

Medical electrical equipment — Radionuclide calibrators — Particular methods for describing performance (IEC 61303:1994)

ICS 11.040.50

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National foreword

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The start and finish of text introduced or altered by corrigendum is indicated in the text by tags. Text altered by IEC corrigendum June 2016 is indicated in the text by AC1 AC1.

The UK participation in its preparation was entrusted to Technical Committee CH/62, Electrical Equipment in Medical Practice.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Descriptors: Medical electrical equipment, radionuclide calibrators, performance, test

English version

**Medical electrical equipment
Radionuclide calibrators
Particular methods for describing performance**

(IEC 1303:1994)

Appareils électromédicaux
Calibrateurs de radionucléides
Méthodes particulières pour décrire les
performances
(CEI 1303:1994)

Medizinische elektrische Geräte
Aktivimeter
Spezielle Verfahren zur Bestimmung der
Leistungsparameter
(IEC 1303:1994)

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Foreword

The text of document 62C(CO)77, future edition 1 of IEC 1303, prepared by SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 61303 on 1994-12-06.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1995-12-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1995-12-01

Annexes designated “normative” are part of the body of the standard.

Annexes designated “informative” are given for information only.

In this standard, Annex ZA is normative and Annex A is informative.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 1303:1994 was approved by CENELEC as a European Standard without any modification.

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1 General

1.1 Scope and object

This International Standard covers RADIONUCLIDE CALIBRATORS of the well type, with a gas-filled IONIZATION CHAMBER as used in the practice of NUCLEAR MEDICINE.

The object of this standard is to identify the most important characteristics of RADIONUCLIDE CALIBRATORS and lay down associated test methods to enable manufacturers to declare the characteristics of their devices in a standardized way and facilitate comparisons between devices.

1.2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards. IEC 788:1984, *Medical radiology — Terminology*. IEC 1145:1992, *Calibration and usage of ionization chamber systems for assay of radionuclides*.

2 Definitions

For the purposes of this International Standard, the following definitions, as well as the definitions given in IEC 788, apply. Defined terms are printed in SMALL CAPITAL LETTERS. An index of defined terms is given in Annex AA.

2.1 RADIOACTIVE STANDARD SOURCE

General term used to refer to the standard sources listed below.

2.1.1

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

2.1.2

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

2.2

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

2.3

OVERALL UNCERTAINTY

quadrature combination of the RANDOM and non-random UNCERTAINTIES at the 68 % confidence limits

2.4

SYSTEM LINEARITY

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

2.5

AIR-DENSITY CHARACTERISTIC

two-dimensional function relating the instrument reading with temperature and pressure

2.6

SAMPLE VOLUME CHARACTERISTIC

function relating the instrument reading and the sample volume for a specified container at a specified position in the IONIZATION CHAMBER

2.7

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 by 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

2.8

IONIZING RADIATION SHIELD

component designed to attenuate the passage of IONIZING RADIATION

2.9

RADIOACTIVE IMPURITY

RADIONUCLIDES in a RADIOACTIVE SOURCE other than the principal RADIONUCLIDE

2.10

REFERENCE VOLUME

volume throughout which the RADIONUCLIDE of a RADIOACTIVE STANDARD SOURCE is distributed