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Tarikh : 24 / 2 / 2017

Pengarah Hospital

Semua Pemegang Lesen (Pusat Perubatan Nuklear)
Di bawah Akta Perlesenan Tenaga Atom 1984 (Akta 304)
Bagi Maksud Perubatan

YBhg. Tan Sri/Datuk/Dato'/Datin/Tuan/Puan,

EDARAN DOKUMEN MANUAL UJIAN KAWALAN MUTU BAGI KEMUDAHAN PERKHIDMATAN PERUBATAN NUKLEAR: *TECHNICAL QUALITY CONTROL PROTOCOL HANDBOOK FOR*

(i) *SCINTILLATION CAMERA AND SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHY (SPECT) SYSTEMS*
(ii) *POSITRON EMISSION TOMOGRAPHY/COMPUTED TOMOGRAPHY (PET/CT) SYSTEMS*
(iii) *DOSE CALIBRATOR, GAMMA COUNTER / WELL COUNTER / THYROID UPTAKE SYSTEM AND GAMMA PROBE*

Adalah saya merujuk kepada perkara tersebut di atas.

2. Kementerian Kesihatan Malaysia (KKM) dari semasa ke semasa sentiasa berusaha untuk mempertingkatkan kualiti dalam perkhidmatan perubatan nuklear iaitu memastikan penghasilan maklumat klinikal yang diperlukan dengan penggunaan sinaran mengion yang optimum kepada pesakit. Penyediaan tiga dokumen ini bertujuan sebagai panduan kepada semua pusat perubatan nuklear kerajaan dan swasta dalam menjalankan ujian kawalan mutu ke atas radas pengimejan dan bukan pengimejan bagi memastikan pematuhan terhadap piawaian dan prestasi yang ditetapkan. Langkah ini secara langsung ini dapat mempertingkatkan kualiti perkhidmatan kepada pesakit dengan amalan budaya yang selamat dan optimum dalam penggunaan sinaran mengion.

3. Untuk makluman YBhg. Tan Sri/Datuk/Dato'/Datin/Tuan/Puan, kandungan penting dalam manual tersebut adalah seperti berikut:

(i) Prosedur pengujian kalawan mutu.
(ii) Parameter ujian bagi standard prestasi dan keselamatan sinaran.
(iii) Contoh format borang pengujian.

.../2

4. Sehubungan itu, bersama-sama ini dilampirkan tiga dokumen berkenaan untuk digunapakai kepada semua pusat perubatan nuklear kerajaan dan swasta terlibat ke arah keperluan perlindungan sinaran di bawah Akta 304. Sebarang pertanyaan lanjut berhubung perkara ini, bolehlah diajukan terus kepada Bahagian Kawalselia Radiasi Perubatan, KKM di talian 03-8892 4965/4678/4729.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Yang Ikhlas,

(DATUK DR. NOOR HISHAM BIN ABDULLAH)
Ketua Pengarah Kesihatan Malaysia

Technical Quality Control Protocol Handbook

Scintillation Camera and SPECT Systems

Medical Radiation Surveillance Division
MINISTRY OF HEALTH MALAYSIA

MINISTRY OF HEALTH
MALAYSIA

TECHNICAL QUALITY CONTROL PROTOCOL HANDBOOK

FOR

SCINTILLATION CAMERA AND SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHY (SPECT) SYSTEMS

PREPARED BY
MEDICAL RADIATION SURVEILLANCE DIVISION
AUGUST 2015

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A. Introduction

INTRODUCTION

The Ministry of Health (MOH) is continuously taking steps to improve the quality of nuclear medicine services. This is to ensure that necessary clinical information is obtained from the optimum use of ionizing radiation to the patients. Over the years, the MOH has taken both administrative and legislative measures to enforce the various requirements under the Atomic Energy Licensing Act 1984 (Act 304).

In order to further upgrade and enhance the quality, safety, and efficacy of nuclear medicine services, the MOH has formulated and initiated the implementation of Quality Assurance Programme (QAP) for both government and private nuclear medicine centres since 2013. The MOH is empowered under Section 17 of Act 304 to implement such programme. The specific requirement of the programme will be imposed under Regulation 53 of Basic Safety Radiation Protection Regulations (BSRP) 2010.

Quality Control (QC) is one of the elements of QAP that has to be carried out at interval period as specified by MOH. QC tests shall be performed at the time of the acceptance and commissioning of the nuclear medicine imaging and non-imaging equipments prior to the use; after replacement of major components that could cause a change in the performance of the machine including image quality and safety of patient; or as routine tests. The performance and safety standards of the nuclear medicine imaging and non-imaging equipments shall be in accordance with the regulatory requirements and relevant code of practice.

This Handbook is designed to be guidance to conduct QC checking on Scintillation Camera and SPECT systems in the aspect of performance and safety standard requirement in accordance with MOH. Wherever applicable, manufacturer's protocol can be followed to perform the test procedures. A complete annual QC report by an approved medical physicist or qualified expert shall be submitted to MOH annually.

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List of Test Parameter

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List of Test Tools

Test tools

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6.	Flood phantom
7.	Planar sensitivity phantom
8.	Movable stand with mounting for point source
9.	Measuring tape
10.	Quadrant bar or orthogonal hole test pattern (OHTP) phantom
11.	An accurate ruler
12.	Tomographic uniformity phantom
13.	COR / MHR / IRC source holder
14.	^{57}Co flood source

Others Tools

No.	Test Tools
1.	SMPTE Test Pattern Installed
2.	Printer To Print Images

D. Testing Procedures

TEST PARAMETER 1: PHYSICAL INSPECTION

Test Parameter **Physical Inspection**

Objective To inspect a scintillation camera, control console, computer, and data storage, display devices for shipping damage, production and design flaws.

Test Tool Not aqpplicable.

Test Procedure

1. Detector housing and support assembly
   Inspect the aluminium casing surrounding the NaI(Tl) crystal for signs of indentation or puncture and the gantry for loose parts or mechanical difficulties. Move the gantry, bed and detector head through all possible motions and to the fullest extent of travel, noting any grinding noises, loose parts, inability to move, or improperly functioning controls.

2. Control panels & Hand control
   Inspect the switches and other controls for loose or broken parts. Check for switches that do not throw securely. Check computer keyboards and accessories for proper operation. Inspect the hand control for proper mechanical operation and confirm that the cable has acceptable strain relief at maximum extension.

3. Image display devices
   Inspect the display screen for scratches, fingerprints, dust or other debris. Inspect the image monitors for any interference patterns, rolling, lines or other signs of improper operation or electrical interference.

4. Image recording devices/data storage
   Inspect the performance of the recording devices/data storage.

5. Emergency devices
   Test each emergency button to ensure that all gantry motion ceases when each button is activated.

6. Collimators
   Inspect the collimators for damage. Load each onto the camera head and ensure that the collimator mounting mechanism is aligned and is working properly. While mounted, activate each motion sensor device to ensure that all gantry motion ceases.

7. Electrical connections, fuses and cables
   Inspect for any loose or broken cable connectors and pinched or damaged cables. Locate all fuses and circuit breakers to enable prompt checking during equipment failure. Ensure that cables are housed, wherever possible, in conduits and are not loose on the floor. Also, ensure that they were placed to allow maximum patient access.

8. Operation and service manuals
   Check that all appropriate documentation (softcopy and hardcopy) is available, including performance specifications.

9. Room condition - Temperature & Humidity (daily)
   Make sure that the room temperature and humidity are according to manufacturer's specification.

Result

No.	Visual inspection of component	Pass/Fail	Comments
1.	Detector housing and support assembly		
2.	Control panels & Hand control		
3.	Image display devices		
4.	Image recording devices/data storage		
5.	Emergency devices		
6.	Collimators		
7.	Electrical connections, fuses and cables		
8.	Operation and service manuals		
9.	Room condition - Temperature & Humidity (daily)		

Tolerance Functional and according to manufacturer's specifications.

Test Frequency Acceptance
Daily (except for emergency button)
Annually

TEST PARAMETER 2: BACKGROUND COUNT RATE

Test Parameter	**Background Count Rate**
Objective	To check the background count rate of a scintillation camera under the conditions of routine clinical imaging with a particular radionuclide.
Test Tool	Not applicable.
Test Procedure	1. Mount the collimator to be used for daily examination (all collimators should be used for acceptance test) and turn the detector head to a scanning position downward. 2. Position the detector head over the center of the table bed. 3. Adjust all the routine settings on the gamma camera console, for a routine acquisition by the radionuclide concerned. 4. Perform a count measurement for a 100 sec recording time without any radiation source at the vicinity of the camera. 5. Record the counts and calculate the background count rate.
Result	Record the results.
Tolerance	≤ 20% of the reference value.
Test Frequency	Acceptance Daily

TEST PARAMETER 3: CENTRING PULSE HEIGHT ANALYSER (PHA) WINDOW SETTINGS

Test Parameter	**Centring Pulse Height Analyser (PHA) Window Settings**
Objective	To test that all preset PHA windows for clinical imaging are properly centred for every radionuclide to be used with the scintillation camera.
Test Tool	1. Point sources consisting of the radionuclides concerned, with source strength of about 10 MBq (250 µCi) or source strength specified by manufacturer, in suitable containers. 2. Source mounting for point source.
Test Procedure	1. Remove the collimator from the detector head (if applicable). Align the head and the source mounting. 2. Mount the source in the source mounting. 3. In the acquisition mode, select the default energy setting for the radionuclide concerned, which sets the energy and window width to be used for clinical imaging. 4. Observe the display to ensure that the respective photopeaks are centred in the window settings. If they are not centred, manually adjust (±5%) each photopeak so that it is centred. Record the peak value that properly centres the photopeak. 5. Remove the source. 6. Repeat steps (2) – (6) for other radionuclides in turn (during acceptance test only).Mount the collimator to be used for daily examination (all collimators should be used for acceptance test) and turn the detector head to a scanning position downward.
Result	Record the results.
Tolerance	Photopeaks must be properly centred.
Test Frequency	Acceptance Daily

TEST PARAMETER 4: ENERGY RESOLUTION

Test Parameter	**Energy Resolution**
Objective	To test the intrinsic response of a scintillation camera to a spatially uniform flux of incident photons over the field of view using a symmetric (centred) energy window over the photopeak.
Test Tool	1. Point source consisting of 10 – 20 MBq (0.3 – 0.5 mCi) of ^{99m}Tc and ^{57}Co disc (source strength specified by manufacturer) in a suitable container mounted in the source holder. 2. Source mounting for point source. 3. Lead mask.
Test Procedure	1. Remove the collimator. Align the head and the source mounting. 2. Place the lead mask to establish Useful Field of View (UFOV) and position the stationary support upon the camera. 3. Place the ^{99m}Tc point source on the support at a distance of 5 UFOV from the detector face. The source should be positioned to give the least possible scatter component. 4. A second radionuclide, ^{57}Co, shall be employed as a reference in order to determine the keV per channel calibration factor. 5. Remove the source, the stationary support and the lead mask.
Result	Record the results.
Tolerance	Manufacturer's specifications.
Test Frequency	Acceptance Under condition (1): Whenever detector system performance is suspected to have changed significantly.

TEST PARAMETER 5: INTRINSIC FLOOD FIELD UNIFORMITY FOR ^{99M}TC

Test Parameter — **Intrinsic Flood Field Uniformity For ^{99m}Tc**

Objective

To test the intrinsic response of a scintillation camera to a spatially uniform flux of incident photons over the field of view using a symmetric (centred) energy window over the photopeak.

Test Tool

1. Point source consisting of 10 – 20 MBq (0.3 – 0.5 mCi) or source strength specified by manufacturer of ^{99m}Tc in solution in a suitable container mounted in the source holder. The count rate should not be greater than 50 kcounts/s with the manufacturer's default PHA window.
2. Source mounting for point source.

Test Procedure

1. Remove the collimator from the detector head. Align the head and the source mounting.
2. Mount the source on the support.
3. Center a 15 – 20% energy window on the ^{99m}Tc photopeak.
4. Acquire an image of minimum 15 x 10^6 counts in selectable pixel matrix and record the time.
5. Remove the source and the support.

Result

Record the results.

a) Qualitative method (comparable with reference image)

Inspect the image for any brightness variations caused by lack of uniformity. For proper examination the contrast must be more than 10%. Variations smaller than 5% can be detected.

b) Quantitative method for UFOV and CFOV (Each Comprises Of Integral Uniformity and Differential Uniformity)

Calculate the integral and differential uniformity for the UFOV and the CFOV, using the available software or if this is not the case, the following method can be used, in order to calculate uniformity:

1) Normalize the image with a nine-point filter.
2) Determine the minimum (min) and the maximum (max) count rate in the pixels within the UFOV and the CFOV.
3) The integral uniformity (IU), can be calculated using the equation:

$$IU = \left(\frac{\max - \min}{\max + \min} \right) x100\%$$

4) Determine the maximum count difference in any 5 contiguous pixels for each row or column of pixels within the UFOV and the CFOV. Find the highest (high) and lowest (low) value of these differences.

5) The differential uniformity (DU), is given by:

$$DU = \left(\frac{high - low}{high + low} \right) x100\%$$

Tolerance

a) Qualitative method : No cold or hot spot.
b) Quantitative method : Manufacturer's specifications.

Test Frequency

Acceptance
Weekly

Note: This test should be done daily if Test Parameter 7 is done weekly.

TEST PARAMETER 6: INTRINSIC SPATIAL RESOLUTION

Test Parameter **Intrinsic Spatial Resolution**

Objective To test the intrinsic spatial resolution of scintillation camera in terms of the FWHM of its line spread function.

Test Tool

1. Point source consisting of 20 – 40 MBq (0.5 – 1 mCi) or source strength specified by manufacturer of ^{99m}Tc in solution in a suitable container.
2. Quadrant bar phantom with bar widths of approximately 2, 3, 3.5 and 4 mm or slit mask for X-axis and Y-axis.

Test Procedure

a) Qualitative (Visual Image) method using quadrant bar phantom

1. Remove the collimator. Align the head and the source mounting.
2. Place the point source on the support.
3. Center a 15 – 20% energy window on the ^{99m}Tc photopeak.
4. Position the quadrant bar phantom upon the camera with the lead bars aligned with the X and Y-axis.
5. Acquire an image of 6 x 10^6 counts depending on the size of the FOV. The matrix size of the image should be 512 x 512 (pixels).
6. Rotate the quadrant bar phantom at 90^o, 180^o, 270^o and 360^o and repeat acquiring.
7. Remove the source, the stationary support, the quadrant bar phantom. Replace the collimator.

b) Quantitative method using slit mask

1. Remove the collimator. Align the head and the source mounting.
2. Cover the detector with the slit mask and center its central slit on the detector, perpendicular to the axis of measurement.
3. Careful alignment is necessary. Place the stationary support upon the camera.
4. Place the point source on the support.
5. Center the 20% energy window on the ^{99m}Tc photopeak.
6. Acquire an image by a count rate not greater than 10000 counts/secs.
7. Acquisition should be performed in X as well as Y-axis.

8. Remove the source, the support and the slit phantom. Replace the collimator.

Result Record the results.

Tolerance

a) Qualitative method : ≤ 20% of manufacturer's specifications.
b) Quantitative method : ≤ 10% of reference value.

Test Frequency Acceptance (Qualitative and Quantitative methods)
Semi-annually (Qualitative method)

TEST PARAMETER 7: SYSTEM FLOOD FIELD UNIFORMITY (ON COMMON CLINICALLY USED COLLIMATOR)

Test Parameter

System Flood Field Uniformity (On Common Clinically Used Collimator)

Objective

To test the system flood field response of a scintillation camera for all general purpose collimators used.

Test Tool

Flood phantom containing 200 – 400 MBq (5 – 10 mCi) of ^{99m}Tc in solution or ^{57}Co flood source of similar activity.

Test Procedure

1. Mount the collimator on the detector head for daily examination (all collimators should be used for acceptance test except pinhole collimator).
2. Place the ^{57}Co or the ^{99m}Tc flood source upon the collimator.
3. Center a 20% window on the radionuclide photopeak.
4. Acquire an image at preset 2 x 10^6 counts. If uniformity correction circuit is fitted at the system, it must be enabled.
5. Remove the flood source.
6. Repeat the above steps for all common clinically used collimators.

Result

Record the results.

Tolerance

a) Qualitative method : No cold or hot spot.
b) Quantitative method : Manufacturer's specifications.

Test Frequency

Acceptance
Daily

Note: This test should be done weekly if Test Parameter 5 is done daily.

TEST PARAMETER 8: SYSTEM SPATIAL RESOLUTION

Test Parameter **System Spatial Resolution**

Objective To test the system spatial resolution of a scintillation camera in terms of the FWHM of its line spread function. This test should be performed for each parallel hole, low energy collimator.

Test Tool

1. Flood phantom containing about 400 - 800 MBq (10 - 20 mCi) of ^{99m}Tc or ^{57}Co flood source of similar source strength.
2. Quadrant bar phantom with bar widths and bar spacings of approximately 2, 3, 3.5 and 4 mm.

Test Procedure

a) Qualitative (Visual Image) method

1. Mount the collimator to be tested on the camera.
2. Place the ^{57}Co or ^{99m}Tc flood source upon the quadrant bar phantom.
3. Center a 15 – 20% energy window on the ^{99m}Tc photopeak.
4. Position the quadrant bar phantom upon the camera with the lead bars aligned with the X and Y-axis.
5. Acquire an image of minimum 6 x 10^6 counts depending on the size of the FOV. The matrix size of the image should be 512 x 512 (pixels).
6. Rotate the quadrant bar phantom at 90^o, 180^o, 270^o and 360^o and repeat acquiring.
7. Remove the source, the stationary support and the quadrant bar phantom.
8. Repeat this procedure for all low energy collimators except the pinhole one.
9. Remove the source and the quadrant bar phantom.

b) Quantitative method

1. Mount the collimator to be tested on the camera and turn to face vertically upward.
2. Position the line source phantom on the face of the collimator and align it with the X-axis and then with the Y-axis of the camera.
3. Center the 20% energy window on the selected isotope photopeak.

4. Acquire an image in a count rate less than 10000 counts/seconds.

5. Repeat this procedure for all low energy collimators except the pinhole.

6. Remove the line source phantom.

Result Record the results.

Tolerance

a) Qualitative method : ≤ 20% of manufacturer's specifications.
b) Quantitative method : ≤ 10% of reference value.

Test Frequency Acceptance
Semi-annually

TEST PARAMETER 9: SYSTEM PLANAR SENSITIVITY

Test Parameter	**System Planar Sensitivity**
Objective	To test the count rate response of a scintillation camera to a radionuclide source of known radioactivity.
Test Tool	Planar sensitivity phantom containing an accurately known amount of radioactivity, about 40 – 160 MBq (1 – 4 mCi) of ^{99m}Tc or other radionuclide such as ^{131}I, in solution.
Test Procedure	1. Mount a low energy, parallel hole collimator on the detector head. Turn the head to face vertically upward. 2. Cover the face of the collimator with a plastic sheet. Place the phantom containing the ^{99m}Tc 10 cm from the surface of the covered collimator face. 3. Center the manufacturer's default PHA window on the photopeak, or the window width used by the manufacturer in determining the specified performance values. 4. Collect an image over a total time of 100 s. Record the total counts in the image frame and the exact time of day. 5. Remove the phantom and count the background for the same time period. Record the total counts in the image frame. 6. Repeat steps (1) – (5) for all other low energy multihole collimators. 7. Repeat steps (1) – (5) with the phantom containing ^{67}Ga or ^{111}In for medium energy multihole collimators (if applicable) and ^{131}I for high energy multihole collimators (if applicable).
Result	Record the results.
Tolerance	Manufacturer's specifications (Acceptance). ≤ 10% of acceptance value (Semi-annually).
Test Frequency	Acceptance Semi-annually

TEST PARAMETER 10: COUNT RATE PERFORMANCE

Test Parameter **10.1 Intrinsic Count Rate Performance**

Objective

To test the intrinsic count rate performance of a scintillation camera in terms of the count rate corresponding to a 20% count loss (two source method).

Test Tool

Two point sources each consisting of about 2 MBq (50 μCi) of ^{99m}Tc in solution in suitable containers.

