



DPC: 23/30475449 DC

BSI Group Headquarters

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000

Fax: +44 (0)20 8996 7400

www.bsigroup.com

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Interested committees:

Title: Draft BS EN IEC 63322 Security of Medical Electrical Equipment Containing High-Activity Sealed Radioactive Sources.

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



62C/873/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER:

IEC 63322 ED1

DATE OF CIRCULATION:

2023-06-09

CLOSING DATE FOR COMMENTS:

2023-08-04

SUPERSEDES DOCUMENTS:

62C/800/CD, 62C/810A/CC

IEC SC 62C : EQUIPMENT FOR RADIOTHERAPY, NUCLEAR MEDICINE AND RADIATION DOSIMETRY

SECRETARIAT:

Germany

SECRETARY:

Ms Regina Geierhofer

OF INTEREST TO THE FOLLOWING COMMITTEES:

PROPOSED HORIZONTAL STANDARD:



Other TC/SCs are requested to indicate their interest, if any, in this CD to the secretary.

FUNCTIONS CONCERNED:

☒ EMC

☐ ENVIRONMENT

☒ QUALITY ASSURANCE

☒ SAFETY

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Recipients of this document are invited to submit, with their comments, notification of any local regulations or technical reasons that may exist and should be considered should this proposal proceed, recognizing that failure to address such requirements could result in the need for new or existing "In Some Countries" clauses. (SEE [AC/22/2007](#) OR [NEW GUIDANCE DOC](#)).

TITLE:

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

NOTE FROM TC/SC OFFICERS:

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162	probability that an attempt to exploit Vi is detected.	65
163		
164		
165		

INTERNATIONAL ELECTROTECHNICAL COMMISSION

**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 containing requirements to protect the MEDICAL ELECTRICAL EQUIPMENT using high-activity radioactive sources against unauthorized access for malicious purposes. The standard complements safety standards by addressing risks such as the unauthorized removal, and other malicious use, of the radioactive sources contained in the equipment.

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

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

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

220
221 Full information on the voting for its approval can be found in the report on voting indicated in
222 the above table.

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

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

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

- 232 • reconfirmed,
233 • withdrawn,
234 • replaced by a revised edition, or
235 • amended.

236

INTRODUCTION

No patent rights identified.

Aware of the need and the urgency for a standard that aims at protecting ME EQUIPMENT containing high-activity 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 standard addresses security of ME EQUIPMENT, and therefore deviates somewhat from the structure established by 60601-1 for standards that are defined as safety standards only. This standard does not in any way impact on the implementation of, or adherence to, the requirements of 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 radioactive sources. This standard establishes security requirements for the two entities based on an assumption of the threat. The appropriate national regulators and other competent organizations will provide additional input regarding the threat level and in response of a security event.

The MANUFACTURER of ME EQUIPMENT containing high-activity 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 resistance against attempts to steal the radioactive sources contained, 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 supported by the leadership of the RESPONSIBLE ORGANIZATION will be both necessary and important to maintain effectiveness of the security system.

The requirements of this standard will be objectively tested by an accredited test house. A certificate will communicate compliance with this standard 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 may succeed in attempts to illegally access and remove the radioactive sources from the ME EQUIPMENT.

The methodology, including the numerical parameters expressed in EN1143-1:2019 "Secure storage units – Requirements, classification and methods of test for resistance to burglary" – Part 1: Safes, ATM safes, strongroom doors and strongrooms¹ is used to quantify the required resistance of ME EQUIPMENT against unauthorized removal of the radioactive source(s).

¹EN1143-1:2019. Secure storage units – Requirements, classification and methods of test for resistance to burglary – Part 1: Safes, ATM safes, strongroom doors and strongrooms,

SECURITY OF ME EQUIPMENT CONTAINING HIGH-ACTIVITY SEALED RADIOACTIVE SOURCES

1 Scope, object and related standards

1.1 Scope

This document establishes security requirements of ME EQUIPMENT using high activity SEALED SOURCES, directly or indirectly, for medical treatment and other clinical procedures. ME EQUIPMENT containing SEALED SOURCES that are defined as Category 1, 2 and 3 radioactive sources by IAEA² are subject to this standard.

