

BS EN 60731:2012



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Medical electrical equipment — Dosimeters with ionization chambers as used in radiotherapy

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National foreword

This British Standard is the UK implementation of EN 60731:2012. It is identical to IEC 60731:2011. It supersedes BS EN 60731:1997, which will be withdrawn on 14 March 2015.

The UK participation in its preparation was entrusted by Technical Committee CH/62/3, Equipment for radiotherapy, nuclear medicine and radiation dosimetry.

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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English version

Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy (IEC 60731:2011)

Appareils électromédicaux -
Dosimètres à chambres d'ionisation
utilisés en radiothérapie
(CEI 60731:2011)

Medizinische elektrische Geräte -
Dosimeter mit Ionisationskammern zur
Anwendung in der Strahlentherapie
(IEC 60731:2011)

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Foreword

The text of document 62C/506/FDIS, future edition 3 of IEC 60731, 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 approved by CENELEC as EN 60731:2012.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2012-12-14
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2015-03-14

This document supersedes EN 60731:1997 + A1:2002.

EN 60731:2012 includes the following significant technical changes with respect to EN 60731:1997 + A1:2002:

The technical modifications versus EN 60731:1997 + A1:2002 concerns performance requirements of RADIOTHERAPY DOSIMETERS intended for the measurement of ABSORBED DOSE TO WATER or AIR KERMA in heavy ion RADIATION FIELDS and SCANNING-CLASS DOSIMETERS normally used for relative dose distribution measurements with a SCANNING SYSTEM such as an automatic water PHANTOM.

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Endorsement notice

The text of the International Standard IEC 60731:2012 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

IEC 60051-1:1997 NOTE Harmonized as EN 60051-1:1998 (not modified).

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60417	data base	Graphical symbols for use on equipment	-	-
IEC 60601-1 + corr. December + corr. December	2005 2006 2007	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1 + corr. March + A11	2006 2010 2011
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2 + corr. March	2007 2010
IEC 60601-1-3	2008	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	EN 60601-1-3 + corr. March	2008 2010
IEC 60601-2-8	2010	Medical electrical equipment - Part 2-8: Particular requirements for basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV	EN 60601-2-8	201X ¹⁾
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 60976	2007	Medical electrical equipment - Medical electron accelerators - Functional performance characteristics	EN 60976	2007
IEC 61010-1 + corr. May	2010 2011	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements	EN 61010-1	2010
IEC 61187	-	Electrical and electronic measuring equipment - Documentation	EN 61187	-
IEC 61267	2005	Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics	EN 61267	2006
IEC 61676	2002	Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology	EN 61676	2002
ISO/IEC Guide 98-3	2008	Uncertainty of measurement - Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)	-	-

¹⁾ To be published.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
ISO/IEC Guide 99	2007	International vocabulary of metrology - Basic and general concepts and associated terms (VIM)	-	-
ISO 3534-1	2006	Statistics - Vocabulary and symbols - Part 1: General statistical terms and terms used in probability	-	-

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INTRODUCTION

This International Standard is applicable to the performance of RADIOTHERAPY DOSIMETERS with IONIZATION CHAMBERS as used in RADIOTHERAPY.

The effectiveness of treatment of PATIENTS receiving RADIOTHERAPY depends on the accuracy of the dose of radiation received, as well as on the accuracy of their spatial distribution. An excessive dose can lead to excessive tissue damage, while an insufficient dose will not provide the therapeutic benefit sought. The equipment covered by this standard plays an essential part in achieving the required accuracy.

This standard is not concerned with the safety aspects of dosimeters. The relevant IEC standards covering safety depend upon the way in which the dosimeter is used:

- if it is used in the PATIENT environment, the requirements for safety applying to dosimeters with IONIZATION CHAMBERS as used in RADIOTHERAPY are contained in IEC 60601-1;
- if it is not used in the PATIENT environment, then the safety requirements for dosimeters with IONIZATION CHAMBERS as used in RADIOTHERAPY are contained in IEC 61010-1.

Dosimeters which comply with this standard should nevertheless be used in accordance with the relevant national or international dosimetry protocol (code of practice). In particular, measurements should be made to determine the ion collection efficiency and polarity effect of the chamber under the exact conditions of use.

MEDICAL ELECTRICAL EQUIPMENT – DOSIMETERS WITH IONIZATION CHAMBERS AS USED IN RADIOTHERAPY

1 Scope and object

1.1 Scope

This International Standard specifies the performance requirements of RADIOTHERAPY DOSIMETERS, intended for the measurement of ABSORBED DOSE TO WATER or AIR KERMA (and their rates and spatial distributions) in PHOTON, ELECTRON, proton or heavy ion RADIATION FIELDS as used in RADIOTHERAPY.

The DOSE MONITORING SYSTEMS incorporated in RADIOTHERAPY treatment machines are not covered by this standard, neither are the re-entrant IONIZATION CHAMBERS used for BRACHYTHERAPY source calibration and constancy check devices.

This standard is applicable to the following types of dosimeter:

- a) FIELD-CLASS DOSIMETERS normally used for
 - 1) the measurement of KERMA or dose in a RADIATION BEAM, either in air or in a PHANTOM;
 - 2) in vivo skin surface or intracavitary measurements of dose on PATIENTS.
- b) REFERENCE-CLASS DOSIMETERS normally used for the calibration of FIELD-CLASS DOSIMETERS;

NOTE REFERENCE-CLASS DOSIMETERS may be used as FIELD-CLASS DOSIMETERS.
- c) SCANNING-CLASS DOSIMETERS normally used for relative dose distribution measurements with a SCANNING SYSTEM such as an automatic water PHANTOM.

1.2 Object

The object of this standard is:

- to establish requirements for a satisfactory level of performance for RADIOTHERAPY DOSIMETERS;
- to standardize methods for the determination of compliance with this level of performance.

Three levels of performance are specified:

- a lower level of performance applying to FIELD-CLASS DOSIMETERS;
- a higher level of performance applying to REFERENCE-CLASS DOSIMETERS;
- a specific level of performance applying to SCANNING-CLASS DOSIMETERS.

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 60417, *Graphical symbols for use on equipment*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*

IEC 60601-2-8:2010, *Medical electrical equipment – Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV*

IEC/TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 60976:2007, *Medical electrical equipment – Medical electron accelerators – Functional performance characteristics*

IEC 61010-1:2010, *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements*

IEC 61187, *Electrical and electronic measuring equipment – Documentation*

IEC 61267:2005, *Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics*

IEC 61676:2002, *Medical electrical equipment – Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology*

ISO/IEC Guide 98-3:2008, *Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

ISO/IEC Guide 99:2007, *International vocabulary of metrology – Basic and general concepts and associated terms (VIM)*

ISO 3534-1:2006, *Statistics – Vocabulary and symbols – Part 1: General statistical terms and terms used in probability*

3 Terms and definitions

For the purpose of this International Standard the terms and definitions listed in index of defined terms and the following apply.

