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TECHNICAL REPORT

colour inside

Nuclear medicine instrumentation – Routine tests – Part 4: Radionuclide calibrators

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INTERNATIONAL
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Part 4: Radionuclide calibrators

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9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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This edition includes the following significant technical change with respect to the previous edition: the test method to determine SYSTEM LINEARITY has been updated to reflect the technical developments of RADIONUCLIDE CALIBRATORS.

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Draft TR	Report on voting
62C/715/DTR	62C/727/RVDTR

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This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

Terms used throughout this document that have been defined in Clause 3 appear in SMALL CAPITALS.

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IMPORTANT – The "colour inside" logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a colour printer.

INTRODUCTION

This technical report is based on the German Standard DIN 6855-11, *Qualitätsprüfung nuklearmedizinischer Messsysteme – Teil 11: Konstanzprüfung von Aktivimetern*, the English document *Protocol for Establishing and Maintaining the Calibration of Medical Radionuclide Calibrators and their Quality Control*, the Austrian document ÖNORM S 5270, *Aktivimeter – Richtlinien für die Konstanzprüfung am Verwendungsort / Radionuclide calibrators – Guidelines for the constancy testing in the field / Calibrateurs de radionucléides – Directives pour l'essai de constance à l'endroit d'utilisation*, of 1 April 1998, and the Spanish document *Protocolo Nacional del Control de Calidad en la Instrumentación en Medicina Nuclear.*

NUCLEAR MEDICINE INSTRUMENTATION – ROUTINE TESTS –

Part 4: Radionuclide calibrators

1 Scope ~~and object~~

This part of IEC 61948 covers the ROUTINE TESTING of RADIONUCLIDE CALIBRATORS used in nuclear medicine. Such devices utilise ionisation chambers of the well type ~~(directly coupled to an appropriate electronic circuitry (IEC 61145))~~ and a direct readout in units of ACTIVITY. Requirements and specific methods to determine performance parameters are described in IEC 61303 ~~and IEC 61145~~. These methods are primarily designed for ACCEPTANCE TESTING.

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*

~~IEC 61145:1992, *Calibration and usage of ionization chamber systems for assay of radionuclides*~~

IEC 61303:1994, *Medical electrical equipment – Radionuclide calibrators – Particular methods for describing performance*

~~IEC 61948-1:2001, *Nuclear medicine instrumentation – Routine tests – Part 1: Radiation counting systems*~~

3 Terms and definitions

For the purpose of this document, the terms and definitions given in IEC TR 60788~~:2004~~, IEC 61303~~:1994 and IEC 61145:1992, some of which are repeated here for convenience~~, and the following ~~terms and definitions~~ apply.

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

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

NOTE Defined terms are printed in small capital letters.

3.1
ACCEPTANCE TEST
~~test carried out at the request and with the participation of the user or his representative to ascertain by determination of proper performance parameters that the instrument meets the specifications claimed by the vendor~~

~~NOTE An ACCEPTANCE TEST should be carried out at the time of installation and when appropriate after major service. During or immediately after acceptance testing, REFERENCE DATA are collected to be used as a standard for comparison with future ROUTINE TESTS.~~

~~[IEC 61948-1:2001, definition 3.2.1]~~

test carried out after new equipment has been installed, or major modifications have been made to existing equipment, in order to verify compliance with contractual specifications

Note 1 to entry: During or immediately after ACCEPTANCE TEST, REFERENCE DATA are collected to be used as a standard for comparison with future ROUTINE TESTS.

[SOURCE: IEC TR 60788:2004, rm-70-01, modified –A note to entry has been added.]

3.2
BACKGROUND RESPONSE
reading of the instrument without intended RADIOACTIVE SOURCE

Note 1 to entry: The BACKGROUND RESPONSE is caused by external radiation fields, but in addition also by electronic noise and contamination.

3.3
CERTIFIED RADIOACTIVE STANDARD SOURCE
RADIOACTIVE SOURCE that has been calibrated by a laboratory recognized as a country's national standardizing laboratory for radioactivity measurements and has been so certified by the aforementioned laboratory

[SOURCE: IEC 61303:1994, 2.1.1]

3.4
IONISATION CHAMBER TEST SOURCE
RADIOACTIVE SOURCE used for the determination of the long-term stability of an ionisation chamber

Note 1 to entry: The half-life of the source shall be greater than five years and the effects of any radioactive contaminants shall be such that the indication of the device over a period of five years would not deviate by more than 0,5 % after decay correction for the known half-life of the principal radionuclide.