1.2 Object

The object of this standard is to specify requirements for the security of ME EQUIPMENT containing high activity SEALED SOURCES(s) with the aim to minimize the risk of unauthorized access to the contained sources, and to serve as the basis for particular standards. This standard 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 standard apply when the radioactive source(s) are contained in the ME EQUIPMENT, i.e. from the time when the radioactive sources are inserted into the ME EQUIPMENT, during the intended medical use and when the ME EQUIPMENT is not being used for its intended purpose or taken out of regular use, until the equipment is being decommissioned, i.e. until all radioactive sources are permanently removed.

1.3 Related standards

The following ISO/IEC standards are related to the safety of ME EQUIPMENT containing radioactive sources.

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

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

² 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.

- The IAEA Code of Conduct on the Safety and Security of Radioactive Sources IAEA, Vienna, 2004 © IAEA.
- Nuclear security recommendations on radioactive material and associated facilities: recommendations. — Vienna: 2011. - ISSN 1816-9317; no. 14, STI/PUB/1487 ISBN 987-92-0-112110-3
- Categorization of radioactive sources. — Vienna, International Atomic Energy Agency, 2005., ISSN 1020-525X; STI/PUB/1227 ISBN 92-0-103905-0
- Security of radioactive sources: implementing guide. — IAEA nuclear security series, ISSN 1816-9317; no. 11 STI/PUB/1387, ISBN 978-92-0-102609-5
- Nuclear security culture: implementing guide. — Vienna: International Atomic Energy Agency, 2008. ISSN 1816-317; no. 7 STI/PUB/1347 ISBN 978-92-0-107808-7.

2 Normative references

The following documents are referred to in the text in such a way that some or all 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: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
- 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

International treaties³ 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. The international conventions that underpin this standard are:

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

The Bibliography contains short-hand references to documents issued by other international organizations of relevance for the content of this document. **[To be completed]**

3 Terms and definitions

IEC, ISO and the IAEA 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>

³ 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 MANUFACTURERS 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.

- IAEA Nuclear Safety and Security Glossary, 2022 (Interim) Edition⁴: available at <https://www.iaea.org/resources/publications/iaea-nuclear-safety-and-security-glossary>

3.1

ACCESS CONTROL

The process by which access to a defined location/object is regulated according to a security policy, and is permitted by only authorized entities (users, processes, or other systems) according to that policy.

[IEC 62918, ed 1.0, 2014]

3.2

ACCESS PATH

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

3.3

ACCOMPANYING DOCUMENTS

document accompanying ME EQUIPMENT, and ME SYSTEM, equipment or an ACCESSORY and containing information for the RESPONSIBLE ORGANIZATION or OPERATOR, particularly regarding BASIC SAFETY, ESSENTIAL PERFORMANCE and SECURITY ARRANGEMENTS

[IEC 60601-1 Ed.3.2, with addition]

3.4

ASSUMPTION OF THREAT

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

3.5

ATTACK PATHWAY

AP

the adversary must go through a number of time-ordered steps, where the steps may be the exploitation of vulnerabilities, traversing areas and then the final step/task of defeating the target.

3.6

BASIC VALUE

BV

number in resistance units allocated to a particular tool.

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

[EN 1143-1:2019]

3.7

BOLTWORK

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

⁴ 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.

393 [EN 1143-1:2019]

394 **3.8**

395 **DUMMY SOURCE**

396 source capsule without radioactive material inside. A dummy source shall have the same form
397 and exterior dimensions as the SEALED SOURCE used in the ME EQUIPMENT.

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

399 **3.9**

400 **ESSENTIAL PERFORMANCE**

401 The performance of a clinical function, other than that related to BASIC SAFETY, where loss or
402 degradation beyond the limits specified by the MANUFACTURER results in an unacceptable RISK.

403 Note ESSENTIAL PERFORMANCE is most easily understood by considering whether its absence or degradation would
404 result in an unacceptable RISK.

405 [IEC 60601-1:ed 3.2, 2020]

406 **3.10**

407 **EXTRINSIC SECURITY**

408 ME EQUIPMENT whose protection against attempts to remove the radioactive sources is partly
409 dependent upon materials incorporated into it, or attached to it, during installation

410 Note 1 to entry: ME EQUIPMENT partly covered by protective building elements such as floor or wall are special types
411 of ME EQUIPMENT with extrinsic security.