NOTE The definitions given in this standard are generally in agreement with those in IEC TR 60788:2004 and ISO International vocabulary of basic and general terms in metrology, except that some definitions have been made more restricted. Any such special definitions should be regarded as applying only to this standard.

Any terms not defined in this standard have the meanings defined in the above publications or are assumed to be in general scientific usage.

Throughout this standard:

- if no material is specified, the term "ABSORBED DOSE" or "dose" means "ABSORBED DOSE TO WATER (in water)" and the term "KERMA" means "AIR KERMA (in air)";
- when the quantity "AIR KERMA (in air)" in units "Gy" is used, the quantity "EXPOSURE" in units "C/kg" is also allowable;

- the term “heavy ion” addresses the range of nuclides from 2-He to 18-Ar in accordance with IAEA Technical Report 398 [2]¹⁾.

3.1

RADIOTHERAPY DOSIMETER

equipment, consisting of a MEASURING ASSEMBLY and one or more CHAMBER ASSEMBLIES, for the measurement of AIR KERMA, ABSORBED DOSE, or their corresponding rates or spatial distributions, in PHOTON, ELECTRON, proton and heavy ion radiation as used in RADIOTHERAPY

NOTE A RADIOTHERAPY DOSIMETER may include the following components:

- one or more STABILITY CHECK DEVICES;
- one or more PHANTOMS or build-up caps.
- one or more extension cables;

3.1.1

CHAMBER ASSEMBLY

IONIZATION CHAMBER and all other parts to which the chamber is permanently attached, except the MEASURING ASSEMBLY

NOTE It includes the electrical fitting and any permanently attached cable.

3.1.1.1

IONIZATION CHAMBER

IONIZING RADIATION detector consisting of a chamber filled with air, in which an electric field insufficient to produce gas multiplication, is provided for the collection at the electrodes of charges associated with the ions and the ELECTRONS produced in the measuring volume of the detector by IONIZING RADIATION

NOTE 1 For this standard, the IONIZATION CHAMBER is considered to consist of the measuring volume, the collecting electrode, the guard electrode (if any), the outer electrode (which consists of the chamber wall and possibly a conducting coating), those parts of the insulator adjacent to the measuring volume, the build-up cap and water-proof housing (if any).

NOTE 2 There are several categories of IONIZATION CHAMBER (see 3.1.1.1.1 to 3.1.1.1.7).

3.1.1.1.1

SHELL CHAMBER

IONIZATION CHAMBER with a measuring volume of between 0,1 cm³ and 1,0 cm³ bounded by a rigid outer electrode mounted on a supporting stem

NOTE 1 The measuring volume is usually symmetrical about the axis of the stem and the chamber is intended to be used with the axis of symmetry perpendicular to the axis of the RADIATION BEAM.

NOTE 2 There are two types of SHELL CHAMBER: THIMBLE CHAMBER and SPHERICAL CHAMBER (see 3.1.1.1.1.1 and 3.1.1.1.1.2).

3.1.1.1.1.1

THIMBLE CHAMBER

SHELL CHAMBER whose outer electrode takes the form of a rigid cylindrical wall closed at one end and mounted at the other on the supporting stem

3.1.1.1.1.2

SPHERICAL CHAMBER

SHELL CHAMBER whose outer electrode takes the form of a rigid spherical wall mounted on the supporting stem

¹⁾ Figures in square brackets refer to the Bibliography.

3.1.1.1.2

PARALLEL-PLATE CHAMBER

IONIZATION CHAMBER with a measuring volume of between approximately 0,01 cm³ and 0,5 cm³ bounded by parallel electrodes

NOTE The chamber is intended to be used with the electrodes perpendicular to the axis of the RADIATION BEAM.

3.1.1.1.3

VENTED CHAMBER

IONIZATION CHAMBER constructed in such a way as to allow the air inside the measuring volume to communicate freely with the atmosphere such that corrections to the RESPONSE for changes in air density need to be made

3.1.1.1.4

SEALED CHAMBER

IONIZATION CHAMBER constructed in such a way as to restrict the pathway between the air inside the measuring volume and the atmosphere sufficiently to ensure that the RESPONSE of the chamber is independent of changes in ambient conditions over a period of time stated by the MANUFACTURER

3.1.1.1.5

UNGUARDED IONIZATION CHAMBER

IONIZATION CHAMBER in which the guard conductor in the cable surrounding the centre (signal) conductor terminates in the cable and does not extend into the stem or body of the CHAMBER ASSEMBLY

3.1.1.1.6

PARTIALLY GUARDED IONIZATION CHAMBER

IONIZATION CHAMBER in which the guard conductor in the cable surrounding the centre (signal) conductor extends well into the stem or body of the CHAMBER ASSEMBLY but does not enter the air in the chamber

3.1.1.1.7

GUARDED IONIZATION CHAMBER

IONIZATION CHAMBER in which the guard conductor in the stem or body of the CHAMBER ASSEMBLY is continuous with a guard electrode that is in contact with the air inside the chamber

3.1.2

MEASURING ASSEMBLY

device to measure the charge (or current) from the IONIZATION CHAMBER and convert it into a form suitable for displaying the values of dose or KERMA or their corresponding rates

3.1.3

STABILITY CHECK DEVICE

device which enables the stability of RESPONSE of the MEASURING ASSEMBLY and/or CHAMBER ASSEMBLY to be checked

NOTE The STABILITY CHECK DEVICE may be a purely electrical device, or a RADIATION SOURCE, or it may include both.

3.2

INDICATED VALUE

value of a quantity derived from the reading of an instrument together with any scale factors indicated on the CONTROL PANEL of the instrument

NOTE The INDICATED VALUE is equivalent to the "uncorrected observations" shown in Figure A.1.

3.3

TRUE VALUE

value of the physical quantity to be measured by an instrument

NOTE The TRUE VALUE is equivalent to the "value of MEASURAND" shown in Figure A.1.

3.4

CONVENTIONAL TRUE VALUE

value used instead of the TRUE VALUE when calibrating or determining the performance of an instrument, since in practice the TRUE VALUE is unknown and unknowable

NOTE 1 The CONVENTIONAL TRUE VALUE will usually be the value determined by the WORKING STANDARD with which the instrument under test is being compared.

