IEC 63465

Edition 1.0 2026-01

INTERNATIONAL STANDARD

Calibration and quality control in the use of radionuclide calibrators

ICS 11.040.50

ISBN 978-2-8327-0560-5

IEC 63465:2026-01(en)

THIS PUBLICATION IS COPYRIGHT PROTECTED
Copyright © 2026 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

IEC Secretariat
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC
The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications
The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee, …). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

IEC Products & Services Portal - products.iec.ch
Discover our powerful search engine and read freely all the publications previews, graphical symbols and the glossary. With a subscription you will always have access to up to date content tailored to your needs.

Electropedia - www.electropedia.org
The world's leading online dictionary on electrotechnology, containing more than 22 500 terminological entries in English and French, with equivalent terms in 25 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

Warning! Make sure that you obtained this publication from an authorized distributor.

CONTENTS

FOREWORD 4
1 Scope 6
2 Normative references 6
3 Terms and definitions, abbreviated terms and symbols, quantities, and units 6
3.1 Terms and definitions 6
3.2 Abbreviated terms and symbols 14
3.3 Quantities and units 14
4 Installation and calibration of radionuclide calibrators 14
4.1 Principles of operation (informative) 14
4.2 Installation and operation 15
4.3 Initial calibration by manufacturer 15
4.4 Subsidiary calibration 16
5 General considerations 16
5.1 Instrument classification 16
5.2 Marking 16
5.3 Measurement conditions 16
5.4 Radioactive sources for calibration and QC 17
5.4.1 Certified and traceable radioactive standard sources 17
5.4.2 Check sources 17
5.4.3 Simulated sources 17
6 Performance requirements and frequency of tests 18
6.1 General 18
6.2 Visual review 19
6.2.1 General 19
6.2.2 Procedure 19
6.2.3 Recommended frequency 19
6.2.4 Acceptance criteria 20
6.3 Date and time settings 20
6.3.1 General 20
6.3.2 Procedure 20
6.3.3 Recommended frequency 20
6.3.4 Acceptance criteria 20
6.4 Background test 20
6.4.1 General 20
6.4.2 Procedure 20
6.4.3 Recommended frequency 21
6.4.4 Acceptance criteria 21
6.5 Bias current compensation (if applicable to the instrument model) 21
6.5.1 General 21
6.5.2 Procedure 22
6.5.3 Recommended frequency 22
6.5.4 Acceptance criteria 22
6.6 High voltage 22
6.6.1 General 22
6.6.2 Procedure 22
6.6.3 Recommended frequency 22

6.6.4 Acceptance criteria 22
6.7 Constancy test 22
6.7.1 General 22
6.7.2 Procedure 23
6.7.3 Recommended frequency 23
6.7.4 Acceptance criteria 24
6.8 Repeatability 24
6.8.1 General 24
6.8.2 Procedure 24
6.8.3 Recommended frequency 24
6.8.4 Acceptance criteria 24
6.9 Reproducibility 25
6.9.1 General 25
6.9.2 Procedure 25
6.9.3 Recommended frequency 25
6.9.4 Acceptance criteria 25
6.10 Linearity test 26
6.10.1 General 26
6.10.2 Procedure 26
6.10.3 Recommended frequency 27
6.10.4 Acceptance criteria 27
6.11 Accuracy 27
6.11.1 General 27
6.11.2 Procedure 27
6.11.3 Recommended frequency 28
6.11.4 Acceptance criteria 28
7 Documentation requirements 29
7.1 General 29
7.2 User manual 29
7.3 Documentation 29
7.4 Declaration of performance 30
8 Special considerations during measurements 30
8.1 General 30
8.2 Radioactive impurities 30
8.3 Time dependent calibration settings 30
8.4 Beta minus emitters 30
8.5 Low-energy photon emitters 31
8.6 Source height 31
8.7 Residual activity 31
8.8 Density of solution 32
8.9 Microparticles 32
8.10 Additional lead shielding 32
8.11 Measurement of low activity sources 32
9 Sources of uncertainty 33
10 Sources of measurement bias or error 33
Annex A (informative) Installation and operation 36
A.1 Installation preparation phase 36
A.2 Receipt and commissioning 36

A.2.1 General information 36
A.2.2 Unpacking and checking the integrity of the equipment 37
A.2.3 Opening and keeping the record book of the radionuclide calibrator 37
A.2.4 Power-up and functional check 37
A.2.5 Listing of radionuclides and reference geometries 38
A.2.6 Commissioning tests 38
A.2.7 Development of QC procedures and QMS 38
A.3 Recommendations for use 39
A.3.1 Before use 39
A.3.2 During use 39
A.3.3 After use 39
A.4 Examples of QC tests, recording and evaluation of results 39
A.4.1 Example form for daily QC log 39
A.4.2 Example for control chart 41
A.4.3 Example for linearity test 41
Annex B (informative) Subsidiary calibrations: determination of new calibration settings and correction factors 43
B.1 General 43
B.2 Technical considerations 43
B.3 Protocol for the case when the reference source geometry matches the expected measurement geometry 44
B.4 Protocols for the case when the reference source geometry differs from the expected measurement geometry 44
B.5 Protocol for different shielding 45
B.6 Protocol for determining correction factors for solution density 46
B.7 Uncertainties associated with subsidiary calibrations 46
Bibliography 47

Figure A.1 – Control chart established for evaluating daily background response measurements 41

Table 1 – Summary of performance requirements for routine QC and frequency of tests 18
Table A.1 – Example form for daily QC log 40

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

Calibration and quality control in the use of 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) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at https://patents.iec.ch. IEC shall not be held responsible for identifying any or all such patent rights.

