SLOVENSKI STANDARD
oSIST prEN IEC 62083:2024

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Programska oprema za medicinske aparate - Zahteve za varnost sistemov za načrtovanje radioterapevtske obravnave

Medical device software - Requirements for the safety of radiotherapy treatment planning systems

Medizinische elektrische Geräte - Festlegungen für die Sicherheit von Bestrahlungsplanungssystemen

Appareils électromédicaux - Exigences de sécurité pour les systèmes de planification de traitement en radiothérapie

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL DEVICE SOFTWARE - REQUIREMENTS FOR THE SAFETY OF RADIOTHERAPY TREATMENT PLANNING SYSTEMS –

FOREWORD

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International Standard IEC 62083 has been prepared by IEC subcommittee 62C: Equipment for radiotherapy (3.2.52) , nuclear medicine and radiation (3.2.46) dosimetry, of IEC technical committee 62: Medical equipment, software, and systems.

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

With this edition the title was changed from medical electrical system (mes) (3.2.32) - requirements for the radiotherapy treatment planning system (RTPS) (3.1.14) to medical device software (3.2.30) - requirements for the safety of radiotherapy treatment planning system (RTPS) (3.1.14) .

The edition of this standard considers many aspects of technology used by healthcare organizations. Clause 16 has been designed to facilitate current practice between radiotherapy (3.2.52) treatment (3.2.66) medical electrical equipment (MEE) (3.2.31) , image guided radiotherapy (IGRT) (3.1.8) medical electrical equipment (MEE) (3.2.31) , radiotherapy treatment planning system (RTPS) (3.1.14) , 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

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 document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs . The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications .

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) (3.1.14) is a device that is used to simulate the application of radiation (3.2.46) to a patient (3.2.40) for a proposed radiotherapy (3.2.52) treatment (3.2.66) . It usually, but not necessarily, provides estimates of absorbed dose (3.2.1) distributions in human tissue using a particular algorithm or series of algorithms. These estimations, referred to in this International Standard as absorbed dose (3.2.1) distributions, are used by a qualified person (3.1.12) in planning a radiotherapy (3.2.52) treatment (3.2.66) course.

The output of a radiotherapy treatment planning system (RTPS) (3.1.14) is used by appropriately qualified person (3.1.12) for clinical decisions and for treatment (3.2.66) delivery. Inaccuracies in the input data, the limitations of the algorithms, errors in the treatment (3.2.66) planning process, or improper use of output data, can represent a safety hazard (3.2.19) to patient (3.2.40) should the resulting output data be used for treatment (3.2.66) purposes. This standard defines requirements to be complied with by manufacturer (3.2.28) in the design and construction of an radiotherapy treatment planning system (RTPS) (3.1.14) in order to provide protection against the occurrence of such hazard (3.2.19) . It establishes the minimum requirements for the contents of the accompanying documentation (3.2.4) (3.2.4) that will permit the operator (3.2.39) to make informed choices during the treatment (3.2.66) planning process.

Generally, a radiotherapy treatment planning system (RTPS) (3.1.14) does not have direct interface to the patient (3.2.40) . 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, radiotherapy treatment planning system (RTPS) (3.1.14) is a software application for medical purposes, therefore, IEC 62304 Medical device software - Software life cycle processes and IEC 62366-1:2015/AMD1:2020 Application of usability (3.2.68) engineering to medical devices apply.

This new edition of the radiotherapy treatment planning system (RTPS) (3.1.14) standard introduces the concept of ensuring consistency of machine calibration (MU/Dose conversion) between the radiotherapy treatment planning system (RTPS) (3.1.14) and the delivery systems. Where an medical electrical equipment (MEE) (3.2.31) has the capability, a check of the consistency of the machine calibration can be performed prior to any treatment (3.2.66) delivery to ensure a match between the plan and medical electrical equipment (MEE) (3.2.31) settings for reference conditions.

IEC 61217 defines coordinate systems and movements, the marking of scales, their zero position, and the direction of movement with increasing value. While the provided coordinate system and movements defined in IEC 61217 is the preferred coordinate system, it was deemed more of a safety risk (3.2.56) to force this coordinate system for use with equipment that was not IEC compliant. Hence the requirement that coordinates will be in the delivery machine’s coordinate system.

IEC TR 63183:2019 provides guidelines on error and warning messages for software used in radiotherapy (3.2.52) . Messages should be implemented according to the guidance of IEC/TR 63183.

In the case of online adaptive radiotherapy (3.1.10) and real-time adaptive radiotherapy (3.2.53) , Clause 16 should be used in conjunction with other particular standards of the IEC 60601-2 series.

type test (3.2.70) that are performed by the manufacturer (3.2.28) , or site test (3.2.58) , that are not necessarily performed by the manufacturer (3.2.28) , are specified (3.2.61) for each requirement. It is understood that site test (3.2.58) can be required from the manufacturer (3.2.28) , per the agreement between the manufacturer (3.2.28) and responsible organization (3.2.55) .