Test Procedure

1. Remove the collimator. Align the head and the source mounting.
2. Place the stationary support upon the gamma camera.
3. Center the 20% energy window on the ^{99m}Tc photopeak.
4. Place the first source at more than 1m from the surface of the crystal and near its center axis, away of objects to minimize scatter radiation.
5. Record the counts for 100 seconds - sufficient time to accumulate 10^6 counts. Register the count rate R_1.
6. Place the second source beside the first and record the R_{12} count rate.
7. Remove the first source and register the second source count rate, R_2.
8. Remove the second source and record the background count rate.
9. Repeat the count rate measurements, R_2, R_{12}, R_1 placing the sources in reverse order.
10. Remove the last source and the lead mask. Replace the collimator.

Result

Record the results.

Express all data as net count rates (counts/s) corrected for background.

Calculate for each set of data the pulse pair resolving time, in seconds from:

$$\tau = \frac{2R_{12}}{(R_1 + R_2)^2} x \ln\left[\frac{(R_1 + R_2)}{R_{12}}\right]$$

Where R_1 and R_2 are the net count rates of the first and second sources and R_{12} is the net count rate of the two sources together, all in counts per second. Average the two values to obtain τ.

Calculate the Input Count Rate (ICR) for a 20% loss, $R_{-20\%}$, from:

$$R_{-20\%} = \frac{1}{\tau} x \ln\left(\frac{10}{8}\right) = \frac{0.2231}{\tau}$$

Calculate the Observed Count Rate (OCR) for a 20% count loss, $C_{-20\%}$, from:

$$C_{-20\%} = 0.8xR_{-20\%}$$

Tolerance

The $R_{-20\%}$ is within ± 10% of the manufacturer's specifications.

Test Frequency

Acceptance
Semi-annually

Test Parameter **10.2 Maximum Count Rate**

Objective

To test the maximum count rate of s scintillation camera.

Test Tool

1. Point source consisting of about 4 MBq (100 – 500 µCi) of ^{99m}Tc in solution in a suitable container.
2. Movable stand with mounting for point source.
3. Measuring tape.

Test Procedure

1. Remove the collimator from the detector head. Turn the head to face horizontally.
2. Centre the manufacturer's default PHA window on the photopeak.
3. Mount the source on the movable stand. Position the latter so that the source is on the central axis of the detector. To minimize radiation scatter, the source should not be close to other objects. Remove the collimator. Align the head and the source mounting.

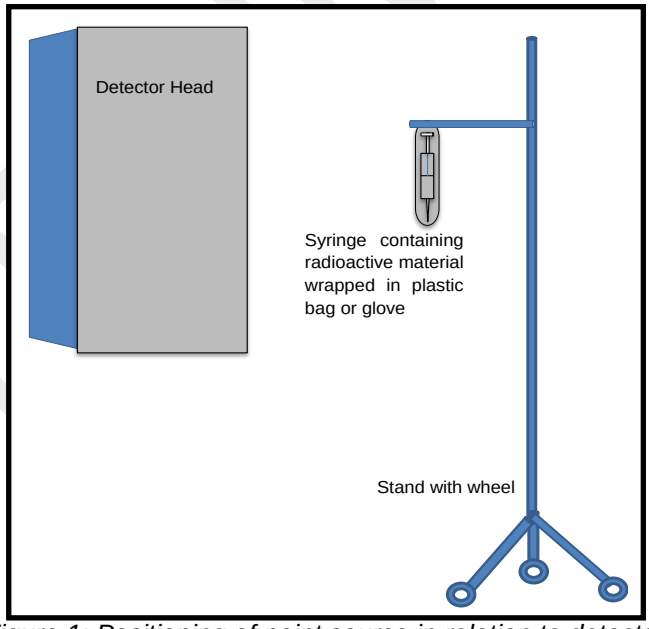

Figure 1: Positioning of point source in relation to detector.

4. Register the count rate as the source is moved progressively closer to the detector face. The count rate will increase to a maximum and then decrease. Record the maximum count rate.
5. Remove the source and stand. Replace the collimator.

Result

Record the results.

Tolerance

The maximum count rate is within ± 10% of the manufacturer's specifications.

Test Frequency

Acceptance
Semi-annually

TEST PARAMETER 11: MULTIPLE WINDOW SPATIAL REGISTRATION (WITH GALLIUM 67 APPLICATION)

Test Parameter

Multiple Window Spatial Registration (With Gallium 67 Application)

Objective

To test that the images acquired at different photon energies superimpose when more than one PHA is used simultaneously in an additive or subtractive mode.

Test Tool

1. Point source consisting of about 40 MBq (1 mCi) of ^{67}Ga in solution in a small vial, in a lead shield 6 mm thick and having a circular aperture 3 mm in diameter.
2. Quadrant bar or orthogonal hole test pattern (OHTP) phantom.

Test Procedure

1. Turn the head to face vertically upward.
2. The activity of the source must ensure a count rate lower than 10,000 c/s through each symmetric 20% photopeak energy window.
3. Images, with 20,000 counts each, shall be acquired with the ^{67}Ga source located at 5 specific points:
    - One point at the center of UFOV.
    - Four off-central points, at a distance from the center equal to 0.75 of the UFOV radius and on X+, X-, Y+, Y- axis respectively.
4. Acquire images in 256 x 256 matrix size so that pixel size is below 2 mm.
5. Separate images should be acquired through separate energy windows of the ^{67}Ga energies and at each location of the source.

Result

Record the results.

Tolerance

≤ 10% of displacement.

Test Frequency

Acceptance
Annually (Applicable only to the system using radionuclide ^{67}Ga for imaging purposes)

TEST PARAMETER 12: DETECTOR HEAD SHIELDING LEAKAGE

Test Parameter **Detector Head Shielding Leakage**

Objective To test that the detector head of scintillation camera responds only to radiation incident upon the crystal after transmission through the collimator.

Test Tool Point sources consisting of about 4 MBq (100 µCi) of ^{99m}Tc and a radionuclide with a photon energy corresponding to the specified design energy of the camera in a suitable container.

Test Procedure

1. Mount a collimator appropriate to the gamma radiation energy of the source on the detector head.
2. Centre the manufacturer's default PHA window for the radionuclide concerned on the photopeak.
3. Position the source consecutively at thirteen sites around the detector head shielding and record the number of counts at each site for a preset time of 100 s. In addition, investigate sites of joints in the shielding, exit points of cables and other reduced shielding areas.
4. Position the source in the centre of the field of view at a distance of 10 cm from the face of the collimator. Record the number of counts for a preset time of 100 s.
5. Remove the source and measure the background count, B, for the same time period.

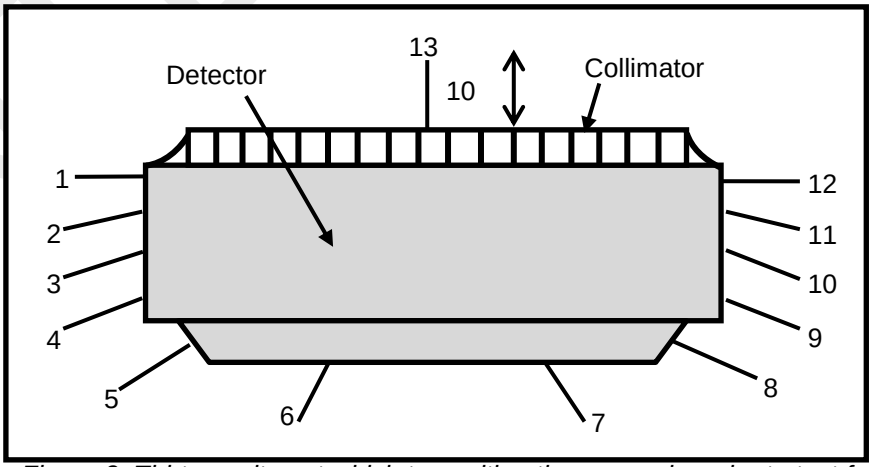

Figure 2: Thirteen sites at which to position the source in order to test for shielding leakage.

Result Record the results.

Tolerance Negligible (No leakage).

Test Frequency Acceptance

TEST PARAMETER 13: IMAGE DISPLAY

Test Parameter **13.1 Visual Display**

Objective

To determine that all of the information in the video signal is displayed on the video display.

Test Tool

1. The Society of Motion Pictures and Television Engineers (SMPTE) test pattern installed in the CT scanner.
2. Display Monitor (CRT or LCD).

Test Procedure

1. Display the SMPTE test pattern on the (CRT or LCD).

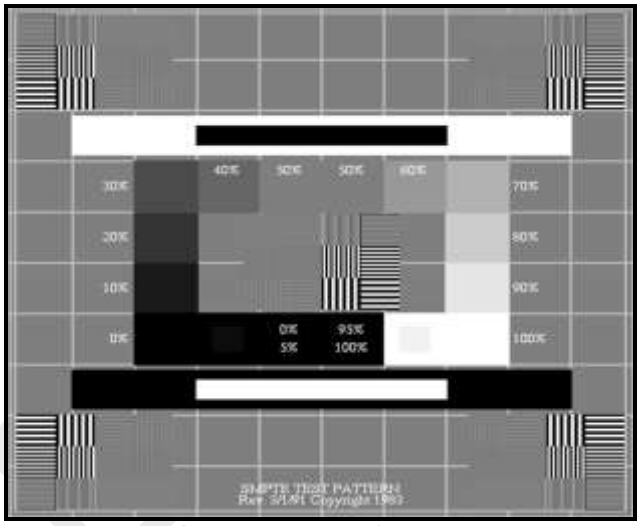

Figure 3: Image of SMPTE

2. Adjust the window width to just encompass the range of numbers comprising the SMPTE test pattern.
3. Adjust the window level to either the lower or middle value of the window so that the entire test pattern is visible.
4. If required, clean the front surface of the monitor and reduce room illumination to the normal viewing level for better evaluation condition.

Result

1. The 5% patch should just be visible inside of the 0% patch.
2. The line pair pattern at the center and all four sides of the image should be clearly resolvable.
3. The 95% patch should be visible inside the 100% patch.
4. The alphanumeric should be sharp and clear.

Tolerance

Manufacturer's specifications.

Test Frequency

Acceptance
Weekly

Test Parameter **13.2 Hardcopy Display**

Objective

To ensure that optimal image quality is reproduced on the hard copy image and that the long term reproducibility of the hard copy image quality.

Test Tool

1. SMPTE test pattern installed in the CT scanner.
2. Film printer to print SMPTE Test pattern.

Test Procedure

1. Ensure that the hardcopy printer is in working order and warmed up.
2. Continue from the test above, display the SMPTE test pattern at the window and level as described in the visual display set-up procedure.
3. If required, adjust the hard-copy camera control so that film densities correspond to the manufacturer's specification.

Result

1. Same as the above test, the 5% patch should just be visible inside of the 0% patch.
2. The line pair pattern at the center and all four sides of the image should be clearly resolvable.
3. The 95% patch should be visible inside the 100% patch.
4. The alphanumeric should be sharp and clear.

Tolerance

Manufacturer's specifications.

Test Frequency

Acceptance
Annually

ADDITIONAL TEST PARAMETER FOR SPECT

TEST PARAMETER 14: ABSOLUTE PIXEL SIZE

Test Parameter **Absolute Pixel Size**

Objective To determine the absolute pixel size in the matrix used for tomographic reconstruction. This test should be performed for all the matrix sizes and tomographic zoom conditions used in clinical practice.

Test Tool One or two point sources and an accurate ruler.

Test Procedure

1. Place the point source on the camera face along the X-axis, about 5 cm from the edge of the field of view.
2. Set up the system to perform a conventional static acquisition of about 50,000 counts using the finest possible matrix size, for example, 256 x 256 or 512 x 512. Ensure that no zoom is used.
3. Acquire one planar image.
4. Now move the point source horizontally to a position about 5 cm away from the other edge of the field of view, by a distance known to within 1 mm.
5. Repeat the acquisition.
6. Repeat the whole procedure by placing the point sources along the Y-axis.
7. Repeat for all tomographic zoom conditions used in clinical practice.

Result Record the results.

Tolerance Difference between the values in X and Y should be less than 5% manufacturer specification.

Test Frequency Acceptance
Semi-annually

Note: For certain system, this test may not be carried out if the result of absolute pixel size can be obtained from other tests such as Test Parameter 6 and 8 (Quality Control Tests For Scintillation Camera).

TEST PARAMETER 15: TOMOGRAPHIC UNIFORMITY (IF APPLICABLE)

Test Parameter — **Tomographic Uniformity (if applicable)**

Objective

To test the tomographic uniformity of a rotating scintillation camera SPECT system.

Test Tool

The tomographic uniformity phantom should be filled with about 200 – 400 MBq (10 – 25 mCi) of ^{99m}Tc, making sure that the activity is well mixed.

Test Procedure

This test should be performed after the test for planar uniformity has been performed.

1. Ensure that all the camera uniformity correction calibration procedures have been correctly performed.
2. Place the phantom with its centre at least within 2 cm of the axis of rotation, as close as possible to the centre of rotation.
3. Ensure that the central axis of the phantom is parallel to the axis of rotation.
4. Set up a tomographic acquisition using a normal matrix size (e.g. 64 x 64 or 128 x 128) and the number of angles used clinically, using a circular orbit.
5. Perform a standard tomographic acquisition, collecting a total of about 106 counts per projection. This typically corresponds to 15 x 10^6 total counts for a phantom 10 cm in length, or about 240 kcounts per angular position for 64 or 128 angle acquisitions.
6. Perform uniformity correction as recommended by the manufacturer.
7. Reconstruct the data with a ramp (or sharp) filter.
8. Where possible, perform attenuation and scatter correction using the method prescribed by the manufacturer. The attenuation correction is essential unless special purpose software is used.

Result

Record the results.

Identify the minimum or maximum value corresponding to the location of a ring artefact as seen in the reconstructed image. Record this value, terming it $C_{min/max}$.

Record the two values along the profile of the uniform source just beyond the edges of the artefact identified, terming them *C1* and *C2*.

Calculate $C_{ave} = (C1 + C2)/2$.

Estimate the contrast as $(C_{min/max} - C_{ave})/(C_{min/max} + C_{ave})$.

	Repeat for all the other transaxial sections within the phantom and determine the maximum absolute value of contrast.
Tolerance	< 10% of difference between maximum and minimum counts/pixel.
Test Frequency	Acceptance Semi-annually

TEST PARAMETER 16: TOMOGRAPHIC RESOLUTION (TR) IN AIR (SPECT RECONSTRUCTED SPATIAL RESOLUTION WITHOUT SCATTER)

Test Parameter

Tomographic Resolution (TR) in Air (SPECT Reconstructed Spatial Resolution Without Scatter)

Objective

To measure the tomographic resolution of the system in air and to ensure that the reconstruction process is not degraded by either the tomographic acquisition or the reconstruction. Note that this is now considered to be the best test of centre of rotation accuracy.

Test Tool

Three small point source of ^{99m}Tc, as used in the test for centre of rotation and alignment.

Test Procedure

1. Place the point source in air as below:
   - within 1 cm of the centre of rotation, near the centre of the field of view.
   - on the axis of rotation, but close to the edge of the field of view (close to $+Y_{MAX}$, ≥ +5 cm X-axis and $-Y_{MAX}$, ≤ -5 cm X-axis), as indicated for the centre of rotation test.
2. Set the radius of rotation to be approximately 15 cm, or if this cannot be achieved, to be as small as possible. Use a circular orbit of rotation.
3. Perform a tomographic acquisition using the matrix size and number of angles used clinically, collecting about 10 000 counts per view.
4. Reconstruct the data with filtered back projection, using either a ramp filter or the sharpest filter that the system will permit.
5. Perform a normal planar (static) acquisition at the home position, using the same acquisition matrix size, etc., as for the tomographic acquisition.

Result

Record the results.

Tolerance

Manufacturer's specification or difference between planar and tomographic resolution should not be more than 2 mm or 10% of the planar resolution.

Test Frequency

Acceptance
Semi-annually

TEST PARAMETER 17: CENTER OF ROTATION (COR) / MULTI HEAD REGISTRATION (MHR) TEST / IMAGE REGISTRATION CORRECTION (IRC) ANALYSIS

Test Parameter

Center Of Rotation (COR) / Multi Head Registration (MHR) Test / Image Registration Correction (IRC) Analysis

Objective

To test the centre of rotation offset, alignment of the camera Y-axis and head tilt with respect to the axis of rotation. This is considered a test to be performed if an error is observed with the test for resolution in air. This is an extended version of a test that should be described in the manufacturer's SPECT system manual.

Test Tool

1. ^{99m}Tc point source, 37 MBq (1 mCi).

   Note: A small ^{99m}Tc point source is used, together with some method of suspending it in air within the field of view, for example, by attaching the source to a long ruler, or a purpose-made supporting device.

2. COR / MHR / IRC source holder.

Test Procedure

1. Using a spirit level, ensure that the camera is accurately aligned so that the head is parallel with the axis of rotation, i.e. that the head is not tilted (but see observations below).

2. Suspend the point source in air within about 2 cm of the axis of rotation and within about 2 cm of the centre of the field of view.

3. Perform a normal tomographic acquisition using COR / MHR / IRC protocol.

Result

Record the results.

Tolerance

2 mm
or
Manufacturer's specifications.

Test Frequency

Acceptance
Weekly (for dedicated cardiac system only)
Monthly

E. Performance and Safety Standards

PERFORMANCE AND SAFETY STANDARDS FOR SCINTILLATION CAMERA AND SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHY (SPECT)

No	Procedure	Tolerance	Frequency
1.	Physical Inspection	Functional and according to manufacturer's specifications	Acceptance Daily (except for emergency button) Annually
2.	Background Count Rate	≤ 20% of the reference value	Acceptance Daily
3.	Centring Pulse Height Analyser (PHA) Window Settings	Photopeaks must be properly centered	Acceptance Daily
4.	Energy Resolution	Manufacturer's specifications	Acceptance Under condition (1)
5.	Intrinsic Flood Field Uniformity For ^{99m}Tc a) Qualitative Method (Comparable With Reference Image) **or** b) Quantitative Method For CFOV And UFOV (Each Comprises Of Integral Uniformity & Differential Uniformity)	 No cold/ hot spot Manufacturer's specifications	Acceptance Weekly **Note**: This test should be done daily if QC Test 7 is done weekly.
6.	Intrinsic Spatial Resolution a) Qualitative (Visual Image) Method b) Quantitative Method	 ≤ 20% of manufacturer's specifications ≤ 10% of reference value	 Acceptance Semi-annually Acceptance
7.	System Flood Field Uniformity (On Common Clinically Used Collimator) a) Qualitative Method b) Quantitative Method	 No cold/ hot spot Manufacturer's specifications	Acceptance Daily **Note**: This test should be done weekly if QC Test 5 is done daily.
8.	System Spatial Resolution a) Qualitative (Visual Image) Method **or** b) Quantitative Method	 ≤ 20% of manufacturer's specifications ≤10% of reference value	Acceptance Semi-annually

No	Procedure	Tolerance	Frequency
9.	System Planar Sensitivity	Manufacturer's specifications (Acceptance) ≤ 10% of acceptance value (Semi-annually)	Acceptance Semi-annually
10.	Count Rate Performance 10.1 Intrinsic Count-Rate Performance 10.2 Maximum Count Rate	 The $R_{-20\%}$ is within ± 10 % of the manufacturer's specifications The maximum count rate is within ± 10 % of the manufacturer's specifications	 Acceptance Semi-annually Acceptance Semi-annually
11.	Multiple-Window Spatial Registration (With Gallium 67 Application)	≤ 10% of displacement	Acceptance Annually (Applicable only to the system using radionuclide Gallium 67 for imaging purposes)
12.	Detector Head Shielding Leakage	Negligible (No leakage)	Acceptance
13.	Image Display 13.1 Visual Display 13.2 Hardcopy Display	 Manufacturer's specifications Manufacturer's specifications	 Acceptance Weekly Acceptance Annually

Note:

(1) Whenever detector system performance is suspected to have changed significantly.

All above tests shall be carried out during commissioning and after replacement of major components.

No	Procedure	Tolerance	Frequency
Additional Test Parameter for SPECT			
14.	Absolute Pixel Size	Difference between the values in X and Y ≤ 5% manufacturer specification	Acceptance Semi-annually
15.	Tomographic Uniformity (If Applicable)	≤ 10% of difference between maximum and minimum counts/pixel	Acceptance Semi-annually
16.	Tomographic Resolution (TR) In Air (SPECT Reconstructed Spatial Resolution Without Scatter)	Manufacturer's specifications or difference between planar and tomographic resolution should not be more than 2 mm or 10% of the planar resolution	Acceptance Semi-annually
17.	Center Of Rotation (COR) / Multi Head Registration (MHR) Test / Image Registration Correction (IRC) Analysis	2 mm or Manufacturer's specifications	Acceptance Weekly (for dedicated cardiac system only) Monthly

Note:

All above tests shall be carried out during commissioning and after replacement of major components.

