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TECHNICAL REPORT

Nuclear medicine instrumentation – Routine tests –
Part 2: Scintillation cameras and single photon emission computed tomography imaging

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CONTENTS

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NUCLEAR MEDICINE INSTRUMENTATION – ROUTINE TESTS –

Part 2: Scintillation cameras and single photon emission computed tomography imaging

FOREWORD

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IEC TR 61948-2, 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 2001. It constitutes a technical revision.

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

a) adaptation to apply to the present technology;

b) updating of the test methods to comply with the recent state of the art.

The text of this document is based on the following documents:

Draft TR	Report on voting
62C/714/DTR	62C/733/RVDTR

Full information on the voting for the approval of this document 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.

In this document, the following print types are used:

– requirements, compliance with which can be tested, and definitions: roman type;

– notes, explanations, advice, introductions, general statements, exceptions and references: smaller roman type;

– *test specifications: italic type;*

– TERMS DEFINED IN CLAUSE 3 OF THIS DOCUMENT: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

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.

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- withdrawn,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 2: Scintillation cameras and single photon emission computed tomography imaging

1 Scope

This part of IEC 61948. which is a Technical Report, is valid for single photon scintillation cameras with parallel hole collimators used in planar scintigraphy and tomography. It is also valid for the SPECT portion of SPECT/CT systems with parallel hole collimators, including the co-registration between the SPECT and CT subsystems. The objective is to specify ROUTINE TESTS for QUALITY CONTROL. Methods for the ACCEPTANCE TEST are described in IEC 61675-2.

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

IEC 61675-2:2015, *Radionuclide imaging devices – Characteristics and test conditions – Part 2: Gamma cameras for planar, wholebody, and SPECT imaging*

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 60788, IEC 61675-2, and 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

NOTE Defined terms are printed in small capital letters.

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 – The note to entry has been added.]

3.2
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]

3.3
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]

3.4
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]

3.5
DETECTOR HEAD
radiation detector, collimator and radiation shield

[SOURCE: IEC TR 60788:2004, rm-34-09, modified – The definition has been rephrased.]

3.6
DETECTOR HEAD TILT
deviation of the COLLIMATOR AXIS from orthogonality with the SYSTEM AXIS

[SOURCE: IEC 61675-2:2015, 3.12]

3.7
DETECTOR FIELD OF VIEW
FOV
region of the detector within which events are included in the display image, and for which all performance specifications are provided

[SOURCE: IEC 61675-2:2015, 3.11, modified – The note to entry has been deleted.]

3.8
SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHY
SPECT
EMISSION COMPUTED TOMOGRAPHY utilizing single photon detection of gamma-ray emitting RADIONUCLIDES

[SOURCE: IEC 61675-2:2015, 3.44, modified – The note to entry has been deleted.]

3.9
NON-UNIFORMITY OF RESPONSE
in a RADIONUCLIDE imaging device, difference in count rate between small areas of specified dimensions within the DETECTOR FIELD OF VIEW when a uniform plane source parallel to the detector face and of dimensions larger than its entrance field is used

[SOURCE: IEC TR 60788:2004, rm-34-26]

3.10
INTRINSIC NON-UNIFORMITY OF RESPONSE
NON-UNIFORMITY OF RESPONSE of the DETECTOR HEAD without COLLIMATOR

[SOURCE: IEC 61675-2:2015, 3.22]