Given that before installation a manufacturer (3.2.28) cannot provide site test (3.2.58) data, data collected during site tests should be provided in a site test (3.2.58) report with the accompanying documentation (3.2.4) by those who test the radiotherapy treatment planning system (RTPS) (3.1.14) at installation.

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1 Scope

This International Standard, with the inclusion of type test (3.2.70) and site test (3.2.58) , applies to the design, manufacture, installation, and maintenance of the radiotherapy treatment planning system (RTPS) (3.1.14) as well as communication of the radiotherapy treatment planning system (RTPS) (3.1.14) with other devices

- used in medical practice;
- that imports data either through input by the operator (3.2.39) or from other devices;
- that outputs data to other devices; and
- that is intended to be
  - for normal use (3.2.36) , under the authority of appropriately qualified person (3.1.12) , by operator (3.2.39) having the required skills and training;
  - used and maintained in accordance with the recommendations given in the instructions for use (3.2.23) , and
  - used within the environmental conditions specified (3.2.61) in the technical description.

This standard applies to any software application that is used for the development, evaluation, or approval of a treatment plan (3.1.18) , whether stand-alone or part of another system.

NOTE: Such software applications include prescribing systems, contouring systems, quality assurance (3.2.45) systems, plan analysis systems, or plan review systems.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 60601-1:2005/AMD1:2012*,*

IEC 60601-1:2005/AMD2:2020*,*

IEC 60601-2-1:2020*, 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 60601-2-1:2020*, 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 60601-2-17:2013*, Medical electrical equipment - Part 2: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment*

IEC 60601-2-44:2009, *Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography*

IEC 60601-2-44:2009/AMD1:2012,

IEC 60601-2-44:2009/AMD2:2016,

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*

IEC 60601-2-68:2014, *Medical electrical equipment - Part 2-68: 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*

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

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

IEC 62366-1:2015/AMD1:2020, *Amendment 1 - Medical devices - Part 1: Application of usability engineering to medical devices*

IEC 62676-1-1:2013, 3.1.36, *Video surveillance systems for use in security applications - Part 1-1: System requirements - General*

IEC TR 62926:2019, *Medical electrical system - Guidelines for safe integration and operation of adaptive external-beam radiotherapy systems for real-time adaptive radiotherapy*

IEC TR 63183:2019, *Guidance on error and warning messages for software used in radiotherapy*

ISO 80000-1:2022, *Quantities and units - Part 1: General*

EN 60601-2-17:2015, *Medical electrical equipment - Part 2-17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005/AMD1:2012/AMD2:2020, IEC TR 60788:2004, and the following apply.

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

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

3.1 Terms defined in this document

3.1.1
action level
threshold value beyond which action is taken

3.1.2
to archive
remove data from its original storage location and place it in a separate storage location from which the data can be retrieved for subsequent use

3.1.3
brachytherapy source model
all physical, geometric and radiation (3.2.46) parameters required to plan a course of radiotherapy (3.2.52) for a particular brachytherapy (3.2.7) radioactive source (3.2.50)

3.1.4
commissioning
<radiotherapy treatment planning system> process of preparing an radiotherapy treatment planning system (RTPS) (3.1.14) for clinical use by determining the operating characteristics and limitations of the radiotherapy treatment planning system (RTPS) (3.1.14), collecting and installing facility specific (3.2.60) data, and, if necessary, instructing personnel

3.1.5
CT scanner
X-ray equipment intended to generate cross-sectional images of the body by computer reconstruction of X-ray transmission (3.2.65) data obtained at different angles, which may include signal analysis and display (3.2.11) equipment, patient (3.2.40) support, support parts and accessories

[SOURCE: IEC 60601-2-44:2009+A1:2012+A2:2016, 201.3.201, modified - notes removed]

3.1.6
equipment model
representation of physical, geometric, and radiation (3.2.46) parameters for any particular equipment required to plan a course of radiotherapy (3.2.52)

3.1.7
export
automated or semi-automated data transfer from one system to another

3.1.8
image guided radiotherapy (IGRT)
radiotherapy (3.2.52) process by which the location of a radiotherapy (3.2.52) beam relative to the intended target volume (3.2.64) within a patient (3.2.40)'s anatomy is determined by imaging of the target volume (3.2.64) and surrounding anatomical structures at the time of treatment (3.2.66), so as to enable any necessary positional corrections to the intended relative location of the beam to the target volume (3.2.64)

Note 1 to entry: The time period of "at the time of treatment (3.2.66)" is specified (3.2.61) in the definitions of real-time IGRT (3.1.15), online IGRT (3.1.10) and offline IGRT (3.1.9).

[SOURCE: IEC 60601-2-68:2014, 201.3.209 modified - Note 1 replaced.]

