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EFOMP'S GUIDELINE

QUALITY CONTROLS IN PET/CT AND PET/MR

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Quality controls in PET/CT and PET/MR

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1. PREMISE

Most literature on routine quality control (QC) in PET/CT scanners is out-of-date or no longer relevant, especially in the light of the latest generation of digital and large field-of-view PET/CT systems. The scenario for PET/MR QC is also confounded, because of the lack of dedicated QC recommendations from professional working bodies for these hybrid scanners.

The EFOMP workgroup (WG) on QC in PET/CT and PET/MR was issued to study and prepare a Guideline on a routine quality control schedule to be performed on digital and non-digital systems. The aim was to identify a set of QC tests that could be simple and easy to perform without the need to have particular phantoms and sophisticated software for image analysis.

A survey on QC in PET/CT and PET/MR was sent to a large community of medical physicists across Europe in June 2020, with the intention of collecting information on the different practices, opinions and relevance of the QC tests, as well as the availability of different phantoms [Reynes2021].

The results of this survey provided useful information that was used by the WG to tailor the set of quality controls that are part of this Guideline.

The execution of these QC would guarantee the operation of PET/CT and PET/MR scanners under optimal conditions ensuring the best performance in routine clinical tasks.

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LIST OF ABBREVIATIONS

AAPM	American Association of Physicists in Medicine
CT	computed tomography
DAQA	daily automated quality assurance
DQA	daily quality assurance
ECF	efficiency calibration factor
FOV	field of view
FWHM	full width at half maximum
GD	geometric distortion
HU	Hounsfield unit
IEC	International Electrotechnical Commission
IQ	image quality
MPE	medical physics expert
MRI (MR)	magnetic resonance imaging (magnetic resonance)
MTF	modulation transfer function
NEMA	National Electrical Manufacturers Association
PET	positron emission tomography
PIU	percentage of uniformity
PMMA	poly(methyl methacrylate)
PMT	photomultiplier
PSD	pulse shape discrimination
QA	quality assurance
QC	quality control
QIBA	Quantitative Imaging Biomarkers Alliance
RF coil	radiofrequency coil
ROI	region of interest
RT	radiotherapy
SiPM	silicon photomultiplier
SNR	signal to noise ratio
SPR	scan projection radiograph
SUV	standardized uptake value
UTE	ultrashort echo time
WG	working group
ZTE	zero echo time

2. INTRODUCTION

The main goal of a PET system is to assess the distribution of molecules, labelled with positron emitting isotopes, inside the human body. A clinical PET scanner has the shape of a hollow cylinder, which typically has an axial dimension of 15-25 cm and the diameter is around 70-90 cm. The cylinder is packed with detector blocks. A detector in PET is formed by the combination of scintillation material (pixels), a light conversion unit and electronics. The typical size of the crystals is 4 x 4 mm (transverse x axial) resulting in more than 20000 crystals. The crystal thickness is about 16-30 mm. Most PET scanners will still use Photomultiplier Tubes (PMTs) as light detectors, the more recent ones have replaced the PMTs with Silicon Photomultipliers (SiPM).

An emitted positron will annihilate with a nearby electron, resulting in two 511 keV photons emitted in nearly opposite directions per decay. This simultaneity allows performing electronic collimation using coincidence detection. The system assumes the path of the photons and the annihilation point are at the same line (collinearity), the so-called line of response. The second assumption is that both photons arrive around the same time (simultaneity). When one of the photons is detected by a crystal, the electronics receive a trigger and a coincidence circuit is opened. The moment a second photon arrives within a very short time (typically < 4 to 8 ns) a coincidence has been detected.

After collection of a high amount of coincidences these data are reconstructed into a PET image. PET technology is continuously under development aiming at increased (effective) sensitivity, better count rate performance and improved spatial, energy and time resolution.

PET imaging involves several steps from radiotracer production and administration, PET data acquisition, data corrections (randoms, scatter, attenuation, normalisation) and image reconstruction which can be performed with different algorithms and settings. The complexity of PET imaging requires a clear quality control procedure at different levels, from tracer production up to the final image formation and interpretation.

Besides the (non)digital PET systems, computed tomography (CT) and magnetic resonance imaging (MRI) are mainly used for attenuation correction and anatomical localization.

The guideline was commented by vendors through COCIR (European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries). All vendors' comments were carefully taken into consideration.

2.1 KEY POINT FOR A QC PROGRAM

The Council Directive 59-2013 [EU59-2013], which issues basic safety standards for protection against the ionising radiations for the Member States, claims the implementation of appropriate quality assurance programmes (Article 60). A quality assurance programme is intended to provide adequate guarantee that the performance of a structure, system, component or procedure will perform satisfactorily in compliance with agreed standards.

A quality assurance program should start with an acceptance test, which is intended to verify that the scanner is operating according to manufacturer's specifications. The acceptance test is performed following the vendor's specification based on international standards, that provide uniform and consistent method for measuring and reporting the specific performance parameters of a scanner. The international standards of reference are published by the National Electrical Manufacturers Association (NEMA) and the International Electrotechnical Commission (IEC) and are regularly reviewed and updated to include technological innovations of the equipment.

The acceptance test should be performed immediately after the installation and prior to clinical use.

After acceptance, a QC programme is specifically required to test the constancy of the performance of the equipment throughout its lifetime and it may differ from that defined from the international standards of reference, these last often being available only under vendor protocol and not for the regular user.

The QC protocol should describe the tests to perform and their periodicity: the results obtained at the first execution after acceptance will establish baseline data and tolerance for comparing all future QC results. Performance testing is carried thereafter on a regular basis (constancy tests) and whenever any maintenance procedure is liable to affect the performance of the scanners (status test).

The QC program defined in such a way will allow to detect and correct short- and long-term deteriorations in quality. The aim of a QC program is to test, with simple and practical procedures, changes in the performance of the PET/CT/MRI scanner, through the use of selected and measurable parameters directly linked to the quality of clinical images; in other words, it helps to detect problems before they can impact clinical studies in terms of safety, image quality, quantify accuracy and patient radiation dose. An effective QC program should include tests that must be simple, practical and compatible with the clinical routine.

The key points of a QC program include the definition of:

- *Type of tests:* they must be identified following phantom availability, guidelines, national legislation, type of the equipment and clinical use of the scanner (i.e. use of PET images for radiotherapy purposes, hybrid scanners).
- *Frequency of tests:* it should be defined considering a compromise between accuracy and feasibility of tests.
- *Tolerances:* they should be established with the guidance from manufacturer recommendations or international guidelines.
- *Corrective actions:* when a QC exceeds the established tolerance, it is essential to clearly define the actions that must be taken (i.e.: repeat the QC, schedule a corrective maintenance, limit the clinic use of the scanner).
- *Responsibilities:* the Medical Physics Expert (MPE) is responsible for the overall supervision of the QC program, including supervision of tests performed by other professionals (e.g. technologists). The nuclear medicine physician is responsible for the final approval for clinical use.
- *Recording:* record keeping is a necessary part of a QC program. Detailed local operating procedures and instructions should also be written, as part of the quality assurance program. The periodic analysis of the tested parameters' trend is fundamental to properly monitor the scanner performance and to promptly identify possible faults.

2.2 OVERVIEW OF THE EXISTING GUIDELINES

Guidelines for QC of PET systems have already been proposed by professional bodies such as the International Atomic Energy Agency [IAEA2009, IAEA2014], the American Association of Physicists in Medicine [AAPM126-2019], the Institute of Physics and Engineering in Medicine [IPEM2013] and the European Association of Nuclear Medicine [EANM2010].

PET acceptance tests have been extensively described by the National Electrical Manufacturers Association [NEMA2018] and the International Electrotechnical Commission [IEC1993] standards.

This document presents the essential tests to ensure operational status of the PET devices. CT and MRI QC are described only in the context of their use for PET (attenuation correction and anatomical localization). For the tests dedicated to these modalities, refer to the specific guidelines.

Each MPE is free to carry out additional QC, to increase the frequency of QC or to decrease the tolerances to adapt to his own clinical configuration and to national regulations.

It was chosen to present only the QCs of the three main manufacturers present in Europe according to our survey [Reynes2021]. The QC presented in the rest of the document may be modified due to upgrades by manufacturers or the arrival of new PET systems.

3. ROUTINE MANUFACTURER QC OR DAILY QUALITY CONTROLS

3.1 PET SCANNER

Routine manufacturer quality controls are procedures set up by the manufacturer of the PET/CT or PET/MR scanner to be run on a routine basis, daily or every day of clinical activity, to guarantee the adequate performance of the PET component. PET daily QCs are performed automatically or semiautomatically after the routine system initialization or start-up and before the first patient, strictly following the manufacturer's recommendations which may require the use of specific sources and phantoms and generally take less than 30 minutes to be performed.

A detailed description of the daily quality control procedures implemented in the available PET systems of the three commonest manufacturers in Europe is presented in Appendix 1.

In general, they consist of a series of tests and/or calibrations of the different components of the electronic chain of detection which may include the gain of the photomultiplier tubes (or photodiodes), the energy window setting, the system timing, the state of the detectors, the evaluation of the emission calibration factor. Usually, the daily quality control procedure ends by showing a sinogram or an image of the specific source or phantom that can be used to detect any deviation from the normality. A report with the parameters measured is then displayed, also with coloured indicators showing the compliance (green) or a mild (yellow) to strong (red) deviation from the tolerance range, eventually requiring corrective actions to be undertaken.

In case of failure of the daily quality control procedure, the user should refer to the manufacturer's recommendation.

In these cases, if possible, the acquisition of a uniform phantom may help the user to know the entity of the failure and its impact on the image quality.

3.2 CT SCANNER

Daily QC is performed with phantoms provided by manufacturers, after the routine system initialization or start-up and before the first patient. Most daily QCs include tube conditioning, air calibration and quick CT quality checks based on the HU and noise measured in water. In addition, weekly, monthly and (bi)annual QCs vary by vendor and usually consists of additional image quality checks, CT dose index (CTDI) measurements, slice thickness calculations, evaluation of artefacts, and evaluation scanner, gantry and table functionalities.

Specific quality control procedures implemented in the available PET/CT systems of the three commonest manufacturers in Europe and proposed phantoms are presented in Appendix 2.

3.3 MR SCANNER

Daily QC is performed with phantoms provided by manufacturers, after the routine system initialization or start-up and before the first patient. The MR daily quality control procedures implemented in the available PET/MR systems of the two most common manufacturers in Europe are presented in Appendix 3.

The safety checks necessary for PET/MR devices must also be carried out every day (for example check for temperature and humidity in the room, oxygen sensor, check patient alert system, check intercom systems, coil status, helium level).

4. QUALITY CONTROLS

All the results and the images of all the quality control performed should be recorded and archived with care. For the same test, the results should be compared with those of the initial quality control (performed after the acceptance test) and trends over time should be analyzed.

Each MPE is free to carry out additional QC, to increase the frequency of QC or to decrease the tolerances to adapt to his own clinical configuration and to his national regulations.

In the event of out-of-tolerance results for one of the tests, it is suggested to follow the national recommendations and inform the device manufacturer. Type and timing for corrective actions should be defined locally by the MPE and the nuclear medicine physician according to the clinical relevance of the problem.

4.1 QUANTITATION

4.1.1 RADIONUCLIDE CALIBRATOR

This paragraph contains the quality control of the radionuclide calibrator used to measure injected activity. Any routine manufacturers QC should be performed as well as the following additional tests. Possible tests are the electronics system diagnostics, the stability of the high voltage and the adjustment of the zero gain. Consult the calibrator instructions for more information. Drift on any of these tests should be observed when measuring the daily check source. Correction factors for vial/syringe geometry should be eventually considered.

Relevant maintenance that are liable to affect the performance of the radionuclide calibrator are replacements of the ionization chamber, electronics, or change in HV supply.

For a detailed description of the QC tests on a radionuclide calibrator refer to the specific guidelines [IEC TR 61948-4, NPL93, AAPM181]

Parameter	Periodicity	Materials needed	Test duration
Physical Inspection	Daily	None	5 min
Background	Daily	None	5 min
Constancy	Daily	Standard source	5 min
Clock synchronization	Monthly	None	5 min
Accuracy	Annually	Standard source	5 min
Precision	Annually	Standard source	10 min
Linearity	Annually	^{18}F source	12 hours
Inter-calibration	Annually	^{18}F source	15 min

Table 1. QC test on the radionuclide calibrator.

4.1.1.1 PHYSICAL INSPECTION

Check the integrity of the calibrator, including the cables and source holder. If applicable, verify that each display segment is visible. If the radionuclide calibrator is part of an automatic dose administration system, check the integrity of all the components as recommended by the manufacturer.

4.1.1.2 BACKGROUND

Purpose: To verify that the background activity is within an acceptable range. Elevated background values could be caused by an external source at proximity, by some contamination of the radionuclide calibrator (chamber or source holder) or by electronic noise. Non-zero background value indicates a severe malfunction of the measurement device.

Procedure: Measure the background for any radionuclide setting to be used that day. Perform the test with the holder in place.

Result: Register the background measured value.

Tolerance: The acceptable measurement of background must be determined at the acceptance tests and any deviation should be investigated.

4.1.1.3 CONSTANCY

Purpose: To check the constancy and reproducibility of the calibrator measurements over time. This check measures the stability of the whole system and each relative setting. A drift in the measurement could be caused by a loss of pressure in the ionization chamber or some electronic problem on the electrometer.

The needed material is a long-lived half-life solid check source, typically ^{137}Cs or ^{68}Ge/^{68}Ga.

Procedure: Measure the check source on the source holder using its own calibrator factor. Repeat the measurement for all nuclides to be used on that day (e.g. ^{18}F, ^{68}Ga).

Result: Record all measurements and check for any trend.

Tolerance: Measurements should be within ±5%.

4.1.1.4 ACCURACY

Purpose: To test the accuracy of the system for a series of selected known sources.

