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International Standard

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Calibration and quality control in the use of radionuclide calibrators

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This draft is submitted to a parallel vote in ISO and in IEC.

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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

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Calibration and quality control in the use of radionuclide calibrators

FOREWORD

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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[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.

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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/XX/FDIS	62C/XX/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

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

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60050-395 and the following 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
acceptance criteria
numerical limits, ranges, or other suitable measures for acceptance of test results

[SOURCE: ISO 22716:2007, 2.1]

3.1.2
accuracy
quality which characterizes the ability of a measuring instrument to provide an indicated value close to a true value of the measurand

[SOURCE: IEC 60050-311:2001, 311-06-08, modified – The domain and the notes were deleted.]

3.1.3
background radiation
ionizing radiation from any origin, natural or artificial, other than the radiation it is desired to detect or measure

[SOURCE: IEC 60050-881:1983, 881-02-13, modified – The second term "ambient radiation" was deleted.]

3.1.4
background response
response of the instrument in the absence of a radioactive source to be measured

Note 1 to entry: A background response is caused by a background radiation in addition to any electronic noise or contamination.

3.1.5
beta particle
electron or positron which has been emitted by an atomic nucleus or neutron in a nuclear transformation

[SOURCE: ISO 921:1997, definition 81]

3.1.6
beta-emitter
material, the nuclei of which emit beta particles

Note 1 to entry: It is possible to classify beta emitters by the maximum energy level of the particles that they release during their disintegration.

Note 2 to entry: When the beta particle emitted is an electron, the beta-emitter is called "beta minus emitter". When the beta particle emitted is a positron, the beta-emitter is called "beta plus emitter", resulting in the emission of photons of 511 keV.

[SOURCE: ISO 3543:2000, 2.3, modified – The terms "beta-emitting isotope" and "beta-emitting source" were deleted and Note 2 was replaced with a new note to entry.]

3.1.7
calibration
set of operations which establishes, by reference to standards, the relationship which exists, under specified conditions, between an indication and a result of a measurement

[SOURCE: IEC 60050-311:2001, 311-01-09, modified – The notes were deleted.]

3.1.8
calibration coefficient
multiplicative value that converts a measurement signal to the measurand of interest

Note 1 to entry: In the case of radionuclide calibrators, the measurement signal is the current and the measurand of interest is the activity.

3.1.9
calibration setting
instrument setting that converts measured current to a displayed activity

Note 1 to entry: A calibration setting was historically referred to as "dial setting".

3.1.10
certified radioactive standard source
radioactive source that has been calibrated by a laboratory recognized as a country's national standardizing laboratory for activity measurements and has been certified by the aforementioned laboratory

[SOURCE: IEC 60050-395:2014, 395-02-03, modified – The noun "radioactivity" was replaced with "activity". The word "so" was removed, as well as the note to entry.]

3.1.11
check source
long-lived radionuclide used to check the constancy of the radionuclide calibrator

3.1.12
combined standard uncertainty
standard uncertainty of the result of a measurement when that result is obtained from the values of a number of other quantities, equal to the positive square root of a sum of terms, the terms being the variances or covariances of these other quantities weighted according to how the measurement result varies with changes in these quantities

[SOURCE: IEC 60076-19-1:2023, 3.3]

3.1.13
commissioning test
test on an item carried out on site, to prove that it is correctly installed and can operate correctly

[SOURCE: IEC 60050-151:2001, 151-16-24]

3.1.14
correction factor
numerical factor by which the uncorrected result of a measurement at the measured conditions is multiplied

Note 1 to entry: For radionuclide calibrator, correction factors to reference conditions are used to take account of differences in the measurement conditions between calibration conditions and those used by the end user

[SOURCE: ISO 8222:2020, 3.1.8 modified – Note 1 to entry was adapted to radionuclide calibrator.]

3.1.15
decay constant
λ
disintegrations per unit time dN/dt for an atomic nucleus divided by the number of nuclei N existing at the same time t

$$\lambda = -\frac{1}{N} \times \frac{\mathrm{d}N}{\mathrm{d}t}$$

Note 1 to entry: The decay constant is expressed in reciprocal seconds (s^{-1}).

Note 2 to entry: The decay constant represents the probability of decay in the limit of small time intervals.

[SOURCE: IEC 60050-395:2014, 395-01-11, modified – Note 2 to entry was modified and Note 3 to entry was deleted.]

