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Medical electrical equipment - Part 2: Particular requirements for the safety of remote-controlled automatically-driven gamma-ray after-loading equipment (IEC 60601-2-17:1989)

Medical electrical equipment -- Part 2: Particular requirements for the safety of remote-controlled automatically-driven gamma-ray after-loading equipment

Medizinische elektrische Geräte -- Teil 2: Besondere Festlegungen für die Sicherheit ferngesteuerter, automatisch betriebener Afterloading-Geräte für Gamma-Strahlung

Appareils électromédicaux -- Partie 2: Règles particulières de sécurité des appareils projecteurs de sources radioactives automatiques télécommandés utilisés en radiothérapie par rayonnement gamma

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Medical electrical equipment
Part 2: Particular requirements for the safety of remote-controlled automatically-driven gamma-ray after-loading equipment
(IEC 601-2-17:1989)

Appareils électromédicaux
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(CEI 601-2-17:1989)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die Sicherheit ferngesteuerter, automatisch betriebener Afterloading-Geräte für Gamma-Strahlung
(IEC 601-2-17:1989)

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CENELEC

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of the International Standard IEC 601-2-17:1989, prepared by SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC TC 62, Electrical equipment in medical practice, was approved by CENELEC as HD 395.2.17 S1 on 1991-12-10.

This Harmonization Document was submitted to the formal vote for conversion into a European Standard and was approved by CENELEC as EN 60601-2-17 on 1996-03-15.

The following date was fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1997-03-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, appendix AA is informative.
For the normative references to international publications with their corresponding European publications, see annex ZA to EN 60601-2-17:1996/A1:1996.

Endorsement notice

The text of the International Standard IEC 601-2-17:1989 was approved by CENELEC as a European Standard without any modification.

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Particular requirements for the safety of remote-controlled automatically-driven gamma-ray afterloading equipment

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety of remote-controlled automatically-driven gamma-ray afterloading equipment

FOREWORD

1) The formal decisions or agreements of the IEC on technical matters, prepared by Technical Committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

2) They have the form of recommendations for international use and they are accepted by the National Committees in that sense.

3) In order to promote international unification, the IEC expresses the wish that all National Committees should adopt the text of the IEC recommendation for their national rules in so far as national conditions will permit. Any divergence between the IEC recommendation and the corresponding national rules should, as far as possible, be clearly indicated in the latter.

4) The IEC has not laid down any procedure concerning marking as an indication of approval and has no responsibility when an item of equipment is declared to comply with one of its recommendations.

PREFACE

This Standard has been prepared by Sub-Committee 62C: High-energy radiation equipment and equipment for nuclear medicine, of IEC Technical Committee No. 62: Electrical equipment in medical practice.

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

Six Months' Rule	Report on Voting
62C(CO)52	62C(CO)54

Full information on the voting for the approval of this Standard can be found in the Voting Report indicated in the above table.

The following IEC publications are quoted in this Standard:

Publications Nos. 601-1 (1977): Safety of medical electrical equipment, Part 1: General requirements.
601-1 (1988): Medical electrical equipment, Part 1: General requirements for safety.
788 (1987): Medical radiology — Terminology.

Other publication quoted:

ISO 361 (1975): Basic ionizing radiation symbol.

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety of remote-controlled automatically-driven gamma-ray afterloading equipment

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INTRODUCTION

This Particular Standard has been amended from the third draft on the basis of discussions held by WG 4 in Zurich from 5th to 7th March 1986 and as decided at the meeting of SC 62C in Budapest. It is intended to supplement the General Standard for safety of medical electrical equipment (IEC Publication 601-1, first edition, 1977)*. As stated in Sub-clause 1.3 of the General Standard, the requirements of this Particular Standard take priority, where appropriate, over those of the General Standard.

The numbers of sections, clauses and sub-clauses of this publication refer to the relevant clauses of IEC Publication 601-1. As in the General Standard, defined terms are printed in small capitals.

SECTION ONE — GENERAL

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 *Scope*

Addition:

1.1.1 This Particular Standard specifies requirements for the safety of remote-controlled automatically-driven EQUIPMENT for gamma-ray therapy of human subjects using AFTERLOADING.

1.1.2 This Standard specifies requirements for AFTERLOADING EQUIPMENT

- which contains and uses only gamma-ray SEALED RADIOACTIVE SOURCES,
- which automatically drives the gamma-ray SEALED RADIOACTIVE SOURCE(S) from a STORAGE CONTAINER to a treatment position inside the SOURCE APPLICATOR(S),
- 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 systems (computer or microprocessors) or non-programmable systems (see also note to Sub-clause 3.2).

This Standard is not intended to apply to EQUIPMENT with neutron RADIOACTIVE SOURCES.

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* The second edition was published in 1988.

1.1.3 This Standard specifies requirements for EQUIPMENT which gives AIR KERMA RATES up to 500 mGy per hour at 1 m from the RADIOACTIVE SOURCES in use. For EQUIPMENT operating outside this range, special precautions may be necessary.

