



DPC: 23 / 30461049 DC

BSI Group Headquarters

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000

Fax: +44 (0)20 8996 7400

www.bsigroup.com

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Interested committees:

Title: BS IEC 63465 Calibration and quality control in the use of radionuclide calibrators

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

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- iii) requires additional national guidance or information

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Responsible Committee Secretary: **Ms Lindsey Ferrari (BSI)**
Direct tel:
E-mail: lindsey.ferrari@bsigroup.com

Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



62C/883/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER:

IEC 63465 ED1

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2023-07-28

CLOSING DATE FOR COMMENTS:

2023-10-20

SUPERSEDES DOCUMENTS:

62C/833/NP, 62C/847/RVN

IEC SC 62C : EQUIPMENT FOR RADIOTHERAPY, NUCLEAR MEDICINE AND RADIATION DOSIMETRY

SECRETARIAT:

Germany

SECRETARY:

Ms Regina Geierhofer

OF INTEREST TO THE FOLLOWING COMMITTEES:

TC 45

PROPOSED HORIZONTAL STANDARD:



Other TC/SCs are requested to indicate their interest, if any, in this CD to the secretary.

FUNCTIONS CONCERNED:

☐ EMC

☐ ENVIRONMENT

☒ QUALITY ASSURANCE

☒ SAFETY

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TITLE:

Calibration and quality control in the use of radionuclide calibrators

NOTE FROM TC/SC OFFICERS:

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**CALIBRATION AND QUALITY CONTROL
IN THE USE OF RADIONUCLIDE CALIBRATORS****FOREWORD**

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- This International Standard IEC 63465 has been prepared by a Joint Working Group of subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Medical equipment, software, and systems, IEC technical committee 45: Nuclear instrumentation, and subcommittee 2: Radiological protection, of ISO technical committee 85: Nuclear energy, nuclear technologies, and radiological protection.

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

Draft	Report on voting
XX/XX/FDIS	XX/XX/RVD

127
128 Full information on the voting for its approval can be found in the report on voting indicated in the
129 above table.

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

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

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

- 138 • reconfirmed,
- 139 • withdrawn,
- 140 • replaced by a revised edition, or
- 141 • amended.

CALIBRATION AND QUALITY CONTROL IN THE USE OF RADIONUCLIDE CALIBRATORS

1 Scope and object

This International Standard specifies the techniques for calibration and usage of pressurised, well-type ionisation chambers for the assay of radionuclides. Such instruments are used to determine the activity, expressed in becquerel (Bq), of photon and some medium to high-energy beta emitting radionuclides.

This standard addresses calibration procedures of ionization chambers or 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 power plants.

This document provides the quality assurance methods and quality control tests for establishing conformity of device acceptability and maintaining acceptable instrument performance. Performance benchmarks vary depending on the user type and application, so information specific to end-users, production-level users, standards laboratories, and instrument manufacturers is provided.

The ionization 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 should be considered part of the scope of this standard.

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 standard.

The standard seeks to replace the following overlapping and outdated publications for radionuclide calibrators/ionisation chambers: IEC TR 61948-4:2019, IEC 61303:1994, IEC 61145:1992 and the New Work Item Proposal ISO/NP 23557.

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*

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

ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*

The usage of these devices in a clinical environment may involve additional normative references or even regulatory requirements. These requirements may depend on the specific use in a medical application.

3 Terms and definitions, abbreviated terms and symbols, quantities and units

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at <https://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

3.1.1 accuracy

quality which characterizes the ability of a measuring instrument to provide an indicated value close to a true value of the measurand

[SOURCE: IEV 311-06-08]

3.1.2 activity, A

number dN of spontaneous nuclear transitions or nuclear disintegrations for a radionuclide of amount N produced during a short time interval dt , divided by this time interval. $A = dN/dt$

NOTE to entry: The SI unit for activity is the becquerel (Bq), defined as disintegrations of a radionuclide per second.

[SOURCE: IEV 391-03-01]

3.1.3 beta emitters

radionuclides that emit beta particles, either in the form of electrons or positrons

NOTE 1 to entry: A beta particle is an electron, of positive or negative charge, emitted by an atomic nucleus in a nuclear transformation.

NOTE 2 to entry: Beta particles with a kinetic energy below 2,5 MeV deposit energy indirectly in the detector through bremsstrahlung produced in the source itself (filling medium and container) and the instrument components and its ancillary accessories. Higher energy beta emitters (beta-particle energy higher than 2,5 MeV) can deposit energy directly in the detector sensitive volume, and radionuclide calibrator sensitivity increases abruptly for these radionuclides.

[SOURCE: IEV 881-02-60, IEV 881-02-59 and [19]]

3.1.4 background

ionising radiation from any origin, natural or artificial, other than the radiation it is desired to detect or measure

[SOURCE: IEV 881-02-13]

3.1.5 calibration

set of operations which establishes, under specified conditions, the relationship between the measured value on a radionuclide calibrator and the measurement value from a certificate of calibration of a standard reference source

NOTE 1 to entry: Users can perform calibration by direct measurement of a standard reference source traceable to national standards.