F. References

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2. International Atomic Energy Agency, Quality Control of Nuclear Medicine Instruments, IAEA-TECDOC-602, IAEA, Vienna (1991).

3. National Electrical Manufacturers Association, NEMA Standards Publication NU1-1994: Performance Measurements of Scintillation Cameras, NEMA, Rosslyn, VA (1994).

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5. Institute Of Physics And Engineering In Medicine, Quality Assurance in Gamma Camera Systems, Rep. 86, IPEM, York (2003).

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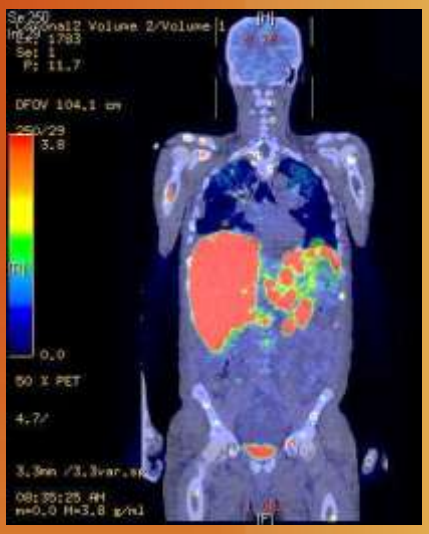


Technical Quality Control Protocol Handbook

Positron Emission Tomography/ Computed Tomography (PET/CT) Systems

Medical Radiation Surveillance Division
MINISTRY OF HEALTH MALAYSIA

MINISTRY OF HEALTH
MALAYSIA

TECHNICAL QUALITY CONTROL PROTOCOL HANDBOOK

FOR

POSITRON EMISSION TOMOGRAPHY/COMPUTED TOMOGRAPHY (PET/CT) SYSTEMS

PREPARED BY
MEDICAL RADIATION SURVEILLANCE DIVISION
AUGUST 2015

CONTENTS

A. Introduction

INTRODUCTION

The Ministry of Health (MOH) is continuously taking steps to improve the quality of nuclear medicine services. This is to ensure that necessary clinical information is obtained from the optimum use of ionizing radiation to the patients. Over the years, the MOH has taken both administrative and legislative measures to enforce the various requirements under the Atomic Energy Licensing Act 1984 (Act 304).

In order to further upgrade and enhance the quality, safety, and efficacy of nuclear medicine services, the MOH has formulated and initiated the implementation of Quality Assurance Programme (QAP) for both government and private nuclear medicine centres since 2013. The MOH is empowered under Section 17 of Act 304 to implement such programme. The specific requirement of the programme will be imposed under Regulation 53 of Basic Safety Radiation Protection Regulations (BSRP) 2010.

Quality Control (QC) is one of the elements of QAP that has to be carried out at interval period as specified by MOH. QC tests shall be performed at the time of the acceptance and commissioning of the nuclear medicine imaging and non-imaging equipments prior to the use; after replacement of major components that could cause a change in the performance of the machine including image quality and safety of patient; or as routine tests. The performance and safety standards of the nuclear medicine imaging and non-imaging equipments shall be in accordance with the regulatory requirements and relevant code of practice.

This Handbook is designed to be guidance to conduct QC checking on PET/CT systems in the aspect of performance and safety standard requirement in accordance with MOH. Wherever applicable, manufacturer's protocol can be followed to perform the test procedures. A complete annual QC report by an approved medical physicist or qualified expert shall be submitted to MOH annually.

B. List of Test Parameter

List of Test Parameter

No.	Parameter
1.	Physical And Mechanical Inspection
2.	PET Normalization
3.	Spatial Resolution
4.	Scatter Fraction, Count Losses And Randoms Measurement
5.	Sensitivity
6.	Energy Resolution
7.	Image Quality & Accuracy Of Attenuation And Scatter Correction
8.	Daily PET QC Procedures
9.	Well Counter Correction
10.	2D Or 3D Activity Concentration Calibration
11.	Test Of PET/CT In Clinical Mode
12.	PET/CT Offset Calibration
13.	PET/CT Image Registration Accuracy
14.	Image Display
14.1	Visual Display
14.2	Hardcopy Display
15.	Computed Tomography Number Calibration

C. List of Test Tools

List of Test Tools

Test tools

No.	Test Tools
1.	^{68}Ge line source / uniform cylindrical ^{68}Ge phantom / uniform cylindrical ^{18}F phantom
2.	Source holder
3.	Point sources
4.	Capillary tubes
5.	70 cm plastic cylinder with off-center line source
6.	Phantom holder
7.	70 cm line source
8.	5-sleeve aluminium phantom
9.	IEC61675-1 / equivalent phantom ^{18}F
10.	Lead bricks or other heavy material (total weight of about 100 kg)
11.	Ruler
12.	70 cm plastic cylinder with off-center line source (scatter phantom) ^{18}F
13.	Fillable cylindrical ^{18}F phantom / NEMA NU2-1994 phantom
14.	VQC phantom / 2 ^{68}Ge rod source / multiple source phantom

Others Tools

No.	Test Tools
1.	SMPTE Test Pattern Installed
2.	Printer To Print Images

D. Testing Procedures

TEST PARAMETER 1: PHYSICAL AND MECHANICAL INSPECTION

Test Parameter **Physical And Mechanical inspection**

Objective To ensure the electromechanical parts of the system are properly installed and functioned.

Test Tool Not applicable.

Test Procedure Carry out visual check on the components of the system.

Data Analysis Electromechanical tests are then typically carried out before other types of test.

Result

No.	Visual inspection of component	Pass/Fail	Comments
1.	Gantry (both PET and CT components)		
2.	Couch		
3.	Emergency button / Sensor / CT Laser		
4.	External Laser (if applicable)		

Tolerance No component of the system is malfunction or not proper installed.

Test Frequency Acceptance
Daily (except for emergency button)
Semi-annually

TEST PARAMETER 2: PET NORMALIZATION

Test Parameter	**PET Normalization**
Objective	To acquire crystal efficiency data for use in correcting acquired sinograms for detector non-uniformities. The use of incorrect normalization data will compromise image quality.
Test Tool	Rotating ^{68}Ge line source or uniform cylindrical ^{68}Ge phantom or uniform cylindrical ^{18}F phantom.
Test Procedure	1. Before starting the acquisition, a backup copy of the previous normalization file should be made. 2. Normalization data should be acquired following the instructions of the manufacturer.
Data Analysis	1. Perform a visual inspection of the normalization sinograms. 2. If no major problems are observed, store the new normalization data in a file, according to the flow chart established by the manufacturer.
Result	

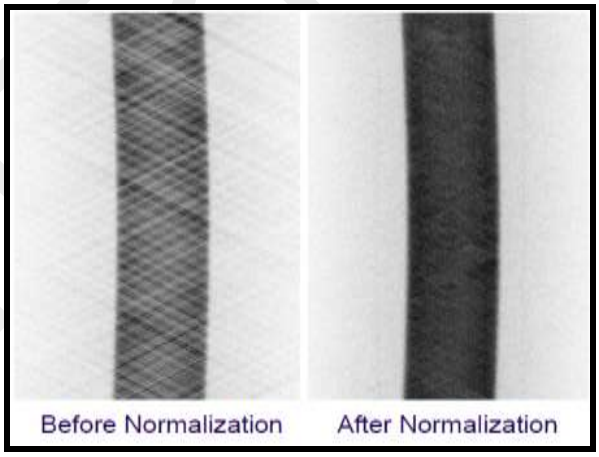


Figure 1: Sinograms with and without normalization.

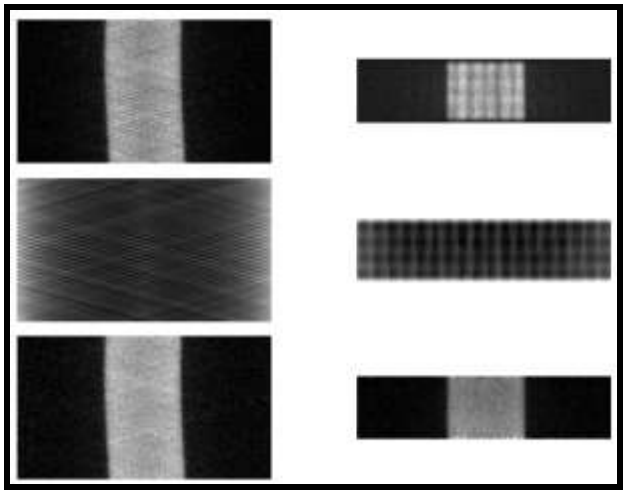


Figure 2: Sinograms.

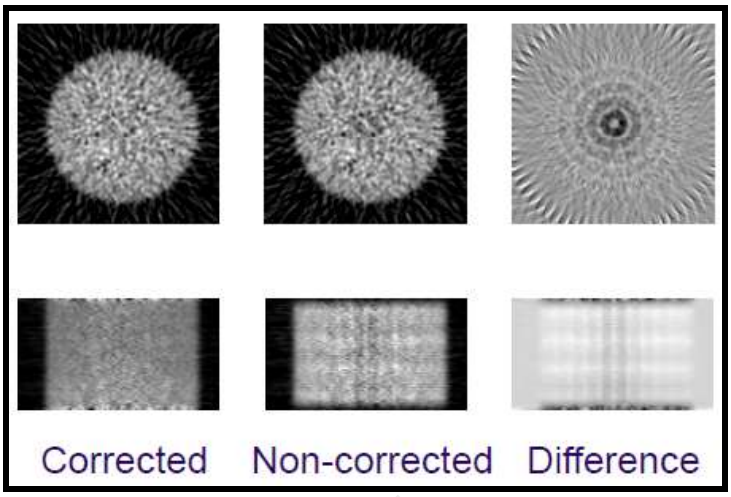


Figure 3: Images with and without correction.

Inspection	Pass/Fail	Comments
Sinogram		

Tolerance

A visual inspection should be acceptable.

Test Frequency

Acceptance

Semi-annually

Under condition:

(1) Whenever detector system performance is suspected to have changed significantly.

(2) This test should be performed whenever servicing is suspected to have affected the test results.

TEST PARAMETER 3: SPATIAL RESOLUTION

Test Parameter **Spatial Resolution**

Objective To measure the tomographic spatial resolution of the system in air and to ensure that spatial resolution is not degraded by either the tomographic acquisition or the reconstruction process.

Test Tool

1. Source holder.
2. 3 point sources of ^{18}F (Typically this can be obtained with a radioactivity of the order of 1 MBq (0.027 mCi). The radioactivity concentration of the starting radioactive solution should thus be about 1000 MBq/mL (or 27 mCi/mL) or less) each.
3. Capillary tubes.

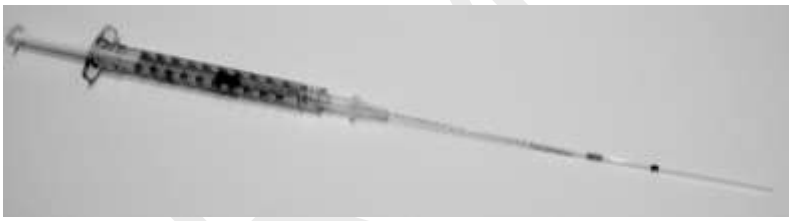


Figure 4: A syringe of the type with a fine needle to put a small amount of ^{18}F solution inside a capillary tube (on right) for the measurement of spatial resolution

Test Procedure

1. In the transverse plane, the sources should be placed in three positions (Figure 5):
   - 1 cm vertically from the center of rotation.
   - at x = 0 cm and y = 10 cm.
   - at x =10 cm and y = 0 cm.

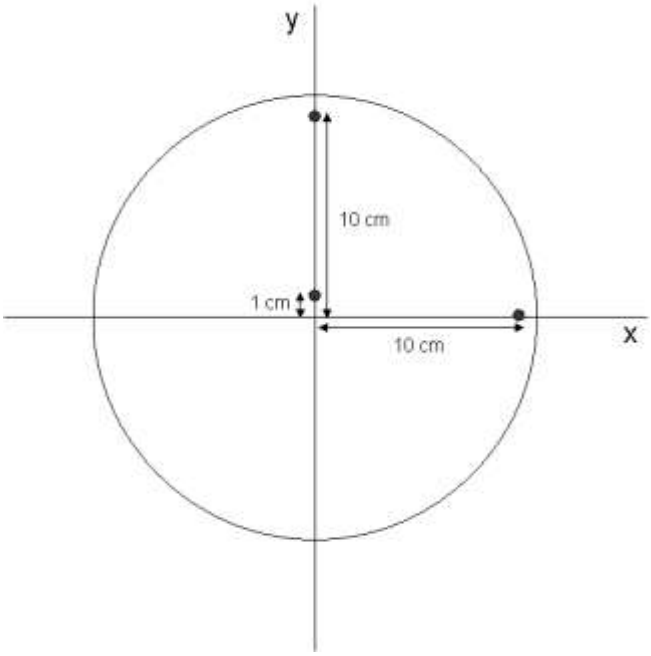


Figure 5: Position of point sources for measurement of spatial resolution.

2. The sources should be suspended in air. It is recommended to use or construct a source holder to hold the sources securely in the correct positions.

3. Two separate acquisitions should be performed, in the center of the axial FOV and at an axial position of a quarter of the FOV.

4. At least 100 000 counts must be acquired for each response function (point) or, in the case of tomographs with significant natural radioactivity in the detector material, a total of 120 000 counts should be acquired.

5. The acquisition should be repeated at the same source positions in 2D and 3D for scanners that have both capabilities.

Data Analysis

1. For each acquisition position, transaxial and sagittal images should be obtained.

2. Profiles across the point source response functions in all three directions (radial, tangential, and axial) will be generated.

3. The full width at half maximum (FWHM) and full width at tenth maximum (FWTM), shown in Figure 6, for all of the point source response functions in all three directions (radial, tangential, and axial) will be calculated using linear interpolation (18 numbers).

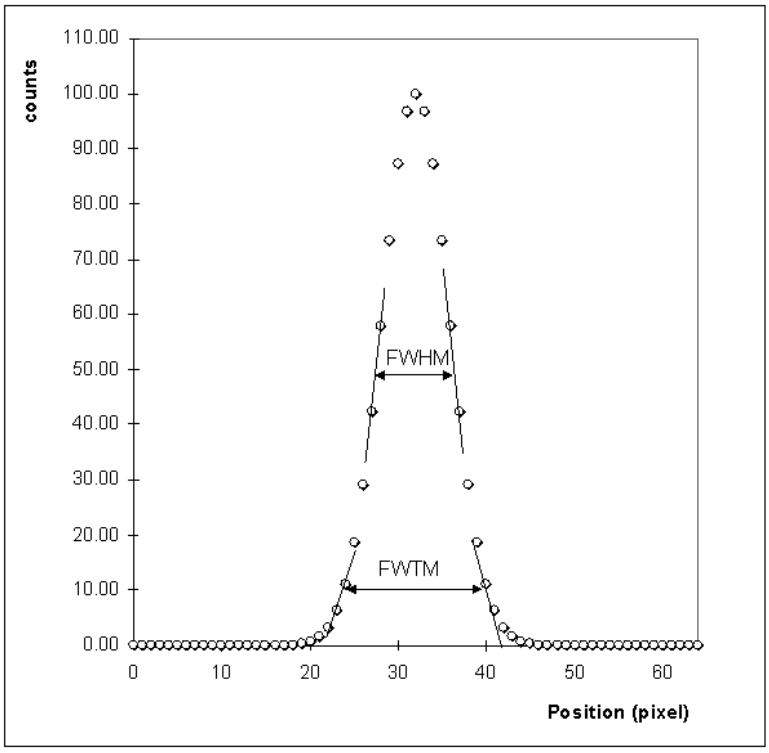


Figure 6: Example of response function, with definition of FWHM and FWTM.

4. The calculated FWHM and FWTM values will be converted to millimeters by multiplying by the pixel size.

5. The radial and tangential resolutions will be averaged using the formulas given in Table 1.

Table 1: Formulas for computing spatial resolution

	Description	Formula
At 1 cm radius		
Transverse	Average x and y for both z positions	$RES = (RESx_{x=0,y=1,z=center} + RESy_{x=0,y=1,z=center} + RESx_{x=0,y=1,z=¼FOV} + RESy_{x=0,y=1,z=¼FOV})/4$
Axial	Average of two z positions (two numbers)	$RES = (RESz_{x=0,y=1,z=center} + RESz_{x=0,y=1,z=¼FOV})/2$
At 10 cm radius		
Transverse radial	Average two transverse for both z positions (four numbers)	$RES = (RESx_{x=10,y=0,z=center} + RESy_{x=0,y=10,z=center} + RESx_{x=10,y=0,z=¼FOV} + RESy_{x=0,y=10,z=¼FOV})/4$
Transverse tangential	Average two transverse positions for both z positions (four numbers)	$RES = (RESy_{x=10,y=0,z=center} + RESx_{x=0,y=10,z=center} + RESy_{x=10,y=0,z=¼FOV} + RESx_{x=0,y=10,z=¼FOV})/4$
Axial resolution	Average two transverse positions for both z positions (four numbers)	$RES = (RESz_{x=10,y=0,z=center} + RESz_{x=0,y=10,z=center} + RESz_{x=10,y=0,z=¼FOV} + RESz_{x=0,y=10,z=¼FOV})/4$

Reconstruction should be made using filtered back-projection with a ramp filter; no further smoothing should be applied.

Matrix	:	
Pixel Size	:	

Result $FWHM_{observed}$

Tolerance $FWHM_{observed} < 1.05FWHM_{expected}$)

Note: Ratio between FWTM and FWHM should approximately be in the range 1.8 – 2.0 (for reference only).

Test Frequency Acceptance

TEST PARAMETER 4: SCATTER FRACTION, COUNT LOSSES AND RANDOMS MEASUREMENT

Test Parameter **Scatter Fraction, Count Losses And Randoms Measurement**

Objective To determine the scatter, count losses and randoms.

Test Tool 70 cm plastic cylinder with off-center line source.

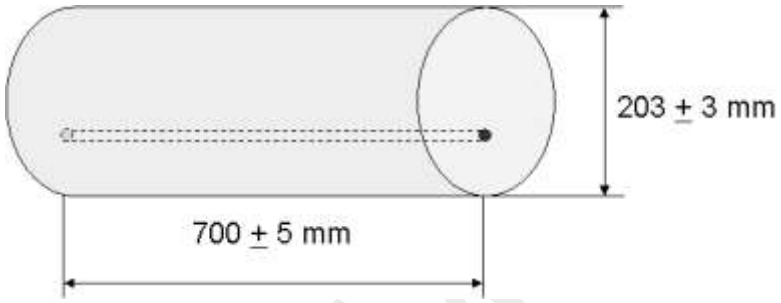


Figure 7: NEMA scatter fraction phantom.

Note: 2D and 3D refer to factory settings.

Test Procedure

1. The initial radioactivity used to fill the line source is then carefully measured using a dose calibrator and the time of measurement recorded.
2. The line source is then inserted into the scatter phantom, placed on the patient bed as shown in Figure 8, with the line source positioned nearest to the bed.
3. The centre of the phantom must be positioned in the axial and transaxial directions to within 5 mm of the centre of the PET scanner.

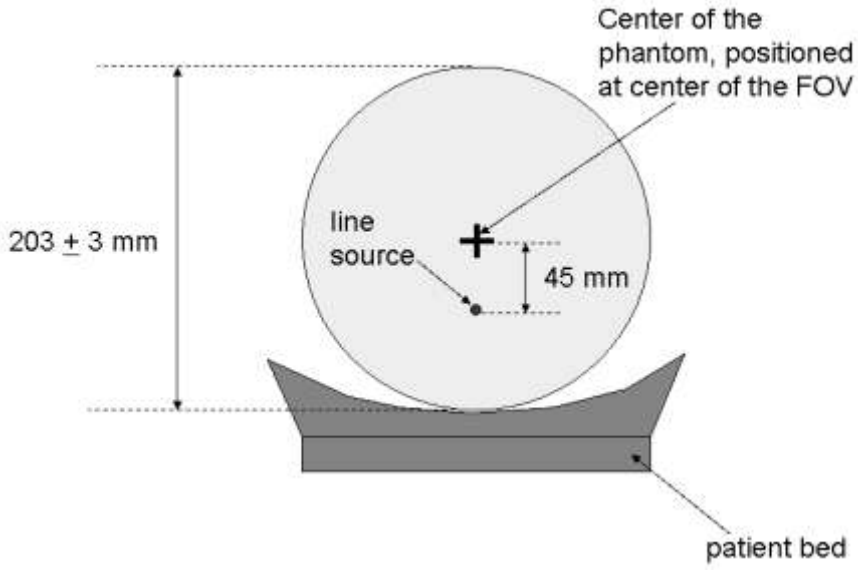


Figure 8: Positioning of the scatter phantom on the patient bed.