Note 2 to entry: The IONISATION CHAMBER TEST SOURCE is used to test the functionality of a RADIONUCLIDE CALIBRATOR under defined conditions.

[SOURCE: IEC 61303:1994, 2.7, modified – Part of the definition has been moved to a note to entry, and a second note to entry has been added.]

3.5
RADIONUCLIDE CALIBRATOR
device for measuring the ACTIVITY of a radioactive sample

[SOURCE: IEC 61303:1994, 2.11]

3.6
REFERENCE DATA
set of data measured immediately after ACCEPTANCE TESTING, using test methods designed for ROUTINE TEST

[SOURCE: IEC TR 61948-1:~~2001~~ 2016,~~3.2.3~~ 3.7]

3.7
ROUTINE TEST
test of a piece of equipment or its components which is repeated at specified intervals, to establish and document changes from the initial status described by REFERENCE DATA

Note 1 to entry: A ROUTINE TEST could be carried out by the user with simple methods and equipment.

[SOURCE: IEC TR 61948-1:~~2001~~ 2016,~~3.2.2~~ 3.8]

3.8
SYSTEM LINEARITY
function relating the observed and predicted ACTIVITY values when the ACTIVITY of a specified RADIOACTIVE SOURCE is varied

[SOURCE: IEC 61303:1994, 2.4]

3.9
TRACEABLE RADIOACTIVE STANDARD SOURCE
RADIOACTIVE SOURCE that has been calibrated by comparing it to a CERTIFIED RADIOACTIVE STANDARD SOURCE or to another TRACEABLE RADIOACTIVE STANDARD SOURCE of the same radionuclide

[SOURCE: IEC 61303:1994, 2.1.2]

~~**3.4**~~
~~**radionuclide factor**~~
~~factor, dependent on the radionuclide, by which the response of the system must be multiplied in order to obtain the correct ACTIVITY reading of a source which has been placed in the ionization chamber~~

~~[IEC 61303:1994, definition 2.2]~~

~~**3.7**~~
~~**radioactive standard source**~~
~~general term used to refer to the standard sources listed below~~

~~[IEC 61303:1994, definition 2.1]~~

4 Test methods

4.1 BACKGROUND RESPONSE

The BACKGROUND RESPONSE ~~shall be~~ is obtained with the setting that corresponds to the most often used nuclide. The measurement ~~should be~~ is made with the sample holder in place. The reading of the background is reported.

4.2 Constancy of instrument response

The constancy of instrument response of the RADIONUCLIDE CALIBRATOR and, hence, its calibration ~~shall be~~ is obtained for a specified radionuclide setting by inserting the IONISATION CHAMBER TEST SOURCE into the measurement position. The instrument reading ~~shall be~~ is compared to the REFERENCE DATA and reported.

4.3 SYSTEM LINEARITY

4.3.1 General

~~The test of SYSTEM LINEARITY shall cover all the range of ACTIVITY used in the facility. The sample of the radionuclide used shall be introduced into the measuring position of the device under test. The ACTIVITY shall be measured so that at least one data point is measured per decade of the instrument scale.~~

The test of SYSTEM LINEARITY covers the range of ACTIVITY from 10 MBq up to 120 % of the maximum ACTIVITY injected into a patient as measured with the device under test and at least up to 1 000 MBq.

4.3.2 Decaying source method

SYSTEM LINEARITY is tested using the radioactive decay of a sample of a short-lived radionuclide, for example ^{99m}Tc. The sample of the radionuclide used is introduced into the measuring position of the device under test and measured at defined points in time. The time intervals between the individual measurements ~~shall be so chosen that at least one data point is measured per decade of the instrument scale~~ are chosen such that at least two data points are acquired per decade of the investigated ACTIVITY.

4.3.3 Data analysis

~~Applying a mono-exponential fit to the measured data in the range 1 MBq and the 80 % of the highest activity used, the ratio of the measured ACTIVITY to expected ACTIVITY shall be calculated for each measurement point.~~

The logarithms of the measured data are plotted against the times of measurement. A straight line is fit to the logarithm of the measured data in the range from 10 MBq up to 1 000 MBq. From the fit, the expected ACTIVITY values (not the logarithm of their values) at the time points of measurement are determined. The ratio of the measured ACTIVITY to the expected ACTIVITY is calculated for each measurement point. The maximum percent deviation is reported.

4.4 Additional checks

When additional checks are recommended in the operation manual, they ~~should~~ are also ~~be~~ performed at the frequency suggested by the MANUFACTURER.