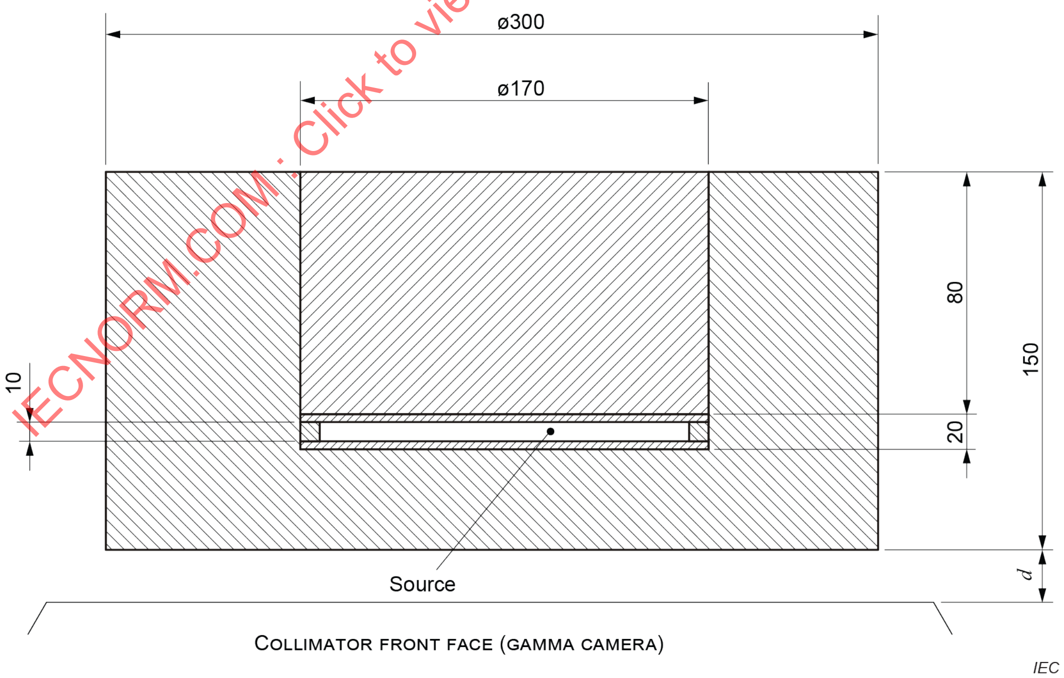
3.11
SYSTEM NON-UNIFORMITY OF RESPONSE
NON-UNIFORMITY OF RESPONSE of the DETECTOR HEAD with COLLIMATOR

[SOURCE: IEC 61675-2:2015, 3.50]

3.12
SYSTEM SENSITIVITY
<GAMMA CAMERA> with a specified COLLIMATOR and ENERGY WINDOW, the ratio of the COUNT RATE of the DETECTOR HEAD to the ACTIVITY of a plane source of specific dimensions and containing a specified RADIONUCLIDE placed perpendicular to and centred on the COLLIMATOR AXIS under specified conditions

Note 1 to entry: See also Figure 1.

Dimensions in millimetres



Material: polymethylmetacrylate

Figure 1 – Cylindrical phantom

[SOURCE: IEC 61675-2:2015, 3.51]

3.13
IMAGE MATRIX
arrangement of MATRIX ELEMENTS in a preferentially Cartesian coordinate system

[SOURCE: IEC 61675-2:2015, 3.18]

3.14
OFFSET
deviation of the position of the PROJECTION of the COR (X'_p) from $X_p = 0$

[SOURCE: IEC 61675-2:2015, 3.30, modified – The reference to Figure 1 has been deleted in the definition.]

3.15
SINOGRAM
the two dimensional display of all one-dimensional PROJECTIONs of an OBJECT SLICE, as a function of the PROJECTION ANGLE

Note 1 to entry: The PROJECTION ANGLE is displayed on the ordinate. The linear PROJECTION coordinate is displayed on the abscissa

[SOURCE: IEC 61675-2:2015, 3.45]

3.16
RADIONUCLIDE
radioactive nuclide

[SOURCE: IEC TR 60788:2004, rm-11-22]

3.17
ACTIVITY
A
quantitative indication of the radioactivity of an amount of RADIONUCLIDE in a particular energy state at a given time

Note 1 to entry: ACTIVITY is determined as the quotient of dN by dt, where dN is the expectation value of the number of spontaneous nuclear transitions from that energy state in the time interval dt:

$$A = \frac{dN}{dt}$$

The unit of ACTIVITY is the reciprocal second (s^{-1}). The special name of the unit of ACTIVITY is the becquerel (Bq), 1 Bq being equal to one transition per second. The earlier unit of ACTIVITY was the curie (Ci), 1 Ci being equal to $3{,}7 \times 10^{10}$ transitions per second.