Procedure: The activity of the source should be traceable to an international standard. Source activity should be greater than 3.7 MBq. Ideally the test should be done with a series for standards of nuclides that are used in the calibrator. Consult the national supplier and measurement standards for guidance. The use of a single source (usually ^{137}Cs or ^{68}Ge/^{68}Ga) in combination with the daily constancy check is sufficient for most programs. However, it is highly encouraged to measure different nuclide standards traceable to a primary standard.

Measure the standard using the holder.

Result: Calculate the relative error of the decay-corrected activity.

Tolerance: Accuracy should be within ±5 %.

4.1.1.5 PRECISION

Purpose: To check the short-term counting reproducibility of the system.

Procedure: A long-lived test source, which could be the same as the constancy or accuracy check, is needed.

A series of 10 consecutive measurements should be performed with the source in the holder. The source should not be removed from the ionization chamber between measurements.

Result: The precision is computed as the percentage of the standard deviation divided by the mean of the measurements.

Tolerance: Precision should be in the ±5 % range.

4.1.1.6 LINEARITY

Purpose: To test that the system is linear in response over a range of dispensed activities.

Procedure: Different methods exist to compute the linearity, for a fast decaying nuclide the easiest one is the decayed source method. Other methods are the shield method and the graded source method. Activities at which non-linearity's appear will be different for different radionuclides, hence it is recommended to be performed with ^{18}F.

Measurements should be performed over all the range of possible administered activities, typically from 37 to 500 MBq.

Result: Plot of measured values in a log-linear graphic should be fitted with a straight line.

Tolerance: Decay corrected values should be within the ±5 %.

4.1.1.7 INTER-CALIBRATION

Purpose: To test the homogeneity of readings of different calibrators with a clinical isotope.

Procedure: Prepare a syringe of ^{18}F with a typical clinical activity (i.e. 200 MBq). Measure the same source with different calibrators.

Result: Calculate the percentage difference in readings.

Tolerance: The maximum percentage difference between the readings of different calibrators should be < 5%.

4.1.2. WEIGHING SCALES

To allow comparability between patients and scan timepoints, PET uptake is normalised by the injected activity and patient weight to give units of Standardised Uptake Value (SUV). Since SUVs are based on body weight, the weighing scales used to measure the weight of the patient need to be accurate and precise for the determination of the SUVs.

There are several approaches to the injected activity calculation, but all of them rely on the weight of the patient. Apart from the quantification of the image, the precise knowledge of patient's weight is important to maintain a constant quantitative accuracy.

Users should be aware of and follow the requirements of any country-specific laws relating to weighing instruments in a hospital environment. As such, all scales used should be Class III approved medical scales suitable for weighing patients in a clinical environment and to assist diagnosis. The scales would have a capacity suitable for the range of patient weights to be measured. Units should be displayed in metric and have scale intervals suitable for the size of patient.

Ideally the scale should meet the following performance specifications:

Patient group	Recommended maximum scale interval
Adults	200g
Young Children	50/100g
Babies	10/20g

Table 2. Patient groups and related maximum scale interval.

A programme of ongoing calibration and repair should be in place to ensure the accuracy and precision of the weighing scales. Factors impacting the accuracy of weighing scales are workload, age, how well they are taken care of and how often they are moved. Frequent changes or extremes of temperature and humidity can also affect the accuracy of weighing scales.

Users should try to avoid moving the scales by placing it in a dedicated location where there is no through-traffic (to minimise damage from passing trolleys etc). The scales should be on a firm, level surface and the scales aligned using the in-built spirit level. If the scales are moved to a new location, the alignment of the base should be checked and adjusted as necessary. The weighing platform should not be touching a fixed object.

4.1.2.1 PHYSICAL INSPECTION

The following checks should be made before the start of the clinical sessions:

- Check that the weighing scales are clean and free from damage (visual inspection).
- If the scales are powered by batteries, make sure the battery voltage warning is not showing (refer to the manufacturer's instructions).
- Check the scales are level and the weighing platform is not touching a fixed object.
- Before weighing each patient, ensure the scales display zero.
- If the scales have more than one weighing range setting, make sure the appropriate range is selected.
- Check functioning of scale by (e.g.) weighing yourself or an object of known weight.

4.1.2.2 ACCURACY & PRECISION

Purpose: As a minimum, the weighing scales should be checked for accuracy and precision on an annual basis.

Procedure: If available, a range of traceable calibration weights covering the typical range of patient weights (10 - 100 kg, in steps of 10 kg) may be used. In the absence or unavailability of calibrated weights, one can choose to verify accuracy and precision of the scale by repeatedly measuring yourself or any other person (with a weight between 50-90 kg) on the scale and any other medically approved scale in the hospital that has been recently calibrated or tested (in the last case, there should not be a large gap in time to avoid weight fluctuations). By measuring your weight, using 2 or more scales the difference between the scale of interest and any other reference scale should be less than 0.5 kg. If needed, the experiment can be repeated several times (e.g. weigh yourself 10 times on one scale and repeat on the scale to be verified – average weights should agree within 0.5 kg and observed standard deviation should be within 0.5 kg).

Method:

- Perform the physical inspection check as detailed above.
- Zero or 'tare' the scales.
- Take at least three repeat measurements, taking the weight or yourself off the scale in-between measurements.

Result: Determine the mean (accuracy) and standard deviation (precision) for each weight increment or yourself.

Tolerance: Difference between expected weight and observed weight (or difference among scales) should be less than 0.5 kg with a standard error of less than 0.5 kg.

4.2 PET SCANNER

Traditional axial field of view (≤ 30 cm) PET scanners are considered in this document.

Large axial field of view PET scanners (> 30 cm) differ in sensitivity, count-rate-activity curves and spatial resolution with respect to traditional FOV PET scanners, thus requiring measurements and phantoms specifically devised for this category of PET scanners [Spencer2021, Prenosil2021].

The quality control tests were chosen with the criterion that the tests could be suitable for practical use, considering possible variations in practices based on the size and type of the hospital, technology and model of the PET/CT and PET/MRI scanners and availability of phantoms.

The quality control tests devised are reported in Table 3 with their periodicity, material and isotope needed to be used and time required for their execution.

Relevant maintenance that are liable to affect the performance of the PET scanner are replacements of detectors, PMTs, PSDs, electronics and reconstruction software.

Test	Parameter(s) tested	Periodicity	Materials needed	Isotope	Test duration
Uniformity/ artefacts	Uniformity	Quarterly and after relevant maintenance	Uniform phantom	^{68}Ge/^{18}F	0.25 – 1h
SUV validation/ quantification accuracy	SUV	Quarterly	Uniform phantom	^{18}F	1h
PET/CT and PET/ MR alignment	PET/CT and PET/ MR deviation(s)	Semi-annually or frequency otherwise indicated and after relevant maintenance	Point/line sealed source(s)	^{22}Na/^{68}Ge/^{18}F	0.3 – 1h
Count rate performance (*)	Linearity	Annually or after relevant maintenance	Uniform cylinder	^{18}F/^{11}C/^{15}O	12 - 14 h for ^{18}F
Image quality	Recovery coefficient Background Variability Correction accuracy	Annually	NEMA IQ phantom (simplified setting)	^{18}F	1.5 – 3h
	Recovery Coefficient Background Variability Correction accuracy	Before using a new isotope (if possible, see Table 4)	NEMA IQ phantom for different isotope used	isotope	1.5 - 3h

Table 3. QC tests on the PET scanner. (*) The linearity test to check the persistence of count rate performance is suggested only for the PET centres that perform clinical dynamic acquisitions (i.e. with ^{82}Rb).

4.2.1 UNIFORMITY/ARTEFACTS

Purpose: To verify the uniformity on the reconstructed slices of a uniformly filled phantom.

Materials: A cylindrical phantom which may exceed the axial FOV length filled with ^{18}F or ^{68}Ge cylindrical phantom.

Procedure: Fill the phantom with a water solution of ^{18}F (about 50 - 100 MBq) and mix thoroughly to get a uniform radioactivity distribution. Add water until completely filled. Centre the phantom in the PET FOV. When available, the acquisition/reconstruction protocol provided by the manufacturer should be followed. In case of unavailability, the clinical whole-body protocol should be used instead. In the case of ^{68}Ge cylindrical phantom, simply place it on the patient's pallet. The same acquisition/reconstruction protocol must be followed for each acquisition.

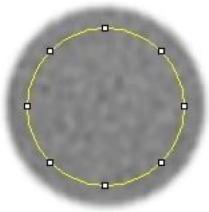


Figure 1. Reconstructed slice of the uniform phantom for inspection for presence of any non-uniformity areas within the 80% of the axial FOV.

Analysis: The reconstructed slices should be inspected for the presence of any non-uniformity areas.

Tolerance: A slice-to-slice variability of less than 10 % for the slices within the central 80 % of the axial FOV [QIBA2014].

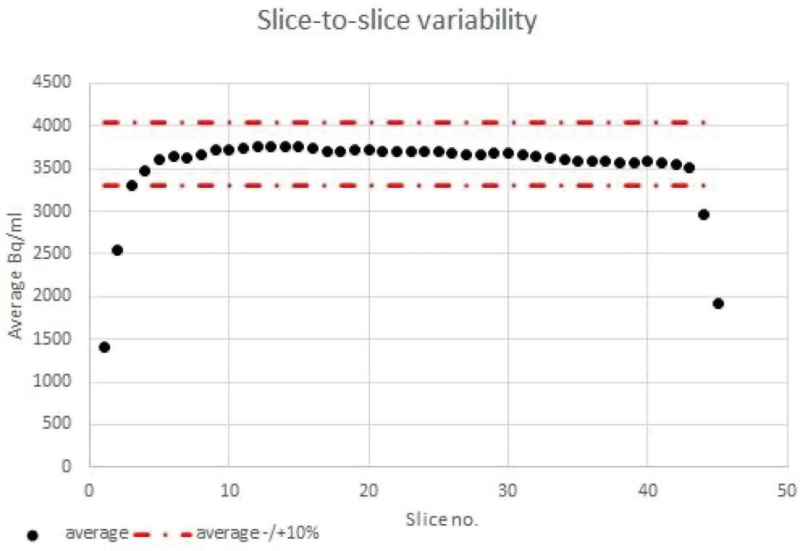


Figure 2. Slice-to-slice variability in the average concentration and the limits of +/- 10 % within the 80 % of the axial FOV.

4.2.2 SUV VALIDATION/QUANTIFICATION ACCURACIES

Purpose: To verify accuracy of SUV values.

Materials: Cylindrical phantom which may cover the axial FOV filled with ^{18}F. Diameter of the phantom should be at least 20 cm. For constancy of SUV, ^{68}Ge phantom can be used.

Procedure: Prepare a syringe with about 50 - 100 MBq of ^{18}F by accurately measuring it in the same dose calibrator used for clinical routine, writing value of activity and time of assay. The clocks used for recording the time assay should be checked against the scanner time. Put the activity in the phantom, mixing with water solution thoroughly to get a uniform radioactivity distribution. Measure the residual activity in the syringe and evaluate the net activity put in the phantom. Add water until the phantom is completely filled. Place the phantom on the phantom holder provided by the manufacturer and move the phantom at the beginning of the CT FOV, making sure that the phantom is centred in the FOV also with respect to the height. In case of no phantom holder, simply place it on the patient's pallet.

The acquisition should be performed by using the protocol provided by the manufacturer. In case no acquisition protocol is provided, the standard protocol used for clinical routine should be used (body, head, ...). Make sure that a low dose CT for attenuation and scatter correction purposes is included in the procedure. Attention should be paid when inserting data regarding ^{18}F activity assayed by the dose calibrator, time of assay and weight of the volume of the ^{18}F solution used to fill the phantom.

Analysis: For each FOV series acquired (head, body, ...), draw a circular ROI on the reconstructed slices with a diameter of 16 ± 1 cm and evaluate the mean value of the SUV on the central slice and on ±1 and ±2 cm slices.

Tolerance: Mean SUV values should be 1.0, ideal tolerance should be ± 5 %, acceptable tolerance ± 10 %.

4.2.3 LINEARITY

Purpose: To verify quantitative accuracy of reconstructed activity concentration (or SUV) over a clinically relevant ranges of activities.

Materials: Uniform cylinder of 6000 to 9000 ml content.

Procedure: Fill the phantom with a water solution of ^{18}F (or ^{11}C) (about 280-300 MBq calibrated at the intended start of the QC) and mix thoroughly to get a uniform radioactivity distribution. Add water until completely filled. Place the phantom on the patient's pallet to simulate clinical conditions. When available, the acquisition/reconstruction protocol routinely used at your site for dynamic or static clinical imaging should be followed. Make sure a low dose CT for attenuation and scatter correction purposes is included in the procedure. Collect the PET emission data during 12 hours (if possible the acquisition protocol may be designed as 10 min PET acquisitions and 50 min intervals). In case ^{11}C or ^{15}O is used for this test, collect the PET emission data for at least 7 half-lives and reconstruct data in 5 or 0.5 min frames, respectively (reconstruct the images using the routinely used clinical protocol).

Analysis: Reconstructed activity values are derived by placing a cylindrical volume of interest, positioned fully within the dimensions of the phantom (1 cm within the outer contour of the phantom) and excluding the 10 % end-planes (at each side of the axial FOV, i.e. within the central 80 % of the axial FOV [QIBA2014] of the reconstructed data). For each reconstructed frame obtain the mean activity concentration in the phantom and plot these as function of calculated/expected (true) activity based on phantom filling information.

Plot the PET image observed average activity concentration as function of true expected activity concentration and observe/evaluate the linearity of the plot and calculate the % difference between observed and true activity concentration.

Tolerance: Reconstructed activity concentrations (or SUV) should be within 10 % of expected values over an activity range of 10 to 200 MBq within the FOV.

4.2.4 IMAGE QUALITY TEST

The following test is a modified version of the image quality test described in the NEMA NU-2 standard [NEMA2018]. It has been simplified for inclusion in the routine PET QA programme. In particular, the test uses six hot spheres and does not require the use of the scatter phantom to simulate activity outside the field of view (FOV).

Purpose: to evaluate the quality of the images acquired and reconstructed using parameters for clinical imaging of the torso.

