



SLOVENSKI STANDARD
oSIST prEN IEC 63322:2024
01-maj-2024

Varnost medicinske električne opreme, ki vsebuje visokoaktivne zaprte radioaktivne vire

Security of medical electrical equipment containing high-activity sealed radioactive sources

Sécurité des appareils électromédicaux contenant des sources radioactives scellées de haute activité

Ta slovenski standard je istoveten z: prEN IEC 63322:2024

<https://standards.iteh.ai/catalog/standards/sist/f8a3b301-a112-45ac-975d-a2806db28351/osist-pren-iec-63322-2024>

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<input checked="" type="checkbox"/> SUBMITTED FOR CENELEC PARALLEL VOTING Attention IEC-CENELEC parallel voting The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	<input type="checkbox"/> NOT SUBMITTED FOR CENELEC PARALLEL VOTING

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TITLE:

Security of Medical Electrical Equipment Containing High-Activity Sealed Radioactive Sources

PROPOSED STABILITY DATE: 2030

NOTE FROM TC/SC OFFICERS:

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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**SECURITY OF ME EQUIPMENT CONTAINING HIGH-ACTIVITY SEALED
RADIOACTIVE SOURCES**

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FOREWORD

178 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising
179 all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international
180 co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and
181 in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports,
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183 preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with
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211 IEC 63322 has been prepared by subcommittee SC 62C: Equipment for radiotherapy, nuclear
212 medicine and radiation dosimetry, of IEC technical committee TC 62: Medical equipment,
213 software, and systems. It is an International Standard containing requirements to protect the
214 MEDICAL ELECTRICAL EQUIPMENT using high-activity RADIOACTIVE SOURCES against unauthorized
215 access for malicious purposes. The standard complements safety standards by addressing risks
216 such as the unauthorized removal, and other malicious use, of the RADIOACTIVE SOURCES
217 contained in the equipment.

218 This standard is the first IEC standard to address the security of ME EQUIPMENT using radioactive
219 sources. It provides requirements that are directed both to the MANUFACTURER of ME EQUIPMENT
220 as well as to the RESPONSIBLE ORGANIZATION using ME EQUIPMENT. The requirements are strictly
221 separated in different Clauses for the MANUFACTURER and the RESPONSIBLE ORGANIZATION to
222 facilitate certification.

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

Draft	Report on voting
XX/XX/FDIS	62C/761//RVD

224
225 Full information on the voting for its approval can be found in the report on voting indicated in
226 the above table.

227 The language used for the development of this International Standard is English (United
228 Kingdom).

229 This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in
230 accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available
231 at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are
232 described in greater detail at www.iec.ch/publications.

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

- 236 • reconfirmed,
- 237 • withdrawn,
- 238 • replaced by a revised edition, or
- 239 • amended.

240

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<https://standards.itih.ai/catalog/standards/sist/f8a3b301-a112-45ac-975d-a2806db28351/osist-pren-iec-63322-2024>

241

INTRODUCTION

242 No patent rights identified.

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

247 This standard addresses security of ME EQUIPMENT, and therefore deviates somewhat from the
248 structure established by 60601-1 for standards that are defined as safety standards only. This
249 standard does not in any way impact on the implementation of, or adherence to, the
250 requirements of 60601-1 regarding BASIC SAFETY and ESSENTIAL PERFORMANCE.

251 The MANUFACTURER and the RESPONSIBLE ORGANIZATION both have responsibilities for the secure
252 use of ME EQUIPMENT containing high-activity RADIOACTIVE SOURCES. This standard establishes
253 security requirements for the two entities based on an assumption of the threat. The appropriate
254 national regulators and other competent organizations will provide additional input regarding
255 the threat level and in response to a security event.

256 The MANUFACTURER of ME EQUIPMENT containing high-activity RADIOACTIVE SOURCES will have
257 responsibility for the requirements that relate to the ME EQUIPMENT itself, such as the
258 equipment's design, the use of materials and components, and other measures that will
259 increase the equipment's physical resistance against attempts to remove the RADIOACTIVE
260 SOURCES unlawfully, including devices that provide a warning in case of such an attempt.

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

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

272 The methodology, including the numerical parameters expressed in EN1143-1:2019 "Secure
273 storage units – Requirements, classification and methods of test for resistance to burglary" –
274 Part 1: Safes, ATM safes, strongroom doors and strongrooms is used to quantify the required
275 physical resistance of SECURED ME EQUIPMENT against unauthorized removal of the RADIOACTIVE
276 SOURCE(s).