NOTE 2 to entry: A calibration is initially performed by the manufacturer.

[SOURCE: IEV 311-01-09, modified]

3.1.6

calibration coefficient

multiplicative value (with units, e.g., pA/MBq) that converts a measured current to an activity value

3.1.7

calibration setting

instrument setting that converts measured current to a displayed activity

NOTE 1 to entry: Determined by the manufacturer for a reference radionuclide calibrator. These are commonly transferred to production units and might not necessarily be traceable. Details must be provided by the manufacturer.

NOTE 2 to entry: Calibration settings can be determined by calculation from a sensitivity curve and nuclear data. If calculated values are reported by the manufacturer, these should be clearly noted. Calibration settings determined using this method are not traceable to national standards.

NOTE 3 to entry: Users can also determine calibration settings for radionuclides and measurement geometries of interest.

3.1.8

certified reference source

standard reference source

radioactive source with an activity traceable to national standards. The source must be accompanied by a certificate of calibration that states measurement geometry, source geometry, activity and respective uncertainty, reference time and purity

NOTE 1 to entry: Certified reference sources can also be used as check sources.

NOTE 2 to entry: Certified reference sources are used for calibration of the instrument and for routine accuracy testing.

[SOURCE: IEC 61145 and IEC 61303, modified]

3.1.9

check source

radioactive source of relatively long half-life used to check the constancy of the radionuclide calibrator

NOTE 1 to entry: These are typically epoxy resin in a vial configuration.

NOTE 2 to entry: Typically, non-calibrated and/or traceable to national standards, and therefore should not be used for accuracy testing.

NOTE 3 to entry: Radioactive impurities must be as low as possible, i.e., the device response over the period of 5 years should not deviate by more than 0.5 % after decay correction for the known half-life of the principal radionuclide.

3.1.10

decay correction

calculation to correct for the decrease of the activity, with time, of a radioactive source due to spontaneous nuclear transformation

NOTE to entry: Decay constant is given by $\lambda = \left(\frac{-1}{N}\right) \frac{dN}{dt}$.

[SOURCE: IEV 881-02-28, modified]

3.1.11

linearity

property where the measured current of an instrument shows a linear response between the measured current and the source activity

NOTE to entry: The method of expression of lack of linearity is different for different kinds of instrument and is established in each particular instance.

[SOURCE: IEV 311-06-05, modified]

3.1.12**measurement geometry**

properties of the radioactive source being measured and its placement in the ionisation chamber

NOTE 1 to entry: Includes source geometry and the measurement set-up (including use of accessories such as dipper type, copper/aluminium shield) used.

NOTE 2 to entry: Calibration settings are determined for specific measurement geometries. Deviation from the measurement geometry might result in an inaccurate measurement.

NOTE 3 to entry: The use of accessories requires a specific calibration setting.

3.1.13**measurement traceability**

property of the result of a measurement or of the value of a standard such that it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties

NOTE 1 to entry: The concept is often expressed by the adjective traceable.

NOTE 2 to entry: The unbroken chain of comparisons is called a traceability chain.

NOTE 3 to entry: Traceability cannot be established in the absence of uncertainties. Instead, a measurement result is said to be traceable within the limits of the uncertainties of both the measurand and the value of the standard against which the measurement is compared [5].

[SOURCE: IEV 311-01-15]

3.1.14**multiplication factor**

a numeric factor by which the radionuclide calibrator reading is to be multiplied to calculate the true activity of a source

3.1.15**quality control**

set of tests to check if the system is working within specifications by comparison between the test value and a reference value

3.1.16**repeatability (of results of measurements)**

closeness of agreement between the results of successive measurements of the same measurand, carried out under the same conditions of measurement

NOTE 1 to entry: The measurements need to be performed within a short interval of time.

NOTE 2 to entry: The measurements must be performed by the same operator, using the same measurement procedure and the same measuring instrument, under the same conditions.

[SOURCE: IEV 311-06-06]

3.1.17**reproducibility (of measurements)**

in this context, corresponds to closeness of agreement between the results of measurements of the same value of a quantity, when the individual measurements are made under different conditions of measurement, i.e., after intervals of time relatively long compared with the duration of a single measurement

[SOURCE: IEV 311-06-07]

3.1.18**simulated source**

sources, also known as “mock” sources, usually containing long-lived radionuclides, alone or in combination, that are chosen to simulate, in terms of photon or particle emission, a short-lived radionuclide of interest

NOTE to entry: Simulated sources are not recommended for calibrating radionuclide calibrators because (although the principal photon energies may be similar) chamber response may not be the same.