Materials: IEC image quality phantom. The lung insert is not used for this test but may not be removable in some phantom designs therefore use of the lung insert is optional. Note: In case the IEC Image quality phantom is not available, other phantoms containing fillable spheres that can simulate 'hot' lesions (i.e. the Jaszczak phantom) can be used instead, and the procedures described for preparation, acquisition and analysis can be followed as well. It should be noted however that results for different phantom designs are not interchangeable and therefore the same phantom design must be used for subsequent measurements.

Procedure:

Preparation
The volume of the background compartment has been found to vary between phantom manufacturers. If no certificate is available from the manufacturer with accurate volumes, the phantom volume should be measured by weighing with the background compartment filled with water and subtracting the empty weight.

Prior to performing the image quality procedure, sites should ensure the scanner has an up-to-date normalisation and a cross-calibration factor measured for the radionuclide calibrator used for assay of the radionuclide.

The clocks used for recording the assay time should be checked against the scanner time (tolerance +/- 1 minute).

Accounting for decay and the volume of the background compartment, determine the activity of radionuclide to draw up to provide the activity concentrations (± 5 %) provided in Table 4 for the background and the spheres at the time of scanning. Allow at least one hour for filling the phantom and positioning on the scanner.

The activity concentrations provided for the phantom are based on a typical injected activity for a 70 kg patient total body study (i.e. for ^{18}F the activity concentration corresponds to 370 MBq per 70,000 ml). If sites routinely use lower injected activities, it is recommended to perform additional acquisitions as the phantom decays to cover the range of injected activities expected.

Radionuclide	Typical Clinical Injected Activity (MBq)	Background Volume Activity (kBq.ml^{-1})	Spheres Volume Activity (kBq.ml^{-1})
^{18}F	370	5.3	21.2
^{68}Ga	200	2.9	11.6
^{124}I [Beijst2016]	74	1.8	18
^{90}Y [Pasciak2014]	~1000	740	2200
^{89}Zr	37	0.5	2

Table 4. Suggested activity concentrations to be used for the preparation of the IEC phantom for selected radionuclides. Note that isotopes different from ^{18}F should be tested in advance to their use, especially when high prompt gamma contribution is present (i.e. ^{124}I).

If performing this test on a PET/MR scanner, special considerations are required for performing the attenuation correction and this is dependent on the manufacturer. Further discussion on how to perform the attenuation correction is provided in section 4.4.1.

Phantom Filling Procedure
Before filling the phantom with activity, make sure the spheres are empty and the phantom background is almost filled to the top with water leaving a bubble for mixing.

Two syringes of activity are required, one for the background and one for the spheres. Record the actual activity and time of assay for both syringes and make sure they are labelled as spheres and background.

For radiation protection reasons, the spheres should be filled first, as the activity needed is lower than the one used in filling the background.

For the spheres, make up a solution of 1000 ml water in a sealable container. Ideally the solution should be weighed to determine the exact volume and ensure high accuracy in the activity concentration for the spheres. Inject the spheres syringe activity into this solution, flush several times and assay the residual in the syringe. Mix the solution carefully to homogenize it.

Using a long needle, inject the solution into all 6 spheres. Next, inject the background syringe activity into the background compartment of the phantom, flush a few times and assay the residual in the syringe. Seal the phantom and gently rotate/roll the phantom to mix the solution. Finally top up the background compartment with water and seal.

The phantom should be positioned on an absorbent pad on the scanner couch with the centre of the spheres aligned axially with the central slice of the scanner. The couch height should be adjusted so the centre of the spheres is centred in the transaxial FOV. If the couch height cannot be adjusted to centre the phantom, a fixed height as close to the centre should be used. The same height must be used for all subsequent measurements.

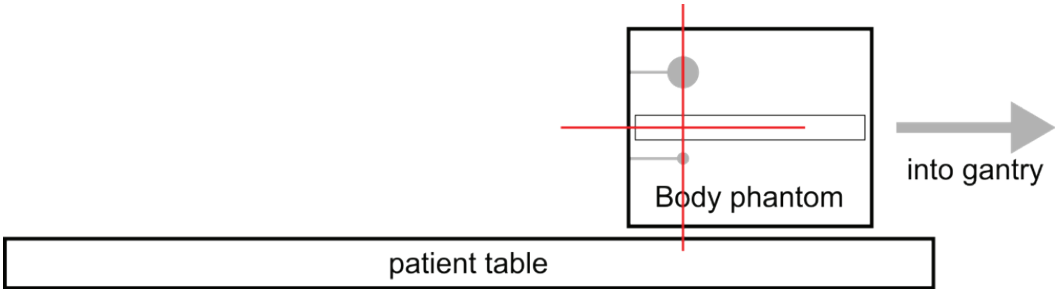


Figure 3. Positioning of the NEMA phantom on patient's table.

As a minimum, two acquisitions should be performed:

- a single static acquisition centred over the spheres using the clinical FDG protocol used over the torso for a 70 kg adult.
- a 2-3 bed position or continuous flow acquisition to cover the whole phantom using the clinical FDG protocol used over the torso for a 70 kg adult.

If testing non-^{18}F radiotracers, the corresponding clinical protocol for that tracer should be used, i.e. a ^{68}Ga-DOTATATE protocol for ^{68}Ga.

To investigate different scan times, the acquisition should ideally be performed in list mode for at least 5 minutes per bed and retrospectively rebinned to shorter time frames.

The PET data should be reconstructed using the standard clinical reconstructions. The raw data and the CTAC should be retained to allow retrospective reconstruction if new reconstruction algorithms or corrections are provided in the future.

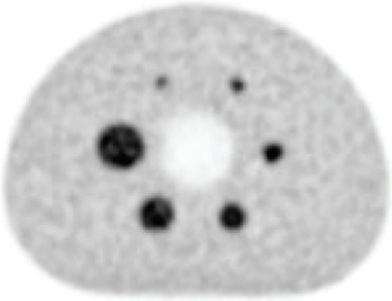


Figure 4. IEC Image quality phantom showing hot spheres filled with ^{18}F-FDG with target-to-background radio of 4.

Analysis: The activity concentration in the background and each of the spheres is measured in the reconstructed PET image and compared to the actual activity concentration. To determine the actual activity concentration, the activity assayed in the radionuclide calibrator should be corrected for any residual activity in the syringe and then decay corrected to the scan start time (series time in the DICOM header).

The software used for analysis of the phantom, should be capable of displaying PET data in kBq.ml^{-1}, allow the manual placement of a 2D region of interest (ROI) and to define a 3D volume of interest based on 50 % of the maximum voxel value adapted for background (VOI A50).

To measure the background activity concentration, select an axial slice in the uniform section of the phan-

tom background away from the spheres. Manually place ≥ 5 cm diameter 2D ROI at least 2 cm from the phantom edge. Measure the mean and standard deviation activity concentration for the ROI and calculate the coefficient of variation.

$$\text{coefficient of variation (\%)} = \frac{\text{standard deviation}}{\text{mean}} \times 100$$

To measure the activity concentration in the spheres, determine the VOI A50 for each sphere in turn. Measure the maximum voxel value and the mean activity concentrations for each sphere.

The recovery coefficients (RC) are then calculated as the ratio of the measured activity concentration to the actual activity concentration for each sphere:

$$\text{recovery coefficient} = \frac{\text{measured activity concentration}}{\text{actual activity concentration}}$$

Tolerance: The mean background activity concentration should be within 5 % of the true activity concentration and the coefficient of variation < 15 %. Tolerances for the RC values should be determined locally based on measurements at commissioning. Different tolerances should be set for reconstructions incorporating point-spread-function (PSF) modelling.

Note: the coefficient of variation defined above clearly differs from the background variability defined in the NEMA NU-2 publication. Thus, no comparison should be done between the values obtained for the two parameters.

4.2.5 PET/CT, PET/MR ALIGNMENT

Purpose: To ensure proper attenuation correction and localization.

Materials: Point/sealed sources as suggested by the manufacturer (see section 7.4).

Procedure: The test should be performed in accordance with the manufacturer's procedure for data collection, reconstruction and analysis. It can also be done by using a clinical protocol for visual analysis.

Tolerance: The reference values are provided by the manufacturer.

4.3 CT SCANNER

The intended use of the CT part differs significantly between institutions: it can be used just for attenuation correction, for anatomical localization, or as a diagnostic CT. With new (model-based) iterative CT reconstruction algorithms, which imply an important reduction of the radiation dose contribution and reduction of image noise, the latter use will probably increase in popularity.

Constancy testing of the system should be performed in accordance with the IEC 61223-3-5 (Ed. 2, 2019) [IEC2019] or following the specific facility's QA program.

From the PET perspective, the main intended objectives of the quality controls on the CT component are the correct alignment of both modalities and the stability of the HU (for a precise attenuation correction). Moreover, the dosimetric issue should be considered in the light of the patient's radiation protection.

Note that the present guideline is complementary to any annual CT survey followed by the national or by any specific CT QC guidelines [IAEA2011, ACR2017]. Also take in consideration that if the PET/CT is used for radiotherapy planning, additional tests should be performed, as discussed in the corresponding section (section 6).

Additional quality controls dedicated to image quality are described in Appendix 2.

Relevant maintenance that are liable to affect the performance of the CT scanner are replacements of X-ray tube, detectors, electronics and reconstruction or scanner software.

Parameter tested	Periodicity*	Materials needed	Test duration
Image artefacts	Monthly	Uniform phantom/Catphan*	10 min
HU Uniformity and noise	Monthly	Uniform phantom/Catphan*	20 min
HU Accuracy	Monthly	Phantom with inserts of different materials/ Catphan	20 min
Slice thickness	Annual	Phantom with ramp or beads	20 min
Dose measure	Annual	16 and 32 cm PMMA phantoms and pencil ionization chamber or similar	1 h

** Catphan phantom is required if CT images are used for RT.*

Note: all tests should be performed after a major intervention of the CT (replacement of the x-ray tube, HU calibration, software upgrade, etc.).

Table 5. Overview of the QC test on the CT scanner.

General remark to phantom types:

Most common vendor-neutral phantoms are the 464 ARC phantom and the 500-600 Catphan family phantoms. Other useful phantoms for advanced image quality tests are listed in the Report 233 of the American Association of Physicists in Medicine Task Group 233 [AAPM233-2019]. In addition, it is mandatory to use the standard CTDI Phantoms for dosimetry measurements.

Most phantoms for quality control are capable of providing an indication of contrast scale, noise, nominal tomographic section thickness, the spatial resolution capability of the system for low and high contrast objects, and measuring the mean CT number of water or of a reference material.

4.3.1 IMAGE ARTEFACTS

Purpose: To ensure that no artefacts are present that could compromise the CT functionality.

Material: A large diameter phantom with a uniform section filled with water or any equivalent material, to evaluate artefacts that may occur in the field of view. If unavailable, the 32 cm PMMA phantom can be used instead.

Procedure: Align the phantom at the centre of the CT FOV and scan it using a clinical CT protocol suitable for the phantom dimensions. Follow the protocol used for HU Uniformity and noise, with the thin reconstructed images.

Analysis: Review all images for the presence of artefacts.

Tolerance: Qualitative analysis, no artefacts should be visible.

4.3.2 HU UNIFORMITY AND NOISE

Purpose: To ensure that the CT numbers are uniform across the field of view.

Material: A dedicated phantom with a uniform section filled with water or any equivalent material.

Procedure: Align the phantom at the centre of the FOV and scan it using a clinical CT protocol. Since image noise depends on scan and reconstruction parameters, these must be unambiguously defined for measurement and when setting baseline values for regular constancy tests.

Analysis: Draw 5 circular ROIs (12, 3, 6, 9 o'clock and at centre) on a single slice within a uniform section of the phantom. The ROI area should be ~ 1 % of the phantom area. Evaluate HU mean and standard deviation. Compute the difference between the peripheral ROI and the central one. The uniformity is computed by subtracting the different peripheral ROI to the central one. Noise is measured as the standard deviation within a ROI, specified in HU. The noise percentage is computed by dividing the standard deviation of each ROI by the mean HU:

$$\text{noise (\%)} = \frac{\sigma_i}{HU_{i(mean)}}.100$$

Tolerance: The uniformity difference between the Centre ROI and the average of the edge ROIs should be 0 ± 10 HU for the Small Body Scan FOV (< 20 cm), 0 ± 20 HU for Large Body Scan FOV is used (> 20 cm) (achievable values of uniformity should be 0 ± 5 HU). Acceptable values of noise should be ± 25 % of baseline value (achievable values of noise should be ± 10 % of baseline values). Different tolerances should be used if phantoms with different materials are used instead.

4.3.3 HU ACCURACY

Purpose: To verify that the CT numbers are within an appropriate interval. All available kV must have been calibrated and tested for acceptance.

Materials: A phantom that has at least uniform sections of 3 different materials, including water, air and a high-density material.

Procedure: Align the phantom at the centre of the FOV and scan it using a clinical CT protocol, suitable for the phantom dimensions.

Analysis: Select a ROI small enough to fit inside the materials and measure the mean HU.

Tolerance: Water HU should be 0 ± 10 HU (achievable value should be ± 5 HU); different tolerances should be applied for different materials where ± 5 % from the reference value specified by the manufacturer should be appropriate.

Note that depending on the phantom, some materials can degrade over time.

4.3.4 RADIATION DOSE

Purpose: To evaluate the accuracy of the CT dose index in air ($CTDI_{air}$).

Material: A pencil ionization chamber or a solid-state dosimeter.

Procedure: Set the pencil ionization chamber in the centre of the FOV, scan it by using the axial modality used at acceptance and register the dose value measured for head ($CTDI_{air\text{-}head}$) and body protocols ($CTDI_{air\text{-}body}$).

Analysis: Compare the $CTDI_{air\text{-}head}$ and $CTDI_{air\text{-}body}$ values with the correspondent values at acceptance.

Tolerance: $CTDI_{air\text{-}head}$ and $CTDI_{air\text{-}body}$ within ± 20 % the correspondent acceptance values.

Note: The evaluation of the accuracy of CT dose index in phantoms for head and body FOV, $CTDI_{w\text{-}head}$, $CTDI_{w\text{-}body}$, is done at acceptance or after major intervention by following IAEA2011 or ACR2007 protocols.

