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Second edition
2004-01

Medical electrical equipment –

Part 2-17:
Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 60601-2-17 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 1989, and its Amendment 1 (1996). Consideration has been given to new IEC standards, amendments to existing IEC standards, developments in technology and clinical usage, and various hazards encountered and envisaged since the preparation of the first edition.

The text of this standard is based on the following documents:

FDIS	Report on voting
62C/363/FDIS	62C/366/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this Particular Standard, the following print types are used:

– requirements, compliance with which can be tested, and definitions: roman type;

– explanations, advice, notes, general statements, exceptions and references: small roman type;

– *test specifications: italic type;*

– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH ARE DEFINED IN CLAUSE 2 OR IN THE GENERAL STANDARD IEC 60601-1, ITS COLLATERAL OR PART 2 STANDARDS, OR IN IEC 60788: SMALL CAPITALS.

NOTE Attention is drawn to the existence, in some countries, of legislation containing requirements for:

– IONIZING RADIATION safety which may not align with the provisions of this Particular Standard, and

– maintenance, quality assurance and other related subjects, which are not covered by this Standard.

The committee has decided that the contents of this publication will remain unchanged until 2008. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

INTRODUCTION

The use of AFTERLOADING EQUIPMENT for BRACHYTHERAPY purposes may expose PATIENTS to danger if the EQUIPMENT fails to deliver the required dose to the PATIENT, or if the EQUIPMENT design does not satisfy standards of electrical and mechanical safety. The EQUIPMENT may also cause danger to persons in the vicinity if the EQUIPMENT itself fails to contain the RADIOACTIVE SOURCE(S) adequately within the STORAGE CONTAINER(S) and/or if there are inadequacies in the design of the TREATMENT ROOM.

This Particular Standard establishes requirements to be complied with by MANUFACTURERS in the design and construction of AFTERLOADING EQUIPMENT for use in temporary BRACHYTHERAPY procedures; it does not attempt to define their optimum performance requirements. Its purpose is to identify those features of design that are regarded, at the present time, as essential for the safe operation of such EQUIPMENT. It places limits on the degradation of EQUIPMENT performance beyond which it can be presumed that a fault condition exists and where an INTERLOCK then operates to return the RADIOACTIVE SOURCE(S) to the STORAGE CONTAINER(S) and afterwards to prevent continued operation of the EQUIPMENT.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Addition:

1.1.101 This Particular Standard specifies requirements for the safety of automatically-controlled EQUIPMENT for BRACHYTHERAPY of patients using AFTERLOADING techniques.

1.1.102 This Standard specifies requirements for automatically-controlled AFTERLOADING EQUIPMENT

– which contains and uses only beta, gamma, and NEUTRON-emitting SEALED RADIOACTIVE SOURCES,
– which automatically drives the sealed radioactive source(s) from a storage container to a treatment position inside the source applicator(s) and returns the source(s) to the storage container,
– which is designed for connection to a PATIENT, and
– with which movements of the RADIOACTIVE SOURCE(S) are carried out automatically by the EQUIPMENT according to a prescribed programme using a powered mechanism whose changes are controlled by the CONTROLLING TIMER(S) and TIMING DEVICES that are either PROGRAMMABLE ELECTRONIC SUB-SYSTEMS (PESS) (computer or microprocessors) or non-programmable systems.

1.1.103 This Standard specifies requirements for EQUIPMENT intended to be

– used under the supervision of QUALIFIED PERSONS;
– maintained at predetermined intervals;
– subject to regular checks by the user.

This Standard does not specify requirements for SEALED RADIOACTIVE SOURCES used with the EQUIPMENT. Such requirements are specified in other standards (see 6.8.3).

1.1.104 The requirements of this Standard are based on the assumptions that:

– a TREATMENT PLAN is available that prescribes appropriate values of the TREATMENT PARAMETERS, and
– the SOURCE STRENGTH(S) of the RADIOACTIVE SOURCE(S) used by the EQUIPMENT is (are) known.

This Standard includes requirements intended to ensure that the prescribed values of the TREATMENT PARAMETERS can be achieved by the EQUIPMENT, in particular that:

– the selected RADIOACTIVE SOURCE(S) is (are) positioned or moved within the SOURCE APPLICATOR in the selected configuration relative to the SOURCE APPLICATOR;
– IRRADIATION is performed by the selected RADIOACTIVE SOURCE configuration for the selected duration;
– IRRADIATION is performed by the EQUIPMENT without causing unnecessary risk to the OPERATOR or other persons in the immediate surroundings.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for safety of automatically-controlled BRACHYTHERAPY AFTERLOADING EQUIPMENT and the compliance test specifications. It presents the general functional requirements of the demand for safety rather than particular technological means of implementation.