412 Note 2 to entry: adapted from EN 1143-1:2019, definition 3.3

413 **3.11**

414 **INSIDER**

415 Trusted person, employee, contractor or supplier, that has information that is not generally
416 known to the public.

417 [SOURCE: IEC62443-1-1, ed 1.0 2009]

418 **3.12**

419 **INSIDER THREAT**

420 The threat that someone, employed by or having a close relationship with the RESPONSIBLE
421 ORGANIZATION, with detailed knowledge of or access to knowledge about an organization's
422 infrastructure (building lay-out, physical properties, operation, computer network and ME
423 EQUIPMENT) that can be used in planning for or performing a security event aimed at obtaining
424 access to the radioactive sources in the ME EQUIPMENT.

425 **3.13**

426 **INTRINSIC SECURITY**

427 when the protection against attempts to remove the radioactive sources only depends upon the
428 materials and construction of its primary manufacture and not upon materials added or attached
429 during installation.

430 Note to entry: adapted from EN 1143-1:2019, definition 3.2

431 **3.14**

432 **INTRUDER**

433 A person that trespasses on the controlled areas in which the medical equipment is used or stored, to
434 obtain unauthorized access to the ME EQUIPMENT and the radioactive sources contained.

3.15**MANUFACTURER**

natural or legal person with responsibility for the design, manufacture, packaging, or labelling of ME EQUIPMENT, assembling an ME SYSTEM, or adapting ME EQUIPMENT or an ME SYSTEM, regardless of whether these operations are performed by that person or on his behalf by another person(s)

NOTE 1 ISO 13485 [30] defines “labelling” as “label, instructions for use, and any other information that is related to identification, technical description, INTENDED PURPOSE and proper use of the ME EQUIPMENT or ME SYSTEM, but excluding shipping documents”.

NOTE 2 “Adapting” includes making substantial modifications to ME EQUIPMENT or an ME SYSTEM already in use.

NOTE 3 In some jurisdictions, the RESPONSIBLE ORGANIZATION can be considered a MANUFACTURER when involved in the activities described.

NOTE 4 Adapted from ISO 14971:2019, definition 3.9.

[IEC 60601-1:ed 3.2, 2020]

3.16**MEDICAL ELECTRICAL EQUIPMENT****ME EQUIPMENT, MEE**

electrical equipment having an APPLIED PART or transferring energy to or from the PATIENT or detecting such energy transfer to or from the PATIENT and which is:

1. provided with not more than one connection to a particular SUPPLY MAINS; and intended by its MANUFACTURER to be used: in the diagnosis, treatment, or monitoring of a PATIENT; or for compensation or alleviation of disease, injury or disability

NOTE 1 ME EQUIPMENT includes those ACCESSORIES as defined by the MANUFACTURER that are necessary to enable the NORMAL USE of the ME EQUIPMENT.

NOTE 2 Not all electrical equipment used in medical practice falls within this definition (e.g. some in vitro diagnostic equipment).

NOTE 3 The implantable parts of active implantable medical devices can fall within this definition, but they are excluded from the scope of this standard by appropriate wording in Clause 1.

NOTE 4 This standard uses the term “electrical equipment” to mean ME EQUIPMENT or other electrical equipment.

[IEC 60601-1:ed 3.2, 2020]

3.17**MOBILE**

term referring to TRANSPORTABLE equipment that, once installed and placed into service, is intended to be moved from one location to another while supported by its own wheels or equivalent means

[IEC 60601-1:ed 3.2, 2020]

3.18**OPERATOR**

person handling equipment

[IEC 60601-1:ed 3.2, 2020]

3.19**OPERATING TIME**

time during which a tool is used attempting to create a change in the test specimen

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

[EN 1143-1:2019]

3.20**RESISTANCE GRADE**

classification designation for burglary resistance

[EN 1143-1:2019]

3.21**RESISTANCE UNIT****RU**

burglary resistance which results from one minute's use of a tool carrying the coefficient 1 and the basic value 0

[EN 1143-1:2019]

3.22**RESISTANCE VALUE**

numerical value in resistance units calculated for each test

[EN 1143-1:2019]

3.23**RESPONSIBLE ORGANIZATION**

entity accountable for the use and maintenance of an ME EQUIPMENT or an ME SYSTEM

NOTE 1 The accountable entity can be, for example, a hospital, an individual clinician or a layperson. In home use applications, the PATIENT, OPERATOR and RESPONSIBLE ORGANIZATION can be one and the same person.