1.1.4 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, and
- used for particular specified clinical purposes, e.g. INTRACAVITARY, INTERSTITIAL or SUPERFICIAL RADIOTHERAPY.

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

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

- an IRRADIATION TREATMENT PRESCRIPTION is available that prescribes appropriate values of the TREATMENT PARAMETERS, and
- the AIR KERMA RATES at 1 m from the RADIOACTIVE SOURCES in the EQUIPMENT 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;
- GAMMA IRRADIATION is delivered from the selected RADIOACTIVE SOURCE configuration for the selected duration;
- GAMMA IRRADIATION is delivered 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 the particular requirements for safety 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*

Remplacement:

A requirement of this Particular Standard replacing or modifying requirements of the General Standard takes priority over the requirements of the General Standard.

1.4 *Environmental conditions*

b) Operation

1) Environment

Replacement:

a) An ambient temperature between +15 °C and +35 °C.

b) A relative humidity between 30% and 75%.

c) An atmospheric pressure between 70 kPa and 110 kPa.

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Addition:

Terms printed in small capitals in this Particular Standard are defined in the General Standard or in IEC Publication 788, or are defined in Appendix AA of this Particular Standard.

In this Particular Standard, IRRADIATION being the actual treatment of the PATIENT, it is regarded as commencing when the RADIOACTIVE SOURCES reach their intended positions in the SOURCE APPLICATORS and as ceasing when they leave at the end of treatment. These transit times are explicitly excluded from the TREATMENT TIME.

3 General requirements

This clause of the General Standard applies except as follows:

Note to Sub-clause 3.2, *Replacement:*

Remote-controlled automatically-driven gamma-ray AFTERLOADING EQUIPMENT should be made and finished with a degree of uniformity and complying with generally accepted principles of sound and safe practice. This recommendation applies to all components including, for example, a programmable electronic system used as a CONTROLLING TIMER, a TIMING DEVICE or an INTERLOCK. As explained in the introduction to the General Standard, hazards arising from a failure of a single component of a protective system can be minimized by careful engineering or by application of redundancy or by protective devices of a mechanical or electrical nature.

4 General requirements for tests

This clause of the General Standard applies except as follows:

Replacement:

4.1 *a) The tests described in this Particular Standard are intended to be type tests but may also be used, as appropriate, by the manufacturer or by the installer as routine tests. Appropriate care should be taken to carry out compliance tests safely, e.g. by using a non-RADIOACTIVE SOURCE wherever possible.*

5 Classification

This clause of the General Standard applies except as follows:

5.1 *Replacement:*

According to the type of protection against electric shock:

EQUIPMENT within the scope of this standard shall be CLASS I EQUIPMENT.

5.2 *Replacement:*

According to the degree of protection against electric shock:

EQUIPMENT within the scope of this Standard shall be TYPE B EQUIPMENT.

5.3 Not applicable.

5.4 Not applicable.

5.5 *Replacement:*

According to the degree of safety of application in the presence of flammable anaesthetics and/or flammable cleaning agents:

EQUIPMENT within the scope of this Standard shall be EQUIPMENT for use in environments where no flammable anaesthetics and/or flammable cleaning agents are present.

5.6 *Replacement:*

According to the mode of operation:

EQUIPMENT within the scope of this Standard shall be suitable for CONTINUOUS OPERATION.

5.7 *Replacement:*

According to the degree of electrical connection between EQUIPMENT and PATIENT:

EQUIPMENT within the scope of this Standard shall be EQUIPMENT with an APPLIED PART, but not specifically designed for application where a functional CONDUCTIVE CONNECTION to the PATIENT is made.

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.1 *Marking on the outside of EQUIPMENT*

Additional items:

aa) The EQUIPMENT shall be provided with permanently affixed and clearly legible markings on the appropriate part showing:

a) the maximum total ACTIVITIES of each of the RADIONUCLIDES for which the EQUIPMENT is designed;

b) the symbol ISO 361 indicating possible radiation hazard;

c) the requirement for the STORAGE CONTAINER(S) to be located only in a TREATMENT ROOM with restricted access, if this is specified (see Sub-clause 30.1.1);

d) additional external supply requirements (e.g. compressed air), if any.

bb) The EQUIPMENT shall be provided with a permanently affixed facility by which either the USER or the manufacturer can indicate the RADIOACTIVE SOURCE(S) and their configurations that can be selected for each CHANNEL.

cc) The EQUIPMENT shall be provided with a permanently affixed facility by which either the USER or the manufacturer can indicate the RADIONUCLIDE(S) that are being kept in the STORAGE CONTAINER(S) and its/their ACTIVITY(IES) and AIR KERMA RATE(S) at 1 m and at given date(s).

dd) Each SOURCE APPLICATOR shall be permanently marked with an individual identification.

ee) Each rigid SOURCE APPLICATOR with a clinically significant asymmetrical feature (e.g. curved or partially shielded) and capable of insertion into a PATIENT in different orientations shall be so marked that its orientation can be identified after insertion unless the ACCOMPANYING DOCUMENTS contain a recommendation that radiographic or other appropriate checks be carried out.