See IEC 61223-3-5 for a detailed test description and interpretation.

4.4 MR SCANNER

This paragraph outlines basic MRI quality controls to test image quality. The QC program proposed does not seek to provide a complete MRI image quality assurance program. Please refer to the different international guidelines for more details as the guideline by the American College of Radiology document [ACR2015], the National Electrical Manufacturers Association standards [NEMA-MS1-2014], the EUROSPIN protocol [EUROSPIN1996] or the American Association of Physicists in Medicine guideline [AAPM100-2010]. The selection of the QC proposed was performed with the aim to test parameters that may affect PET images through the attenuation correction and that can be performed with a homogeneous phantom. The parameters to be controlled in this context are uniformity, signal-to-noise ratio and attenuation map. Appendix 3 contains a description of other important QC that must be added to completely test the performance of a MR scanner.

4.4.1 SPECIFICITY OF PET/MR: THE ATTENUATION ISSUE

PET/MR scanners use a dedicated method for patient attenuation corrections. Attenuation coefficients need to be derived from MR data because of the lack of CT or transmission information [Beyer2016]. The MR-based attenuation correction applied in clinical routine is based on the acquisition of a dedicated MR sequence, followed by tissue segmentation; fixed attenuation coefficients are then assigned to each segmented compartment (Figure 5).

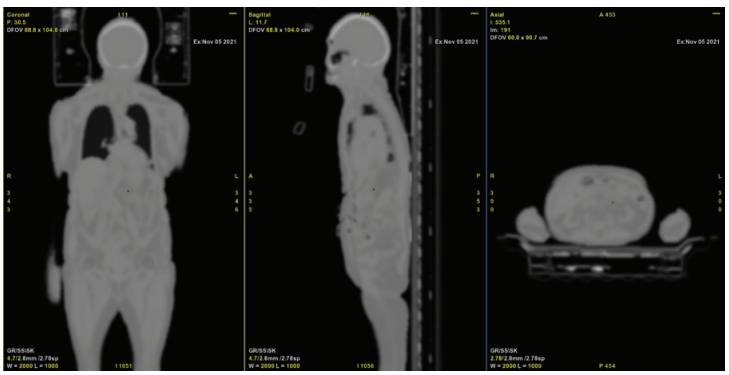


Figure 5. Attenuation map of a patient in the 3 planes (Signa PET/MR, GE). 4 tissues are segmented in the head (soft tissue, air, adipose tissue, bone) and 3 for the rest of the body (soft tissue, air, adipose tissue). The head coil and the patient table are visible in the attenuation map.

Another issue is that the field of view is smaller in MR than in PET, which leads to a truncation of the attenuation map for body portions that exceed the dimensions of the FOV in MR. This is often the case for the patient's arms especially for large patients (Figure 6). Several methods can be used to correct the truncation of the attenuation map. For example, the missing information can then be filled in using the patient outer contour calculated with the non-attenuation corrected PET images. Another solution used the measurement and quantification of the B0 and gradient nonlinearities (HUGE method) to provide an extension of the FOV. Finally, patient table and the RF coils are often invisible in the MR data. Predefined attenuation maps (templates based from CT) for the patient table and rigid coils are usually added to the patient attenuation map.

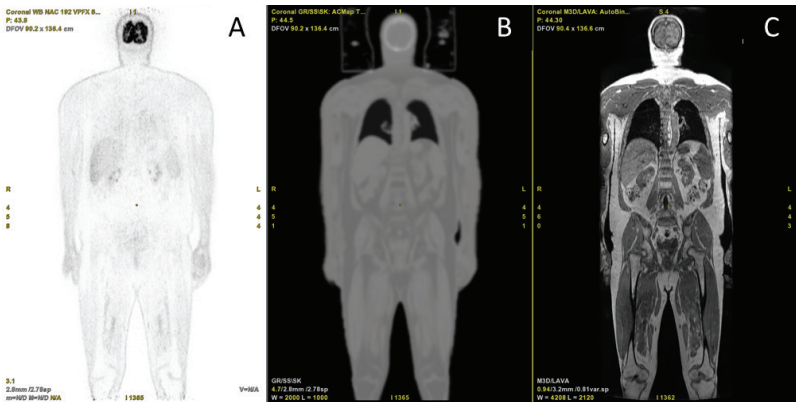


Figure 6. Coronal slice of a patient (Signa PET/MR, GE): non-attenuation corrected PET (A), attenuation map (B) and MR sequence (C). The patient arms are visible in PET but only partially in MR. The attenuation map was corrected with truncation correction based on PET.

This MR attenuation correction method cannot be used for phantom experiments. The composition of some phantoms is different from that of human tissues, such that the patient's tissue segmentation algorithms may not be able to properly visualize phantom components. In addition, several issues make the accurate quantification of the attenuation coefficients in phantoms challenging:

- Usually, pure water is used for PET phantom inserts and background compartments filling. Water may introduce strong artefacts in MR images, because the signal response is not homogeneous. Indeed, NaCl or other fluids which change the dielectric properties must be added to the water solution, increasing signal homogeneity during MR imaging of phantoms [Boellaard2015, Ziegler2015, Lennie2021, McGarry2020].

- In addition, MR-based attenuation correction considers the fluid phantom filling as it provides sufficient MR signal, but it does not correct for plastic or synthetic materials commonly used in PET phantom housings, not visible in MR image. Consequently, phantom walls are systematically ignored in the MR-based attenuation map [Boellaard2015].

Several publications demonstrated that the MR-based attenuation correction leads to insufficient quantification results for radioactive spheres as compared to CT-based attenuation correction for the NEMA IQ phantom [Boellaard2015, Ziegler2015]. Artefacts in the attenuation map and degradation of the image quality are also reported.

Similar results are obtained for the phantom used for the SUV validation [Keller2016], where the use of a MR based attenuation map caused an underestimation of the real radioactivity concentration of -16 %.

Based on these reported results, it can be concluded that MR-based attenuation correction in phantom is inadequate. In order to obtain reliable and robust QC results, alternative and dedicated methods for phantoms' attenuation correction are needed, especially if concerning multicentre studies with PET/MR [NEMA-MS2-2014, Harries2020, Rausch2021].

The most frequent solution is to use a pre-defined attenuation map obtained from a CT acquisition of phantoms provided by the manufacturer (so-called CT template), in order to obtain attenuation coefficients of all phantom parts. This map is registered to the non-attenuated PET images and subsequently used during the PET reconstruction process. During PET acquisitions (on PET/MR), the phantom needs to be placed carefully at a pre-defined position in the PET field of view to ensure alignment between attenuation map and PET data. To guarantee a reproducible phantom placement, a defined set of phantom holders have to be used. If CT maps were used to correct for the attenuation the data of the PET phantom, this validates "only" the PET component of the hybrid imaging system and does not allow to derive any conclusion about the quantitative accuracy of PET data of that same imaging system if MR-AC methods are then applied in patients.

4.4.2 MR TESTS FOR PET/MR

We recommend testing the MR sequence most commonly used in clinical routine and all sequences used for attenuation correction with the corresponding coil. If several coils are commonly used in clinical routine, care should be taken to alternate the checked coil at each test.

As reported in paragraph 4.4.1, it is currently not possible to test the accuracy of the attenuation sequence used in PET/MR using phantoms. No dedicated test object, which should contain compartments that produce different MR signals and with different attenuation properties, are available. A procedure using clinical images is proposed in this protocol. Manufacturers should in the future propose alternative solutions to test this issue under controlled conditions. In literature, alternative solutions with home-made phantoms are proposed [McGarry2020, Yuan2012, Rausch2021, Harries2020], but they still remain pilot study to be proposed in a quality control program.

Parameter	Periodicity	Materials needed	Test duration
Uniformity of image signal	Monthly	Homogeneous phantom	15 min/sequence/coil
Signal to Noise Ratio	Monthly	Homogeneous phantom	15 min/sequence/coil
Attenuation map	Acceptance or after relevant upgrade in the sequence used for attenuation correction	10 clinical patients	1 hour

Table 6. PET/MR QC proposed with the aim to test parameters that may affect PET images.

Relevant maintenance that are liable to affect the performance of the MR scanner are replacements of coils, electronics, reconstruction software and upgrade in the sequence used for attenuation corrections.

4.4.3 UNIFORMITY

Purpose: To check the ability of the system to depict uniform regions of a phantom with the same intensity.

Material: Any homogeneous phantom, or homogeneous section of a phantom, can be used for this test.

Procedure: Any multislice acquisition could be used. See the recommendations of the chosen standard and manufacturer's recommendations.

Analysis: Uniformity is measured in a central ROI of 75 to 80 % of the phantom diameter. Uniformity can be measured as the difference between the maximum and the minimum of the pixels in the ROI. The result is usually displayed as a percentage of uniformity (PIU):

$$PIU=100.\left(1-\frac{S_{max}-S_{min}}{S_{max}+S_{min}}\right)$$

where S_{min} is the minimal pixel intensity and Smax the maximum pixel intensity in the area. For multi-element surface antennas, it is recommended to use several ROI of the acquired image to make the measurement not only for one central ROI.

Tolerance: Depending on the guideline, the field strengths, the coil, the sequence and the object size. For example, for small fields of view (< 20 cm), the uniformity should be > 80 %.

4.4.4 SIGNAL TO NOISE RATIO

Purpose: To measure the signal to noise ratio (SNR) in all three orthogonal planes.

Material: Any homogeneous phantom, or homogeneous section of a phantom, can be used for this test as for uniformity measurement.

Procedure: Any multislice acquisition could be used. See the recommendations of the chosen standard and manufacturer's recommendations.

Analysis: The signal $\bar{S}$ is usually measured as the average of the intensities in a ROI of size equal to 75 - 80 % of the diameter of the phantom as for the uniformity. Noise can be computed from measurements in a single image by selecting ROI in empty zones (air, outside the phantom). SNR can be defined as:

$$SNR=\frac{\bar{S}}{\sigma_{bkg}}$$

where σ_{bkg} is the standard deviation of a background ROI in the air.

Tolerance: Acceptance criteria for SNR cannot be given in general terms since the values will always be system specific (due to RF coil, scan conditions, phantom, etc.). However, SNR measures obtained during acceptance testing should form the baseline or reference values used in the subsequent quality assurance program.

4.4.5 ATTENUATION MAP MEASUREMENT IN PET/MR

Purpose: The specificity of PET/MRI control comes from the use of DIXON, Caipirinha, or short echo time sequences (ZTE or UTE) for attenuation correction via tissue differentiation (soft tissue, air, adipose tissue, bone) thanks to their different relaxation times and classification algorithms.

The aim is to test the accuracy of the segmentation method and the efficacy of truncation correction methods.

Material: Attenuation maps of 10 clinical patients can be used for this test.

Procedure: Test 10 attenuation maps of patients with different morphology and localization acquired with the standard sequence used for attenuation correction and coils used in clinical routine.

Analysis: For each map, verify that the segmentation has correctly identified the expected number of compartments (soft tissue, air, lung, adipose tissue, and eventually bone). Place a ROI on the different compartments (in a large structure, far as possible from tissues interface) and verify that the linear attenuation coefficient assigned to each of them is consistent with the range indicated in table 7. In case of presence of truncation correction method, verify that, the peripheral regions (typically the external part of the arms) that are not visible in MRI are included into the attenuation map.

Tolerance: The identified linear attenuation coefficient (LAC) of different compartments must be consistent with the expected LAC:

Compartments	**Expected LAC (cm^{-1})***
Background air	0.0
Lung	0.018 - 0.0224
Soft tissue	0.1
Adipose tissue	0.085 - 0.086
Bone	0.11 – 0.2485

*[Oehmigen2018]

Table 7. Ranges of expected LAC in different compartments.

In all cases, the attenuation map used for each patient must be visually checked in PET/MR. If there is an artifact in the attenuation map, images without attenuation correction should be used to assist in the interpretation and use of quantitative values extracted from the PET should be avoided.

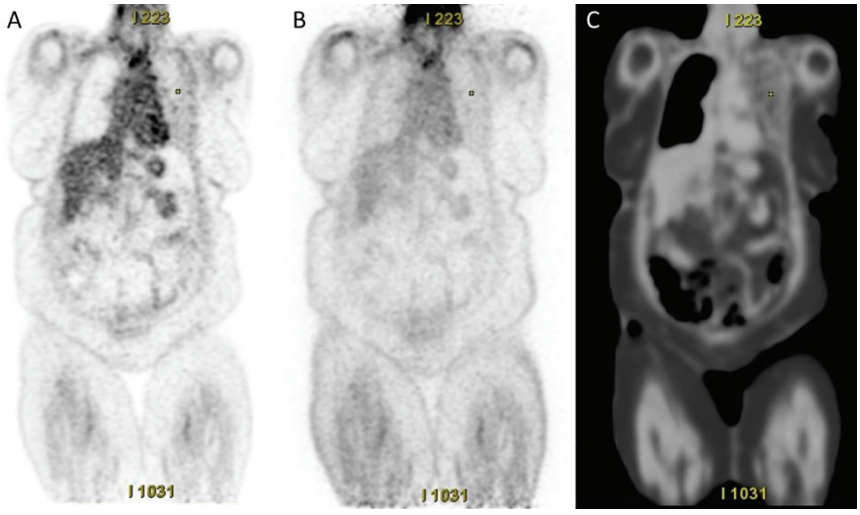


Figure 7. Coronal slice of a patient (Signa PET/MR, GE): attenuation corrected PET (A), non-attenuation corrected PET (B), attenuation map (C). The attenuation map shows a left lung segmentation error resulting in over-correction in the attenuation corrected PET image.