NOTE 2 Education and training is included in "use."

[IEC 60601-1:ed 3.2, 2020]

3.24**SEALED SOURCE**

radioactive material sealed in a capsule or associated with a material to which it is closely bonded, this capsule or bonding material being strong enough to maintain leaktightness of the sealed source under the conditions of use and wear for which it was designed

[ISO 9978:2020]

3.25**SECURED ME EQUIPMENT**

MEDICAL ELECTRICAL EQUIPMENT that complies with the requirements for security in this standard.

3.26**SECURITY ARRANGEMENT (MEASURES)**

Measures intended to prevent a nuclear security threat from completing criminal or intentional unauthorized acts involving or directed at nuclear material, other radioactive material, associated facilities, or associated activities or to detect or respond to nuclear security events.

518 [IAEA Nuclear Safety and Security Glossary, 2022 (Interim) Edition]

519 **3.27**

520 **SECURITY CULTURE**

521 The continued recognition of security in the overall and specific management of ME EQUIPMENT.

522 **3.28**

523 **SECURITY GROUP**

524 ME EQUIPMENT subject to this standard that contains SEALED RADIOACTIVE SOURCES of IAEA
525 category 1 or category 2, or category 3. Such ME EQUIPMENT, for the purposes of this standard,
526 is grouped into three SECURITY GROUPS A, B and C, with different security requirements.

527 **3.29**

528 **SITE SECURITY GUIDE**

529 A planning guide written by the MANUFACTURER giving a suggested outline of the SECURITY
530 ARRANGEMENTS to be considered for the security of the location in which the ME EQUIPMENT is
531 used or stored.

532 **3.30**

533 **SITE SECURITY MANUAL**

534 A manual documenting the policies and procedures that the RESPONSIBLE ORGANIZATION has
535 adopted according to the requirements of this standard.

536 **3.31**

537 **STATIONARY**

538 term referring to equipment that, once installed and placed into service, is not intended to be
539 moved from one place to another

540 [IEC 60601-1:ed 3.2, 2020]

541 **3.32**

542 **STRONGROOM**

543 storage unit which protects against burglary and when closed has internal side lengths in all
544 directions > 1 m

545 Note to entry: Strongrooms may be cast *in situ*, constructed from pre-fabricated elements or a combination of both.

546 [EN 1143-1:2019]

547 **3.33**

548 **STRONGROOM DOOR**

549 door with lock(s), BOLTWORK and frame intended for giving access to a STRONGROOM

550 [EN 1143-1:2019]

551 **3.34**

552 **TO BOLT**

553 to throw the BOLTWORK or the bolt of the lock (if there is no BOLTWORK) to a position where it
554 fixes the door in closed position

555 [EN 1143-1:2019]

556 **3.35**

557 **TO LOCK**

558 to block a thrown BOLTWORK by action of a lock

559 [EN 1143-1:2019]

3.36**TO CLOSE**

to move the door so that it becomes possible to bolt it.

[EN 1143-1:2019]

3.37**TOOL COEFFICIENT**

number in resistance units per minute allocated to a group of tools

Note 1 to entry: For Annex B. A: The tool coefficient represents factors such as noise, smoke, fumes and other effects, which increase the likelihood of a burglary attack being detected.

Note 2 to entry: The tool coefficient represents tool efficiency and factors such as noise, smoke, fumes and other effects, which increase the likelihood of a burglary attack being detected.

[EN 1143-1:2019]

3.38**TRANSPORTABLE**

term referring to equipment that, **once installed and placed into service**, is intended to be moved from one place to another whether or not connected to a supply and without an appreciable restriction of range

Example MOBILE equipment, PORTABLE equipment. and BODY-WORN equipment

[IEC 60601-1:ed 3.2, 2020]

3.39**VULNERABILITY**

circumstances that have the potential to directly lead to, or to be a required part of, a successful removal of the source(s) from a ME EQUIPMENT.