NOTE 2 The possible bounds within which the CONVENTIONAL TRUE VALUE will lie are equivalent to the "values of MEASURAND due to incomplete definition" shown in Figure A.1.

3.4.1

STANDARD

<metrology> instrument which defines, represents physically, maintains or reproduces the unit of measurement of a quantity (or a multiple or submultiple of that unit) in order to transfer it to other instruments by comparison

3.4.1.1

NATIONAL STANDARD

<metrology> STANDARD recognized by an official national decision as the basis for fixing the values and UNCERTAINTIES in that country of all other STANDARDS of the given quantity

3.4.1.2

WORKING STANDARD

<metrology> STANDARD which is traceable to the NATIONAL STANDARD

3.5

MEASURED VALUE

best estimate of the TRUE VALUE of a quantity, being derived from the INDICATED VALUE of an instrument together with the application of all relevant CORRECTION FACTORS and the CALIBRATION FACTOR

NOTE The MEASURED VALUE is the "final result of measurement" shown in Figure A.1.

3.5.1

ERROR OF MEASUREMENT

difference remaining between the MEASURED VALUE of a quantity and the TRUE VALUE of that quantity

3.5.2

OVERALL UNCERTAINTY

UNCERTAINTY associated with the MEASURED VALUE

NOTE 1 I.e. it represents the bounds within which the ERROR OF MEASUREMENT is estimated to lie.

NOTE 2 For the purpose of this standard the OVERALL UNCERTAINTY may be taken as the EXPANDED UNCERTAINTY corresponding to a confidence level of 95 % (see Annex A).

3.5.3

EXPANDED UNCERTAINTY

quantity defining an interval about the result of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the MEASURAND

3.6

CORRECTION FACTOR

dimensionless multiplier which corrects the INDICATED VALUE of an instrument from its value when operated under particular conditions to its value when operated under stated REFERENCE CONDITIONS

3.7

INFLUENCE QUANTITY

any external quantity that may affect the performance of an instrument

NOTE See Table 5, Table 6 and Table 7 for examples of INFLUENCE QUANTITIES.

3.8

INSTRUMENT PARAMETER

any internal property of an instrument that may affect the performance of this instrument

NOTE See Table 5, Table 6 and Table 7 for examples of INSTRUMENT PARAMETERS.

3.9

REFERENCE VALUE

particular value of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER chosen for the purposes of reference

NOTE I.e. the value of an INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) at which the CORRECTION FACTOR for dependence on that INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) is unity.

3.9.1

REFERENCE CONDITIONS

conditions under which all INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS have their REFERENCE VALUES

3.10

STANDARD TEST VALUES

value, values, or range of values of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER, which are permitted when carrying out calibrations or tests on another INFLUENCE QUANTITY or INSTRUMENT PARAMETER

3.10.1

STANDARD TEST CONDITIONS

conditions under which all INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS have their STANDARD TEST VALUES

3.11

PERFORMANCE CHARACTERISTIC

one of the quantities used to define the performance of an instrument

NOTE E.g. RESPONSE or LEAKAGE CURRENT.

3.11.1

RESPONSE

<CHAMBER ASSEMBLY with MEASURING ASSEMBLY> quotient of the INDICATED VALUE divided by the CONVENTIONAL TRUE VALUE at the position of the REFERENCE POINT of the IONIZATION CHAMBER

<MEASURING ASSEMBLY> quotient of the INDICATED VALUE divided by the input charge or current

<IONIZATION CHAMBER> quotient of the ionization charge or current divided by the CONVENTIONAL TRUE VALUE

3.11.1.1

SPECIFIED ENERGY RESPONSE

RESPONSE of an IONIZATION CHAMBER calculated or measured for that type of chamber as a function of RADIATION QUALITY

3.11.2

RESOLUTION

<display> smallest change of reading to which a numerical value can be assigned without further interpolation

<analogue display> smallest fraction of a scale interval that can be determined by an observer under specified conditions

<digital display> smallest significant increment of the reading

3.11.3

EQUILIBRATION TIME

time taken for a reading to reach and remain within a specified deviation from its final steady value after a sudden change in an INFLUENCE QUANTITY has been applied to the instrument

3.11.4

RESPONSE TIME

time taken for a reading to reach and remain within a specified deviation from its final steady value after a sudden change in the quantity being measured

3.11.5

STABILIZATION TIME

time taken for a stated PERFORMANCE CHARACTERISTIC to reach and remain within a specified deviation from its final steady value after the MEASURING ASSEMBLY has been switched on and the polarizing voltage has been applied to the IONIZATION CHAMBER

3.11.6

CHAMBER ASSEMBLY LEAKAGE CURRENT

leakage current

any current in the signal path arising in the CHAMBER ASSEMBLY which is not produced by ionization in the measuring volume

NOTE It is distinguished from ZERO DRIFT or ZERO SHIFT which arise in the MEASURING ASSEMBLY.

3.11.7

MEASURING ASSEMBLY ZERO DRIFT

zero drift

continuous change in the near zero reading of the MEASURING ASSEMBLY in the "measure" condition with no signal present

3.11.8

MEASURING ASSEMBLY ZERO SHIFT

zero shift

sudden change in the near zero reading of the MEASURING ASSEMBLY when the setting control is changed from the "zero" condition to the "measure" condition, with no signal present

3.11.9

NON-LINEARITY

deviation from linearity

NOTE Quantified as follows: on each range the half full reading M is taken as a reference; the input signal Q required to produce this REFERENCE SCALE READING is measured. At another reading m produced by an input signal q , the percentage deviation from linearity is given by:

$$100 \cdot ((m \cdot Q / M \cdot q) - 1)$$

For a MEASURING ASSEMBLY set to the "dose" mode, the input signal is electric charge; for a MEASURING ASSEMBLY set to the "dose rate" mode, the input signal is electric current.

3.12

VARIATION

relative difference, $\Delta y/y$, between the values of a PERFORMANCE CHARACTERISTIC y , when one INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) assumes successively two specified values, the other INFLUENCE QUANTITIES (and INSTRUMENT PARAMETERS) being kept constant at the STANDARD TEST VALUES (unless other values are specified)

3.13

LIMITS OF VARIATION

maximum permitted VARIATION of a PERFORMANCE CHARACTERISTIC

NOTE If LIMITS OF VARIATION are stated as $\pm L$ %, the VARIATION $\Delta y/y$, expressed as a percentage, shall remain in the range from $-L$ % to $+L$ %.

