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BSI Standards Publication

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 60601-2-1:2009+A1:2014)

bsi.

National foreword

This British Standard is the UK implementation of EN 60601-2-1:2015. It is identical to IEC 60601-2-1:2009, incorporating amendment 1:2014. It supersedes BS EN 60601-2-1:1998 which will be withdrawn on 15 September 2018.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by [A1] 〈A1〉.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/3, Equipment for radiotherapy, nuclear medicine and radiation dosimetry.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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Amendments/corrigenda issued since publication

Date	Text affected
31 October 2016	IEC amendment 1:2014 changes incorporated

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-1

October 2015

ICS 11.040.60

Supersedes EN 60601-2-1:1998

English Version

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 60601-2-1:2009 + A1:2014)

Appareils électromédicaux - Partie 2-1: Exigences particulières de sécurité de base et de performances essentielles pour les accélérateurs d'électrons dans la gamme de 1 MeV à 50 MeV
(IEC 60601-2-1:2009 + A1:2014)

Medizinische elektrische Geräte - Teil 2-1: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Elektronenbeschleunigern im Bereich von 1 MeV bis 50 MeV
(IEC 60601-2-1:2009 + A1:2014)

This European Standard was approved by CENELEC on 2015-09-15. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

European foreword

The text of document 62C/474/FDIS, future edition 3 of IEC 60601-2-1, and the text of document 62C/532/CDV, future IEC 60601-2-1/A1, prepared by SC 62C "Equipment for radiotherapy, nuclear medicine and radiation dosimetry", of IEC/TC 62 "Electrical equipment in medical practice" were submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-1:2015.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2016-06-15
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-09-15

This document supersedes EN 60601-2-1:1998.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standards IEC 60601-2-1:2009 and IEC 60601-2-1:2009/A1:2014 were approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60976:2007	NOTE	Harmonized as EN 60976:2007 (not modified).
IEC 62366	NOTE	Harmonized as EN 62366.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Annex ZA of EN 60601-1:2006 applies, except as follows:

Publication	Year	Title	EN/HD	Year
Addition to Annex ZA of EN 60601-1:2006:				
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 61217	1996	Radiotherapy equipment - Coordinates, movements and scales	EN 61217	1996

Annex ZZ
(informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and within its scope the Standard covers all relevant essential requirements given in Annex I of EU Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EU Directives can be applied to the products falling within the scope of this standard.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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 60601-2-1 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 1998 and its Amendment 1 (2002). It constitutes a technical revision.

This third edition addresses the following issues not covered in previous editions:

– alignment with the new relevant collateral standards;
– new technologies in radiotherapy, including:
  • stereotactic radiosurgery (SRS) and stereotactic radiotherapy (SRT);
  • intensity modulated radiotherapy (IMRT);
  • electronic imaging devices (e.g. EPID);
  • moving beam radiotherapy (dynamic therapy).

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

FDIS	Report on voting
62C/474/FDIS	62C/480/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 7 includes subclauses 7.1, 7.2, etc.);
– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular 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 maintenance result 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 use of ELECTRON ACCELERATORS for RADIOTHERAPY 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 RADIATION adequately 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 ELECTRON ACCELERATORS for use in RADIOTHERAPY; 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 where an INTERLOCK then operates to prevent continued operation of the ME EQUIPMENT.

Clause 201.10 contains limits beyond which INTERLOCKS prevent, INTERRUPT or TERMINATE IRRADIATION in order to insure ESSENTIAL PERFORMANCE is maintained to avoid an unsafe condition. TYPE TESTS that are performed by the MANUFACTURER, and/or SITE TESTS, which are not necessarily performed by the MANUFACTURER, are SPECIFIED for each requirement. It is understood that SITE TESTS may or may not be required of the MANUFACTURER, per the agreement between the MANUFACTURER and end user.

Given that before installation a MANUFACTURER cannot provide SITE TEST data, data available from SITE TESTS should be incorporated in the ACCOMPANYING DOCUMENTS, in the form of a SITE TEST report, by those who test the ME EQUIPMENT at installation.

This International Standard was first published in 1981. It was amended in 1984 and 1990. A second edition was published in 1998 and amended in 2002. This third edition is prompted by the need to align this particular standard with the third edition of the general standard, IEC 60601-1:2005.

IEC 60976 and IEC/TR 60977 are closely related to this standard. The former specifies test methods and reporting formats for performance tests of ELECTRON ACCELERATORS for use in RADIOTHERAPY, with the aim of providing uniform methods for conducting such tests. The latter is not a standard per se, but suggests performance values, measured per the methods specified in IEC 60976, that could be achievable with present technology.

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

201.1 Scope, object and related standards

Clause 1 of the general standard[1)] applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTRON ACCELERATORS, hereafter referred to as ME EQUIPMENT, in the range 1 MeV to 50 MeV, used for treatment of PATIENTS.

This particular standard, with the inclusion of TYPE TESTS and SITE TESTS, applies respectively to the manufacture and some installation aspects of ELECTRON ACCELERATORS

– intended for RADIOTHERAPY in human medical practice, including those in which the selection and DISPLAY of operating parameters can be controlled automatically by PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS),
– that, under NORMAL CONDITIONS and in NORMAL USE, deliver a RADIATION BEAM of X-RADIATION and/or ELECTRON RADIATION having
  - NOMINAL ENERGY in the range 1 MeV to 50 MeV,
  - maximum ABSORBED DOSE RATES between 0,001 Gy × s^{-1} and 1 Gy × s^{-1} at 1 m from the RADIATION SOURCE,
  - NORMAL TREATMENT DISTANCES (NTDs) between 0,5 m and 2 m from the RADIATION SOURCE,

and

– intended to be
  - 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. STATIONARY RADIOTHERAPY or MOVING BEAM RADIOTHERAPY,
  - maintained in accordance with the recommendations given in the INSTRUCTIONS FOR USE,
  - subject to regular quality assurance performance and calibration checks by a QUALIFIED PERSON.

NOTE 1 In this particular standard, all references to installation refer to installation in the RESPONSIBLE ORGANIZATION'S premises.

NOTE 2 In this particular standard, all references to ABSORBED DOSE refer to ABSORBED DOSE in water.

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

IEC 61271 gives guidance on the designation of ME EQUIPMENT movements; the marking of scales, their zero positions and the direction of movement with increasing value (see 201.7.4.101).

IEC 60676 specifies methods of testing and disclosure of functional performance of medical ELECTRON ACCELERATORS. The standard is intended to facilitate comparisons of accelerator-based ME EQUIPMENTs of different manufacture. IEC 60676 contains no safety requirements, and is therefore not required for compliance with this particular standard. It should also be noted (as stated in the Introduction to IEC 60976:2007) that tests specified in IEC 60976 are not necessarily appropriate for ensuring that any individual medical ELECTRON ACCELERATOR conforms to the declared functional performance during the course of its working lifetime.

NOTE 3 IEC/TR 60977, *Medical electrical equipment – Medical electron accelerators – Guidelines for functional performance characteristics*, is a related technical report that provides performance guidelines. It shall not be construed as a standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ELECTRON ACCELERATORS in the range 1 MeV to 50 MeV and to specify tests to check compliance to those requirements.

NOTE The adoption of this standard helps to ensure that the ME EQUIPMENT

- maintains PATIENT safety during ME EQUIPMENT movements and failure of the SUPPLY MAINS,
- delivers the pre-selected RADIATION TYPE, NOMINAL ENERGY, and ABSORBED DOSE,
- delivers the RADIATION in accordance with the pre-selected relationship of the RADIATION BEAM to the PATIENT, by utilizing STATIONARY RADIOTHERAPY, MOVING BEAM RADIOTHERAPY, RADIATION BEAM modifying devices, etc., without causing unnecessary risk to the PATIENT, the OPERATOR, other persons or the environment.

201.1.3 Collateral standards

Addition:

Collateral standards published after the date of publication of this standard shall only apply subject to further amendment to this standard.

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 particular standard.

IEC 60601-1-6 apply as modified in Clauses 206. IEC 60601-1-3, IEC 60601-1-8 and 60601-1-10[2] do not apply. All other published collateral standards in the IEC 60601-1 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.

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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 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of sections, 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 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 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

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

NOTE Informative references are listed in the bibliography on page 60.

Addition:

IEC/TR 60788:2004, *Medical electrical equipment – Glossary of defined terms* (available in English only)

IEC 61217:1996, *Radiotherapy equipment – Coordinates, movements and scales*

201.3 Terms and definitions

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

NOTE An index of defined terms is to be found at the end of the document.

Addition:

201.3.201
AMBIENT DOSE EQUIVALENT
$H^*(10)$
DOSE EQUIVALENT at the point of interest in the actual RADIATION FIELD defined as DOSE EQUIVALENT which would be generated in the associated oriented and expanded RADIATION FIELD at a depth of 10 mm on the radius of the ICRU sphere which is oriented opposite to the direction of incident RADIATION

NOTE 1 An oriented and expanded RADIATION FIELD is an idealized RADIATION FIELD which is expanded and in which the radiation is additionally oriented in one direction.

NOTE 2 See also ICRU definition of AMBIENT DOSE EQUIVALENT in ICRU Report 39.

201.3.202
CONTROLLING TIMER
device to measure the time during which IRRADIATION occurs and, if a predetermined time is reached, TO TERMINATE IRRADIATION

201.3.203
ELECTRON BEAM APPLICATOR
BEAM LIMITING DEVICE for ELECTRON RADIATION beams

201.3.204
ELECTRONIC IMAGING DEVICE
EID
device consisting of one or more RADIATION DETECTORS and associated electronics, which enables anatomical structures of a PATIENT to be viewed as a digital radiograph at a viewing screen

[IEC 60976:2007, definition 3.5]

201.3.205
ELECTRONIC PORTAL IMAGING DEVICE
EPID
device consisting of a two-dimensional RADIATION DETECTOR and associated electronics, placed substantially normal to the RADIATION BEAM AXIS, which enables anatomical structures of a PATIENT to be viewed as a digital radiograph at a viewing screen, using the medical ELECTRON ACCELERATOR'S RADIATION BEAM as the RADIATION SOURCE

NOTE 1 The primary function of an EPID is in verification of PATIENT set-up, and so replaces the need for port films for this same purpose.

[IEC 60976:2007, definition 3.6]

NOTE 2 This definition is not included in IEC/TR 60788.

201.3.206
GANTRY
part of the ME EQUIPMENT supporting the RADIATION HEAD

201.3.207
GEOMETRICAL RADIATION FIELD
geometrical projection of the distal end of the BEAM LIMITING DEVICE on a plane orthogonal to the REFERENCE AXIS, as seen from the centre of the front surface of the TARGET/ELECTRON RADIATION window; the GEOMETRICAL RADIATION FIELD may be defined at any distance from the front surface of the TARGET for X-RADIATION, or from the ELECTRON RADIATION window for ELECTRON RADIATION

201.3.208
HARD-WIRED
term used where the features of a system can be modified only by physically removing and re-routing wires

201.3.209
INTENSITY MODULATION RADIATION THERAPY
IMRT
treatment procedure requiring, in general, the coordinated control of photon or electron fluence, beam orientation relative to the PATIENT, and beam size of the external beam, either in a continuous or a discrete manner, and as pre-determined by a treatment plan

NOTE The primary purpose of IMRT is to improve the conformity of the dose distribution to the planned TARGET VOLUME, while minimizing dose to surrounding healthy tissue.

201.3.210
INTERRUPTION OF IRRADIATION/TO INTERRUPT IRRADIATION
stopping of/to stop IRRADIATION and movements with the possibility of continuing without reselecting operating conditions

201.3.211
MOVING BEAM RADIOTHERAPY
RADIOTHERAPY with any planned displacement of the RADIATION FIELD or PATIENT relative to each other or with any planned change of ABSORBED DOSE distribution

201.3.212
NOMINAL ENERGY
ENERGY
<ELECTRON RADIATION> ENERGY stated by the MANUFACTURER to characterize the RADIATION BEAM

<X-RADIATION> ENERGY stated by the MANUFACTURER to characterize the radiation BEAM

201.3.213
NORMAL TREATMENT DISTANCE
NTD
<ELECTRON RADIATION> SPECIFIED distance measured along the REFERENCE AXIS from the ELECTRON RADIATION window to the distal end of the ELECTRON BEAM APPLICATOR or to a SPECIFIED plane

<X-RADIATION> SPECIFIED distance measured along the REFERENCE AXIS from the front surface of the TARGET to the ISOCENTRE or, for ME EQUIPMENT without an ISOCENTRE, to a SPECIFIED plane

201.3.214
PASSWORD
<RADIOTHERAPY> sequence of keystrokes that permits OPERATOR access for NORMAL USE or to reset INTERLOCKS and, with a different sequence of keystrokes, permits access for adjustment and maintenance

201.3.215
PATIENT SUPPORT
<RADIOTHERAPY> assembly of ME EQUIPMENT that supports the PATIENT

201.3.216
PRIMARY/SECONDARY DOSE MONITORING COMBINATION
utilization of two DOSE MONITORING SYSTEMS where one is arranged to be the PRIMARY and the other the SECONDARY DOSE MONITORING SYSTEM

201.3.217
QUALIFIED PERSON
person recognised by a competent authority as having the requisite knowledge and training to perform particular duties

201.3.218
RADIATION TYPE
nature of the waves or corpuscles comprising the RADIATION

NOTE E.g. whether the RADIATION is X-RADIATION or ELECTRON RADIATION.

201.3.219
REDUNDANT DOSE MONITORING COMBINATION
utilization of two DOSE MONITORING SYSTEMS where both systems are arranged TO TERMINATE IRRADIATION according to the pre-selected number of DOSE MONITOR UNITS

201.3.220
RELATIVE SURFACE DOSE
ratio of the ABSORBED DOSE on the REFERENCE AXIS, at the depth of 0,5 mm, to the maximum ABSORBED DOSE on the REFERENCE AXIS, both measured in a PHANTOM with its surface at a SPECIFIED distance

201.3.221
SITE TEST
after installation, test of an individual device or ME EQUIPMENT to establish compliance with SPECIFIED criteria

201.3.222
STEREOTACTIC RADIOTHERAPY
SRT
treatment procedure in which RADIATION BEAMS of generally small size are oriented from various angles, and precisely positioned relative to a TARGET VOLUME within the PATIENT

NOTE Precise location of the TARGET VOLUME is enabled by use of a three-dimensional frame of reference, which may include anatomical registration points or markers, and immobilisation methods, or imaging techniques.

201.3.223
STEREOTACTIC RADIOSURGERY
SRS
SPECIFIC version of STEREOTACTIC RADIOTHERAPY, in which a single high dose of RADIATION is delivered to the TARGET VOLUME, using a STEREOTACTIC FRAME OF REFERENCE in conjunction with anatomical registration points

201.3.224
STEREOTACTIC FRAME OF REFERENCE
three-dimensional coordinate system for numerical specification of the position of those parts of a PATIENT anatomy intended for SRS/SRT treatment

201.3.225
TERMINATION OF IRRADIATION
TERMINATE IRRADIATION
stopping of/to stop IRRADIATION and movements, with no possibility of restarting without the reselection of all operating conditions

NOTE 1 I.e. returning/to return to the PREPARATORY STATE.