3.1.9
offline adaptive radiotherapy
process wherein the patient (3.2.40) setup or treatment plan (3.1.18) is adjusted for application in subsequent treatment (3.2.66) delivery sessions

[SOURCE: IEC 60601-2-1:2020, 201.3.232]

3.1.10
online adaptive radiotherapy
process wherein the patient (3.2.40) setup or treatment plan (3.1.18) is adjusted immediately prior to or during the therapeutic irradiation session requiring operator (3.2.39) initiated adjustments

Note 1 to entry: the patient (3.2.40) stays on the patient positioner (3.2.41) and is immobile during and in-between adaptive calculations and treatment (3.2.66).

[SOURCE: IEC 60601-2-1:2020, 201.3.233]

3.1.11
patient model
representation of physical, anatomical, or physiological parameters for a particular patient (3.2.40) required to plan a course of radiotherapy (3.2.52)

3.1.12
qualified person
person recognised by a competent authority as having the requisite knowledge and training to perform particular duties

[SOURCE: IEC 60601-2-1:2020, 201.3.237, modified - Word "specified" replaced by "particular" in the definition.]

3.1.13
radiation treatment prescription
quantitative description of the clinical aims that guide treatment (3.2.66) planning

Note 1 to entry: For radiotherapy (3.2.52) treatment (3.2.66), this may include various levels of detail, such as the treatment (3.2.66) site, delivery method, dose per fraction, number of fractions and total dose.

3.1.14
radiotherapy treatment planning system (RTPS)
computer system, that is used to develop simulations and to determine, evaluate, and approve optimal arrangements of the application of radiation (3.2.46) to a patient (3.2.40) for radiotherapy (3.2.52) treatment (3.2.66)

Note 1 to entry: An radiotherapy treatment planning system (RTPS) (3.1.14) usually, but not necessarily, provides estimations of absorbed dose (3.2.1) distributions in human tissue using a particular algorithm or algorithms. These algorithms provide simulations of radiation (3.2.46) that typically emanates from, but

not necessarily limited to, medical electron accelerators, light ion (3.2.26) beam medical equipment, gamma beam therapy equipment (3.2.17), or brachytherapy (3.2.7) equipment.

Note 2 to entry: An radiotherapy treatment planning system (RTPS) (3.1.14) is any software application that participates in the development, evaluation, or approval of a treatment plan (3.1.18), whether stand-alone or part of another system.

Note 3 to entry: An radiotherapy treatment planning system (RTPS) may include software for interfacing with peripherals. Examples of peripherals are digitizer, CT scanner (3.1.5), surface scanner, printer, film scanner.

3.1.15
real-time adaptive radiotherapy
radiotherapy (3.2.52) that, throughout therapeutic irradiation (3.2.24), monitors patient (3.2.40) anatomy or physiology and based upon that information, allows autonomous adjustments of treatment (3.2.66) parameters throughout the therapeutic irradiation without operator (3.2.39) intervention

[SOURCE: IEC 60601-2-1:2020, 201.3.243]

3.1.16
table top
device attached to the table top support (3.2.63) to which registration or immobilization devices are attached and upon which the patient (3.2.40) is placed

Note 1 to entry: The table top (3.1.16) can be exchangeable.

[SOURCE: IEC 60601-2-64:2014, 201.3.238, modified - Words "an exchangeable device attached to the patient positioner" have been replaced by "device attached to the table top support", and note added.]

3.1.17
treatment parameter
data that describes one aspect of the irradiation (3.2.24) or setup of a patient (3.2.40) during radiotherapy (3.2.52)

Note 1 to entry: Examples of a treatment parameter (3.1.17) include such values as radiation (3.2.46) energy, source strength ,treatment (3.2.66) time, imaging and patient positioner (3.2.41) settings.

[SOURCE: IEC 60601-2-17:2013, 201.3.214, modified - Information in the note was removed from the definition.]

3.1.18
treatment plan
all information that is intended for use by appropriately qualified persons (3.1.12) for the purpose of prescribing or administering radiotherapy (3.2.52) treatment (3.2.66), including any information to be transmitted to other equipment

Note 1 to entry: Typical other equipment include treatment (3.2.66) management systems and treatment (3.2.66) delivery systems.

3.2 Terms defined in other documents

3.2.1
absorbed dose

[SOURCE: IEC/TR 60788:2004, rm-13-08]

3.2.2
absorbed dose rate

[SOURCE: IEC/TR 60788:2004, rm-13-09]

3.2.3
accessory

[SOURCE: IEC 60601-1:2005+A1:2012+A2:2020, 3.3]

3.2.4
accompanying documentation

[SOURCE: IEC 62366-1:2015/AMD1:2020]

3.2.5
adaptive radiotherapy

[SOURCE: IEC 60601-2-1:2020, 201.3.201]

3.2.6
afterloading

[SOURCE: IEC 60601-2-17:2013, 201.3.201]

3.2.7
brachytherapy

[SOURCE: IEC/TR 60788:2004, rm-42-52]

3.2.8
computed tomography (CT)

[SOURCE: IEC/TR 60788:2004, rm-41-20]

3.2.9
cone beam computed tomography (CBCT)