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Date: 10 April 2024

Origin: International

Latest date for receipt of comments: 29 May 2024

Project No. 2022/01809

Responsible committee: CH/62/3 Equipment for radiotherapy, nuclear medicine and radiation dosimetry

Interested committees:

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

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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.

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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 Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.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/911/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER:

IEC 63465 ED1

DATE OF CIRCULATION:

2024-04-05

CLOSING DATE FOR COMMENTS:

2024-06-28

SUPERSEDES DOCUMENTS:

62C/883/CD, 62C/906A/CC

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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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CALIBRATORS****FOREWORD**

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- This International Standard IEC 63465 has been prepared by a Joint Working Group of 122 subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC 123 technical committee 62: Medical equipment, software, and systems, IEC technical committee 45: 124 Nuclear instrumentation, and subcommittee 2: Radiological protection, of ISO technical committee 125 85: Nuclear energy, nuclear technologies, and radiological protection.

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

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

49
50 Full information on the voting for its approval can be found in the report on voting indicated in the
51 above table.

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

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

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

- 60 • reconfirmed,
61 • withdrawn,
62 • revised.

63

CALIBRATION AND QUALITY CONTROL IN THE USE OF RADIONUCLIDE CALIBRATORS

1 Scope

This standard 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 emitting radionuclides.

This document addresses calibration procedures of ionisation 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 QC tests for establishing conformity of device acceptability and maintaining acceptable instrument performance. Performance benchmarks vary depending on the application, so information specific to end-users, production-level users, standards laboratories, and instrument manufacturers is provided.

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 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 documentary standards 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.

JCGM 100:2008 GUM with minor corrections. Evaluation of measurement data — Guide to the expression of uncertainty in measurement.

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 terms and definitions given in IEC 60050-395, as well as the following apply.

ISO and IEC maintain terminological 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 acceptance test

contractual test to prove to the customer that the item meets certain conditions of its specification.

[SOURCE: IEV 151-16-23]

3.1.3

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]

3.1.4

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 unit is becquerel (Bq).

[SOURCE: IEV 395-01-05]

3.1.5

background

radiation field in which the instrument is intended to operate, including background produced by naturally occurring radioactive material.

[SOURCE: IEC Glossary
<https://std.iec.ch/terms/terms.nsf/0/5DCD91CE49C068DEC1257BF6004ADBE0?OpenDocument>]

136 **3.1.6**137 **beta particle**

138 electron or positron which has been emitted by an atomic nucleus or neutron in a nuclear
139 transformation.

140 [SOURCE: ISO 921:1997, definition 81]

141 **3.1.7**142 **beta-emitter**

143 material, the nuclei of which emit beta particles.

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

146 Note 2 to entry: When the beta particle emitted is an electron, the beta-emitter is called a beta minus emitter. When the
147 beta particle emitted is a positron, the beta-emitter is called a beta plus emitter, resulting in the emission of photons of
148 511 keV.

149 [SOURCE: ISO 3543:2000, 2.3, modified – beta-emitting isotopes and beta-emitting source were deleted,
150 Note 2 to entry was added]

151 **3.1.8**152 **bias**153 **measurement bias**

154 estimate of a systematic measurement error.

155 [SOURCE: JCGM 200:2012]

156 **3.1.9**157 **calibration**

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

160 [SOURCE: IEC 311-01-09, modified - Note 1 and 2 were deleted]

161 **3.1.10**162 **calibration coefficient**

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

164 **3.1.11**165 **calibration setting**166 **dial setting**

167 instrument setting that converts measured current to a displayed activity.

168 **3.1.12**169 **certified radioactive standard source**

170 radioactive source that has been calibrated by a laboratory recognized as a country's national
171 standardizing laboratory for radioactivity measurements and has been so certified by the
172 aforementioned laboratory.

173 Note to entry: This entry was numbered 393-12-27 in IEC 60050-393:2003.

174 [SOURCE: IEV 395-02-03]

175 **3.1.13**

176 **check source**

177 long half-lived radionuclide used to check the constancy of the radionuclide calibrator.

178 **3.1.14**

179 **combined standard uncertainty**

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

184 [SOURCE: IEC Glossary]

185 **3.1.15**

186 **commissioning test**

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

188 [SOURCE: IEV 151-16-24]

189 **3.1.16**

190 **correction factor**

191 numerical factor by which the uncorrected result of a measurement at the measured conditions is
192 multiplied.

193 Note to entry: Correction factors to standard conditions are used to take account of differences in the measurement
194 environment between calibration conditions and those used by the end user.

195 [SOURCE: ISO 8222:2020, 3.1.8 modified – Note 1 to entry was changed]

196 **3.1.17**

197 **coverage factor**

198 numerical factor (k) used as a multiplier of the combined standard uncertainty in order to obtain an
199 expanded uncertainty (see ISO 1995: Guide to the expression of uncertainty in measurement).

200 [SOURCE: IEC Glossary]

201 **3.1.18**

202 **decay constant, λ**

203 disintegrations per unit time dN/dt for an atomic nucleus divided by the number of nuclei N existing
204 at the same time t .

205
$$\lambda = \left(\frac{-1}{N} \right) \frac{dN}{dt}$$

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

207 Note 2 to entry: The decay constant may be considered the total probability of radioactive decay (disintegration and/or
208 nuclear transition).

209 Note 3 to entry: This entry was numbered 393-14-18 in IEC 60050-393:2003.

210 [SOURCE: IEV 395-01-11]

211 3.1.19**212 decay correction**

213 method for estimating the activity present at a given time.

