

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –

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

Appareils électromédicaux –

Partie 2-17: Exigences particulières pour la sécurité de base et les performances essentielles des appareils projecteurs de sources radioactives à chargement différé automatique utilisés en brachythérapie



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CONTENTS

FOREWORD.....	3
INTRODUCTION.....	6
201.1 Scope, object and related standards	7
201.2 Normative references	9
201.3 Terms and definitions	10
201.4 General requirements.....	12
201.5 General requirements for testing ME EQUIPMENT.....	12
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	12
201.7 ME EQUIPMENT identification, marking and documents.....	13
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	17
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	18
201.10 Protection against unwanted and excessive radiation HAZARDS.....	18
201.11 Protection against excessive temperatures and other HAZARDS.....	37
201.12 Accuracy of controls and instruments and protection against hazardous outputs	37
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	40
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	40
201.15 Construction of ME EQUIPMENT	40
201.16 ME SYSTEMS.....	40
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.....	40
Annex A (informative) General guidance and rationale.....	41
Bibliography.....	42
Index of defined terms used in this particular standard.....	43
Table 201.101 – Colours of lights and their meanings	14

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-17: Particular requirements for the basic safety and essential performance 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 IEC subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition, published in 2004. 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 and second editions. This edition constitutes a technical revision which brings this standard in line with IEC 60601-1:2005+A1:2012 and its collateral standards.

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

FDIS	Report on voting
62C/575/FDIS	62C/579/RVD

Full information on the voting for the approval of this particular 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 standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201.7 includes subclauses 201.7.1, 201.7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 201.7.1, 201.7.2 and 201.7.2.1 are all subclauses of Clause 201.7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this collateral standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

A list of all parts of the IEC 60601 series, published under the general title *MEDICAL ELECTRICAL EQUIPMENT*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

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

INTRODUCTION

The delivery of RADIOTHERAPY over short distances is called BRACHYTHERAPY. BRACHYTHERAPY is delivered by positioning RADIATION SOURCES within or adjacent to the tissue to be treated. Historically, RADIOACTIVE SOURCES were handled manually, resulting in IRRADIATION of the OPERATOR'S hands. AFTERLOADING generally refers to the technique of placing an applicator into or adjacent to the tissue to be treated, and introducing one or more RADIATION SOURCE(S) only after the applicator position has been confirmed. This procedure minimizes the time during which the operator is exposed to the RADIATION SOURCE(S). Manual AFTERLOADING techniques were developed in the 1950s and are used routinely today for permanent implants, but less frequently for temporary implants.

Temporary implants require the use of higher dose rates, to ensure that the treatment can be completed in a length of time easily tolerated by the PATIENT. In the 1980s, automatic remote AFTERLOADING techniques were developed, that could move a RADIOACTIVE SOURCE or SOURCES through connecting tubes from a shielded safe to the applicators implanted in the patient. Because the SOURCE(S) could be moved remotely, the risk of exposure to personnel could be eliminated.

In 2007 an automatic remote afterloader was introduced that replaced the conventional RADIOACTIVE SOURCE(S) with an X-ray source. This device otherwise performed similarly to AFTERLOADERS containing RADIOACTIVE SOURCES. However, the X-ray source could be disabled when not in use, removing any risk of IRRADIATION. BRACHYTHERAPY devices that employ X-ray source(s) are subject to the requirements of IEC 60601-2-8, in addition to those of this standard.

The use of AFTERLOADING ME EQUIPMENT for BRACHYTHERAPY purposes may expose PATIENTS to danger if the ME EQUIPMENT fails to deliver the required dose to the PATIENT, or if the ME EQUIPMENT design does not satisfy standards of electrical and mechanical safety. The ME EQUIPMENT may also cause danger to persons in the vicinity if the ME EQUIPMENT itself fails to contain the RADIOACTIVE SOURCE(S) adequately within the STORAGE CONTAINER(S), if the X-RAY TUBE is energized inappropriately, 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 ME 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 ME EQUIPMENT. It places limits on the degradation of ME EQUIPMENT performance beyond which it can be presumed that a fault condition exists and at which an INTERLOCK then operates to disable the X-RAY TUBE(S) or return the RADIOACTIVE SOURCE(S) to the STORAGE CONTAINER(S) and afterwards to prevent continued operation of the ME EQUIPMENT.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of automatically-controlled BRACHYTHERAPY AFTERLOADING ME EQUIPMENT, hereafter referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This standard applies to automatically-controlled BRACHYTHERAPY AFTERLOADING ME EQUIPMENT used for treatment or alleviation of disease.

This standard specifies requirements

a) for automatically-controlled AFTERLOADING ME EQUIPMENT

- 1) which contains and uses only beta, gamma, or NEUTRON-emitting SEALED RADIOACTIVE SOURCES, or BRACHYTHERAPY X-RAY SOURCES designed and constructed for use with automatically-controlled AFTERLOADING ME EQUIPMENT,
- 2) which automatically drives the RADIATION SOURCE(S) from a STORAGE CONTAINER or, in the case of BRACHYTHERAPY X-RAY SOURCES, a reference location outside the PATIENT, to a treatment position inside the SOURCE APPLICATOR(S) and returns the RADIATION SOURCE(S) to the STORAGE CONTAINER or the BRACHYTHERAPY X-RAY SOURCE(S) to the reference location,
- 3) which is designed for connection to a PATIENT, and
- 4) with which movements of the RADIATION SOURCE(S) are carried out automatically by the ME 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 and

b) for ME EQUIPMENT intended to be

¹ The general standard is IEC 60601-1:2005+A1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

- 1) for NORMAL USE, operated under the authority of appropriately licensed or QUALIFIED PERSONS by OPERATORS having the required skills for a particular medical application, for particular specified clinical purposes, e.g. remote AFTERLOADING BRACHYTHERAPY;
- 2) maintained in accordance within the recommendations given in the INSTRUCTIONS FOR USE;
- 3) subject to regular quality assurance performance and calibration checks by a QUALIFIED PERSON.

This standard does not specify requirements for SEALED RADIOACTIVE SOURCES. Requirements for the design of X-RAY TUBES used with the ME EQUIPMENT are specified in other IEC standards. See for example: IEC 60601-2-28:2010.

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) or the REFERENCE AIR-KERMA RATE of the RADIATION SOURCE(S) used by the ME EQUIPMENT is (are) known.

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

- the selected RADIATION 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 RADIATION SOURCE configuration for the selected duration;
- IRRADIATION is performed by the ME EQUIPMENT without causing unnecessary RISK to the OPERATOR or other persons in the immediate surroundings.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for automatically-controlled BRACHYTHERAPY AFTERLOADING ME EQUIPMENT.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this standard.