NOTE 2 Events that TERMINATE IRRADIATION and stop movements include the following:

- when the pre-selected value of DOSE MONITOR UNITS is reached,
- when the pre-selected value of elapsed time is reached,
- a deliberate manual act,
- the operation of an INTERLOCK,
- in MOVING BEAM RADIOTHERAPY, when the pre-selected value of an angular or linear dimension is exceeded.

201.3.226
TRANSMISSION DETECTOR
RADIATION DETECTOR through which the RADIATION BEAM passes

〖A1〗 *Text deleted* 〖A1〗

201.4 General requirements

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

201.4.3 ESSENTIAL PERFORMANCE

Addition:

Requirements of 201.10 are identified as ESSENTIAL PERFORMANCE requirements.

201.5 General requirements for testing ME EQUIPMENT

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

201.5.1 TYPE TESTS

Additional subclause:

201.5.1.101 Test grades

Three grades of TYPE TEST and two of SITE TEST procedures are SPECIFIED in 201.10 of this particular standard. Their requirements are as follows:

– TYPE TEST grade A: An analysis of ME EQUIPMENT design, as related to the SPECIFIED RADIATION safety provisions, which shall result in a statement included in the technical description, regarding the working principles or constructional means by which the requirement is fulfilled.

– TYPE TEST/SITE TEST grade B: Visual inspection or functional test or measurement of the ME EQUIPMENT. The test shall be in accordance with the procedure SPECIFIED IN this particular standard and shall be based on operating states, including fault condition states, which are achievable only without interference with the circuitry or construction of the ME EQUIPMENT.

– TYPE TEST/SITE TEST grade C: Functional test or measurement of the ME EQUIPMENT. The test shall be in accordance with the principle SPECIFIED in this particular standard. The SITE TEST procedure shall be included in the technical description. When the procedure involves operating states that require interference with circuitry or the construction of the ME EQUIPMENT, the test should be performed by, or under the direct supervision of the MANUFACTURER or his agent.

201.5.4 Other conditions

〈A1〉 *Item 5.4 a) of the general standard does not apply.*

Replacement of item 5.4 d):

d) Where cooling water is required, water as required in the technical description is used.

Addition:

The manufacturer shall state in the ACCOMPANYING DOCUMENTS any additional requirement for testing.〈A1〉

201.5.9 Determination of APPLIED PARTS and ACCESSIBLE PARTS

201.5.9.2.1 Test finger

Addition:

Where the nature of the installation renders parts inaccessible per the test with the standard test finger and they can only be made accessible by use of a TOOL, those parts will not be considered ACCESSIBLE PARTS. The ACCOMPANYING DOCUMENTS shall describe such situations.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

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

201.7.2.4 ACCESSORIES

Addition:

The dimensions of the GEOMETRICAL RADIATION FIELD at NTD and the distance from the distal end to NTD shall be clearly legible on the outside of all interchangeable and non-adjustable BEAM LIMITING DEVICES (BLDs) and ELECTRON BEAM APPLICATORS.

Each manually interchangeable WEDGE FILTER shall be clearly marked to establish its identity.

201.7.2.20 Removable protective means

Addition:

Where the requirements of the subclause of the general standard are wholly or partly met by the nature of the installation, compliance at installation should be checked by inspection; the results should be included in the SITE TEST report.

201.7.3 Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts

Additional subclause:

201.7.3.101 RADIATION HEAD

〈A1〉 Removal of the covers of the RADIATION HEAD shall expose safety sign 10 of Table D.2 of the general standard, indicating “Follow instructions for use”. 〈A1〉

201.7.4 Marking of controls and instruments

Additional subclause:

201.7.4.101 Provision of scales and indications for moving parts

The following shall be provided:

a) a mechanical scale or a numerical indication for each available movement;
b) a means to align the PATIENT with respect to the REFERENCE AXIS (e.g. LIGHT FIELD, lasers etc.);
c) a means to determine RADIATION SOURCE TO SKIN DISTANCE (e.g. scale, numerical indication, or lasers).

The designation, direction of increasing value and zero position of all movements shall comply with IEC 61217 (see Figure 201.108).

Compliance is checked by inspection.

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 other control panels, the colours of the lights shall accord with the following:

RADIATION BEAM "on" yellow

READY STATE green

NOTE In the TREATMENT ROOM or at other locations, these states may require urgent action or caution; different colours, in accordance with the Table 201.101 below, may therefore be used in such locations.

Table 101.101 – Colours of indicator lights and their meaning for ME EQUIPMENT

Colour	Meaning
Red	Warning – immediate response by the OPERATOR is required
Yellow	Caution – prompt response by the OPERATOR is required
Green	Ready for use
Any other colour	Meaning other than that of red, yellow or green

Urgent action required in response to an unintended state of operation red

PREPARATORY STATE other colour

201.7.9 ACCOMPANYING DOCUMENTS

Addition:

Data required in the technical description to support Clause 201.10 SITE TEST compliance is given in Table 201.102.

Table 201.102 – Data required in the technical description to support Clause 201.10 SITE TEST compliance

Compliance subclause	Statement regarding data from TYPE TESTS grade A	Details of, and results from, TYPE TESTS grade B	Details of, and results from, TYPE TESTS grade C	SPECIFIC procedures and test conditions for SITE TESTS grade B	SPECIFIC procedures and test conditions for SITE TESTS grade C
201.10.1.2.101.1.2	*b) d) e)*		*d)*		*a) b) c)*
201.10.1.2.101.1.3	*a) b)*		*b) c)*		*b)*
201.10.1.2.101.1.4	*d) e) f)*			*a) b) c) d) e) f)*	
201.10.1.2.101.1.5				a) b)	
201.10.1.2.101.1.6	*a) b) c) d)*				*b) c) d)*
201.10.1.2.101.1.7	*a)*				*b)*
201.10.1.2.101.2	*a) b) c)*			*a) d)*	*b) c)*
201.10.1.2.101.3	*b) c) d) e)*			*a)*	*b) c) d) e)*
201.10.1.2.101.4	*a) b) c) d) e)*			*a) b) c) d) e)*	
201.10.1.2.101.5	*c)*		*c)*	*a) b)*	
201.10.1.2.101.6	*c) f)*		*d) e)*	*a) b)*	*c) d) e) f)*
201.10.1.2.101.7.1				*a)*	*b)*
201.10.1.2.101.7.2				*a) c)*	*b)*
201.10.1.2.101.7.3.1	†				†
201.10.1.2.101.7.3.2				*a) c) d)*	*b)*
201.10.1.2.101.8				*a) b) c) d) e) f) g)*	
201.10.1.2.101.9	*a)*			*a)*	
201.10.1.2.101.10	*e)*			*a) b) c) d) e)*	
201.10.1.2.101.11	†				
201.10.1.2.101.12	*a) c)*			*a) b) c) d)*	
201.10.1.2.101.13	*a)*			*a) b)*	
201.10.1.2.101.14	*a) b)*				*a) b)*
201.10.1.2.102.1	†			†	
201.10.1.2.102.2		†		†	

Compliance subclause	Statement regarding data from TYPE TESTS grade A	Details of, and results from, TYPE TESTS grade B	Details of, and results from, TYPE TESTS grade C	SPECIFIC procedures and test conditions for SITE TESTS grade B	SPECIFIC procedures and test conditions for SITE TESTS grade C
201.10.1.2.102.3			†		
201.10.1.2.103.2.1		*a) b) c) d)*		*a) b) c) d)*	
201.10.1.2.103.2.2	*c)*	*a) 1), a) 2), b)*		*a) b)*	*c)*
201.10.1.2.103.3		†			
201.10.1.2.103.4		†			
201.10.1.2.103.5	† ← *grade A or grade C test* →		†		†
201.10.1.2.104.1		*a) b)*		*a) b)*	
201.10.1.2.104.2			†		
201.10.1.2.104.3	*b)*	*a)*			
201.10.1.2.104.4	†			†	
201.10.1.2.104.5		†			
201.14.101	†				‡
201.101.1	†				
201.101.2	†				
201.101.3	†				
201.101.5	†				

NOTE † denotes requirement of subclause having no other SPECIFIC identification.

Clauses and subclauses in this particular standard that require the provision of information in the ACCOMPANYING DOCUMENTS, INSTRUCTIONS FOR USE and the technical description are given in Table 201.103.

Table 201.103 – Clauses and subclauses in this particular standard that require the provision of information in the ACCOMPANYING DOCUMENTS, INSTRUCTIONS FOR USE and the technical description

Check reference	ACCOMPANYING DOCUMENTS	INSTRUCTIONS FOR USE	Technical description
1			201.5.1.101
2	201.5.4		
3	201.5.9.2.1		
4	201.7.3.101		
5			201.7.9
6			201.8.11.1
7		201.9.2.101 *1)*	
8		201.9.2.102 d)	
9		201.9.2.103 e)	
10	201.9.2.4.101		
11	201.9.8.101 b)		
12	201.9.101		
13			201.10 (see Table 201.102)
14	201.10.1.2.101.1.2 c) (Note)		
15			201.10.1.2.101.1.2 d)
16		201.10.1.2.101.2 b)	
17			201.10.1.2.101.3 b), c), e)
18			201.10.1.2.101.4 d) (Note)
19		201.10.1.2.101.5 b)	
20			201.10.1.2.101.7.3.1
21		201.10.1.2.101.10 e)	
22		201.10.1.2.101.12 a), d)	
23		201.10.1.2.101.13 a)	
24		201.10.1.2.101.14 a)	
25	201.10.1.2.103.2.1 b)		
26			201.10.1.2.104.1 b)
27			201.10.1.2.104.3 b)
28		201.14.101 e)	
29	201.17		
30	201.101.2		
31	201.101.3		
NOTE The check reference is given as an aid for checking the availability of compliance documentation.			

201.7.9.2.15 Environmental protection

Addition:

NOTE The USER's radiological protection adviser is, generally, the person responsible for the identification and disposal of material that may exhibit RADIOACTIVITY.

To assist the RESPONSIBLE ORGANIZATION's radiological protection adviser, the following data shall be provided:

– ENERGIES and corresponding maximum ABSORBED DOSE RATES at NTD under conditions of NORMAL USE for
  - X-RADIATION (with and without any ADDED FILTER if NORMAL USE is possible in both these states), and
  - ELECTRON RADIATION;
– dimensioned shape of the maximum GEOMETRICAL RADIATION FIELDS at NTD for X-RADIATION and ELECTRON RADIATION;
– location(s), referenced to accessible points on the RADIATION HEAD, of:
  - the front surface of the TARGET, and
  - the ELECTRON BEAM RADIATION window;
– available directions of the RADIATION BEAM;
– if a RADIATION BEAM shield is incorporated, its transmission factor at each X-RADIATION ENERGY;
– guidance and precautions regarding the identification, handling and disposal of ME EQUIPMENT or ME EQUIPMENT parts that may exhibit RADIOACTIVITY.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

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

201.8.4.2 ACCESSIBLE PARTS including APPLIED PARTS

Addition:

〈A1〉 The requirements of 8.4.2 d) of the general standard do not apply where the installation prevents the test rod or the test pin from being inserted into the openings concerned. The ACCOMPANYING DOCUMENTS shall state when these conditions apply. 〈A1〉

201.8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

201.8.7.1 General requirements

Addition to item b):

– with the ME EQUIPMENT energised in the PREPARATORY STATE and with the worst possible combination of simultaneously powered movements.

201.8.11 MAINS PARTS, components and layout

201.8.11.1 Isolation from the SUPPLY MAINS

Replacement of item b):

b) Means for isolation, except for those circuits that have to remain connected for safety reasons, e.g. vacuum pumps, room lights and certain safety INTERLOCKS, shall be incorporated either in the ME EQUIPMENT or externally in as many locations as may be considered necessary. Where such means are to be wholly or partly met by installation, the requirements shall be included in the technical description.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies, except as follows:

201.9.2 HAZARDS associated with moving parts

201.9.2.1 General

Addition:

NOTE 1 The phrase "to set-up automatically" or "automatic set-up" is used to denote the moving of ME EQUIPMENT parts automatically to the positions required for the start of a PATIENT treatment.

NOTE 2 The term "pre-programmed movements" is used where movement of ME EQUIPMENT parts takes place according to a previously planned programme, without intervention by the OPERATOR, during a PATIENT treatment; the treatment is referred to as a "pre-programmed treatment".

201.9.2.2.5 Continuous activation

Item 9.2.2.5 b) of general standard does not apply.

〖A1〗 *Text deleted* 〖A1〗

201.9.2.4 Emergency stopping devices

Additional subclause:

201.9.2.4.101 Motors emergency stop

Readily identifiable and accessible means for stopping all movements within the limits given in 201.9.2.101 shall be provided in HARD-WIRED circuit or have an equivalent safety switching function, and be independent of any PESS. These means shall be near to, or on, the PATIENT SUPPORT system and the TCP. The means provided near to, or on, the TCP shall also TERMINATE IRRADIATION. The time to effect these disconnections shall not exceed 100 ms. When any of the means are to be incorporated on site by the RESPONSIBLE ORGANIZATION, the requirements and SITE TEST procedures shall be SPECIFIED in the ACCOMPANYING DOCUMENTS, the results should be incorporated in the SITE TEST report.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS, and by inspection and measurement of stopping distances and disconnection times using suitable measuring instruments; in order to eliminate the effects of variable personal reaction times, measurements shall start at the instant the personally actuated switch contacts open or close.

Additional subclauses:

201.9.2.101 GANTRY, RADIATION HEAD and PATIENT SUPPORT system

a) General

1) When the RADIATION HEAD or any other part is provided with a means designed to reduce in NORMAL USE the risk of collision, including with the PATIENT, the operation and limitations of each control shall be described in the INSTRUCTIONS FOR USE.

2) When the RADIATION HEAD or any other part (including ACCESSORY items) is not designed with a control to reduce, in NORMAL USE, the risk of collisions, the collision risks shall be stated in the ACCOMPANYING DOCUMENTS.

3) Interruption or failure of powered movements or of the SUPPLY MAINS for the ME EQUIPMENT shall cause any parts in motion to be stopped within the limits given in item b) 3) and c) 3) of this subclause.

4) For automatic set-up and for the checks of pre-programmed movements before treatment, the overshoot shall not exceed 2° for rotational displacements and 5 mm for linear displacements.

〈A1〉 5) For the patient support system, these requirements shall apply when the system is unloaded and when it is loaded with a distributed mass of 135 kg. 〈A1〉

b) Rotational movements

1) The minimum speed available for each movement shall not exceed $1° \times s^{-1}$.

2) No speed shall exceed $7° \times s^{-1}$ unless pre-programmed, and identified as an acceptable risk, through MANUFACTURER'S RISK ANALYSIS.

3) When rotating at the speed nearest to but not exceeding, $1° \times s^{-1}$, the angle between the position of the moving part at the instant of operating any control to stop the movement and its final position shall not exceed 0,5°. For speeds faster than $1° \times s^{-1}$, it shall not exceed 3°.

Exception – Requirement b) 2) above does not apply to the BEAM LIMITING SYSTEM (BLS).

c) Linear movements

1) The minimum speed available for displacements 20, 21, 22 and 23 as specified in the IEC 61217 Figure 13c of the RADIATION FIELD edges, and displacements 9, 10 and 11 as specified in Figure 201.108 of the PATIENT SUPPORT system shall not exceed $10 \text{ mm} \times s^{-1}$.

2) No speed shall exceed $100 \text{ mm} \times s^{-1}$ unless pre-programmed, and identified as an acceptable RISK, through MANUFACTURERS RISK ANALYSIS.