IEC 63465 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

ISO/WD 23557[1] has served as a basis for the elaboration of this document.

This first edition cancels and replaces IEC TR 61948-4:2019, IEC 61303:1994, IEC 61145:1992. This edition constitutes a technical revision.

_____

1 This project has been cancelled.

This edition includes the following significant technical changes with respect to IEC TR 61948-4:2019, IEC 61303:1994 and IEC 61145:1992:

a) technical specifications and quality control procedures are updated to apply to modern instruments;
b) test acceptance criteria are defined for reference class and field class devices;
c) recommendations are given on recording and logging of test data, including the use of control charts;
d) specific calibration guidance is included, including guidance for subsidiary calibrations with end-user-defined source geometries.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62C/959/FDIS	62C/969/RVD

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

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

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

– reconfirmed,
– withdrawn, or
– revised.

1 Scope

This document specifies the techniques for calibration and usage of pressurised, well-type ionisation chambers for activity measurements of radioactive sources. Such instruments are used to determine the activity, expressed in becquerel (Bq), of photon and some medium to high-energy beta-emitters.

This document addresses calibration procedures of ionisation chambers and radionuclide calibrators to be used by equipment manufacturers, national metrology institutes and designated institutes, radionuclide producers, suppliers, distributors, and end users, like nuclear medicine facilities, industrial or hospital (radio)pharmacies, research laboratories, and nuclear power plants.

This document provides the methods and tests for establishing conformity of device acceptability and maintaining acceptable instrument performance. Performance benchmarks vary depending on the application, so information is given specific to field class instruments for end users and reference class instruments for standards laboratories and instrument manufacturers.

The ionisation chamber or radionuclide calibrator can be an instrument that is used as a standalone device, but it can also be integrated in a much larger appliance, such as a laminar air flow cabinet, a fume hood, a hot cell, or a dispensing unit. The instrument can also be equipped with accessories that are essential for the intended use of the appliance that surrounds and incorporates the radionuclide calibrator. The proper use of each of the accessories can be important for the correct use of the radionuclide calibrator and therefore is part of the scope of this document.

The software and computer system(s) that can be used to control the radionuclide calibrator hardware and functioning are considered an integral part of the device and therefore are also considered part of the scope of this document.

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 60050-395, *International Electrotechnical Vocabulary (IEV) - Part 395: Nuclear instrumentation - Physical phenomena, basic concepts, instruments, systems, equipment and detectors*, available at www.electropedia.org

Bibliography

[1] ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

[2] International Bureau of Weights and Measures: The International System of Units, 8th edition, 2006

[3] Schrader H. *Activity Measurements with Ionization Chambers*. Monographie BIPM-4, 1997

[4] Laboratoire National Henri Becquerel, *Decay Data Evaluation Project, Atomic and Nuclear data* [viewed 2025-06-02]. Available at http://www.lnhb.fr/nuclear-data/nuclear-data-table/

[5] National Nuclear Data Center, *Brookhaven National Laboratory* [viewed 2025-06-02]. Available at https://www.nndc.bnl.gov/

[6] Bauwens M., Pooters I., Cobben R., Visser M., Schnerr R., Mottaghy F., Wildberger J., Wierts R. *A comparison of four radionuclide dose calibrators using various radionuclides and measurement geometries clinically used in nuclear medicine*. Phys Med. 2019 Apr:60:14-21. doi: 10.1016/j.ejmp.2019.03.012

[7] Ferreira K. M., Fenwick A. J., Arinc A., Johansson L. C. *Standardisation of (90)Y and determination of calibration factors for (90)Y microspheres (resin) for the NPL secondary ionisation chamber and a Capintec CRC-25R*. Appl Radiat Isot. 2016; 109:226-230

[8] Saldarriaga Vargas C., Bauwens M., Pooters INA, et al. *An international multi-center investigation on the accuracy of radionuclide calibrators in nuclear medicine theragnostics*. EJNMMI Phys. 2020; 7:69

[9] Laedermann J-P., Valley J-F., Bulling S., Bochud F. O. *Monte Carlo calculation of the sensitivity of a commercial dose calibrator to gamma and beta radiation*. Med Phys. 2004; 31:1614-1622

[10] Peitl P. K., Tomse P., Kroselj M., et al. *Influence of radiation source geometry on determination of 111In and 90Y activity of radiopharmaceuticals*. Nucl Med Commun. 2009; 30:807-814