IEC 60601-1-3 and IEC 60601-1-10² do not apply. All other published collateral standards in the IEC 60601 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

² IEC 60601-1-10, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed loop controllers*

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1:2005+A1:2012, is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral 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 or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral 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 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography on page 42.

Clause 2 of the general standard applies, except as follows:

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012³

³ A consolidated edition 3.1 exists, including IEC 60601-1:2005 and its Amendment 1:2012.

IEC 60601-2-1:2009, *Medical electrical equipment – Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV*

IEC 60601-2-8:2010, *Medical electrical equipment – Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV*

IEC 60601-2-11:2013, *Medical electrical equipment - Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment*

IEC/TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 61005:2003, *Radiation protection instrumentation – Neutron ambient dose equivalent (rate) meters*

IEC 62083:2009, *Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems*

201.3 Terms and definitions

For the purposes of this particular standard, the terms and definitions given in IEC 60601-1:2005+A1:2012 and IEC/TR 60788:2004 apply, except as follows:

NOTE 1 An index of defined terms is found beginning on page 43.

NOTE 2 In this particular standard, IRRADIATION refers to the entire process of exposing the PATIENT to RADIATION SOURCES in positions and for periods of time appropriate for TREATMENT. TRANSIT times are explicitly excluded from the TREATMENT TIME.

Addition:

201.3.201

AFTERLOADING

automatically-controlled transfer of one or more SEALED RADIOACTIVE SOURCES or X-ray sources between a STORAGE CONTAINER or, in the case of X-ray sources, a reference position, and pre-positioned SOURCE APPLICATORS for BRACHYTHERAPY

201.3.202

ALARM SIGNAL

signal, the purpose of which is to alert the OPERATOR to an abnormal condition in the PATIENT or the equipment that may develop into a safety HAZARD which requires OPERATOR awareness or action

201.3.203

BETA SOURCE STRENGTH

ABSORBED DOSE RATE in water at 2 mm along the perpendicular bisector from a RADIATION SOURCE emitting beta RADIATION

Note 1 to entry: The unit of beta source strength is Gy s^{-1} at 2 mm.

Note 2 to entry: Multiples (milli, mega, etc.) are permitted.

201.3.204

BRACHYTHERAPY

RADIOTHERAPY using one or more RADIATION SOURCES with the RADIATION SOURCE/SOURCES inside or close to the TARGET VOLUME

Note 1 to entry: Brachytherapy techniques include interstitial, intracavitary, superficial or intraluminal radiotherapy.

201.3.205**CONTINUATION OF IRRADIATION****CONTINUATION**

<RADIOTHERAPY> re-starting IRRADIATION after INTERRUPTION OF IRRADIATION without re-selection of operating conditions

201.3.206**DWELL TIME**

time a RADIATION SOURCE or a RADIATION SOURCE TRAIN remains at a selected TREATMENT position or the time the BRACHYTHERAPY X-RAY SOURCE remains activated at a selected TREATMENT position

201.3.207**INITIATION OF IRRADIATION****INITIATION**

commencing IRRADIATION from the READY STATE when the READY STATE was attained by carrying out the selection and confirmation of the operating conditions and not by INTERRUPTION OF IRRADIATION

201.3.208**NEUTRON SOURCE STRENGTH**

ABSORBED DOSE RATE IN WATER of a RADIATION source emitting NEUTRONS

Note 1 to entry: The unit of NEUTRON SOURCE STRENGTH is, for the purposes of this standard, Gy s^{-1} at 1 cm.

Note 2 to entry: Multiples (milli, mega, etc.) are permitted.

201.3.209**PHOTON SOURCE STRENGTH**

REFERENCE AIR KERMA RATE along the perpendicular bisector from a RADIATION SOURCE emitting PHOTONS

Note 1 to entry: The unit of PHOTON SOURCE STRENGTH is Gy s^{-1} at 1 m.

Note 2 to entry: Multiples (milli, mega, etc.) are permitted.

201.3.210**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 ME EQUIPMENT

Note 1 to entry: The RADIOACTIVE SOURCE TRAIN is usually selected to give a specified dose distribution.

201.3.211**REFERENCE AIR KERMA RATE**

AIR KERMA RATE in air at a reference distance of 1 m, after correction for air ATTENUATION and scattering

Note 1 to entry: The symbol for REFERENCE AIR KERMA RATE is $\dot{K}_R$.

201.3.212**SOURCE STRENGTH**

PHOTON SOURCE STRENGTH, BETA SOURCE STRENGTH, or NEUTRON SOURCE STRENGTH of a RADIATION SOURCE, whichever is applicable for the intended use of the ME EQUIPMENT

201.3.213**TRANSIT**

the process through which the RADIATION SOURCES move from the STORAGE CONTAINER(S) or, in the case of BRACHYTHERAPY X-RAY SOURCES, a reference position to a treatment position or move from a treatment position to the STORAGE CONTAINER(S) or reference position

201.3.214

TREATMENT PARAMETER

factor that describes one aspect of the irradiation of a PATIENT during RADIOTHERAPY, such as RADIATION ENERGY, SOURCE STRENGTH, TREATMENT TIME

201.3.215

TREATMENT TIME

the sum of the DWELL TIMES which constitute a TREATMENT

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.1 Conditions for application to ME EQUIPMENT or ME SYSTEMS

Addition:

IEC 60601-2-8:2010, *Medical electrical equipment – Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV* applies to AFTERLOADING ME EQUIPMENT that incorporates one or more X-RAY TUBES.

201.4.3 ESSENTIAL PERFORMANCE

Addition:

Requirements of 201.10.1.2.101, 201.10.1.2.102, 201.10.2.101, and 201.10.2.102 are identified as ESSENTIAL PERFORMANCE requirements.

201.4.10.2 SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

Addition:

SUPPLY MAINS in this standard shall be assumed to have the following characteristics:

- a sufficiently low internal impedance to prevent voltage fluctuations exceeding $\pm 5\%$ between the on-load and off-load steady states.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

Addition:

201.5.101 TYPE TESTS

Appropriate care should be taken to carry out compliance tests safely, for example by using a non-RADIOACTIVE SOURCE wherever possible. TYPE TESTS described in this particular standard may also be used by the MANUFACTURER or by the installer as routine tests.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.6 Mode of operation

Replacement:

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

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.20 Removable protective means

Replacement:

ME EQUIPMENT shall be declared as unsuitable for alternative applications that require the removal of a protective means to utilise a particular function.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

Addition:

201.7.2.101 General

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

- a) the maximum total SOURCE STRENGTHS of each of the RADIONUCLIDES for which the ME EQUIPMENT is designed, if the ME EQUIPMENT uses one or more RADIOACTIVE SOURCES;
- 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 201.10.2.101.2);
- d) additional external supply requirements (e.g. compressed air), if any.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.7.2.102 ME EQUIPMENT with more than one RADIATION SOURCE

For ME EQUIPMENT with more than one RADIATION SOURCE, the ME EQUIPMENT shall be provided with a permanently affixed means (e.g. a PESS) by which either the RESPONSIBLE ORGANIZATION or the MANUFACTURER can indicate the RADIATION SOURCES and their configurations that can be selected for each CHANNEL.