3) The distance between the position of the moving part at the instant of operating any control to stop the movement and its final position shall not exceed 10 mm for any speed greater than $25 \text{ mm} \times s^{-1}$, and 3 mm for speeds not exceeding $25 \text{ mm} \times s^{-1}$.

Exception – Requirement 2) above does not apply to the BEAM LIMITING SYSTEM (BLS).

Compliance is checked as follows:

1) by inspection of the INSTRUCTIONS FOR USE and the facilities provided;

2) by interruption of the SUPPLY MAINS a) to powered movements, b) to the ME EQUIPMENT, and measurement of the stopping distances. In order to eliminate the effects of variable personal reaction times, measurement shall start at the instant the personally actuated switch contacts open or close. In determining a stopping distance, the measurement shall be repeated five times; on each occasion, the part in motion shall stop within the allowable distance;

3) by inspection and measurement.

201.9.2.102 Operation of movements of ME EQUIPMENT parts from inside the TREATMENT ROOM

a) It shall not be possible to operate motorized movements of ME EQUIPMENT parts which may cause physical injury to the PATIENT, without continuous personal action by the OPERATOR on two switches simultaneously. Each switch, when released, shall be capable of interrupting movement; one switch may be common to all movements.

NOTE Linear or rotational adjustments of BLDs are not considered to be likely causes of injury to the PATIENT unless ACCESSORIES are fitted that do not have integral safety devices/touch guards or are otherwise considered to present a safety hazard, e.g. some types of ELECTRON BEAM APPLICATORS.

b) For ME EQUIPMENT intended to be set up automatically, it shall not be possible to initiate or maintain movements associated with this condition without continuous personal action by the OPERATOR simultaneously on the automatic set-up switch and a switch common to all movements.

c) The switches required in a) and b) above shall be located close to the PATIENT SUPPORT system, so that, by careful observation, the OPERATOR can avoid possible injury to the PATIENT. At least one of the switches required in a) and b) shall be HARD-WIRED or have an equivalent safety switching function.

d) The INSTRUCTIONS FOR USE shall contain advice that, when either an intended remotely controlled movement from the TCP or a pre-programmed movement is included in the treatment prescription, with the PATIENT finally positioned, a check of all intended or planned movements should be made by the OPERATOR before leaving the TREATMENT ROOM.

Compliance is checked by inspection.

201.9.2.103 Operation of movements of ME EQUIPMENT parts from outside the TREATMENT ROOM

a) It shall be impossible to initiate or maintain movements associated with automatic set-up without continuous personal action by the OPERATOR simultaneously on the automatic set-up switch and a switch common to all movements. Each switch, when released, shall be capable of stopping movement; at least one of the switches shall be HARD-WIRED.

b) After ME EQUIPMENT parts have been set up automatically and/or pre-programmed, it shall be impossible to adjust any movement parameter before the pre-programmed treatment has been completed, without causing TERMINATION OF IRRADIATION.

c) For ME EQUIPMENT that has not been pre-programmed, it shall be impossible to adjust any movement parameter during IRRADIATION without causing TERMINATION OF IRRADIATION.

d) For ME EQUIPMENT that has not been pre-programmed, it shall be possible to adjust movement parameters before IRRADIATION, or after TERMINATION OF IRRADIATION, but only when there is continuous personal action by the OPERATOR on two switches simultaneously. Each switch, when released, shall be capable of stopping movement; one switch shall be HARD-WIRED or have an equivalent safety switching function and shall be common to all movements.

e) The INSTRUCTIONS FOR USE shall include the recommendation that the OPERATOR should have an unobstructed view of the PATIENT before and during IRRADIATION.

f) Any INTERRUPTION OF IRRADIATION or TERMINATION OF IRRADIATION shall cause all ME EQUIPMENT parts in motion to be stopped within the limits given in 201.9.2.101.

Compliance is checked for a), b), c), d) and e) by inspection; and for f) as required in 201.9.2.101.

201.9.7 Pressure vessels and parts subject to pneumatic and hydraulic pressure

Additional subclause:

201.9.7.101 Change of pressure

If a hazardous situation can arise from a change in the pressure of a system used to provide power for movements, all movement shall stop from any speed within the limits SPECIFIED in 201.9.2.101.

Compliance is checked by simulation of a fault condition, operation of protective devices and measurement of stopping distances.

201.9.8 HAZARDS associated with support systems

Additional subclause:

201.9.8.101 Attachment of ACCESSORIES

a) Where means are provided to permit the attachment of ACCESSORIES supplied by the MANUFACTURER, in particular those for shaping the RADIATION BEAM or influencing the ABSORBED DOSE distribution, such means shall be designed to retain those ACCESSORIES securely under all conditions of NORMAL USE.

Compliance is checked by inspection, and by consideration of design data and applied safety factors.

b) The ACCOMPANYING DOCUMENTS shall contain maintenance requirements, and define the conditions and limits of use for the ACCESSORIES supplied; they should include guidance regarding design limits for other ACCESSORIES manufactured or commissioned by the RESPONSIBLE ORGANIZATION.

Compliance is checked by inspection.

Additional subclause:

201.9.101 Relative movement between immobilisation devices and patient support system

ME EQUIPMENT MANUFACTURERS that provide immobilisation devices shall carry out a RISK ANALYSIS to determine what factors could result in relative movement between the immobilisation device (e.g. head-frame) and the PATIENT SUPPORT system. This analysis shall at least include consideration of:

– strength of the immobilisation device and how much it will flex when supporting the PATIENT; and

– the possibility of fixings attaching the immobilisation device to the PATIENT SUPPORT system becoming loose or undone.

Compliance is checked by the inspection of the RISK MANAGEMENT FILE.

201.10 Protection against unwanted and excessive radiation HAZARDS

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

NOTE Throughout this clause, data for a percentage ABSORBED DOSE requirement should be obtained from measurements made during identical settings of DOSE MONITOR UNITS and, except where alterations are essential for the comparison.

201.10.1 X-RADIATION

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

Replacement:

201.10.1.2.101 Protection against incorrect ABSORBED DOSE in the TREATMENT VOLUME

201.10.1.2.101.1 Monitoring and control of ABSORBED DOSE

201.10.1.2.101.1.1 Types of DOSE MONITORING SYSTEMS

Two independent DOSE MONITORING SYSTEMS shall be provided.

201.10.1.2.101.1.2 DOSE MONITORING SYSTEMS

The RADIATION DETECTORS specified in 201.10.1.2.101.1.3 shall form part of two DOSE MONITORING SYSTEMS from whose outputs, displayed as DOSE MONITOR UNITS, the ABSORBED DOSE at a reference point in the TREATMENT VOLUME can be calculated.

The DOSE MONITORING SYSTEMS shall satisfy the following requirements:

a) malfunctioning of one DOSE MONITORING SYSTEM shall not affect the correct functioning of the other;

b) failure of any common element that could change the response of either DOSE MONITORING SYSTEM by more than 5 % shall TERMINATE IRRADIATION;

c) when separate power supplies are used, failure of either supply shall TERMINATE IRRADIATION and prevent further IRRADIATIONS;

NOTE Failure of a power supply includes failure to supply a voltage or current within the range necessary for correct functioning of the DOSE MONITORING SYSTEM as SPECIFIED in the ACCOMPANYING DOCUMENTS.

d) the DOSE MONITORING SYSTEMS shall be arranged either as a REDUNDANT DOSE MONITORING COMBINATION or as a PRIMARY/SECONDARY DOSE MONITORING COMBINATION. In the case of a REDUNDANT DOSE MONITORING COMBINATION, both systems shall be capable of the performance stated in the technical description. In the case of a PRIMARY/SECONDARY DOSE MONITORING COMBINATION, at least the PRIMARY DOSE MONITORING SYSTEM shall be capable of the stated performance. Whichever combination is provided, its performance for ABSORBED DOSE RATES up to twice the SPECIFIED maximum shall be included in the technical description;

e) if selected circuit parameters in the DOSE MONITORING SYSTEMS are changed automatically with changes of RADIATION TYPE or ENERGY, the changes in one DOSE MONITORING SYSTEM shall be independent of those in the other system.

Compliance is checked as follows:

a) SITE TEST grade C – Principle: verification of the functioning of each DOSE MONITORING SYSTEM with generated or simulated malfunction of the other system.

b) TYPE TEST grade A – Statement regarding which elements are common to both systems, and how failure of each of these elements will TERMINATE IRRADIATION.

b) SITE TEST grade C – Principle: verification of the functioning of the INTERLOCK producing TERMINATION OF IRRADIATION by simulation of failure of each common element.

c) SITE TEST grade C – Principle: verification of the functioning of the INTERLOCK producing TERMINATION OF IRRADIATION, by generation or simulation of power failure.

d) TYPE TEST grade C – Principle: verification of the functioning of the DOSE MONITORING SYSTEMS at up to twice the SPECIFIED ABSORBED DOSE RATES for the ME EQUIPMENT in which they are used; functioning may also be verified with the systems removed from the ME EQUIPMENT and tested by other means.

d) TYPE TEST grade A – Statement regarding the performance of the chosen combination of DOSE MONITORING SYSTEMS.

e) TYPE TEST grade A – Statement regarding the independence of systems with change of circuit parameters.

201.10.1.2.101.1.3 RADIATION DETECTORS

a) Two RADIATION DETECTORS shall be provided in the RADIATION HEAD; at least one of these shall be a TRANSMISSION DETECTOR centred on the REFERENCE AXIS on the PATIENT side of all FIELD FLATTENING and BEAM SCATTERING FILTERS.

b) The RADIATION DETECTORS may be of permanent or movable type. Permanent RADIATION DETECTORS shall be removable only by using tools. Movable RADIATION DETECTORS shall be INTERLOCKED to prevent IRRADIATION if they are incorrectly positioned; means shall be provided to ensure that operation of the INTERLOCKS is tested before each IRRADIATION. Movement of a RADIATION DETECTOR away from the REFERENCE AXIS during IRRADIATION shall TERMINATE IRRADIATION.

c) Hermetically sealed RADIATION DETECTORS shall be sealed independently of one another. A certificate of integrity of sealing, at the date of test, should accompany all RADIATION DETECTORS.

NOTE 1 If a certificate is supplied, the RESPONSIBLE ORGANIZATION should record the date of the integrity test when installing a spare RADIATION DETECTOR.

Compliance is checked as follows:

a) TYPE TEST grade A – Statement regarding the position of the axis-centred RADIATION DETECTOR and the FIELD FLATTENING and BEAM SCATTERING FILTERS.

b) TYPE TEST grade A – Statement regarding the operation of the INTERLOCKS and how to ensure that their operation is tested before each IRRADIATION.

b) TYPE TEST grade C – Principle: verification that

- *the displacement of each RADIATION DETECTOR, in turn, from the REFERENCE AXIS, prevents IRRADIATION,*
- *with the radiation detectors correctly positioned, TERMINATION OF IRRADIATION occurs at all ELECTRON and X-radiation energies when any radiation detector is moved away from the REFERENCE AXIS.*

b) SITE TEST grade C – Principle: verification of the functioning of the INTERLOCKS by generation or simulation of the fault condition.

c) TYPE TEST grade C – Principle: verification of the integrity of seals.

NOTE 2 Each RADIATION DETECTOR supplied, including spares, should be accompanied by a certificate of integrity of sealing at the date of test.

201.10.1.2.101.1.4 Selection and DISPLAY of DOSE MONITOR UNITS

a) The DISPLAYS from the DOSE MONITORING SYSTEMS should be clearly legible, of the same design, placed close together and close to a DISPLAY of the pre-selected number of DOSE MONITOR UNITS at the TCP. Each of the DISPLAYS shall have only one scale and no scale multiplying factor.

b) In systems employing visual DISPLAY terminals, two independent visual DISPLAY terminals shall be used or, when the readings of both DOSE MONITORING SYSTEMS are displayed on the same visual DISPLAY terminal, a back-up visual DISPLAY terminal or a conventional DISPLAY shall also be used for at least one of the readings.

c) Any PRIMARY/SECONDARY DOSE MONITORING COMBINATION shall have separate, clearly identified DISPLAYS.

d) The DISPLAYS of DOSE MONITOR UNITS shall show increasing numbers, so that an overdose will give a reading and, together with the DISPLAY of the pre-selected number of DOSE MONITOR UNITS, shall maintain their readings after INTERRUPTION or TERMINATION OF IRRADIATION.

e) Before a new IRRADIATION can be initiated, it shall be necessary to reset the DISPLAYS to zero. IRRADIATION shall not be possible until a selection of DOSE MONITOR UNITS has been made at the TCP.

f) In the event of failure of the SUPPLY MAINS, or a component, which causes INTERRUPTION or TERMINATION OF IRRADIATION, the DOSE MONITOR UNIT information displayed at the time of failure shall be stored in a displayable form in at least one system for a minimum of 20 min.

Compliance is checked as follows:

a) b) c) SITE TEST grade B – Procedure: inspect the DISPLAYS.

d) e) f) TYPE TEST grade A – Statement regarding DISPLAYS and overdose condition.

d) SITE TEST grade B – Procedure: verify DISPLAY readings after INTERRUPTION OF IRRADIATION and after TERMINATION OF IRRADIATION.

e) SITE TEST grade B – Procedure: at one ENERGY for each RADIATION TYPE, initiate IRRADIATION and observe the functioning of the three DISPLAYS; without zeroing the DISPLAYS, attempt to initiate IRRADIATION. Zero the DISPLAYS and, without making a selection of DOSE MONITOR UNITS, again attempt to initiate IRRADIATION.

f) SITE TEST grade B – Procedure: generate a DISPLAY of DOSE MONITOR UNITS, switch off SUPPLY MAINS, verify that the displayed dose information is retained for at least 20 min.

201.10.1.2.101.1.5 ▌A1⟩ VERIFICATION of data coherence and selection of treatment parameters ⟨A1▐

a) Where the selection of system operating conditions requires action in the TREATMENT ROOM and at the TCP, selection at one location shall not give a DISPLAY at the other until the selection at both locations has been completed;

or

where the selection of system operating conditions can be performed from either within the TREATMENT ROOM or at the TCP, the selected conditions shall be displayed in both locations.

b) IRRADIATION shall be prevented if any selection made in the TREATMENT ROOM does not agree with the selection made at the TCP.

A1 c) Consistency, correctness and completeness of the data set imported shall be checked by the ME EQUIPMENT before it can be accepted for IRRADIATION.

In the case of failure of the consistency, correctness or completeness of the data set being loaded, IRRADIATION shall not be allowed to commence.

In the case of abnormal TERMINATION OF IRRADIATION the data set necessary to reconstruct the treatment delivered shall be recorded. (See also 201.10.1.2.101.14).

In the case of restarting after abnormal TERMINATION OF IRRADIATION, the consistency, correctness and completeness of the data set needed for continuation of IRRADIATION shall be checked by the ME EQUIPMENT before it can be accepted for IRRADIATION.

MANUFACTURER shall state in the ACCOMPANYING DOCUMENTS the data set required to perform IRRADIATION.

NOTE Data set may consist of TPS information, CT images, machine model, etc. that are needed for correct treatment delivery.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding data set required to perform IRRADIATION

TYPE TEST grade C – Principle: Verification of preventing IRRADIATION in the case of incorrectness of the loaded data set. A1

201.10.1.2.101.1.6 TERMINATION OF IRRADIATION by monitoring device

a) Both DOSE MONITORING SYSTEMS shall be capable, independently, of TERMINATING IRRADIATION. Means shall be provided to test the correct operation of both systems.

b) Both systems in a REDUNDANT DOSE MONITORING COMBINATION shall be set TO TERMINATE IRRADIATION when the selected number of DOSE MONITOR UNITS has been reached.

