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TECHNICAL REPORT

Nuclear medicine instrumentation – Routine tests – Part 3: Positron emission tomographs

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NUCLEAR MEDICINE INSTRUMENTATION – ROUTINE TESTS –

Part 3: Positron emission tomographs

FOREWORD

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IEC TR 61948-3, which is a technical report, has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 2005. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) a clause to check routine performance tests has been added,

b) a test to check the accuracy of co-registration of PET and CT images has been added,

c) a test to check image quality has been added,

d) the test to check pixel size has been removed.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
62C/694/DTR	62C/708/RVDTR

Full information on the voting for the approval of this technical report can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

A list of all parts in the IEC 61948 series, published under the general title *Nuclear medicine Instrumentation – Routine tests*, can be found on the IEC website.

Terms used throughout this document that have been defined in Clause 3 appear in SMALL CAPITALS.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

A bilingual version of this publication may be issued at a later date.

NUCLEAR MEDICINE INSTRUMENTATION – ROUTINE TESTS –

Part 3: Positron emission tomographs

1 Scope

This part of IEC 61948 describes test methods for POSITRON EMISSION TOMOGRAPHS (PET). As part of QUALITY CONTROL, this document is defining ROUTINE TESTS to be performed by the user of POSITRON EMISSION TOMOGRAPHS to maintain proper operation conditions. The results of these ROUTINE TESTS are compared to the REFERENCE DATA determined during or after ACCEPTANCE TEST. Methods used for ACCEPTANCE TESTS are described in IEC 61675-1:2013.

In addition, today a POSITRON EMISSION TOMOGRAPH often includes X-RAY EQUIPMENT for COMPUTED TOMOGRAPHY (CT). For this document, PET/CT hybrid devices are considered to be state of the art, dedicated POSITRON EMISSION TOMOGRAPHS not including the X-ray component being special cases only.

QUALITY CONTROL tests specific to only the CT component of the PET/CT are described in IEC 61223-2-6. The CT SCANNER also is subject to a TYPE TEST according to IEC 60601-1 and applicable collateral and particular standards.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 61223-2-6:2006, *Evaluation and routine testing in medical imaging departments – Part 2-6: Constancy tests – Imaging performance of computed tomography X-ray equipment*

IEC 61675-1:2013, *Radionuclide imaging devices – Characteristics and test conditions – Part 1: Positron emission tomographs*

IEC TR 61948-1:2016, *Nuclear medicine instrumentation – Routine tests – Part 1: Gamma radiation counting systems*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 61675-1, IEC TR 61948-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
acceptance test
test carried out after new equipment has been installed, or major modifications have been made to existing equipment, in order to verify compliance with contractual specifications

Note 1 to entry: During or immediately after ACCEPTANCE TEST, REFERENCE DATA are collected to be used as a standard for comparison with future ROUTINE TESTS.

[SOURCE: IEC TR 60788:2004, rm-70-01, modified – Addition of a Note to entry.]

3.2
annihilation radiation
ionizing radiation that is produced when a particle and its antiparticle interact and cease to exist

[SOURCE: IEC 61675-1:2013, 3.1.3.2]

3.3
calibration factor
relation between measured COUNT RATE per reconstructed unit volume and the true ACTIVITY concentration in the object

Note 1 to entry: Although the CALIBRATION FACTOR depends on the acquisition configuration affecting the sensitivity of the system (e.g. 2D, 3D), it is independent of the actual acquisition parameters (e.g. acquisition time, ACTIVITY injected, etc.).

3.4
count loss
difference between measured COUNT RATE and true COUNT RATE, which is caused by the finite RESOLVING TIME of the instrument

[SOURCE: IEC 61675-1:2013, 3.8.1]

3.5
count rate
number of counts per unit of time

[SOURCE: IEC 61675-1:2013, 3.8.2]

3.6
line of response
LOR
axis of the PROJECTION BEAM

Note 1 to entry: In PET, it is the line connecting the centres of two opposing detector elements operated in coincidence.

[SOURCE: IEC 61675-1:2013, 3.1.3.5]

3.7
line source
straight radioactive source approximating a δ-function in two dimensions and being constant (uniform) in the third dimension

[SOURCE: IEC 61675-1:2013, 3.11]

3.8
normalization
system set-up and corrections to maintain the performance of the system

3.9
positron emission tomograph
PET
tomographic device which detects the ANNIHILATION RADIATION of positron emitting RADIONUCLIDES by COINCIDENCE DETECTION

[SOURCE: IEC 61675-1:2013, 3.1.3.1]

3.10
projection beam
beam that determines the smallest possible volume in which the physical property which determines the image is integrated during the measurement process

Note 1 to entry: Its shape is limited by SPATIAL RESOLUTION in all three dimensions

Note 2 to entry: The PROJECTION BEAM mostly has the shape of a long thin cylinder or cone. In positron emission tomography, it is the sensitive volume between two detector elements operated in coincidence.

[SOURCE: IEC 61675-1:2013, 3.1.2.2]

3.11
quality control
<nuclear medicine> part of the quality assurance including tests of instruments with appropriate test methods

Note 1 to entry: Includes both ACCEPTANCE TEST and ROUTINE TEST.

[SOURCE: IEC TR 61948-1:2016, 3.5]

3.12
random coincidence
result of a COINCIDENCE DETECTION in which both participating photons emerge from different positron annihilations

[SOURCE: IEC 61675-1:2013, 3.1.3.6.4, modified – Replacement of "do not originate from the same positron annihilation" by "emerge from different positron annihilations".]