214 Note 1 to entry: The formula for decay correcting is: $A_t = A_0 \exp(-\lambda t_e)$ where A_0 is the activity at a reference time t_0 , A_t is
215 the activity at time t , λ the decay constant of the radionuclide of interest, and t_e is the elapsed time (expressed in s),
216 where $t_e = t - t_0$.

217 Note 2 to entry: It is important to use the correct half-life to determine the decay correction value.

218 3.1.20**219 error****220 error of measurement****221 measurement error**

222 measured quantity value minus a reference quantity value.

223 [SOURCE: ISO 17123-1:2014]

224

225 3.1.21**226 expanded uncertainty**

227 quantity defining an interval about the result of a measurement that may be expected to
228 encompass a large fraction of the distribution of values that could reasonably be attributed to the
229 measured quantity.

230 Note to entry: The expanded uncertainty is defined by the following formula:

231
$$U = k u_c$$

232 Where u_c is the combined standard uncertainty of a result of a measurement and k is the coverage factor defined as the numerical
233 factor used as a multiplier of the combined standard uncertainty, see Guide to the expression of uncertainty in measurement (ISO
234 1995)).

235 [SOURCE: IEC Glossary]

236 3.1.22**237 human error**

238 discrepancy between the human action taken or omitted, and that intended or required.

239 Note to entry: For example, performing an incorrect action; omitting a required action; miscalculation; misreading a value.

240 [SOURCE: IEC 192-03-14]

241 3.1.23**242 linearity (of a measuring instrument)**

243 ability of a measuring instrument to provide an indication having a linear relationship with a defined
244 quantity other than an influence quantity.

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

246 [SOURCE: IEC 311-06-05, modified – Note 1 to entry was changed]

247 3.1.24**248 measurand**

249 particular quantity subject to measurement

250 [SOURCE: IEV 311-01-03]

251 **3.1.25**

252 **measurement**

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

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

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

256 [SOURCE: ISO/IEC GUIDE 99:2007 2.1, modified – Note 3 to entry was deleted]

257 **3.1.26**

258 **measurement bias**

259 **bias**

260 estimate of a systematic measurement error.

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

262 **3.1.27**

263 **measurement geometry**

264 **geometry**

265 physico-chemical properties of the source, its container, the environment, and the accessories
266 used for measurement.

267 Note to entry: Physico-chemical properties include:

- 268 • For the source, its volume, density, composition (example: microparticles), etc.
- 269 • For the container and the accessories, the atomic composition (example: glass or plastic).
- 270 • For the ambient conditions (i.e., temperature, relative humidity), and shielding.

271 **3.1.28**

272 **multiplication factor**

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

275 Note 1 to entry: Commonly expressed as, e.g., “450 X 10”, meaning that the instrument reading with a calibration setting of 450
276 should be multiplied by a factor of 10 to give the true activity. For example, Capintec settings implemented in their software are Y-90
277 (55 X 10) and Lu-177 (450 X 10).

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

279 **3.1.29**

280 **quality assurance**

281 **QA**

282 Planned, systematic, and preventive actions that are required to ensure that materials, products,
283 or services meet specified requirements.

284 [SOURCE: ISO 13628-2:2006, 3.34]

- 285 **3.1.30**
286 **quality control**
287 **QC**
288 inspection, test or examination to ensure that materials, products or services conform to specified
289 requirements.
290 Note to entry: Additional information can be found in ISO/IEC 17025 [1].
291 [SOURCE: ISO 13628-2:2006, 3.35, modified – QC and Note to entry were added]
- 292 **3.1.31**
293 **quality management system**
294 management system with which an organization will be directed with regard to product quality.
295 [SOURCE: IEC Glossary]
- 296 **3.1.32**
297 **radioactive half-life, $T_{1/2}$**
298 time required for the activity of a radionuclide to decrease to half of its initial value.
299 Note to entry: The radioactive half-life is related to the decay constant λ by the expression: $T_{1/2} = \ln 2 / \lambda \approx 0,693 / \lambda$. This
300 quantity is expressed in seconds (s).
301 [SOURCE: IEV 395-01-12]
- 302 **3.1.33**
303 **radioactive impurities**
304 radionuclides in a radioactive source other than the principal radionuclide.
- 305 **3.1.34**
306 **radionuclidic purity**
307 the ratio, expressed as percentage, of the activity of the desired radionuclide to the total activity
308 of the source.
- 309 **3.1.35**
310 **radioactive source**
311 any quantity of radioactive material which is intended for use as a source of ionising radiation.
312 [SOURCE: IEV-881-06-02]
- 313 **3.1.36**
314 **radionuclide calibrator**
315 re-entrant pressurised ionisation chamber with associated electronics used to measure current
316 produced by a radioactive source and display in units of activity.
- 317 **3.1.37**
318 **reference device**
319 primary device possessing accurately known parameters used as a standard for calibrating
320 secondary devices.
321 [SOURCE: ISO 16890-3:2016, 3.4.2]

3.1.38**reference geometry**

measurement geometry used during a calibration.

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.

3.1.39**reference volume**

volume of radioactive solution in the container for which the calibration was performed.

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

3.1.40**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, 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 to entry: The concept of “measurement procedure” is defined in VIM 2.5.

[SOURCE: IEV 311-06-06]

3.1.41**reproducibility (of 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 “principle of measurement” and “method of measurement” are respectively defined in VIM 2.3 and 2.4.

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: IEV 311-06-07]

3.1.42**simulated source****mock source**