

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

The European Standard EN 62083:2001 has the status of a
British Standard

ICS 11.040.60

National foreword

This British Standard is the official English language version of EN 62083:2001. It is identical with IEC 62083:2000.

The UK participation in its preparation was entrusted to Technical Committee CH/81, Radiotherapy equipment, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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Summary of pages

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English version

Medical electrical equipment
Requirements for the safety of radiotherapy treatment planning systems
(IEC 62083:2000)

Appareils électromédicaux
Règles particulières de sécurité
pour les systèmes de planification de
traitement en radiothérapie
(CEI 62083:2000)

Medizinische elektrische Geräte
Festlegungen für die Sicherheit von
Bestrahlungsplanungssystemen
(IEC 62083:2000)

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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.

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CENELEC

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

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Foreword

The text of document 62C/280/FDIS, future edition 1 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 2000-12-01

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) 2001-09-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2003-12-01

NOTE In this standard, the following print types are used:

- requirement: in roman type;
- *test specifications: in italic type;*
- notes: in smaller roman type.

Annexes designated "normative" are part of the body of the standard.

Annexes designated "informative" are given for information only.

In this standard, annexes A, C and ZA are normative and annex B is informative.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 62083:2000 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 60601-2-1 NOTE: Harmonized as en 60601-2-1:1998 (not modified).

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INTRODUCTION

A RADIOTHERAPY TREATMENT PLANNING SYSTEM (RTPS) is a device, usually a PROGRAMMABLE ELECTRONIC 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, USER 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 USER to make informed choices during the TREATMENT PLANNING process.

NOTE As it is not used in the presence of PATIENTS, an RTPS 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. Clause 3 contains related information.

MEDICAL ELECTRICAL EQUIPMENT – Requirements for the safety of radiotherapy treatment planning systems

1 Scope and object

This International Standard applies to the design, manufacture and some installation aspects of an RTPS

- for use in RADIOTHERAPY TREATMENT PLANNING in human medical practice;
- that imports data either through input by the OPERATOR or direct from other devices;
- that outputs data either in printed form for review or direct 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.

An RTPS developed by a USER for its own use exclusively is not within the scope of this standard, but it is highly recommended that the principles of this standard be applied in its creation and use. If such an RTPS is provided to another USER in which the developers do not directly control its use, and is represented as being suitable for use, then the developers assume the role of MANUFACTURER, and this standard applies.

An RTPS is principally a software application, and the object of this standard is to establish the requirements for features, associated documentation, and testing of the software. Requirements for SAFETY of hardware are not included in this standard, as they vary with the nature of the hardware. See 3.1 and annex A for hardware requirements.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for safety*

IEC 60601-1-2, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-4, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems*

IEC 60788, *Medical radiology – Terminology*

IEC 60950, *Safety of information technology equipment*

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*

IEC 61000-4-3, *Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test*

IEC 61000-4-4, *Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 4: Electrical fast transient/burst immunity test. Basic EMC Publication*

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

ICRU report 42:1987: *Use of Computers in External Beam Radiotherapy Procedures with high Energy Photons and Electrons*

3 Relationship to other standards

3.1 Hardware SAFETY standards

Requirements for the SAFETY of hardware, such as for protection against electric shock and fire, and to assure for ELECTROMAGNETIC COMPATIBILITY, are not included in this standard. SAFETY requires that these subjects be addressed by the MANUFACTURER separately 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.

3.2 Software SAFETY standards

An RTPS is principally a software application for a medical purpose.

IEC Collateral Standard 60601-1-4 applies (see clause 16).

3.3 IEC 61217 Radiotherapy equipment – Coordinates, movements and scales

IEC 61217 gives guidance on the designation of 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.

4 Terminology and definitions

For the purpose of this International Standard, the following terms and definitions apply, in addition to the index of defined terms listed in annex C.