3.14

EFFECTIVE RANGE OF INDICATED VALUES

EFFECTIVE RANGE

range of INDICATED VALUES for which an instrument complies with a stated performance

NOTE 1 The maximum (minimum) effective INDICATED VALUE is the highest (lowest) in this range.

NOTE 2 The concept of EFFECTIVE RANGE may, for example, also be applied to readings and to related quantities not directly indicated by the instrument e.g. input current.

3.15

RATED RANGE OF USE

RATED RANGE

range of values of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER within which the instrument will operate within the LIMITS OF VARIATION

NOTE Its limits are the maximum and minimum RATED VALUES.

3.15.1

MINIMUM RATED RANGE

least range of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER over which the instrument shall operate within the specified LIMITS OF VARIATION

3.16

REFERENCE POINT OF THE CHAMBER

REFERENCE POINT

point of an IONIZATION CHAMBER, which during the calibration of the chamber, is brought to coincidence with the point at which the CONVENTIONAL TRUE VALUE is specified

3.17

MEDICAL ELECTRICAL EQUIPMENT

ME EQUIPMENT

electrical equipment having an APPLIED PART or transferring energy to or from the PATIENT or detecting such energy transfer to or from the PATIENT and which is:

- a) provided with not more than one connection to a particular SUPPLY MAINS; and
- b) intended by its MANUFACTURER to be used:
 - 1) in the diagnosis, treatment, or monitoring of a PATIENT; or
 - 2) for compensation or alleviation of disease, injury or disability

[IEC 60601-1:2005, 3.63]

3.18

SUPPLY MAINS

source of electrical energy not forming part of ME EQUIPMENT or ME SYSTEM

[IEC 60601-1:2005, 3.120]

3.19

PATIENT

living being (person or animal) undergoing a medical, surgical or dental procedure

[IEC 60601-1:2005, 3.76]

3.20

TOOL

extra-corporeal object that can be used to secure or release fasteners or to make adjustments

[IEC 60601-1:2005, 3.127]

3.21

CALIBRATION FACTOR

<CHAMBER ASSEMBLY with an associated MEASURING ASSEMBLY> factor which converts the INDICATED VALUE, corrected to stated REFERENCE CONDITIONS, to the CONVENTIONAL TRUE VALUE at the position of the REFERENCE POINT of the IONIZATION CHAMBER

<IONIZATION CHAMBER calibrated on its own without a specified MEASURING ASSEMBLY> factor which converts the ionization charge or current, corrected to REFERENCE CONDITIONS, to the CONVENTIONAL TRUE VALUE at the position of the REFERENCE POINT OF THE CHAMBER

NOTE This is the reciprocal of RESPONSE under REFERENCE CONDITIONS.

3.22

REFERENCE INDICATED VALUE

INDICATED VALUE at which the CALIBRATION FACTOR of an instrument is determined

3.23

REFERENCE SCALE READING

reading corresponding to the REFERENCE INDICATED VALUE

3.24

FIELD-CLASS DOSIMETER

dosimeter whose performance and stability are sufficient for it to be used to make ordinary routine measurements

3.25

REFERENCE-CLASS DOSIMETER

dosimeter whose performance and stability are sufficient for it to be used to calibrate other dosimeters

3.26

SCANNING-CLASS DOSIMETER

dosimeter whose performance and stability are sufficient for it to be used to measure relative dose distributions in connection with a SCANNING SYSTEM

3.27

SCANNING SYSTEM

apparatus to displace an IONIZATION CHAMBER in order to measure the spatial dose or dose rate distribution of a RADIATION BEAM

3.28

TYPE TEST

test on a representative sample of the equipment with the objective of determining if the equipment, as designed and manufactured, can meet the requirements of this standard

[IEC 60601-1:2005, 3.135]

NOTE The purpose of the TYPE TEST is to verify whether or not the design of the instrument renders it capable of meeting the requirements of the specification.

3.29

ROUTINE TEST

test carried out on all instruments of a production or delivery batch

3.30

ABSORBED DOSE TO WATER

D

quotient of $d\bar{\varepsilon}$ by dm where $d\bar{\varepsilon}$ is the mean energy imparted by IONIZING RADIATION to water of mass dm

NOTE 1 The unit of ABSORBED DOSE TO WATER is Gy (where $1 \text{ Gy} = 1 \text{ J}\cdot\text{kg}^{-1}$).

NOTE 2 This definition is derived from the definition in C.4 of ICRU 33 [1]²⁾.

3.30.1

ABSORBED DOSE RATE TO WATER

$\dot{D}$

quotient of dD by dt , where dD is the increment of ABSORBED DOSE TO WATER in the time interval dt

NOTE 1 The unit of ABSORBED DOSE RATE TO WATER is $\text{Gy}\cdot\text{s}^{-1}$ ($\text{Gy}\cdot\text{min}^{-1}$; $\text{Gy}\cdot\text{h}^{-1}$).

NOTE 2 This definition is derived from the definition in C.5 of ICRU 33 [1].

3.31

AIR KERMA

K

quotient of dE_{tr} by dm where dE_{tr} is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dm

NOTE 1 The unit of AIR KERMA is Gy (where $1 \text{ Gy} = 1 \text{ J}\cdot\text{kg}^{-1}$).

NOTE 2 This definition is derived from the definition in C.6 of ICRU 33 [1].

3.31.1

AIR KERMA RATE

$\dot{K}$

quotient of dK by dt , where dK is the increment of AIR KERMA in the time interval dt

NOTE 1 The unit of AIR KERMA RATE is $\text{Gy}\cdot\text{s}^{-1}$ ($\text{Gy}\cdot\text{min}^{-1}$; $\text{Gy}\cdot\text{h}^{-1}$).

NOTE 2 This definition is derived from the definition in C.7 of ICRU 33 [1].

3.32

EXPOSURE

X

quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the ELECTRONS (negatrons and positrons) liberated by PHOTONS in air of mass dm are completely stopped in air

²⁾ Numbers in square brackets refer to the Bibliography.

NOTE 1 The unit of EXPOSURE is $C \cdot kg^{-1}$.

NOTE 2 This definition is derived from the definition in C.8 of ICRU 33 [1].

3.32.1 EXPOSURE RATE

$\dot{X}$
quotient of dX by dt , where dX is the increment of EXPOSURE in the time interval dt

NOTE 1 The unit of EXPOSURE RATE is $C \cdot kg^{-1} \cdot s^{-1}$ ($C \cdot kg^{-1} \cdot min^{-1}$; $C \cdot kg^{-1} \cdot h^{-1}$).