3.40**VULNERABILITY ASSESSMENT****VA**

Formal description and evaluation of the vulnerabilities in a system.

[IEC 62443-2-1, ed 1.0, 2010]

4 Overview of requirements and responsibilities

Both the MANUFACTURER and the RESPONSIBLE ORGANIZATION have responsibilities to ensure that ME EQUIPMENT with high activity SEALED SOURCES can be used securely, and this standard includes, separately, requirements for the MANUFACTURER and for the RESPONSIBLE ORGANIZATION, respectively. This Clause gives an overview of the requirements on the MANUFACTURER and the RESPONSIBLE ORGANIZATION. All explicit requirements are listed in Clauses 6 and 7, respectively.

The MANUFACTURER will address all requirements related to the design and construction of the ME EQUIPMENT, and the RESPONSIBLE ORGANIZATION will address the requirements related to the local installation and organizational measures to be implemented.

The SECURITY ARRANGEMENTS made by the MANUFACTURER or by the RESPONSIBLE ORGANIZATION shall not affect the INTENDED USE, the ESSENTIAL PERFORMANCE, BASIC SAFETY, and serviceability, as defined in IEC 60601-1, (including amendments) and collateral standards.

The requirements stated in this standard for the ME EQUIPMENT shall be met regardless of if the SECURITY ARRANGEMENTS are integrated in a new ME EQUIPMENT or if they are retrofitted to an existing model of the ME EQUIPMENT.

Technical documentation, manuals, and procedures required for the operation and storage of the ME EQUIPMENT may contain security sensitive information. The MANUFACTURER and the RESPONSIBLE ORGANIZATION shall ensure that the information is protected.

4.1 Assumption of threat

Security risk management and VULNERABILITY ASSESSMENT shall be performed under the following ASSUMPTION OF THREAT:

- the intrusion is performed by a small group of perpetrators that could blend in with the categories of people that are normally found at the site
- an INSIDER may be involved
- the location of the ME EQUIPMENT is known
- the perpetrators have full information regarding the construction of the ME EQUIPMENT
- operating procedures and control functions for the ME EQUIPMENT are known
- the perpetrators will have access to hand/machine tools
- the attack may be assisted by cyber intrusion into the ME EQUIPMENT's control system.

It is assumed that the tools carried by the perpetrators have capacities and characteristics that are comparable to the capacities and characteristics of the tools used to test compliance of the ME EQUIPMENT with the required RESISTANCE GRADE.

4.2 Vulnerability assessment

The vulnerability of ME EQUIPMENT in this context is an assessment of the ease with which an unauthorized person can access the ME EQUIPMENT itself, and then remove the source contained in the ME EQUIPMENT. The results of the VULNERABILITY ASSESSMENT serve as the basis for the design of the SECURITY ARRANGEMENTS required for the ME EQUIPMENT, as well as for the security measures in the location in which the ME EQUIPMENT is used or stored. The ASSUMPTIONS OF THREAT stated in Clause 4.1 will be used in the assessment. Annex C contains a guide to the performance of a VULNERABILITY ASSESSMENT by the MANUFACTURER and the RESPONSIBLE ORGANIZATION.

4.3 Required resistance of three groups of ME equipment

The ME EQUIPMENT subject to this standard contains SEALED SOURCES with different activities (A). The IAEA has analyzed most radionuclides and established the activity above which the security of the sources should be considered. This activity value is referred to as the D-value of the radionuclide. The IAEA has grouped the sources into five categories based on the A/D-ratios (denoted A/D-values). ME EQUIPMENT subject to this standard contains SEALED SOURCES of IAEA categories 1-3. Such ME EQUIPMENT, for the purposes of this standard, is grouped into three SECURITY GROUPS, A, B and C according to Table 1.

Table 1 – ME EQUIPMENT, SECURITY GROUPS and RESISTANCE GRADE requirement

SECURITY GROUP of ME EQUIPMENT	Radioactive Source Category	Required RESISTANCE GRADE
A	1	III
B	2	II
C	3	I

640

641 The specific security requirements for the different SECURITY GROUPS are given in Clause
642 6.

643 This standard uses the methodology developed for the standard EN 1143-1:2019 to define the
644 requirement of resistance for ME EQUIPMENT containing radioactive sources. It also aligns to EN
645 1143 for the procedure to be applied in the testing of compliance with the required RESISTANCE
646 GRADE. The methodology and testing procedure is given in Annex B.