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SECURITY OF ME EQUIPMENT CONTAINING HIGH-ACTIVITY SEALED RADIOACTIVE SOURCES

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1 Scope, object and related standards

1.1 Scope

287 This document establishes security requirements of ME EQUIPMENT using high activity SEALED
288 RADIOACTIVE SOURCES, directly or indirectly, for medical treatment and other clinical procedures.
289 ME EQUIPMENT containing SEALED RADIOACTIVE SOURCES that are defined as Category 1, 2 and 3
290 radioactive sources by IAEA¹ are subject to this standard.

1.2 Object

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

298 The requirements of this standard apply when the RADIOACTIVE SOURCE(s) are contained in the
299 ME EQUIPMENT, i.e. from the time when the RADIOACTIVE SOURCE(s) are inserted into the ME
300 EQUIPMENT, during the INTENDED USE and when the ME EQUIPMENT is not being used for its
301 INTENDED PURPOSE or taken out of regular use, until the equipment is being decommissioned,
302 i.e. until all RADIOACTIVE SOURCE(s) are permanently removed from the equipment.

303

1.3 Related standards

305 The following ISO/IEC standards are related to the safety of ME EQUIPMENT containing
306 RADIOACTIVE SOURCES.

- 307 • IEC 60601-1-8: Medical electrical equipment — Part 1-8: General requirements for basic
308 safety and essential performance — Collateral standard: General requirements, tests
309 and guidance for alarm systems in ME EQUIPMENT and medical electrical systems
- 310 • IEC 60601-2-11: ME EQUIPMENT - Part 2-11: Particular requirements for the basic safety
311 and essential performance of gamma beam therapy equipment.
- 312 • IEC 60601-2-17: ME EQUIPMENT - Part 2-17: Particular requirements for the basic safety
313 and essential performance of automatically controlled brachytherapy afterloading
314 equipment.
- 315 • PD IEC/TR 80001-2-5: Application of risk management for IT-networks
316 incorporating medical devices – Part 2-5: Application guidance – Guidance on distributed
317 alarm systems.
- 318 • ISO 14971:2019: Medical devices – Application of risk management to medical devices
- 319 • ISO/TR 14971: Medical devices - Guidance on the application of ISO 14971.

320

¹ Categorization of radioactive sources – Vienna: International Atomic Energy Agency, 2005. (IAEA safety standards series, ISSN 1020-525X; no. RS-G-1.9) STI/PUB/1227 ISBN 92-0-103905-0.

321 The following Nuclear Safety Standards and Nuclear Security Guidance published by the
322 International Atomic Energy Agency (IAEA) are related to this standard:

- 323 • The IAEA Code of Conduct on the Safety and Security of Radioactive Sources IAEA,
324 Vienna, 2004.
- 325 • Nuclear security recommendations on radioactive material and associated facilities:
326 recommendations. — Vienna: 2011. - ISSN 1816–9317; no. 14, STI/PUB/1487 ISBN
327 987–92– 0–112110–3
- 328 • Categorization of radioactive sources. — Vienna, International Atomic Energy Agency,
329 2005., ISSN 1020–525X; STI/PUB/1227 ISBN 92–0–103905–0
- 330 • Security of radioactive sources: implementing guide. — IAEA nuclear security series,
331 ISSN 1816-9317; no. 11 STI/PUB/1387, ISBN 978-92-0-102609-5
- 332 • Nuclear security culture: implementing guide. — Vienna: International Atomic Energy
333 Agency, 2008. ISSN 1816– 317; no. 7 STI/PUB/1347 ISBN 978–92–0–107808–7.
- 334 • Computer Security Techniques for Nuclear Facilities, Technical Guidance. IAEA Nuclear
335 Security Series No. 17-T(Rev.1).STI/PUB/1921, ISBN 978-92-0-123620-3

336 2 Normative references

337 The following documents are referred to in the text in such a way that some or all their content
338 constitutes requirements of this document. For dated references, only the edition cited applies.
339 For undated references, the latest edition of the referenced document (including any
340 amendments) applies.

- 341 • IEC-60601-1: Medical electrical equipment – Part 1: General requirements for basic
342 safety and essential performance.
- 343 • EN-1143-1:2019: Secure storage units – Requirements, classification and methods of
344 test for resistance to burglary – Part 1: Safes, ATM safes, strongroom doors and
345 strongrooms

346 International treaties² contain obligations to be implemented by each State Party, i.e.,
347 commitments to make every effort to prevent unlawful access to radioactive materials, such as
348 SEALED RADIOACTIVE SOURCES. The international conventions that underpin this standard are:

- 349 • The Convention on the Physical Protection of Nuclear Material from 1979 which entered
350 into force in 1987 and its Amendment from 2005, which entered into force 2016.
- 351 • The International Convention on the Suppression of Acts of Nuclear Terrorism from
352 2005, which entered into force in 2007.

353 The Bibliography contains short-hand references to documents issued by other international
354 organizations of relevance for the content of this document.

