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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>See Eesti standard EVS-EN IEC 62083:2026 sisaldab Euroopa standardi EN IEC 62083:2026 ingliskeelset teksti.</p> <p>Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 06.02.2026.</p> <p>Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.</p>	<p>This Estonian standard EVS-EN IEC 62083:2026 consists of the English text of the European standard EN IEC 62083:2026.</p> <p>This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.</p> <p>Date of Availability of the European standard is 06.02.2026.</p> <p>The standard is available from the Estonian Centre for Standardisation and Accreditation.</p>
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English Version

Medical device software - Requirements for the safety of radiotherapy treatment planning systems (IEC 62083:2025)

Logiciels de dispositifs médicaux - Exigences de sécurité
pour les systèmes de planification de traitement en
radiothérapie
(IEC 62083:2025)

Medizinische elektrische Geräte - Festlegungen für die
Sicherheit von Bestrahlungsplanungssystemen
(IEC 62083:2025)

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Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

The text of document 62C/957/FDIS, future edition 3 of IEC 62083, prepared by SC 62C "Equipment for radiotherapy, nuclear medicine and radiation dosimetry" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 62083:2026.

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2027-02-28 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2029-02-28 document have to be withdrawn

This document supersedes EN 62083:2009 and all of its amendments and corrigenda (if any).

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The text of the International Standard IEC 62083:2025 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standard indicated:

IEC 60601-1:2005	NOTE	Approved as EN 60601-1:2006 (not modified) +A11:2011
IEC 61217:2011	NOTE	Approved as EN 61217:2012 (not modified)
IEC 62304:2006	NOTE	Approved as EN 62304:2006 (not modified)
IEC 62304:2006/A1:2015	NOTE	Approved as EN 62304:2006/A1:2015 (not modified)
IEC 60601-2-8:2010	NOTE	Approved as EN 60601-2-8:2015 (not modified)
IEC 60601-2-8:2010/A1:2015	NOTE	Approved as EN 60601-2-8:2015/A1:2016 (not modified)
ISO 13485:2016	NOTE	Approved as EN ISO 13485:2016 (not modified) +A11:2021
ISO 27789:2021	NOTE	Approved as EN ISO 27789:2021 (not modified)
IEC 62366-1:2015/A1:2020	NOTE	Approved as EN 62366-1:2015/A1:2020 (not modified)
IEC 60601-2-1:2020	NOTE	Approved as EN IEC 60601-2-1:2021 (not modified)
IEC 60601-2-17:2013	NOTE	Approved as EN 60601-2-17:2015 (not modified)

IEC 60601-2-68:2025	NOTE	Approved as EN IEC 60601-2-68:2025 (not modified)
IEC 60601-2-44:2009	NOTE	Approved as EN 60601-2-44:2009 (not modified) +A11:2011
IEC 62676-1-1:2013	NOTE	Approved as EN 62676-1-1:2014 (not modified)
IEC 60601-2-64:2014	NOTE	Approved as EN 60601-2-64:2015 (not modified)
ISO 13485	NOTE	Approved as EN ISO 13485
ISO 14971:2019	NOTE	Approved as EN ISO 14971:2019 (not modified) +A11:2021
IEC 61157:2007	NOTE	Approved as EN 61157:2007 (not modified)
IEC 60601-2-11:2013	NOTE	Approved as EN 60601-2-11:2015 (not modified)
IEC 60601-1-3:2008	NOTE	Approved as EN 60601-1-3:2008 (not modified) +A11:2016
IEC 62304	NOTE	Approved as EN 62304
IEC 81001-5-1:2021	NOTE	Approved as EN IEC 81001-5-1:2022 (not modified)
IEC 62366-1:2015	NOTE	Approved as EN 62366-1:2015 (not modified)
IEC 60601-2 (series)	NOTE	Approved as EN 60601-2-8:2015/A1 (series)

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Logiciels de dispositifs médicaux - Exigences de sécurité pour les systèmes de planification de traitement en radiothérapie



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

FOREWORD

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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*

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>