5. QC FOR ACCREDITATION PROGRAM

There are several accreditation schemes for PET aimed at harmonising procedures to ensure image quality and quantitative measures (SUVs) are comparable across PET centres. These schemes are usually mandatory for centres participating in clinical trials, but can be applied for harmonisation of clinical practice. Sites already part of an accreditation scheme should follow the specific instructions provided by the accreditation body. It may be possible to combine the accreditation acquisition with the image quality test used for routine QC to avoid duplication of effort. Where an accreditation scheme is not available it is recommended that sites perform equivalent phantom procedures and use the EARL specifications as guidance for harmonisation of local PET scanners. In addition to ^{18}F fillable phantoms, there has been interest in use of ^{68}Ge phantoms [Chauvie2016] which eliminate a lot of the user variation seen with the ^{18}F equivalent.

Accreditation Scheme	Phantom Used	Key Differences
EARL	IEC Image quality phantom	• No scatter phantom • 6 hot spheres • Sphere:background ratio 9.7:1 • 5 mins acquisition time
UK PET Core Lab	IEC Image quality phantom	• No scatter phantom • 6 hot spheres • Sphere:background ratio 5:1 • Variable acquisition times
Italian Foundation on Lymphoma	IEC Image quality phantom	• No scatter phantom • 6 hot spheres • Sphere: background ratio 4:1 • Variable acquisition times
SNMMI Clinical Trials Network	SNM-CTN Anthropomorphic phantom	• No scatter phantom • 6 to 9 hot spheres • Sphere: background ratio 4.9:1 • 4 min per bed

Table 8. Accreditation schemes available and key differences from the procedure described in NEMA NU-2 2018 [Sunderland2015].

The most used phantom for accreditation schemes is the IEC Image quality phantom [IEC2013]. The procedure employed is a modified version of the NEMA image quality test [NEMA2018] using 6 hot spheres in the body phantom, but without the additional scatter phantom. The exact procedure is dependent on the accreditation scheme, with variable sphere to background ratios and acquisition times used, as listed in Table 8. The idea behind the different strategies however is the same, that is to use the NEMA phantom for the purpose of matching image quality and quantitative measures across scanners and institutions.

The activity concentration in the spheres is measured in the reconstructed PET image and compared to the true activity concentration (where the true activity concentration is determined from the assayed activity from the radionuclide calibrator corrected for decay and residual activity in the syringe). The recovery coefficients are calculated as the ratio of the measured activity concentration to the true activity concentration for each sphere. The recovery coefficients are then plotted against the sphere diameter to generate a 'recovery curve'.

To determine limits for harmonisation, the recovery curves for a range of scanners and reconstructions are measured. The optimal harmonisation is selected where the recovery curves converge. The result of harmonisation therefore reduces the variance across scanners and institutions in an attempt to obtain comparable

results. It may be that this results in a certain degree of bias (as seen in Figure 8) particularly if older generation PET systems are included.

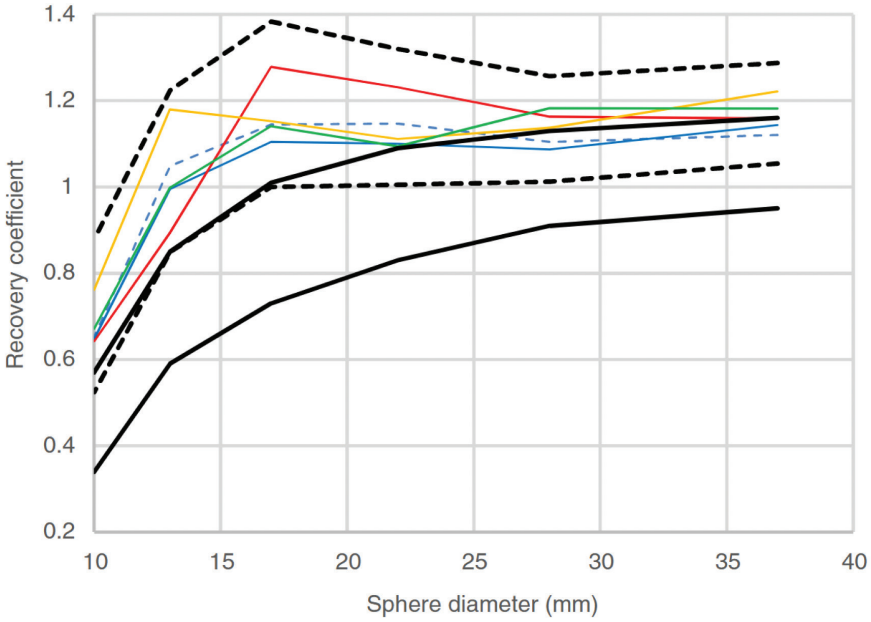


Figure 8. Examples of harmonised SUVmax recovery curves [Kaalep2018-2].

There are different limits for the recovery coefficients depending on the accreditation scheme and how the PET data are to be used. Different limits are also required depending on whether point spread function modelling is included within the reconstruction or if non-^{18}F based tracers are used. As a guide, EARL publishes the limits used on their website (EANM Research Ltd, no date). Two standards are currently used for ^{18}F, EARL1 is for reconstructions without the scanner point spread function (PSF) modelled in the reconstruction [Kaalep2018-1] and EARL2 for reconstructions including the PSF [Kaalep2018-2]. For sites to achieve accreditation with EARL, the recovery coefficients for mean (A50) and max should fall within the ranges for EARL1 (without PSF) or for mean (A50), peak and max for EARL2 (with PSF). At present, EARL accreditations for other isotopes (^{68}Ga and ^{89}Zr) are available as well.

6. QC FOR RADIOTHERAPY APPLICATIONS

The scope of testing and tolerances for use of PET/CT or PET/MR in radiotherapy will depend on the intended use.

1. For centres using diagnostic PET/CT or PET/MR for visual comparison with other imaging to guide volume delineation, the key tests are:

- PET to CT or MR alignment - this should be performed according to the procedure in section 4.2.5

- Integrity and display of PET data - it is important to test the data transfer to the planning system retains the integrity of the data, including
  - PET to CT or MR fusion
  - image orientation
  - display of SUV

This can be tested by transferring PET/CT or PET/MR scans of the uniform cylinder to check SUV quantification and the PET to CT or MR alignment QC images to check alignment on the planning workstation.

2. For applications where the PET/CT or PET/MR data is registered to the planning CT to aid in radiotherapy volume delineation, the accuracy of the registration should be assessed. The required tolerance for registration accuracy will depend on treatment type and tumour location. Greater accuracy of registration can be achieved if external lasers, flat couch-top and full radiotherapy set up are used. However, registration can be greatly improved simply by using a flat couch top and use of the radiation therapy immobilizers similar to radiotherapy which may be sufficient for some applications.

Accuracy of rigid and deformable registration techniques can be assessed using physical and virtual phantoms and through use of fiducial markers. AAPM Report 132 [AAPM132] provides further details on methods of assessment for image registration algorithms.

Moreover, particular attention should be paid to the critical issues related to PET/MR imaging when it is used for the radiotherapy treatment planning, as evidenced by the literature [Paulus2014, Paulus2016]. MR distortion tests should be performed according to the manufacturer procedure in Appendix 3.

3. For the most complex applications where the CT component of the PET/CT replaces the planning CT for direct planning and dose calculation, the PET/CT scanner will need to undergo rigorous commissioning and routine QC similar to the radiotherapy CT simulator.

The centre will also require a flat indexed couch-top, external radiotherapy lasers and access to patient positioning and immobilisation devices used in the radiotherapy department. The quality assurance requirements and tolerances for CT scanners and image evaluation for CT simulation in radiotherapy applications are provided in AAPM Report 83 [AAPM83]. Most of these tests are applicable to the PET/CT and in consultation with radiotherapy physics can be translated to the routine QA program for the PET scanner. It should be noted that some of these QC tests may overlap with the routine CT scanner QC so it may be possible to combine some tests with little modification to avoid duplication.

Since the tolerances for radiotherapy simulation are much tighter, the PET to CT alignment should undergo more rigorous testing including the couch deflection under load.

7. PHANTOMS AND SEALED SOURCES USED FOR PET QUALITY CONTROLS – PHANTOMS DESCRIPTION

7.1 SEALED SOURCES FOR DAILY PET QUALITY CONTROL

Manufacturers use sealed sources of different shapes and isotopes for PET daily control (Table 9). These sealed sources must be renewed regularly to ensure the minimum activity recommended to perform the quality controls.

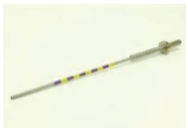
	Philips	General Electric		Siemens
Isotope (half-life)	^{22}Na (2.60 years)	^{68}Ge (270.95 days)		^{68}Ge (270.95 days)
Nominal activity	3.7 MBq	55 MBq	37-55 MBq	74-92.5 MBq
Shape	Point source	Annulus source	Line source	Cylindrical source
Replacement period	2 years	2 years	2 years	1-2 years
				

Table 9. Comparison of sealed sources used for daily PET quality control.

7.2 PHANTOMS USED FOR PET QUALITY CONTROLS

7.2.1 SUV AND CROSS CALIBRATION PHANTOM

All manufacturers offer a cylindrical phantom fillable with water to calibrate and evaluate the radioactive concentration, SUV value and cross-calibration with the calibrator (Table 10). The dimensions of these phantoms and in particular the length vary according to the manufacturers but the principle is identical. These phantoms are delivered with a support allowing them to be placed in the centre of the PET field of view.

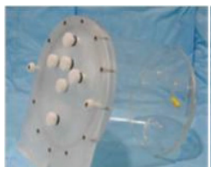
	Philips	General Electric	Siemens
Diameter (cm)	20	20	20
Height (cm)	29	17	30
Volume (litres)	9.293	5.640	9.425
			

Table 10. Comparison of fillable cylinders used for SUV calibration.

7.2.2 NEMA IMAGE QUALITY PHANTOM

The most common phantom used for characterizing image quality and for accreditation programs is the IEC Image quality phantom [IEC-61675-1-2013] (Figure 9). It consists of a body phantom built of acrylic glass material with a volume of 9.7 litres (interior length of phantom: 180 mm). Six fillable spheres of various sizes (inner diameter: 10, 13, 17, 22, 28 and 37 mm) can be inserted into the body phantom in the same plane. A lung insert containing styrofoam can be positioned in the centre of the phantom.

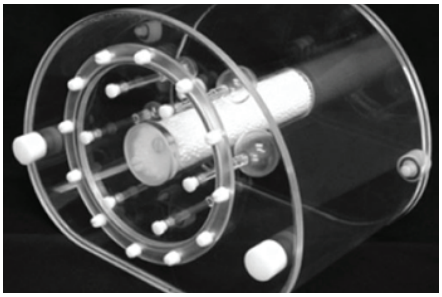


Figure 9. IEC Image quality phantom.

7.3 PHANTOMS USED FOR CT QUALITY CONTROLS

7.3.1 QUALITY IMAGE PHANTOMS PROVIDED BY PET/CT MANUFACTURERS

All manufacturers provided a CT image quality phantom with their PET/CT. The phantom has a uniform section filled with water or equivalent material. The phantom also has at least one section with a minimum of 3 different materials: water and air are mandatory and the last one could be an acrylic zone. The Image Quality phantom could also contain other layers for different tests (resolution, slice thickness, contrast). These phantoms are delivered with a support allowing them to be placed in the centre of the CT system field of view.

7.3.1.1 PHILIPS HEALTHCARE: SYSTEM PERFORMANCE PHANTOM

The system performance phantom is composed of 2 sections: Head and Body. The Head section of the phantom is a PVC shell of diameter 20 cm filled with water and consisting of three layers in order to perform different tests:

- The physical layer, used to measure the resolution and slice thickness
- The liquid layer, used to measure noise and uniformity
- The multi-spindle layer, used to check contrast.

The body phantom is a 30 cm diameter nylon cylinder (absorption 100 ± 10 HU) including a Teflon pin (absorption 890 ± 50 HU) and a water compartment (0 ± 10 HU).

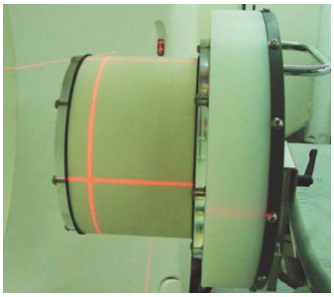


Figure 10. System performance phantom (Philips).

7.3.1.2 SIEMENS HEALTHINEERS: CT PHANTOM

The CT quality phantom, specific to a type of scanner, is composed of different parts:

- Water phantom
- Reference marking
- Wire and ball phantom (not used for QC tests)
- Slice thickness phantom

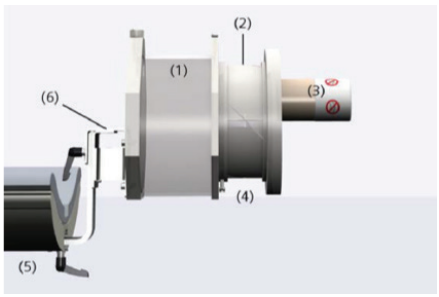


Figure 11. CT quality Phantom (Siemens Healthineers) including 1) water phantom, (2) reference marking, (3) wire and ball phantom, (4) slice thickness phantom, (5) patient table, (6) phantom holder bracket.

7.3.1.3 GE HEALTHCARE: QA PHANTOM

The QA phantom contains two sections, each corresponding to a single scan plane. Section 1 of the phantom provides an indication of the contrast scale, nominal tomographic section thickness and the spatial resolution capability of the system for high contrast objects. Section 2 of the phantom provides an indication of noise, uniformity and detectability for low contrast.

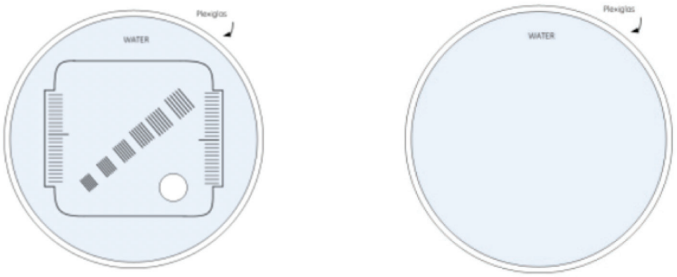


Figure 12. QA phantom (GE) is composed of section 1 (left) and section 2 (right).

7.3.2 OTHER PHANTOMS

Other phantoms available for CT characterization, such as the 464 ACR and the 500-600 Catphan family, are independent from PET/CT vendors (Figure 13).