Compliance is checked by inspection of the ME EQUIPMENT or the ACCOMPANYING DOCUMENTS.

201.7.2.103 ME EQUIPMENT with RADIOACTIVE SOURCES

Where the ME EQUIPMENT uses RADIOACTIVE SOURCES, it shall be provided with a permanently affixed means by which either the RESPONSIBLE ORGANIZATION or the MANUFACTURER can indicate the RADIONUCLIDE(S) that are being kept in the STORAGE CONTAINER(S) and its/their SOURCE STRENGTH(S) on given date(s).

201.7.2.104 Interchangeable SOURCE APPLICATORS

Each interchangeable SOURCE APPLICATOR shall be permanently marked, or where appropriate, marked on the packaging, with specific identification.

201.7.2.105 Rigid SOURCE APPLICATORS

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.

Compliance is checked by inspection of the ME EQUIPMENT or the ACCOMPANYING DOCUMENTS.

201.7.8 Indicator lights and controls

201.7.8.1 Colours of indicator lights

Replacement:

Where indicator lights are used on the TREATMENT CONTROL PANEL (TCP), or on other control panels, the colours of the lights shall accord with those shown in Table 201.101:

Table 201.101 – Colours of lights and their meanings

Colour	Meaning
Red	– Immediate action required in response to an unintended state of operation
Yellow	– RADIOACTIVE SOURCE(S) at the treatment position(s), or X-RAY TUBE(S) energized
Yellow (flashing)	– RADIOACTIVE SOURCE(S) or X-RAY TUBE(S) (if energized) in TRANSIT
Green	– READY STATE
White	– ME EQUIPMENT switched on but all the operations required to reach the READY STATE not yet carried out

The status of the ME EQUIPMENT shall be indicated also by means other than the colour; e.g. by the shape or location of the indicator, or by accompanying text.

For AFTERLOADING ME EQUIPMENT other than that intended to be operated in the vicinity of the PATIENT, indicator lights in the TREATMENT ROOM, but not on the TCP, to indicate that the RADIOACTIVE SOURCE(S) is (are) either at the treatment position(s) or in TRANSIT, or that the X-RAY TUBE(S) is (are) energized, shall be red in colour.

NOTE This colour is required because any OPERATOR in the TREATMENT ROOM observing a red light should take immediate action.

Compliance is checked by inspection of the ME EQUIPMENT.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.2 INSTRUCTIONS FOR USE

201.7.9.2.12 Cleaning, disinfection and sterilisation

Addition:

INSTRUCTIONS FOR USE shall also include a warning of the RISK that may arise during wet or steam sterilisation whereby liquids may become trapped in cavities and subsequently transferred to other parts of the system. This warning shall include the RISK of corrosive damage to the SEALED RADIOACTIVE SOURCE(S) or to the BRACHYTHERAPY X-RAY SOURCE(S) and the SOURCE DRIVE MECHANISM(S) in the event that trapped liquids are present.

201.7.9.2.15 Environmental protection*Addition:*

The instructions for use shall provide instructions for the disposal of SEALED RADIOACTIVE SOURCE(S).

*Additional subclauses:***201.7.9.2.101 Checking INTERLOCKS**

INSTRUCTIONS FOR USE shall contain instructions for checking INTERLOCKS and recommendations for the frequency of such checks.

201.7.9.2.102 Checking the security of couplings and connections

INSTRUCTIONS FOR USE shall contain instructions for the procedures to be carried out to check the security of the connection, if any, of RADIATION SOURCE(S) to SOURCE DRIVE MECHANISM(S), and of the couplings of CHANNEL(S) to SOURCE APPLICATOR(S).

201.7.9.2.103 Need for special procedures after a failure of a CONTROLLING TIMER

INSTRUCTIONS FOR USE shall contain an explanation of the need for special procedures after a failure of a CONTROLLING TIMER (see 201.10.1.2.103.3.2 and 201.10.2.103.2 of this particular standard).

201.7.9.2.104 Failure of RADIOACTIVE SOURCE to return to the STORAGE CONTAINER

INSTRUCTIONS FOR USE shall contain advice on the recommended procedures to be adopted in the case of failure of a RADIOACTIVE SOURCE to return to the STORAGE CONTAINER and on any emergency equipment that may be required.

201.7.9.2.105 TRANSIT ABSORBED DOSE

INSTRUCTIONS FOR USE shall contain information on AIR KERMA (or ABSORBED DOSE) at relevant reference points during the TRANSIT from the STORAGE CONTAINER or reference position to the TREATMENT position and the return of a specified RADIATION SOURCE.

INSTRUCTIONS FOR USE shall advise that the expected total TRANSIT dose should be determined and, if necessary, allowed for in dose calculations.

Where appropriate, INSTRUCTIONS FOR USE shall also contain a warning that the accurate achievement of the prescribed dose may be compromised if many TRANSITS of the RADIATION SOURCE(S) from the STORAGE CONTAINER or reference position are carried out during the treatment.

201.7.9.2.106 Limitations of CHANNELS and SOURCE APPLICATOR(S)

INSTRUCTIONS FOR USE shall state:

- the minimum radii of curvature for specified inside diameters of CHANNEL(S) and SOURCE APPLICATOR(S) which are allowable for normal operation;
- the conditions of the positional arrangements of CHANNEL(S) and SOURCE APPLICATOR(S) under which the agreement required by 201.12.1.102.1 of this particular standard is not achieved, with an explanation of the relation to the clinical purposes for which the ME EQUIPMENT is specified (see 201.1.1 of this particular standard);
- the nature of any obstacles of CHANNEL(S) and SOURCE APPLICATOR(S) that might impede the free passage of RADIATION SOURCE(S) or RADIOACTIVE SOURCE TRAIN(S).

201.7.9.2.107 Check for contamination

Where appropriate, INSTRUCTIONS FOR USE shall contain recommendations regarding appropriate checks for leakage of radioactive material from the RADIOACTIVE SOURCE(S).

201.7.9.2.108 Asymmetric SOURCE APPLICATOR check

Where appropriate (see 201.7.2.105), INSTRUCTIONS FOR USE shall contain a recommendation that radiographic or other checks be carried out on the orientation of asymmetric SOURCE APPLICATOR(S).