647 **4.4 SECURITY CULTURE**

648 The implementation of a SECURITY CULTURE, supported by the executive leadership of the
649 RESPONSIBLE ORGANIZATION, is essential to obtain effective security of the ME EQUIPMENT of
650 SECURITY GROUPS A-C. The SECURITY CULTURE will recognize the necessity of effective ACCESS
651 CONTROL, information security as well as the importance of informed and competent staff. The
652 principles applied will be documented and included in the RESPONSIBLE ORGANIZATION'S SITE
653 SECURITY MANUAL.

654 **4.5 Responsibilities for the security of ME EQUIPMENT of SECURITY GROUPS A, B and C**

655 Both the MANUFACTURER and the RESPONSIBLE ORGANIZATION have responsibilities to ensure that
656 ME EQUIPMENT of SECURITY GROUPS A, B and C can be installed, used, and stored securely. The
657 responsibilities for the two entities differ. This standard formulates the requirements that must
658 be met by the MANUFACTURER (Clause 6) and the RESPONSIBLE ORGANIZATION (Clause 7) to fulfill
659 the responsibilities.

660 **4.5.1 Overview of Requirements for the MANUFACTURER**

661 To comply with this standard, the MANUFACTURER will determine the SECURITY GROUP of the ME
662 EQUIPMENT and perform a VULNERABILITY ASSESSMENT of the ME EQUIPMENT. The result of the
663 VULNERABILITY ASSESSMENT will serve as the input to the design and construction of the SECURITY
664 ARRANGEMENTS deemed necessary to meet the required RESISTANCE GRADE. The MANUFACTURER
665 can also comply with this standard by offering a cabinet that meets the resistance requirements
666 of this standard or by only allowing the ME EQUIPMENT (containing radioactive sources) to be
667 placed in a room (a strongroom) that meets the resistance requirements of this standard. The
668 STRONGROOM is the RESPONSIBLE ORGANIZATION'S responsibility, but the MANUFACTURER can still
669 comply with this standard if the MANUFACTURER can provide evidence that the ME EQUIPMENT will
670 not be equipped with radioactive sources unless the following information has been obtained
671 by the MANUFACTURER

- 672 • a certificate that the STRONGROOM meets the requirements of this standard verified
673 according to EN1143-1:2019, or
- 674 • a documented assessment of the design and construction of the STRONGROOM made by an
675 accredited test house including a statement that the STRONGROOM meets requirements on
676 par with the requirements stated in this standard, or
- 677 • a statement from the authority issuing the RESPONSIBLE ORGANIZATION'S license to operate,
678 that the national security requirements for the STRONGROOM the RESPONSIBLE ORGANIZATION
679 is obliged to comply with, permits the placement of the ME EQUIPMENT in question in that
680 room.

681 An intrusion detection system will be applied to the ME EQUIPMENT to detect unauthorized
682 attempts to access the sources. The ACCOMPANYING DOCUMENTS provided by the MANUFACTURER
683 to the RESPONSIBLE ORGANIZATION will include information how to connect and integrate the
684 intrusion detection system to the RESPONSIBLE ORGANIZATION'S security system. The
685 ACCOMPANYING DOCUMENTS will also provide evidence that the ME EQUIPMENT meets the
686 requirements of ESSENTIAL PERFORMANCE under normal use, service and maintenance. The
687 MANUFACTURER will further provide information and guidance regarding appropriate

688 complementary SECURITY ARRANGEMENTS that should be considered by the RESPONSIBLE
689 ORGANIZATION; this information will be provided in a SITE SECURITY GUIDE.