355 3 Terms and definitions

356 IEC, ISO and the IAEA maintain terminology databases for use in standardization at the
357 following addresses:

- 358 • IEC glossary: available at <https://std.iec.ch/terms/terms.nsf/welcome?OpenForm>

² 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 standard, the MANUFACTURER(s) of ME EQUIPMENT and the RESPONSIBLE ORGANIZATION as the equipment user. This standard provides requirements for how the ME EQUIPMENT shall be secured to protect against unauthorized access of the RADIOACTIVE SOURCES contained and for 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.

- 359 • ISO Online browsing platform: available at <https://www.iso.org/obp>
- 360 • IAEA Nuclear Safety and Security Glossary, 2022 (Interim) Edition³: available at
- 361 <https://www.iaea.org/resources/publications/iaea-nuclear-safety-and-security-glossary>

362

363 **3.1**364 **ACCESS PATH**

365 The path or route that one or more persons can take to arrive at the desired location or point in
366 a defined location

367 **3.2**368 **ASSUMPTION OF THREAT**

369 the set of assumptions used to set the level of the threat. The ASSUMPTION OF THREAT is used
370 when performing risk assessments in general and VULNERABILITY ASSESSMENTS in particular

371 **3.3**372 **ATTACK PATHWAY**373 **AP**

374 the adversary must go through several time-ordered steps, where the steps may be the
375 exploitation of vulnerabilities, traversing areas and then the final step/task of defeating the
376 target

377 **3.4**378 **BASIC VALUE**379 **BV**

380 number in resistance units allocated to a particular tool

381 Note to entry: The basic value represents problems in obtaining, transporting, conditions (e.g. water cooling and
382 power availability) and using the relevant tool at the site in question, and the necessary knowledge and experience
383 for its efficient use.

384 [EN 1143-1:2019]

385 **3.5**386 **BOLTWORK**

387 mechanism by which a closed door is held such that, until it is in the withdrawn position, the
388 door cannot be opened

389 Note to entry: the term BOLTWORK is used only in Annex B.

390 [EN 1143-1:2019]

391 **3.6**392 **CABINET**

393 Storage unit which protects its contents against burglary and when closed has at least one
394 internal side \leq 1m length

395 Note to entry: The definition is adapted from the definition of a safe in EN1143-1:2019.

396 [EN 1143-1:2019]

³ IAEA nuclear safety and security glossary, Terminology used in nuclear safety, nuclear security, radiation protection and emergency preparedness and response, 2022 (Interim) Edition, International Atomic Energy Agency.

397 **3.7**
 398 **COMPLEMENTARY SECURITY ARRANGEMENT**
 399 Temporary SECURITY ARRANGEMENTS deemed necessary to protect against criminal or
 400 intentional unauthorized acts during the time permanent protective measures are disabled or
 401 absent or their effectiveness reduced

402 Note to entry: an example of a COMPLEMENTARY SECURITY ARRANGEMENT is a guard on duty when all or a part of the
 403 permanent protective measures are disabled, which may be the case during service and maintenance. Another
 404 example when COMPLEMENTARY SECURITY ARRANGEMENTS may be needed is when moving an equipment between two
 405 protected areas.

406 **3.8**
 407 **DUMMY SOURCE**
 408 Source capsule without radioactive material inside with the same form and exterior dimensions
 409 as the SEALED SOURCE used in the ME EQUIPMENT

410 Note to entry: dummy sources are used during testing of the ME EQUIPMENT to establish the RESISTANCE GRADE.

411 **3.9**
 412 **INSIDER THREAT**
 413 Threat of an INSIDER planning for or obtaining illicit access to the RADIOACTIVE SOURCE(s) in the
 414 ME EQUIPMENT

415 **3.10**
 416 **INTRINSIC SECURITY**
 417 The protection against unauthorized attempts to remove the RADIOACTIVE SOURCES that is either
 418 built into the ME EQUIPMENT or added to or attached to the ME EQUIPMENT during installation, and
 419 that will remain attached to the ME EQUIPMENT during NORMAL USE

420 **3.11**
 421 **INTRUSION**
 422 Unauthorized act of compromising a system

423 Note to entry: the definition has been modified.

424 [IEC 62443-1-1, ed. 1.0 (2009)]

425 **3.12**
 426 **INTRUSION DETECTION SYSTEM**
 427 A system that contains the capability to detect an INTRUSION and also contains an alarm function
 428 that is activated should an INTRUSION be detected

429 **3.13**
 430 **OPERATING TIME**
 431 time during which a tool is used attempting to create a change in the test specimen

432 Note to entry: In the context of this standard, there are also operating times considered during which no visible
 433 modifications/changes are caused to the test specimen.

434 [EN 1143-1:2019]

435 **3.14**
 436 **RESISTANCE GRADE**
 437 classification designation for burglary resistance

438 [EN 1143-1:2019]