201.7.9.2.109 Functional checks and maintenance

INSTRUCTIONS FOR USE shall contain recommendations to the RESPONSIBLE ORGANIZATION on the regular functional checks to be performed and the required maintenance of the ME EQUIPMENT that should ensure continued safe use, particularly on the maintenance of the SOURCE DRIVE MECHANISM.

Where appropriate, the INSTRUCTIONS FOR USE shall include recommendations to carry out tests using non-RADIOACTIVE SOURCES, or BRACHYTHERAPY X-RAY SOURCES that are not energized.

201.7.9.2.110 Limitations on source transitions

The INSTRUCTIONS FOR USE shall contain the maximum number of transitions of the RADIATION SOURCE(S) and of the inactive (dummy) source(s), if present, from the STORAGE CONTAINER or reference position to the SOURCE APPLICATOR and back to the STORAGE CONTAINER or reference position. The INSTRUCTIONS FOR USE shall also explain the necessary next steps when the limit is reached; e.g. replacement of source or cable. If no limit on number of transitions is imposed, the INSTRUCTION FOR USE shall state this.

201.7.9.2.111 Checking the SOURCE STRENGTH(s) of the RADIATION SOURCE(S)

Where appropriate, INSTRUCTIONS FOR USE shall contain a recommendation that a measurement be made from which the SOURCE STRENGTH of each newly received RADIATION SOURCE can be determined with sufficient accuracy and compared with any values used internally by the ME EQUIPMENT.

201.7.9.3 Technical description

201.7.9.3.1 General

Addition:

The technical description shall state:

- a) whether the ME EQUIPMENT is specified and intended for use only with the STORAGE CONTAINER(S) in a TREATMENT ROOM with restricted access (see 201.10.2.101.2);
- b) the RADIONUCLIDE(S), if any, the corresponding maximum SOURCE STRENGTH(S) of the RADIOACTIVE SOURCE(S) for which the ME EQUIPMENT is designed and the corresponding LEAKAGE RADIATION from the STORAGE CONTAINER;
- c) the range of permissible configurations for the RADIOACTIVE SOURCE TRAIN(S), if any;
- d) whether it is permissible to use RADIOACTIVE SOURCES from other suppliers, in which case dimensions and tolerances of the capsules for the RADIOACTIVE SOURCES shall be stated;
- e) whether it is permissible to use BRACHYTHERAPY X-RAY SOURCES from other suppliers, in which case dimensions and tolerances of the BRACHYTHERAPY X-RAY SOURCES shall be stated;

- f) the international standards whose requirements the RADIATION SOURCES should meet, together with any other specific requirements;
- g) whether it is permissible to have SOURCE APPLICATORS from other suppliers, in which case relevant dimensions and tolerances shall be stated, and a recommendation given that such SOURCE APPLICATORS should be tested for compliance with requirements on position and security of couplings;
- h) the tolerances for:
 - RADIATION SOURCE positioning during TREATMENT;
 - TRANSIT TIME;
 - DWELL TIME;
 - X-RAY TUBE VOLTAGE ramp-up and ramp-down time.
- i) for ME EQUIPMENT using one or more RADIOACTIVE SOURCES, that the requirements in this particular standard cannot guarantee that the presence of a RADIOACTIVE SOURCE outside the STORAGE CONTAINER will be indicated under all fault conditions, and therefore that the use of an independent radiation monitor appropriate for the radiation type in the vicinity of the patient is essential;
- j) that where provided, an independent RADIATION monitor adjacent to any part of the ME EQUIPMENT should be capable of giving a visible indication of RADIATION and should function properly at all RADIATION levels that might be expected in the vicinity of the ME EQUIPMENT;
- k) that the radiation monitor should continue to function and give the indication for at least two hours after a power failure (e.g. battery backup).

The technical description shall contain details for the connection of the suitable device(s) that can ensure an INTERRUPTION (see 201.10.1.2.101.7 and 201.10.2.101.8).

The technical description shall provide guidance and precautions regarding the identification, handling and disposal of ME EQUIPMENT or ME EQUIPMENT PARTS that may exhibit RADIOACTIVITY.

The technical description shall include one or more dose distributions that are representative of the clinical use of the device. The description(s) of the dose distribution(s) shall include the influence of the SOURCE APPLICATOR.

Compliance with the terms of 201.7.9 is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.4 Limitation of voltage, current or energy

201.8.4.2 Accessible parts and applied parts

Addition:

- aa) Accessible HIGH VOLTAGE cables designed to carry X-RAY TUBE CURRENT shall incorporate a flexible conductive screen having a maximum resistance of $1 \Omega \text{ m}^{-1}$ of length, covered with a non-conductive material capable of protecting the screen against mechanical damage in NORMAL USE.

The screen shall be connected to the conductive ENCLOSURE of the HIGH VOLTAGE GENERATOR and to that of the X-RAY TUBE ASSEMBLY.

Compliance shall be checked by visual inspection and by measurement.

The flexible conductive screen shall not be considered to satisfy a requirement for a protective earth connection between the devices connected by the cable.

- bb) Detachable HIGH VOLTAGE CABLE CONNECTIONS shall be designed so that the use of TOOLS is required to disconnect them.

Provision shall be made to prevent the appearance of an unacceptably HIGH VOLTAGE in the MAINS PART or in any other low voltage circuit as a result of a defect or anomalous switching phenomenon in the HIGH VOLTAGE circuit.

NOTE This can be achieved for example:

- by provision of a winding layer or a conductive screen connected to the PROTECTIVE EARTH TERMINAL between HIGH VOLTAGE and low voltage circuits;
- by provision of a voltage limiting device across terminals to which external devices are connected and between which an excessive voltage might arise if the external path becomes discontinuous.

Compliance shall be checked by inspection of design data and construction.

201.8.6 Protective earthing, functional earthing and potential equalization of ME EQUIPMENT

Addition:

201.8.6.101 PROTECTIVE EARTH TERMINAL

For special applications of X-RAY TUBE ASSEMBLIES or for RADIATION measuring devices, parts connected to the PROTECTIVE EARTH TERMINAL and intended to be inserted into body cavities are permitted to carry functional currents.

In such cases, adequate information shall be included in the INSTRUCTIONS FOR USE, explaining the particular RISKS and the conditions, such as the integrity of the PROTECTIVE EARTH CONNECTION, necessary for maintaining safe operating conditions.

Compliance is checked by inspection and test. Compliance test procedures shall be SPECIFIED in the ACCOMPANYING DOCUMENTS.