The PRIMARY DOSE MONITORING SYSTEM of a PRIMARY/SECONDARY DOSE MONITORING COMBINATION shall be set to terminate IRRADIATION when the selected number of DOSE MONITOR UNITS has been reached; the SECONDARY DOSE MONITORING SYSTEM shall be set to terminate irradiation when the pre-selected number of DOSE MONITOR UNITS has been exceeded, either by not more than 10 % if a percentage margin is used, or by not more than the equivalent of 0,25 Gy ABSORBED DOSE at NTD if a fixed margin is used. Where there is a choice between fixed and percentage margins, the one providing the lesser difference shall be used.

c) INTERLOCKS shall ensure that the system that has not caused TERMINATION OF IRRADIATION is tested between, or prior to, IRRADIATIONS to verify its capability TO TERMINATE IRRADIATION.

d) TERMINATION OF IRRADIATION may be achieved by means other than primary dosimetry systems (e.g. GANTRY angle), in which case the other means are considered as the primary termination system and the dosimetry system will provide secondary means of termination. The dosimetry system shall be set TO TERMINATE IRRADIATION at a dose related value not greater than 110 % of the intended.

Compliance is checked as follows:

a)b) TYPE TEST grade A – Statement regarding the DOSE MONITORING SYSTEMS and margins (where used).

b)d) SITE TEST grade C – Principle: verification of the functioning of TERMINATION OF IRRADIATION by each system when the other is disabled. Test at one ENERGY for each RADIATION TYPE.

c) TYPE TEST grade A – Statement regarding how to ensure that the capability of the non-terminating system to TERMINATE IRRADIATION is verified between, or prior to, IRRADIATIONS.

c) SITE TEST grade C – Principle: verification of the functioning of INTERLOCKS at one ENERGY for each RADIATION TYPE.

d) TYPE TEST grade A – Statement describing the means for termination and the margins allowed.

201.10.1.2.101.1.7 Monitoring of distribution of ABSORBED DOSE

To protect against gross distortion of the distribution of ABSORBED DOSE, e.g. resulting from failure of fixed ADDED FILTERS, electronic control systems or computer based control systems

a) the RADIATION DETECTORS described in 201.10.1.2.101.1.2, or other RADIATION DETECTORS, shall monitor different parts of the RADIATION BEAM to detect symmetrical and non-symmetrical changes of the dose distribution;

b) means shall be provided TO TERMINATE IRRADIATION before an additional ABSORBED DOSE of 0,25 Gy is delivered when, at the depth SPECIFIED for flatness measurements, either the ABSORBED DOSE distribution is distorted by more than 10 %, or the signals from the RADIATION DETECTORS indicate a change greater than 10 %, in the ABSORBED DOSE distribution.

Compliance is checked as follows:

a) TYPE TEST grade A – Statement regarding how to ensure that different parts of the RADIATION BEAM are monitored by the RADIATION DETECTORS.

b) SITE TEST grade C – Principle: verification that an INTERLOCK operates to TERMINATE IRRADIATION before an additional ABSORBED DOSE of 0,25 Gy is delivered to the RADIATION FIELD at the depth SPECIFIED for flatness measurements when a distortion, equivalent to a change of greater than 10 % in the ABSORBED DOSE distribution, is induced by SPECIFIED means. An elapsed time of at least 2 s shall be allowed between the time RADIATION is first emitted and the introduction of the distortion. This test shall be conducted for all available ENERGIES of X-RADIATION, and at the maximum and minimum ENERGIES for ELECTRON RADIATION.

201.10.1.2.101.2 CONTROLLING TIMER

a) A CONTROLLING TIMER, with a DISPLAY at the TCP, shall be provided. It shall

1) be a "count-up" type,

2) switch on and off with IRRADIATION,

3) retain its reading after INTERRUPTION or TERMINATION OF IRRADIATION,

4) require resetting to zero after TERMINATION OF IRRADIATION before a subsequent IRRADIATION is possible,

5) protect against failure of the DOSE MONITORING SYSTEMS by TERMINATING IRRADIATION when a pre-determined time has elapsed,

6) be independent of any other system or subsystem controlling the TERMINATION OF IRRADIATION.

b) Means shall be provided to limit the setting of the CONTROLLING TIMER to a value, given in the INSTRUCTIONS FOR USE, which is not greater than 120 % of the time required to deliver the intended number of DOSE MONITOR UNITS, or 0,1 min, whichever is the greater, as calculated from the set dose and expected dose rate.

c) INTERLOCKS shall ensure that the ability of the CONTROLLING TIMER to TERMINATE IRRADIATION is tested between, or prior to, IRRADIATIONS.

d) The CONTROLLING TIMER shall be graduated;

1) either in minutes and decimals of minutes,

2) or in seconds,

but not in any combination of 1) and 2).

Compliance is checked as follows:

a) TYPE TEST grade A – Statement regarding 6): independence of TERMINATION OF IRRADIATION.

a) SITE TEST grade B – Procedure: at one ENERGY for each RADIATION TYPE, verify that the CONTROLLING TIMER

1) counts up with IRRADIATION,

2) switches on and off with IRRADIATION,

3) retains its reading after INTERRUPTION or TERMINATION OF IRRADIATION,

4) requires resetting to zero after TERMINATION OF IRRADIATION before a subsequent IRRADIATION can be initiated,

5) TERMINATES IRRADIATION when the pre-selected time has elapsed.

b) TYPE TEST grade A – Statement regarding the value of the time margin.

b) SITE TEST grade C – Principle: verification of the value of the limit setting.

c) TYPE TEST grade A – Statement regarding how to ensure that the capability for TERMINATION OF IRRADIATION is tested between, or prior to, IRRADIATIONS.

c) SITE TEST grade C – Principle: verification of the functioning of the INTERLOCKS.

d) SITE TEST grade B – Procedure: inspect the graduations of the CONTROLLING TIMER.

201.10.1.2.101.3 ABSORBED DOSE RATE

a) A DOSE RATE MONITORING SYSTEM shall be provided. There shall be a DISPLAY of the reading of this system at the TCP (number of DOSE MONITOR UNITS per second, or per minute) from which the ABSORBED DOSE RATE at a reference point in the TREATMENT VOLUME can be calculated. The RADIATION DETECTOR(S) described in 201.10.1.2.101.1.2 may form part of this DOSE RATE MONITORING SYSTEM.

b) If, under any fault conditions, the ME EQUIPMENT can deliver an ABSORBED DOSE RATE at NTD of more than twice the maximum SPECIFIED in the technical description, means shall be provided TO TERMINATE IRRADIATION when the ABSORBED DOSE RATE exceeds a value of not more than twice the maximum SPECIFIED. The value of the ABSORBED DOSE RATE that produces TERMINATION OF IRRADIATION shall be given in the technical description.

c) If, under any fault conditions, the ME EQUIPMENT can deliver an ABSORBED DOSE RATE at NTD of more than ten times the maximum SPECIFIED in the technical description, a RADIATION BEAM monitoring device, which shall use a circuit independent of the DOSE RATE MONITORING SYSTEM, shall be incorporated on the PATIENT side of the RADIATION BEAM distribution system. This shall limit the excess ABSORBED DOSE at any point in the RADIATION FIELD to less than 4 Gy. The value of the excess ABSORBED DOSE shall be given in the technical description.

NOTE 1 In ME EQUIPMENT capable of producing both X-RADIATION and ELECTRON RADIATION, the TERMINATION OF IRRADIATION may need to be completed before the generation of the next pulse of RADIATION.

NOTE 2 Only one DOSE RATE MONITORING SYSTEM is required by items a) and b) of this subclause, thus the second DOSE MONITORING SYSTEM may be used to meet the requirements of item c).

d) The means that protect against a possible overdose due to an ABSORBED DOSE RATE of more than twice the SPECIFIED maximum, and limit the excess ABSORBED DOSE to less than 4 Gy, as required respectively in b) and in c) above, shall be tested between, or prior to, IRRADIATIONS for their ability to function.

e) If the ABSORBED DOSE RATE at NTD, averaged over any continuous time interval of not more than 5 s, is less than the intended ABSORBED DOSE RATE by a factor given in the technical description, TERMINATION OF IRRADIATION shall occur.

NOTE 3 During the first 10 s of IRRADIATION, the factor may differ from that associated with the remainder of the IRRADIATION.

Compliance is checked as follows:

a) SITE TEST grade B – Procedure: verify DISPLAY of the readings at one ENERGY for each RADIATION TYPE.

b) TYPE TEST grade A – Statement regarding the values of maximum SPECIFIED ABSORBED DOSE RATE and of the excess ABSORBED DOSE RATE that cause TERMINATION OF IRRADIATION.

b) SITE TEST grade C – Principle: verification of the functioning of the means for producing TERMINATION OF IRRADIATION.

c) TYPE TEST grade A – Statement regarding the design of RADIATION BEAM monitoring device and the value of the excess ABSORBED DOSE that causes TERMINATION OF IRRADIATION.

c) SITE TEST grade C – Principle: verification of the functioning of the RADIATION BEAM monitoring device by generating or simulating excess ELECTRON BEAM current.

d) TYPE TEST grade A – Statement regarding testing between, or prior to, IRRADIATIONS.

d) SITE TEST grade C – Principle: verification of the functioning of the INTERLOCK(S) by attempting to IRRADIATE when the means to limit ABSORBED DOSE RATE and ABSORBED DOSE have not been tested.

e) TYPE TEST grade A – Statement regarding TERMINATION OF IRRADIATION.

e) SITE TEST grade C – Principle: verification of TERMINATION OF IRRADIATION by generation or simulation of a change of the ABSORBED DOSE RATE by the given factor.

201.10.1.2.101.4 Selection and DISPLAY of RADIATION TYPE

For ME EQUIPMENT capable of both X-RADIATION and ELECTRON RADIATION:

a) after TERMINATION OF IRRADIATION, further IRRADIATION shall be prevented until the selection of RADIATION TYPE has been made afresh at the TCP;

b) the RADIATION TYPE selected shall be displayed at the TCP before and during IRRADIATION;

c) an INTERLOCK shall ensure that only the selected RADIATION TYPE can be emitted;

d) INTERLOCKS shall prevent X-IRRADIATION when ACCESSORIES SPECIFIED for ELECTRON IRRADIATION are fitted, e.g., ELECTRON BEAM APPLICATORS, and shall prevent ELECTRON IRRADIATION when ACCESSORIES SPECIFIED for X-IRRADIATION are in place, e.g. WEDGE FILTERS;

NOTE As a special procedure when ELECTRON RADIATION is selected, a limited amount of X-IRRADIATION ABSORBED DOSE may be delivered for portal imaging of the RADIATION FIELD. When this facility is available, a typical procedure and the value of any limit of associated ABSORBED DOSE should be given in the technical description.

e) X-IRRADIATION shall be prevented when RADIATION BEAM distribution or current control devices SPECIFIED for ELECTRON IRRADIATION are in place, e.g., ELECTRON BEAM SCATTERING FILTERS or ELECTRON RADIATION beam scanning devices. ELECTRON IRRADIATION shall be prevented when RADIATION BEAM distribution or current control devices SPECIFIED for X-IRRADIATION are in place, e.g. X-RADIATION FIELD FLATTENING FILTERS.

Compliance is checked as follows:

a) to e) TYPE TEST grade A – Statement regarding the means used to ensure compliance.

a) SITE TEST grade B – Procedure: attempt to initiate IRRADIATION without selecting RADIATION TYPE.

b) SITE TEST grade B – Procedure: verify functioning of DISPLAYS for all possible selections.

c) SITE TEST grade B – Procedure: verify functioning of SPECIFIED INTERLOCKS.

d) e) SITE TEST grade B – Procedure: verify functioning of SPECIFIED INTERLOCKS when incorrect RADIATION BEAM modifying ACCESSORIES are fitted.

201.10.1.2.101.5 Selection and DISPLAY of ENERGY

a) After TERMINATION OF IRRADIATION, further IRRADIATION shall be prevented until the selection of ENERGY has been made afresh at the TCP. This condition shall not apply to ME EQUIPMENT capable of generating RADIATION BEAMS of only one ENERGY.

b) ME EQUIPMENT capable of generating RADIATION BEAMS of different ENERGIES shall DISPLAY at the TCP, before and during IRRADIATION, the value of the selected ENERGY as SPECIFIED in the INSTRUCTIONS FOR USE.

c) IRRADIATION shall be TERMINATED if the mean ENERGY, E_i[3)], of the ELECTRONS striking:

- the X-RADIATION TARGET, deviates by more than ±20 % during X-IRRADIATION,
- the ELECTRON RADIATION window, deviates by more than ±20 % or ±2 MeV, whichever is the lesser during ELECTRON IRRADIATION,

from the value of mean ENERGY that would occur under normal operating conditions for the selected ENERGY and mode of operation.

Compliance is checked as follows:

a) SITE TEST grade B – Procedure: attempt to initiate RADIATION without selecting an ENERGY.

b) SITE TEST grade B – Procedure: verify functioning of the DISPLAYS for SPECIFIED selections.

c) TYPE TEST grade A – Statement regarding INTERLOCK operation.

c) TYPE TEST grade C – Principle: operation of the INTERLOCK with IRRADIATION, performed under conditions of the SPECIFIED mean ENERGY deviation at all selectable ENERGIES.

201.10.1.2.101.6 Selection and DISPLAY of STATIONARY RADIOTHERAPY and MOVING BEAM RADIOTHERAPY

For ME EQUIPMENT capable of STATIONARY RADIOTHERAPY and MOVING BEAM RADIOTHERAPY:

a) after TERMINATION OF IRRADIATION, further IRRADIATION shall be prevented until STATIONARY RADIOTHERAPY or MOVING BEAM RADIOTHERAPY has been selected afresh at the TCP;

b) the mode of operation and, where selectable for MOVING BEAM RADIOTHERAPY, the directions of motion shall be displayed at the TCP;

c) if there is movement during STATIONARY RADIOTHERAPY, TERMINATION OF IRRADIATION shall occur;

d) during MOVING BEAM RADIOTHERAPY, TERMINATION OF IRRADIATION shall occur if the actual position of a moving part differs by more than 5° or 10 mm at NTD from the position required by calculation using the actual DOSE MONITOR UNITS delivered; information sufficient to enable the continuation of IRRADIATION shall be available for at least 20 min (see also 201.10.1.2.101.1.4f));

〈A1〉 NOTE These tolerances are not additive. 〈A1〉

e) the INTERLOCKS implicit in d) shall include two position sensors or other means to ensure that any single fault failure of the sensors implicit in d) shall prevent RADIATION or, in the event of position monitoring failure during treatment, to TERMINATE the beam;

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3) See ICRU Report 35: Section 3.3 (Energy).

f) for MOVING BEAM RADIOTHERAPY, if a rotational movement can be performed from a selected start angle to a selected stop angle in either clockwise or counter clockwise directions (e.g. by continuous rotation of GANTRY, BLD or PATIENT SUPPORT system through the 180° position), a selection of the direction of rotation shall be required at the TCP. When clockwise rotation is selected, IRRADIATION shall be TERMINATED during counter clockwise rotation, and vice versa.