3.1.19

source geometry

characteristics of a radioactive source measured on a radionuclide calibrator, including, the type and composition of the container used; volume of solution in the container; and density of solution

NOTE to entry: Deviation from the source geometry might result in inaccurate activity measurements.

3.1.20

radioactive impurity

radionuclides in a radioactive source other than the principal radionuclide

3.1.21

radioactive source

any quantity of radioactive material which is intended for use as a source of ionising radiation

[SOURCE: IEV-881-06-02]

3.1.22

reference volume

volume of radioactive solution in the container for which the calibration setting was determined

NOTE to entry: Deviations from the reference volume might result in measurement bias without volume corrections.

3.1.23

radionuclide calibrator

re-entrant pressurised ionisation chamber with associated electronics used to measure current produced by a radioactive source and display in units of activity

3.1.24

reference geometry

measurement geometry used to determine a calibration setting

NOTE to entry: Radioactive sources must be prepared as close as possible to the reference geometry to avoid the use of corrections and/or inaccurate activity measurements.

3.2 Abbreviated terms and symbols

BIPM International Bureau of Weights and Measures

QA quality assurance

QC quality control

SI International System

3.3 Quantities and units

In the present document, units of the International System (SI) are used¹. The definitions of radiation quantities are given in IEC 60050-395.

The following units may also be used:

- for energy: electron-volt (symbol: eV), $1 \text{ eV} = 1,602 \times 10^{-19} \text{ J}$;
- for time: years (symbol: a), days (symbol: d), hours (symbol: h), minutes (symbol: min), seconds (symbol: s);
- for radioactivity: becquerel (symbol: Bq), $1 \text{ Ci} = 3.7 \times 10^{10} \text{ Bq}$.

¹ International Bureau of Weights and Measures: The International System of Units, 8th edition, 2006.

Multiples and submultiples of SI units will be used, when practicable, according to the SI system

4 Installation and calibration of radionuclide calibrators

4.1 Installation and operation

The instrument shall be installed and operated in accordance with the manufacturer's instructions and/or applicable regulation requirements. Additional information regarding specific types of installation and operation is provided in Annex A.

4.2 Initial calibration by manufacturer

A radionuclide calibrator is usually supplied with calibration settings for the most commonly used radionuclides in a specific geometry (see 4.4). This initial calibration is developed, for a specific radionuclide calibrator, in conjunction with metrology laboratories and provided to the end user (through sensitivity curves) by the instrument manufacturer. Manufacturers determine calibrations by direct measurement with as many primary standards or traceable secondary reference sources as possible on a reference radionuclide calibrator. In the case of new radionuclides for which a standard is not yet available or for radionuclides for which a primary or secondary standard is not reasonably accessible, the manufacturer may provide a calculated value based on energy response curves and published radionuclide decay data. The manufacturer should clearly state the conditions of the initial calibration of the reference radionuclide calibrator as direct measurement or calculated value, and clearly note the specific geometric configuration used during the measurement process.

These initial calibrations are then transferred as calibration settings to production units. The reproducible transfer of calibration settings depends upon reproducible physical specifications. Therefore, the manufacturer should assure that all production chambers strictly conform to stated material specifications, physical dimensions, and tolerances. Some manufactures adjust the response of the production unit to match as closely as possible the reference chamber. This may be done by assaying a certified reference source on both the master device and the production unit, and then adjusting the response of the production unit to match the reference device. This additional step reduces manufacturing variability and improves overall accuracy when compared to the reference radionuclide calibrator. However, since the response adjustment is typically done with just one (or a few) specific radionuclide source(s), the validity of the calibration settings of production units provided by the manufacturer for other radionuclides or measurement conditions cannot be guaranteed. Secondary calibrations (see 4.3) may be required to ensure accurate performance of production units for the (wide) variety of radionuclides and measurement conditions utilized by the end user. Manufacturers should confirm the expected radionuclide calibrator response on production units with a primary standard(s) or traceable certified reference source(s) and provide the measurement conditions (source(s) and measurement set-up, response parameter(s)) and results of such measurement checks as part of the quality control certificate issued with each radionuclide calibrator. The manufacturer must also provide a means to reproduce the initial measurement conditions. This is usually done by providing the same type of chamber liner and source holder with the production unit that was used to make initial calibration measurements.

The manufacturer should give special attention to the initial calibration of production units that are part of a larger appliance, such as radionuclide calibrators or ionization chambers integrated in a laminar air flow cabinet, a fume hood, a hot cell, or a dispensing unit. The conditions in which the production units were calibrated or verified against the reference chamber may differ from the conditions for the end user. The production unit can be equipped with additional accessories, such as manual or automated source positioning systems (e.g., an elevator, a holder) that can position the source in the well, or changes that might have been applied to the well, the inner wall of the chamber, the liner, or the dipper. Each adaptation may influence the calibration or verification steps and should be clearly communicated by the manufacturer to the end user.