4. Tomographic acquisitions must be performed at time intervals of less than half the half-life of the radionuclide, $T_{½}$.

5. Acquisitions should be performed until true event losses are less than 1%.

6. The durations of individual acquisitions, T_{acq}, should be less than one quarter of $T_{½}$, and such that each acquisition accumulates not less than 500 000 prompt counts.

Data Analysis

1. If randoms estimation is available, prompt and random sinograms should be generated for each acquisition *j* of slice *i*, for the entire axial field of view (FOV), except for scanners with an axial FOV greater than 65 cm, in which case only slices in the central 65 cm should be reconstructed. If no randoms estimate is available, only prompt sinograms are generated.

2. No corrections should be applied for variations in detector sensitivity, motion, randoms, scattering, dead time or attenuation. Oblique sinograms are reformatted into a single sinogram for each slice by single slice rebinning.

3. For each prompt sinogram *i* of acquisition *j*, all pixels whose distance from the central axis of the phantom is greater than 12 cm should be set to zero (Figure 9) (for reference only).

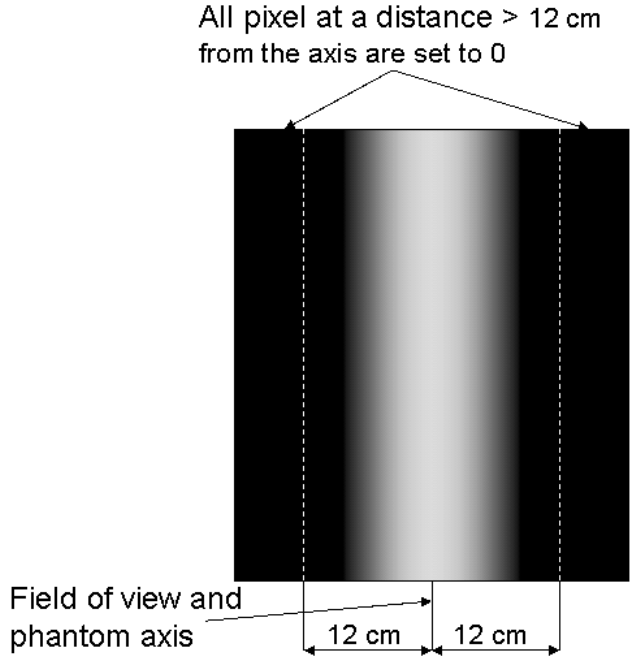


Figure 9: Schematic example of a sinogram sum profile and definition of the ROI.

4. For each projection angle, i.e. for each row of the sinogram, the maximum pixel value shall be determined and the projection shifted to align it with the central pixel of the sinogram. A sum projection is then calculated, by summing all the rows of the sinogram (Figure 10).

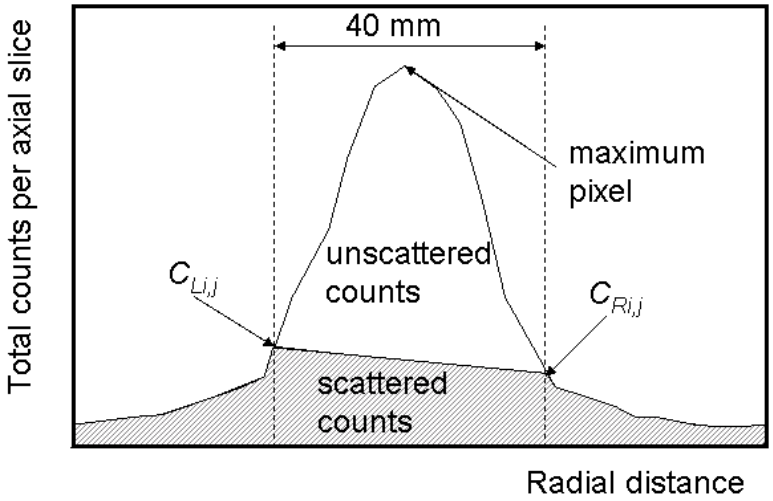


Figure 10: Integration of scattered counts in the projection sum profile.

5. In the projection sum profile, counts $C_{Li,j}$ and $C_{Ri,j}$ at a distance of ±20 mm from the maximum pixel are obtained.

6. The number of scattering plus random event counts $C_{r+s\ i,j}$ is then obtained as the sum of all the counts outside the ± 20 mm strip and the trapezoidal area delimited by $C_{Li,j}$ and $C_{Ri,j}$ inside the ± 20 mm strip. The total event count $C_{Tot\ i,j}$ is obtained from the sum of all pixels in the sum projection.

7. The average activity $A_{ave,j}$ in the phantom for each acquisition j is calculated as:

$$A_{ave,j} = \left(\frac{A_j}{\ln 2}\right)\left(\frac{T_{1/2}}{T_{acq,j}}\right)\left[1-\exp\left(\frac{-\ln 2 T_{acq,a}}{T_{1/2}}\right)\right]$$

where A_j is the activity at the beginning of the jth acquisition, obtained from the radioactivity measured in the dose calibrator at time T_{cal} given as:

$$A_j = A_{cal}\exp\left[\frac{-\ln 2(T_{cal}-T_j}{T_{1/2}}\right]$$

and $T_{acq,\,j}$ is the duration of the jth acquisition.

8. In each randoms sinogram i of acquisition j, set all pixels located further than 12 cm from the centre of the phantom to zero. Find the number of random counts in sinogram i of acquisition j, $C_{r,i,j}$, by summing the remaining counts.

   Calculate the scatter fraction $SF_{i,j}$ for each slice i and acquisition j as

$$SF_{i,j} = \frac{\sum_j C_{r+s,i,j} - \sum_j C_{r,i,j}}{\sum_j C_{Tot,i,j} - \sum_j C_{r,i,j}}$$

Then compute the system scatter fraction as

$$SF_j = \frac{\sum_i \sum_j C_{r+s,i,j} - \sum_i \sum_j C_{r,i,j}}{\sum_i \sum_j C_{Tot,i,j} - \sum_i \sum_j C_{r,i,j}}$$

The Noise equivalent count (NEC) rate is computed as follows. First the total event rate $R_{Tot,i,j}$ for each slice *i* is calculated as

$$R_{Tot,i,j} = \frac{C_{Tot,i,j}}{T_{acq,j}}$$

Then, for each slice *i*, the true event rate $R_{t,i,j}$, the random event rate $R_{r,i,j}$, and the scatter event rate $R_{s,i,j}$ are calculated, respectively, as

$$R_{t,i,j} = \frac{\left(C_{Tot,i,j} - C_{r+s,i,j}\right)}{T_{acq,j}}$$

$$R_{r,i,j} = \frac{C_{e,i,j}}{T_{acq,j}}$$

and

$$R_{s,i,j} = \frac{C_{r+s,i,j} - C_{r,i,j}}{T_{acq,j}}$$

where $T_{acq,j}$ is the duration of frame *j*.

The NEC rate for each slice *i* of acquisition *j* is computed as

$$R_{NEC,i,j} = \frac{R_{t,i,j}^2}{R_{Tot,i,j} + kR_{r,i,j}}$$

where the factor *k* is set to 0 for tomographs that does not perform direct randoms subtraction, and 1 for scanners that use direct randoms subtraction, to account for the fact that the estimation of the randoms is noisy.

The system NEC rate, $R_{NEC,j}$, is calculated as the sum of $R_{NEC,i,j}$ over all slices *i*.

Result

$SF_{observed}$	:		$NEC_{observed}$	:	
$SF_{expected}$	:		$NEC_{recommended}$	:	

Tolerance

$SF_{observed} < 1.05 SF_{expected}$
$NEC_{observed} \geq NEC_{recommended}$

Test Frequency

Acceptance

TEST PARAMETER 5: SENSITIVITY

Test Parameter **Sensitivity**

Objective To determine the rate of detected true coincidence events per unit of radioactivity concentration for a standard source configuration.

Test Tool

1. Phantom holder.
2. 70 cm line source.
3. 5-sleeve aluminium phantom.

Test Procedure

1. The radioactivity of the source, A_{cal}, should be accurately measured in a dose calibrator and the time of measurement, T_{cal}, recorded.
2. The phantom for sensitivity measurements is completed by a set of five sleeves consisting of aluminium tubes 700 mm long, each with a wall thickness of 1.25 mm, with increasing diameters according to Figure 11 and Table 2.

Table 2: Dimensions Of The Sensitivity Measurement Phantoms

Tube no.	ID[a] (mm)	OD[b] (mm)	Thickness (mm)	Length (mm)
1	3.9	6.4	1.25	700
2	7.0	9.5	1.25	700
3	10.2	12.7	1.25	700
4	13.4	15.9	1.25	700
5	16.6	19.1	1.25	700

ID[a]: Internal diameter
OD[b]: Outer diameter

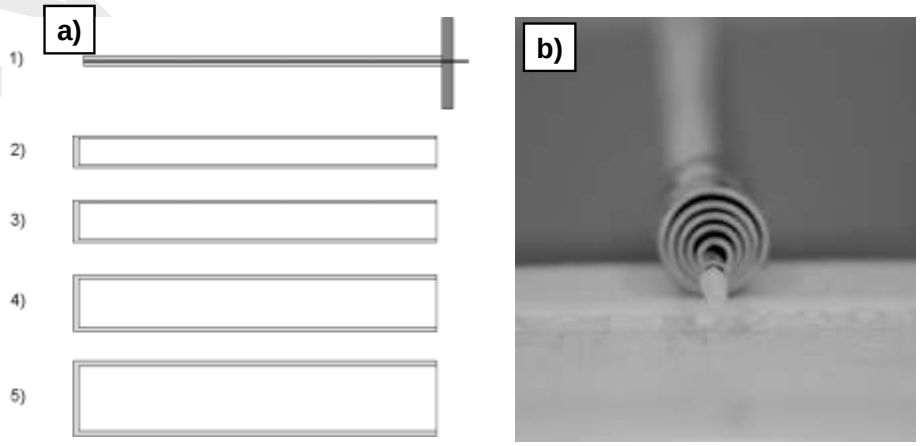


Figure 11: Sensitivity measurement phantom; (a) Schematic, (b) Actual.

3. The phantom is positioned in air, supported at each end by low density materials.
4. Starting with the smallest sleeve containing the line source only, perform an acquisition.

5. Increase wall thickness by adding the next smallest sleeve and repeat the acquisition, until acquisitions with all sleeves have been made.

6. To check variation of sensitivity within FOV, perform acquisitions as above for phantoms and line sources at 10 cm offset from the central axis.

7. For systems capable of acquisition in both 2-D and 3-D, measurements should be performed in both modes.

Data Analysis

1. The time of the commencement of a measurement, T_j, and the duration T_{acq} including the time required to move the detectors, are recorded, along with the number of counts collected.

2. The rate in counts per second $R_{j,i}$ shall be determined for each measurement associated with each of the five sleeves, designated by index *j* (*j* = 1-5) and for each slice, designated by the index *i* (*i* = 1 to the number of slices), by dividing the number of counts collected in the sinogram of the slice by the duration T_{acq}.

3. For each measurement associated with each of the five sleeves and for each slice, the count rate for isotope decay will be corrected for radioactive decay using the following formula:

$$R_{CORR,j,i} = R_{j,i} \cdot e^{(T_j - T_{cal})/T_{1/2}}$$

where T_j is the time of the *j*th acquisition and T_{cal} is the time of phantom radioactivity calibration. After decay correction, the cumulative count rate is calculated using the following expression:

$$R_{CORR,j} = \sum_i R_{CORR,j,i}$$

for each accumulated sleeve thickness. The data are then fitted to the following equation:

$$R_{CORR,j,i} = R_{CORR,0} e^{-2\mu_M X_j}$$

where $R_{CORR,0}$ represents the unattenuated count rate. The linear attenuation coefficient of the sleeve material, μ_M, is allowed to vary to compensate for scattered radiation, and X_j represent the accumulated sleeve wall thickness. The fitting procedure yields estimates of $R_{CORR,0}$ and μ_M.

The system sensitivity S_{tot} is then obtained by dividing the unattenuated count rate $R_{CORR,0}$ by the total radioactivity A_{cal}:

$$S_{tot} = \frac{R_{CORR,0}}{A_{cal}} .$$

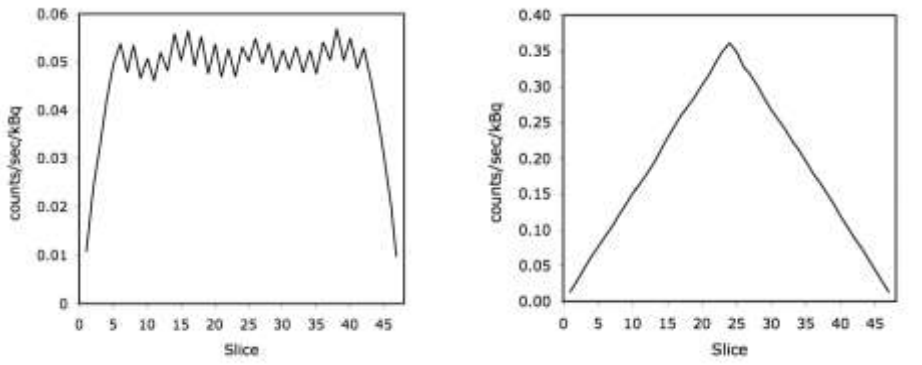
The same procedure is followed for the measurements obtained when the phantom and line source are 10 cm from the central axis.

The axial sensitivity profile is calculated using the data from the

acquisition with the smallest sleeve, for the position at 0 cm offset. Using the corrected count rates $R_{CORR,1,i}$ for the slices and the total count rate $R_{CORR,1}$, the axial sensitivity for slice i is obtained by the following formula:

$$S_i = \frac{R_{CORR,1,i}}{R_{CORR,1}} S_{tot}$$

A sensitivity profile can be obtained by plotting S_i against slice number. Maximum and minimum values can be recorded. Typical plots of axial sensitivity profiles in 2-D and 3-D are shown in Figure 12.



(a) (b)

Figure 12: Typical axial sensitivity profiles in (a) 2-D and (b) 3-D.

Result

Sensitivity$_{tot}$ (observed) at 0 cm = _____
Sensitivity$_{tot}$ (observed) at 10 cm = _____

Tolerance

$S_{tot,observed} > 0.95 S_{tot,expected}$

Test Frequency

Acceptance
Annually

TEST PARAMETER 6: ENERGY RESOLUTION

Test Parameter **Energy Resolution**

Objective To determine the energy resolution and to ensure that the efficiency of light collection is within the specifications.

Test Tool

1. Source holder.
2. 1 point source of ^{22}Na, 3.7 MBq (100 μCi).

Test Procedure

1. The source should be placed at the centre of the FOV, suspended in air.
2. Follow the manufacturer's procedure for energy testing or for energy spectra collection and display.
3. Acquire for a time sufficient to obtain no less than 10 000 counts in the peak of the energy distribution.

Data Analysis

1. Using the manufacturer's procedure for energy testing, obtain the per cent energy resolution of the system.

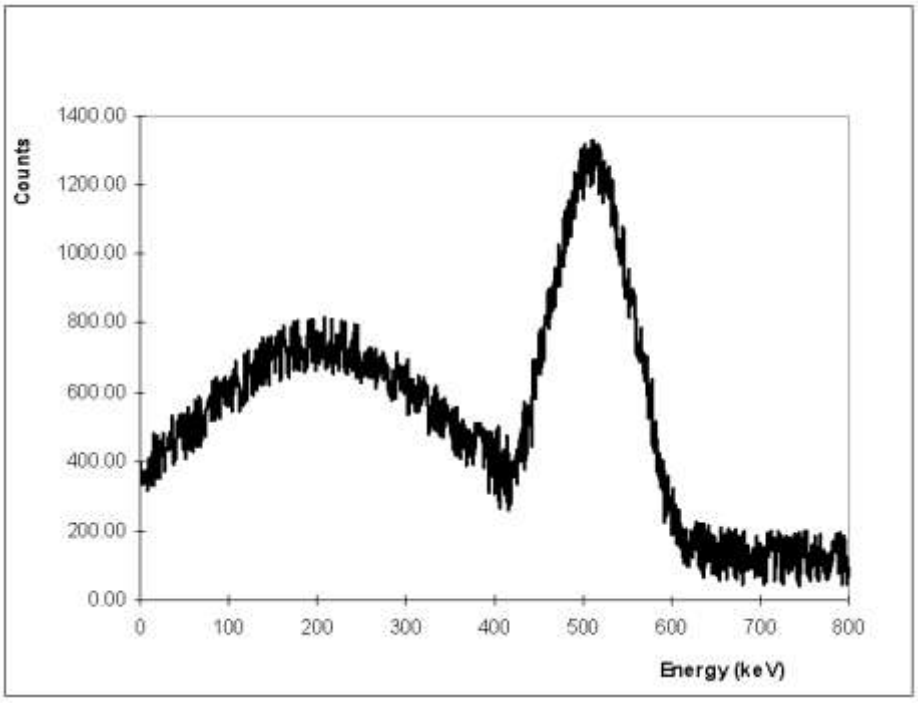


Figure 13: Example of an acquired energy spectrum; energy resolution can be calculated from FWHM of the energy peak distribution.

2. Energy calibration factor can be obtained by calculating the peak position using a parabolic fit to the top of the peak. Using this factor, the FWHM can be converted into units of energy (keV). Energy resolution can then be calculated using the following relation:

$$R_E = 1000 \frac{FWHM}{500}$$

Result	$R_{Eobserved}$
Tolerance	$R_{Eobserved} < 1.05R_{Eexpected}$ **Note:** $R_{Eobserved}$ and $R_{Eexpected}$ should be in percentage.
Test Frequency	Acceptance

TEST PARAMETER 7: IMAGE QUALITY & ACCURACY OF ATTENUATION AND SCATTER CORRECTION

Test Parameter	**Image Quality & Accuracy Of Attenuation And Scatter Correction**
Objective	To produce images simulating those obtained in a total body imaging study involving both hot and cold lesions.
Test Tool	IEC61675-1 or equivalent phantom ^{18}F (≈ 1.5 mCi); 70 cm plastic cylinder with off-center line source (scatter phantom) ^{18}F (≈ 3 mCi). **Note**: ^{18}F solution of 5.3 ± 0.27 kBq /mL

Figure 14: IEC61675-1/NEMA 2001/2007 body phantom.

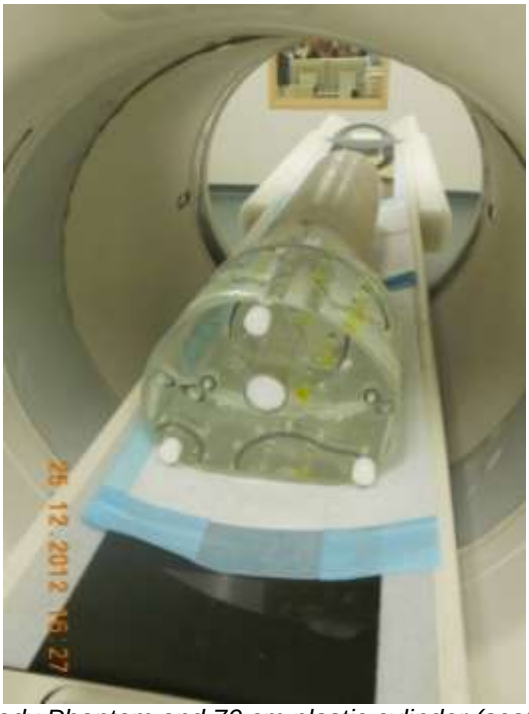


Figure 15: IEC body Phantom and 70 cm plastic cylinder (scatter phantom) set up during the test.