NOTE 2 This definition is derived from the definition in C.9 of ICRU 33 [1].

3.33 ACCOMPANYING DOCUMENT

document accompanying ME EQUIPMENT, an ME SYSTEM, equipment or an ACCESSORY and containing information for the RESPONSIBLE ORGANIZATION or OPERATOR, particularly regarding BASIC SAFETY and ESSENTIAL PERFORMANCE

[IEC 60601-1:2005, 3.4]

3.34 INSTRUCTIONS FOR USE

those parts of ACCOMPANYING DOCUMENTS giving the necessary information for safe and proper use and operation of the equipment

[IEC TR 60788:2004, rm-82-02]

3.35 RESPONSIBLE ORGANIZATION

entity accountable for the use and maintenance of an ME EQUIPMENT or an ME SYSTEM

[IEC 60601-1:2005, 3.101]

3.36 OPERATOR

person handling equipment

[IEC 60601-1:2005, 3.73]

3.37 MANUFACTURER

natural or legal person with responsibility for the design, manufacture, packaging, or labelling of ME EQUIPMENT, assembling an ME SYSTEM, or adapting ME EQUIPMENT or an ME SYSTEM, regardless of whether these operations are performed by that person or on that person's behalf by a third party

[IEC 60601-1:2005, 3.55]

3.38 COVARIANCE

COVARIANCE of two RANDOM VARIABLES is a measure of their mutual dependence. The COVARIANCE of RANDOM VARIABLES y and z is defined by

$$\text{cov}(y,z) = \text{cov}(z,y) = E \{ [y - E(y)][z - E(z)] \}$$

which leads to

$$\text{cov}(y,z) = \text{cov}(z,y)$$

$$= \iint (y - \mu_y)(z - \mu_z) p(y,z) dy dz$$

$$= \iint y z p(y,z) dy dz - \mu_y \mu_z$$

where $p(y,z)$ is the joint PROBABILITY DENSITY FUNCTION of two variables y and z . The COVARIANCE $\text{cov}(y,z)$ [also denoted by $v(y,z)$] may be estimated by $s(y_i, z_i)$ obtained from n independent pairs of simultaneous observations y_i and z_i of y and z ,

$$s(y_i, z_i) = \frac{1}{n-1} \sum_{i=1}^n (y_i - \bar{y})(z_i - \bar{z})$$

$$\text{where } \bar{y} = \frac{1}{n} \sum_{i=1}^n y_i \text{ and } \bar{z} = \frac{1}{n} \sum_{i=1}^n z_i$$

NOTE The estimated COVARIANCE of the two means $\bar{y}$ and $\bar{z}$ is given by $s(\bar{y}, \bar{z}) = s(y_i, z_i)/n$.

[ISO/IEC GUIDE 98-3:2007, definition C.3.4]

3.39

COMBINED STANDARD UNCERTAINTY

STANDARD UNCERTAINTY of the result of a measurement when that result is obtained from the values of a number of other quantities, equal to the positive square root of a sum of terms, the terms being the VARIANCES or COVARIANCES of these other quantities weighted according to how the measurement result varies with changes in these quantities

[ISO/IEC GUIDE 98-3:2007, 2.3.4]

3.40

COVERAGE FACTOR

numerical factor used as a multiplier of the COMBINED STANDARD UNCERTAINTY in order to obtain an EXPANDED UNCERTAINTY

[ISO/IEC GUIDE 98-3:2007, 2.3.6]

3.41

DEGREES OF FREEDOM

number of terms in a sum minus the number of constraints on the terms of the sum

[ISO 3534-1:2006, 2.54]

3.42

DISTRIBUTION FUNCTION OF A RANDOM VARIABLE X

DISTRIBUTION FUNCTION

$F(x)$

function of x giving the probability of the EVENT $(-\infty, x)$

[ISO 3534-1:2006, 2.7]

3.43

PROBABILITY DISTRIBUTION

PROBABILITY MEASURE induced by a RANDOM VARIABLE

NOTE The probability on the whole set of values of the RANDOM VARIABLE equals 1.

[ISO 3534-1:2006, 2.11]

3.44

PROBABILITY DENSITY FUNCTION

$f(x)$

non-negative function which when integrated from $-\infty$ to x gives the DISTRIBUTION FUNCTION evaluated at x of a CONTINUOUS DISTRIBUTION

NOTE $f(x)dx$ is the "probability element" , $f(x)dx = P_r(x < X < x+dx)$.

[ISO 3534-1:2006, 2.26]

3.45

RANDOM VARIABLE

function defined on a SAMPLE SPACE where the values of the function are ordered k -tuplets of real numbers

[ISO 3534-1:2006, 2.10]

NOTE 1 A RANDOM VARIABLE that may take only isolated values is said to be "discrete". A RANDOM VARIABLE that may take on any value within a finite or infinite interval is said to be "continuous".

NOTE 2 The PROBABILITY OF AN EVENT A is denoted, by $P_r(A)$ or $P(A)$.

3.46

STANDARD DEVIATION

σ

positive square root of the VARIANCE

[ISO 3534-1:2006, 2.37]

NOTE Whereas a type A STANDARD UNCERTAINTY is obtained by taking the square root of the statistically evaluated VARIANCE, it is often more convenient to evaluate a non-statistical equivalent STANDARD DEVIATION first and then to obtain the equivalent VARIANCE by squaring the STANDARD DEVIATION.

3.47

STANDARD UNCERTAINTY

UNCERTAINTY of the result of a measurement expressed as a STANDARD DEVIATION

[ISO/IEC GUIDE 98-3:2007, 2.3.1]

3.48

TYPE A EVALUATION OF STANDARD UNCERTAINTY

TYPE A EVALUATION

method of evaluation of UNCERTAINTY by the statistical analysis of series of observations

[ISO/IEC GUIDE 98-3:2007, 2.3.2]

NOTE For convenience this is sometimes called the type A STANDARD UNCERTAINTY.

3.49

TYPE B EVALUATION OF STANDARD UNCERTAINTY

TYPE B EVALUATION

method of evaluation of UNCERTAINTY by means other than the statistical analysis of series of observations

[ISO/IEC GUIDE 98-3:2007, 2.3.3]

NOTE For convenience this is sometimes called the type B STANDARD UNCERTAINTY.