690 4.5.2 Overview of Requirements for the RESPONSIBLE ORGANIZATION

691 To comply with this standard, the RESPONSIBLE ORGANIZATION will perform a VULNERABILITY
692 ASSESSMENT of the premises in which the ME EQUIPMENT is used or stored. The RESPONSIBLE
693 ORGANIZATION will provide the necessary interface, as specified by the MANUFACTURER, to
694 connect the intrusion detection system used for the ME EQUIPMENT to the security system used
695 by the RESPONSIBLE ORGANIZATION. In case the ME EQUIPMENT will be placed in a STRONGROOM,
696 to comply with this standard, the RESPONSIBLE ORGANIZATION must provide evidence that the
697 STRONGROOM meets the resistance requirements stated in this standard. For MOBILE ME
698 EQUIPMENT, the RESPONSIBLE ORGANIZATION will provide an anchoring point that fulfils the
699 requirements in this standard in every room where the ME EQUIPMENT will be used for clinical
700 purposes.

701 The RESPONSIBLE ORGANIZATION will ensure that the SECURITY ARRANGEMENTS implemented does
702 not delay access to the treatment room in the case of a medical emergency during ongoing
703 treatment. This standard will require the RESPONSIBLE ORGANIZATION to control access to the
704 locations/rooms in which the ME EQUIPMENT is used or stored. These rooms will be given the
705 appropriate markings and signages of hosting ME EQUIPMENT containing radioactive sources.

706 The RESPONSIBLE ORGANIZATION will maintain a SITE SECURITY MANUAL to document the SECURITY
707 ARRANGEMENTS and procedures, including the implementation of a SECURITY CULTURE. Sensitive
708 security related information, e.g., the VULNERABILITY ASSESSMENT and its results and the ACCESS
709 CONTROL SYSTEM, will be protected as highly confidential information.

710 5 General requirements for testing of ME EQUIPMENT of security groups A, B 711 and C

712 5.1 Type and Site Tests

713 ME EQUIPMENT of SECURITY GROUPS A, B and C will be submitted to TYPE TESTS and inspections,
714 as required, to establish compliance with the requirements of Clause 6 of this standard.

715 Security arrangements made by the RESPONSIBLE ORGANIZATION for the location in which the ME
716 EQUIPMENT is used or stored, will be subject to SITE TESTS and inspections to establish
717 compliance with the requirements of Clause 7 of this standard.

718 All tests and inspections shall be documented. For TYPE TESTS, reference is made to Annex B.

719 5.1.1 Test grades

720 5.1.1.1 For the Manufacturer

721 Three grades of TYPE TESTS and inspection are used in this standard. Their requirements are
722 as follows:

723 **TYPE TEST grade A:** (For the MANUFACTURER) An analysis of ME EQUIPMENT design, as related
724 to the requirements in this standard, which shall result in a statement included in the technical
725 description, regarding the working principles or constructional means by which the requirements
726 are fulfilled.

727 **TYPE TEST grade B:** (For the MANUFACTURER) Visual inspection or functional test or
728 measurement of the ME EQUIPMENT. The test shall be in accordance with the procedure specified
729 in this standard and shall be based on operating states, including fault condition states, which
730 are achievable only without interference with the circuitry or construction of the ME EQUIPMENT.

TYPE TEST grade C: (For the MANUFACTURER) Functional test or measurement of the ME EQUIPMENT. The test shall be in accordance with the principle specified in this standard.

Inspection: The required function, as specified in Clause 6, is inspected, and the result of inspection is documented.

5.1.1.2 For the Responsible Organization

One grade of SITE TEST and inspection are used in this standard.

SITE TEST grade B: (For the RESPONSIBLE ORGANIZATION) Visual inspection or functional test or measurement of the components constituting the SECURITY ARRANGEMENTS and their interactions at the facility housing the ME EQUIPMENT. The tests shall be in accordance with the procedures specified in this standard and shall be based on operating states, including fault condition states, which are achievable only without interference with the circuitry or construction of the ME EQUIPMENT. Already available evidence of compliance, e.g. certificates of compliance may be used.

Inspection: The required function, as specified in Clause 7, is inspected, and the result of inspection is documented.

5.2 Determination of the RESISTANCE GRADE

ME EQUIPMENT that is designed and constructed to resist a tool attack aimed to create an opening in the device to remove the radioactive sources, may be associated with a degree of robustness that will help resist the attack and protect the radioactive sources from being removed. This property is referred to as the equipment's resistance. The determination of whether the ME EQUIPMENT complies with the resistance requirements of this standard, expressed as the required RESISTANCE GRADE for the SECURITY GROUP the specific ME EQUIPMENT belongs to, is conducted as a TYPE TEST grade C (Clause 6).

