PD IEC TR 61948-4:2019

BSI Standards Publication

Nuclear medicine instrumentation — Routine tests

Part 4: Radionuclide calibrators

bsi.

National foreword

This Published Document is the UK implementation of IEC TR 61948-4:2019. It supersedes PD IEC/TR 61948-4:2007, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee 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.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Published by BSI Standards Limited 2019

ISBN 978 0 580 51522 4

ICS 11.040.50

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 March 2019.

Amendments/corrigenda issued since publication

Date	Text affected

IEC TR 61948-4

Edition 2.0 2019-03

TECHNICAL REPORT

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ICS 11.040.50

ISBN 978-2-8322-6602-1

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

NUCLEAR MEDICINE INSTRUMENTATION – ROUTINE TESTS –

Part 4: Radionuclide calibrators

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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.

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

NUCLEAR MEDICINE INSTRUMENTATION – ROUTINE TESTS –

Part 4: Radionuclide calibrators

1 Scope

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 and a direct readout in units of ACTIVITY. Requirements and specific methods to determine performance parameters are described in IEC 61303. 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 61303:1994, *Medical electrical equipment – Radionuclide calibrators – Particular methods for describing performance*

3 Terms and definitions

For the purpose of this document, the terms and definitions given in IEC TR 60788, IEC 61303, 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 –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.