3.50

MEASUREMENT UNCERTAINTY

UNCERTAINTY OF MEASUREMENT
UNCERTAINTY

non-negative parameter characterizing the dispersion of the QUANTITY VALUES being attributed to a MEASURAND, based on the information used

[ISO/IEC GUIDE 99:2007, 2.26]

3.51

VARIANCE

V

MOMENT OF ORDER r where r equals 2 in the CENTRED PROBABILITY DISTRIBUTION of the RANDOM VARIABLE

[ISO 3534-1:2006, 2.36]

4 General requirements

4.1 BASIC SAFETY and ESSENTIAL PERFORMANCE

During the IMMUNITY tests for ELECTROMAGNETIC COMPATIBILITY (see 6.2.6) BASIC SAFETY and ESSENTIAL PERFORMANCE shall be guaranteed.

ESSENTIAL PERFORMANCE is guaranteed if the limits listed in Table 7 are not exceeded during the IMMUNITY tests. ESSENTIAL PERFORMANCE is also ensured if during the IMMUNITY tests the reading of the MEASURING ASSEMBLY, or the data output, are clearly characterized as invalid, e.g. by means of a warning message or in case of a latch-up.

NOTE Examples of warning messages for invalid readings are high voltage error or overload messages.

4.2 Performance requirements

For a complete dosimeter to comply with this standard, each of its components shall comply with the individual requirements in the appropriate clauses or subclauses in addition to the general requirements. The MANUFACTURER shall state whether a TYPE TEST or a ROUTINE TEST was used for a particular parameter.

For equipment which does not fulfil all the requirements of this standard, information shall be provided about those clauses with which it does not comply.

The performance requirements to be met

- for the CHAMBER ASSEMBLY are given in Clause 5;
- for the MEASURING ASSEMBLY are given in Clause 6;
- for the STABILITY CHECK DEVICE are given in Clause 7.

4.3 REFERENCE VALUES and STANDARD TEST VALUES

The MANUFACTURER shall state, either in the INSTRUCTIONS FOR USE, or on the test sheets, the REFERENCE VALUE of each of the INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS as listed in Table 1 and Table 2.

For those INFLUENCE QUANTITIES that can be controlled,

- a) the REFERENCE VALUE shall be the value customarily used during the radiation calibration of the equipment;
- b) the STANDARD test value shall be the REFERENCE VALUE.

4.4 General test conditions and methods

4.4.1 STANDARD TEST CONDITIONS

The STANDARD TEST CONDITIONS, as defined by the STANDARD TEST VALUES listed in Table 1 and Table 2, shall be met during the test procedure, except

- a) for the INFLUENCE QUANTITY under investigation;
- b) where local conditions of temperature and relative humidity are outside the STANDARD TEST CONDITIONS. In this case, the tester shall justify the validity of the test results.

4.4.2 Test of components

The following requirements apply:

- a) The preferred procedure for verifying that the performance requirements are met is to test the components separately, in which case:
 - tests on the IONIZATION CHAMBER shall be performed using a "high-precision" MEASURING ASSEMBLY;
 - tests on the MEASURING ASSEMBLY shall be carried out using a "high-precision" current or charge source as required, connected to the input.

In this context, "high precision" means that the PERFORMANCE CHARACTERISTICS of the test equipment shall be such that they perturb the value of the particular PERFORMANCE CHARACTERISTIC being measured by less than one-quarter of the LIMITS OF VARIATION.

- b) Any tests may be carried out using the complete dosimeter, in particular this is the preferred method for investigating the effects of radio-frequency electromagnetic fields and ELECTROSTATIC DISCHARGES on a cable-connected IONIZATION CHAMBER supplied with a MEASURING ASSEMBLY as a system. Some tests performed with the whole system cannot give information as to whether the origin of a VARIATION lies in the CHAMBER ASSEMBLY or in the MEASURING ASSEMBLY (e.g. LEAKAGE CURRENT and ZERO DRIFT). If a complete system is tested and the relevant INFLUENCE QUANTITY affects both parts, the quadratic sum of the separate LIMITS OF VARIATION may be taken as an overall limit of VARIATION.
- c) When a CHAMBER ASSEMBLY and a MEASURING ASSEMBLY are tested separately, but supplied as a system, the two components shall be connected and the combined equipment shall have a measured overall RESPONSE within $\pm 0,5$ % of the overall RESPONSE calculated from the RESPONSES of the separate assemblies.

4.4.3 RATED or EFFECTIVE RANGE of dose (or KERMA) rates

NOTE 1 In the case of dose (or KERMA) measurements, the dose rate (or KERMA rate) can be regarded as an INFLUENCE QUANTITY. In this case, the term RATED RANGE of dose rate (or KERMA rate) is applicable.

NOTE 2 In the case of dose rate (or KERMA rate) measurements, this quantity is an INDICATED VALUE. In this case, the term EFFECTIVE RANGE of dose rate (or KERMA rate) is used.

The following requirements apply:

- a) When a CHAMBER ASSEMBLY is tested separately, the RATED or EFFECTIVE RANGE of dose (or KERMA) rates shall fulfil the appropriate requirements in Clause 5.
- b) When a MEASURING ASSEMBLY is tested separately, the equivalent parameter is determined as the RATED or EFFECTIVE RANGE of input currents and this shall fulfil the appropriate requirements in Clause 6.
- c) When however, by choice or necessity, the chamber and MEASURING ASSEMBLIES are tested together, the RATED or EFFECTIVE RANGE of dose (or KERMA) rates shall fulfil the relevant requirements in both Clauses 5 and 6.

4.4.4 UNCERTAINTY OF MEASUREMENT

When measurements of VARIATION are made to verify that equipment complies with specified LIMITS OF VARIATION, the OVERALL UNCERTAINTY of these measurements of VARIATION should be negligible compared with the specified LIMITS OF VARIATION.

If this is not possible, the OVERALL UNCERTAINTY of the measurement of VARIATION shall be taken into account in the evaluation of the equipment under test by adding the OVERALL UNCERTAINTY to the LIMITS OF VARIATION allowed.

If the OVERALL UNCERTAINTY exceeds one-fifth of the LIMITS OF VARIATION for any PERFORMANCE CHARACTERISTIC, then this shall be stated.

NOTE For the purpose of this STANDARD the OVERALL UNCERTAINTY may be taken as the EXPANDED UNCERTAINTY corresponding to a confidence level of 95 % (see Annex A).

4.4.5 Adjustments during test

Compliance tests shall be performed with the instrument ready for use (including ACCESSORIES if any), after the STABILIZATION TIME and after making preliminary adjustments as necessary. During tests, adjustments may be repeated at intervals as long as such an adjustment does not interfere with the effect to be verified. For example, the zero setting may be adjusted whenever necessary except during tests for measuring ZERO DRIFT and ZERO SHIFT.