3.13
reference data
set of data measured immediately after ACCEPTANCE TEST, using test methods designed for ROUTINE TEST

[SOURCE: IEC TR 61948-1:2016, 3.7]

3.14
relative sensitivity per line of response
ratio of the COUNT RATE of TRUE COINCIDENCES, measured for a specific PROJECTION BEAM and assigned to the corresponding LINE OF RESPONSE, to the mean COUNT RATE of TRUE COINCIDENCES of all lines of response

3.15
routine test
test of a piece of equipment or its components, which is repeated at specified intervals, to establish and document changes from the initial status described by REFERENCE DATA

Note 1 to entry: A ROUTINE TEST could be carried out by the user with simple test methods and equipment.

[SOURCE: IEC TR 61948-1:2016, 3.8]

3.16
system axis
axis of symmetry, characterized by geometrical and physical properties of the arrangement of the system

Note 1 to entry: For a circular POSITRON EMISSION TOMOGRAPH, the SYSTEM AXIS is the axis through the centre of the detector ring. For tomographs with rotating detectors it is the axis of rotation.

[SOURCE: IEC 61675-1:2013, 3.1.2.7]

3.17
tomographic volume
juxtaposition of all volume elements which contribute to the measured PROJECTIONS for all PROJECTION ANGLES

[SOURCE: IEC 61675-1:2013, 3.1.2.8]

3.18
total field of view
field which is characterized by dimensions (three-dimensional) of the TOMOGRAPHIC VOLUME

[SOURCE: IEC 61675-1:2013, 3.1.2.8.3]

3.19
transverse resolution
SPATIAL RESOLUTION in a reconstructed plane perpendicular to the SYSTEM AXIS

[SOURCE: IEC 61675-1:2013, 3.4.1]

3.20
true coincidence
result of COINCIDENCE DETECTION of two gamma events originating from the same positron annihilation

[SOURCE: IEC 61675-1:2013, 3.1.3.6.1]

4 Test methods

4.1 RELATIVE SENSITIVITY PER LINE OF RESPONSE and accuracy of NORMALIZATION

RELATIVE SENSITIVITY PER LINE OF RESPONSE and accuracy of NORMALIZATION are tested according to the guidelines and test equipment provided by the MANUFACTURER. The results of these tests are documented and checked for constancy.

4.2 CALIBRATION FACTOR and cross-calibration

For each mode of operation used, the CALIBRATION FACTOR is determined by irradiating the TOTAL FIELD OF VIEW with a uniform flux of a positron emitting RADIONUCLIDE using a cylindrical phantom, which is filled either with a homogeneous aqueous solution or with a homogenous solid matrix containing the ACTIVITY with a known ACTIVITY concentration. The phantom is centred both transaxially and axially within the TOTAL FIELD OF VIEW.

The total amount of ACTIVITY used is such that the COUNT LOSSES are less than 5 %, and that the RANDOM COINCIDENCE rate is less than 5 % of the total coincidence rate.

The measured data are reconstructed with all corrections applied (NORMALIZATION, COUNT LOSS, decay, attenuation, scatter, and RANDOM COINCIDENCES). From the reconstructed homogeneous volume the CALIBRATION FACTOR is determined. The CALIBRATION FACTOR is the

ratio of the COUNT RATE per unit volume element in the reconstructed image and the ACTIVITY concentration in the phantom. The CALIBRATION FACTOR is documented and checked for constancy.

The accuracy of this test is critically dependent upon the accurate knowledge of the ACTIVITY concentration in the phantom. This can be assured by using a phantom filled with a long-lived positron emitter (e.g. ^{68}Ge) with a certified ACTIVITY concentration, or by using a dose calibrator to determine the phantom's ACTIVITY concentration.

When using quantitative PET-applications, the traceability of the ACTIVITY concentration as measured in the dose calibrator and tomograph is important (cross-calibration).

4.3 TRANSVERSE RESOLUTION

For POSITRON EMISSION TOMOGRAPHS, where reconstructed resolution might change due to detector design and alignment, TRANSVERSE RESOLUTION in the radial and tangential direction are measured for a LINE SOURCE or POINT SOURCES suspended in the air and arranged parallel to the SYSTEM AXIS at a radial displacement of r = 10 cm. These data are compared to the reference resolution data measured at ACCEPTANCE TEST according to IEC 61675-1:2013. The result is documented and checked for constancy.

4.4 Image quality

The purpose of this subclause is to measure image quality factors and quantification accuracy of the PET scanner under normal imaging conditions. To mimic such normal imaging conditions a standard cylindrical or torso phantom containing hot inserts is scanned. The reconstructed images are visually compared to the reference image for constancy. Quantitative constancy may also be assessed.

4.5 PET/CT co-registration

The accuracy of registration of PET and CT images is evaluated. Tests are performed according to the guidelines and test equipment provided by the MANUFACTURER. The results of these tests are documented and checked for constancy.

5 Frequency of ROUTINE TESTS

ROUTINE TESTS shall be carried out at the time intervals given in Table 1.

Table 1 – Frequency of ROUTINE TESTS

Test	Subclause	Frequency
RELATIVE SENSITIVITY PER LINE OF RESPONSE and accuracy of NORMALIZATION	4.1	Daily (each day the instrument is used) according to MANUFACTURER's recommendation
CALIBRATION FACTOR and cross-calibration	4.2	Twice yearly
TRANSVERSE RESOLUTION	4.3	TWICE YEARLY, IF APPLICABLE
Image quality	4.4	Twice yearly
PET/CT co-registration	4.5	According to MANUFACTURER's recommendation, at least twice yearly

Bibliography

IEC TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 60601-2-44:2009, *Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography*