



IEC 63465

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# INTERNATIONAL STANDARD

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**Calibration and quality control in the use of radionuclide calibrators**



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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<sup>1</sup> 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.

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<sup>1</sup> 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](http://www.iec.ch/members_experts/refdocs). The main document types developed by IEC are described in greater detail at [www.iec.ch/publications](http://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](http://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- withdrawn, or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](http://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, 8<sup>th</sup> 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] Saldaña Vargas C., Bauwens M., Pooters I.N.A., 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](http://www.electropedia.org)
- [27] IEC 60050-881, *International Electrotechnical Vocabulary (IEV) - Part 881: Radiology and radiological physics*, available at [www.electropedia.org](http://www.electropedia.org)
- [28] ISO 921:1997, *Nuclear energy - Vocabulary*<sup>3</sup>
- [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](http://www.electropedia.org)

<sup>3</sup> 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](http://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](http://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*<sup>4</sup>

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<sup>4</sup> This project has been cancelled.