

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

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भारतीय मानक मसौदा
चिकित्सा विद्युत उपकरण
रेडियोथेरेपी में उपयोग के लिए आयनीकरण कक्षों से बने डोसीमीटर
(IEC 60731:2011+AMD1:2016 CSV, संशोधित)

Draft Indian Standard

Medical electrical equipment
Dosimeters with ionization chambers as used in Radiotherapy
(IEC 60731:2011+AMD1:2016 CSV, MOD)

[ICS 11.040.50]

Electromedical, Diagnostic Imaging and Radiotherapy
Equipment Sectional Committee, MHD 15

Last date for comments:
18 May, 2024

NATIONAL FOREWORD

(Adoption clause will be added later)

The text of IEC standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'; and
- Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standard also exists. The corresponding Indian Standards, which are to be substituted in their respective places, are listed below along with their degree of equivalence for the editions indicated:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	IS 13450 (Part 1) : 2024 Medical electrical equipment : Part 1 General requirements for basic safety and essential performance (Third Revision)	Modified

IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests	IS 13450 (Part 1/Sec 2): 2023 Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance Section 2 Electromagnetic Disturbances — Requirements and Tests (IEC 60601-1-2: 2020, MOD) (<i>second revision</i>)	Modified
IEC 60601-1-3 Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment	IS 13450 (Part 1/Sec 3): 2023 Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance Section 3 Radiation Protection in Diagnostic X-Ray Equipment (IEC 60601-1-3: 2021, MOD) (<i>first revision</i>)	Modified
IEC 60601-2-8 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	IS 13450 (Part 2/Sec 8): 2019/IEC 60601-2-8: 2015 Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 8 Therapeutic X-ray equipment operating in the range 10 kV to 1 MV	Identical
IEC/TR 60788:2004, Medical electrical equipment – Glossary of defined terms	IS/IEC/TR 60788 : 2004 Medical electrical equipment - Glossary of defined terms	Identical
IEC 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements	IS 17724 (Part 1) : 2023 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 1 General Requirements (IEC 61010-1: 2010 + AMD1:2016 + COR1:2019, MOD)	Modified
IEC 61187, Electrical and electronic measuring equipment – Documentation	IS 6756 : 2001 Electrical and electronic measuring equipment - Documentation (<i>First Revision</i>)	Identical
IEC 61676:2002, Medical electrical equipment – Dosimetric instruments used for	IS/IEC 61676 : 2002 Medical electrical equipment Dosimetric instruments used for non-invasive	Identical

non-invasive measurement of X-ray tube voltage in diagnostic radiology	measurement of X-ray tube voltage in diagnostic radiology	
ISO 3534-1 Statistics – Vocabulary and symbols – Part 1: General statistical terms and terms used in probability	IS 7920 (Part 1) : 2012 Statistical - Vocabulary and symbols: Part 1 general statistical terms and terms used in probability (<i>Third Revision</i>)	Modified
ISO/IEC Guide 99:2007 International vocabulary of metrology – Basic and general concepts and associated terms (VIM)	IS/ISO/IEC GUIDE 99 : 2007 International vocabulary of metrology -Basic and general concepts and associated terms (VIM)	Identical

The technical committee has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that these are acceptable for use in conjunction with this standard:

<i>International Standard</i>	<i>Title</i>
IEC 60417	Graphical symbols for use on equipment
IEC 60976:2007	Medical electrical equipment – Medical electron accelerators – Functional performance characteristics
IEC 61267:2005	Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics
ISO/IEC Guide 98-3:2008	Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)

This standard is a modified adoption as some of the Indian Standards cross-referred (Column 2) in the table above are not identical to the referred (Column 1) International Standards.

The standard also makes a reference to the BIS Certification Marking of the product, details of which are given in National Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with **IS 2: 2022** ‘Rules for rounding off numerical values (*second revision*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Introduction

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

The effectiveness of treatment of PATIENTS receiving RADIOOTHERAPY 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 RADIOOTHERAPY 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 RADIOOTHERAPY 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.

Scope

This International Standard specifies the performance requirements of RADIOOTHERAPY 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 RADIOOTHERAPY.

The DOSE MONITORING SYSTEMS incorporated in RADIOOTHERAPY 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.

NATIONAL ANNEX A
(National Foreword)

A-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the Bureau of Indian Standards Act, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

The technical content of the document has not been enclosed as it is identical with the corresponding IEC standard. For details, please refer to IEC 60731:2011+AMD1:2016 CSV or kindly contact:

Head of Department
Medical Equipment and Hospital Planning Department
Bureau of Indian Standards
9 Bahadur Shah Zafar Marg
New Delhi-110002
Email: mhd@bis.gov.in
hmhd@bis.gov.in