Compliance is checked as follows:

a) SITE TEST grade B – Procedure: attempt to initiate IRRADIATION without selection of STATIONARY or MOVING BEAM RADIOTHERAPY, at one ENERGY for each RADIATION TYPE.

b) SITE TEST grade B – Procedure: verify functioning of the DISPLAYS for the SPECIFIED selections.

c) TYPE TEST grade A – Statement regarding the changes in rotational angle and linear displacements that cause TERMINATION OF IRRADIATION.

c) SITE TEST grade C – Principle: verification of the TYPE TEST data.

d) e) TYPE TEST grade C – Principle:

1) verification of the functioning of INTERLOCKS under SPECIFIED fault conditions at two widely separated positions, with one of each pair of position sensors disabled in turn, at maximum and minimum speeds in each rotation and displacement direction (see 201.9.2.101);

2) verification that information to enable IRRADIATION to be continued is available 20 min after TERMINATION OF IRRADIATION.

d) e) SITE TEST grade C – Principle: verification of the functioning of INTERLOCKS with one of each pair of position sensors disabled in turn, and verification that information to allow IRRADIATION to be continued, is available 20 min after TERMINATION OF IRRADIATION.

f) TYPE TEST grade A – Statement regarding TERMINATION OF IRRADIATION when attempting rotation movement in the opposite direction to that selected.

f) SITE TEST grade C – Principle: verification of inhibition of IRRADIATION after selecting MOVING BEAM RADIOTHERAPY and attempting to initiate IRRADIATION:

- *without selecting either direction of rotation,*
- *selecting clockwise rotation and then rotating counter clockwise,*
- *selecting counter clockwise rotation and then rotating clockwise.*

201.10.1.2.101.7 RADIATION BEAM production and distribution systems

201.10.1.2.101.7.1 Selection and DISPLAY of TARGETS or other movable RADIATION BEAM production devices

For ME EQUIPMENT having interchangeable TARGETS or other movable RADIATION BEAM production devices (e.g. ENERGY slits):

a) if more than one of the same type of device can be used at one ENERGY for one RADIATION TYPE, IRRADIATION shall be prevented until the selection of a SPECIFIC device has been made and its identity displayed at the TCP;

b) two independent INTERLOCKS shall prevent or TERMINATE IRRADIATION if any element of the device is not positioned correctly.

Compliance is checked as follows:

a) SITE TEST grade B – Procedure: attempt to initiate IRRADIATION without selecting a SPECIFIC device; verify functioning of the DISPLAY.

b) SITE TEST grade C – Principle: the disablement of one of the INTERLOCKS and the attempted initiation of IRRADIATION with each device incorrectly positioned; repeat with the other INTERLOCK disabled.

201.10.1.2.101.7.2 Selection and DISPLAY of FIELD FLATTENING and BEAM SCATTERING FILTERS

For ME EQUIPMENT incorporating movable FIELD FLATTENING or BEAM SCATTERING FILTERS:

a) if more than one FILTER system can be used at one ENERGY of one RADIATION TYPE:
   1) IRRADIATION shall be prevented until a new selection, either of a SPECIFIC FIELD FLATTENING FILTER or of a SPECIFIC BEAM SCATTERING FILTER, has been made at the TCP,
   2) the identity of the FILTER(S) in use shall be displayed at the TCP;
b) two independent INTERLOCKS shall prevent or TERMINATE IRRADIATION if the selected FILTER(S) is(are) not correctly positioned;
c) any FILTER which is removable by hand shall be clearly marked to establish its identity.

Compliance is checked as follows:

a) SITE TEST grade B – Procedure:
   1) attempt to initiate IRRADIATION without the selection of a SPECIFIC FILTER;
   2) verify functioning of the DISPLAY.
b) SITE TEST grade C – Principle: disablement of one INTERLOCK and the attempted initiation of IRRADIATION with each FILTER positioned incorrectly; repeat with the second INTERLOCK disabled.
c) SITE TEST grade B – Procedure: visually inspect all FILTER(S) for identity markings and compare them with the DISPLAYS in a) 2) above.

201.10.1.2.101.7.3 RADIATION BEAM distribution systems not using FIELD FLATTENING or BEAM SCATTERING FILTERS

NOTE In this subclause, "RADIATION BEAM distribution systems" are hereinafter referred to as "distribution systems".

The following requirements are additional to those of 201.10.1.2.101.7.1.

201.10.1.2.101.7.3.1 ME EQUIPMENT in which the distribution is achieved by means other than those using FIELD FLATTENING or BEAM SCATTERING FILTERS, e.g. by ELECTRON BEAM scanning

Two independent devices, with corresponding INTERLOCKS, shall monitor the control signals to prevent or TERMINATE IRRADIATION when the values of the control signals exceed the limits SPECIFIED in the technical description.

Compliance is checked as follows:

a) TYPE TEST grade A – Statement regarding prevention or TERMINATION OF IRRADIATION when control signals exceed SPECIFIED limits.

b) SITE TEST grade C – Principle: verification, at one ENERGY for each RADIATION TYPE, of the functioning of control signal monitors and of the INTERLOCKS preventing or TERMINATING IRRADIATION.

201.10.1.2.101.7.3.2 ME EQUIPMENT incorporating selectable distribution systems

a) After TERMINATION OF IRRADIATION, further IRRADIATION shall be prevented until the selection of a SPECIFIC distribution system has been made afresh at the TCP.
b) Two independent INTERLOCKS shall prevent IRRADIATION if the selected distribution system is not correctly positioned.
c) The identity of the distribution system in use shall be displayed at the TCP.
d) Any distribution system which is removable by hand shall be clearly marked to establish its identity.

Compliance is checked as follows:

a) SITE TEST grade B – Procedure: attempt to initiate IRRADIATION without selecting a SPECIFIC distribution system.

b) SITE TEST grade C – Principle: disablement of one INTERLOCK and attempted initiation of IRRADIATION with each distribution system positioned incorrectly; repeat with the second INTERLOCK disabled.

c) SITE TEST grade B – Procedure: verify functioning of the DISPLAY.

d) SITE TEST grade B – Procedure: visually inspect all distribution systems for identity markings and compare them with the DISPLAYS in c) above.

201.10.1.2.101.8 Selection and DISPLAY of WEDGE FILTERS and PROGRAMMABLE WEDGE FIELDS (PWF)

a) After TERMINATION OF IRRADIATION, further IRRADIATION shall be prevented until a SPECIFIC WEDGE FILTER, PWF, or "no WEDGE FILTER", has been selected afresh at the TCP.

b) ME EQUIPMENT supplied with a system of WEDGE FILTERS shall be provided with a DISPLAY at the TCP showing which WEDGE FILTER (or "no WEDGE FILTER") is in use; each WEDGE FILTER shall be clearly marked to establish its identity (see 201.7.2.4).

c) IRRADIATION shall be prevented if a selected WEDGE FILTER is incorrectly positioned.

d) There shall be a clearly visible indication in the TREATMENT ROOM of the orientation of the thin end of the WEDGE FILTER which, in the 0° position of BLS and WEDGE FILTER rotation, shall point towards the GANTRY (see Figure 201.108 axis 4, and IEC 61217, 2.5 and Figure 7).

e) When a WEDGE FILTER can be positioned otherwise than as in f) below (see IEC 61217, 2.5 and Figure 7), then, in addition to the requirements of a), b) and c), there shall be a DISPLAY in the TREATMENT ROOM and at the TCP of:

   1) the angular displacement of the WEDGE FILTER relative to the 0° position SPECIFIED in *d)*; and

   2) the linear displacement(s) of the axis of rotation of the WEDGE FILTER from the axis of rotation of the BLS.

f) For ME EQUIPMENT supplied with a mechanism, removable only by using tools, for automatically inserting and retracting WEDGE FILTERS, DISPLAYS shall show:

   1) when the selected WEDGE FILTER has been correctly inserted; and

   2) either i) the pre-selected number of DOSE MONITOR UNITS with the WEDGE FILTER inserted [a], and that with the WEDGE FILTER retracted [b]; i.e. DISPLAY [a] and [b],

      or ii) the pre-selected number of DOSE MONITOR UNITS with the WEDGE FILTER inserted [a], and the ratio [a]/[a+b] of the number of DOSE MONITOR UNITS with the WEDGE FILTER inserted to the total number of DOSE MONITOR UNITS, i.e. DISPLAY [a] and [a]/[a+b],

      or iii) the total number of pre-selected DOSE MONITOR UNITS, [a+b], and that with the WEDGE FILTER inserted, [a]; i.e. DISPLAY [a +b] and [a].

g) ME EQUIPMENT capable of delivering PWF shall be provided with a DISPLAY at the TCP showing which PWF is in use, along with a DISPLAY of the orientation of the particular PWF.

Compliance is checked as follows:

a) SITE TEST grade B – Procedure: attempt IRRADIATION without selecting a SPECIFIC WEDGE FILTER, PWF, or "no WEDGE FILTER".

b) SITE TEST grade B – Procedure: inspect WEDGE FILTERS for identity markings; verify that DISPLAYS agree.

c) SITE TEST grade B – Procedure: attempt IRRADIATION with a WEDGE FILTER incorrectly positioned.

d) SITE TEST grade B – Procedure: verify that the indication of the thin end of the WEDGE FILTER can be seen clearly and that the orientation is correct.

e) SITE TEST grade B – Procedure: verify, for all angles of insertion and for three positions of displacement, that the indication of the orientation of the thin end of the WEDGE FILTER and its displacement(s) is/are displayed in both locations.

f)g) SITE TEST grade B – Procedure: verify operation of the DISPLAYS.

201.10.1.2.101.9 [A1] ELECTRON BEAM APPLICATORS, SRS/SRT BLDS and trays for RADIATION BEAM modifying devices [A1]

If an [A1] ELECTRON APPLICATOR [A1] or other RADIATION BEAM modifying device is selected, the IRRADIATION shall be prevented

1) if the selection made in the TREATMENT ROOM does not agree with the selection at the TCP,
2) until a [A1] ELECTRON BEAM APPLICATOR, SRS/SRT BLD [A1] and/or tray for a RADIATION BEAM modifying device has been selected at the TCP,
3) if the selected [A1] ELECTRON BEAM APPLICATOR, SRS/SRT BLD [A1] and/or tray for a RADIATION BEAM modifying device is incorrectly positioned.

Compliance is checked as follows:

a) TYPE TEST grade A – Statement regarding identification, selection and coding of [A1] ELECTRON BEAM APPLICATORS, SRS/SRT BLDS [A1] and trays for RADIATION BEAM modifying devices, and of the associated INTERLOCKS providing for the correct DISPLAYS and preventing IRRADIATION when selection or positioning is incorrect.

b) SITE TEST grade B – Procedure: attempt IRRADIATION

1) for at least two non-agreeing selections,

2) without selecting a [A1] ELECTRON BEAM APPLICATORS, SRS/SRT BLD [A1] and/or tray for a RADIATION BEAM modifying device,

3) with an incorrectly positioned [A1] ELECTRON BEAM APPLICATORS, SRS/SRT BLD [A1] or tray for a RADIATION BEAM modifying device.

201.10.1.2.101.10 Control of ME EQUIPMENT use

NOTE 1 201.14.101f) permits designated PASSWORDS as alternatives to key control when control is effected by PESS.

a) Key control shall

1) control unlocking and switching on of the ME EQUIPMENT to the STAND-BY STATE, and from there to the PREPARATORY STATE. After selection of all treatment parameters has been completed, the READY STATE may be achieved without further operation of the key. IRRADIATION or a sequence of IRRADIATIONS shall remain prevented until RESPONSIBLE ORGANIZATION enabled by PASSWORD or dedicated mechanical key.
2) select the mode for NORMAL USE, all service modes, all other modes and the locked-off condition.

b) The condition of external INTERLOCKS shall be indicated at the TCP.

c) Means shall be provided to connect an aural indication of the READY STATE to be given in the TREATMENT ROOM, and for an indication of the READY STATE to be given at other locations.

d) During IRRADIATION, in addition to the DISPLAY of RADIATION TYPE required by 201.10.1.2.101.4b), there shall be a DISPLAY at the TCP to indicate IRRADIATION; means shall be provided for this DISPLAY to be given at other locations. The aural indication of the READY STATE in the TREATMENT ROOM and its indication elsewhere, required in c) above, shall continue during IRRADIATION; the tone may be changed.

e) The INSTRUCTIONS FOR USE shall contain the following:

1) details of the facilities provided for the connection of external INTERLOCKS that prevent, TERMINATE, or INTERRUPT IRRADIATION from selected locations, e.g. if TREATMENT ROOM doors or other means of access to CONTROLLED AREAS have not been closed, or are opened; and also the facilities required by d) above;

2) advice that the resetting of the external INTERLOCKS required in 1) above should be possible only from inside the CONTROLLED AREAS that they protect, e.g. by using a time delay device to permit exit and door closure after checking that, apart from the PATIENT, no one remains in the CONTROLLED AREAS;

3) a list of the INTERLOCKS that can be reset only by the use of removable dedicated mechanical key(s);

NOTE 2 Any dedicated mechanical key in e) 3) above is additional to that required by 201.10.1.2.101.10a)1).

4) the conditions to be complied with by the RESPONSIBLE ORGANIZATION to ensure the correct functioning of:

- the external INTERLOCKS;
- the aural indications in the TREATMENT ROOM during the READY STATE and IRRADIATION;
- the DISPLAY, at other locations, of the indications of the READY STATE and of IONIZING RADIATION.

Compliance is checked as follows:

a) SITE TEST grade B – Procedure: for 1) and 2), verify that key control is provided and that each selected state and condition is indicated in turn at the TCP; verify the functioning of the dedicated mechanical key.

b) c) d) SITE TEST grade B – Procedure: verify, as appropriate, visual and aural indications.

e) TYPE TEST grade A – Statement regarding connection of the INTERLOCKS, conditions for RESPONSIBLE ORGANIZATION compliance, advice regarding resetting external INTERLOCKS and the list of INTERLOCKS that can be reset only by dedicated mechanical keys.

e) SITE TEST grade B – Procedure: verify functioning and resetting of external INTERLOCKS.

201.10.1.2.101.11 Starting conditions

NOTE 201.14.101f) permits designated PASSWORDS as alternatives to key control when control is effected by PESS.

It shall be possible to start IRRADIATION in NORMAL USE only by OPERATOR action at the TCP when the READY STATE is indicated and after RESPONSIBLE ORGANIZATION enablement by PASSWORD or by the dedicated mechanical key (see 201.10.1.2.101.10a)1)).

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding IRRADIATION in NORMAL USE initiated only from the TCP.

201.10.1.2.101.12 INTERRUPTION OF IRRADIATION

a) It shall be possible TO INTERRUPT IRRADIATION and movements of the ME EQUIPMENT simultaneously, at any time, from the TCP and from other locations as SPECIFIED in the INSTRUCTIONS FOR USE.

b) After an INTERRUPTION OF IRRADIATION, without any change to, or re-selection of, the operating parameters existing immediately before the INTERRUPTION OF IRRADIATION, it shall be possible to re-start IRRADIATION, but only from the TCP.

c) If a change is made to any operating parameter during INTERRUPTION OF IRRADIATION unless part of the intended procedure, the ME EQUIPMENT shall assume the TERMINATION OF IRRADIATION state.

d) If the conditions existing immediately before the INTERRUPTION OF IRRADIATION have been reinstated, then, it should be possible to resume IRRADIATION; for example if, in order to assist or verify the position of the PATIENT, it is necessary to enter the TREATMENT ROOM, move the GANTRY, PATIENT, or PATIENT SUPPORT, then, when all the conditions existing before INTERRUPTION OF IRRADIATION are reinstated, it should be possible to resume IRRADIATION without reselection of the original treatment parameters. Conditions and tolerances allowable under this exception, in addition to those given in 201.10.1.2.101.6d), shall be given in the INSTRUCTIONS FOR USE.