4.4.6 Test conditions particular to CHAMBER ASSEMBLIES

When testing compliance with the performance requirements in Clause 5 (except for those in 5.2.1, 5.2.3 and 5.2.10) the polarizing voltage may be applied to the chamber for 1 h before taking a measurement.

4.4.7 Test conditions particular to MEASURING ASSEMBLIES

The following requirements apply:

- a) Tests on the effect of electromagnetic fields and ELECTROSTATIC DISCHARGES shall be made with the type of CHAMBER ASSEMBLY normally supplied connected to the input of the MEASURING ASSEMBLY.
- b) Tests on ZERO DRIFT and ZERO SHIFT shall be made with the input of the MEASURING ASSEMBLY disconnected and shielded with a conducting grounded (earthed) screen, for example a metal dust cap.
- c) Unless otherwise specified in the detailed instructions for testing, all other tests shall be made with a source of either electric charge or current connected to the input of the MEASURING ASSEMBLY as follows:
 - 1) measurements on dosimeters shall be made with a charge source connected to the input. This circuit shall be able to inject variable accurately known discrete amounts of charge to the input either
 - aa) by charging or discharging a capacitor through a resistor (to limit the peak current to less than the maximum RATED input current), or
 - bb) by applying a constant current for a known time (where this constant current is less than the maximum RATED input current).

The output of this charge source shall have been calibrated before use and be traceable to a NATIONAL STANDARD (either directly to a charge STANDARD or indirectly to voltage and capacitance STANDARDS or to voltage, resistance and time STANDARDS);

- 2) measurements on dose rate meters shall be made with a current source connected to the input. This circuit shall be able to inject variable accurately known constant currents to the input.

The output of this current source shall have been calibrated before use and be traceable to a NATIONAL STANDARD (either directly to a current STANDARD or indirectly to voltage and resistance STANDARDS).

NOTE 1 If tests are being made on a dosimeter/dose rate meter with signal/guard input terminals which are at the polarizing voltage away from ground (earth) then the output circuit of the charge or current source will need to be "floating";

NOTE 2 The output circuit of the charge source needs to have a sufficiently high impedance so as not to cause a measurable increase in ZERO DRIFT or charge leakage;

NOTE 3 The output circuit of the current source should not influence the measured current. Some electrometers have FET protecting input resistors which may influence the current from non-ionization chamber type current sources.

4.4.8 Test conditions particular to STABILITY CHECK DEVICES

When testing compliance with the performance requirements in Clause 7, the reference MEASURING ASSEMBLY used shall be either that type intended to be checked by the STABILITY CHECK DEVICE or another instrument of equivalent or superior performance.

Additionally, in the case of an overall STABILITY CHECK DEVICE the reference CHAMBER ASSEMBLY used shall be one of a type intended to be checked by the STABILITY CHECK DEVICE.

4.4.9 Use of STABILITY CHECK DEVICES

Wherever a test method suggests the use of a STABILITY CHECK DEVICE but a suitable STABILITY CHECK DEVICE is not available, then it is permissible to use an external caesium-137 or cobalt-60 GAMMA RADIATION beam together with a reliable method for positioning the IONIZATION CHAMBER in a reproducible field.

4.5 Summary tables

Table 1 and Table 2 summarize the reference and STANDARD TEST VALUES.

Table 3 and Table 4 summarize the performance requirements (for FIELD-CLASS DOSIMETERS) under STANDARD TEST CONDITIONS.

Table 5, Table 6 and Table 7 summarize the RATED RANGES of INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS and the specified LIMITS OF VARIATION for FIELD-CLASS DOSIMETERS of the PERFORMANCE CHARACTERISTICS affected.

The tables do not give the complete detail which is given in Clauses 5 and 6.

Table 1 – REFERENCE CONDITIONS and STANDARD TEST CONDITIONS – CHAMBER ASSEMBLY

INFLUENCE QUANTITY OR INSTRUMENT PARAMETER	REFERENCE VALUES	STANDARD TEST VALUES
<u>ALL IONIZATION CHAMBERS</u>		
Field size	As at calibration	REFERENCE VALUE
Chamber orientation	As at calibration	REFERENCE VALUE
Source-chamber distance	As at calibration	REFERENCE VALUE
Depth of chamber in PHANTOM (g/cm ²)	As at calibration	REFERENCE VALUE
Source to PHANTOM distance	As at calibration	REFERENCE VALUE
Material of PHANTOM	As at calibration	Reference material
Temperature	+20 °C	+15 °C to +25 °C
Relative humidity	50 %	30 % to 75 %
Ambient pressure	101,3 kPa	Atmospheric pressure
External fields	Zero	So small as not to affect the reading
STRAY RADIATION in X-ray room	Zero	As small as possible
Dose rate	As at calibration	EFFECTIVE RANGE
Polarizing voltage	Stated by the MANUFACTURER	REFERENCE VALUE ±10 %
STABILIZATION TIME	1 h after switch-on	> 15 min after switch-on
<u>SHELL CHAMBERS</u>		
RADIATION QUALITY:		
– X-RADIATION in free air	1,8 mm Cu HVL	REFERENCE VALUE
– X- and γ -radiation in free air	⁶⁰ Co	REFERENCE VALUE
– X- and γ -radiation in PHANTOM	⁶⁰ Co	REFERENCE VALUE
– high-energy X- and γ -radiation	⁶⁰ Co	REFERENCE VALUE
– ELECTRONS	⁶⁰ Co or ELECTRONS as at calibration	REFERENCE VALUE
– protons	⁶⁰ Co	REFERENCE VALUE
– heavy ions	⁶⁰ Co	REFERENCE VALUE
<u>PARALLEL-PLATE CHAMBERS</u>		
RADIATION QUALITY:		
– X-RADIATION	0,36 mm Al HVL, tungsten anode	REFERENCE VALUE
– ELECTRONS	⁶⁰ Co or ELECTRONS as at calibration	REFERENCE VALUE
– protons	⁶⁰ Co	REFERENCE VALUE
– heavy ions	⁶⁰ Co	REFERENCE VALUE

