each department create detailed written test procedures at acceptance specific for each instrument in use. By following standard test procedures, consistency in future test results can be assured and trends monitored. Care must be taken to ensure that compatible procedures are used for calibration and testing, for example when using vendor-supplied phantoms during installation and other—commercial or home-made—phantoms for regular testing. Any simplified test to be subsequently applied for regular QC should be made at acceptance to establish reference data.

Table 1 Acceptance testing for a gamma camera: planar imaging mode. *Equipment type*: scintillation Anger gamma camera

Test	Purpose	Acceptance	Reference
GC(ACC)1. Physical inspection	To check the total system for shipping damage (e.g. gantry, console, collimators, collimator touch pads, computer, data storage, display devices), and production and design flaws	X	
GC(ACC)2. Computer clock	To verify the correct time of day of the scintillation camera data acquisition and processing computer		X
GC(ACC)3. Energy window setting for ^{99m}Tc	To check and centre the preset energy window setting on the ^{99m}Tc photopeak		X
GC(ACC)4. Energy resolution for ^{99m}Tc	To check that energy resolution for ^{99m}Tc meets specifications	X [1]	X
GC(ACC)5. Background count rate	To detect radioactive contamination/excess electronic noise		X
GC(ACC)6. Intrinsic uniformity for ^{99m}Tc, with default PHA window – visual and quantitative	To measure the response to a spatially uniform flux of ^{99m}Tc photons, for uniformity and overall sensitivity, with the default PHA window. *Note*: If intrinsic uniformity is unsatisfactory, stop further testing until the problem causing nonuniformity has been resolved	X [1]	X
GC(ACC)7. Energy window setting – other radionuclides to be used clinically	To test that preset energy windows are properly centred for the energies of other clinically used radionuclides		X
GC(ACC)8. Intrinsic flood field uniformity for radionuclides other than ^{99m}Tc – visual and quantitative	To assess uniformity of response for all other radionuclides to be used clinically		X
GC(ACC)9. Intrinsic spatial resolution and linearity for ^{99m}Tc – quantitative (NEMA method)	To measure intrinsic spatial resolution (full-width at half-maximum and full-width at tenth-maximum) and nonlinearity (integral and differential) over the whole field of view of the detector (with the method that closely approximates that used for creating specifications)	X [1]	
GC(ACC)10. Intrinsic spatial resolution and linearity for ^{99m}Tc – visual (user phantom)	To check spatial resolution and linearity with test patterns available within the department, such as quadrant bar pattern or orthogonal hole pattern. *Note*: If intrinsic spatial resolution or linearity is unsatisfactory, stop further testing until the problem has been resolved		X
GC(ACC)11. Extrinsic uniformity for ^{99m}Tc (or ^{57}Co) – visual and quantitative	To test the uniformity of response for each collimator type using a flood phantom		X
GC(ACC)12. Extrinsic spatial resolution and linearity – quantitative (NEMA method)	To test the extrinsic spatial resolution of a scintillation camera in terms of the full-width at half-maximum of its line-spread function; this test should be performed for each collimator	X [1]	
GC(ACC)13. Extrinsic spatial resolution and linearity – visual	To obtain an overall impression of the spatial resolution and linearity over the whole collimated field of view of the detector, with a spatial resolution pattern, such as quadrant bar pattern or orthogonal hole pattern		X
GC(ACC)14. System planar sensitivity	To test the count rate response of a scintillation camera with collimator to a radionuclide source of known radioactivity	X [1]	X
GC(ACC)15. Multiple window spatial registration	To test that the images acquired at different photon energies superimpose when imaged simultaneously, in an additive or subtractive mode	X [1]	X
GC(ACC)16. Pixel size	To determine the absolute size of a pixel	X [1]	X
GC(ACC)17. Detector head shielding leakage	To test that the shielding of the gamma camera is adequate	X [1]	
Optional			
GC(ACC)18. Intrinsic uniformity for ^{99m}Tc – through asymmetric energy windows	To more critically assess uniformity under sensitive conditions that check the photomultiplier tuning and corrections.Note: This test is useful when the uniformity image obtained with a symmetrical energy window is of poor quality.		X
GC(ACC)19. Intrinsic count rate performance – in air	To test the intrinsic count rate performance of the camera to an increasing flux of incident photons. To determine the count rate at 20% count loss and to determine the maximum observed count rate. This test is dependent on surrounding scatter conditions: care should be exercised when comparing results with specifications.	X [1]	X
GC(ACC)20. Intrinsic uniformity and spatial resolution at 75k counts per second	To test the imaging performance (uniformity and spatial resolution) at a high photon flux of 75k counts per second.These tests should be performed if high count rate clinical studies are to be performed.	X [1]	X
GC(ACC)21. Collimator hole alignment	To test the septal alignment and septal angulation for parallel hole collimators. *Note*: This is a sensitive test to assess the integrity of parallel hole collimators, and supplements extrinsic uniformity test of the collimator.		X [6, 7]

