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Nuclear medicine instrumentation – Routine tests –

Part 4: Radionuclide calibrators

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

NUCLEAR MEDICINE INSTRUMENTATION – ROUTINE TESTS –

Part 4: Radionuclide calibrators

FOREWORD

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IEC 61948-4, which is a technical report, has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
62C/387/DTR	62C/401/RVC

Full information on the voting for the approval of this technical report can be found in the report on voting indicated in the above table.

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

In this technical report the following print types are used:

- requirements, compliance with which can be tested, and definitions: in roman type;
- explanation, advice, introductions, general statements, exceptions and reference: in smaller roman type;
- *test specifications: in italic type*;
- TERMS DEFINED IN CLAUSE 3 OF THIS TECHNICAL REPORT OR LISTED IN THE INDEX OF DEFINED TERMS: SMALL CAPITALS.

A list of all parts of the IEC 61948 series, published under the general title *Nuclear medicine instrumentation – Routine tests,* can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under http://webstore.iec.ch in the data related to the specific publication. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

A bilingual version of this publication may be issued at a later date.

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 technical report covers the routine testing of radionuclide calibrators used in nuclear medicine. Such devices utilise ionization 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 referenced documents are indispensable for the application 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 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 purposes of this document, the terms and definitions given in IEC 60788:2004, IEC 61303:1994 and IEC 61145:1992, some of which are repeated here for convenience, and the following terms and definitions apply.

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]

3.2
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 A ROUTINE TEST could be carried out by the user with simple methods and equipment.

[IEC TR 61948-1:2001, definition 3.2.2]

3.3
ionization chamber test source
RADIOACTIVE SOURCE used for the determination of the long-term stability of an ionization chamber. 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

[IEC 61303:1994, definition 2.7]

NOTE The IONIZATION CHAMBER TEST SOURCE is used to test the functionality of a radionuclide calibrator under defined conditions.

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]

3.5
system linearity
function relating the observed and predicted ACTIVITY values when the activity of a specified RADIOACTIVE SOURCE is varied

[IEC 61303:1994, definition 2.4]

3.6
background response
reading of the instrument without intended radioactive source

NOTE The BACKGROUND RESPONSE is caused by external radiation fields, but in addition also by electronic noise and contamination.

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

[IEC 61303:1994, definition 2.1]

3.7.1
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

[IEC 61303:1994, 2.1.1]

3.7.2
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

[IEC 61303:1994, 2.1.2]

3.8
reference data
a set of data measured immediately after acceptance testing, using test methods designed for routine testing

[IEC TR 61948-1:2001, definition 3.2.3]

3.9
radionuclide calibrator
device for measuring the activity of a radioactive sample

[IEC TR 61303:1994, definition 2.11]

4 Test methods

4.1 BACKGROUND RESPONSE

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

4.2 Constancy of instrument response

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

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.

4.3.2 Decaying source method

SYSTEM LINEARITY is tested using the radioactive decay of a sample of a short-lived radionuclide, e.g. ^{99m}Tc. 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.

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.

4.4 Additional checks

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

4.5 Frequency of ROUTINE TESTS

ROUTINE TEST shall be carried out at the time intervals given in Table 1.

Table 1 – Frequency of ROUTINE TESTS

Test	Clause	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	Yearly
Additional checks according to operator's manual	4.4	According to manufacturer recommendations