1.3 Particular Standards

ADDITION:

1.3.101 Relationship to the General Standard

This Particular Standard is to be read in conjunction with IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*, with its Amendments 1 (1991) and 2 (1995) – hereinafter referred to as the General Standard – which it amends and supplements. As in the General Standard, the requirements are followed by compliance tests.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. The changes to the text of the General and Collateral Standards are specified by the use of the following words:

"Replacement" means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard;

"Addition" means that the text of this Particular Standard is additional to the requirements of the General Standard;

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses, figures or tables which are additional to those of the General Standard are numbered starting from 101: additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

The term “this Standard “ is used to make reference to the General Standard and this Particular Standard taken together.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

The requirements of this Particular Standard take priority over those of the General Standard.

1.3.102 Relationship to other standards and documents

NOTE See Appendix L for normative references.

1.5 Collateral Standards

Addition:

1.5.101 IEC 60601-1-1

All clauses and subclauses of Collateral Standard IEC 60601-1-1apply.

1.5.102 IEC 60601-1-2

All clauses and subclauses of Collateral Standard IEC 60601-1-2 apply.

1.5.103 IEC 60601-1-3

Collateral Standard IEC 60601-1-3 does not apply.

1.5.104 IEC 60601-1-4

All clauses and subclauses of Collateral Standard IEC 60601-1-4 apply.

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Addition:

For the purposes of this document, the terms and definitions given in the General Standard or in its Collateral Standards and the following apply.

NOTE 1 The Index of defined terms at the end of this document lists defined terms alphabetically with their source reference.

NOTE 2 In this Particular Standard, IRRADIATION refers to the entire process of exposing the patient to RADIOACTIVE SOURCES in positions and for periods of time appropriate for TREATMENT. TRANSIT times are explicitly excluded from the TREATMENT TIME.

NOTE 3 Although the actual titles of the persons fulfilling the following roles may vary from country to country, in this Particular Standard the term 'OPERATOR' is used to denote the person controlling the BRACHYTHERAPY EQUIPMENT during treatment, and the term 'USER' to denote the organization or individual responsible for the use and maintenance of the BRACHYTHERAPY AFTERLOADING EQUIPMENT. The terms 'radiotherapist' and 'radiation oncologist', although not used in this Particular Standard, are used in many countries to denote the person exercising medical supervision and responsibility for determining and prescribing PATIENT treatment.

2.1 EQUIPMENT parts, auxiliaries and ACCESSORIES

Additional definitions:

2.1.101
ABBREVIATIONS
The following abbreviations are used in this standard:

– PESS programmable electronic sub-system
– SFC single fault condition
– TCP treatment control panel

2.1.102
BETA SOURCE STRENGTH
ABSORBED DOSE RATE [Gy s^{-1}] in water at 2 mm along the perpendicular bisector from a RADIOACTIVE SOURCE emitting beta RADIATION

2.1.103
BRACHYTHERAPY
INTRACAVITARY, INTERSTITIAL, SUPERFICIAL or INTRALUMINAL RADIOTHERAPY using one or more SEALED RADIOACTIVE SOURCES

2.1.104
CONTINUATION
in <RADIOTHERAPY>, re-starting IRRADIATION after INTERRUPTION of IRRADIATION without re-selection of OPERATING conditions

2.1.105
DWELL TIME
time a RADIOACTIVE SOURCE or a RADIOACTIVE SOURCE TRAIN remains at a selected TREATMENT position

2.1.106
GAMMA SOURCE STRENGTH
REFERENCE AIR KERMA RATE of a BRACHYTHERAPY SOURCE emitting gamma rays. The unit of GAMMA SOURCE STRENGTH is Gy s^{-1} at 1 m

NOTE Multiples (milli, mega, etc.) are permitted.

2.1.107
INITIATION
in <RADIOTHERAPY>, commencing IRRADIATION from the READY STATE when the READY STATE was attained by carrying out selection and confirming the operating conditions and not by INTERRUPTION OF IRRADIATION

2.1.108
INTERRUPTION OF IRRADIATION, TO INTERRUPT RADIATION
stopping IRRADIATION prior to TERMINATION OF IRRADIATION with the possibility of CONTINUATION without reselection of operating conditions

2.1.109
INTRALUMINAL RADIOTHERAPY
RADIOTHERAPY in which one or more RADIOACTIVE SOURCES, with or without SOURCE APPLICATORS, are introduced into a body lumen such as a blood vessel, airway, or the gastrointestinal tract

2.1.110
NEUTRON SOURCE STRENGTH
dose rate of a brachytherapy source emitting neutrons. The unit of NEUTRON SOURCE STRENGTH is Gy s^{-1} at 1 m

2.1.111
QUALIFIED PERSON
person recognized by a competent authority as having the requisite knowledge and training to perform particular duties

2.1.112
RADIOACTIVE SOURCE TRAIN
sequence of SEALED RADIOACTIVE SOURCES, possibly separated by non-RADIOACTIVE spacers, either permanently combined or selected prior to each IRRADIATION, and used in AFTERLOADING EQUIPMENT. The RADIOACTIVE SOURCE TRAIN is usually selected to give a specified dose distribution