Test Procedure

1. The 2.8 and 3.7 cm spheres shall be filled with cold water to mimic cold lesion imaging.

2. The 1.0, 1.3, 1.7 and 2.2 cm spheres are to be filled with an ^{18}F solution that has either 4 or 8 times higher radioactivity concentration than the background.

3. The spheres shall be positioned in such a manner that the centers of all spheres shall be in the same transverse slice, at a 5.72 cm radius from the centre of the phantom, with the 1.7 cm sphere positioned along the horizontal axis of the phantom (see Figure 16).

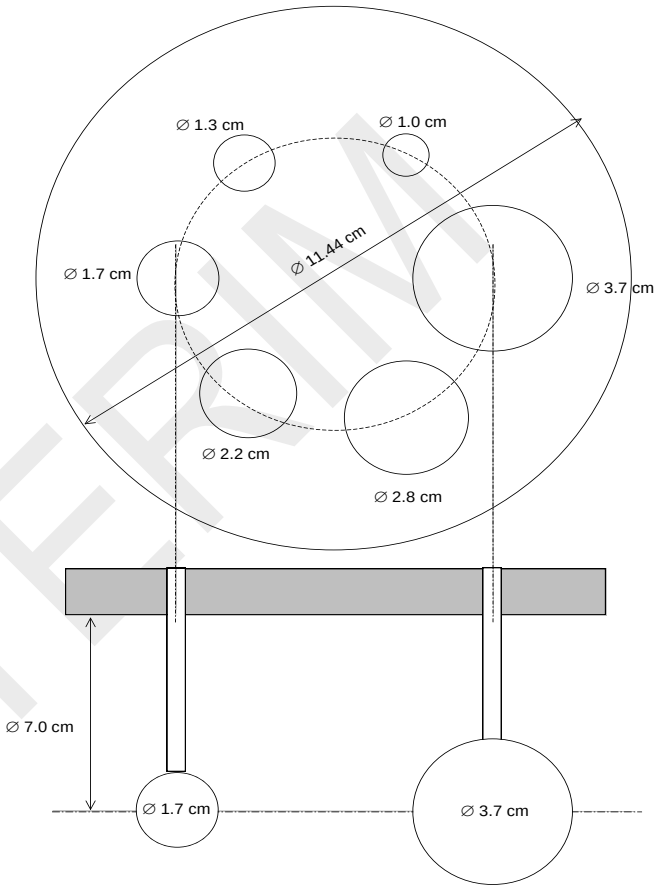


Figure 16: Insert for hollow spheres in the image quality phantom.

4. The body phantom shall be positioned at the end of the table in a head first, supine position and shall be positioned axially in the scanner so that the centre of the spheres is at the middle slice of the scanner and positioned transaxially so that the centre of the phantom is centered in the scanner. The phantom should also be aligned so that the plane through the centers of the spheres is coplanar to the middle slice of the scanner to within 3 mm throughout the length of the phantom.

5. The total scan time for each bed position will therefore be equal to 60 min x (axial step/100 cm), when the bed is moved by an axial step between two positions in a whole body scan.

6. On scanners capable of both 2D and 3D operation, the test should be performed in both modes.

Data Analysis

(i) Image quality

1. One transverse slice shall be used in the image quality analysis.

2. Circular region of interests (ROIs) shall be drawn on each hot and cold sphere.

3. ROIs of the same sizes as the ROIs drawn on the hot and cold spheres shall be drawn in the background of the phantom on the slice centered on the spheres.

4. Twelve 37 mm diameter ROIs shall be drawn throughout the background at a distance of 15 mm from the edge of the phantom but no closer than 15 mm to any sphere (see Figure 17).

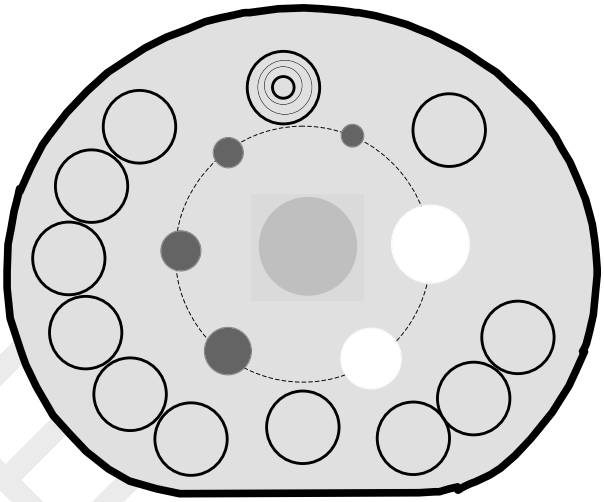


Figure 17: Image quality analysis: Placement of background regions of interest.

5. ROIs of the same sizes as the smaller spheres (10, 13, 17, 22, and 28 mm) should be drawn concentric to each of the 37 mm ROIs on the background region.

6. The same set of background ROIs shall also be drawn on the slices as close as possible to +2 cm, +1 cm, -1 cm, and -2 cm on either side of the central slice.

7. A total of 60 background ROIs of each size, 12 ROIs on each of five slices, shall be drawn. The locations of the ROIs must be the same in each of the replicate scans. The average counts in each background ROI shall be recorded.

(ii) Accuracy of attenuation and scatter corrections

1. A circular ROI of 3.0 ± 0.2 cm in diameter shall be drawn, centred as precisely as possible, on the lung insert.

2. The average pixel value within the ROI, $C_{lung,i}$ should be recorded for each slice *i*. With perfect corrections for scattering and attenuation, this value would be close to zero.

3. 12 circular ROIs that are 3.0 ± 0.2 cm in diameter shall be placed on each slice *i* at the background locations specified in the previous section (Figure 17), and the average pixel values within each ROI, $C_{B,i}$ should be recorded.

4. The accuracy of the scattering and attenuation corrections is assessed by measuring the average pixel value with the lung insert ROI as a percentage of the background, and expressing it as the per cent relative error $\Delta C_{lung,i}$ for each slice *i* as follows:

$$\Delta C_{lung,i} = 100 \cdot \frac{C_{lung,i}}{C_{B,i}}$$

where $C_{lung,i}$ is the average counts in the ROI placed over the lung insert and $C_{B,i}$ is the average of the twelve 3.7 cm background ROIs drawn for the image quality analysis.

(iii) Accuracy of radioactivity quantitation

1. The radioactivity concentration in the background compartment of the image quality phantom as specified at the beginning of this section to be 5.3 ± 0.27 kBq/mL. Therefore, the true radioactivity concentration is assumed to be known within 5% and should be denoted A_B.

2. Using the option provided by the manufacturer to display radioactivity concentration in MBq/mL, the average activity $C_{B,i}$, of the twelve 3.7 cm background ROIs drawn for the image quality analysis in slice i shall be recorded in MBq/mL as $A_{B,i}$ and the quantitation error ΔA_i in slice *i* shall be calculated as:

$$\Delta A_i = 100 \frac{A_{B,i} - A_B}{A_B}$$

Result

Sphere size (mm)	Contrast (%)	Bg. Variability (%)
	4i x 8s	4i x 8s
10		
13		
17		
22		
28*		
37*		
Ave residual (%) over lung insert		

*Cold sphere

Tolerance Acceptable visual assessment.

Note: A 5% tolerance criterion with respect to the baseline established values for all image quality parameters, based on the three replicate measurements, is recommended.

Test Frequency Acceptance
Annually

TEST PARAMETER 8: DAILY PET QC PROCEDURES

Test Parameter	**Daily PET QC Procedures**
Objective	To assess the constancy of the detector performance and to allow early detection of any sudden change.
Test Tool	^{68}Ge line source or cylindrical ^{68}Ge phantom or ^{22}Na point source.
Test Procedure	Using the system's daily PET QC acquisition protocol, set up and acquire the detector stability scan or equivalent daily stability test.
Data Analysis	Sinograms (Figure 18 and 19) /blocks (Figure 20) should be subject to a careful visual inspection for the presence of pronounced diagonal streak artifacts and then compared with previously acquired reference sinograms.

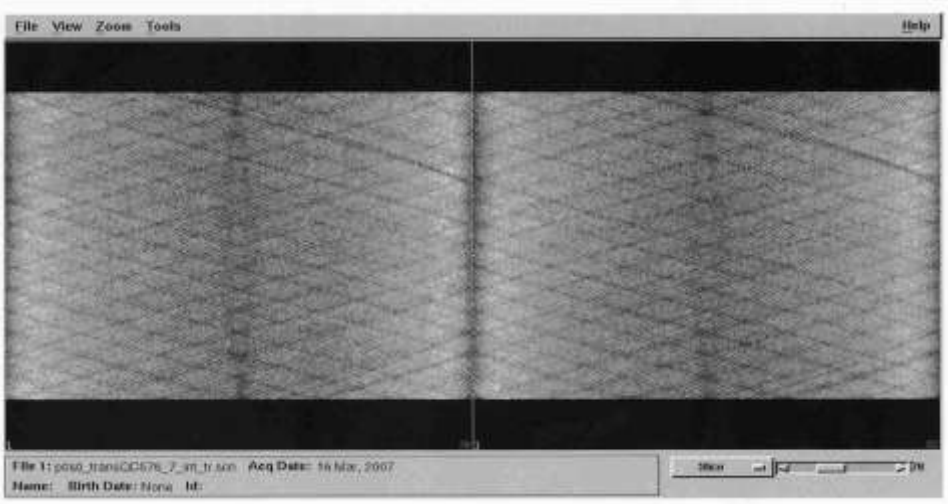


Figure 18: An example of detector stability acquisition on a PET/CT using a ^{137}Cs rotating source (courtesy of L. Indovina and A Giordano, Catholic University, Rome).

Figure 19: An example of a daily QC sinogram acquired on a PET/CT using a ^{22}Na source (courtesy of L. Indovina and A Giordano, Catholic University, Rome).

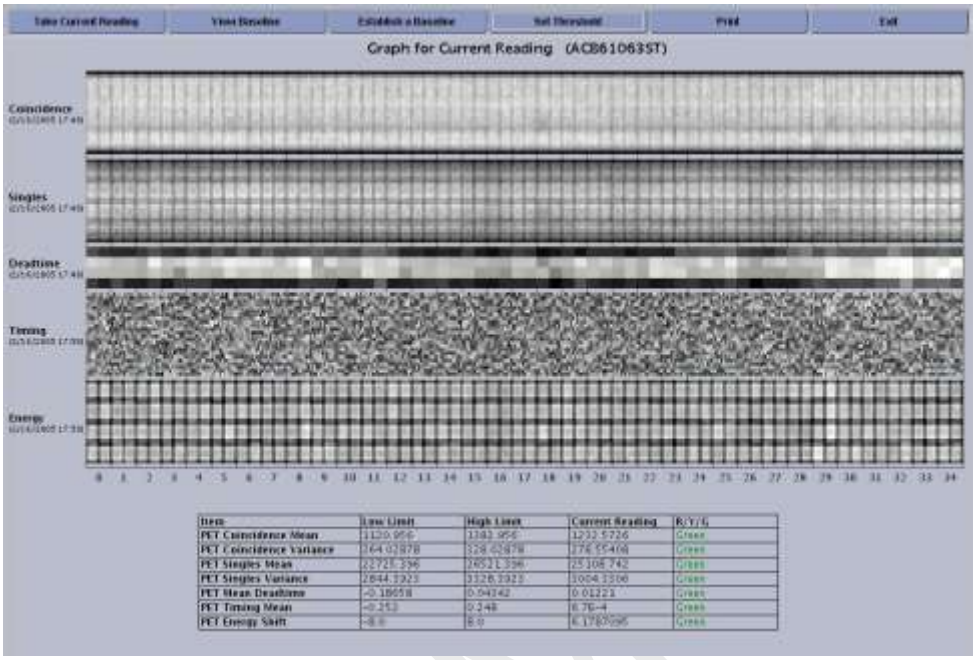


Figure 20: An example of a daily QC blocks.

Result Pass/Fail

Tolerance Manufacturer's specifications.

Test Frequency Acceptance
Daily

TEST PARAMETER 9: WELL COUNTER CORRECTION

Test Parameter **Well Counter Correction**

Objective

1. To transform detected count rate to radioactivity concentration.
2. To determine calibration factor from image voxel intensity to true radioactivity concentration.

Test Tool Fillable cylindrical ^{18}F phantom (≤ 0.5 mCi) or NEMA NU2-1994 phantom (≤ 1 mCi for 2D; ≤ 0.5 mCi for 3D).

Figure 21: Fillable cylindrical ^{18}F phantom.

Test Procedure Follow the manufacturer's procedures (Figure 22 for reference only).

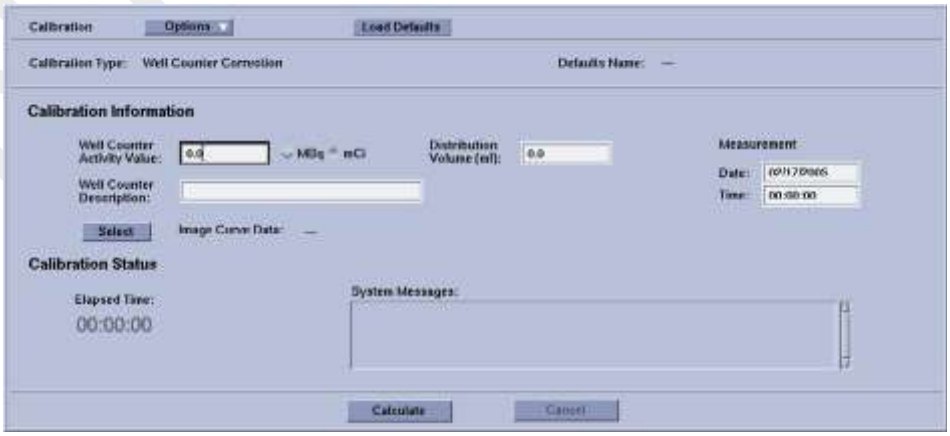


Figure 22: Parameter in the control console.

Result Calibration factor = _____

Tolerance Manufacturer's specifications.

Test Frequency Acceptance
Quarterly

TEST PARAMETER 10: 2D OR 3D ACTIVITY CONCENTRATION CALIBRATION

Test Parameter **2D Or 3D Activity Concentration Calibration**

Objective To acquire scanner efficiency data for use in correcting acquired sinograms for detector non-uniformities.

Test Tool Fillable cylindrical ^{18}F phantom (≤ 0.5 mCi) or NEMA NU 2-1994 phantom (≤ 1 mCi for 2D; ≤ 0.5 mCi for 3D).

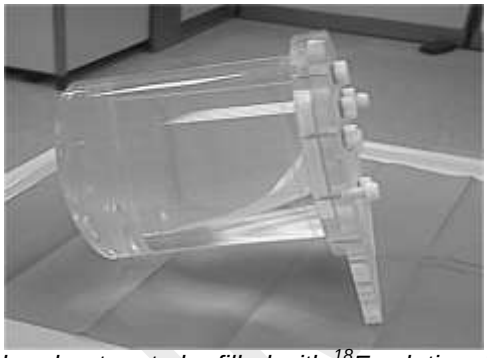


Figure 23: A cylinder phantom to be filled with ^{18}F solution. Phantoms like this are used for normalization of the PET detector, for radioactivity concentration calibration and for uniformity testing.

Test Procedure

1. Before starting the acquisition, make a backup copy of the previous calibration file.
2. The acquisition should consist of an adequate number of total counts, in order to achieve good data statistics.

   When no indications are given or readily available, at least 20 million counts should be acquired.
3. A useful method of checking standard uptake value (SUV) accuracy is to scan a phantom with a known amount of radioactivity and volume/weight using a multibed clinical protocol. If the radioactivity in the phantom, the calibration time of the radioactivity and the weight of phantom volume are entered as part of the patient details, then the measured SUV should be 1.

$$\text{SUV} = \frac{\text{Decay corrected activity concentration (kBq/ml)}}{\text{Injected dose (kBq)} \,/\, \text{Patient weight (g)}}$$

Data Analysis Compare calibration data obtained with previous results and manufacturers indications.

Result SUV = _____

Tolerance 10% from expected results.

Test Frequency Acceptance
Annually

TEST PARAMETER 11: TEST OF PET/CT IN CLINICAL MODE

Test Parameter **Test Of PET/CT In Clinical Mode**

Objective To check the overall operation of the system in patient scan mode. This is a test of all the components involved in performing a clinical scan and is intended to identify problems with the PET and CT subsystems, including attenuation correction, bed motion, reconstruction and PET/CT registration.

Test Tool Uniform cylindrical ^{68}Ge or fillable cylindrical ^{18}F phantom, ≤ 18.5 MBq (≤ 0.5 mCi).

Test Procedure Perform a two bed PET/CT scan for 5 min at each bed position. Define bed positions to overlap at the centre of phantom.

Scanning protocol: _____
Filter: _____

Data Analysis Visually inspect reconstructed images for artifacts, and then confirm proper co-registration of PET and CT images.

Result

Inspection	Pass/Fail	Comment
Artifact		
Co-registration of PET and CT images		

Tolerance Inspect reconstructed images to check proper acquisition and reconstruction of CT and PET data at both bed positions. Reconstructed PET and CT images should appear uniform. Ensure that PET and CT data appear to be correctly co-registered. If co-registration problem is suspected, perform a PET/CT co-registration procedure to update the system's co-registration parameters and repeat the test. If co-registration appears correct and image artifacts are seen in the CT images, it may be possible to correct for them by renormalizing the detector. If this does not correct the problem, the PET scanner needs to be serviced.

Test Frequency Acceptance
Annually

TEST PARAMETER 12: PET/CT OFFSET CALIBRATION

Test Parameter	**PET/CT Offset Calibration**
Objective	To determine the *x*, *y* and *z* offsets required to register acquired PET and CT images.
Test Tool	Volumetric Quality Control (VQC) phantom or two ^{68}Ge rod source or multiple source phantom.
Test Procedure	Acquire PET/CT scan of alignment phantom according to manufacturer's instructions.
Data Analysis	Compute the x, y and z offsets required to register PET and CT images and store in a file for where it can be accessed by fusion software.
Result	x = ____; y = ____; z = ____
Tolerance	Manufacturer's specifications.
Test Frequency	Acceptance Semi-annually

TEST PARAMETER 13: PET/CT IMAGE REGISTRATION ACCURACY

Test Parameter **PET/CT Image Registration Accuracy**

Objective To assess qualitatively the accuracy of the registration of the images obtained with the PET and CT scanners.

Test Tool

1. IEC61675-1 or equivalent phantom ^{18}F (≈ 1.5 mCi).

   Note: ^{18}F solution of 5.3 ± 0.27 kBq /mL

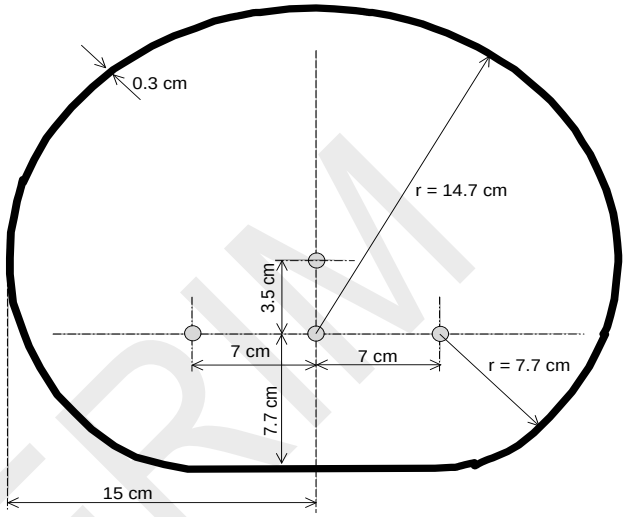


Figure 24: Image quality phantom (IEC standard 61675-1).

2. Lead bricks or other heavy material (total weight of about 100 kg).
3. Ruler.

Test Procedure

1. The "body compartment" shall be filled with an ^{18}F solution of 5.3 kBq/mL radioactivity concentration.
2. The 2.8 and 3.7 cm spheres shall be filled with cold water. The 1.0, 1.3, 1.7 and 2.2 cm spheres shall be filled with an ^{18}F solution that is either 4 or 8 times hotter than the background (sphere:background = 4:1 or 8:1).
3. The spheres shall be positioned in such a manner that the centres of all spheres shall be in the same transverse slice, at a 5.72 cm radius from the centre of the phantom with the 1.7 cm sphere positioned along the horizontal axis of the phantom.
4. The lead bricks (or equivalent heavy weights) shall be uniformly distributed over 1.5 m length of the table adjacent to the quality phantom.
5. The phantom shall be positioned at the end of the table in a supine position and shall be positioned axially in the scanner so that the centre of the spheres is at the middle slice of the scanner and positioned transaxially so that the centre of the phantom is cantered in the scanner.