3.1.16
decay correction
method for calculating the activity at a given time based on the decay

$$A_t = A_0 \exp(-\lambda t_e) \text{where}$$

A_0 is the activity at a reference time t_0;

A_t is the activity at a given time t;

λ is the decay constant of the radionuclide of interest;

t_e is the elapsed time (expressed in s), where $t_e = t - t_0$ and can be positive (decrease in activity compared with the reference time) or negative (increase in activity compared with the reference time)

Note 1 to entry: It is important to use the correct decay constant to determine the decay correction value.

3.1.17
error
error of measurement
measurement error
measured quantity value minus a reference quantity value

[SOURCE: ISO 17123-1:2014, 3.1.12]

3.1.18
expanded uncertainty
U
quantity defining an interval about the result of a measurement that can be expected to encompass a large fraction of the distribution of values that can reasonably be attributed to the measurand

$$U = k\, u_c$$

where

u_c is the combined standard uncertainty of a result of a measurement;

k is the coverage factor defined as the numerical factor used as a multiplier of the combined standard uncertainty (see ISO ISO/IEC Guide 98-3)

[SOURCE: IEC 60076-19-1:2023, 3.4, modified – The symbol "U" and the formula were added.]

3.1.19
field class instrument
radionuclide calibrator used in nuclear medicine facilities, industrial or hospital (radio)pharmacies, research laboratories, and nuclear power plants

3.1.20
human error
discrepancy between the human action taken or omitted, and that intended or required

EXAMPLE Performing an incorrect action; omitting a required action; miscalculation; misreading a value.

[SOURCE: IEC 60050-192:2015, 192-03-14]

3.1.21
linearity
<measuring instrument> ability of a measuring instrument to provide an indication having a linear relationship with a defined quantity other than an influence quantity

Note 1 to entry: With radionuclide calibrators, the measured current has a linear relationship with the source activity.

[SOURCE: IEC 60050-311:2001, 311-06-05, modified – Note 1 to entry was adapted to radionuclide calibrators.]

3.1.22
measurand
particular quantity subject to measurement

[SOURCE: IEC 60050-311:2001, 311-01-03]

3.1.23
measurement
process of experimentally obtaining one or more values that can reasonably be attributed to a quantity

Note 1 to entry: Measurement does not apply to nominal properties.

Note 2 to entry: Measurement implies comparison of quantities, including counting of entities.

[SOURCE: ISO/IEC Guide 99:2007, 2.1, modified – The words "quantity values" were replaced with "values", and Note 3 to entry was deleted.]

3.1.24
measurement bias
bias
estimate of a systematic measurement error

[SOURCE: ISO/IEC Guide 99:2007, 2.18]

3.1.25
measurement geometry
geometry
<radionuclide calibrator> physico-chemical properties of the source, its container, the environment, and the accessories used for measurement

Note 1 to entry: Physico-chemical properties include the following:

- for the source, the volume, density, composition (example: microparticles), etc.;
- for the container and the accessories, the atomic composition (example: glass or plastic);
- for the environment, the ambient conditions (example: temperature, relative humidity), and shielding.

3.1.26
multiplication factor
numeric scaling factor that is part of the calibration by which the radionuclide calibrator reading is to be multiplied to calculate the true activity of a source

Note 1 to entry: Commonly expressed as, for example, "450 × 10", meaning that the instrument reading with a calibration setting of 450 is multiplied by a factor of 10 to give the true activity.

Note 2 to entry: In many modern instruments, multiplication factors can be applied in software.

3.1.27
quality assurance
QA
planned, systematic, and preventive actions that are required to ensure that materials, products, or services meet specified requirements

[SOURCE: ISO 13628-2:2006, 3.34, modified – The abbreviated term "QA" has been added.]

3.1.28
quality control
QC
inspection, test or examination to ensure that materials, products or services conform to specified requirements

Note 1 to entry: Additional information can be found in ISO/IEC 17025 [1].

[SOURCE: ISO 13628-2:2006, 3.35, modified – The abbreviated term "QC" and Note 1 to entry were added.]

3.1.29
quality management system
QMS
part of a management system with regard to quality

Note 1 to entry: The QMS is presented here as a framework described by ISO 9000 and ISO 9001 and comprises three core elements: quality control, quality assurance and quality improvement.

[SOURCE: ISO 9000:2015, 3.5.4, modified – The abbreviated term "QMS" and Note 1 to entry were added.]

3.1.30
radioactive impurities
radionuclides in a radioactive source other than the principal radionuclide

3.1.31
radionuclidic purity
ratio, expressed as percentage, of the activity of the desired radionuclide to the total activity of the source

3.1.32
radioactive source
radioactive material which is intended for use as a source of ionising radiation

[SOURCE: IEC 60050-881:1983, 881-06-02, modified – The phrase "any quantity of" was removed.]