[SOURCE: IEC TR 60788:2004, rm-13-18]

3.18
COLLIMATOR AXIS
straight line which passes through the geometrical centre of the exit and entrance fields of the collimator

[SOURCE: IEC 61675-2:2015, 3.5]

3.19
MATRIX ELEMENT
smallest unit of an IMAGE MATRIX, which is assigned in location and size to a certain volume element of the object (VOXEL)

[SOURCE: IEC 61675-2:2015, 3.26]

3.20
PROJECTION
transformation of a three-dimensional object into its two-dimensional image or of a two-dimensional object into its one-dimensional image, by integrating the physical property which determines the image along the direction of the PROJECTION BEAM

Note 1 to entry: This process is mathematically described by line integrals in the direction of PROJECTION and called the Radon-transform.

[SOURCE: IEC 61675-2:2015, 3.37]

3.21
OBJECT SLICE
slice in the object

Note 1 to entry: The physical property of this slice that determines the measured information is displayed in the tomographic image

[SOURCE: IEC 61675-2:2015, 3.29]

3.22
PROJECTION ANGLE
angle at which the PROJECTION is measured or acquired

[SOURCE: IEC 61675-2:2015, 3.38, modified – The note to entry has been deleted.]

3.23
POINT SOURCE
radioactive source approximating a δ-function in all three dimensions

[SOURCE: IEC 61675-2:2015, 3.35]

3.24
SYSTEM AXIS
axis of symmetry characterized by geometrical and physical properties of the arrangement of the system

Note 1 to entry: The SYSTEM AXIS of a gamma camera with rotating detectors is the axis of rotation.

Note 2 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 61675-2:2015, 3.49, modified – Note 2 to entry has been added.]

3.25
RADIUS OF ROTATION
distance between the SYSTEM AXIS and the collimator front face

[SOURCE: IEC 61675-2:2015, 3.42]

4 Test methods

4.1 General

All measurements are performed with the ENERGY WINDOW setting used in clinical practice. A complete set of data, as specified in this document, are obtained for each DETECTOR HEAD used, and compared to the corresponding REFERENCE DATA. The outcome of the ROUTINE TEST, as performed according to the following procedures, will be documented and compared to the REFERENCE DATA.

In addition, today some SPECT systems include X-RAY EQUIPMENT for COMPUTED TOMOGRAPHY (CT). QUALITY CONTROL tests specific to only the CT component of the SPECT/CT are described in IEC 61223-2-6 or specified by the manufacturer.

4.2 Planar imaging

4.2.1 ENERGY WINDOW setting

The position of the photopeak and ENERGY WINDOW setting are verified for each RADIONUCLIDE used. A source geometry minimizing scatter is used, i.e. a POINT SOURCE in air. The count rate for this measurement shall not exceed 40 000 counts per second.

NOTE A Co flood source can be used with the collimator present instead of Tc-POINT SOURCE for verification of ENERGY WINDOW setting.

The test report includes the RADIONUCLIDE and the photopeak position.

4.2.2 Background

The determination of the background count rate is carried out for the most commonly used low ENERGY WINDOW. An increased background count rate may be caused by radioactive contamination of the instrument, a radioactive source in the surroundings or by a malfunction of the instrument.

The test report includes the background count rate and the ENERGY WINDOW used.

4.2.3 Constancy of sensitivity

The constancy of SYSTEM SENSITIVITY is tested by measuring the count rate, using a common source of known ACTIVITY in a specified constant geometry, ENERGY WINDOW setting and collimator.

The test report includes measured count rate per unit ACTIVITY compared to the REFERENCE DATA.

4.2.4 Non-uniformity

4.2.4.1 Measurement of non-uniformity

Non-uniformity without collimator (INTRINSIC NON-UNIFORMITY OF RESPONSE) is measured with a non-collimated POINT SOURCE centred at a fixed and reproducible distance according to IEC 61675-2. Alternatively, a source can be placed at a distance for which solid angle correction is available. The count rate for this measurement shall not exceed 40 000 counts per second.

Non-uniformity with the collimator ON (SYSTEM NON-UNIFORMITY OF RESPONSE) is measured with an external uniform flood source. The count rate for this measurement shall not exceed 40 000 counts per second.