6. The phantom should be also aligned so that the plane through the centers of the spheres is coplanar to the middle slice of the scanner to within 3 mm throughout the length of the phantom.

7. The lead bricks should be uniformly distributed over a 1.5 m length on the table adjacent to the image quality phantom.

Data Analysis

1. For both cases (in the presence and in the absence of the heavy weights), the centers of all spheres shall be visually examined in all three directions on both PET and CT to ensure that they are adequately registered, spatially within 1 voxel.

2. The edge of the phantom shall also be examined to ensure that the edge of the phantom, as seen on the PET scan, appropriately matches the phantom boundaries, as seen on the CT scan.

Result

Inspection	Pass/Fail	Comment
Image co-register at centre of spheres within 1 mm?		
Image co-register at edge of phantom within 1 mm?		

Tolerance

Within ± 1 pixel (or ± 1 mm, whichever is smaller) when using a 512 x 512 matrix.

Test Frequency

Acceptance

Under condition:

(1) Whenever detector system performance is suspected to have changed significantly

TEST PARAMETER 14: IMAGE DISPLAY

Test Parameter **14.1 Visual Display**

Objective

To determine that all of the information in the video signal is displayed on the video display.

Test Tool

1. The Society of Motion Pictures and Television Engineers (SMPTE) test pattern installed in the CT scanner.
2. Display Monitor (CRT or LCD).

Test Procedure

1. Display the SMPTE test pattern on the (CRT or LCD).

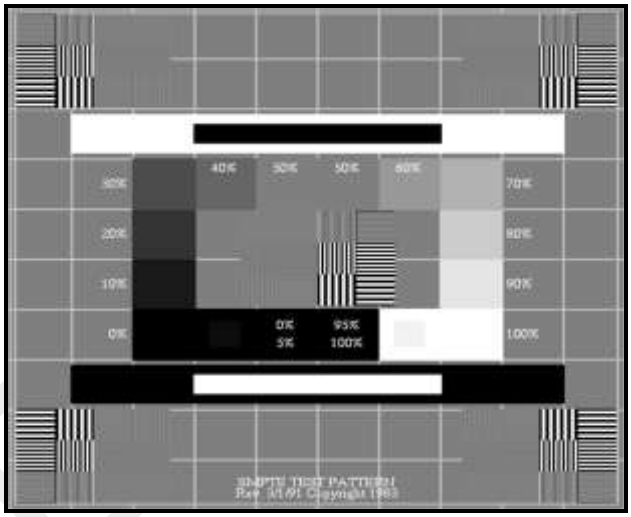


Figure 25: Image of SMPTE.

2. Adjust the window width to just encompass the range of numbers comprising the SMPTE test pattern.
3. Adjust the window level to either the lower or middle value of the window so that the entire test pattern is visible.
4. If required, clean the front surface of the monitor and reduce room illumination to the normal viewing level for better evaluation condition.

Result

1. The 5% patch should just be visible inside of the 0% patch.
2. The line pair pattern at the center and all four sides of the image should be clearly resolvable.
3. The 95% patch should be visible inside the 100% patch.
4. The alphanumeric should be sharp and clear.

Tolerance

Manufacturer's specifications.

Test Frequency

Acceptance
Weekly

Test Parameter **14.2 Hardcopy Display**

Objective

To ensure that optimal image quality is reproduced on the hard copy image and that the long term reproducibility of the hard copy image quality.

Test Tool

1. SMPTE test pattern installed in the CT scanner.
2. Film printer to print SMPTE Test pattern.

Test Procedure

1. Ensure that the hardcopy printer is in working order and warmed up.
2. Continue from the test above, display the SMPTE test pattern at the window and level as described in the visual display set-up procedure.
3. If required, adjust the hard-copy camera control so that film densities correspond to the manufacturer's specification.

Result

1. Same as the above test, the 5% patch should just be visible inside of the 0% patch.
2. The line pair pattern at the center and all four sides of the image should be clearly resolvable.
3. The 95% patch should be visible inside the 100% patch.
4. The alphanumeric should be sharp and clear.

Tolerance

Manufacturer's specifications.

Test Frequency

Acceptance
Annually

TEST PARAMETER 15: COMPUTED TOMOGRAPHY NUMBER CALIBRATION

Test Parameter **Computed Tomography Number Calibration**

Objective To ensure that the CT numbers for water are within the appropriate limits.

Test Tool Phantom filled with water

Test Procedure

1. Place the phantom on the table centered at the isocenter of the scanner with the long axis of the phantom aligned with the *z* axis of the scanner.
2. Select a FOV that covers the phantom and about a 3 cm surrounding area.
3. Acquire a scout scan and a single, 1 mm thick, image slice of the phantom for alignment purposes. Use these images to ensure that the phantom is centered in the FOV and aligned with the *x*, *y* and *z* axes.

Data Analysis

1. Review the entire image for the presence of artifacts. If any artifacts are present, even subtle ones, compare this image with previous images to determine if these are new artifacts. If they are new, do not make any measurements of CT numbers, uniformity or noise before discussing the artifacts with the responsible medical physicist. If there are no new artifacts, or if told to do so by the responsible medical physicist, proceed with the measurements.
2. Select an ROI sufficiently small to fit inside the regions of water (4 – 10 cm^2), and measure the average CT number of water in the phantom image. Plot the values on the control chart.
3. Use the same sized ROI to measure the average value and its standard deviation of the water in the centre of the phantom, and the average value of the water near the periphery of the phantom. The locations of these two areas should be the same as those measured previously for consistency of the results.

Result ____ Hounsfield unit (HU) (center)

Tolerance Either there should be no artifacts in the image or the artifacts should be very subtle. Most importantly, there should be no new artifacts in the image compared with previous images of the same phantom. The values of CT numbers should be within ± 5 HU of the values specified by the manufacturer.

Test Frequency Acceptance
Daily

Note: In addition to the QC tests of CT described in Test 14 – 15, there are additional QC tests that should be carried out on an annual basis. These are the same as the diagnostic CT parameter.

E. Performance and Safety Standards

PERFORMANCE AND SAFETY STANDARDS FOR POSITRON EMISSION TOMOGRAPHY/COMPUTED TOMOGRAPHY (PET/CT) SYSTEMS

No.	Procedure	Tolerance	Frequency
1.	Physical And Mechanical Inspection	No component of the system is malfunction or not proper installed	Acceptance Daily (except for emergency button) Semi-annually
2.	PET Normalization	A visual inspection should be acceptable	Acceptance Semi-annually Under condition (1) Under condition (2)
3.	Spatial Resolution	$FWHM_{observed} < 1.05FWHM_{expected}$	Acceptance
4.	Scatter Fraction, Count Losses And Randoms Measurement	$SF_{observed} < 1.05SF_{expected}$ $NEC_{observed} \geq NEC_{recommended}$	Acceptance
5.	Sensitivity	$S_{tot,observed} > 0.95S_{tot,expected}$	Acceptance Annually
6.	Energy Resolution	$R_{Eobserved} < 1.05R_{Eexpected}$	Acceptance
7.	Image Quality & Accuracy Of Attenuation And Scatter Correction	Acceptable visual assessment	Acceptance Annually
8.	Daily PET QC Procedure	Manufacturer's specifications	Acceptance Daily
9.	Well Counter Correction	Manufacturer's specifications	Acceptance Quarterly
10.	2D Or 3D Activity Concentration Calibration	10% from expected results	Acceptance Annually
11.	Test Of PET/CT In Clinical Mode	Reconstructed PET and CT images should appear uniform. Ensure that PET and CT data appear to be correctly co-registered	Acceptance Annually
12.	PET/CT Offset Calibration	Manufacturer's specifications	Acceptance Semi-annually

No	Procedure	Tolerance	Frequency
13.	PET/CT Image Registration Accuracy	Within ±1 pixel (or ±1 mm, whichever is smaller) when using a 512 × 512 matrix	Acceptance Under condition (1)
14.	Image Display 14.1 Visual Display 14.2 Hardcopy Display	 Manufacturer's specifications Manufacturer's specifications	 Acceptance Weekly Acceptance Annually
15.	Computed Tomography Number Calibration	Within ± 5 HU of the values specified by the manufacturer	Acceptance Daily

Note:

(1) Whenever detector system performance is suspected to have changed significantly.
(2) This test should be performed whenever servicing is suspected to have affected the test results.

All above tests shall be carried out during commissioning and after replacement of major components.

F. References

REFERENCES

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Technical Quality Control Protocol Handbook

Dose Calibrator
Gamma Counter/ Well Counter/ Thyroid Uptake System
Gamma Probe

Medical Radiation Surveillance Division
MINISTRY OF HEALTH MALAYSIA

MINISTRY OF HEALTH
MALAYSIA

TECHNICAL QUALITY CONTROL PROTOCOL HANDBOOK

FOR

DOSE CALIBRATOR
GAMMA COUNTER / WELL COUNTER / THYROID UPTAKE SYSTEM
GAMMA PROBE

PREPARED BY
MEDICAL RADIATION SURVEILLANCE DIVISION
AUGUST 2015

CONTENTS

A. Introduction

INTRODUCTION

The Ministry of Health (MOH) is continuously taking steps to improve the quality of nuclear medicine services. This is to ensure that necessary clinical information is obtained from the optimum use of ionizing radiation to the patients. Over the years, the MOH has taken both administrative and legislative measures to enforce the various requirements under the Atomic Energy Licensing Act 1984 (Act 304).

In order to further upgrade and enhance the quality, safety, and efficacy of nuclear medicine services, the MOH has formulated and initiated the implementation of Quality Assurance Programme (QAP) for both government and private nuclear medicine centres since 2013. The MOH is empowered under Section 17 of Act 304 to implement such programme. The specific requirement of the programme will be imposed under Regulation 53 of Basic Safety Radiation Protection Regulations (BSRP) 2010.

Quality Control (QC) is one of the elements of QAP that has to be carried out at interval period as specified by MOH. QC tests shall be performed at the time of the acceptance and commissioning of the nuclear medicine imaging and non-imaging equipments prior to the use; after replacement of major components that could cause a change in the performance of the machine including image quality and safety of patient; or as routine tests. The performance and safety standards of the nuclear medicine imaging and non-imaging equipments shall be in accordance with the regulatory requirements and relevant code of practice.

This Handbook is designed to be guidance to conduct QC checking on non-imaging equipments; Dose Calibrator, Gamma Counter / Well Counter / Thyroid Uptake System and Gamma Probe in the aspect of performance and safety standard requirement in accordance with MOH. Wherever applicable, manufacturer's protocol can be followed to perform the test procedures. A complete annual QC report by an approved medical physicist or qualified expert shall be submitted to MOH annually.

B. List of Test Parameter

List of Test Parameter

No.	Parameter
	Dose Calibrator
1.	Physical Inspection
2.	Accuracy And Precision
3.	Linearity Of Activity Response
3.1	Decaying Source Method
3.2	Graded Sources Method (Optional)
4.	Background Response
5.	Operational Checks Of Reproducibility (Constancy)
6.	Geometric Variation Of Sources Within Active Measurement Volume
6.1	Syringe Test
6.2	Vial Test
	Gamma Counter / Well Counter / Thyroid Uptake System
1.	Physical Inspection
2.	Auto Calibration Or Daily Test (If Applicable)
3.	Constancy
4.	Isotope Efficiency (Sensitivity)
5.	Chi-square
	Gamma Probe
1.	Physical Inspection
2.	Display And Sound
3.	Spatial Selectivity And Spatial Resolution
3.1	Spatial Selectivity: Radial Sensitivity Distribution (Far-Field)
3.2	Spatial Resolution: Lateral Sensitivity Distribution
4.	Sensitivity
5.	Shielding
6.	Energy Selection (Where Applicable)

C. List of Test Tools

List of Test Tools

Test tools

Dose Calibrator

No.	Test Tools
1.	Sealed low, medium and high energy gamma radiation sources (standard vial type), certified to ± 5% overall uncertainty or less.
2.	Source holder
3.	Remote handling device for sources/ sample vial
4.	Short-lived radionuclide (^{99m}Tc or ^{131}I or ^{18}F) in solution, initial activity equal to or greater than the highest activity for which the instrument is to be used.
5.	Sample vial
6.	Remote pipetting device
7.	Log linear graph paper (2 or 3 cycle) and (3 or 4 cycle)
8.	Syringe (10 ml) or vial (20 ml or 30 ml)
9.	Saline solution

Gamma Counter / Well Counter / Thyroid Uptake System

No.	Test Tools
1.	^{137}Cs, ^{57}Co or ^{152}Eu (optional) standard sources

Gamma Probe

No.	Test Tools
1.	^{99m}Tc point source (less than 100 µCi)
2.	Centrifuge tube
3.	Graph paper
4.	Geometry set
5.	Ruler
6.	Cardboard paper
7.	Collimator

D. Testing Procedures

DOSE CALIBRATOR

TEST PARAMETER 1: PHYSICAL INSPECTION

Test Parameter

Physical Inspection

Objective

To inspect a radionuclide calibrator for general condition. The electromechanically parts of the system are properly installed and functioned. Test of any damage, deficiencies or flaws.

Test Tool

Not applicable.

Test Procedure

1. Inspect the instrument housing for evidence of damage. Particularly examine the surroundings of the ionization chamber for signs of deformation or indentation.
2. Inspect all controls, plug-in modules, push-buttons and switches. Check for loose knobs, controls that are difficult to adjust, plug-in modules that cannot be correctly seated and switches that cannot be securely thrown.
3. Inspect all connectors. Check that none are missing and examine cables, plugs and sockets for evidence of damage.
4. Inspect all accessories such as remote handling devices, source holders, well liners and ^{99}Mo breakthrough kits. Check that none are missing or damaged.
5. Check any accompanying sealed radiation sources for external radioactive contamination or leakage.
6. Check that both operation and service manuals are available.
7. Note the location of all fuses and check that replacements are available.
8. Check the compatibility of the power supply requirements with the available supply and make any necessary adjustments.
9. Note the location of any container for drying agent and check the condition of the agent. If it shows a high water content, remove, oven-dry and replace it.
10. Initiate the instrument log-book, making an inventory of the instrument and its accessories and recording their condition on receipt, with particular reference to any damage, deficiencies or flaws and the action taken to correct them.

Data Analysis

Visual test & electrical safety test.

Result

No.	Visual inspection of component	Pass/Fail	Comments
1.	Room temperature, humidity		
2.	Room cleanliness		
3.	Physical & Mechanical Inspection		
	a) Chamber		
	b) Electrometer Display/ Screen		

	c) Cable / wire		
	d) Printer		
	e) Well liner (Chamber insert)		
	f) Dipper (Source holder)		
	g) Check source		
	h) Button control		
	i) QC Tools (if applicable)		
4.	System function		
	a) Display reading (Ci/Bq)		
	b) Number display		

Tolerance No component of the system is malfunction or not proper installed.

Test Acceptance
Frequency Daily (Each day of use)
Annually

TEST PARAMETER 2: ACCURACY AND PRECISION

Test Parameter **Accuracy And Precision**

Objective To test the accuracy and precision of a radionuclide calibrator in activity measurements in standard geometry at selected gamma-radiation energies.

Test Tool

1. Sealed low, medium and high energy gamma radiation sources (standard vial type), certified to ± 5% overall uncertainty or less, e.g.:

Radionuclide	Principal photon energies	Half-life	Activity
^{57}Co	122 keV	271 d	185 MBq (5 mCi)
^{133}Ba	81, 356 keV	10.7 y	9.3 MBq (250 uCi)
^{137}Cs	662 keV	30.0 y	7.4 MBq (200 uCi)
^{68}Ge (optional)	511 keV	271 d	37 MBq (1 mCi)

Note:

a) It is recommended that the ^{137}Cs and ^{133}Ba sources be replaced when the activity is below 100 µCi. It is recommended to replace a ^{57}Co source when the activity is less than 1 mCi. Certificate of the source should be kept.
b) For centre using ^{18}F, ^{68}Ge calibration source is recommended to be used.
c) Calibration sources used should have similar photon energy with the radioisotope used for clinical procedures.

2. Source holder.

3. Remote handling device for sources

Test Procedure

For each gamma-radiation source in turn:

1. Select the operational conditions appropriate to the radionuclide concerned.

2. Insert the source into the source holder by means of the remote handling device and introduce the source holder into the instrument.

3. Allow sufficient time for the reading to stabilize.

4. Measure and record the activity for at least 3 readings, subtracting the background reading if necessary.

5. Repeat step 4 to a total of 10 successive measurements with lapse time of half an hour for each measurement.

6. Remove the source holder from the instrument and extract the source by means of the remote handling device.

Note: the background reading to be subtracted from subsequently measured activities. Alternatively, if an adjustable zero control is provided, adjust this for zero reading.

Data Analysis

1. To assess accuracy, calculate for each source the percentage difference between the mean measured activity, Ā, and the certified activity, C, of the source corrected for radioactive decay to the day of measurement that is:

$$((\bar{A} - C) / C) \times 100$$

2. To assess precision, calculate for each source the percentage differences between the individual measured activities, A_i, and their mean Ā, that is:

$$((A_i - \bar{A}) / \bar{A}) \times 100$$

Result

Type of Source : _____
Activity initially (Ci or Bq) : _____ on _____
Half-life : _____ years

Data for Precision Test

No. of reading or set time	Activity, A_i (Ci or Bq)	Activity, A_i (Ci or Bq)	Activity, A_i (Ci or Bq)	[Ave A_i (A_{im}) – Bkg] (Ci or Bq)	Ave A_m	100[(A_i - A_m) / A_m]
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						

Background Readings (Ci or Bq)					
Mean Value (Ci or Bq)					

Data for Accuracy Test

Certified Activity, C will be:

$$A_i = A_o\, e^{-\lambda t} \quad \text{where, } \lambda = 0.693 / t_{½}$$

% different between measured and certified activity is

$$\frac{(A_m - C)}{C} \times 100\ \%$$

Record whether or not the results confirm acceptable performance. If not, indicate follow-up action taken.

Tolerance The accuracy is within ± 10%.

The precision of individual measured activities is within ± 5%.

Test Frequency Acceptance
Annually

TEST PARAMETER 3: LINEARITY OF ACTIVITY RESPONSE

3.1 Decaying Source Method

Test Parameter Objective

To test the linearity of the activity response of a radionuclide calibrator over the range of activities for which it is to be used.

Test Tool

1. Short-lived radionuclide (^{99m}Tc or ^{131}I or ^{18}F) in solution, initial activity equal to or greater than the highest activity for which the instrument is to be used (e.g. 1110 MBq (30 mCi)).
2. Sample vial.
3. Remote pipetting device.
4. Source holder.
5. Remote handling device for sample vial.
6. Log linear graph paper (3 or 4 cycle)

Test Procedure

1. Transfer the radionuclide solution to the sample vial by means of the remote pipetting device. Cap the vial firmly.
2. Select the operational conditions appropriate to the radionuclide concerned.
3. Insert the sample vial into the source holder by means of the remote handling device and introduce the source holder into the instrument.
4. Allow sufficient time for the reading to stabilize with lapse time of an hour for each measurement (^{99m}Tc).
5. Measure and record the activity, subtracting the background reading if necessary. Record the exact time of day corresponding to the measurement.
6. Remove the source holder from the instrument and extract the sample vial by means of the remote handling device.
7. Repeat steps 2 - 6 regularly over a period several times greater than the physical half-life of the radionuclide, sufficient for the source to decay to an activity equal to or less than the lowest activity for which the instrument is to be used.

   Note: the background reading to be subtracted from subsequently measured activities. Alternatively, if an adjustable zero control is provided, adjust this for zero reading.

Data Analysis

1. Record the results on a graph showing measured activity against lapsed time on 3 or 4 cycle log linear paper (Figure 1).
2. With the aid of a transparent ruler, fit the best straight line possible to the data points in the lower activity region. Extrapolate this line upward to obtain an activity value corresponding to the time of the initial reading measurement.