Compliance is checked as follows:

a) TYPE TEST grade A – Statement regarding INTERRUPTION OF IRRADIATION from other locations and recommended SITE TESTS peculiar to individual ME EQUIPMENTS.

a) SITE TEST grade B – Procedure: at one ENERGY for each RADIATION TYPE

1) verify the simultaneous INTERRUPTION OF IRRADIATION and movements from:

- *the TCP,*
- *from any other location provided;*

2) perform other tests as may be recommended by the MANUFACTURER.

b) SITE TEST grade B – Procedure: at one ENERGY for each RADIATION TYPE, verify the restart of IRRADIATION after INTERRUPTION OF IRRADIATION.

c) TYPE TEST grade A – Statement regarding the conditions allowable under the exception.

c) SITE TEST grade B – Procedure: at one ENERGY for each RADIATION TYPE, verify the transition to the TERMINATION OF IRRADIATION state,

d) SITE TEST grade B – Procedure: at one ENERGY for each RADIATION TYPE initiate IRRADIATION; INTERRUPT IRRADIATION and change the position of the GANTRY and PATIENT SUPPORT; reinstate their original positions and recommence IRRADIATION; the tolerances to be applied for reinstatement are those given in 201.10.1.2.101.6d).

201.10.1.2.101.13 TERMINATION OF IRRADIATION

a) It shall be possible TO TERMINATE IRRADIATION and movements at any time from the TCP and from other locations as SPECIFIED in the INSTRUCTIONS FOR USE. This control shall be HARD-WIRED or have equivalent safety switching function and be independent of any PESS.

b) During RADIOTHERAPY, if any operating parameter is adjusted, TERMINATION OF IRRADIATION shall occur. The values of parameters may only be adjusted during RADIOTHERAPY as a result of having been pre-programmed before the start of IRRADIATION or except as may be permitted in 201.10.1.2.101.12c).

Compliance is checked as follows:

a) TYPE TEST grade A – Statement regarding TERMINATION OF IRRADIATION from other locations.

a) SITE TEST grade B – Procedure: verify, at one ENERGY for each RADIATION TYPE, TERMINATION OF IRRADIATION and movements from the TCP and any other location provided.

b) SITE TEST grade B – Procedure: verify TERMINATION OF IRRADIATION when any one of the operating parameters is adjusted during RADIOTHERAPY.

201.10.1.2.101.14 Abnormal TERMINATION OF IRRADIATION

NOTE 1 201.14.101f) permits designated PASSWORDS as alternatives to key control when control is effected by PESS.

If TERMINATION OF IRRADIATION has occurred by any means other than normal operation of the monitoring device,

a) a SPECIFIC DISPLAY shall be given at the TCP. In ME EQUIPMENT with a visual DISPLAY terminal, data shall be displayed regarding the cause of each TERMINATION OF IRRADIATION; the INSTRUCTIONS FOR USE shall contain details of warnings of associated potential safety hazards;

b) further IRRADIATION shall not be achievable without resetting the INTERLOCK causing the abnormal TERMINATION OF IRRADIATION by the use of a designated mechanical key at the TCP.

NOTE 2 The designated mechanical key of b) above, is additional to that referred to in 201.10.1.2.101.10a)1).

Compliance is checked as follows:

a) TYPE TEST grade A – Statement regarding warnings given of potential safety hazards.

a) SITE TEST grade C – Principle: verification of functioning of the DISPLAY by activation of INTERLOCKS to cause unplanned TERMINATION OF IRRADIATION.

b) TYPE TEST grade A – Statement regarding INTERLOCKS that can be reset only by use of the designated mechanical key.

b) SITE TEST grade C – Principle: causation of TERMINATION OF IRRADIATION by SPECIFIED means, followed by attempted initiation of IRRADIATION without the use of a designated mechanical key.

201.10.1.2.102 Protection against STRAY RADIATION in the RADIATION FIELD

201.10.1.2.102.1 STRAY X-RADIATION during ELECTRON IRRADIATION

The percentage ABSORBED DOSE on the REFERENCE AXIS due to X-RADIATION at a depth of 100 mm beyond the practical ELECTRON range shall not exceed the values given in Table 201.104 and as set out in Figure 201.101[4)].

The measurement shall be made in a PHANTOM, the incident surface being normal to the REFERENCE AXIS at NTD and dimensioned at least 5 cm more than the RADIATION FIELD; its depth is to be at least 5 cm more than the depth of measurement.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding percentage stray X-RADIATION during ELECTRON IRRADIATION for all ELECTRON BEAM APPLICATORS and ENERGIES.

SITE TEST grade B – Procedure: perform measurements, as described, at maximum square RADIATION FIELD and at all ENERGIES.

Table 201.104 – Limits of STRAY X-RADIATION during ELECTRON IRRADIATION (see Figure 201.101)

ELECTRON ENERGY, MeV	1	15	35	50
STRAY X-RADIATION, %	3	5	10	20

201.10.1.2.102.2 RELATIVE SURFACE DOSE during X-IRRADIATION

With a RADIATION FIELD of 30 cm × 30 cm, or the largest available square RADIATION FIELD less than 30 cm × 30 cm, the RELATIVE SURFACE DOSE shall not exceed the values given in Table 201.105 and as set out in Figure 201.102.

4) See ICRU Report 35: Section 3.3 (Energy); 3.3.2.3 (Range measurements); 9.2.6.1 (X-ray contamination); etc.

The measurement shall be made in a PHANTOM dimensioned and positioned as in 201.10.1.2.102.1. All RADIATION BEAM modifying devices removable without the use of tools shall be removed from the RADIATION BEAM. All FIELD FLATTENING FILTERS shall remain in their SPECIFIED positions.

Compliance is checked as follows:

TYPE TEST grade B – Procedure: verify RELATIVE SURFACE DOSE for all ENERGIES, as SPECIFIED above.

SITE TEST grade B – Procedure: verify RELATIVE SURFACE DOSE for all ENERGIES, as SPECIFIED above.

Table 201.105 – Limits of RELATIVE SURFACE DOSE during X-IRRADIATION (see Figure 201.102)

NOMINAL ENERGY, MV	1	2	5	8 to 30	40 to 50
RELATIVE SURFACE DOSE, %	80	70	60	50	65

201.10.1.2.102.3 STRAY NEUTRON RADIATION

This requirement shall apply only when the ENERGY of the ELECTRONS anywhere exceeds 10 MeV.

An estimate of the neutron ENERGY distribution and a value for STRAY NEUTRON RADIATION shall be derived from measurements, averaged over a cross-sectional area not exceeding 800 cm^2, of either:

- the neutron ABSORBED DOSE at the ISOCENTRE, as a percentage of the X-RADIATION ABSORBED DOSE measured on the REFERENCE AXIS at the ISOCENTRE in a 10 cm × 10 cm RADIATION FIELD, or
- the maximum neutron fluence rate to be expected at the ISOCENTRE for a stated X-RADIATION ABSORBED DOSE RATE.

Compliance is checked as follows:

TYPE TEST grade C – Principle: for all ENERGIES of X-RADIATION or, if X-RADIATION is not available, for the ENERGY of ELECTRON RADIATION producing the maximum ABSORBED DOSE or maximum fluence rate due to STRAY NEUTRON RADIATION, performance of measurements to obtain the data required. The method, conditions and results of determination for the chosen alternative shall be stated; account shall be taken of the pulsed nature of the RADIATION, the neutron ENERGY spectrum, the effects of the accompanying X-RADIATION and of NEUTRON RADIATION scattered from surrounding structures. The measurements shall be made with the BLDs fully closed and fully opened.

201.10.1.2.103 Protection against RADIATION in the PATIENT plane outside the RADIATION FIELD

201.10.1.2.103.1 General

For ME EQUIPMENT delivered with an ADDED FILTER, if operation with and without the ADDED FILTER can be achieved, the requirements of this subclause shall be satisfied for both conditions.

The boundaries applying to the requirements of this subclause are shown in Figure 201.103.

201.10.1.2.103.2 LEAKAGE RADIATION through BEAM LIMITING DEVICES

NOTE 1 All measurements of LEAKAGE RADIATION exclude the area of the residual rectangular RADIATION FIELD.

NOTE 2 In ME EQUIPMENT using a primary, non-adjustable, BLD for PROTECTIVE SHIELDING in the region between the TARGET/ELECTRON RADIATION window and the adjustable BLDs, *M* is the area at NTD on a plane perpendicular to the REFERENCE AXIS of the geometrical projection of the distal end of that primary BLD, as seen from the centre of the front surface of the TARGET/ELECTRON RADIATION window (for the definition of M_{10}, see 201.10.1.2.103.2.2a)).

NOTE 3 The NTDs for the ELECTRON RADIATION and X-RADIATION modes may differ in the same ELECTRON ACCELERATOR, thus area *M* may differ for this reason as well as that stated in 201.10.1.2.103.2.2a) below.

NOTE 4 A multi-element BLD comprises a SPECIFIED number of RADIATION attenuating structures, assembled and controlled to define a RADIATION FIELD; such an assembly is sometimes referred to as a multileaf collimator. A supplementary multi-element BLD is one that, at choice, may be a temporary or a permanent addition to an existing BLS.

NOTE 5 MANUFACTURERS will use a 10 cm × 10 cm field, or a SPECIFIED reference field. This allowance is detailed in IEC 60976, 5.2.

201.10.1.2.103.2.1 X-RADIATION

Measurements of LEAKAGE RADIATION through all combinations of BLDs shall be made with any residual aperture shielded by at least two TENTH-VALUE LAYERS OF X-RADIATION absorbing material[5]. For non-overlapping BLDs, measurements shall be made at minimum RADIATION FIELD size.

Adjustable or interchangeable BLDs shall be provided. Where any set or combinations of BLDs (including any multi-element BLDs) can overlap, these requirements shall apply to each independent set or combination measured together at the same time:

a) each BLD (excluding those multi-element BLDs for which c) applies) shall attenuate X-RADIATION such that anywhere in the area *M*, excepting the residual rectangular RADIATION FIELD, the ABSORBED DOSE due to LEAKAGE RADIATION does not exceed 2 % of the maximum ABSORBED DOSE measured on the REFERENCE AXIS at NTD in a 10 cm × 10 cm RADIATION FIELD;

b) for RADIATION FIELDS of any size, the average ABSORBED DOSE D_{LX}, due to LEAKAGE RADIATION through the BLDs, including multi-element BLDs, in the area *M*, shall not exceed 0,75 % of the maximum ABSORBED DOSE on the REFERENCE AXIS at NTD in a 10 cm × 10 cm RADIATION FIELD. If this limit is exceeded when areas of greater than 300 cm^2 at NTD are protected by multi-element BLDs, the conditions under which the limit is exceeded and the extent to which the limit is exceeded shall be stated in the ACCOMPANYING DOCUMENTS;

c) when a multi-element BLD is provided that by itself does not comply with the requirements of a) and b) above, and consequently requires adjustable or interchangeable BLDs in order to comply, these shall be adjusted automatically to provide the minimum size rectangular RADIATION FIELD surrounding the RADIATION FIELD defined by the multi-element BLD;

d) the ABSORBED DOSE due to LEAKAGE RADIATION through the parts of a multi-element BLD that project into the rectangular RADIATION FIELD formed by the automatically adjustable BLDs referred to in c) above shall not exceed 5 % of the maximum ABSORBED DOSE measured on the REFERENCE AXIS at NTD in a 10 cm × 10 cm RADIATION FIELD;

e) for equipment which is SPECIFIED by the MANUFACTURER as to be used in IMRT or in other dose delivering techniques requiring raised DOSE MONITOR UNITS compared with conventional therapy, the RADIATION limits given in this subclause should be lowered by at least a factor of 2.

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5) See ICRP 33 (234 et seq.).

Compliance is checked as follows:

a) *TYPE TEST grade B – Procedure:*

1) *locate the area of maximum LEAKAGE RADIATION from the evaluation of DIRECT or INDIRECT RADIOGRAMS produced at maximum X-RADIATION ENERGY and at NTD for BLD settings of maximum RADIATION FIELD size FX_{max} by minimum RADIATION FIELD size FY_{min}. Repeat for settings of FX_{min} by FY_{max};*

2) *perform a RADIATION DETECTOR measurement at the point of maximum LEAKAGE RADIATION. The cross-sectional area of the RADIATION DETECTOR shall not exceed 1 cm^2; the measurement shall be made in a PHANTOM at the depth of the ABSORBED DOSE maximum. Repeat for all X-RADIATION ENERGIES.*

a) *SITE TEST grade B – Procedure: perform a RADIATION DETECTOR measurement as described in the TYPE TEST data for a) 2) above, at the X-RADIATION ENERGY corresponding to the maximum LEAKAGE RADIATION.*

b) *TYPE TEST grade B – Procedure: perform RADIATION DETECTOR measurements as in a) 2) above, at each of the 24 points shown in Figure 201.104, for symmetrical settings of those BLDs provided to produce rectangular RADIATION FIELDS at maximum field size FX_{max} by minimum field size FY_{min}. Determine D_{LX}, the average of all these measurements, as a percentage of the maximum ABSORBED DOSE measured on the REFERENCE AXIS at NTD in a 10 cm × 10 cm RADIATION FIELD. Repeat for symmetrical settings of FX_{min} by FY_{max}. Repeat for all X-RADIATION ENERGIES. If a multi-element BLD exists, then open adjustable or interchangeable BLDs to a square RADIATION FIELD of area 300 cm^2 and close the multi-element BLDs to the smallest opening consistent with this area (e.g. using a thin T or + shaped field). Perform RADIATION DETECTOR measurements in the area protected by the multi-element BLDs. From these measurements calculate the average ABSORBED DOSE D_{LX} due to LEAKAGE RADIATION through the BLDs, including multi-element BLDs, in the area M.*

NOTE The use of two-dimensional arrays of RADIATION DETECTORS may shorten the time required for this test.

b) *SITE TEST grade B – Procedure: as TYPE TEST.*

c) *TYPE TEST grade B – Procedure: use DIRECT or INDIRECT RADIOGRAMS to demonstrate the capability of automatic adjustment of the adjustable or interchangeable BLDs.*

c) *SITE TEST grade B – Procedure: use DIRECT or INDIRECT RADIOGRAMS to confirm the automatic adjustment capability.*

d) *TYPE TEST grade B – Procedure:*

1) *close up all the elements of an opposed pair of multi-element assemblies symmetrically to give the minimum aperture. Open two pairs of elements, one fully and the other partially, furthest away from the REFERENCE AXIS. From the evaluation of DIRECT or INDIRECT RADIOGRAMS, locate the point of maximum LEAKAGE RADIATION outside the now T-shaped residual minimum aperture. Repeat for all X-RADIATION ENERGIES;*

2) *perform RADIATION DETECTOR measurements under the conditions given in the TYPE TEST data for a) 2) above.*

d) *SITE TEST grade B – Procedure: perform a RADIATION DETECTOR measurement at the position of, and under the same conditions as, the highest value of LEAKAGE RADIATION given in the TYPE TEST a) 2) above.*

201.10.1.2.103.2.2 ELECTRON RADIATION

a) Adjustable or interchangeable BLDs, and/or ELECTRON BEAM APPLICATORS shall be provided. Each BLD and/or ELECTRON BEAM APPLICATOR shall attenuate all IONIZING RADIATION (excluding NEUTRON RADIATION) incident on the BLDs, ELECTRON BEAM APPLICATORS and other parts of the RADIATION HEAD, and limit SCATTERED RADIATION outside the ELECTRON RADIATION FIELD, either in the area *M*, or in the area M_{10} which includes *M* and any area outside *M* that results from extending the periphery of the GEOMETRICAL RADIATION FIELD by 10 cm, so that

NOTE Hereinafter, including 201.10.1.2.103.3, *M* represents *M* or M_{10}, whichever is applicable.

