Draft for Public Comment

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Responsible committee: CH/62/3 Equipment for radiotherapy, nuclear medicine and radiation dosimetry

Interested committees:

Title: Draft BS EN 62083 Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems.

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

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ii) affects other national standard(s)
iii) requires additional national guidance or information

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at **https://standardsdevelopment.bsigroup.com/**. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex **(e.g. 3.1)**	Paragraph/Figure/ Table/Note	**Type of comment**	**Commend (justification for change) by the MB**	**Proposed change by the MB**	**Secretariat observations on each comment submitted**
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

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62C/735/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER: **IEC 62083 ED3**	
DATE OF CIRCULATION: **2019-01-18**	CLOSING DATE FOR COMMENTS: **2019-03-15**
SUPERSEDES DOCUMENTS: **62C/732/RR**	

IEC SC 62C : EQUIPMENT FOR RADIOTHERAPY, NUCLEAR MEDICINE AND RADIATION DOSIMETRY	
SECRETARIAT: Germany	SECRETARY: Mr Norbert Bischof
OF INTEREST TO THE FOLLOWING COMMITTEES: SC 62B	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CD to the secretary.
FUNCTIONS CONCERNED: ☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY	

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT – REQUIREMENTS FOR THE SAFETY OF RADIOTHERAPY TREATMENT PLANNING SYSTEMS

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International Standard IEC 62083 has been prepared by IEC subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition replaces the second edition of IEC 62083, published in 2009.

The edition of this standard considers many aspects of technology used by healthcare organizations. Clause 17 has been designed to facilitate current practice between RADIOTHERAPY TREATMENT MEE, IGRT MEE, RTPS, and Radiotherapy Treatment Management Systems. To pursue compatibility the equipment standards for this equipment are being developed in parallel as much as possible to facilitate workflow communication.

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

FDIS	Report on voting

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Full information on the voting for the approval of this standard 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 standard, the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type;

– explanations, advice, general statements, exceptions and notes: in small roman type;

– *test specifications: in italic type;*

– TERMS USED THROUGHOUT THIS STANDARD THAT HAVE BEEN LISTED IN THE INDEX OF DEFINED TERMS AND DEFINED IN CLAUSE 3, OR IN OTHER STANDARDS: SMALL CAPITALS.

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.

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INTRODUCTION

A RADIOTHERAPY TREATMENT PLANNING SYSTEM (RTPS) is a device that is used to simulate the application of RADIATION to a PATIENT for a proposed RADIOTHERAPY TREATMENT. It usually, but not necessarily, provides estimates of ABSORBED DOSE distributions in human tissue using a particular algorithm or series of algorithms. These estimations, referred to in this International Standard as ABSORBED DOSE distributions, are used by a QUALIFIED PERSON in planning a course of RADIOTHERAPY.

The output of an RTPS is used by appropriately QUALIFIED PERSONS for clinical decisions and for treatment delivery. Inaccuracies in the input data, the limitations of the algorithms, errors in the TREATMENT PLANNING process, or improper use of output data, may represent a safety HAZARD to PATIENTS should the resulting data information be used for TREATMENT purposes. This standard defines requirements to be complied with by MANUFACTURERS in the design and construction of an RTPS in order to provide protection against the occurrence of such HAZARDS. It establishes the minimum requirements for the contents of the ACCOMPANYING DOCUMENTS that will permit the OPERATOR to make informed choices during the TREATMENT PLANNING process.

Generally, an RTPS does not have direct interface to the PATIENTS, so it is not MEDICAL ELECTRICAL EQUIPMENT as defined by IEC 60601-1. Consequently, this standard is written in an independent format rather than as a particular standard to IEC 60601-1. For the purpose of this standard, RTPS is a software application for medical purposes, therefore, IEC 62304 Medical device software - Software life cycle and IEC 62366 Application of usability engineering to medical devices processes applies.