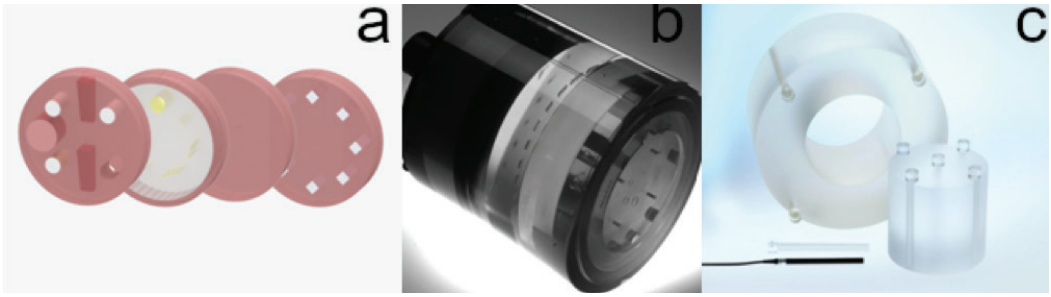


Figure 13. 464 ACR phantom (A), Catphan 600 (B), CTDI phantoms (C).

To quantify the scanner output for head and body examinations, various PMMA phantoms are used with a diameter of 16 cm and 32 cm respectively.

7.4 PHANTOMS USED FOR MR QUALITY CONTROLS

Phantoms used for MRI quality tests can be either provided by the manufacturer or proposed in a specific standard (Eurospin, ACR MRI Phantom). Phantom contents are in the form of an aqueous solution or gelling solution (agarose) doped with paramagnetic components (copper sulphate). Phantoms supplied with the MR device are usually made up of spheres and cylinders the size of the head and body. Concretely, two approaches can be distinguished for MR quality control phantom. The first is based on the use of several phantoms, each dedicated to the measurement of a metric or a group of quality control metrics (Eurospin or Spinsafety phantom). The second approach consists in using a single phantom containing several structures intended to measure different metrics or groups of quality control metrics (ACR phantom).

7.4.1 PHANTOMS PROVIDED BY PET/MR MANUFACTURERS

The two PET/MR manufacturers used a spherical phantom for daily MR quality control.

7.4.1.1 SIEMENS HEALTHINEERS

Siemens supplies several phantoms for MRI quality control:

- a 17 cm diameter sphere simulating a head, filled with a solution equivalent to water and placed on a foam support;
- a body phantom composed of a hollow phantom filled with a solution equivalent to water and a sphere of diameter 24 cm filled with an equivalent solution of fat (oil).

Figure 14. Phantoms for MRI Quality Control on the mMR (Siemens Healthineers).

7.4.1.2 GE HEALTHCARE

The GE company provides several dedicated MRI test objects with their PET / MRI device:

- DQA-III phantom allowing the extraction of many parameters (noise, SNR, uniformity, distortion, thickness and cut profile, spatial resolution);
- Head phantom sphere (17 cm in diameter) and its charger;
- Body phantom sphere and its charger;
- Cylinders, parallelepipeds, spheres of varying sizes.

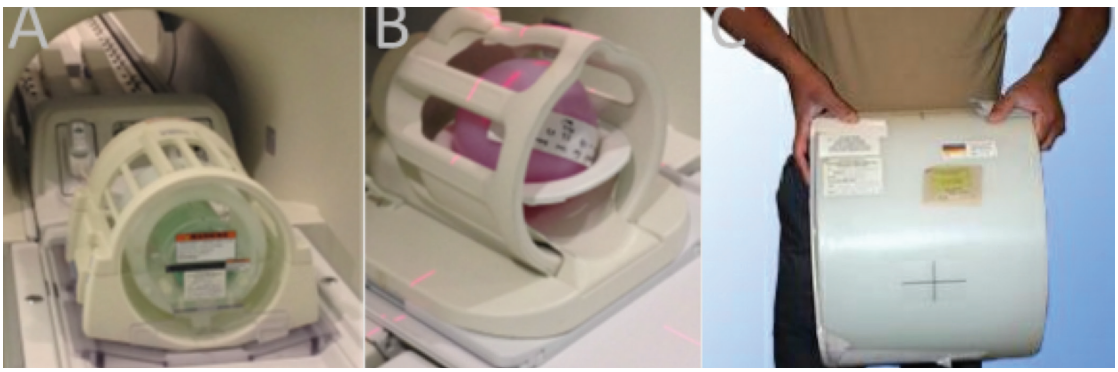


Figure 15. Phantom DQA-III (A), Head phantom (B), body phantom (C).

7.4.2 OTHER PHANTOMS USED FOR MR

Many phantoms are available deriving from different international guidelines for MR QC as the American College of Radiology document [ACR2015], the National Electrical Manufacturers Association standards [NEMA-MS1-2014, NEMA-MS2-2014, NEMA-MS3-2014], the EUROSPIN protocol [EUROSPIN1996] or the American Association of Physicists in Medicine guideline [AAPM100-2010].

Many homogeneous phantoms or phantoms with a homogeneous part are available such as Eurospin Test object T01 or water-only region of the ACR phantom.

There are also phantoms dedicated to measuring geometrical distortions:

- Phantom of known dimensions with insert of known lengths such Eurospin Test object T02 and ACR phantom
- Isotropic test object such as a ball or a cube can be used and acquired according to the 3 planes
- Test objects containing a three-dimensional grid (Quasar grid3D, NEMA).

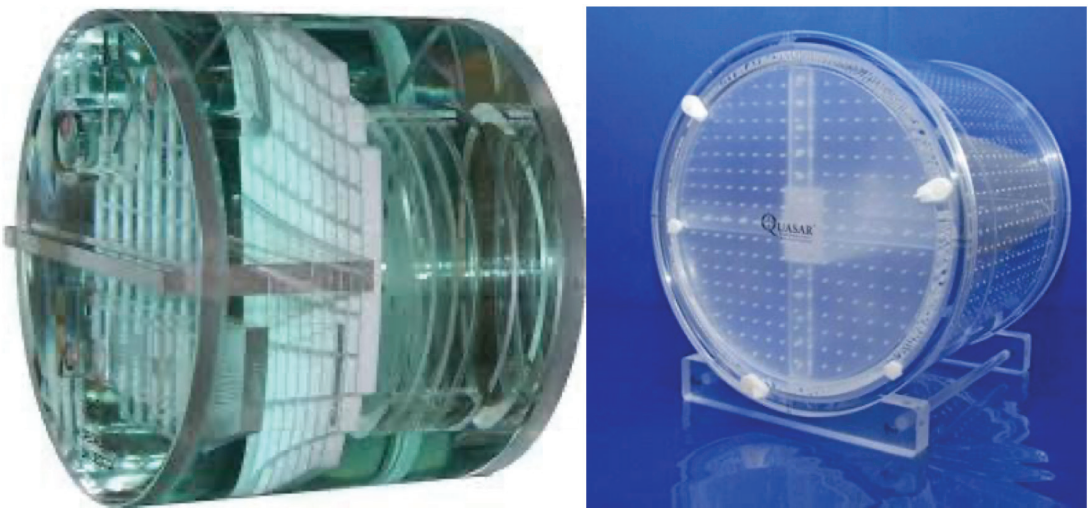


Figure 16. ACR phantom (American College of Radiology), QUASAR MRID3D geometric distortion (ModusQA).

Slice parameters (position, thickness and spacing) can be measured with test objects inserted in multipurpose phantoms, most of which utilize inclined surfaces (Eurospin Test object T02, ACR phantom, NEMA).

For measurements of high-contrast resolution, phantoms include small high contrast structures such as:
- Eurospin Test object T04
- phantom insert containing arrays of successively smaller diameter high contrast objects (AAPM report 100)
- ACR phantom with individual small bright spots (resolution insert - water filled holes drilled in a small block of plastic).

For low-contrast resolution measurement, a phantom with a set of low contrast objects of varying size and contrast must be used. For example, ACR phantom is composed of 4 slices with rows of small disks of varying thickness, each disk has 10 spokes of 3 holes each, with the hole diameter decreasing with increasing spoke number.

7.5 PHANTOMS USED FOR MULTI-MODALITY IMAGING

7.5.1 SEALED SOURCES USED FOR PET/CT

The three manufacturers propose an object to test the superposition of the volumes of PET and CT. The object is composed of several linear or point radioactive sources placed in several planes which are visible in both modalities (Table 11).

	Philips	General Electric	Siemens
Isotope (halflife)	^{22}Na (2.60 years)	^{68}Ge (270.95 days)	^{68}Ge (270.95 days)
Nominal activity	6 x 0.37 MBq	5 x 0.7 MBq	2 x 37 – 46.25 MBq
Shape	6 disc sources (25.4 mm overall diameter x 6.35 mm thick) with a support	5 sphere sources insert in a phantom	2 line sources with a support
Replacement period	2 years	2 years	1 years
			

Table 11. Comparison of sealed sources used for PET/CT alignment control.

7.5.2 PHANTOMS USED FOR PET/MR

The two manufacturers propose an object to test the superposition of the volumes of PET and MR. The object is composed of several linear or point radioactive sources placed in several plavwnes which are visible in both modalities (Table 12).

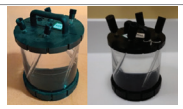
	General Electric Signa	Siemens mMR
Isotope (halflife)	^{68}Ge (270.95 days)	^{68}Ge (270.95 days)
Nominal activity	5 x 0.7 MBq	2 x 37 – 46.25 MBq
Shape	5 spherical sources insert in a phantom (sphere diameter 17 mm)	2 line sources insert in a phantom
Replacement period	2 years	1-2 years
		

Table 12. Comparison of sealed sources used for PET/MR alignment control.

GE also provides sealed sources (three ^{68}Ge spheres of 0.7 GBq) to verify the position of the examination table and coils.

Figure 17. Sealed sources for the positioning of examination table and coils (GE)

APPENDIX 1 ROUTINE MANUFACTURER QC ON THE PET COMPONENT OR DAILY QUALITY CONTROLS

The daily quality control procedures implemented in available PET systems of the 3 main manufacturers are summarized in this part. PET Daily Quality assurance (DQA) is performed automatically or semiautomatically with phantoms provided by manufacturers, after the routine system initialization or start-up and before the first patient.

A1.1 PHILIPS HEALTHCARE

The PET Daily QC program includes the following procedures:

System Initialization: The System Initialization restarts the hardware and firmware on the system and performs a series of self-diagnostics. If the system initialization fails, the program stops.

Result: Passed/not passed.

Check sensors: The hardware sensors test verifies that voltages, currents, and temperatures are correct for PET gantry electronics.

Baseline collection: The system collects the analogue offsets of all photomultiplier channels as baseline data, which are used by the scanner processing electronics as a reference in each data collection. If baseline values measured are outside the established range, the system automatically performs an offset calibration and then recollects the baseline data.

Result: The system displays average value of baseline value collected and a message indicating a Successful/Failed status.

PMT gain calibration (only for non-digital systems): The PMT Gain Calibration optimizes the electronic gain for each PMT channel with an iterative process (usually 10 iterations). If the system cannot calibrate all the PMTs for the target gain value within the allowed number of tries, the system displays a Failed message.

Result: The system displays the average and maximum error and a message indicating a Successful/Failed status.

VBias calibration (only for digital systems): The VBias test varies the offset voltages to the photo-diodes in the digital detectors to determine the voltage needed to optimize event detection. No source is required. When performing Daily QC, the system first determines if a valid VBias calibration file is available. If one is available, the system does not perform another calibration. If a valid VBias calibration file is not available, the system then performs the calibration.

Energy test and analysis: The Energy Test and Analysis collects ListView data and calculates the energy centroids and FWHM. If the system detects a problem with the Energy test, it automatically performs an Energy calibration. The system then performs another Energy test to confirm the problem is corrected.

Result: Average value of the centroids and FWHM.

Timing test: The Timing Test compares the system timing against the calibration settings.

Result: Timing resolution of the system.

Detector uniformity test (only for digital systems): The system checks to ensure that all crystals are detecting approximately the same number of events. This test indicates an error if excessive quantities of crystals are not reporting the expected number of events.

Emission sinogram collection and analysis: The system automatically collects an Emission QC Sinogram for two minutes with the ^{22}Na source centered in a 256 mm FOV. The user can display and analyse the image (7 sinograms) to detect deviations from normal sinogram.

The purpose of the test is to alert you when system drift affects image quality or if acquisition hardware is defective.

Result: Image of the source sinograms, linearity value.

Hardware Sensors test: The Hardware Sensors test verifies that voltages and currents are correct for PET gantry electronics.

At the end of each test, the system displays a PASSED, SUCCESS, NOTICE, WARNING, or FAILURE message.

In case of failure: If one test fails, the system lists recommended actions. If corrective action fails the local Service Representative must be called.

A1.2 GE HEALTHCARE

General Electric recommends a daily check of the PET detectors, before the first examinations, following a procedure called PET DQA (Daily Quality Assurance). The PET DQA program is a measurement of detector performance compared to a baseline and does not include calibration or adjustment of the detectors. It measures the current state of the PET detector and provides a visual and a parametric data report. The control is performed with a ^{68}Ge annulus phantom (PET Annulus DQA phantom) positioned in the center field of view on a dedicated support or with a ^{68}Ge line source (rotating pin) at the edge of the field of view. The PET DQA takes about 3 to 16 minutes depending on the activity of the annulus phantom or line source.

The PET DQA includes the following verifications:

- Coincidences: Measure the number of coincidence events associated with each crystal element.
- Singles: Measure the number of singles events detected in each crystal.
- Deadtime: Displays the fraction of time that each detector block is busy. A high value may indicate noisy electronics or a light leak in the detector. A zero value indicates a loss of signal which should match low values in singles and coincidence.
- Timing: Displays the calculated timing error for each crystal. Large area patterns may indicate a defect and point to the suspected component.
- Energy: Displays the peak energy spectrum of all crystals. Changes in room temperature strongly influence the PET energy shift, which is automatically corrected by the front-end electronics based on direct measurement of the detector's temperature.

