IEC 62083

Edition 3.0 2025-12

INTERNATIONAL STANDARD

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

ICS 11.040.60

ISBN 978-2-8327-0914-6

IEC 62083:2025-12(en)

IEC Secretariat
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC
The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications
The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee, …). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

IEC Products & Services Portal - products.iec.ch
Discover our powerful search engine and read freely all the publications previews, graphical symbols and the glossary. With a subscription you will always have access to up to date content tailored to your needs.

Electropedia - www.electropedia.org
The world's leading online dictionary on electrotechnology, containing more than 22 500 terminological entries in English and French, with equivalent terms in 25 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

Medical device software - 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.

2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.

3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.

4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.

5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.

6) All users should ensure that they have the latest edition of this publication.

7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.

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) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at https://patents.iec.ch. IEC shall not be held responsible for identifying any or all such patent rights.

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]

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*

Bibliography

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

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

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

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

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

[6] 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*

[7] IEC 60601-2-8:2010/AMD1:2015, *Amendment 1 - Medical electrical equipment - Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV*

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

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

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

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

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

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

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

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

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

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

[18] ICRU Report 91:2014, Prescribing, recording, and reporting of stereotactic treatments with small photon beams

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

[20] ICRU Report 93:2016, Prescribing, recording, and reporting light ion beam therapy

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

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

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

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

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

[26] 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*

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

[28] IEC 60601-2-68:2025, *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*

[29] 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*

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

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

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

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

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

[35] ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

[36] ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

[37] IEC TR 60601-4-5:2021, *Medical electrical equipment - Part 4-5: Guidance and interpretation - Safety-related technical security specifications*

[38] IEC 61157:2007, *Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment*

[39] IEC/TR 61258:2008, *Guidelines for the development and use of medical electrical equipment educational materials*

[40] IEC 60601-2-11:2013, *Medical electrical equipment - Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment*

[41] IEC 60601-1-3:2008, *Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment*

[42] IEC 62304, *Medical device software - Software life cycle processes*

[43] IEC 81001-5-1:2021, *Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle*

[44] IEC 62366-1:2015, *Medical devices - Part 1: Application of usability engineering to medical devices*

[45] ISO 8601-1:2019, *Date and time — Representations for information interchange — Part 1: Basic rules*

[46] IEC 60601-2 (all parts), Medical electrical equipment - Part 2: Particular requirements for the basic safety and essential performance

_____