When ME EQUIPMENT is kept in a cabinet, the cabinet will have the same requirement on resistance grade as the ME EQUIPMENT. The resistance grade of a cabinet is determined in the same way as the resistance grade for the ME EQUIPMENT, as described in Clause 5.3.1 and Annex B. Similarly, when ME EQUIPMENT is used and/or stored in a STRONGROOM, the STRONGROOM shall comply with the same resistance requirements as the ME EQUIPMENT placed in the STRONGROOM. Providing the evidence of the resistance of a STRONGROOM is normally the responsibility of the RESPONSIBLE ORGANIZATION.

5.2.1 Calculation of resistance values to determine compliance with the required Resistance Grade

A tool attack is characterized and quantized by the tools used, the time the tools are used (denoted the OPERATING TIME) and the characteristics of the tools used. The OPERATING TIME is the time during which a tool is used attempting to create a change in the test specimen, which then implies that the time it takes to e.g. replace a broken tool or to select another drill bit is not included in the OPERATING TIME. A tool is characterized by its BASIC VALUE (BV), measured in RESISTANCE UNITS, which represents problems in obtaining, transporting, using and operating the relevant tool at the site in question, including the necessary knowledge and experience for its efficient use. Another characteristic of a tool is its TOOL COEFFICIENT, measured in RESISTANCE UNITS per minute. The TOOL COEFFICIENT represents factors such as noise, smoke, fumes and other effects, which increase the likelihood of a burglary attack being detected. The RESISTANCE VALUE, V_R , for a tool attack test is calculated according to the following expression

(equation 1 in ref. 1143):

$$V_R = (\sum t \cdot c) + \sum BV \quad (1)$$

776 Where t is the OPERATING TIMES, c is the highest TOOL COEFFICIENT of the attack tools used and
 777 Σ BV is the sum of the BASIC VALUES for all attack tools used.

778 If the V_R is equal to that specified for the required RESISTANCE GRADE, the test has been
 779 successful in that the equipment meets the required resistance. If the V_R is less than required,
 780 the equipment has failed the test.

781 See Annex B for a description of the test procedure.

782 5.3 Certificate of compliance

783 Compliance with this standard is obtained by providing evidence that the requirements stated
 784 in this standard are met. Evidence, normally obtained from an accredited test-house, or as the
 785 result of an inspection, shall be provided to a certification body accredited to issue certificates
 786 for this standard.

787 5.3.1 Complying with the required RESISTANCE GRADE of the ME equipment

788 A certificate of compliance with the requirements on RESISTANCE GRADE in this standard can be
 789 obtained by the MANUFACTURER by two different routes;

790 A. Approved results after testing according to the test procedures described in this
 791 standard

792 B. Approved results after testing according to the test procedures described in EN 1143-
 793 1:2019

794 The certificate issued after following route A shall state that the ME EQUIPMENT fulfills the
 795 requirements stated in this standard.

796 The certificate issued after following route B shall state that the ME EQUIPMENT fulfills the
 797 requirements on RESISTANCE GRADE stated in this standard, and that the fulfillment of the
 798 requirements have been verified by testing according to EN 1143-1:2019. See also Annex B.

799 6 Requirements for security of ME EQUIPMENT belonging to SECURITY GROUPS A, 800 B and C

801 Compliance with the requirements in this Clause rests upon the MANUFACTURER.

802 6.1 SECURITY GROUP of the ME EQUIPMENT

803 The MANUFACTURER shall determine the SECURITY GROUP of the ME EQUIPMENT (Clause 4.1, Table
 804 1). An overview of the requirements for mechanical protection of the ME EQUIPMENT is given in
 805 Table 6.1

806 **Table 2 Mechanical protection requirements for ME EQUIPMENT of SECURITY GROUP A-C**

Equipment	Security	SECURITY GROUP ^(***)	RESISTANCE GRADE	Anchoring [kN]
Stationary	Intrinsic/Extrinsic	A	3	50 ^(*)
		B	2	50 ^(*)
		C	1	50 ^(*)
	Cabinet or STRONG ROOM ^(****)	A	3	N/A
		B	2	N/A
		C	1	N/A