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**Varnost medicinske električne (ME) opreme, ki vsebuje visokoaktivne zaprte radioaktivne vire (IEC 63322:2025)**

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

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

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

**Ta slovenski standard je istoveten z: EN IEC 63322:2025**

SIST EN IEC 63322:2025

<https://standards.sist.si/catalog/standards/sist/18a3b301-a112-45ac-975d-a2806db28351/sist-en-iec-63322-2025>

**ICS:**

11.040.50      Radiografska oprema      Radiographic equipment

**SIST EN IEC 63322:2025**

**en**



EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN IEC 63322**

September 2025

ICS 11.040.50

English Version

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radioactive sources  
(IEC 63322:2025)**

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This European Standard was approved by CENELEC on 2025-09-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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SIST EN IEC 63322:2025

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European Committee for Electrotechnical Standardization  
Comité Européen de Normalisation Electrotechnique  
Europäisches Komitee für Elektrotechnische Normung

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

**EN IEC 63322:2025 (E)****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 (dop) 2026-09-30 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2028-09-30 document have to be withdrawn

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**Endorsement notice**

The text of the International Standard IEC 63322:2025 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 60601-2-11:2013	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.cenelec.eu](http://www.cenelec.eu).

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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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IEC 63322

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# INTERNATIONAL STANDARD

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**(<https://standards.iteh.ai>)**  
**Document Preview**

[SIST EN IEC 63322:2025](https://standards.iteh.ai/catalog/standards/sist/f8a3b301-a112-45ac-975d-a2806db28351/sist-en-iec-63322-2025)

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