Table 2 Acceptance testing for a gamma camera: whole-body scanning mode. *Equipment type*: scintillation Anger gamma camera

Test	Purpose	Acceptance	Reference
WB(ACC)1. Uniformity	To check uniformity of scan speed over the full length of a scan, and in particular at either ends of the scan path; for a dual pass scanner, to also visualise and assess the significance of image overlap; to test that there is no loss of count density at the lateral edges of the whole body scan; to test the attenuation of the patient pallet		X [10]
WB(ACC)2. Spatial resolution and linearity – without scatter	To test the spatial resolution and linearity parallel and perpendicular to the direction of motion, without scatter material	X [1]	X
Optional			
WB(ACC)3. Spatial resolution and linearity – visual	To assess spatial resolution and linearity using a spatial resolution test pattern (e.g. quadrant bar or orthogonal hole pattern) and to assess any longitudinal misalignment from a comparison of the whole-body image with the static image obtained with the same counts and physical set-up; for a dual pass scanner, to also visualize and assess the significance of image overlap.		X

Table 3 Acceptance testing for a gamma camera: SPECT[a]. *Equipment type*: scintillation Anger gamma camera – with or without CT

Test	Purpose	Acceptance	Reference
SPECT(ACC)1. Centre of rotation	To test the alignment of a detector in the X and Y axes		X [9]
SPECT(ACC)2. Tomographic spatial resolution - in air (no scatter)	To measure the tomographic spatial resolution of the system in air, and to ensure that the reconstruction process is not degraded by either the tomographic acquisition or the reconstruction	X [1]	X
SPECT(ACC)3. Detector to detector sensitivity	For multiple-head SPECT systems: a total system test to determine the difference in sensitivity between the acquired tomographic data from the collimated detectors.	X [1]	X
SPECT(ACC)4. Overall system performance: uniformity and contrast resolution	To test tomographic uniformity and contrast resolution, and to test the attenuation correction[b]; a total performance phantom (e.g. Jaszczak) should be used		X
Optional			
SPECT(ACC)5. Tomographic resolution – with scatter	To measure the tomographic resolution of the system under clinical conditions; that is, with a radius of rotation that is realistic, and with scatter present. to give an indication of the resolution which is likely to be achieved clinically	X [1]	X

[a] Before starting acceptance testing of the tomographic performance of the system: planar performance must be satisfactory and accepted; calibration of the tomographic centre of rotation and the detector head alignments with respect to the patient bed must be performed according to the manufacturer's recommendations for all clinically used detector head configurations; and high count uniformity correction maps for correction of acquired SPECT data must be acquired. Tests should be performed for each detector head individually, and in combination where appropriate.

[b] Radionuclide source attenuation correction systems should be checked against the manufacturer's specification, using methods recommended by the manufacturer.