IEC 61217 defines coordinate systems and movements, the marking of scales, their zero position, and the direction of movement with increasing value. The means of applying IEC 61217 are SPECIFIED in appropriate clauses and subclauses of this standard.

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MEDICAL ELECTRICAL EQUIPMENT – REQUIREMENTS FOR THE SAFETY OF RADIOTHERAPY TREATMENT PLANNING SYSTEMS

1 Scope

This International Standard applies to the design, manufacture, installation, and maintenance of the software in a RADIOTHERAPY TREATMENT PLANNING SYSTEM (RTPS)

- in human medical practice;
- that imports data either through input by the OPERATOR or from other devices;
- that outputs data to other devices; and
- which is intended to be
  - for NORMAL USE, under the authority of appropriately QUALIFIED PERSONS, by OPERATORS having the required skills and training;
  - used and maintained in accordance with the recommendations given in the INSTRUCTIONS FOR USE, and
  - used within the environmental conditions SPECIFIED in the technical description.

This standard applies to any software application that participates in the development, evaluation, or approval of a TREATMENT PLAN, whether standalone or part of another system.

NOTE Such products include prescribing systems, contouring systems, QUALITY ASSURANCE systems, plan analysis systems, or plan review systems.

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 60601-1:2005 + A1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-2-1:2014, *Medical electrical equipment – Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV*

IEC 60601-2-11:1997, *Medical electrical equipment – Part 2: Particular requirements for the safety of gamma beam therapy equipment*

IEC 60601-2-17:2013, *Medical electrical equipment – Part 2: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment*

IEC 60601-2-64:2014, *Medical electrical equipment – Part 2: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment*

IEC 60601-2-68:2014, *Medical electrical equipment – Part 2: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and RADIONUCLIDE beam therapy equipment*

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

IEC 61217:2011, *Radiotherapy equipment – Coordinates, movements and scales*

IEC 62304:2006, *Medical device software – Software life cycle processes*

IEC 62366-1:2015, *Medical devices – Application of usability engineering to medical devices*

IEC TR 80001-2-8:2016 Application of risk management for IT-networks incorporating medical devices – Part 2-8: Application guidance – Guidance on standards for establishing the security capabilities identified in IEC TR 80001-2-2

ICRU Report 42:1987, *Use of Computers in External Beam Radiotherapy Procedures with High Energy Photons and Electrons*

ICRU Report 29:1978, *Dose Specification for Reporting External Beam Therapy with Photons and Electrons*

ICRU Report 50:1993, *Prescribing, Recording and Reporting Photon Beam Therapy*

ICRU Report 62:1999, *Prescribing, Recording and Reporting Photon Beam Therapy (Supplement to ICRU Report 50)*

ICRU Report 71:2004, *Prescribing, Recording and Reporting Electron Beam Therapy*

ICRU Report 78:2007, *Prescribing, Recording and Reporting Proton-Beam Therapy*

ICRU Report 83:2010, *Prescribing, recording, and reporting photon-beam intensity-modulated radiation therapy (IMRT)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, and IEC TR 60788:2004 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
ACTION LEVEL
parameter value above or below where action is taken

3.2
ADAPTIVE RADIOTHERAPY
RADIOTHERAPY that monitors PATIENT anatomy or physiology and, based upon the monitored information, allows changes to TREATMENT PARAMETERS throughout the course of TREATMENT

Note 1 to entry: IMAGE GUIDED RADIATION THERAPY (IGRT) is one form of ADAPTIVE RADIOTHERAPY

[SOURCE: 60601-2-1:20xx, 201.3.202; standard in FDIS stage]

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3.3
COMMISSIONING
<radiotherapy treatment planning system> process of preparing a RTPS for clinical use by determining the operating characteristics and limitations of the RTPS, collecting and installing facility specific data and educating and training personnel on the function, performance, and limitations of the RTPS