201.8.8.3 Dielectric strength

Addition:

NOTE See IEC 60601-2-8:2010.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies, except as follows:

201.10.1 X-RADIATION

201.10.1.2 ME EQUIPMENT intended to produce diagnostic or therapeutic X-RADIATION

Addition:

BRACHYTHERAPY EQUIPMENT that uses one or more X-RAY SOURCE(S) shall also comply with the provisions of IEC 60601-2-8:2010.

NOTE The main requirements of this subclause are grouped. The first group of subclauses (201.10.1.2.101.x) applies to NORMAL USE and NORMAL CONDITION and its objective is the safe and satisfactory achievement of the prescribed TREATMENT PARAMETERS. The second group (201.10.1.2.102.x) is designed to give protection against other than NORMAL USE. The last group (201.10.1.2.103.x) of subclauses applies to SINGLE FAULT CONDITIONS and its objective is to protect the PATIENT and the OPERATORS from HAZARD.

201.10.1.2.101 Protection in NORMAL USE and NORMAL CONDITION

201.10.1.2.101.1 Indication of the position of BRACHYTHERAPY X-RAY SOURCE(S)

This subclause specifies the indications that are required to indicate to the OPERATOR that the BRACHYTHERAPY X-RAY SOURCE(S) is(are) following the prescribed programme.

Indicator lights coloured and arranged to comply with 201.7.8.1 of this particular standard or other means of indication shall be provided on the TCP and also where INITIATION is performed if this is different from the TCP:

- to indicate when the BRACHYTHERAPY X-RAY SOURCE(S) are in their selected treatment position(s) or carrying out their selected treatment movements within the tolerances specified in 201.12.1.102.1;
- to indicate when the BRACHYTHERAPY X-RAY SOURCE(S) are energized;
- to indicate when BRACHYTHERAPY X-RAY SOURCE(S) are both energized and in TRANSIT.

Compliance is checked by inspection and operation of the ME EQUIPMENT.

201.10.1.2.101.2 Key control of possibility of setting CONTROLLING TIMER and of selection, confirmation and movement of X-RAY TUBE(S)

Setting the CONTROLLING TIMER (see 201.10.1.2.101.4), selection and confirmation (see 201.10.1.2.101.6), and energizing the X-RAY TUBE(S) (see 201.10.1.2.101.7) shall be possible only after an operation or activation has been carried out by use of a removable special TOOL (which may be a key) and while the special TOOL or key remains in its operating position.

In addition, setting the CONTROLLING TIMER (see 201.10.1.2.101.4), selection and confirmation (see 201.10.1.2.101.6) shall be possible only after an operation has been carried out by use of an additional key. This key may be a designated PASSWORD when control is effected by PESS.

Compliance is checked by inspection and operation of the ME EQUIPMENT.

201.10.1.2.101.3 Verification of output of X-RAY TUBE(S)

The design of the ME EQUIPMENT shall require the OPERATOR to measure the output of the X-RAY TUBE(S) prior to PATIENT treatment. The ME EQUIPMENT shall:

- provide facilities for measuring the X-RAY TUBE output in terms of REFERENCE AIR KERMA RATE;
- relate the measurement of output to all parameters that are proportional to output, such as the electrical current through the X-RAY TUBE;
- prevent TREATMENT if the measured output is not within the manufacturer's stated limits;
- allow the OPERATOR to correct the TREATMENT TIME based on the measurement of output.

Where IRRADIATION time is used to control ABSORBED DOSE there shall be an INTERLOCK to ensure stable and accurate X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT during IRRADIATION, or there must be a backup INTERLOCK based on FLUENCE.

201.10.1.2.101.4 TREATMENT TIME

201.10.1.2.101.4.1 CONTROLLING TIMER

ME EQUIPMENT shall be provided with a CONTROLLING TIMER for each BRACHYTHERAPY X-RAY SOURCE or BRACHYTHERAPY X-RAY SOURCE train:

- that can be set to any value of DWELL TIME in an appropriate range,
- that can implement different parts of a prescribed programme of movements and positions of the BRACHYTHERAPY X-RAY SOURCE(S) within the TREATMENT TIME if the ME EQUIPMENT is designed for such implementation,
- that can be set or confirmed only at the TCP,
- that temporarily stops during INTERRUPTION, and
- that automatically TERMINATES IRRADIATION at a treatment position when the CONTROLLING TIMER reaches the set DWELL TIME value.

The CONTROLLING TIMER that controls DWELL TIME shall be graduated in hours, minutes, seconds and decimal fractions of a second, or a subset of these units. Decimal values shall not be used other than to indicate fractions of a second.

NOTE Where the dwell time and the total TREATMENT TIME are significantly different, the equipment can be provided with two timers.

For the provision of protection in the case of a SINGLE FAULT CONDITION of the CONTROLLING TIMER, see 201.10.1.2.103.2.

Compliance is checked by inspection and operation of the ME EQUIPMENT.

201.10.1.2.101.4.2 Setting of DWELL TIMES before INITIATION and prevention of changes in the set value

INITIATION shall not be possible until (see 201.10.1.2.101.5)

- at least one DWELL TIME has been set to a value greater than zero, or
- operations have been carried out at the TCP to confirm a set of selections, including DWELL TIMES, when this set of selections is part of a TREATMENT PLAN that has been made by means of a RADIOTHERAPY TREATMENT PLANNING SYSTEM that complies with IEC 62083, or
- after operations have been carried out at the TCP to confirm each selection, including DWELL TIMES, when the selection has been made other than at the TCP or other than by means of a RADIOTHERAPY TREATMENT PLANNING SYSTEM that complies with IEC 62083.

ME EQUIPMENT shall be so designed that after INITIATION no change in the set value is possible until TERMINATION OF IRRADIATION.

Compliance is checked by inspection and operation of the ME EQUIPMENT.

201.10.1.2.101.5 Indications by the CONTROLLING TIMER of TREATMENT TIME and DWELL TIME

201.10.1.2.101.5.1 DISPLAY of time

The value(s) at any moment of the SCALE READING(S) of the time(s) being measured by the CONTROLLING TIMER(S) required by 201.10.1.2.101.4.1, the set value(s) of DWELL TIME(S) and/or the remaining TREATMENT TIME shall be DISPLAYED on the TCP and also where the operations are made, if this is different from the TCP (see 201.10.1.2.101.7d).

Compliance is checked by inspection and operation of the ME EQUIPMENT.

201.10.1.2.101.5.2 Counting direction

The DISPLAYED SCALE READING(S) of the CONTROLLING TIMER(S) referred to in 201.10.1.2.101.5.1 may either increase from zero or decrease from the set DWELL TIME value.