Table 4 Acceptance testing for PET. Full normalization and gantry calibration (PET/CT) must precede the acceptance testing. *Equipment type*: whole-body positron emission tomograph (fixed and mobile systems)

Test	Purpose	Acceptance	Reference
PET(ACC)1. Physical inspection	To check the total system for shipping damage (e.g. gantry, console, computer, display devices) and production and design flaws	X	
PET(ACC)2. Computer clock	To verify the correct time of day of the data acquisition and processing computer		X
PET(ACC)3. PET sensitivity	To define the rate at which coincidence events are detected in the presence of radioactive sources at activity levels where count rate losses are negligible	X [11]	X
PET(ACC)4. PET uniformity	To describe the ability to measure the same activity independent of location within the imaging field of view	X [11]	X
PET(ACC)5. Spatial resolution	To measure the intrinsic spatial resolution (full-width at half-maximum and full-width at tenth-maximum) according to NEMA and compare with the manufacturer's specification	X [11]	X
PET(ACC)6. Count rate performance	To measure the count rate as a function of (decaying) activity over a wide range of activities; Peak NEC value and corresponding count rate should be compared with the manufacturer's specification; true, random and scatter count rates and scatter fraction could be determined for future reference	X [11]	X
PET(ACC)7. Image quality (not mandatory)	To determine the hot and cold spot image quality of the standardized image quality phantom described in the NU 2-2007 document [11]; this test is to measure recovery coefficients and signal to noise ratio performance of the imaging system		X

Table 5 X-ray CT – as part of PET/CT and SPECT/CT systems (acceptance tests for diagnostic applications)

Test	Purpose	Acceptance	Reference
CT(ACC)1. Physical inspection	To check the CT scanner part of the PET/CT or SPECT/CT system for shipping damage and production and design flaws	X	
CT(ACC)2. X-ray CT scanner acceptance	The CT scanner is an X-ray device that must be checked according to national radiation safety legislation under the direction of the appropriate radiation protection adviser and medical physics expert for diagnostic radiology; acceptance tests will include those for performance as well as those for radiation safety	X	X
CT(ACC)3. CT number accuracy	To check the accuracy of the CT numbers	X	X
CT(ACC)4. PET/CT or SPECT/CT image registration	To check that PET or SPECT data and CT data are accurately superimposed for attenuation correction and image fusion		X

Table 6 Acceptance testing for a radionuclide calibrator. *Equipment type*: gas ionization chamber; the checks also apply to a scintillation-based calibrator, but additional checks may apply (see manufacturer's documentation)

Test	Purpose	Acceptance	Reference
RC(ACC)1. Physical inspection	To check the total system for shipping damage (e.g. ionization chamber and source holders, computer, display devices) and production and design flaws	X	
RC(ACC)2. Clock accuracy	To ensure that the calibrator clock is set accurately to the time of day		X
RC(ACC)3. High voltage	To check the correct operating voltage	X	X
RC(ACC)4. Zero adjustment	To check that the display is at zero when no radioactivity is present		X
RC(ACC)5. Background counts	To check background response under operational conditions appropriate for a particular radionuclide; to detect contamination		X
RC(ACC)6. Accuracy	To check the accuracy of the activity readings for radionuclides	X [26]	X
RC(ACC)7. Precision	To check that the random fluctuation in measurements is due to the random nature of radioactive decay alone		X
RC(ACC)8. Linearity	To confirm that the calibration setting for a particular radionuclide indicates the correct activity over the entire range of use, from the maximum activity (in the GBq range) to the lowest activity to be measured (in the MBq range).	X	X
RC(ACC)9. Geometry	To calibrate the response of the calibrator to a radioactive source placed at different heights in the ionization chamber		X
RC(ACC)10. Calibration of different containers and volumes – for different radionuclides	To obtain calibration factors for the measurement of a radioactive source in different containers and with different volumes for clinically used radionuclides		X

Table 7 Acceptance testing for a thyroid uptake probe. *Equipment type*: nonimaging scintillation detector