4.1

EQUIPMENT MODEL/EQUIPMENT MODELLING

all physical, geometric and RADIATION parameters required to plan a course of RADIOTHERAPY for particular EQUIPMENT. The process of establishing the EQUIPMENT MODEL is referred to as "EQUIPMENT MODELLING"

4.2

BRACHYTHERAPY SOURCE MODEL/BRACHYTHERAPY SOURCE MODELLING

all physical, geometric and RADIATION parameters required to plan a course of RADIOTHERAPY for a particular BRACHYTHERAPY RADIOACTIVE SOURCE. The process of establishing the BRACHYTHERAPY SOURCE MODEL is referred to as "BRACHYTHERAPY SOURCE MODELLING"

4.3

PATIENT ANATOMY MODEL/ANATOMY MODELLING

all physical and anatomical parameters required to plan a course of RADIOTHERAPY for a particular PATIENT. The process of establishing the PATIENT ANATOMY MODEL is referred to as "ANATOMY MODELLING"

4.4

TREATMENT PLAN/TREATMENT PLANNING

all PATIENT and dosimetric information that is intended for use by appropriately QUALIFIED PERSONS for the purpose of prescribing or administering RADIOTHERAPY treatment. A TREATMENT PLAN includes information transmitted to other EQUIPMENT for which the use of the information for prescribing or administering IRRADIATION is indirect. A printed or plotted TREATMENT PLAN is referred to as a TREATMENT PLAN report

4.5

RADIOTHERAPY TREATMENT PLANNING SYSTEM (RTPS)

a device, usually a PROGRAMMABLE ELECTRONIC SYSTEM including its associated peripherals, that is used to simulate the application of RADIATION to a PATIENT for a proposed RADIOTHERAPY treatment. It usually, but not necessarily, provides estimations of ABSORBED DOSE distribution in human tissue using a particular algorithm or algorithms. These algorithms provide simulations of RADIATION that is typically from, but not necessarily limited to, MEDICAL ELECTRON ACCELERATORS, GAMMA BEAM THERAPY EQUIPMENT, or RADIOACTIVE SOURCES when BRACHYTHERAPY is planned.

5 General requirements for tests

5.1 Testing during development

Compliance with IEC 60601-1-4 requires identification of HAZARDS, assessment of their RISKS, and appropriate verification and validation of RISK controls. Demonstration of compliance with the requirements of this standard shall be included as part of the above processes, with explicit reference to each requirement. Compliance data shall be retained by the MANUFACTURER as a permanent record. Each test shall include a protocol containing all the necessary input data, sufficient detail to provide for exact reproducibility, and the expected result. A summary description of the tests performed to demonstrate compliance to each clause and subclause of this standard shall be included in the technical description.

5.2 Testing during installation

The MANUFACTURER shall provide an installation test document as part of the technical description that includes, as a minimum, performance of the ABSORBED DOSE distribution calculation algorithm tests given in 11.2. The tests shall also demonstrate correct functioning of the RTPS hardware components and their ability to achieve predetermined results when performing TREATMENT PLANNING functions.

NOTE Due to the complexity of TREATMENT PLANNING functions, it is usually not possible for the MANUFACTURER to demonstrate complete fitness for use of the RTPS at time of installation. Operational problems detected after installation will normally be addressed subject to the conditions of the contract (see also item b) of clause 16).

6 ACCOMPANYING DOCUMENTS

The technical description and the INSTRUCTIONS FOR USE shall contain the information as required by this standard (see table 1 for references).

Table 1 – Clauses and subclauses in this standard that require the provision of information in the ACCOMPANYING DOCUMENTS and the technical description

Check reference	INSTRUCTIONS FOR USE	Technical description
1		5.1
2		5.2
3		7.4 a)
4	7.4 b)	
5	7.5	
6		7.7 a)
7		7.7 b)
8	7.8	
9	8.1 g)	
10		8.2 b)
11	9.1 a)	
12	9.2 a)	
13	9.2 c)	
14	9.3 c)	
15	10.2 a)	
16	10.5 a)	
17		11.1 a)
18	11.1 b)	
19		11.2 a)
20	11.2 c)	
21		11.2 c)
22	11.2 d)	
23		11.2 e)
24		13
25	15	
26	16 b)	
27	17 a)	
28	17 b)	
29	17 d)	
30	18	
31		A.1
32	A.3	
33		A.3
34		Annex B
NOTE The check reference is given as an aid for checking the availability of compliance documentation.		