Reference: The Baseline must be established once every quarter, immediately after a quarterly PET detector calibration, after annulus phantom / line source replacements and after service events where calibrations are performed.

Results: At the end of the inspection, a summary is displayed indicating the status of each test (pass/fail information) performed by comparison to the reference as well as red/yellow/green indicators with the following status:

- Green: the value is within an acceptable range of variation from the baseline reading.
- Yellow: the system shows increased variation from the baseline reading, but you may use the system as long as the graph of the corresponding test is defect-free.
- Red: the value falls outside the range of acceptable variation from the baseline reading. Review for corrective action (such as calibration or repair).

Detailed inspection of the results for each detector block or crystal in the form of graphs is also available. It includes:

- A graph provides a graphic display of each DQA test, compared to its baseline. By moving the cursor over the graphs, the data value of the corresponding module, block, crystal row, crystal column is displayed at the bottom of the screen. Graph should display homogenous values across each module, block and crystal.

- A table of calculation with current reading, acceptances values and the corresponding red/yellow/green status for:
  - PET coincidence mean and variance: The average and standard deviation of the coincidences for all crystals
  - PET singles mean and variance: The average and standard deviation of singles for all crystals
  - PET mean deadtime: The average deadtime of all blocks
  - PET timing mean: The average timing adjustment of all crystals
  - PET Energy shift: The average difference in energy peak location of the current reading from the baseline reading

- A table of individual checks on the module, block or crystal levels and the corresponding red/yellow/green status:
  - Coincidence and singles Rate: Checks the coincidence rate and singles rate of all individual blocks and crystals
  - Block Busy: Measures the block busy in each block
  - Timing Changes: Reflects changes in coincidence timing per block
  - Gain Changes: Detects the changes in effective anode gain at the block level, at each block and the average gain of all blocks
  - Temperature Status: Verifies the temperature sensors inside the PET gantry and detector modules fall within the acceptable range
  - Module ID Mismatch: Compares the actual module ID numbers against the list of Module IDs currently stored in the system during calibrations.
  - Source Phantom Life: Displays the number of days remaining until time to replace the annulus phantom or line source. The Phantom Life Test is based on the number of coincidence events detected over a period of time.

In case of failure: If one or more DQA tests fail, the system lists recommended actions beneath the Summary Report table. If corrective action fails the local Service Representative must be called.

- If the corresponding test results fall outside the range of acceptable values, the user may need to perform a new detector calibration:
  - Yellow: Update tuning is recommended.
  - Red: Update tuning is required.

- If the temperature falls outside the specified range:
  - Yellow: Configuration is outside the normal range. Check room temperature and status.
  - Red: Defect detected in configuration. Service attention is required.

- If the annulus phantom or line source activity, and phantom life remaining, measured in days, falls below acceptable levels:
  - Yellow: Phantom activity low. The phantom should be planned to replace when the indicator is Yellow. It will turn Yellow around the 24-month period depending on the actual phantom activity and system performance.
  - Red: Phantom activity below minimum activity, replace phantom. It will turn Red about 60 days prior to when the maximum acquisition time is reached. The DQA results will not be displayed when the maximum acquisition time is reached.

- If deviations (non-homogeneity, missing data) are present in the graph, the local Service Representative must be called.

A1.3 SIEMENS HEALTHINEERS

Siemens recommends to perform a daily quality control at least once a day and prior to scanning patients. The PET Daily Quality Check performs a calibration to normalize variations in PET detector responses. The control can be performed with a ^{68}Ge cylindrical phantom positioned in the center field of view on a dedicated support. Another solution (optional and licence dependent) is proposed by Siemens without phantom: QualityGuard option uses intrinsic radioactive properties of Lutetium present on LSO detectors to automatically calibrate itself, eliminating the need for an external source for daily and weekly PET quality control. QualityGuard performs PET quality Check during the night.

The PET daily Quality check performed with ^{68}Ge phantom takes up to 30 minutes depending on the activity of the phantom. When it is performed with Lutetium during the night it takes several hours. In all cases, the results produced determine the readiness of the system for scanning or whether service is needed. The procedure includes:

- Daily normalization of the detector response based on a phantom scan or background LSO acquisition
- Computation and verification of the PET calibration factor (ECF)
- Normalization results display and sinogram inspection.

Two other options are also available from the PET Quality Check window in recent model:

- Partial setup: it performs partial detector setup, quality check and normalization. The Partial Detector Setup procedure generates crystal region maps and crystal energy profiles. The Partial Setup should be performed weekly for optimal PET performance. If Partial Setup has not been performed within seven days, it will be automatically performed during the next PET Quality Check.

- Full setup: it performs full detector setup, time alignment, quality check and normalization. Full Setup is required to run every 90 days (or after power loss).

Reference: Typical range for each parameter and each PET model.

Result: When the PET Quality Check procedure is complete, the results are displayed in the Report section of the dialog. The software calculates the number of counts.MBq^{-1} (ECF). These values are compared to the system tolerances. If the system quality result is PASS, and a green checkmark is displayed. If the ECF value is out of range, the system quality result is FAIL and a red cross is displayed. If the PET Quality Check is successful, the user has to save the normalization.

It is possible to display the normalization sinogram in the Sinogram Viewer. The sinogram viewer displays the sinogram corresponding to the selected plane and shows all planes with indicators marking the physical location of the currently selected detector pair. The sinogram must be visually inspected for obvious artefacts, such as dark diagonal streaks.

Detailed inspection of the results is also available in the System Quality Report, which contains the detailed results of the PET Quality Check and tolerances:

- Block noise (numbers of blocks out of the range)
- Block efficiency (numbers of blocks out of the range)
- Measured randoms (%)
- Scanner efficiency (cps.Bq^{-1}.ml^{-1})
- Scatter ratio (%)
- Scanner efficiency correction factor (ECF) (Bq.s.counts^{-1})
- Image plane efficiency (%)
- Block timing offset (bin)
- Block timing width (bin)
- Time alignment residual (mm)
- Time alignment fit (x/y) (mm)

It is possible to display and print reports of previous tests.

In case of a failure:
If the ECF value is out of range, the system quality result is FAIL. In this case, it is possible to reject the new normalization map, the previous normalization map will then be used by default. If the PET Quality Check fails, the user has to repeat the PET Quality Check with a Full Setup. If problems persist, the user has to contact Siemens Healthineers Service representative.

Unusual patterns or structure in the sinogram must also be reported to Siemens Healthineers service representatives.

APPENDIX 2 QUALITY CONTROL ON THE CT COMPONENT

The routine procedures implemented in available CT systems of the 3 main manufacturers are summarized in this part. CT quality assurance is performed automatically or semiautomatically with phantoms provided by manufacturers, after the (daily) routine system initialization or start-up.

The main advantage of using manufacturer specific phantoms is that most CT systems include software to automatically process QC data, applied in specific imaging protocols. Vendor neutral phantoms enable a better comparison between different systems and imaging protocols, but could be slow and cumbersome for weekly tests, hence it is only recommended for annual tests or when there is a lack of manufacturer phantoms.

Besides the routine CT procedures, additional tests can be performed on the CT scanner. The tests reported in paragraph A2.2 suggest the most significant QCs that can be performed. More detailed international guidelines on this topic are provided by IAEA [IAEA2011] or ACR [ACR2017].

A2.1 MANUFACTURER ROUTINE QUALITY CONTROLS

A2.1.1 PHILIPS HEALTHCARE

A2.1.1.1 DAILY QC

The daily CT QC program includes the following procedure:

Short Tube Conditioning: it brings the x-ray tube to the normal operating temperature. This process is required daily before any scans are performed on patients, or after 8 to 10 hours of scanner inactivity.

A2.1.1.2 AIR CALIBRATION (WEEKLY)

Air calibration is part of normal system maintenance and helps to reduce ring artefacts.

This procedure should be performed midday because it must be done at stable, operating temperature.

Warning: If ring artefacts are observed in the acquired images, perform Air Calibration. If ring artefacts persist, the local Service Representative must be contacted.

A2.1.1.3 HEAD IQ CHECK (WEEKLY)

Head IQ check is performed by using the Head section of the system performance phantom, which is a PVC shell filled with water and consist of three layers for different tests (resolution and slice thickness, noise and uniformity, contrast).

Result: CT number, uniformity and noise values

Reference: CT number in the range (102.17;114.7 HU); Uniformity in the range (-8;8 HU); noise in the range (7.9;10.7 HU)

In case of a failure: The user should ensure that the phantom is properly positioned, aligned and level and repeat the test. If any test fails again, report the findings to the local Service Representative before scanning patients in order to ensure safe operation.

A2.1.1.4 CONSTANCY TEST (MONTHLY)

Constancy test is performed by using both Head and Body (with water hole and teflon pin) sections of the system performance phantom.

Result: CT number, noise and uniformity values for Head and Body sections and spatial resolution and slice thickness are reported, with 'passed/not passed' message.

In case of a failure: the user is advised to ensure that the phantom is properly aligned and levelled and to repeat the test. In case of failure persistence, the user must report the findings to the local Service Representative.

A2.1.2 SIEMENS HEALTHINEERS

A2.1.2.1 DAILY QC

The daily CT QC program includes the following procedures:

Check-up (every 12 hours): An automatic procedure that also contains a CT Calibration. This procedure executes a set of functions to calibrate and check the scanning system. This ensures a well-conditioned system. During the procedure the system scans an empty field of view under different voltages, currents and collimations. Functions called are:

- Getter - tube gettering - x-ray tube conditioning
- Filament Adaptation - adjustment of the filament current, increase of filament current after filament vaporization
- Defective Channels Correction - lowering the contribution (or eventually switching off) of defective channels - can also raise the signal of before marked channel if the characteristic improves during following Check-ups
- Calibration - determine changes in sensitivity - contains Air Calibration
- Tube Collimator Check - check the correct opening width and Z position of the collimator

Calibration (after the first 1 - 2 hours of workload after Check-up and/or if the system was idle for more than one hour): performs Calibration (see above)

Daily QC (daily before any scanning): An automatic procedure to determine if the CT scanning system is operating with normal tolerance of Homogeneity and Noise values. It uses a CT phantom to verify the CT number of water and measure pixel noise and tube voltage

Results: The CT value of water (calculated in Hounsfield units and the Pixel noise of images (calculated as a standard deviation).

Reference: Automatically evaluated as a part of the test procedure.

A2.1.3 GE HEALTHCARE

A2.1.3.1 DAILY QC

The daily CT QC program includes the following procedures:

Warm Up the CT X-Ray Tube (at least once per 24 hour period, any time the system sits idle for two or more hours). Tube Warmup is used to ready the X-ray tube for patient scanning or calibration. The warm up brings the CT X-ray tube to its optimal operating temperature. The X-ray tube warm up procedure reduces the possibility of artifacts and may aid in prolonging the life of the tube.

Fast Calibration (daily air calibration): A periodic air calibration for the CT scanner is required and it has to be done daily. This calibration is called Fast Calibration. Air calibration helps to optimize and maintain CT image quality between system calibrations. It is recommended to run the Fast Calibration upon completion of the first CT X-ray Tube Warmup of the day. In any case, warm up the tube before fast calibration if more than two hours have elapsed since the last warm-up. The system runs a DAS convertor check and CT collimator calibration, followed by a two minute gantry balance check. These steps are followed by Mylar Window Check and Fast Calibration sequence.

Water Cal: Water calibration or CT Number Adjustment is used to adjust the HU of water to 0.

A2.2 QUALITY CONTROLS ON THE CT SCANNER

To ensure that the CT scanner is properly functioning and to ensure that it is being utilized optimally, several quality control tests can be performed in addition to those required by the manufacturer.

The tests reported in the following table are just a suggestion of the most significant QCs that can be performed to guarantee an optimal level of performance.

Parameter	Periodicity	Materials needed	Test duration
High contrast spatial resolution	Annually	Phantom with line pair inserts/ metallic wire insert/Catphan	15 min 30 min (MTF)
Low contrast detectability	Annually	Phantom with low contrast detail insert/Catphan	15 min
Slice thickness	Annually	Phantom with ramp or beads	20 min
Scout accuracy	Annually	Ruler or phantom of known length	15 min
Radiation beam width	Annually	External radiation detector	30 min

A2.2.1 HIGH CONTRAST SPATIAL RESOLUTION

Purpose: To evaluate the spatial resolution performance

Material: Line pair phantom with a range of spatial frequencies; metallic wire or hole insert phantom

Procedure: The test should be performed in accordance with the IAEA 2011 or ACR2017 protocols for acquisition and analysis.

Tolerance: Using the line pair phantom, line pairs are compared with the reference.

Metallic wire or hole insert phantom, with a tolerance of MTF ± 10 % of the manufacturer's value.

A2.2.2 LOW CONTRAST DETECTABILITY

Purpose: To evaluate low contrast resolution by detecting low signals in a noisy background

Material: A phantom with low contrast inserts with different dimensions

Procedure: The test should be performed in accordance with the ACR2017 protocol for acquisition and analysis.

Tolerance: Depending on the phantom, inserts with low contrast should be visible. Note: in the IEC, low contrast detectability is not included due to its subjective and observer-dependent interpretation.

A2.2.3 SLICE THICKNESS

Purpose: To evaluate the slice thickness of the reconstructed image in the cranio-caudal direction.

Material: A ramp phantom with a known angle α for the axial mode acquisition. A phantom with a metal disc or bead for the helical mode acquisition.

Procedure: Align the phantom at the centre of the FOV and scan it using a clinical CT protocol.

Analysis:

- Axial mode: plot the signal profile across the ramp and evaluate the full width at half maximum (FWHM).

The slice thickness is:

$$d = FWHM \cdot \tan \alpha$$

- Helical mode: determine the slice sensitivity profile in the z axis direction. Determine CT_{max} and CT_b, hence the CT_{half} number corresponding to half the maximum height using the following relationship:

$$CT_{half} = \frac{(CT_{max} - CT_b)}{2} + CT_b$$

  Determine the FWHM by calculating the distance between the two points corresponding to the CT_{half} values. Simple linear interpolation may be used to obtain this distance more accurately. This distance represents the imaged slice width.