4.5 Frequency of ROUTINE TESTS

ROUTINE TESTS ~~shall be~~ are carried out at the time intervals given in Table 1.

Table 1 – Frequency of ROUTINE TESTS

Test	Subclause	Frequency
BACKGROUND RESPONSE with sample holder for one radionuclide setting	4.1	Daily (each day the instrument is used)
Constancy of instrument response for one radionuclide setting	4.2	Daily (each day the instrument is used)
~~Constancy of instrument response for all radionuclide settings used~~	~~4.2~~	~~Weekly~~
SYSTEM LINEARITY for one radionuclide setting	4.3	Twice yearly
Additional checks according to operator's manual	4.4	According to MANUFACTURER's recommendations

Bibliography

~~DIN 6855-11, *Qualitätsprüfung nuklearmedizinischer Messsysteme – Teil 11: Konstanzprüfung von Aktivimetern*~~

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IEC TR 61948-1:2016, *Nuclear medicine instrumentation – Routine tests – Part 1: Gamma radiation counting systems*

Index of defined terms

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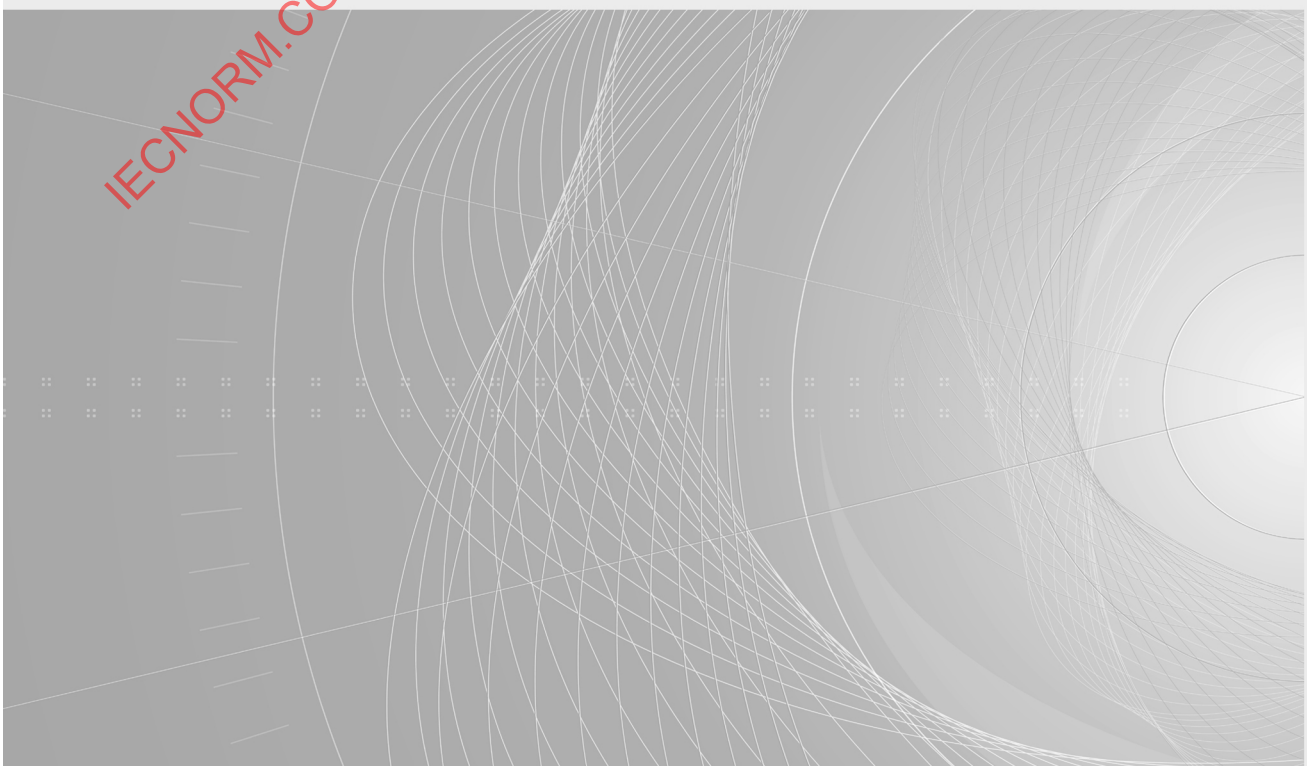

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[SOURCE: IEC TR 61948-1:2016, 3.7]

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