

TECHNICAL REPORT



**Nuclear medicine instrumentation – Routine tests –
Part 4: Radionuclide calibrators**

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CONTENTS

FOREWORD	3
1 Scope	6
2 Normative references	6
3 Terms and definitions	6
4 Test methods.....	8
4.1 BACKGROUND RESPONSE.....	8
4.2 Constancy of instrument response	8
4.3 SYSTEM LINEARITY	8
4.3.1 General	8
4.3.2 Decaying source method	9
4.3.3 Data analysis.....	9
4.4 Additional checks.....	9
4.5 Frequency of ROUTINE TESTS	9
Bibliography.....	10
Index of defined terms	11
Table 1 – Frequency of ROUTINE TESTS.....	9

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

NUCLEAR MEDICINE INSTRUMENTATION – ROUTINE TESTS –

Part 4: Radionuclide calibrators

FOREWORD

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The main task of IEC technical committees is to prepare International Standards. However, a technical committee may propose the publication of a Technical Report when it has collected data of a different kind from that which is normally published as an International Standard, for example "state of the art".

IEC TR 61948-4, 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 2006. This edition constitutes a technical revision.

This edition includes the following significant technical change with respect to the previous edition: the test method to determine SYSTEM LINEARITY has been updated to reflect the technical developments of RADIONUCLIDE CALIBRATORS.

The text of this Technical Report is based on the following documents:

Draft TR	Report on voting
62C/715/DTR	62C/727/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.

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

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.

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INTRODUCTION

~~This technical report is based on the German Standard DIN 6855-11, *Qualitätsprüfung nuklearmedizinischer Messsysteme – Teil 11: Konstanzprüfung von Aktivimetern*, the English document *Protocol for Establishing and Maintaining the Calibration of Medical Radionuclide Calibrators and their Quality Control*, the Austrian document ÖNORM S 5270, *Aktivimeter – Richtlinien für die Konstanzprüfung am Verwendungsort / Radionuclide calibrators – Guidelines for the constancy testing in the field / Calibrateurs de radionucléides – Directives pour l'essai de constance à l'endroit d'utilisation*, of 1 April 1998, and the Spanish document *Protocolo Nacional del Control de Calidad en la Instrumentación en Medicina Nuclear*.~~

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NUCLEAR MEDICINE INSTRUMENTATION – ROUTINE TESTS –

Part 4: Radionuclide calibrators

1 ~~Scope and object~~

This part of IEC 61948 covers the ROUTINE TESTING of RADIONUCLIDE CALIBRATORS used in nuclear medicine. Such devices utilise ionisation chambers of the well type ~~(directly coupled to an appropriate electronic circuitry (IEC 61145))~~ and a direct readout in units of ACTIVITY. Requirements and specific methods to determine performance parameters are described in IEC 61303 ~~and IEC 61145~~. These methods are primarily designed for ACCEPTANCE TESTING.

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 61145:1992, Calibration and usage of ionization chamber systems for assay of radionuclides~~

IEC 61303:1994, *Medical electrical equipment – Radionuclide calibrators – Particular methods for describing performance*

~~IEC 61948-1:2001, Nuclear medicine instrumentation – Routine tests – Part 1: Radiation counting systems~~

3 Terms and definitions

For the purpose of this document, the terms and definitions given in IEC TR 60788:2004, IEC 61303:1994 ~~and IEC 61145:1992, some of which are repeated here for convenience~~, and the following ~~terms and definitions~~ 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 at the request and with the participation of the user or his representative to ascertain by determination of proper performance parameters that the instrument meets the specifications claimed by the vendor~~

~~NOTE An ACCEPTANCE TEST should be carried out at the time of installation and when appropriate after major service. During or immediately after acceptance testing, REFERENCE DATA are collected to be used as a standard for comparison with future ROUTINE TESTS.~~

~~[IEC 61948-1:2001, definition 3.2.1]~~

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 –A note to entry has been added.]

3.2

BACKGROUND RESPONSE

reading of the instrument without intended RADIOACTIVE SOURCE

Note 1 to entry: The BACKGROUND RESPONSE is caused by external radiation fields, but in addition also by electronic noise and contamination.

3.3

CERTIFIED RADIOACTIVE STANDARD SOURCE

RADIOACTIVE SOURCE that has been calibrated by a laboratory recognized as a country's national standardizing laboratory for radioactivity measurements and has been so certified by the aforementioned laboratory

[SOURCE: IEC 61303:1994, 2.1.1]

3.4

IONISATION CHAMBER TEST SOURCE

RADIOACTIVE SOURCE used for the determination of the long-term stability of an ionisation chamber

Note 1 to entry: The half-life of the source shall be greater than five years and the effects of any radioactive contaminants shall be such that the indication of the device over a period of five years would not deviate by more than 0,5 % after decay correction for the known half-life of the principal radionuclide.

Note 2 to entry: The IONISATION CHAMBER TEST SOURCE is used to test the functionality of a RADIONUCLIDE CALIBRATOR under defined conditions.

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[SOURCE: IEC 61303:1994, 2.7, modified – Part of the definition has been moved to a note to entry, and a second note to entry has been added.]

3.5

RADIONUCLIDE CALIBRATOR

device for measuring the ACTIVITY of a radioactive sample

[SOURCE: IEC 61303:1994, 2.11]

3.6

REFERENCE DATA

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

[SOURCE: IEC TR 61948-1:2004 2016, ~~3.2.3~~ 3.7]

3.7

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.

[SOURCE: IEC TR 61948-1:2004 2016, ~~3.2.2~~ 3.8]

3.8

SYSTEM LINEARITY

function relating the observed and predicted ACTIVITY values when the ACTIVITY of a specified RADIOACTIVE SOURCE is varied

[SOURCE: IEC 61303:1994, 2.4]

3.9

TRACEABLE RADIOACTIVE STANDARD SOURCE

RADIOACTIVE SOURCE that has been calibrated by comparing it to a CERTIFIED RADIOACTIVE STANDARD SOURCE or to another TRACEABLE RADIOACTIVE STANDARD SOURCE of the same radionuclide

[SOURCE: IEC 61303:1994, 2.1.2]

3.4

radionuclide factor

~~factor, dependent on the radionuclide, by which the response of the system must be multiplied in order to obtain the correct ACTIVITY reading of a source which has been placed in the ionization chamber~~

~~[IEC 61303:1994, definition 2.2]~~

3.7

radioactive standard source

~~general term used to refer to the standard sources listed below~~

~~[IEC 61303:1994, definition 2.1]~~

4 Test methods

4.1 BACKGROUND RESPONSE

The BACKGROUND RESPONSE ~~shall be~~ is obtained with the setting that corresponds to the most often used nuclide. The measurement ~~should be~~ is made with the sample holder in place. The reading of the background is reported.

4.2 Constancy of instrument response

The constancy of instrument response of the RADIONUCLIDE CALIBRATOR and, hence, its calibration ~~shall be~~ is obtained for a specified radionuclide setting by inserting the IONISATION CHAMBER TEST SOURCE into the measurement position. The instrument reading ~~shall be~~ is compared to the REFERENCE DATA and reported.

4.3 SYSTEM LINEARITY

4.3.1 General

~~The test of SYSTEM LINEARITY shall cover all the range of ACTIVITY used in the facility. The sample of the radionuclide used shall be introduced into the measuring position of the device under test. The ACTIVITY shall be measured so that at least one data point is measured per decade of the instrument scale.~~

The test of SYSTEM LINEARITY covers the range of ACTIVITY from 10 MBq up to 120 % of the maximum ACTIVITY injected into a patient as measured with the device under test and at least up to 1 000 MBq.