Tolerance: For nominal slice thickness < 1 mm, the measured value should be within ±0.5 mm, for nominal values > 2 mm, the measured value should be within ± 1.0 mm. Between 1 and 2 mm, acceptance values can be applied linearly between ± 0.5 and 1.0 mm.

See IEC 61223-3-5 for a detailed test description and interpretation.

A2.2.4 SCOUT ACCURACY

Purpose: To ensure that the scan projection radiograph (SPR) image accurately indicates the patient position

Material: Ruler or phantom preferably 50 cm or more long. Whatever the phantom, its length must be accurately known.

Procedure: Place the test tool along the long axis of the couch and scan the tool with a 1 mm (or the thinnest available) slice width axial acquisition at each end of the scan sequence or a 1 mm (or the thinnest available) reconstructed display width.

Analysis: The two CT slices acquired of the markers based on the SPR image should be centred over each marker

Tolerance: The accuracy of the SPR should be ± 2 mm of the set value (achievable ± 1 mm).

See IEC 61223-3-5 for a detailed test description and interpretation.

A2.2.5 X-RAY BEAM WIDTH

Purpose: The X ray beam width is a measure of the collimated beam width along the Z axis. As in multislice CT the X ray beam width is larger than the total image width, the entity of this phenomenon (over-beaming) must be known.

Material: Special X ray detector, strip of gafchromic film, array of termoluminescent detectors.

Procedure: The test should be performed in accordance with the IAEA2011 or ACR2017 protocols for acquisition and analysis.

Tolerance: The X ray beam width should be within IEC or manufacturer's specifications according to the used method.

See IEC 61223-3-5 for a detailed test description and interpretation.

APPENDIX 3 QUALITY CONTROL ON THE MR COMPONENT

This appendix presents the daily startup procedures of the MR scanner and outlines a recommended list of MRI quality controls to test image quality. The QC program proposed does not seek to provide a complete MRI image quality assurance program nor to replace the existing guidelines [ACR2015, NEMA-MS1-2014, EUROSPIN1996, AAPM100-2010]. In particular, some "advanced tests" for special techniques (spectroscopy, diffusion...) are not included.

A3.1 MANUFACTURER ROUTINE QUALITY CONTROL

A3.1.1 GENERAL ELECTRIC HEALTHCARE

MR Quality control is an important part of the daily start up procedure. General Electric recommends performing a Daily Quality Assurance procedure to track overall system or RF coil functionality before patient scanning. Two daily automated quality assurance (DAQA) tests are proposed: the DAQA SNR (Signal to noise ratio) test and the DAQA system test.

DAQA SNR test: The DAQA SNR test can be run with a variety of coil/phantoms/holder. Always use the same phantom, the same positioning of the phantom and the same landmark. The user has to choose the desired SNR testing plane (axial, sagittal or coronal). The DAQA SNR test takes 5 minutes for each testing plane. The system collects one signal image and one noise image for the desired testing plane.

The system displays the values for signal, noise, SNR, Transmit Gain in 0.1dB units and the center frequency in units of Hz in the Test Complete window. No reference value is defined, but the results can be compared to the previously acquired values.

DAQA system test: it is run using a Head Sphere (17 cm diameter) and the Split Head coil or the PET/MR 8-channel Brain coil. The DAQA system test takes 15 minutes. The system acquires signal images from all three planes and noise image in the axial plane.

The axial images are used to calculate center frequency, transmit gain, SNR.

For geometric accuracy, measurements are performed on three planes images to calculate the diameter of the phantom relative to the known diameter of the sphere phantom.

Ghosting level is measured as G/S if the SNR is ≥ 100 otherwise the reported value is (G-N)/S with:

- The ghost (G) is the average value in a ROI beyond the phantom area in the phase-encoding direction.
- The signal (S) is the average value in a ROI within the phantom.
- The noise (N) is the average value in a ROI outside the phantom in frequency encoding direction.

The system displays results as for the SNR test. It also reports the ghosting level (%), geometric distortion and maximal geometric distortion. There is no reference value but the results can be compared to the previously acquired values.

A3.1.2 SIEMENS HEALTHINEERS

Siemens recommends performing a coil check as Daily Quality Assurance. The other quality tests are performed only during the preventive maintenance. Siemens uses a spherical phantom to assess signal-to-noise ratio (SNR), uniformity and artefacts.

A3.2 QUALITY CONTROLS ON THE MR SCANNER

We recommend testing the MR sequence most commonly used in clinical routine and all sequences used for attenuation correction with the corresponding coil. If several coils are commonly used in clinical routine, care should be taken to alternate the checked coil at each test.

Parameter	Periodicity	Materials needed	Test duration
Uniformity of image signal*	Monthly	Homogeneous phantom	15 min/sequence/coil
Ghosting	Monthly	Homogeneous phantom	15 min/sequence/coil
Signal to Noise Ratio*	Monthly	Homogeneous phantom	15 min/sequence/coil
Geometric distortion	Annually	Specific phantom	
Slice parameters	Annually	Specific phantom	30 min/sequence/coil
Spatial resolution	Annually	Specific phantom	15 min/sequence/coil
Attenuation map*	Annually	10 clinical patients	1 hour

**test described in paragraph 4.4.4*

Table A3.1: MR scanner QC tests overview.

A3.2.1 GENERAL REMARKS TO PHANTOM TYPES

Phantoms used for MRI quality tests can be either provided by the manufacturer or proposed in a specific standard (Eurospin, ACR MRI Phantom) (see section 7.4). Phantom contents are in the form of an aqueous solution or gelling solution (agarose) doped with paramagnetic components (copper sulphate). Concretely, two approaches can be distinguished for MR quality control phantom: the use of several phantoms, each dedicated to the measurement of a metric (Eurospin or Spinsafety phantom) or the use of a single phantom containing several structures intended to measure different metrics (ACR phantom).

A3.2.2 GHOSTING

Purpose: Ghost is an artefact in which a faint copy of the imaged object appears superimposed on the image, displaced from its true location. Effects are more evident in low signal level areas but usually they overlay the main portions of the image as well, altering the image intensities. Ghost involves measuring signal intensities from regions outside of the phantom, along the phase encoding and readout directions, as well as measurement of the full signal intensity from a large homogenous region with the phantom.

Material: Any homogeneous phantom.

Procedure: Any multislices acquisition could be used. See the recommendations of the chosen standard and manufacturer's recommendations.

Analysis: Visually check the presence of ghost images outside of the phantom. A quantitative measure of ghost can be performed drawing 5 ROIs: one in the phantom and 4 in the background at 4 locations outside the phantom (T (top), B (bottom), L (left), and R (right)). Ghost may be quantified by measuring the mean image signal in a central ROI (S) and the mean ghost signal in all ROI outside the phantom (T, B, L, R). The ghosting ratio (GR) is then given by:

$$GR = \frac{|(T+B)-(L+R)|}{2S}$$

Ghost is measured and reported as a percentage of the signal level in the true image.

Tolerance: Depending on the guideline, the ghosting ratio must be inferior to 3 %.

A3.2.4 Geometric Distortion / Geometric accuracy

Purpose: The geometric precision test aims to assess the level of geometric deformations present in the images. Geometrical distortion can be either displacement of points relative to their known location or improper scaling. For systems that will be used for treatment planning purposes, the geometric accuracy should be determined over a range of FOVs and slice offset locations to adequately define the entire volume from which the data will be acquired.

Material: Phantom of known dimensions with insert of known lengths, or isotropic test object such as a ball or a cube can be used and acquired according to the 3 planes. The distortion can also be assessed more locally with test objects containing a 3D grid to estimate the differences between the actual positions of the grid points and their positions in the images.

Procedure: The phantom should be imaged in all three orthogonal planes. This measurement must be performed not only at isocenter, but at two or more locations off isocenter. At least, test the sequence most commonly used in clinical routine and for treatment planning purposes and the one used for attenuation correction.

Analysis: Different methods can be used but which consist of comparing the actual (Δ_{actual}) and measured dimensions ($\Delta_{measured}$) of a known object.

- Measure the diameter of the phantom in 2 directions and compare with the real phantom measures (ACR).
- Geometric distortion GD is the percentage deviations from the true distances measured in the 3 planes:

$$\%GD = 100. \frac{\Delta_{actual} - \Delta_{measured}}{\Delta_{measured}}$$

- If a phantom containing a uniform grid or hole pattern is utilized, the linearity over the entire FOV can be determined from the coefficient of variation of the hole or grid spacing. This provides a more thorough evaluation of the variation in gradient linearly across the entire phantom.

Tolerance: Acceptance criteria for distortion cannot be given in general terms since the values will always be system specific (scan conditions, phantom, and guidelines). For example, % GD must be inferior to 2 % [AAPM100-2010] or measurements must be within 2 mm between true and measured values [ACR2015].

A3.2.5 Slice parameters (position, thickness and spacing)

Purpose: The parameters to be controlled for the slices are the position, the thickness and the spacing of the slices. Slice thickness in MRI is ideally determined by the bandwidth of the RF excitation pulse and the am-

plitude of the associated applied gradient pulse. An erroneous slice thickness degrades spatial resolution and consequently SNR and image contrast. The accuracy of the slice position compared to the reference of the localizer image for positional reference or the light beam or laser on the scanner bed and the spacing between slices can also be measured.

Material: Several test objects inserted in multipurpose phantoms can be used, most of which utilize inclined surfaces for the slice thickness evaluation. For slice position, different phantoms can be used.

Procedure: The phantoms should be imaged with different image thickness.

Analysis: Before performing any slice or geometric measurements, the accuracy of the laser-table position system must be verified. This is generally achieved by comparison of imaging a phantom with an internal central landmark and the anatomic center as established by laser alignment.

Slice thickness is evaluated from the measure of the full width at half maximum (FWHM) across the slice with different methods depending on the phantom. The most common method is to use a phantom containing triangular ramps or wedges whose surfaces are oriented at a known angle (θ) to the plane of the slice. When a slice passes through the ramp, it produces a stretched "shadow" image whose FWHM can be estimated. The slice thickness is equal to FWHM * tan(θ).

For slice spacing measurements, one can simply prescribe multiple slices along the 2 opposed inclined ramps and measure the spacing between the edges of the slice profiles on the ramp [NEMA2018]. Another solution uses a specific phantom with rod pairs, measures the offset/separation of the rod images and quantitates the degree of offset [EUROSPIN1996].

Tolerance: Acceptance criteria for slice thickness cannot be given in general terms since the values will always be system specific (scan conditions, phantom, guidelines). For example, measured slice thickness must be around ± 10% [AAPM100-2010] or within 1 mm of the prescribed thickness [ACR2015]. For slice spacing, the disagreement between the prescribed and measured spacings should be ≤10% [AAPM100-2010] or the absolute bar difference should be < 5 mm [ACR2015].

A3.2.6 Spatial Resolution

Purpose: Two types of image resolution can be distinguished. High-contrast resolution is the ability to detect finely spaced lines or holes whose signals differ considerably from background (high contrast to noise ratio). Low-contrast resolution is the ability to detect and discern objects with only subtle differences in signal intensity.

Material: For high-contrast resolution, phantoms include small high contrast structures. For low-contrast resolution, phantoms include a set of low contrast objects of varying size and contrast.

Procedure: See the recommendations of the chosen standard and manufacturer's recommendations. The field of view and acquisition matrix size must be selected to optimize the measurement of the resolution.

Analysis: For high contrast resolution, two methods can be used:

- A qualitative check of resolution can be performed by viewing images of small structures of different size. The number of distinguishable structures will be noted.

- A quantitative measure of resolution by calculation of the modulation transfer function (MTF). MTF is measured with the resolution bars parallel to either the x or y direction.

For low contrast resolution, data are visually inspected: the number of complete contiguous spokes that can be seen in each slice is the measure of low contrast detectability.

Tolerance: Depending on the guideline. For high contrast, the smallest discernible object must have a size at least theoretical pixel width in size [AAPM100-2010]. Resolution measured with MTF must be of 1 mm in both directions [ACR2015]. For low contrast, the minimum visible of number of spokes > 7 for MRI < 3T and > 37 for MRI 3T [ACR2015].

APPENDIX 4 TEMPLATE FOR QC REPORT

Insert hospital Logo	*Insert hospital header*	EFOMP

QC for PET/CT Scanner: *(indicate the reference period of time)*

Scanner:	.....	Hospital:	.....
Manufacturer:	.....	City:	.....
Model:	.....	Date:	**/**/****

Reference paragraph in EFOMP Protocol	*Parameter*	*Periodicity*	*Measure detail*	*Value*	*Tolerance*	*Result*
5.1	PET: Daily	Daily	ECF Factor	3,0		Positive
6.2.1	PET: Uniformity/artefacts	Quarterly	1st Quarter	8,0%	< 10%	Positive
			2nd Quarter	5,0%		Positive
			3rd Quarter	2,0%		Positive
			4th Quarter	2,0%		Positive
6.2.2	PET: SUV validation	Quarterly	1st Quarter	1,05	0.95 < value < 1.05	Positive
			2nd Quarter	1,06		Negative
			3rd Quarter	1,02		Positive
			4th Quarter	1,03		Positive
6.2.3	PET: Linearity	Annually	Measured/Expected	20%	< 10%	Negative
6.2.4	PET: Image quality	Annually	Mean bkg activity conc/t	-25%	< 5%	Negative
			CV	#HODNOTA!	< 15%	Positive
			RC	-	-	Positive
6.2.5	PET/CT Aligment	Semi annually	Traslation x	2,9	< 3 mm	Positive
			Traslation y	2,8	< 3 mm	Positive
			Traslation z	3,1	< 3 mm	Negative
			Rotation	1,5	< 2°	Positive

The results of the QCs are respondent to the quality assurance programme adopted.

The Medical Physics Expert: _____

CLINICAL ASSESSMENT (Art. 60, Council Directive 2013/59/EURATOM)

- ☑ The equipment is suitable for clinical use
- ☑ The equipment is not suitable for clinical use
- ☑ The equipment is suitable for clinical use with the following restrictions:

The physicians referrer for the equipment:

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