The DISPLAYED SCALE READING(S) of the remaining TREATMENT TIME shall decrease from the computed value of TREATMENT TIME.

NOTE In the case of long TREATMENT TIMES it is a particularly important safeguard for the OPERATOR to see directly the remaining TREATMENT TIME.

In the case of failure of the CONTROLLING TIMER the total duration of IRRADIATION at any treatment position shall be retrievable (see 201.10.1.2.103.2).

Compliance is checked by inspection and operation of the ME EQUIPMENT.

201.10.1.2.101.5.3 Storage and preservation of information

The SCALE READING(S) referred to in 201.10.1.2.101.5.1 shall remain DISPLAYED

- after any TERMINATION OF IRRADIATION until re-set to zero or until the setting operation of 201.10.1.2.101.4.2, or until the SUPPLY MAINS is INTERRUPTED (see 201.10.1.2.103.1), and
- after an INTERRUPTION until the subsequent CONTINUATION (see 201.10.1.2.101.7a).

Compliance is checked by inspection and operation of the ME EQUIPMENT.

201.10.1.2.101.6 Selection and confirmation of CHANNELS, BRACHYTHERAPY X-RAY SOURCE(s), and positions and movements of BRACHYTHERAPY X-RAY SOURCE(s)

In ME EQUIPMENT in which it is possible

- to select from several modes of operation,
- to select from several CHANNELS,
- to select from several individual BRACHYTHERAPY X-RAY SOURCES,
- to select from several positions of the BRACHYTHERAPY X-RAY SOURCES,
- to select between a stationary and a moving position for the BRACHYTHERAPY X-RAY SOURCES, or
- to select from different programmes of intermittent movement,

the ME EQUIPMENT shall be so designed and constructed that INITIATION is possible only either

- after operations to make such selections have been carried out at the TCP, or
- after operations have been carried out at the TCP to confirm a set of selections when this set of selections is part of a TREATMENT PLAN that has been made by means of a RADIOTHERAPY TREATMENT PLANNING SYSTEM that complies with IEC 62083, or
- after operations have been carried out at the TCP to confirm each selection when the selections have been made other than at the TCP or other than by means of a RADIOTHERAPY TREATMENT PLANNING SYSTEM that complies with IEC 62083.

After INITIATION, adjustments to BRACHYTHERAPY X-RAY SOURCE location shall be permitted only when real-time position information (e.g. fluoroscopy) is available. In this case, a log shall be maintained by the PESS of all source movements. The operations described above shall again be possible only after TERMINATION OF IRRADIATION has been reached or induced.

Compliance is checked by inspection and operation of the ME EQUIPMENT.

201.10.1.2.101.7 INITIATION, CONTINUATION, INTERRUPTION, and TERMINATION (OF IRRADIATION)

- a) ME EQUIPMENT shall be so designed and constructed that both INITIATION and CONTINUATION are possible only by an operation at the location required in 201.10.1.2.101.7d).

Compliance is checked by inspection and operation of the ME EQUIPMENT.

- b) ME EQUIPMENT shall be provided with means for INTERRUPTION by removing the HIGH VOLTAGE from the X-RAY TUBE(S),
- either by an operation at the location required in 201.10.1.2.101.7d),
 - or by the means required in 201.10.1.2.101.8.

The means that causes the removal of the HIGH VOLTAGE shall not use a PESS to cause or control the removal.

Compliance is checked by inspection and by operation of the ME EQUIPMENT.

- c) ME EQUIPMENT shall be provided with means for TERMINATION (of IRRADIATION) additional to the CONTROLLING TIMER (see 201.10.2.101.4)
- that can be activated only after INTERRUPTION, and
 - that prevents subsequent energizing of the X-RAY TUBE(S) until further setting and selection operations required by subclauses 201.10.1.2.101.4.2 and 201.10.1.2.101.6 have been carried out, the means being an operation at the location required in 201.10.1.2.101.7d).

Compliance is checked by inspection and by operation of the ME EQUIPMENT.

- d) ME EQUIPMENT shall be so designed and constructed that the operations referred to in 201.10.1.2.101.7a), 201.10.1.2.101.7b) and 201.10.1.2.101.7c) (except for the means required in 201.10.1.2.101.8) for any one CHANNEL or for any one specified group of CHANNELS may be carried out only at one location that shall be:
- either at the TCP,
 - or on some single part of the ME EQUIPMENT.

Where the ME EQUIPMENT is designed for the simultaneous IRRADIATION of more than one PATIENT, the single part of the ME EQUIPMENT that is the location for all four operations of INITIATION, CONTINUATION, INTERRUPTION and TERMINATION (of IRRADIATION) for one PATIENT may be different from the single part for another PATIENT..

Compliance is checked by inspection and by operation of the ME EQUIPMENT.

- e) Where the operations referred to in 201.10.1.2.101.7a), 201.10.1.2.101.7b) and 201.10.1.2.101.7c) are not located at the TCP, INITIATION shall be possible only after an operation specifically to attain the READY STATE has been carried out at the TCP.

Compliance is checked by inspection and by operation of the ME EQUIPMENT.

201.10.1.2.101.8 Distant INTERRUPTION

Except when the TCP is in the TREATMENT ROOM, ME EQUIPMENT shall be provided with connections for devices (e.g. emergency switches) that can be positioned remotely from the location(s) described in 201.10.1.2.101.7d) and that can cause the de-energizing of the X-RAY TUBES and prevent them from being subsequently energized until an appropriate further operation is carried out. Technical details required for the connection of a suitable device shall be given in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection and by operation of the ME EQUIPMENT.

201.10.1.2.102 Protection against other than NORMAL USE

NOTE The following requirement is intended to provide safeguards against unauthorized use and interference.

ME EQUIPMENT shall be provided with means for preventing the ME EQUIPMENT from being operated by any person who has not been appropriately authorised by the RESPONSIBLE ORGANISATION. The means could be the removal of the TOOL or key referred to in 201.10.1.2.101.2.

Compliance is checked by inspection.

201.10.1.2.103 Protection in NORMAL USE while in SINGLE FAULT CONDITION**201.10.1.2.103.1 General**

This subclause specifies the requirements that provide protection against HAZARDS from unwanted or excessive RADIATION while the ME EQUIPMENT is in any of the following SINGLE FAULT CONDITIONS (each being dealt with in detail in subsequent subclauses):

- failure of the main energy supply (see 201.10.1.2.103.2);
- failure of the CONTROLLING TIMER (see 201.10.1.2.103.3);
- failure of the BRACHYTHERAPY X-RAY SOURCE to be in its intended position (see 201.10.1.2.103.4);
- failure of the SOURCE DRIVE MECHANISM (see 201.10.1.2.103.4.3);
- failure of the connections to the X-RAY TUBE (see 201.10.1.2.103.5);
- failure of INTERLOCKS (see 201.10.1.2.103.6);
- failure to de-energize an X-RAY TUBE (see 201.10.1.2.103.7).
- incomplete coupling of the CHANNELS and the SOURCE APPLICATORS (see 201.10.1.2.103.8).

