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Calibration and quality control in the use of radionuclide calibrators

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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.
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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/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

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