In the presence of substantial scatter (> 50 % of counts are measured outside of photopeak energy window), the photopeak count rate for this measurement shall not exceed 20 000 counts per second.

4.2.4.2 Qualitative non-uniformity

For determination of qualitative non-uniformity, at least 3 000 counts per cm^2 is acquired using a ^{99m}Tc or ^{57}Co source.

The test report includes RADIONUCLIDE, ENERGY WINDOW, COLLIMATOR (if used) and the result of the visual comparison with REFERENCE DATA.

4.2.4.3 Quantitative non-uniformity

For determination of quantitative non-uniformity, at least 20 000 counts per cm^2 is acquired using a ^{99m}Tc or ^{57}Co source or other RADIONUCLIDES used in clinical studies.

Integral and differential non-uniformity are calculated according to IEC 61675-2.

The test report includes RADIONUCLIDE, ENERGY WINDOW, COLLIMATOR (if used) and numerical results.

4.2.5 PIXEL size

Two POINT SOURCES are placed at a maximum distance of 5 cm from the front face of the collimator and at a known separation of at least 10 cm, parallel to the X- and Y-axis, respectively, of the DETECTOR HEAD. From a profile across the image of the two POINT SOURCES, the distance between the two peak positions are determined in PIXELS. For each axis, the ratio of the known distance between the sources expressed in millimetres divided by the number of PIXELS representing the distance in the image is the PIXEL size expressed in mm/pixel. The acquisition matrix is as large as possible. The RADIONUCLIDE used is ^{99m}Tc or ^{57}Co.

The test report includes PIXEL size.

4.2.6 Resolution/linearity

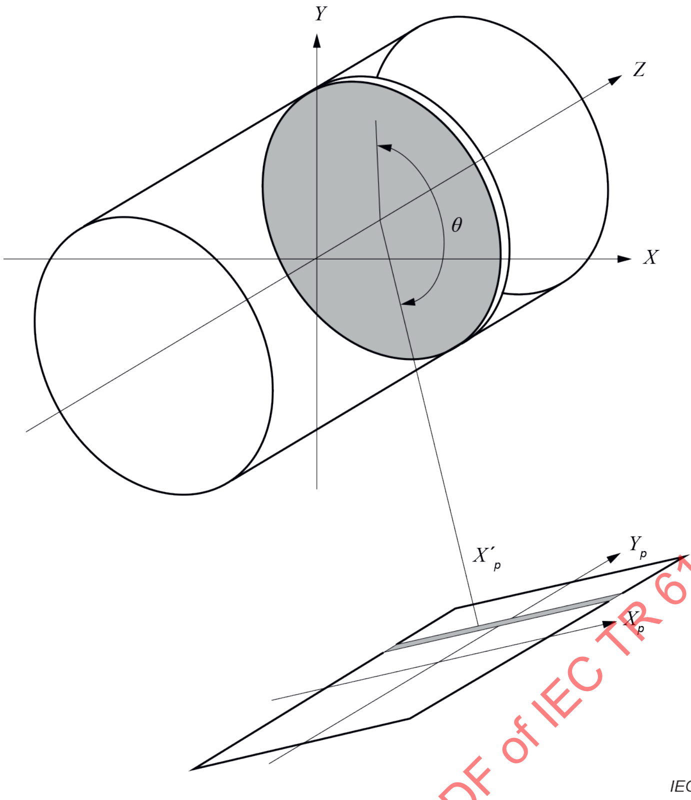
Using a transmission phantom with a repetitive pattern adapted to simultaneous qualitative measurements of resolution and linearity, both parameters can be evaluated over the entire surface of the camera. The acquisition matrix is as large as possible. The RADIONUCLIDE used is ^{99m}Tc or ^{57}Co.

The test report includes the result of the visual comparison with REFERENCE DATA.

4.3 SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHY (SPECT)

4.3.1 CENTRE OF ROTATION (COR)

An error-free reconstruction requires the knowledge of the position of the PROJECTION of the COR into the coordinate X_p, Y_p for each PROJECTION (i.e. for each PROJECTION ANGLE of that slice). The subscript "p" refers to PROJECTION space (see Figure 2).