The indications of SINGLE FAULT CONDITIONS are specified in 201.10.1.2.103.11.

201.10.1.2.103.2 Protection during failure of the primary energy supply

In the event of a failure of the primary energy supply (e.g. SUPPLY MAINS, compressed air, etc.) for the ME EQUIPMENT:

- TERMINATION OF IRRADIATION shall be automatically induced no later than the end of the TREATMENT TIME;
- the provisions required by subclauses 201.10.1.2.101.2, 201.10.1.2.101.7 (with the exception of INITIATION and CONTINUATION), 201.10.1.2.101.8 and 201.10.1.2.103 shall remain in force until all X-RAY TUBES are de-energized.

Instructions regarding maintenance and recharging of batteries or other devices required for compliance with this subclause shall be given in the ACCOMPANYING DOCUMENTS.

Procedures for INITIATION and CONTINUATION OF IRRADIATION shall be SPECIFIED in the INSTRUCTIONS FOR USE.

Compliance is checked by inspection and operation of the ME EQUIPMENT with interruption of the SUPPLY MAINS.

201.10.1.2.103.3 Protection during failure of CONTROLLING TIMER**201.10.1.2.103.3.1 General**

The requirements of this subclause are intended to prevent hazard to the PATIENT and to ensure that the RESPONSIBLE ORGANIZATION can determine the ABSORBED DOSE received by the PATIENT.

201.10.1.2.103.3.2 Limitation of IRRADIATION

The ME EQUIPMENT shall be so designed and constructed that:

- a failure of the CONTROLLING TIMER (see 201.10.1.2.101.4.1) or the electrical supply to a CONTROLLING TIMER controlling the BRACHYTHERAPY X-RAY SOURCE(S) in any CHANNEL or group of CHANNELS such that ceasing of IRRADIATION at the current TREATMENT position either is not or will not be induced by the CONTROLLING TIMER at the end of the selected DWELL TIME shall be automatically detected before the PATIENT receives an additional ABSORBED DOSE of 0,25 Gy over the intended ABSORBED DOSE at 10 mm; and
- the X-RAY TUBES shall automatically be de-energized as soon as the failure is detected.

NOTE The means for satisfying this requirement can be an additional TIMING DEVICE.

Compliance is checked by inducing a suitable failure as specified by the MANUFACTURER and checking the operation of the ME EQUIPMENT.

201.10.1.2.103.3.3 Check of correct function

INTERLOCKS shall be provided to ensure that the capability of all CONTROLLING TIMERS to induce TERMINATION (of IRRADIATION) has been tested and proved satisfactory prior to INITIATION.

Compliance is checked by inspection and by operation of the ME EQUIPMENT.

201.10.1.2.103.4 Protection during failure of the positional accuracy and movement of the BRACHYTHERAPY X-RAY SOURCE(S) and of the SOURCE DRIVE MECHANISM

201.10.1.2.103.4.1 Protection during failure of the positional accuracy of the BRACHYTHERAPY X-RAY SOURCE(S) during TREATMENT

ME EQUIPMENT shall be provided with means whereby if any BRACHYTHERAPY X-RAY SOURCE at any time during TREATMENT fails to be in its intended position (within the tolerances specified by the MANUFACTURER),

- such failure shall be detected, and
- as soon as failure is detected, the X-RAY TUBE(S) shall be automatically de-energized.

Compliance is checked by inspection and operation of the ME EQUIPMENT in such a way as to cause an appropriate failure as specified by the MANUFACTURER.

201.10.1.2.103.4.2 Protection during failure of movement of a BRACHYTHERAPY X-RAY SOURCE during TRANSIT

ME EQUIPMENT shall be provided with means whereby if any BRACHYTHERAPY X-RAY SOURCE at any time during TRANSIT fails to move to its intended position (within the tolerances for both time and position specified by the MANUFACTURER),

- such failure shall be detected, and
- as soon as the failure has been detected, energizing of the HIGH-VOLTAGE circuit shall be automatically prevented.

Compliance is checked by inspection and operation of the ME EQUIPMENT in such a way as to cause an appropriate failure as specified by the MANUFACTURER.

201.10.1.2.103.4.3 Protection during failure of the SOURCE DRIVE MECHANISM

To provide protection against failure of the SOURCE DRIVE MECHANISM, its electrical supply, its control, or the function of its electrical components, ME EQUIPMENT shall be provided with alternative means:

- independent of the normal electrical part of the SOURCE DRIVE MECHANISMS, and
- capable of being operated to de-energize the X-RAY TUBE(S).

Compliance is checked by inducing an appropriate failure as specified by the MANUFACTURER and operating the ME EQUIPMENT or by inspection.

201.10.1.2.103.5 Protection against failure of the connections (if any) to the X-RAY TUBE(S)

Where the ME EQUIPMENT has demountable mechanical connections between the X-RAY TUBE(S) and the SOURCE DRIVE MECHANISM, means shall be provided to test automatically the mechanical connection after this connection is made before TREATMENT is initiated.

The force that the SOURCE DRIVE MECHANISM can automatically apply to the BRACHYTHERAPY X-RAY SOURCE(S) shall be limited to one fourth of the force that the BRACHYTHERAPY X-RAY SOURCE(S) or the mechanical connection to the BRACHYTHERAPY X-RAY SOURCE(S) can withstand.

Compliance is checked by inspection of the ME EQUIPMENT and of the MANUFACTURER'S relevant information (i.e. test results, calculations, specifications of materials used and of processing specifications for these materials).

201.10.1.2.103.6 Protection against failure of INTERLOCKS

Means shall be provided so that the correct function of all radiation safety INTERLOCKS can be checked.

Compliance is checked by inspection.

201.10.1.2.103.7 Detection of failure to de-energize an X-RAY TUBE

ME EQUIPMENT shall be provided with means to detect failure to de-energize the supply to an X-RAY TUBE. When such failure is detected, the X-RAY TUBE(S) shall be automatically de-energized.

Compliance is checked by inspection and operation of the ME EQUIPMENT in such a way as to cause an appropriate failure as specified by the MANUFACTURER.