1) the ABSORBED DOSE, as a percentage of the maximum ABSORBED DOSE on the REFERENCE AXIS at NTD, shall not exceed a maximum of 10 % in the area between a line 2 cm outside the periphery of the GEOMETRICAL RADIATION FIELD and the boundary of *M*, and

2) the average ABSORBED DOSE D_{LE}, due to LEAKAGE RADIATION in the area between a line 4 cm outside the periphery of the GEOMETRICAL RADIATION FIELD and the boundary of the area *M*, shall not exceed the limits of allowable LEAKAGE RADIATION which are 1 % for ELECTRON ENERGIES up to and including 10 MeV, rising to 10 % for ELECTRON ENERGIES from 35 MeV to 50 MeV, as shown in Figure 201.105.

Measurements of LEAKAGE RADIATION shall be made with the ELECTRON BEAM directed into air, using a RADIATION DETECTOR of cross-sectional area not exceeding 1 cm^2, suitably protected against RADIATION that has been scattered from material beyond the RADIATION DETECTOR.

b) The ABSORBED DOSE measured at 2 cm outside the surface of the volume containing the body of any ELECTRON BEAM APPLICATOR from its distal end to within 10 cm of the ENCLOSURE shall not exceed 10 % of the maximum ABSORBED DOSE on the REFERENCE AXIS at NTD.

c) When BLDs for X-IRRADIATION are used as part of a BLS for ELECTRON IRRADIATION, they shall be INTERLOCKED to prevent ELECTRON IRRADIATION when their actual position differs from the required position by more than 10 mm at NTD.

Compliance is checked as follows:

a) 1) TYPE TEST grade B – Procedure:

- *produce RADIOGRAMS at NTD, with 10 mm of TISSUE EQUIVALENT MATERIAL as BUILD UP, using ELECTRON BEAM APPLICATORS/BLDs of all sizes, at their corresponding maximum and minimum ENERGIES of the whole range of ENERGIES available . Locate the (single) point of maximum ABSORBED DOSE in the area between the line 2 cm outside the GEOMETRICAL RADIATION FIELD and the periphery of the area M;*
- *perform a RADIATION DETECTOR measurement at the (single) point, located above, under the same conditions used for obtaining the RADIOGRAMS; the ABSORBED DOSE shall not exceed 10 % of the maximum ABSORBED DOSE on the REFERENCE AXIS at NTD.*

a) 2) TYPE TEST grade B – Procedure: perform RADIATION DETECTOR measurements, under the same conditions as in a) 1) above, at 2 cm intervals along the eight line-segments of the area M (see Figure 201.106), from points 5 cm outside the periphery of the GEOMETRICAL RADIATION FIELD ($5 \times \sqrt{2}$ cm on the diagonals) to the boundary of M. Determine D_{LE}, the average value of the RADIATION DETECTOR readings as a percentage of the maximum ABSORBED DOSE on the REFERENCE AXIS at NTD, for each ELECTRON BEAM APPLICATOR/BLD.

a) SITE TEST grade B – Procedure: perform RADIOGRAM and RADIATION DETECTOR measurements, at the worst case combination of ELECTRON BEAM APPLICATOR and ELECTRON ENERGY SPECIFIED in the TYPE TEST data from a) 2) above.

b) TYPE TEST grade B – Procedure: measure the ABSORBED DOSE at 2 cm from the surface of all ELECTRON BEAM APPLICATORS at their SPECIFIED maximum and minimum ENERGIES.

b) SITE TEST grade B – Procedure: perform a single measurement at the point of maximum LEAKAGE RADIATION derived from the TYPE TEST data. The measurement point should be 2 cm away from the surface of the ELECTRON BEAM APPLICATOR.

c) TYPE TEST grade A – Statement regarding INTERLOCKS preventing ELECTRON IRRADIATION when the X-RADIATION BLDs are incorrectly positioned by more than 10 mm at NTD.

c) SITE TEST grade C – Principle: verification of functioning of the INTERLOCK that prevents ELECTRON IRRADIATION if the X-RADIATION BLDs are incorrectly positioned.

201.10.1.2.103.3 LEAKAGE RADIATION (excluding NEUTRONS) outside the area *M*

The ME EQUIPMENT shall be provided with PROTECTIVE SHIELDING that attenuates IONIZING RADIATION so that, in a plane circular surface of radius 2 m centred on and orthogonal to the REFERENCE AXIS at the ISOCENTRE, and excluding the area *M*, the ABSORBED DOSE due to LEAKAGE RADIATION, excluding NEUTRON RADIATION, shall not exceed

a) a maximum of 0,2 %, and

b) an average of 0,1 %,

of the maximum ABSORBED DOSE measured at the centre of the plane in a 10 cm × 10 cm RADIATION FIELD.

To avoid LEAKAGE RADIATION through the BLDs from influencing the measurements, the BLDs shall be closed to minimum aperture at central axis and, where necessary, suitable absorbing material added so that the area *M* is protected by a total of at least three TENTH-VALUE LAYERS from the X-RADIATION BEAM.

Compliance is checked as follows:

TYPE TEST grade B – Procedure:

a) with axis 1 at 0°, 90° or 270°, and axis 4 at 0° (see Figure 201.108), determine points of high LEAKAGE RADIATION at all X-RADIATION ENERGIES and at the highest ENERGY of ELECTRON RADIATION. Perform RADIATION DETECTOR measurements at these points to obtain the value of the maximum percentage ABSORBED DOSE due to LEAKAGE RADIATION. Use may be made of DIRECT or INDIRECT RADIOGRAMS or of RADIOGRAPHIC FILMS;

b) assess the results obtained from a) and, using the combination of conditions giving the highest LEAKAGE RADIATION, perform RADIATION DETECTOR measurements at the 24 positions shown in Figure 201.107; these shall be averaged over a RADIATION DETECTOR area up to, but not exceeding, 100 cm^2. The average of the 24 measurements shall be used to determine the value of average percentage ABSORBED DOSE due to LEAKAGE RADIATION.

SITE TEST grade C – Principle: performance of RADIATION DETECTOR measurements at the 24 positions shown in Figure 201.107 under the conditions identified for TYPE TEST b).

201.10.1.2.103.4 LEAKAGE NEUTRON RADIATION outside the area *M*

This requirement shall apply only when the ENERGY of the ELECTRONS incident on the TARGET or ELECTRON RADIATION window exceeds 10 MeV.

Under conditions of NORMAL USE, the ABSORBED DOSE due to neutrons outside the area *M*, in the plane defined in 201.10.1.2.103.3, shall not exceed a maximum of 0,05 % and an average of 0,02 % of the X-RADIATION ABSORBED DOSE in a 10 cm × 10 cm RADIATION FIELD, at the point of intersection with the REFERENCE AXIS. Values of ABSORBED DOSE shall be averaged over areas not exceeding 800 cm^2.

Compliance is checked as follows:

TYPE TEST grade B – Procedure: for all ENERGIES of X-RADIATION or, if X-RADIATION is not available, for the ENERGY of ELECTRON RADIATION producing the maximum ABSORBED DOSE or maximum NEUTRON fluence rate due to STRAY NEUTRON RADIATION, perform measurements and record the method, conditions and results. Calculate the average value and indicate the areas where the 0,02 % is exceeded. Account shall be taken of the pulsed nature of the RADIATION, the NEUTRON energy spectrum, the effects of the accompanying X-RADIATION and the NEUTRON RADIATION scattered from surrounding structures. NEUTRON measurements shall be made with the BLDs fully closed.

201.10.1.2.103.5 LEAKAGE RADIATION under fault conditions

Means shall be provided TO TERMINATE IRRADIATION if the ELECTRON BEAM is not correctly incident on the TARGET or ELECTRON RADIATION window. In the plane defined in 201.10.1.2.103.3, when the ABSORBED DOSE RATE due to LEAKAGE RADIATION outside the area *M* exceeds the equivalent of five times the limits SPECIFIED in 201.10.1.2.103.3, TERMINATION OF IRRADIATION shall occur. The ABSORBED DOSE RATE due to LEAKAGE RADIATION shall be averaged over not more than 10 s and expressed as a percentage of the ABSORBED DOSE RATE on the REFERENCE AXIS under the fault conditions, in a 10 cm × 10 cm RADIATION FIELD.

Compliance is checked as follows:

TYPE TEST grade C – Principle: verification of the functioning of the means TO TERMINATE IRRADIATION, or

TYPE TEST grade A – Statement regarding how this requirement is met and verified.

SITE TEST grade C – Principle: verification of TERMINATION OF IRRADIATION under fault conditions.

201.10.1.2.104 RADIATION safety for PATIENTS and others

NOTE The plan view boundaries applying to the requirements of this subclause are shown in Figure 201.103.

201.10.1.2.104.1 LEAKAGE X-RADIATION outside the PATIENT plane

a) Except within the volume formed by a plane of radius 2 m, centred on and orthogonal to the REFERENCE AXIS at the ISOCENTRE and the boundary for measurement shown in Figure 201.103 (elevation view) the ABSORBED DOSE due to LEAKAGE X-RADIATION, at 1 m from

   – the path of the ELECTRONS between the ELECTRON gun and the TARGET or ELECTRON RADIATION window, and

   – the REFERENCE AXIS,

   shall not exceed 0,5 % of the maximum ABSORBED DOSE measured on the REFERENCE AXIS at NTD in a 10 cm × 10 cm RADIATION FIELD.

b) Areas investigated in a) above which

   – can come into close proximity with the PATIENT during IRRADIATION, and

   – where the LEAKAGE X-RADIATION at 5 cm from the surface of the ENCLOSURE can exceed 0,5 % of the maximum ABSORBED DOSE,

   shall be SPECIFIED in the technical description with their related levels of ABSORBED DOSE and conditions of measurement.

Compliance is checked as follows:

a) TYPE TEST grade B – Procedure: for all ENERGIES of X-RADIATION and for the highest ENERGY of ELECTRON RADIATION, use RADIOGRAMS to identify points of high LEAKAGE X-RADIATION. Perform RADIATION DETECTOR measurements, averaged over an area not exceeding 100 cm^2, at these points. The BUILD UP at the RADIATION DETECTOR for points of high LEAKAGE X-RADIATION shall be equivalent to that used for the measurement of the maximum ABSORBED DOSE. DIRECT or INDIRECT RADIOGRAMS, or RADIOGRAPHIC FILMS may be used.

b) TYPE TEST grade B – Procedure: using the data obtained in a) above, perform RADIATION DETECTOR measurements, averaged over an area not exceeding 10 cm^2, at identified points 5 cm from the surface of the ENCLOSURE; record the expected levels of LEAKAGE X-RADIATION exceeding 0,5 %, their positions and the related conditions.

a) b) SITE TEST grade B – Procedure: perform RADIATION DETECTOR measurements at three points of highest LEAKAGE X-RADIATION, identified in TYPE TESTS a) and b) above, using the conditions recorded.

201.10.1.2.104.2 Leakage NEUTRON RADIATION outside the PATIENT plane

This requirement shall apply only when the ENERGY of the ELECTRONS at the ELECTRON RADIATION window or TARGET exceeds 10 MeV.

Except within the volume defined in 201.10.1.2.104.1a), and under the same conditions, the ABSORBED DOSE due to leakage neutron radiation shall not exceed 0,05 % of the maximum ABSORBED DOSE due to ELECTRON RADIATION or X-RADIATION.

Measurements, averaged over areas not exceeding 800 cm^2, shall be made under conditions of NORMAL USE but with the BLDs fully closed.

Compliance is checked as follows:

TYPE TEST grade C – Principle: performance of measurements at the highest X-RADIATION ENERGY or, if there is only ELECTRON RADIATION available, at the ELECTRON RADIATION ENERGY producing the maximum ABSORBED DOSE or maximum neutron fluence rate due to stray NEUTRON RADIATION. Account shall be taken of the pulsed nature of the RADIATION, the neutron ENERGY spectrum, the effects of the accompanying X-RADIATION and NEUTRON RADIATION scattered from surrounding structures.

201.10.1.2.104.3 EMISSION of IONIZING RADIATION after TERMINATION OF IRRADIATION, due to INDUCED RADIOACTIVITY

This requirement shall apply only when the ENERGY of the ELECTRONS at the TARGET or ELECTRON RADIATION window exceeds 10 MeV.

a) The AMBIENT DOSE EQUIVALENT, $H^*(10)$, due to IONIZING RADIATION from the ME EQUIPMENT at the end of a 4 h series of IRRADIATIONS of 4 Gy at the maximum SPECIFIED ABSORBED DOSE RATE, separated by off periods of 10 min, shall not exceed the following values when accumulated over a period of 5 min starting not more than 30 s after the final TERMINATION OF IRRADIATION:

   - 10 μSv at any readily accessible place 5 cm from the surface of the ENCLOSURE, and
   - 1 μSv at 1 m from the surface of the ENCLOSURE.

   Alternatively, the ambient dose equivalent rate measured during the period starting not more than 30 s after the final TERMINATION OF IRRADIATION and extending to not more than 3 min from that time, shall not exceed the following values:

   - 200 $\mu Sv \times h^{-1}$ at any readily accessible place 5 cm from the surface of the ENCLOSURE, and
   - 20 $\mu Sv \times h^{-1}$ at 1 m from the surface of the ENCLOSURE.

   NOTE The presence of beta particles may add to the skin dose.

b) Precautions that should be taken during servicing and disposal (e.g. limitations to the handling time of parts that may exhibit RADIOACTIVITY and compliance with national and international regulations regarding disposal and transport of material exhibiting RADIOACTIVITY) shall be SPECIFIED in the technical description (see 201.7.9.2.15).

Compliance is checked as follows:

a) TYPE TEST grade B – Procedure: perform and record method, results and positions, of dose measurements averaged over an area not exceeding 10 cm^2 at a distance of 5 cm from the surface of the ENCLOSURE, and not exceeding 100 cm^2 at a distance of 1 m from the surface, under the following conditions:

   - *maximum X-RADIATION ENERGY or, if X-RADIATION is not available, the ENERGY of ELECTRON RADIATION used in TYPE TEST 201.10.1.2.103.4;*
   - *RADIATION FIELD 10 cm × 10 cm.*

b) TYPE TEST grade A – Statement regarding precautions to be taken during servicing and disposal (see 201.7.9.2.15*)*

201.10.1.2.104.4 Retractable RADIATION BEAM shield (see 201.7.9.2.15)

Any retractable RADIATION BEAM shield shall be INTERLOCKED for correct position during IRRADIATION.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding INTERLOCK preventing incorrect operation.