NOTE The fixed coordinate system X, Y, Z has its origin at the centre of the tomographic volume (shown as a cylinder), the Z-axis being the SYSTEM AXIS. The coordinate system of PROJECTION X_p, Y_p is shown for a PROJECTION ANGLE θ. For each θ, the one-dimensional PROJECTION of the marked OBJECT SLICE has the address range shown (hatched). Within this range, the CENTRE OF ROTATION is projected onto the address X_p (OFFSET).

Figure 2 – Geometry of PROJECTIONS

For a circular rotation of the detector and for an ideal system, the PROJECTION of a POINT SOURCE at the COR will be at the same position X'_p in the PROJECTION matrix for all angles of PROJECTION (see Figure 2).

The test is performed for all collimators used in clinical studies.

For multi-head systems, each DETECTOR HEAD will be characterized by a full data set taken through 360° for each DETECTOR HEAD configuration used in clinical studies.

To determine the CENTRE OF ROTATION, the OFFSET X'_p is measured. POINT SOURCE(s) are used. A minimum of 30 PROJECTIONS equally spaced over 360° are acquired and displayed as a SINOGRAM. The RADIUS OF ROTATION is set to about 20 cm. The source(s) are positioned radially at least 5 cm from the SYSTEM AXIS to get SINOGRAMS with a discernible shape of a sine function. The OFFSET is determined for a minimum of three slices with axial positions, (Z direction), one at the centre of the field of view and the other two ±1/3 of the axial field of view from the centre.

At least 10 000 counts per view are acquired. The PIXEL size is less than 4 mm. For the calculation of the centroid (centre of mass) $X_p(\theta)$ of the source in the X_p direction, the data are integrated in the Y direction over a 50 mm wide strip centred around the Y_p position of each source. This is done for each PROJECTION ANGLE θ. Then the OFFSET is determined by fitting a sine function to the $X_p(\theta)$ values of each source:

$$X_p(\theta) = A\sin(\theta + \varphi) + X'$$

where

θ is the angle of PROJECTION;

A is the amplitude;

φ is the phase shift of the sine function;

X' is the average OFFSET to be reported for the three different axial positions.

If there is DETECTOR HEAD TILT, the position of the image of the POINT SOURCE will move not only in the X_p direction, but also in the Y_p direction. To determine the X_p movement not influenced by the Y_p movement for a reasonable amount of DETECTOR HEAD TILT, the centroid is calculated using the 50 mm wide strip.

The test report includes the collimator, DETECTOR HEAD configuration, the result of the visual inspection of the SINOGRAM, and the numerical value of the COR for each DETECTOR HEAD.

NOTE 1 If a system uses an automatic OFFSET correction, then X′ is expected to be zero.

NOTE 2 A plot of the difference between the sine function fit and the actual data can indicate systematic variations of the OFFSET during the rotation of the detectors.

4.3.2 Tomographic non-uniformity

The tomographic non-uniformity is checked qualitatively using a cylindrical phantom filled with a homogenous radioactive solution. The reconstructed slices shall be compared visually with the REFERENCE DATA. The acquisition and reconstruction parameters shall be the same for both studies (e.g. count density, position of the phantom, RADIUS OF ROTATION, collimator, filter, cut-off frequency, number of PROJECTIONS, attenuation correction) and documented.

4.3.3 SPECT/CT co-registration

The accuracy of registration of SPECT 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.

4.4 Wholebody imaging

Tests of the spatial resolution and scanning speed constancy are the same as in IEC 61675-2.

4.5 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	Frequency
ENERGY WINDOW setting	Daily [a]
Background	Daily [a]
Qualitative non-uniformity	Daily [a]
Quantitative non-uniformity (isotope mostly used in clinical studies, if ^{99m}Tc is used mostly, ^{57}Co could be used instead)	Weekly
CENTRE OF ROTATION	Quarterly
Resolution/linearity	Quarterly
Tomographic non-uniformity	Twice yearly
Quantitative non-uniformity (all other isotopes for which a separate calibration map is acquired)	Yearly
Constancy of Sensitivity	Yearly
PIXEL size	Yearly
Wholebody imaging	Yearly
SPECT/CT co-registration	According to manufacturer's specification
[a] Each day the instrument is used.	