3.4
CT SCANNER
X-RAY EQUIPMENT intended to generate cross-sectional images of the body by computer reconstruction of X-ray transmission data obtained at different angles, which may include signal analysis and display equipment, PATIENT SUPPORT, support parts and ACCESSORIES

[SOURCE: IEC 60601-2-44:2009+A1:2012, 201.3.201, modified – notes removed]

3.5
EQUIPMENT MODEL
all physical, geometric, and RADIATION parameters for any particular ME EQUIPMENT required to plan a course of RADIOTHERAPY

3.6
EQUIPMENT MODELLING
process of establishing the EQUIPMENT MODEL

3.7
EXTERNAL BEAM EQUIPMENT
EBE
external RADIATION equipment utilizing MEDICAL ELECTRON ACCELERATORS, LIGHT ION BEAM equipment or RADIONUCLIDE BEAM THERAPY EQUIPMENT

Note 1 to entry: This note applies to the French text only.

[SOURCE: IEC 60601-2-68:2014, 201.3.207, modified – Note rephrased.]

3.8
EXTERNAL MONITORING DEVICE
device that can be connected to MEE and monitors patient anatomy or physiology

[SOURCE: IEC 60601-2-1:20xx, 201.3.223, standard in FDIS stage]

3.9
GANTRY
part of the MEE supporting the RADIATION HEAD

Note 1 to entry: The GANTRY is any mechanical device that supports the RADIATION HEAD regardless of movement limitations.

[SOURCE: IEC 60601-2-1:20xx, 201.3.224, standard in FDIS stage]

3.10
IMAGE-GUIDED RADIOTHERAPY
IGRT
RADIOTHERAPY process by which the location of a RADIOTHERAPY beam relative to the intended TARGET VOLUME within a PATIENT'S anatomy is determined by imaging of the TARGET VOLUME and surrounding anatomical structures at the time of TREATMENT, so as to enable any necessary positional corrections to the intended relative location of the beam to the TARGET VOLUME

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Note 1 to entry: The time period of "at the time of TREATMENT" is specified in the definitions of REAL-TIME IGRT, ONLINE IGRT and OFFLINE IGRT.

Note 2 to entry: This note applies to the French language only.

[SOURCE: IEC 60601-2-68:2014, 201.3.209 modified – Notes added.]

3.11
IRRADIATION TREATMENT PRESCRIPTION

instructions for a course of radiation treatment to be used as input to TREATMENT PLANNING, for plan acceptance criteria and for tracking of treatment progress

Quantitative description of the clinical aims that guide the TREATMENT PLANNING.

NOTE For radiotherapy treatment, this includes various levels of detail, as a minimum the treatment site, delivery method, dose per fraction, number of fractions and total dose.

3.12
NOMINAL ENERGY
numerical value stated by the MANUFACTURER to identify the RADIATION BEAM

[SOURCE: IEC 60601-2-1:20xx, 201.3.233, standard in FDIS stage]

3.13

PATIENT MODEL
all physical and anatomical parameters for a particular patient required to plan a course of RADIOTHERAPY

3.14
PATIENT MODELLING
process of establishing the PATIENT MODEL

3.15
PATIENT POSITIONER
<radiotherapy> assembly of equipment upon which the PATIENT is placed and positioned for RADIOTHERAPY

NOTE 1 The PATIENT POSITIONER includes the TABLE TOP and TABLE TOP SUPPORT.

[SOURCE: IEC 60601-2-1:20xx, 201.3.237, standard in FDIS stage]

3.16
QUALIFIED PERSON
person recognised by a competent authority as having the requisite knowledge and training to perform particular duties

[SOURCE: IEC TR 60788:2004, rm-85-04, modified – Word "specified" replaced by "particular" in the definition.]

3.17
QUALITY ASSURANCE
QA
part of quality management focused on providing confidence that quality requirements will be fulfilled

Note 1 to entry: Unless given requirements fully reflect the needs of the RESPONSIBLE ORGANIZATION, QUALITY ASSURANCE will not be complete.

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