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Interested committees:

Title: Draft BS IEC 63322 Ed.1.0 Security of Medical Electrical Equipment Containing High-Activity Sealed Radioactive Sources.

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- iii) requires additional national guidance or information

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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 Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.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

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

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	Commend (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/800/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER: IEC 63322 ED1	
DATE OF CIRCULATION: 2021-01-08	CLOSING DATE FOR COMMENTS: 2021-04-02
SUPERSEDES DOCUMENTS: 62C/757/NP, 62C/761/RVN	

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	

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

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IEC 63322 has been prepared by subcommittee 62C: Equipment for Radiotherapy, Nuclear Medicine, and Radiation Dosimetry of IEC technical committee Electrical Equipment in Medical Practice. It is an International Security Standard, containing requirements to protect the electrical medical equipment using high-activity radioactive sources against unauthorized access for malicious purposes. The standard complements safety standards by addressing external risks such as theft and other malicious use of contained radioactive sources.

This standard, which will complement the general standard 60601-1, is the first security standard published by the IEC. It provides additional requirements that are directed to manufacturers of ME equipment and to the responsible organization using the ME equipment, respectively. The text of this International Standard is based on the following documents:

Draft	Report on voting
XX/XX/FDIS	XX/XX/RVD

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

140 The language used for the development of this International Standard is.

141 This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in
142 accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available
143 at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are
144 described in greater detail at <http://www.iec.ch/standardsdev/publications>.

145

146

INTRODUCTION

147 Aware of the need and the urgency for a standard that aims at protecting medical electrical
148 equipment with high-activity radioactive sources from unauthorized access by terrorists or
149 criminals, a majority of the National Committees voted in February 2020 in favour of establishing
150 a security standard to address that risk. The extent of the scope, the complexity of the
151 equipment concerned, and the specific nature of some of the protective measures and the
152 corresponding tests for verifying them, require competence in security.

153 Security of ME equipment with high-activity radioactive sources is a combination of measures
154 at the equipment itself, i.e. its design and construction and measures in the location where the
155 equipment is used or stored. The requirements of this standard that relate to the design and
156 construction of ME equipment are directed towards the manufacturer and requirements
157 regarding the use and storage of the equipment and the contained radioactive sources [after
158 delivery and acceptance of the ME equipment until the radioactive sources have been removed
159 or disposed] are directed to the responsible organization.

160 The manufacturer and the responsible organization share responsibility for the security in the
161 use of ME equipment. Any modification in the threat level, such as heightened level, will have
162 to be dealt with by the responsible organization in communication with the regulator and other
163 national responsible organization.

164 Although this standard is not a safety standard, it does not impact on, the requirements of
165 60601-1 regarding basic safety and essential performance

166

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

1 Scope

This document applies to MEDICAL ELECTRICAL EQUIPMENT using HIGH ACTIVITY SEALED RADIOACTIVE SOURCES for medical treatment and other clinical procedures. The sources considered by this standard include Category 1, 2 and 3 sources as defined by IAEA¹.

This document addresses the design criteria of the equipment that protects the radioactive sources from unauthorized access, provides requirements and guidance for assessing their level of security [requirements that are relevant for the manufacturer] and provides requirements for location of use or storage [requirements that are relevant for the responsible organization].

This document specifies what the accompanying documentation shall contain regarding the security arrangements applying to the room housing the ME equipment containing high activity sealed radioactive sources.

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.

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.

60601-1 Ed 3.2 2020-8: 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 treaties² 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:

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.

² While the international treaties are binding to the State Parties, they do not contain requirements that are directly applicable or useful for the target groups of this standard; the manufacturers of ME equipment and the responsible organization for the use and storage of ME equipment with high-activity radioactive sources. This standard provides requirements for how the ME equipment shall be protected 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.