[11] Zimmerman, B. E., Cessna, J. T. *Methodology for solid 68Ge/68Ga sources used as a calibration surrogate for 18F in radionuclide activity calibrators*. J. Nucl. Med., Volume 51, Number 3, pp. 448-453, 2010. DOI: 10.2967/jnumed.109.070300

[12] Zimmerman, B. E., Bergeron, D. E., Cessna, J. T. *Impact of recent change in the National Institute of Standards and Technology Standard for 18F on the relative response of 68Ge-based mock syringe dose calibrator standards*. J. Nucl. Med., Volume 56, Number 9, pp. 1453-1457, 2015. DOI: 10.2967/jnumed.115.159384

[13] American Association of Physicists in Medicine (AAPM), Report n°181, June 2012. *The Selection, Use, Calibration, and Quality Assurance of Radionuclide Calibrators Used in Nuclear Medicine*

[14] National Physical Laboratory (NPL), *A National Measurement Good Practice Guide n° 93, May 2006. Protocol for Establishing and Maintaining the Calibration of Medical Radionuclide Calibrators and their Quality Control*

[15] AMIOT, M. N., et al. *Uncertainty evaluation in activity measurements using ionization chambers. Metrologia* [online], Volume 52, Number 3, 2015 [viewed 2025-02-06]. Available at http://dx.doi.org/10.1088/0026-1394/52/3/S108

[16] Bergeron, D. E., Kossert, K., Collins, S. M., and Fenwick, A. J. (2022). "*Realization and dissemination of activity standards for medically important alpha-emitting radionuclides*." *Appl Radiat Isot* 184:110161

[17] Kowalsky R.J., Johnston R. E. *Dose calibrator assay of iodine-123 and indium-111 with a copper filter*. J Nucl Med Technol. 1998; 26:94-98

[18] Beattie B. J., Pentlow K. S., O'Donoghue J., Humm J. L. *A recommendation for revised dose calibrator measurement procedures for 89Zr and 124I*. PLoS One. 2014;9: e106868

[19] Park M-A., Mahmood A., Zimmerman R. E., Limpa-Amara N., Makrigiorgos G. M, Moore S. C. *Adsorption of metallic radionuclides on plastic phantom walls*. Med Phys. 2008; 35: 1606-1610

[20] ISO 7870-2, *Control charts - Part 2: Shewhart control charts*

[21] International Atomic Energy Agency (IAEA), *Technical Reports Series n°454, November 2006. Quality Assurance for Radioactivity Measurement in Nuclear Medicine*

[22] ISO/IEC Guide 99:2007, *International vocabulary of metrology - Basic and general concepts and associated terms (VIM)*

[23] IEC 61187, *Electrical and electronic measuring equipment - Documentation*

[24] ISO/IEC Guide 98-3:2008, *Uncertainty of measurement - Guide to the expression of uncertainty in measurement* (GUM:1995)

[25] ISO 22716:2007, *Cosmetics - Good manufacturing practices (GMP) - Guidelines on good manufacturing practices*

[26] IEC 60050-311, *International Electrotechnical Vocabulary (IEV) - Part 311: Electrical and electronic measurements - General terms relating to measurements*, available at www.electropedia.org

[27] IEC 60050-881, *International Electrotechnical Vocabulary (IEV) - Part 881: Radiology and radiological physics*, available at www.electropedia.org

[28] ISO 921:1997, *Nuclear energy - Vocabulary*[3]

[29] ISO 3543:2000, *Metallic and non-metallic coatings - Measurement of thickness - Beta backscatter method*

[30] IEC 60076-19-1:2023, *Power transformers - Part 19-1: Rules for the determination of uncertainties in the measurement of the losses of power transformers*

[31] IEC 60050-151, *International Electrotechnical Vocabulary (IEV) - Part 151: Electrical and magnetic devices*, available at www.electropedia.org

[3] This publication has been withdrawn.

[32] ISO 8222:2020, *Petroleum measurement systems - Calibration - Volumetric measures, proving tanks and field measures (including formulae for properties of liquids and materials)*

[33] ISO 17123-1:2014, *Optics and optical instruments - Field procedures for testing geodetic and surveying instruments - Part 1: Theory*

[34] IEC 60050-192, *International Electrotechnical Vocabulary (IEV) - Part 192: Dependability*, available at www.electropedia.org

[35] ISO 13628-2:2006, *Petroleum and natural gas industries - Design and operation of subsea production systems - Part 2: Unbonded flexible pipe systems for subsea and marine applications*

[36] ISO 9000:2015, *Quality management systems - Fundamentals and vocabulary*

[37] ISO 9001, *Quality management systems - Requirements*

[38] IEC 60050-704, *International Electrotechnical Vocabulary (IEV) - Part 704: Transmission*, available at www.electropedia.org

[39] ISO/IEC 2382:2015, *Information technology - Vocabulary*

[40] ISO/WD 23557, *Calibration, quality assurance and use of radionuclides calibrators in nuclear medicine*[4]

_____

[4] This project has been cancelled.