Test	Purpose	Acceptance	Reference
TP(ACC)1. Physical inspection	To check the total system for shipping damage (e.g. collimator and probe mounting, cables, computer) and production and design flaws		X
TP(ACC)2. Energy calibration and energy window setting	To calibrate and test the energy window settings and establish the operating voltage and gain settings; to ensure that the operating (preset) energy window is centred over the photo peak		X
TP(ACC)3. Background count rate	To measure the count rate level without surrounding radioactivity		X
TP(ACC)4. Energy resolution	To measure and test the energy resolution for the radionuclide given in the specifications, and also for ^{131}I	X	X
TP(ACC)5. Sensitivity	To establish the sensitivity for a known amount of radioactivity of a specific radionuclide measured in a constant geometry; this measurement forms the basis for QC constancy tests		X
TP(ACC)6. Counting precision	To check that the uncertainty in the measurement is primarily due to the random nature of radioactive decay; this tests the stability of the overall electronics and cable connections		X
TP(ACC)7. Linearity of response	To test the linearity of the count rate over the range of activities to be used clinically		X
TP(ACC)8. Geometry	To determine the count responses to a radioactive source measured at different longitudinal and lateral distances from the scintillation detector		X

Table 8 Acceptance testing for a nonimaging intraoperative probe. *Equipment type*: nonimaging gamma ray detecting probe; any type of detector

Routine test	Purpose	Acceptance	Reference
PR(ACC)1. Physical inspection	To check for damage to the probe (crystal, shielding and collimator), the measuring unit, and cables		X
PR(ACC)2. Power source (battery-powered systems)	To check that the unit is operating at full battery operating voltage before use; to check the battery autonomy, to ensure that the batteries are capable of supplying total power requirements for the full duration of use; see the manufacturer's procedure		X
PR(ACC)3. Energy window calibration	To ensure correct energy window settings for all radionuclides to be used clinically		X
PR(ACC)4. Energy resolution	To verify the energy resolution for a particular radionuclide	X [30]	X
PR(ACC)5. Background count rate	To check background level when no activity is present (this forms the basis for future QC tests); measure for all probes and collimators		X
PR(ACC)6. Sensitivity in scatter medium	To test sensitivity in a situation close to the clinical situation	X [30]	X
PR(ACC)7. Sensitivity to scatter	To check sensitivity to scatter which is related to the energy window setting; this is important since probes are often used in relatively high scatter backgrounds	X [30]	X
PR(ACC)8. Spatial resolution in scatter	To check the collimator and crystal position geometry	X [30]	
PR(ACC)9. Shielding – side and back shielding	Important since probes are often used to locate low activity sources near to high activity sources	X [30]	
PR(ACC)10. Counting precision	To check that the uncertainty in the measurement is primarily due to the random nature of radioactive decay	X [30]	X
PR(ACC)11. Linearity of count rate response - with scatter	To test the clinical situation; important when quantitative measurements are to be made	X [30]	X
Optional			
PR(ACC)12. Sensitivity in air	To establish and test the sensitivity for a known amount of radioactivity of a specific radionuclide measured in a constant geometry with respect to the probe; test with an appropriate long half-life (e.g. ^{57}Co) source as well as clinical radionuclides; test for each probe and collimator	X [30]	X

Table 9 Acceptance testing for a manual or automatic gamma counting system – in vitro. *Equipment type*: single-sample or multi-sample gamma counter, with scintillation detector

Routine test	Purpose	Acceptance	Reference
AGC(ACC)1. Physical inspection	To ensure that there is no damage to the instrument, in particular the crystal housing and connectors, and electronic units	X	
AGC(ACC)2. Energy window calibration	To ensure that the window settings of the pulse height analyzer are appropriate for all radionuclides to be measured	X	X
AGC(ACC)3. Energy resolution	To verify the energy resolution in terms of the full-width at half-maximum for the radionuclide given in the specifications (usually ^{137}Cs)	X	X
AGC(ACC)4. Linearity of energy response	To test the energy window settings for linearity with respect to radiation energy		X
AGC(ACC)5. Background count rate	To measure the count rate without radioactivity for the energy windows to be used, and for an integral energy window setting above a specific low baseline setting		X
AGC(ACC)6. Sensitivity	To test the sensitivity of the system to a certified radionuclide source	X	X
AGC(ACC)7. Counting precision	To check that the uncertainty in the measurement is primarily due to the random nature of radioactive decay		X
AGC(ACC)8. Linearity of activity response	To determine the linearity of response to increasing amounts of radioactivity		X