201.10.1.2.103.8 Protection against incomplete coupling of the CHANNELS and the SOURCE APPLICATORS

- a) Where the parts of the CHANNELS or SOURCE APPLICATORS are designed to allow uncoupling by the OPERATOR, the ME EQUIPMENT shall incorporate means for verifying that the parts are completely coupled and, if this is not the case, either
- prevent the X-RAY TUBE(S) from being energized, or
 - ensure that the BRACHYTHERAPY X-RAY SOURCE(S) do not move past the point of coupling and are automatically returned to the reference position if they are not properly coupled.

Compliance is checked by inspection and operation of the ME EQUIPMENT with incorrect coupling.

- b) Procedures for initiation and continuation of irradiation shall be addressed in the instructions for use.

Compliance is checked by inspection of the INSTRUCTIONS FOR USE.

201.10.1.2.103.9 Availability of information regarding the CONTINUATION of IRRADIATION

In the event of any failure described in 201.10.1.2.103.2, 201.10.1.2.103.3.2 or 201.10.1.2.103.8 information necessary to resume IRRADIATION according to the preset parameters shall be retrievable for a period of at least 10 h from the time of failure or until a permanent record has been made (see also 201.12.1.102.3).

Compliance is checked in the same way as for 201.10.1.2.103.2, 201.10.1.2.103.3.2 and 201.10.1.2.103.8.

The ACCOMPANYING DOCUMENTS shall contain an explanation of the procedures(s) to retrieve this information and to restore this information to resume the TREATMENT.

Compliance is checked by examination of the ACCOMPANYING DOCUMENTS.

201.10.1.2.103.10 Correction prior to further IRRADIATION

Subsequent to any failures described in 201.10.1.2.103.2, 201.10.1.2.103.3.2 and 201.10.1.2.103.3.3, neither INITIATION nor CONTINUATION shall be possible by NORMAL USE. The ACCOMPANYING DOCUMENTS shall contain:

- specific instructions on corrective actions for each of the failures described in 201.10.1.2.103.2, 201.10.1.2.103.3.2 and 201.10.1.2.103.3.3;
- an explanation of any special procedures(s) such as radiation surveys, source output measurement, etc., that should be carried out.

Compliance is checked in the same way as for 201.10.1.2.103.2, 201.10.1.2.103.3.2 and 201.10.1.2.103.3.3.

201.10.1.2.103.11 Indication of SINGLE FAULT CONDITIONS

201.10.1.2.103.11.1 Indication(s) of failure

ME EQUIPMENT shall be provided with visible ALARM SIGNALS such as indicator lights complying with 201.7.8.1 or other means of indication that are activated when any of the following failures has occurred:

- failure of a CONTROLLING TIMER (see 201.10.1.2.103.3);
- failure of movement of a BRACHYTHERAPY X-RAY SOURCE (see 201.10.1.2.103.4);
- failure of a SOURCE DRIVE MECHANISM (see 201.10.1.2.103.4.3);
- failure of the connection to an X-RAY TUBE (see 201.10.1.2.103.5);
- failure of an INTERLOCK when ME EQUIPMENT has the means to detect failure of the radiation safety INTERLOCK (see 201.10.1.2.103.6);
- failure to de-energize an X-RAY TUBE (see 201.10.1.2.103.7).
- failure of a coupling of the CHANNEL and the SOURCE APPLICATOR (see 201.1.1.2.103.8);

Compliance is checked by inspection and by operation with a fault as specified by the MANUFACTURER.

201.10.1.2.103.11.2 Indication of failure of movement of an BRACHYTHERAPY X-RAY SOURCE

Following an INITIATION of movement, if any BRACHYTHERAPY X-RAY SOURCE does not arrive at its intended position, an audible ALARM SIGNAL and a visible ALARM SIGNAL at the location required by 201.10.1.2.101.7d) shall be activated within a time interval specified by the MANUFACTURER in the INSTRUCTIONS FOR USE.

NOTE: Requirements for clearing of ALARMS are given in IEC 60601-1-8.

Compliance is checked by inspection and by operation with a fault as specified by the MANUFACTURER.

201.10.1.2.103.11.3 Indication that radiation safety INTERLOCKS have operated because of SINGLE FAULT CONDITIONS

ME EQUIPMENT shall be provided with a visible ALARM SIGNAL to indicate when normal movement of the BRACHYTHERAPY X-RAY SOURCE(S) has been prevented by any of the conditions referred to in subclauses 201.10.1.2.103.2, 201.10.1.2.103.3.2, 201.10.1.2.103.3.3 and 201.10.1.2.103.4.

Compliance is checked by inspection.

201.10.2 ALPHA, BETA, GAMMA, NEUTRON RADIATION and other particle radiation

Addition:

NOTE The main requirements of this subclause are grouped. The first group of subclauses (201.10.2.101.x) applies to NORMAL USE and NORMAL CONDITION and its objective is the safe and satisfactory achievement of the prescribed TREATMENT PARAMETERS. The second group (201.10.2.102.x) is designed to give protection against other than NORMAL USE. The last group of subclauses (201.10.2.103.x) applies to SINGLE FAULT CONDITIONS and its objective is to protect the PATIENT and the OPERATORS from hazard.

201.10.2.101 Protection in NORMAL USE and NORMAL CONDITION

201.10.2.101.1 General

The requirements of this subclause cover the shielded storage of the RADIOACTIVE SOURCES, the indications of their positions, the timing and selection of modes of treatment, and the control of movements. They do not cover the temporary storage of RADIOACTIVE SOURCES under emergency conditions or the transport of the ME EQUIPMENT from one area with restricted access to another.

201.10.2.101.2 Limitation of LEAKAGE RADIATION from the STORAGE CONTAINER(S)

Requirements a) and b) shall be met for each specified STORAGE CONTAINER with all combinations of RADIOACTIVE SOURCES specified in the ACCOMPANYING DOCUMENTS as suitable to be contained within the STORAGE CONTAINER.

a) General use of the STORAGE CONTAINER(S)

This requirement shall be met except where the STORAGE CONTAINER(S) are specified in the ACCOMPANYING DOCUMENTS as being suitable for installation and use only in a TREATMENT ROOM with restricted access.

The DOSE EQUIVALENT RATE at any position 50 mm from the surface of the STORAGE CONTAINER or any other surface permanently fixed to it shall not exceed $0,01 \text{ mSv h}^{-1}$.

The DOSE EQUIVALENT RATE at any position 1 m from the surface of the STORAGE CONTAINER or any other surface permanently fixed to it shall not exceed $0,001 \text{ mSv h}^{-1}$.

Compliance is checked by the following tests:

- *for measurements at 50 mm the DOSE EQUIVALENT RATE shall be averaged over an area up to but not exceeding 10 cm^2 ;*
- *for measurements at 1 m the DOSE EQUIVALENT RATE shall be averaged over an area up to but not exceeding 100 cm^2 ;*