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Security of ME equipment containing high-activity sealed radioactive sources

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 12/25

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NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 63322

September 2025

ICS 11.040.50

English Version

Security of ME equipment containing high-activity sealed radioactive sources (IEC 63322:2025)

Sécurité des appareils EM contenant des sources radioactives scellées de haute activité (IEC 63322:2025)

Sicherheit medizinischer elektrischer Geräte, die hochradioaktive umschlossene Strahlenquellen enthalten (IEC 63322:2025)

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European foreword

The text of document 62C/945/FDIS, future edition 1 of IEC 63322, 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 63322:2025.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2026-09-30
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In the official version, for Bibliography, the following notes have to be added for the standard indicated:

IEC 60601-2-11:2013	NOTE	Approved as EN 60601-2-11:2015 (not modified)
IEC 60601-2-17:2013	NOTE	Approved as EN 60601-2-17:2015 (not modified)
ISO/IEC 17025	NOTE	Approved as EN ISO/IEC 17025
ISO 14971:2019	NOTE	Approved as EN ISO 14971:2019 (not modified) + A11:2021
ISO/TR 24971:2020	NOTE	Approved as CEN ISO/TR 24971:2020 (not modified)
IEC 62366-1:2015	NOTE	Approved as EN 62366-1:2015 (not modified)
IEC 62052-31:2024	NOTE	Approved as EN IEC 62052-31:2024 (not modified)
IEC 61675-2:2015	NOTE	Approved as EN 61675-2:2015 (not modified)
IEC 62598:2011	NOTE	Approved as EN 62598:2013 (not modified)
IEC 60601-2-64:2014	NOTE	Approved as EN 60601-2-64:2015 (not modified)
ISO/IEC 80079-34:2018	NOTE	Approved as EN ISO/IEC 80079-34:2020 (not modified)

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cencenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A12	2014
+ A2	2020		+ A2	2021
-	-		+ A13	2024

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Security of ME equipment containing high-activity sealed radioactive sources

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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Security of ME equipment containing high-activity sealed radioactive sources

FOREWORD

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IEC 63322 has been prepared by subcommittee SC 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee TC 62: Medical equipment, software, and systems. It is an International Standard.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62C/945/FDIS	62C/950/RVD

Full information on the voting for its approval 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.

In this document, the following print types are used:

– requirements and definitions: roman type;

– *test specifications: italic type;*

– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

– TERMS DEFINED IN IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

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

Two new international treaties were entered into force in the early 21st century, namely the International Convention on the Suppression of Acts of Nuclear Terrorism (2007) [1][1] and the Amendment to the Convention on the Physical Protection of Nuclear Material (2016) [2]. International treaties contain obligations to be implemented by each State Party, i.e., commitments to make every effort to prevent unlawful access to radioactive materials, such as SEALED RADIOACTIVE SOURCES. While the international treaties are binding to the State Parties, they do not contain requirements that are directly applicable or useful for the different target groups of this document, the MANUFACTURERS of ME EQUIPMENT and the RESPONSIBLE ORGANIZATION as the equipment user. This document provides requirements on how to secure ME EQUIPMENT in order to protect against unauthorized access of the SEALED RADIOACTIVE SOURCES contained and on SECURITY ARRANGEMENTS in the location in which the ME EQUIPMENT is used or stored. These requirements are consistent with the intentions and goals of the international treaties.

Aware of the need and the urgency for a standard that aims at protecting ME EQUIPMENT containing high-activity SEALED RADIOACTIVE SOURCES from unauthorized access, 20 participating members of the National Committees voted in February 2020 in favor of establishing a security standard to address this risk.

This document complements safety standards for ME EQUIPMENT containing high-activity SEALED RADIOACTIVE SOURCES, for example [3] and [4], by addressing security, and therefore deviates somewhat from the structure established by IEC 60601-1 for standards that are defined as safety standards only. This document does not in any way impact on the implementation of, or adherence to, the requirements of IEC 60601-1 regarding BASIC SAFETY and ESSENTIAL PERFORMANCE.

The MANUFACTURER and the RESPONSIBLE ORGANIZATION both have responsibilities for the secure use of ME EQUIPMENT containing high-activity SEALED RADIOACTIVE SOURCES. This document establishes security requirements for the two entities based on an assumption of the threat. The requirements are strictly separated in different clauses for the MANUFACTURER and the RESPONSIBLE ORGANIZATION to facilitate certification. The appropriate national regulators and other competent organizations will provide additional input regarding the threat level and in response to a security event. The MANUFACTURER of ME EQUIPMENT containing high-activity SEALED RADIOACTIVE SOURCES will have responsibility for the requirements that relate to the ME EQUIPMENT itself, such as the equipment's design, the use of materials and components, and other measures that will increase the equipment's physical resistance against attempts to remove the SEALED RADIOACTIVE SOURCES unlawfully, including devices that provide a warning in case of such an attempt.

The RESPONSIBLE ORGANIZATION will have responsibility for the security requirements that relate to the location where the equipment is used or stored, that the staff is well informed and that there are actions planned in case there is a security event. The implementation of a SECURITY CULTURE [5] supported by the leadership of the RESPONSIBLE ORGANIZATION will be both necessary and important to maintain effectiveness of the security system.

The compliance with the requirements of this document will be objectively tested by an accredited test house. A certificate will communicate compliance with this document and help to build trust among the users and with patients and the public. The overall impact of all measures taken by the MANUFACTURER and by the RESPONSIBLE ORGANIZATION will contribute to reducing the risk that perpetrators can succeed in attempts to illegally access and remove the SEALED RADIOACTIVE SOURCES from the ME EQUIPMENT.

[1] Numbers in square brackets refer to the Bibliography

The methodology, including the numerical parameters, expressed in EN 1143-1:2019 is used to quantify the required physical resistance of SECURED ME EQUIPMENT against unauthorized removal of the SEALED RADIOACTIVE SOURCES.

1 Scope

This document establishes security requirements of ME EQUIPMENT using high-activity SEALED RADIOACTIVE SOURCES, directly or indirectly, for medical treatment and other clinical procedures. ME EQUIPMENT containing SEALED RADIOACTIVE SOURCES that are defined as Category 1, 2 and 3 RADIOACTIVE SOURCES by IAEA [6] are subject to this document.

The object of this document is to specify requirements for the security of ME EQUIPMENT containing high-activity SEALED RADIOACTIVE SOURCES with the aim to minimize the risk of unauthorized access to the contained SEALED RADIOACTIVE SOURCES, and to serve as the basis for other standards. This document contains requirements for the MANUFACTURER of the ME EQUIPMENT and, separately, for the RESPONSIBLE ORGANIZATION regarding security at the location during use and storage.

The requirements of this document apply when the SEALED RADIOACTIVE SOURCES are contained in the ME EQUIPMENT, i.e. from the time when the SEALED RADIOACTIVE SOURCES are inserted into the ME EQUIPMENT, during the INTENDED USE and when the ME EQUIPMENT is not being used for its INTENDED USE or taken out of regular use, until the equipment is being decommissioned, i.e. until all SEALED RADIOACTIVE SOURCES are permanently removed from the equipment.

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/AMD1:2020

EN 1143-1:2019, *Secure storage units – Requirements, classification and methods of test for resistance to burglary – Part 1: Safes, ATM safes, strongroom doors and strongrooms*

EN 1300:2023, *Secure storage units – Classification for high security locks according to their resistance to unauthorized opening*

EN 1627:2021, *Pedestrian doorsets, windows, curtain walling, grilles and shutters - Burglar resistance - Requirements and classification*

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