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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

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This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 62083 edition 3.1 contains the third edition (2025-12) [documents 62C/957/FDIS and 62C/966/RVD] and its amendment 1 (2026-11) [documents 62C/981/CDV and 62C/991/RVC].

In this Redline version, a vertical bar appears in the margin wherever the technical content has been modified by amendment 1. Additions are shown in green text, and deletions are shown in red strikethrough text. A separate Final version with all changes accepted is included in this publication.

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

This third edition cancels and replaces the second edition published in 2009. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

– modification of the title from Medical electrical system - Requirements for the safety of radiotherapy treatment planning systems, to Medical device software - Requirements for the safety of radiotherapy treatment planning systems;
– adaptive radiotherapy is added in Clause 16;
– the title reflects different implementations of radiotherapy treatment planning systems.

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

FDIS	Report on voting
62C/957/FDIS	62C/966/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.

The language used for the development of this International Standard is English.

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/publications.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

– reconfirmed,
– withdrawn, or
– revised.

INTRODUCTION

A radiotherapy treatment planning system is used to simulate the application of radiation to a patient. An important function of radiotherapy treatment planning system is to provide estimates of absorbed dose distributions in tissue using a particular algorithm or series of algorithms. These estimations, referred in this document as absorbed dose distributions, are used by a qualified person in planning a radiotherapy treatment course.

This document recognizes that modern radiotherapy treatment planning system use off-the-shelf hardware with manufacturer written software and therefore concerns itself with the safety of radiotherapy treatment planning software that is type tested against the hardware configurations specified by the manufacturer. It is this combination of software and hardware that is referred to as the radiotherapy treatment planning system in this document.

The output of a radiotherapy treatment planning system 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, can represent a safety hazard to patients should the resulting output data be used for treatment purposes. This document defines requirements to be compliant with by manufacturers in the design and development of a radiotherapy treatment planning system in order to provide protection against the occurrence of such hazards. It establishes the minimum requirements for the contents of the accompanying documentation that will permit the operator to make informed choices during the treatment planning process.

Generally, a radiotherapy treatment planning system does not have direct interface to the patients. Consequently, this document is written in an independent format rather than as a particular standard to IEC 60601-1:2005.

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

IEC 61217:2011 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 61217:2011 is the preferred coordinate system, it was deemed more of a safety risk 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.

This third edition of this document considers many aspects of technology used by healthcare organizations. Clause 16 has been designed to facilitate current practice between radiotherapy treatment medical electrical equipment, image guided radiotherapy medical electrical equipment, radiotherapy treatment planning systems, 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.

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

Type tests that are performed by the manufacturer, or site tests that are not necessarily performed by the manufacturer, are specified for each requirement. It is understood that site tests can be required from the manufacturer, per the agreement between the manufacturer and the responsible organization.

Given that before installation a manufacturer cannot provide site test data, data collected during site tests can be provided in a site test report with the accompanying documentation by those who test the radiotherapy treatment planning system at installation.

Further reading:

IEC 62304:2006, *Medical device software - Software life cycle processes* [4]

IEC 62304:2006/AMD1:2015, Amendment 1 - *Medical device software - Software life cycle processes* [5]

IEC 60601-2-8:2010, *Medical electrical equipment – Part 2-8: Particular requirements for basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV* [6]

IEC 60601-2-8:2010/AMD1:2015 [7]

ISO 13485:2016, *Medical devices - Quality management systems - Requirements for regulatory purposes* [8]

ISO 27789:2021*, Health informatics - Audit trails for electronic health records* [9]

ICRU Report 29:1978*, Dose Specification for Reporting External Beam Therapy with Photons and Electrons* [10]

ICRU Report 42:1987, *Use of Computers in External Beam Radiotherapy Procedures with High Energy Photons and Electrons* [11]

ICRU Report 50:1993, *Prescribing, Recording and Reporting Photon Beam Therapy* [12]

ICRU Report 62:1999, *Prescribing, Recording and Reporting Photon Beam Therapy (Supplement to ICRU Report 50)* [13]

ICRU Report 71:2004, *Prescribing, Recording and Reporting Electron Beam Therapy* [14]

ICRU Report 78:2007, *Prescribing, Recording and Reporting Proton-Beam Therapy* [15]

ICRU Report 83:2010, *Prescribing, Recording, and Reporting Photon-Beam Intensity - Modulated Radiation Therapy (IMRT)* [16]

ICRU Report 85:2013, *Fundamental Quantities and Units for Ionizing Radiation* [17]

ICRU Report 91:2014, *Prescribing, Recording, and Reporting of Stereotactic Treatments with Small Photon Beams* [18]

ICRU Report 89:2016, *Prescribing, Recording, and Reporting Brachytherapy for Cancer of the Cervix* [19]

ICRU Report 93:2016, *Prescribing, Recording, and Reporting Light Ion Beam Therapy* [20]

*Dosimetry of interstitial brachytherapy sources: Recommendations of the AAPM Radiation Therapy Committee Task Group No. 43*Med. Phys., 1995, 22, p. 209-234 [21]

Technical Reports Series No. 430, *Commissioning and Quality Assurance of Computerized Planning Systems for Radiation Treatment of Cancer, International Atomic Energy Agency, Vienna, 2004 [22]*

IMRT Commissioning Tests Instructions for Planning, Measurement, and Analysis, AAPM Task Group 119, Version 10/21/2009 [23]

INTRODUCTION to Amendment 1

The third edition of IEC 62083 was published in 2025. This amendment is intended to update the type test in 6.5.5 (“Installation of radiotherapy treatment planning system”) to add the missing compliance check.

The missing compliance check was noticed during the review of the 62C/957/FDIS and commented accordingly by National Committees. At the November 2025 meeting of IEC SC 62C in Milan, Italy, the subcommittee decided to initiate an amendment to address the comment and should not wait until the next update of IEC 62083.

1 Scope

This document, with the inclusion of type tests and site tests, applies to the design, manufacture, installation, and maintenance of the radiotherapy treatment planning system.

This document applies to the communication of the radiotherapy treatment planning system with other devices

– used in medical practice,
– that imports data either through input by the operator or from other devices,
– that outputs data to other devices, and
– that 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 document applies to any software application that is used for the development, evaluation, or approval of a treatment plan, whether stand-alone or part of another system.

NOTE Such software applications include prescribing systems, image registration, contouring systems, quality assurance 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.

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

IEC 60601-1:2005, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*

IEC 60601-1:2005/AMD1:2012, *Amendment 1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*

IEC 60601-1:2005/AMD2:2020, *Amendment 2 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/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