3.1.33
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

3.1.34
reference clock
clock of very high stability, accuracy, and reliability which is used as the single reference standard for the clocks in a synchronized network

[SOURCE: IEC 60050-704:1993, 704-13-10]

3.1.35
reference device
device, which is calibrated against national standards, possessing accurately known parameters used for calibrating secondary devices

3.1.36 ISO
reference geometry
<radionuclide calibrator> measurement geometry used during a calibration

Note 1 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.

3.1.37
reference volume
<radionuclide calibrator> volume of radioactive solution in the container for which the calibration was performed

3.1.38
repeatability
<results of measurements> closeness of agreement between the results of successive measurements of the same measurand, carried out under the same conditions of measurement, i.e.:

– by the same measurement procedure,
– by the same observer,
– with the same measuring instruments, used under the same conditions,
– in the same laboratory,
– at relatively short intervals of time

Note 1 to entry: The concept of "measurement procedure" is defined in ISO/IEC Guide 99:2007, 2.6.

[SOURCE: IEC 60050-311:2001, 311-06-06]

3.1.39
reproducibility
< measurements> 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:

– principle of measurement;
– method of measurement;
– observer;
– measuring instruments;
– reference standards;
– laboratory;
– under conditions of use of the instruments, different from those customarily used;
– after intervals of time relatively long compared with the duration of a single measurement

Note 1 to entry: The concepts of “measurement principle” and “measurement method” are respectively defined in ISO/IEC Guide 99:2007, 2.4 and 2.5.

Note 2 to entry: The term “reproducibility” also applies to the instance where only certain of the above conditions are taken into account, provided that these are stated.

[SOURCE: IEC 60050-311:2001, 311-06-07]

3.1.40
simulated source
mock source
long-lived radionuclide, used alone or in combination with others to simulate, in terms of photon or particle emission, a short-lived radionuclide of interest

[SOURCE: IEC 60050-395:2014, 395-02-06, modified – The term "mock source" was added and Note 1 to entry was deleted.]

3.1.41
source geometry
<radionuclide calibrator> physico-chemical characteristics of a radioactive source measured on a radionuclide calibrator, including its volume, density, and composition (example: microparticles), and the type and composition of the container used

Note 1 to entry: Deviation from the source geometry can result in inaccurate activity measurements.

3.1.42
traceable radioactive standard source
radioactive source that has been calibrated by comparing it to a certified radioactive standard source or to another standardized radioactive source of the same radionuclide

[SOURCE: IEC 60050-394:2014, 395-02-04, modified - Note 1 to entry was deleted.]

3.1.43
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 a documented unbroken chain of calibrations, 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.

[SOURCE: IEC 60050-311:2001, 311-01-15, modified – The word "documented" was added and the word “comparisons” was replaced with “calibrations”. Note 3 to entry was deleted.]

3.1.44
uncertainty
<measurement> parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand

Note 1 to entry: Various ways to estimate uncertainty are defined in ISO/IEC Guide 98-3.

Note 2 to entry: Uncertainty of measurement comprises, in general, many components. Some of these components can be evaluated from the statistical distribution of the results of a series of measurements and can be characterized by experimental standard deviations. Other components, which can also be characterized as standard deviations, are evaluated from the assumed probability distributions based on experience or other information.

[SOURCE: IEC 60050-311:2001, 311-01-02, modified – Note 1 to entry was deleted and Notes 2 and 3 to entry were modified.]

3.1.45
user manual
document provided by the manufacturer that describes how to use a functional unit, and that can include description of the rights and responsibilities of the user, the owner, and the supplier of the unit

Note 1 to entry: The user manual is often labelled “user guide”, "owner's manual" or "operator's manual".

[SOURCE: ISO/IEC 2382:2015, modified – The notes to entry were replaced with a new note to entry.]

3.2 Abbreviated terms and symbols

SI International System

3.3 Quantities and units

In this document, the International System of Units is used [2][2].

The following units for time are used:

– days (symbol: d);
– hours (symbol: h);
– minutes (symbol: min);
– seconds (symbol: s).

Multiples and submultiples of SI units are used, when practicable, according to the SI system.

The definitions of radiation quantities are given in IEC 60050-395.

4 Installation and calibration of radionuclide calibrators

4.1 Principles of operation (informative)

Radionuclide calibrators are based on ionisation chambers that generate a radionuclide-dependent current proportional to the source's activity. They are calibrated to determine calibration coefficients or, more commonly, define calibration settings to convert the measured current into an activity for a given radionuclide. Furthermore, ionisation current and thus activity measurement depends on the measurement geometry (see Clause 8) [3].

[2] Numbers in square brackets refer to the Bibliography.