3. Check the negative slope of the line to ensure that it is consistent with the known physical half-life of the radionuclide. This may conveniently be done by dividing the time for the measured activity to fall to 1/10 of its initial value, determined in step 2, by 3.32 and comparing the result with the physical half-life.

4. Examine the graph for systematic departures of the data points from the fitted straight line; such discrepancies indicate non-linearity of the activity response of the instrument.

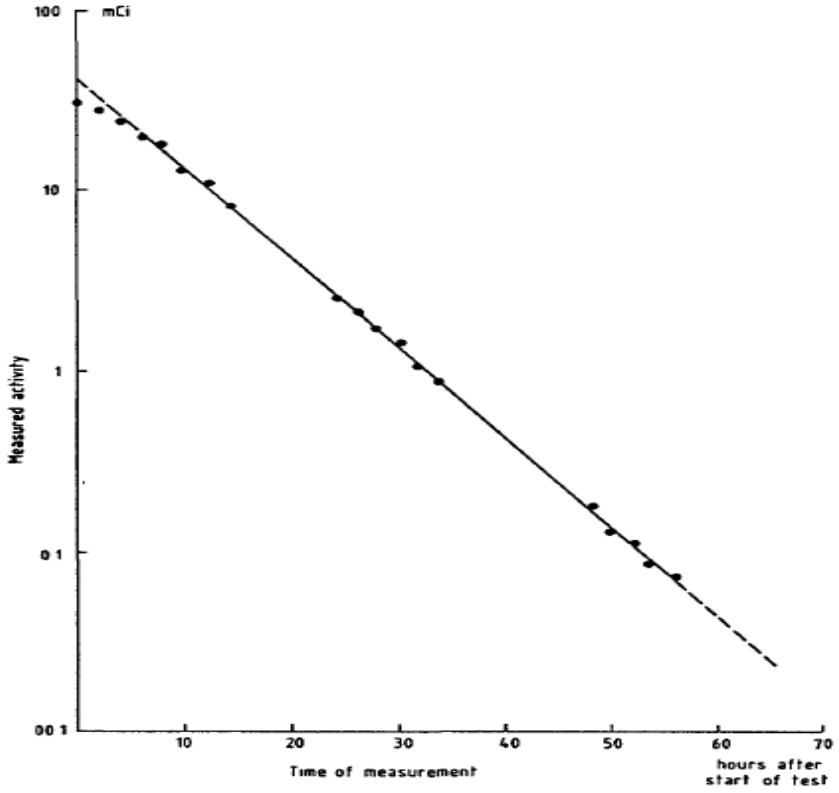


Figure 1: Test of Linearity of Activity Response: Decaying Source Method. A ^{99m}Tc source having an initial activity of 1.5 GBq (41 mCi) was used. Non-linearity is apparent in the upper part of the graph.

Result

Manufacturer of Dose Calibrator: _____
Model of Dose Calibrator: _____
Radionuclide use for routine reproducibility checks: _____
Initial Activity: _____

Radio nuclide	Calibration			Measurement		Activity corrected for decay (Ci or Bq)	Measured Source Activity (Ci or Bq)			
	Activity (Ci or Bq)	Date	Time (hr)	Date	Time (hr)		Min	Max	Mean	% Error

Note: Using the above data to plot graph.

Tolerance	The linearity is within ± 10% of the values corresponding to the straight line fitted to the data points.
Test Frequency	Acceptance Annually

Test Parameter **3.2 Graded Sources Method (Optional)**

Objective

To test the linearity of the activity response of a radionuclide calibrator over the range of activities for which it is to be used.

Test Tool

1. Radionuclide of moderate half-life (e.g. ^{131}I) in solution, activity equal to or greater than twice the highest activity for which the instrument is to be used (e.g. 7.4 GBq (200 mCi)).
2. Sample vial.
3. Remote pipetting device.
4. Source holder.
5. Remote handling device for sample vial.
6. Log linear graph paper (2 or 3 cycle).

Test Procedure

Caution: The extensive handling of a large amount of radioactive material in this method necessitates the use of gloves, radiation shields and remote pipetting and handling devices. If ^{131}I is used, it must be pipetted and stored for decay in a fume hood with adequate air flow. If these protective devices are not available, do not proceed.

1. Pipette into a series of sample vials by means of the remote pipetting device decreasing volumes of the radionuclide solution, with activities covering the range of interest (e.g. 10, 5, 2, 1, 0.5, 0.2, 0.1 ml of a solution having an activity about 370 MBq/ml (10 mCi/ml)). Bring up the total volume in each vial to constant volume (e.g. 20 ml) with water. Cap the vials firmly.
2. Select the operating conditions appropriate to the radionuclide concerned.
3. Note the background reading to be subtracted from subsequently measured activities. Alternatively, if an adjustable zero control is provided, adjust this for zero reading.
4. Insert the sample vial having the highest activity into the source holder by means of the remote handling device and introduce the source holder into the instrument.
5. Allow sufficient time for the reading to stabilize.
6. Measure and record the activity, subtracting the background reading if necessary.
7. Remove the source holder from the instrument and extract the sample vial by means of the remote handling device.
8. Repeat steps 4 – 7 for each of the other sample vials in turn.

Data Analysis

1. Record the results on a graph showing measured activity against volume of radionuclide solution on 2 or 3 cycle log-log paper (Figure 2).

2. With the aid of a transparent ruler, fit the best straight line possible to the data points in the lower activity region.

3. Extrapolate the line to cover the full range of measured activities.

4. Examine the graph for systematic departures of the data points from the fitted straight line; such discrepancies indicate non-linearity of the activity response of the instrument.

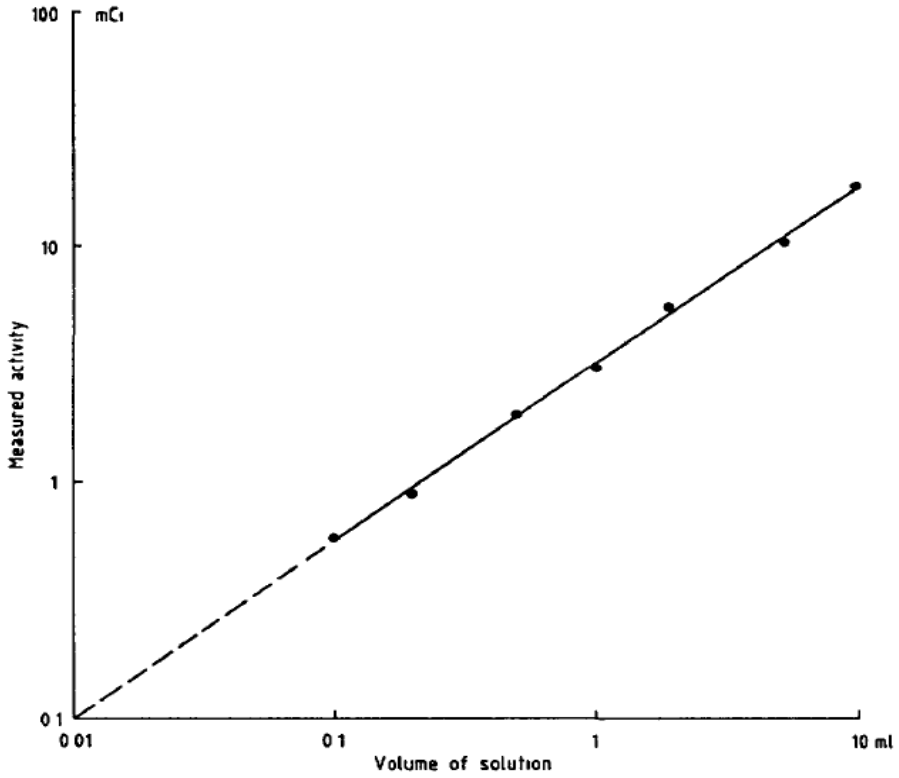


Figure 2: Test of Linearity of Activity Response: Graded Sources Method. The sources were prepared from a solution of having an activity concentration of 78 MBq/ml (2.1 mCi/ml).

Result Record the results.

Tolerance The linearity is within ± 10% of the values corresponding to the straight line fitted to the data points.

Test Frequency Acceptance
Annually

TEST PARAMETER 4: BACKGROUND RESPONSE

Test Parameter **Background Response**

Objective To test the background response of a radionuclide calibrator under conditions in which any increase in response is most readily observable.

Test Tool Not applicable.

Test Procedure

1. Select operational conditions appropriate to any chosen radionuclide with a low rate of emission of photon energy as evidenced by a low gamma-radiation dose constant (for example; press the ^{51}Cr and ^{133}Xe button).
2. Record the background reading in activity units of the radionuclide concerned. Alternatively, if an adjustable zero control is provided, adjust this for zero reading and record its setting.

Data Analysis Record whether or not the results confirm acceptable performance. If not, indicate follow-up action taken.

Result

Setting button	Reading 1 (Ci or Bq)	Reading 2 (Ci or Bq)	Reading 3 (Ci or Bq)	Average (Ci or Bq)
^{51}Cr				
^{133}Xe				

Tolerance While specific limits of acceptability cannot be laid down for the results of the test, an increase in background response of 20% or greater would call for further investigation.

Test Frequency Acceptance
Daily (Each day of use)

TEST PARAMETER 5: OPERATIONAL CHECKS OF REPRODUCIBILITY (CONSTANCY)

Test Parameter		**Operational Checks Of Reproducibility (Constancy)**
Objective		To check the day-to-day reproducibility of performance of a radionuclide calibrator in measurements on standard calibration source.
Test Tool	1.	Long-lived sealed medium-energy gamma-radiation source, activity about 7.4 MBq (200 µCi). ^{133}Ba or ^{137}Cs source is suitable. A certified source may be used, through the manner of its use does not require that its activity be known.
	2.	Source holder.
	3.	Remote handling device for source.
Test Procedure	1.	Select the operating conditions appropriate to the radionuclide in most common use (e.g. ^{133} Ba or ^{137}Cs).
	2.	Insert the gamma-radiation source into the source holder by means of the remote handling device and introduce the source holder into the instrument.
	3.	Allow sufficient time for the reading to stabilize.
	4.	Measure and record the apparent activity, subtracting the background reading if necessary.
	5.	Remove the source holder from the instrument and extract the source by means of the remote handling device.
	6.	Repeat steps 1 - 5 until 3 successive measurements achieved.
	7.	The procedure should then be carried out on the following day.
Data Analysis	1.	Record the results on a control chart showing apparent activity plotted against date.
	2.	Results on successive days should be closely distributed about a straight line corresponding to the radioactive decay of the source. An initial point on this line may be established as the mean of ten replicate measurements on the day concerned.
	3.	The negative slope is determined by the physical half-life of the radionuclide constituting the source. For the purpose of the test, decay may be considered linear over a period short compared with the half-life (e.g. 1 year).
	4.	Limits of acceptability may be indicated by two other straight lines parallel to the first, but respectively above and below it at a distance determined by the precision of the instrument as specified by the manufacturer (e.g. ± 5% of expected activity). If an individual result lies outside these limits, this may be taken to indicate faulty performance.

Result

Date: _____
Calibration source: _____

No. of reading	1	2	3	Average
Data (Ci or Bq)				

Tolerance

The reproducibility of performance should be such that all individual measured activities are within ± 5% of the mean measured activity, provided that radioactive decay has a negligible effect over the measurement period.

IAEA recommended for repair or replacement if the error exceed 10%.

Test Frequency

Acceptance
Daily (Each day of use)
Annually

TEST PARAMETER 6: GEOMETRIC VARIATION OF SOURCES WITHIN ACTIVE MEASUREMENT VOLUME

Test Parameter **6.1 Syringe Test**

Objective

This test is designed to show that correct readings can be obtained regardless of the sample size or geometry.

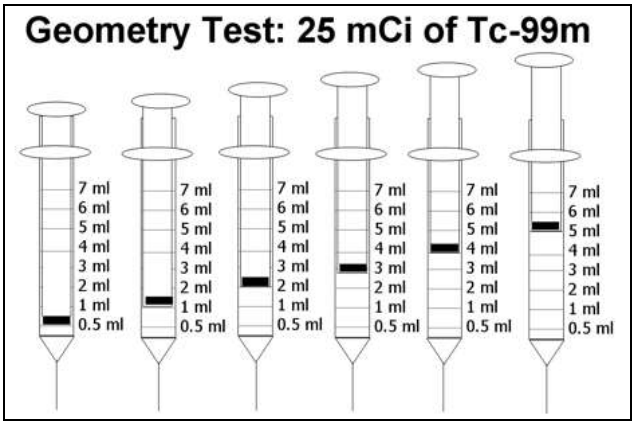
Test Tool

1. ^{99m}Tc (10 mCi) or ^{18}F (10 mCi).
2. Syringe (10 ml).
3. Saline solution.

Test Procedure

1. In a small vial, mix 2.0 ml of a solution of ^{99m}Tc with an activity concentration between 1 and 10 mCi/ml.
2. Set out a second small vial containing non-radioactive saline solution.
3. Draw 0.5 ml of the ^{99m}Tc solution into the syringe and assay it.
4. Record the volume and activity of the first assayed sample.
5. Remove the syringe from the calibrator, draw an additional 0.5 ml of non-radioactive saline into the same syringe (total volume 1.0 ml) and assay again. Record the volume and measured activity on the table.
6. Repeat step 5 twice more until you have assayed 1.5 ml and 2.0 ml volumes and recorded them.
7. Assay the vial used to draw saline into the syringe. If the measured activity is greater than 1% of the 0.5 ml syringe assay, ^{99m}Tc was lost during filling. Repeat the procedure.
8. Divide the average activity by the activity indicated for each volume. The quotient is a volume correction factor.
9. If any correction factors are greater than 1.05 or less than 0.95, it will be necessary to make a correction table that will allow you to convert from “indicated activity” to “true activity”. If this is necessary, be sure to label the table “syringe geometric dependence”, and note the date of the test as well as the model number and serial number of the dose calibrator.

Data Analysis



The following table displays the sample data collected during a Geometry Test. The dose calibrator has passed the test.

Sample Volume	Activity (mCi)
0.5	25.5
1.0	25.3
2.0	25.0
3.0	24.8
4.0	24.7
5.0	24.5
6.0	24.4

Result

Model: _____ Serial Number: _____

Syringe Test	Type____	Volume____	Decay correct if test not completed in 10 min	
Date	**Time**	**Volume**	**$(Activity)_v$**	**Volume cf = Avg/$(Activity)_v$**
		Average		

Tolerance

If the difference of various readings of the same activity exceeds ± 10% because of different geometric configurations, a correction should be carried out.

Test Frequency

Acceptance

Whenever dose calibrator system performance is suspected to have changed significantly.

Test Parameter	**6.2**	**Vial Test**
Objective		This test is designed to show that correct readings can be obtained regardless of the sample size or geometry.
Test Tool	1.	^{99m}Tc (10 mCi) or ^{18}F (10 mCi).
	2.	Vial (20 ml or 30 ml).
	3.	Saline solution.
Test Procedure	1.	It therefore is necessary to perform this test on every different vial used (e.g., 10 ml, 30 ml) as well as every different syringe used (e.g., 1 ml, 3 ml, 5 ml, 10 ml).
	2.	For example, to test a 10 ml syringe for linearity, one first places 1.0 ml of ^{99m}Tc in a 10 ml syringe.
	3.	The activity is then measured in the dose calibrator and the value obtained is recorded.
	4.	The activity is then diluted with water to 2.0 ml, 3.0 ml, 4.0 ml, 5.0 ml, etc, up to 10 ml.
	5.	At each of these points a reading is taken and the value recorded.
	6.	Data are then evaluated to determine the effect of sample geometry on the dose calibrator reading.
	7.	If the instrument is geometry-dependent, ideally one should notify the manufacturer that the calibrator has failed acceptance testing and a new calibrator should be requested.
	8.	If the decision is made to keep the instrument, it may be necessary to routinely correct readings obtained when using calibrator.
	9.	To check the background response of a radionuclide calibrator under the operational conditions appropriate to a particular radionuclide.

Result Model: _____ Serial Number: _____

Vial Test	Type____	Volume____	Decay correct if test not completed in 10 min	
Date	**Time**	**Volume**	**$(Activity)_v$**	**Volume cf = Avg/$(Activity)_v$**
		Average		

Tolerance If the difference of various readings of the same activity exceeds ± 10% because of different geometric configurations, a correction should be carried out.

Test Acceptance

Frequency Whenever dose calibrator system performance is suspected to have changed significantly.

GAMMA COUNTER / WELL COUNTER / THYROID UPTAKE SYSTEM

TEST PARAMETER 1: PHYSICAL INSPECTION

Test Parameter **Physical Inspection**

Objective To check for any damage to the counter, measuring unit, and cables.

Test Tool Not applicable.

Test Procedure

1. Inspect the instrument housing for evidence of damage.
2. Inspect all controls.
3. Check for loose knobs.
4. Inspect all connectors. Check that none are missing and examine cables.

Note: Check the compatibility of the power supply requirements with the available supply and make any necessary adjustments. Initiate the instrument log-book, making an inventory of the instrument and its accessories and recording their condition on receipt, with particular reference to any damage, deficiencies or flaws and the action taken to correct them (For acceptance only).

Result

No.	Visual inspection of component	Pass/Fail	Comments
1.	Room temperature, humidity		
2.	Room cleanliness		
3.	Physical & Mechanical Inspection		
	a) Chamber		
	b) Electrometer Display/ Screen		
	c) Cable / wire		
	d) Printer		
	e) Well liner (if applicable)		
	f) Check source		
	g) Button control/ Keyboard		
	h) QC Tools (if applicable)		
4.	System function		
	a) Display reading		
	b) Number display (if applicable)		

Tolerance No damage.

Test Frequency Acceptance
Daily (Each day of use)

TEST PARAMETER 2: AUTO CALIBRATION OR DAILY TEST (IF APPLICABLE)

Test Parameter	**Auto Calibration Or Daily Test (If Applicable)**
Objective	To monitor the stability of resolution over time.
Test Tool	^{137}Cs and ^{152}Eu (optional) standard sources.
Test Procedure	1. The calibration is performed with ^{137}Cs where the procedure makes use of its 662 keV and the 32 keV peaks to automatically adjust the high voltage, gain and zero offset to provide a calibration of approximately 2.0 keV per channel in the MCA. 2. Next, ^{152}Eu provides multiple gammas over an energy range of 41 keV to 1408 keV. 3. This test also calculates detector resolution by determining the FWHM (full width-half maximum) area of the peak and dividing by the peak centroid location. 4. For peaks such as the 662 keV peak of ^{137}Cs whose shape is symmetrical or appears to follow a Gaussian distribution, the FWHM is generally close to 2.35 σ. 5. For flat-faced detectors the resolution should be ≤ 8 percent measured at the ^{137}Cs 662 keV peak. For well detectors the resolution should be ≤ 8.5 percent.
Result	Based on manufacturer results.
Tolerance	Manufacturer's specifications.
Test Frequency	Acceptance Daily (Each day of use)

TEST PARAMETER 3: CONSTANCY

Test Parameter	**Constancy**
Objective	The sensitivity of well counters and NaI(Tl) probes can be diminished because of voltage drift. To detect such a sensitivity reduction constancy of the system must be checked.
Test Tool	A long-lived source, such as ^{137}Cs or ^{57}Co.
Test Procedure	1. The count rate is influenced by geometric variations; measurements have to be performed under the same conditions. 2. As an alternative, measurements sensitivity can be determined.
Result	Based on manufacturer results.
Tolerance	Manufacturer's specifications.
Test Frequency	Acceptance Daily (Each day of use)

TEST PARAMETER 4: ISOTOPE EFFICIENCY (SENSITIVITY)

Test Parameter	**Isotope Efficiency (Sensitivity)**
Objective	If the absolute activity of the measured sample is necessary, the sensitivity measurements for the gamma ray energy of interest must be determined using a standard of the radioactive sample with known activity. This correction factor can be applied to the count-rates of samples of unknown radioactivity when counted at the same settings as the standard to give the absolute activity.
Test Tool	A standard of the radioactive sample with known activity.
Test Procedure	1. The count-rate with known activity should be determined using a measurement time of one minute. The result should be given in counts / minute*MBq. Since the count-rate varies with sample size, sensitivity should be given for a 1 ml sample. 2. Measurements sensitivity should be determined for each isotope used. 3. For isotopes with a short half-life the radioactive decay between the timings of the dose calibrator and probe measurements must be considered. 4. If measurements sensitivity is determined instead of constancy check, only the isotope, which is used with the highest frequency, needs to be assessed. 5. At installation, a reference value for each used isotope must be determined.
Result	Based on manufacturer results.
Tolerance	Manufacturer's specifications.
Test Frequency	Acceptance Quarterly or Semi-Annually

TEST PARAMETER 5: CHI-SQUARE

Test Parameter **Chi-square**

Objective The readings of repeated measurements must not exceed statistical variations. This can be checked by chi-square statistics.

