Irish Standard
I.S. EN 62083:2009

Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems (IEC 62083:2009 (EQV))

I.S. EN 62083:2009

Incorporating amendments/corrigenda issued since publication:

This document replaces:	*This document is based on:*	*Published:*
EN 62083:2001	EN 62083:2009 EN 62083:2001	11 December, 2009 8 June, 2001

This document was published under the authority of the NSAI and comes into effect on:

9 February, 2010

ICS number:
11.040.60

NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W NSAI.ie

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

I.S. EN 62083:2009

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 62083

December 2009

ICS 11.040.60

Supersedes EN 62083:2001

English version

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

(IEC 62083:2009)

Appareils électromédicaux - Exigences de sécurité pour les systèmes de planification de traitement en radiothérapie (CEI 62083:2009)

Medizinische elektrische Geräte - Festlegungen für die Sicherheit von Bestrahlungsplanungssystemen (IEC 62083:2009)

This European Standard was approved by CENELEC on 2009-11-01. 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, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

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

Central Secretariat: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 62083:2009 E

Foreword

The text of document 62C/473/FDIS, future edition 2 of IEC 62083, 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 62083 on 2009-11-01.

This European Standard supersedes EN 62083:2001.

EN 62083:2009 constitutes a technical revision, which brings this standard in line with changes to the other standards referred to in this standard.

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)	2010-08-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2012-11-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive MDD (93/42/EEC). See Annex ZZ.

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.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 62083:2009 was approved by CENELEC as a European Standard without any modification.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

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

Publication	Year	Title	EN/HD	Year
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
IEC 60601-1-2 (mod)	-[1)]	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	2007[2)]
IEC 60601-2-1	2009	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 2-11: Particular requirements for the safety of gamma beam therapy equipment	EN 60601-2-11	1997
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 60950-1 (mod)	-[1)]	Information technology equipment - Safety - Part 1: General requirements	EN 60950-1 + A11	2006[2)] 2009
IEC 61000-4-1	-[1)]	Electromagnetic compatibility (EMC) - Part 4-1: Testing and measurement techniques - Overview of IEC 61000-4 series	EN 61000-4-1	2007[2)]
IEC 61000-4-2	-[1)]	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test	EN 61000-4-2	2009[2)]
IEC 61000-4-3	-[1)]	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3	2006[2)]
IEC 61000-4-4	-[1)]	Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test	EN 61000-4-4	2004[2)]
IEC 61217	-[1)]	Radiotherapy equipment - Coordinates, movements and scales	EN 61217	1996[2)]
IEC 62304	-[1)]	Medical device software - Software life-cycle processes	EN 62304 + corr. November	2006[2)] 2008

[1)] Undated reference.

[2)] Valid edition at date of issue.

Publication	Year	Title	EN/HD	Year
IEC 62366	2007	Medical devices - Application of usability engineering to medical devices	EN 62366	2008
ICRU Report 42	1987	Use of Computers in External Beam Radiotherapy Procedures with High Energy Photons and Electrons	-	-

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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 second edition replaces the first edition of IEC 62083, published in 2000. This edition constitutes a technical revision, which brings this standard in line with changes to the other standards referred to in this standard.

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

FDIS	Report on voting
62C/473/FDIS	62C/479/RVD

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.

INTRODUCTION

A RADIOTHERAPY TREATMENT PLANNING SYSTEM (RTPS) is a device, usually a PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM 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 distribution in human tissue using a particular algorithm or 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 as important information in RADIOTHERAPY TREATMENT PLANNING. 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 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.

SPECIFIC types of input data and calculation algorithms are not addressed in this standard. These are dependent on many factors, such as available technology, RESPONSIBLE ORGANIZATION preference, and the type of TREATMENT being planned. However, this standard establishes the safety requirements that are common to algorithms. It also 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 is not used in the presence of 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.

- Relationship to other standards

The BASIC SAFETY of hardware, such as for protection against electric shock and fire, and for assuring ELECTROMAGNETIC COMPATIBILITY requires that these subjects be addressed by the MANUFACTURER through compliance with an appropriate standard, depending upon the nature and environment of the hardware used for the RTPS. See Annex A for hardware safety standards.

A RTPS is principally a software application for medical purposes. IEC 62304 applies (see Clause 14).

IEC 61217 gives guidance on the designation of ME EQUIPMENT 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.

IEC 62366 applies (see Clause 16).

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

1 Scope

This International Standard applies to the design, manufacture and some installation aspects of a radiotherapy treatment planning systems(RTPS)

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

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

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*

IEC 60601-2-1:2009, *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/TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 60950-1, *Information technology equipment – Safety – Part 1: General requirements*

IEC 61000-4-1, *Electromagnetic compatibility (EMC) – Part 4-1: Testing and measurement techniques – Overview of IEC 61000-4 series*

IEC 61000-4-2, *Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test*