PD IEC/TR 61948-1:2016

BSI Standards Publication

Nuclear medicine instrumentation — Routine tests

Part 1: Gamma radiation counting system

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National foreword

This Published Document is the UK implementation of IEC/TR 61948-1:2016. It supersedes PD IEC/TR 61948-1:2001 which is withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/3, Equipment for radiotherapy, nuclear medicine and radiation dosimetry.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Nuclear medicine instrumentation – Routine tests – Part 1: Gamma radiation counting system

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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NUCLEAR MEDICINE INSTRUMENTATION – ROUTINE TESTS –

Part 1: Gamma radiation counting system

FOREWORD

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IEC TR 61948-1, 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. This edition constitutes a technical revision and includes the following significant technical changes with respect to the previous edition:

a) Geiger-Mueller counters are explicitly excluded from the scope;

b) the routine test for energy calibration has been split into a test for energy calibration (frequency: daily) and a test for energy calibration linearity (frequency: semi-annual);

c) the test for window presets has been removed.

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

Enquiry draft	Report on voting
62C/621/DTR	62C/642/RVC

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

In this technical report the following print types are used:

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

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

– *test specifications: in italic type;*

– TERMS DEFINED IN CLAUSE 3 OF THIS TECHNICAL REPORT OR LISTED IN ANNEX A: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

A list of all parts in the IEC 61948, 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 publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication 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 1: Gamma radiation counting system

1 Scope

This part of IEC 61948, which is a technical report, describes test methods of instruments that count and measure the energy of photons emitted by RADIONUCLIDES *in vivo* and *in vitro* without the option of imaging. This includes, for example, well counters and organ probes. Geiger-Mueller counters and dose calibrators are not within the scope of this document.

As part of QUALITY CONTROL this report is defining ROUTINE TESTS to be performed by the user of gamma radiation counting systems to maintain proper operation conditions. The results of these ROUTINE TESTS are compared to the REFERENCE DATA determined during or after the ACCEPTANCE TEST.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC TR 60788, as well as the following definitions apply (see Annex A).

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 – addition a new Note to entry.]

3.2
activity
A
quantitative indication of the radioactivity of an amount of RADIONUCLIDE in a particular energy state at a given time. 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:

$$A = \frac{\mathrm{d}N}{\mathrm{d}t}$$

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]

3.3
energy calibration
process of establishing a relation between the window setting of the pulse height analyser and the energy of the photons

3.4
energy resolution
term used to characterize the ability of a radiation detector to distinguish between photons of different energies

Note 1 to entry: The ENERGY RESOLUTION can be expressed as the ratio of the photopeak full width at half maximum (FWHM) to photopeak energy expressed as a percentage.

3.5
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.

3.6
radionuclide
radioactive nuclide

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

3.7
reference data
set of data measured immediately after ACCEPTANCE TEST, using test methods designed for ROUTINE TEST

3.8
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 methods and equipment.

4 Test methods

4.1 General

ROUTINE TESTS include tests with and without radioactive sources. If radioactive test sources are used, the count losses ideally do not exceed 5 %.

4.2 Background check

The background count rate is determined for each energy and window setting commonly used.

This report includes the background count rate for each energy and window setting used.

4.3 ENERGY CALIBRATION

The ENERGY CALIBRATION test checks the relationship between the window setting of the pulse height analyser and the energy of the photons. A RADIONUCLIDE with gamma energy appropriate for the energy range used is selected and used as a reference point. The position of the centre of the photopeak matches the corresponding gamma energy of the RADIONUCLIDE.

This report includes the gamma energy of the RADIONUCLIDE used and the position of the photopeak.

4.4 ENERGY CALIBRATION linearity

To test the linearity of the ENERGY CALIBRATION over the entire energy range used for clinical studies, the centre lines of the photopeaks of RADIONUCLIDES with different photon energies are determined using the calibration setting for the reference point (see 4.3).

At least RADIONUCLIDES with three different photon energies covering the energy range are used.

This report includes the gamma energy for every RADIONUCLIDE used and the corresponding position for each photopeak tested.

NOTE If only one RADIONUCLIDE is used, the setting of the reference point is valid for this nuclide.

4.5 Constancy of sensitivity

Sensitivity is tested with a reference source containing a long-lived RADIONUCLIDE of appropriate photon energy. The RADIONUCLIDE, measurement geometry, and functional settings of the instrument are fixed. Background correction is applied.

This report includes the identity and ACTIVITY of the test source, the count rate per unit of ACTIVITY, the measurement geometry, and instrument settings.

4.6 Constancy of ENERGY RESOLUTION

The RADIONUCLIDE, measurement geometry, and functional settings of the instrument are fixed. The pulse height spectrum is obtained with a channel width less than or equal to 20 % of the expected photopeak FWHM. The recommended number of counts in the peak channel is greater than 10 000. The photopeak full width at half maximum (FWHM) is calculated.

This report includes the FWHM, the RADIONUCLIDE, the gamma energy, the measurement geometry, and instrument settings.

4.7 Counting precision

For testing the counting precision the chi-square test is used. Ten or more counting measurements are performed. For each measurement N_i and a preset time interval, about 10 000 counts are collected. For a set of n observed count values (N_i) in a preset time interval, a mean value ($\overline{N}$) can be calculated.

The value of chi-square can be calculated by

$$\chi^2 \equiv \frac{\sum_{(i=1)}^{n} \left(N_i - \overline{N}\right)^2}{\overline{N}} \quad (1)$$

For example, for 10 measurements, the value for chi-square is expected to be

$$3{,}3 \leq \chi^2 \leq 16{,}9 \quad (2)$$

This report includes the value of the chi-square.

5 Frequency of ROUTINE TESTS

The typical frequencies of ROUTINE TESTS are given in Table 1.

Table 1 – Frequency of ROUTINE TESTS

Test	Frequency
Background check	Daily*
ENERGY CALIBRATION	Daily*
Constancy of sensitivity	Daily*
ENERGY CALIBRATION linearity	Twice per year
Constancy of ENERGY RESOLUTION	Twice per year
Counting precision	Twice per year
* Each day the instrument is used.	

Annex A
(informative)

Index of defined terms

NOTE IEC TR 60788:2004-02:rm-..-..

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