Table 2 – REFERENCE CONDITIONS and STANDARD TEST CONDITIONS – MEASURING ASSEMBLY

INFLUENCE QUANTITY OF INSTRUMENT PARAMETER	REFERENCE VALUES	STANDARD TEST VALUES
Temperature	+20 °C	+15 °C to +25 °C
Relative humidity	50 %	30 % to 75 %
STRAY RADIATION at MEASURING ASSEMBLY	Zero	< 7,5 µSv/h
Battery condition	New batteries	Within useful life
MAINS VOLTAGE	Nominal	Nominal ±1 %
Mains frequency	Nominal	Nominal ±1 Hz
Reading	As at calibration	REFERENCE SCALE READING
Range	As at calibration	Reference range
Input current	Stated by the MANUFACTURER	REFERENCE VALUE
Operating position	Stated by the MANUFACTURER	Reference position
STABILIZATION TIME	1 h after switch-on	> 15 min after switch-on

Table 3 – Limits of PERFORMANCE CHARACTERISTICS at STANDARD TEST CONDITIONS – CHAMBER ASSEMBLY

PERFORMANCE CHARACTERISTICS	Limits	Subclause
LEAKAGE CURRENT	±0,5 % ^a	5.2.1
Long-term stability	±1,0 % ^b	5.2.2.1
Accumulated dose stability	±1,0 % ^c	5.2.2.2
^a Of ionization current produced by minimum RATED or effective dose rate. ^b Of RESPONSE per year for cobalt-60 or caesium-137 GAMMA RADIATION. ^c Of RESPONSE per 10 ⁴ Gy for any RADIATION QUALITY in the RATED RANGE.		

Table 4 – Limits of PERFORMANCE CHARACTERISTICS at STANDARD TEST CONDITIONS – MEASURING ASSEMBLY

PERFORMANCE CHARACTERISTICS	Limits	Subclause
RESOLUTION	$\pm 0,5 \%$ ^a	6.2.2
Repeatability	$\pm 0,5 \%$ ^b	6.2.3
Long-term stability	$\pm 1,0 \%$ ^c	6.2.4
ZERO DRIFT – dosimeter	$\pm 1,0 \%$ ^d	6.3.1
ZERO DRIFT – dose rate meter	$\pm 1,0 \%$ ^e	6.4.1
ZERO SHIFT – dosimeter	$\pm 1,0 \%$ ^f	6.3.2
ZERO SHIFT – dose rate meter	$\pm 1,0 \%$ ^e	6.4.2
NON-LINEARITY – dosimeter	$\pm 0,5 \%$ ^g	6.3.3
NON-LINEARITY – dose rate meter	$\pm 1,0 \%$ ^g	6.4.3
RESPONSE TIME	< 3 s	6.4.5
^a Of minimum effective reading. ^b Relative STANDARD DEVIATION at minimum effective INDICATED VALUE. ^c Of RESPONSE per year to input charge or current in the RATED or EFFECTIVE RANGE. ^d Of rate of change of INDICATED VALUE produced by minimum RATED or effective input current. ^e Of the INDICATED VALUE produced by minimum RATED or effective input current. ^f Of minimum effective INDICATED VALUE. ^g Of RESPONSE at 0,5 full reading on each range.		

Table 5 – LIMITS OF VARIATION of PERFORMANCE CHARACTERISTICS for effects of INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS – CHAMBER ASSEMBLY

INFLUENCE QUANTITY or INSTRUMENT PARAMETER	MINIMUM RATED RANGE	LIMITS OF VARIATION	Note	Sub-clause
<u>ALL IONIZATION CHAMBERS</u>				
STABILIZATION TIME	15 min to 2 h	±0,5 %	a	5.2.3
Post-irradiation leakage	5 s after IRRADIATION ^k	±1,0 %	b	5.2.4
Minimum dose rate	As specified by MANUFACTURER	±0,5 %	c	5.2.5.1
Maximum dose rate	As specified by MANUFACTURER	– 1,0 %	a	5.2.5.2
Maximum ABSORBED DOSE per pulse	As stated by MANUFACTURER	– 1,0 %	a	5.2.6
STRAY RADIATION effect	Specified conditions	±1,0 %	a	5.2.8
Guard/collector insulation	±1 V ^k	≥ 1 x 10 ¹¹ Ω	–	5.2.9
Cable microphony	Specified conditions	±0,1 pA	–	5.2.10
Polarity of polarizing voltage	Maximum permitted positive and negative values	1,0 %	d	5.2.11
<u>SHELL CHAMBERS</u>				
RADIATION QUALITY:				
– X-RADIATION in free air	2 mm Al to 3 mm Cu HVL (70 kV to 250 kV or 30 keV to 140 keV)	±2,0 %	e, f	5.3.1.2
– X- and γ-radiation in free air	1,8 mm Cu HVL to ⁶⁰ Co (200 kV or 100 keV to 1,33 MeV)	±4,0 %	g, f	5.3.1.3
– X- and γ-radiation in <u>PHANTOM</u>	0,42 mm Cu HVL to ⁶⁰ Co (140 kV or 60 keV to 1,33 MeV)	±4,0 %, or ±2,0 %	g, f h, f	5.3.1.4
– high-energy X- and γ-radiation in <u>PHANTOM</u>	⁶⁰ Co to 25 MV	±2,0 %	h	5.3.1.5
– ELECTRONS in PHANTOM	9 MeV to 25 MeV	±2,0 %	h	5.3.1.6
– protons in PHANTOM	50 MeV to 250 MeV	±2,0 %	h	5.3.1.77
– heavy ions in PHANTOM	100 MeV/u to 450 MeV/u	±2,0 %	h	5.3.1.88
Field size – Stem scatter	As specified by MANUFACTURER	±1,0 %	a	5.3.2.2
Field size – Stem leakage	As specified by MANUFACTURER	±0,5 %	a	5.3.2.3
Orientation – Rotation	0° to 360°	±0,5 %	a	5.3.3.1
Orientation – Tilt	±5°	±1,0 %	a	5.3.3.2
<u>PARALLEL-PLATE CHAMBERS</u>				
RADIATION QUALITY:				
– X-RADIATION	0,05 mm Al to 2 mm Al HVL (12 kV to 70 kV or 8 keV to 30 keV)	±2,0 %	e, f	5.4.1.1
– ELECTRONS in PHANTOM	5 MeV to 25 MeV	±1,0 %	i	5.4.1.2
– PROTONS in PHANTOM	50 MeV to 250 MeV	±2,0 %	i	5.4.1.3
– heavy ions in PHANTOM	100 MeV/u to 450 MeV/u	±2,0 %	i	5.4.1.4
Field size	As specified by MANUFACTURER	±2,0 %	a	5.2.7
Orientation – Tilt	±5°	±1,0 %	a	5.4.2