Test Tool ^{137}Cs source.

Test Procedure

1. For a minimum of ten measurements (n) of the same source, the mean value (*N)* of the measured counts (*Ni*) must be calculated.

2. Each measurement should reach a minimum of 10,000 counts. Using these values, chi-square can be calculated:

$$X^2 = \frac{\sum_{i=1}^{n}(N_i - \bar{N})^2}{\bar{N}}$$

3. Interpreting the Chi-Square results – Chi-Square values are given in the following table for 5, 10, 15 and 20 repetitions. The Chi-Square results should fall between the 0.95 and 0.05 probability values in the table below almost all of the time. The more stringent 0.90 and 0.01 values are given for reference.

Number of Repetitions	0.95	0.90	0.10	0.05
5	0.711	1.06	7.78	9.49
10	3.33	4.17	14.7	16.9
15	6.57	7.79	21.1	23.7
20	10.1	11.7	27.2	30.1

Result Based on manufacturer results.

Test	Counts
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	

Chi-Square value: _____

Tolerance Manufacturer's specifications.

Test Frequency Acceptance
Manufacturer's recommendations

GAMMA PROBE

TEST PARAMETER 1: PHYSICAL INSPECTION

Test Parameter **Physical Inspection**

Objective To check for any damage to the probe, measuring unit, and cables.

Test Tool Not applicable.

Test Procedure

1. All components should be regularly checked for signs of physical damage.
2. In particular the probe and collimators should be checked for nicks, cracks and chips that would indicate damage or deterioration of the outer surfaces. Surface cracks and chips could lead to a loss of shielding or ingress of moisture.
3. Signs of damage to the probe tip could indicate physical shock to the probe, which may result in a loosening of the detector crystal with loss of directional properties, shift in spectral response or change in sensitivity.
4. Take particular care to examine for any cracks or sharp edges which could lead to biological contamination or result in tears in the sterile sheath during surgery.
5. The cables and connectors should be examined for damage such as nicks, exposed wires, crushed sections and loss of insulation.
6. It is important to consider aspects of electrical safety and the possibility of electric shock even from battery powered units which may operate at several hundred volts to the probe.
7. Equipment with any exposed wiring or damage to the insulation should be taken to the hospital medical equipment servicing unit or returned to the manufacturer for repair.

Note: Electromechanical tests are then typically carried out before other types of test.

Result

No.	Visual inspection of component:	Pass/Fail	Comments
1.	Probe		
2.	Display unit		
3.	Cable		
4.	Collimator shield (if applicable)		
5.	Battery		
6.	Check source		
7.	Bluetooth/ dongle		

Tolerance	Functional and according to manufacturer specification.
Test Frequency	Acceptance Before clinical use

TEST PARAMETER 2: DISPLAY AND SOUND

Test Parameter **Display And Sound**

Objective All kinds of display have to be adapted to the special situation in an operation cabinet.

Test Tool Not Applicable

Test Procedure

1. An acoustic display should enable the user to visually concentrate to the operation field during measurement.
2. Therefore a clear correlation between the acoustic tone and the measurement signal has to be available.
3. For the quantitative results either a digital or analogue display is necessary which has to be clearly readable from at least 2 m distance.
4. To cope with the statistical variation and to influence the inertia of the display measurement interval respectively time constant should be adjustable.

Result

Inspection	Pass/Fail	Comment
Sound Acoustic		
Digital display or Analogue		

Tolerance

Sound Acoustic: Good correlation between measurement signal and tone.

Digital Display : Continuous display reading with adjustable measurement time interval.

or

Analogue : Suitable measurement interval with adjustable time constant.

Test Frequency Acceptance
Before clinical use

TEST PARAMETER 3: SPATIAL SELECTIVITY AND SPATIAL RESOLUTION

Test Parameter **3.1** **Spatial Selectivity: Radial Sensitivity Distribution (Far-Field)**

Objective

To test the spatial resolution of a gamma probe in terms of the FWHM.

Test Tool

1. ^{99m}Tc point source (less than 3.7 MBq (100 µCi)).
2. Centrifuge tube.

3. Graph paper.
4. Geometry set.
5. Ruler.
6. Cardboard paper.
7. Collimator.

Test Procedure

1. The sensitivity distribution is evaluated equidistant to the measurement area (frontal radiation entrance window) dependant on the polar angle.
2. Variations of the distribution with the distance are mainly due to the relative position of radiation entrance window and detector crystal.
3. The radial sensitivity distribution at 1 cm to 30 cm distance (far field) describes the width of the measurement cone out of which radiation is detected.
4. The full width at half maximum (FWHM) of the distribution function is a good quality criterion for the detectability of lymph nodes in presence of non target radiation (injection depot, background).
5. With a broad measurement cone the background signal can exceed the target signal of the lymph node, which then cannot be detected.
6. A small cone mainly reduces background maintaining a constant target signal [Figure 1].
7. Therefore with increased background in the target area (e.g. mamma carcinoma, prostate carcinoma) a smaller FWHM of radial sensitivity distribution is desired.

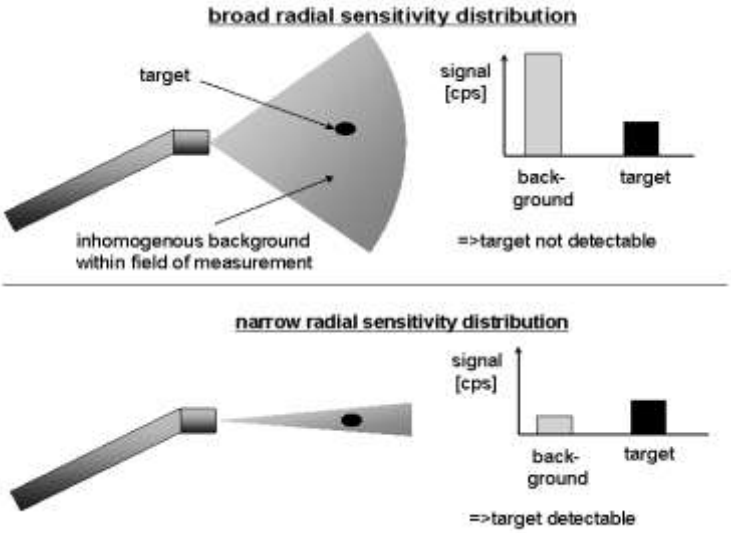


Figure 1: Radial sensitivity distribution and detectability of a lymph node.

Result Draw a graph of counts versus angle using graph paper.

	FWHM
Spatial Selectivity	^{o}

Tolerance FWHM ≤ 40^{o} or manufacturer's specifications.

Test Frequency Acceptance
Annually

Test Parameter 3.2 Spatial Resolution: Lateral Sensitivity Distribution

Objective To test the spatial resolution of a gamma probe in terms of the FWHM.

Test Tool

1. ^{99m}Tc point source (less than 3.7 MBq (100 µCi)).
2. Centrifuge tube.

3. Graph paper.
4. Geometry set.
5. Ruler.
6. Cardboard paper.
7. Collimator.

Test Procedure

1. The spatial resolution (lateral sensitivity distribution) can be determined if a probe is scanned laterally above a Tc-99m point source.
2. The FWHM gives the minimal distance (10 cm) at which two point sources (lymph nodes) can be detected separately [Figure 2].

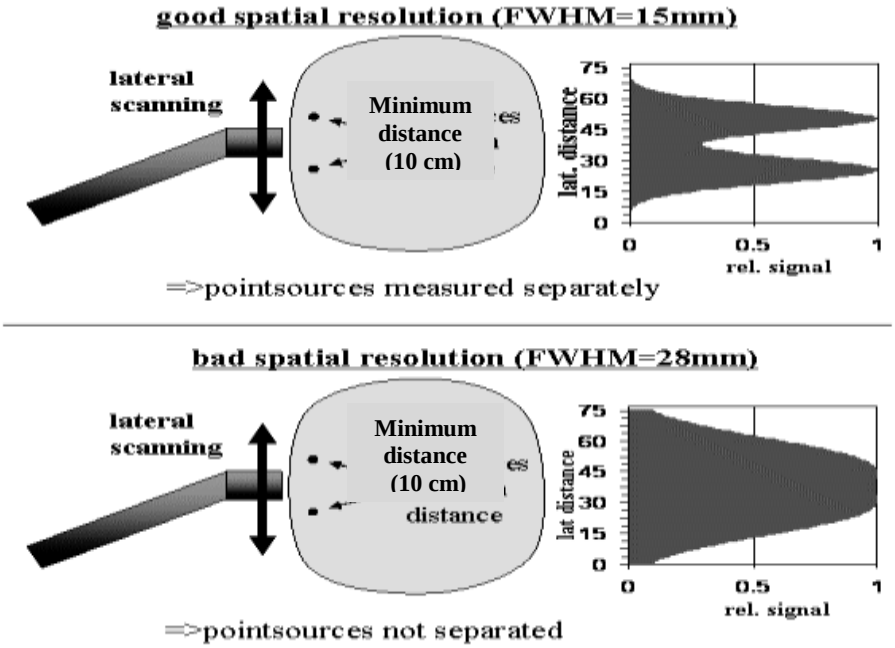


Figure 2: Resolution and separation of two lymph nodes.

3. Spatial resolution depends on the distance between source and probe crystal. For comparison and simplification we measured at a minimal distance of 1 cm to the front end of the probe which is inside the variation of true lymph node depth.

4. To separate neighbouring lymph nodes and perform an adequate exact localization the FWHM of the lateral sensitivity distribution should be better than the typical distance between neighbouring lymph nodes or a typical node diameter in the preparation region.

5. Therefore we recommend a spatial resolution better than 25 mm for lymph nodes in the axilla, inguinal and illiacal region. Increased requirements have to be set up for lymph nodes that are close together (e.g. in the head-, neck- and supraclavicular region).

6. Probes or probe/collimator combinations for these applications should have a FWHM of less than 15 mm.

Result Draw a graph of counts versus angle using graph paper.

	FWHM
Spatial Resolution	mm

Tolerance FWHM ≤ 15 mm or manufacturer's specifications.

Test Frequency Acceptance
Annually

TEST PARAMETER 4: SENSITIVITY

Test Parameter **Sensitivity**

Objective To demonstrate that the count rate detected by the system is reproducible over time given that all the equipment settings are constant.

Test Tool

1. ^{57}Co (in the form of a “pencil marker” or “disk marker”) or ^{99m}Tc.
2. Stopwatch.
3. A perspex test block (optional).

Test Procedure

1. All system settings should be set as for routine clinical use, including the energy window.
2. Users should note that this means that the ^{57}Co test source is being counted with the window set to ^{99m}Tc, that is, an “Incorrect” window. This is justified since the energy window for ^{99m}Tc will overlap with the ^{57}Co photopeak for all current probes, and so a detectable count rate will be obtained. Changes in the sensitivity within the ^{99m}Tc window will therefore still be detected with this arrangement, though it is possible that future probes will have narrower energy windows and so will not give sufficient counts – refer to the manufacturer if in doubt. Note that the use of the standard clinical energy window setting also reduces the risk of the probe energy window being left set on ^{57}Co after the QA check.
3. A timed period of counting to measure a minimum of 5,000 counts should be set and the counts per second recorded. Note that some systems may only allow a short fixed counting time (say 10 seconds), in which case it may be necessary to repeat this count interval several times to collect a total of at least 5,000 counts.
4. Deviation of a control reading from the mean of more than 2 standard deviations (sd) should occur less than 5 % of the time; repeat the measurements if this occurs and if the reading is more than 2 sd from the reference mean value take investigative action. Note that the expected value (the “reference mean value”) should be established when the QA programme is first set up.
5. Obtain a measure of the sensitivity with exactly same set up as for routine checking, recording at least 10,000 counts in a set time. Calculate the count rate (cps) and record this as the reference value. This reference value must be corrected as the standard source decays (Co-57 has a half life of 270 days).
6. Faults may be indicated by either a fall in counts (less sensitive) or a rise in count rate (more sensitive), and all changes in sensitivity, both gain or loss, must be investigated.

7. The probe is placed vertically in a drilled hole on the upper surface with the detector face directly above the tip of a Co-57 pencil source inserted into a second drilled hole [Figure 3].

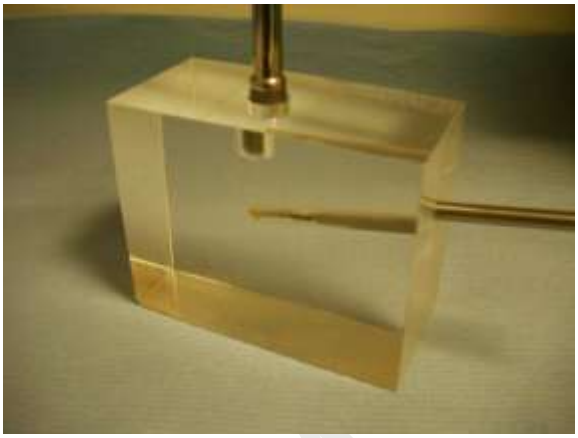


Figure 3: A Perspex test block suitable for the measurement of probe sensitivity.

8. The distance between the probe tip and the pen tip is about 30 mm.

Note: Method could be based on manufacturer recommendation.

Result

Pulse rate	cps
Activity	kBq
Pulse rate/activity	cps/kBq

Tolerance

Within ± 10% of acceptance value
or
≥ 5 cps/kBq

Test Frequency

Acceptance
Annually

TEST PARAMETER 5: SHIELDING

Test Parameter **Shielding**

Objective To check any leakage of the probe.

Test Tool ^{99m}Tc point source (less than 29.6 MBq (0.8 mCi)).

Test Procedure

1. Out of constructional reasons the shielding of a probe mostly has a weak area.
2. A high background source (e.g. injection spot at mamma- or prostate-carcinoma) in the direction of such a leakage can lead to false orientation [Figure 4].
3. The lymph node should produce a higher signal than any background source.
4. Assuming an uptake of 0.1% for a lymph node the leak sensitivity should not exceed 0.1% of the system sensitivity.

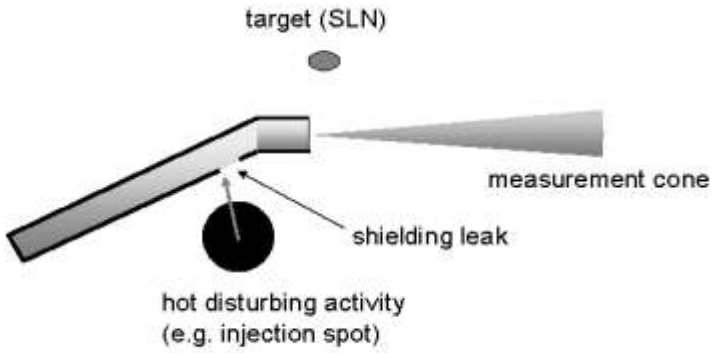


Figure 4: Apparent SLN in the measurement cone by background activity nearby a shielding leak.

Result

Count	1	2	3	4	5	Average
Position 1						
Position 2						

Maximum average count = _____
Count when the source at the opening of the probe = _____
Percentage of shielding leakage = _____

Tolerance ≤ 0.1 % of maximum system sensitivity.

Test Frequency Acceptance
Annually

TEST PARAMETER 6: ENERGY SELECTION (WHERE APPLICABLE)

Test Parameter **Energy Selection (Where Applicable)**

Objective To ensure that the operating energy window is centred on the photopeak. With the presence of scatter medium and high background activity compton photons produce an additional blurring of the spatial information. Energy discrimination that separates compton and photopeak signal is therefore important.

Test Tool Not Applicable

Test Procedure

1. The standard procedure for sentinel node detection uses ^{99m}Tc labelled colloid, and so the ^{99m} Tc isotope energy window must be set on the analyzer following the manufacturer's instructions.
2. It is crucial that the correct setting is used for all surgical procedures.
3. The same window must be used for all QA procedures to ensure reproducibility between QA measurements, and if a non ^{99m}Tc window is set for QA, say to match a ^{57}Co check source, then the person performing the QA must take particular care to re-set the window to ^{99m}Tc.
4. Changes to the energy window will be reflected in the sensitivity checks, so there is no recommended separate test of the energy window.
5. Some systems may allow more detailed inspection of the energy window and/or the spectrum of detected events, and the manufacturer's procedures should be followed to apply these tests.

Result Compton/photopeak discrimination; check of energy selection possible.

Window setting	Count 1 (cpm)	Count 2 (cpm)	Count 3 (cpm)	Average count
^{57}Co - Threshold: 112 keV - Window: 20 keV				
^{99m}Tc - Threshold: 130 keV - Window: 40 keV				
Percentage difference between both setting				

* Threshold: Base reading

Tolerance Manufacturer's specifications.

Test Frequency Acceptance
Before clinical use
Annually

E. Performance and Safety Standards

PERFORMANCE AND SAFETY STANDARDS FOR NON-IMAGING EQUIPMENTS

QC Tests for Dose Calibrator

No.	Test Parameter	Tolerance	Frequency
1.	Physical Inspection	No component of the system is malfunction or not proper install	Acceptance Daily (Each day of use) Annually
2.	Accuracy And Precision	The accuracy is within ± 10% The precision of individual measured activities is within ± 5%	Acceptance Annually
3.	Linearity Of Activity Response 3.1 Decaying Source Method 3.2 Graded Sources Method (Optional)	The linearity is within ± 10% of the values corresponding to the straight line fitted to the data points	Acceptance Annually
4.	Background Response	While specific limits of acceptability cannot be laid down for the results of the test, an increase in background response of 20% or greater would call for further investigation	Acceptance Daily (Each day of use)
5.	Operational Checks Of Reproducibility (Constancy)	The reproducibility of performance should be such that all individual measured activities are within ± 5% of the mean measured activity, provided that radioactive decay has a negligible effect over the measurement period IAEA recommended for repair or replacement if the error exceed 10%	Acceptance Daily (Each day of use) Annually
6.	Geometric Variation Of Sources Activity Within Active Measurement Volume 6.1 Syringe Test 6.2 Vial Test	If the difference of various readings of the same activity exceeds ± 10% because of different geometric configurations, a correction should be carried out	Acceptance Whenever dose calibrator system performance is suspected to have changed significantly.

QC Tests for Gamma Counter / Well Counter / Thyroid Uptake System

No.	Test Parameter	Tolerance	Frequency
1.	Physical Inspection	No damage	Acceptance Daily (Each day of use)
2.	Auto Calibration Or Daily Test (If Applicable)	Manufacturer's specifications	Acceptance Daily (Each day of use)
3.	Constancy	Manufacturer's specifications	Acceptance Daily (Each day of use)
4.	Isotope Efficiency (Sensitivity)	Manufacturer's specifications	Acceptance Quarterly or Semi-annually
5.	Chi-square	Manufacturer's specifications	Acceptance Manufacturer's recommendations

QC Tests for Gamma Probe

No.	Test Parameter	Tolerance	Frequency
1.	Physical Inspection	Functional and according to manufacturer's specifications	Acceptance Before clinical use
2.	Display And Sound: Sound Acoustic Digital Display **or** Analogue	 Good correlation between measurement signal and tone Continuous display with adjustable measurement time interval Suitable measurement interval with adjustable time constant	Acceptance Before clinical use
3.	Spatial Selectivity & Spatial Resolution 3.1 Spatial Selectivity: Radial Sensitivity Distribution (Far-Field) 3.2 Spatial Resolution: Lateral Sensitivity Distribution	 FWHM ≤ 40° or Manufacturer's specifications FWHM ≤ 15 mm or Manufacturer's specifications	Acceptance Annually
4.	Sensitivity	Within ± 10% of acceptance value or ≥ 5 cps/kBq	Acceptance Annually

No.	Test Parameter	Tolerance	Frequency
5.	Shielding	≤ 0.1% of maximum system sensitivity	Acceptance Annually
6.	Energy Selection (Where Applicable)	Manufacturer's specifications	Acceptance Before clinical use Annually

Note:

All above tests shall be carried out during commissioning and after replacement of major components.

F. References

REFERENCES

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