Table 10 Acceptance testing for radiation monitoring instruments: exposure meter, contamination monitor, personnel monitor. *Equipment type*: any type of ionizing radiation detection monitor. The radiation protection adviser should be consulted to ensure compliance with national legislation and guidance on radiation dose measuring instruments

Routine test	Purpose	Acceptance	Reference
RM(ACC)1. Physical inspection	To check the total system for shipping damage and production faults	X	
RM(ACC)2. Battery voltage	To check the battery level	X	X
RM(ACC)3. Background count rate	To measure the count rate level in an ambient environment without nearby radioactivity		X
RM(ACC)4. Sensitivity	To measure the sensitivity to the radionuclides with which the instrument will be used	X	X
RM(ACC)5. Accuracy, precision and linearity of response	To measure the accuracy, precision and linearity of response at energies most commonly used; the radiation protection adviser should be consulted to ensure compliance with national legislation and guidance on radiation dose measuring instruments		X

Table 11 Acceptance testing for a preclinical PET. *Equipment type*: small-animal positron emission tomograph

Test	Purpose	Acceptance	Reference
PCP(ACC)1. Physical inspection	To check the total system for shipping damage (e.g. gantry, console, computer, display devices) and production faults	X	
PCP(ACC)2. Computer clock	To verify the correct time of day of the scanner data acquisition and processing computer		X
PCP(ACC)3. Background count rate	To detect excess electronic noise; it should be compatible with the expected random count rate in the absence of positron emitting sources. This value should be provided by the manufacturer	X	X
PCP(ACC)4. Detector check	To check that all detectors/blocks are working		X
PCP(ACC)5. Blank scan	To test and visualize proper functioning of detector modules; visual inspection of 2-D sinograms; to be performed with a rod source spanning the whole axial field of view		X
PCP(ACC)6. Energy calibration/energy resolution	To check that the photopeak in the spectra of each detector/block is correctly aligned with the expected 511 keV value (a further calibration could be required); check the energy resolution of the whole system by summing the energy spectra of each detector/block; compare it with the manufacturer's specification	X	X
PCP(ACC)7. Energy window setting	To check that the preset energy window meets the specification		X
PCP(ACC)8. Spatial resolution – quantitative (NEMA method)	To measure the intrinsic spatial resolution (full-width at half-maximum and full-width at tenth-maximum) and compare with the manufacturer's specification	X [37]	
PCP(ACC)9. Sensitivity – quantitative (NEMA method)	To measure the absolute sensitivity expressed as the fraction of positron annihilation events detected as true coincidence events and compare with the manufacturer's specification; this test should be performed in accordance with the standard method described in the NU 4-2008 document	X [37]	
PCP(ACC)10. Count rate performance	To measure count rate as a function of (decaying) activity over a wide range of activities; peak NEC value, and corresponding count rate, should be compared with the manufacturer's specification; true, random and scatter count rate and scatter fraction could be performed for future reference; this test could be performed in accordance with the standard method described in the NU 4-2008 document	X [37]	X
PCP(ACC)11. Image quality	To determine the hot and cold spot image quality of the standardized image quality phantom described in the NU 4-2008 document; this test is to measure recovery coefficients and the signal to noise ratio performance of the imaging system		X
PCP(ACC)12. Uniformity	To estimate axial uniformity across image planes by imaging a uniformly filled object and compare with the manufacturer's specification	X [37]	
PCP(ACC)13. Linearity check	To measure the response of the imaging system as a function of (decaying) activity over a wide range of activities; this test could be performed with a user phantom or with the image quality phantom described in the NU 4-2008 document		X
PCP(ACC)14. Attenuation and scatter correction (if applicable)	To measure the effectiveness of the attenuation and scatter correction, if these are implemented, and compare with the manufacturer's specification; this test could be performed with the standard method described in the NU 4-2008 document	X [37]	X

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