SLOVENSKI STANDARD
SIST EN 61303:1995

01-maj-1995

Medical electrical equipment - Radionuclide calibrators - Particular methods for describing performance (IEC 1303:1994)

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

Medizinische elektrische Geräte - Aktivimeter - Spezielle Verfahren zur Bestimmung der Leistungsparameter

Appareils électromédicaux - Calibrateurs de radionucléides - Méthodes particulières pour décrire les performances

Ta slovenski standard je istoveten z: **EN 61303:1995**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

SIST EN 61303:1995 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61303

January 1995

ICS 11.040.50

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)

This European Standard was approved by CENELEC on 1994-12-06. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

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.

ANNEX ZA (normative)

OTHER INTERNATIONAL PUBLICATIONS QUOTED IN THIS STANDARD WITH THE REFERENCES OF THE RELEVANT EUROPEAN PUBLICATIONS

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

NOTE : When the international publication has been modified by CENELEC common modifications, indicated by (mod), the relevant EN/HD applies.

IEC Publication	Date	Title	EN/HD	Date
788	1984	Medical radiology - Terminology	HD 501 S1	1988
1145	1992	Calibration and usage of ionization chamber systems for assay of radionuclides	-	-

NORME INTERNATIONALE
INTERNATIONAL STANDARD

CEI
IEC
1303

Première édition
First edition
1994-09

Appareils électromédicaux – Calibrateurs de radionucléides – Méthodes particulières pour décrire les performances

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

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

CODE PRIX
PRICE CODE N

Pour prix, voir catalogue en vigueur
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT – RADIONUCLIDE CALIBRATORS – PARTICULAR METHODS FOR DESCRIBING PERFORMANCE

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international cooperation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. 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. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

2) The formal decisions or agreements of the IEC on technical matters, prepared by technical committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

3) They have the form of recommendations for international use published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

International Standard IEC 1303 has been prepared by sub-committee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this standard is based on the following documents:

DIS	Report on voting
62C(CO)77	62C(CO)78

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

Annex A is for information only.

In this standard the following print types are used:

- requirements, compliance with which can be tested, and definitions: in roman type;
- notes, explanations, advice, instructions, general statements, exceptions and references: in smaller type;
- *test specifications: in italic type;*
- TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 AND IN IEC 788: SMALL CAPITALS.

MEDICAL ELECTRICAL EQUIPMENT – RADIONUCLIDE CALIBRATORS – PARTICULAR METHODS FOR DESCRIBING PERFORMANCE

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.

2.11 *RADIONUCLIDE CALIBRATOR*

Device for measuring the ACTIVITY of a radioactive sample.

2.12 *INSTRUMENT ACCURACY*

Ratio of the most probable MEASURED VALUE over the TRUE VALUE.

2.13 *RANDOM UNCERTAINTY*

Observed standard deviation of a set of repeated measured values.