SITE TEST grade B – Procedure: attempt TO IRRADIATE with the beam shield incorrectly positioned.

201.10.1.2.104.5 Adventitious IONIZING RADIATION

NOTE Clause 10 of the general standard has been replaced. This is a replacement subclause for 10.1.1 of the general standard.

For ME EQUIPMENT or ME EQUIPMENT parts not intended to produce IONIZING RADIATION for RADIOTHERAPY and which form part of an ELECTRON ACCELERATOR, IONIZING RADIATION caused by high voltages shall not produce an AMBIENT DOSE EQUIVALENT, $H^*(10)$, exceeding 5 μSv in 1 h at a distance of 5 cm from any ACCESSIBLE SURFACE.

Compliance is checked as follows:

TYPE TEST grade C – Procedure: perform and record method, positions and results of measurements, averaged over an area not exceeding 10 cm^2, in order to assess the dose due to small angle beams; use a RADIATION DETECTOR suitable for the ENERGY of the emitted RADIATION.

Controls and adjustments are set at the position resulting in the maximum EMISSION of X-RADIATION. Single failures of components causing the least favourable situation are provoked in turn.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard does not apply.

NOTE Accuracy of controls and instruments (12.1 of the general standard) does not apply as it is covered by 201.9. USABILITY (12.2 of the general standard) does not apply as it is covered by Clause 206. Protection against hazardous output (12.4 of the general standard) does not apply as it is covered by 201.10.

201.13 HAZARDOUS SITUATIONS and fault conditions

Clause 13 of the general standard applies

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies, except as follows:

Additional subclause:

201.14.101 PROGRAMMABLE ELECTRONIC SUBSYSTEMS

a) The safety provisions of this standard shall apply to any PESS the failure of which may produce a safety hazard.

b) Software and firmware control programmes shall be secured against access or modification without authorization from the MANUFACTURER.

NOTE Unauthorized access to software or firmware could create hazardous conditions, make the ME EQUIPMENT non-compliant with the requirements of this standard, and give the MANUFACTURER good reason to refute warranty claims.

c) Prevention or TERMINATION OF IRRADIATION and the stopping of movements, shall occur when a PESS that is part of a monitoring, measuring or control device fails to maintain its safety function.

d) There shall be only manual control for the initiation of IRRADIATION; thereafter, pre-programmed control of IRRADIATION and movements by PESS is permitted.

e) Devices under PESS control, designed to set up or pre-position ME EQUIPMENT parts from data supplied by a computer-based information file or other means of input, shall provide means for the comparison of the actual setting of the ME EQUIPMENT parameters with those of the input data; IRRADIATION shall be prevented when any difference exceeds the SPECIFIED and pre-defined limits set by the RESPONSIBLE ORGANIZATION in accordance with instructions and data given in the INSTRUCTIONS FOR USE.

f) When control is effected by PESS, designated PASSWORDS are permitted alternatives for enabling or disabling functions where, in other types of control systems, a key control or designated (mechanical) key is required, e.g. 201.10.1.2.101.10, 201.10.1.2.101.11, 201.10.1.2.101.14b).

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding the philosophy and realisation of safe operation using PESS.

SITE TEST grade C – Principle: verification of correct functioning as SPECIFIED by the MANUFACTURER.

A1 g) Consistency, correctness and completeness of the data set imported shall be checked before it can be accepted by the ME EQUIPMENT for IRRADIATION. (See also 201.10.1.2.101.1.5)

In the case of failure of the consistency, correctness or completeness of the data set being loaded, IRRADIATION shall not be allowed to commence.

In the case of abnormal TERMINATION OF IRRADIATION the data set necessary to reconstruct the treatment delivered shall be recorded.

In the case of restarting after abnormal TERMINATION OF IRRADIATION, the consistency, correctness and completeness of the data set needed for continuation of IRRADIATION shall be checked by the ME EQUIPMENT before it can be accepted for IRRADIATION.

MANUFACTURER shall state in the ACCOMPANYING DOCUMENTS the data required to perform IRRADIATION. A1

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies.

201.16 ME SYSTEMS

Clause 16 of the general standard does not apply.

201.17 ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies, except as follows:

Additional subclauses:

201.17.101 Additional requirements

A1 The requirements and tests of Clause 17, with the additions given in 201.17.102 and 201.17.103, shall apply to ELECTRON ACCELERATORS.

NOTE Integral ITE is considered as part of the ELECTRON ACCELERATOR. A1

The site(s) used for measurements shall be typical of those generally used for the installation of ELECTRON ACCELERATORS; they may be those of RESPONSIBLE ORGANIZATIONS or of the MANUFACTURER. Any allowances made shall be justified and included in the ACCOMPANYING DOCUMENTS.

The requirements for compliance shall be those applying to PERMANENTLY INSTALLED ME EQUIPMENT.

201.17.102 Radio-frequency EMISSIONS

For radio-frequency EMISSIONS, the attenuation of ELECTROMAGNETIC DISTURBANCES by structures within the bounds of the exterior walls from which measurements are made at a distance, shall be regarded as though this attenuation were due to the inherent attenuation of the ME EQUIPMENT.

Compliance is checked by measurements, made in accordance with IEC 60601-1-2, at 30 m from the exterior walls of the building containing the location in which the ME EQUIPMENT has been installed.

201.17.103 IMMUNITY to radio-frequency electromagnetic fields

For IMMUNITY to radio-frequency electromagnetic fields, the attenuation provided by the structural protection against IONIZING RADIATION shall be regarded as though this was due to the inherent attenuation of the ME EQUIPMENT.

Compliance is checked by tests made in accordance with IEC 60601-1-2. The test antenna shall be placed at 3 m from the outside of the structural protection against IONIZING RADIATION.

Additional clauses:

201.101 ELECTRONIC IMAGING DEVICES (e.g. EPID)

201.101.1 Image coordinates and orientation

The image shall comply with the coordinate system (IEC 61217) and shall identify the orientation.

Compliance is checked by:

TYPE TEST grade A: Statement regarding image coordinate and orientation.

201.101.2 Image scale factor

The image scale factor(s) shall be stated in the ACCOMPANYING DOCUMENTS and be indicated on the image.

Compliance is checked by:

TYPE TEST grade A : Statement regarding image scale factor(s).

201.101.3 Image field of view and alignment

The size of the image field of view and its displacement relative to the imaging RADIATION BEAM AXIS shall be stated in the ACCOMPANYING DOCUMENTS. Any displacement shall be indicated on the image.

Compliance is checked by:

TYPE TEST grade A : Statement regarding the field of view size and alignment accuracy.

201.101.4 EID PATIENT clearance

NOTE This is covered by 201.9.2.101.

201.101.5 Artefacts

Based on the intended use, the MANUFACTURER shall carry out a RISK ANALYSIS of the effect of image loss due to artefacts in an EID-generated image. This analysis shall at least include consideration of:

– whether an artefact could be mistaken for detail that could result in an incorrect treatment; and
– whether an artefact would be obvious to a OPERATOR.

The MANUFACTURER shall ensure that no hazardous situation with unacceptable risk arises in SINGLE FAULT CONDITION.

Compliance is checked by:

TYPE TEST grade A – Statement regarding known possible artefacts and their effect on the image quality.

206 Usability

IEC 60601-1-6:2006 applies, except as follows:

Addition:

NOTE 1 Although it will not be possible to apply IEC 60601-1-6:2006 retroactively to existing ME EQUIPMENT and to those that have passed beyond the stage identified above, examination of the available design and process control data may provide substantial verification.

NOTE 2 When IEC 60601-1-6:2006 is withdrawn, its replacement IEC 62366, *Medical devices – Application of usability engineering to medical devices*, applies.

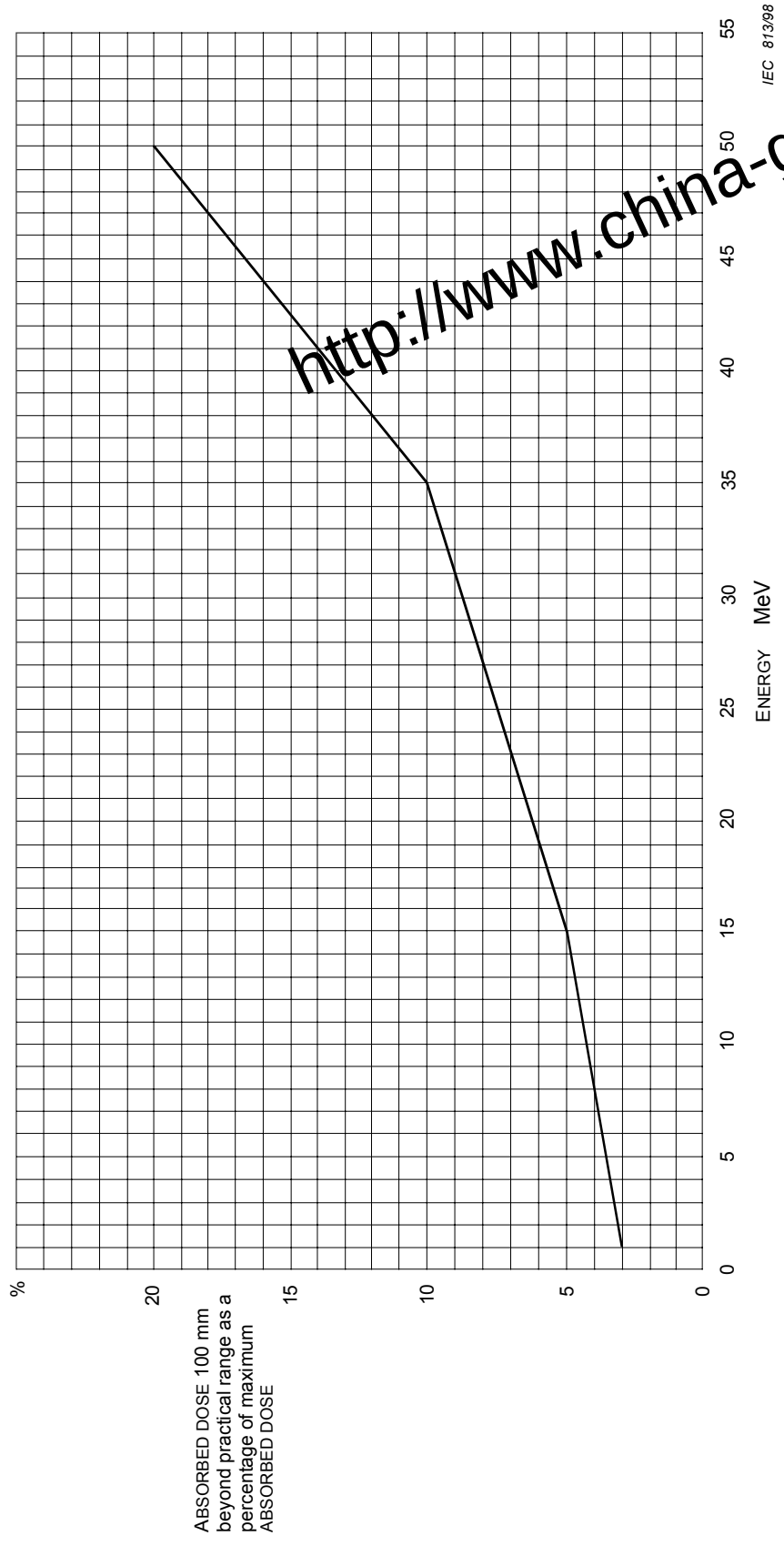


Figure 201.101 – Limits of STRAY X-RADIATION during ELECTRON IRRADIATION (201.10.1.2.102.1)

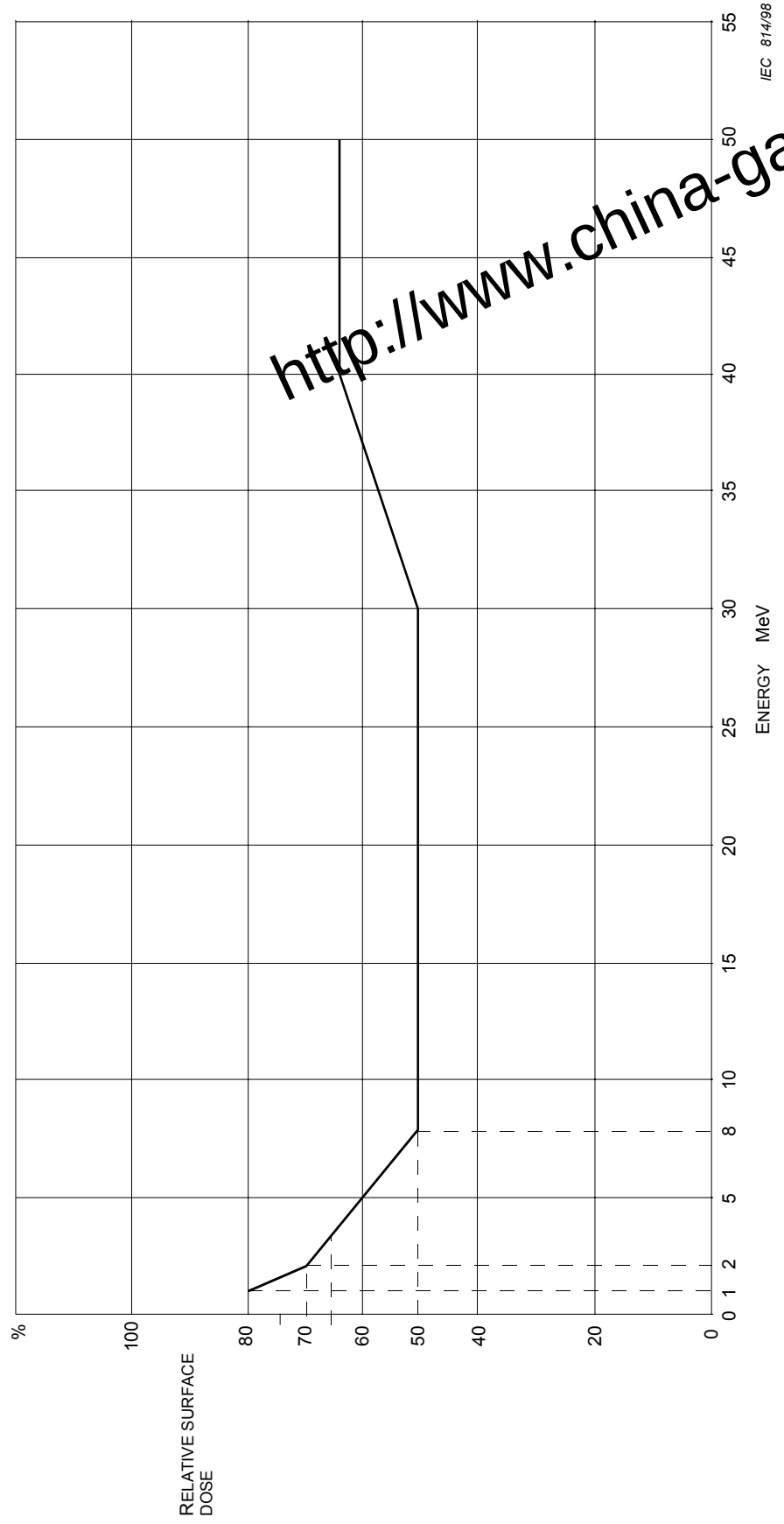


Figure 201.102 – Limits of RELATIVE SURFACE DOSE during X-IRRADIATION (201.10.1.2.102.2)

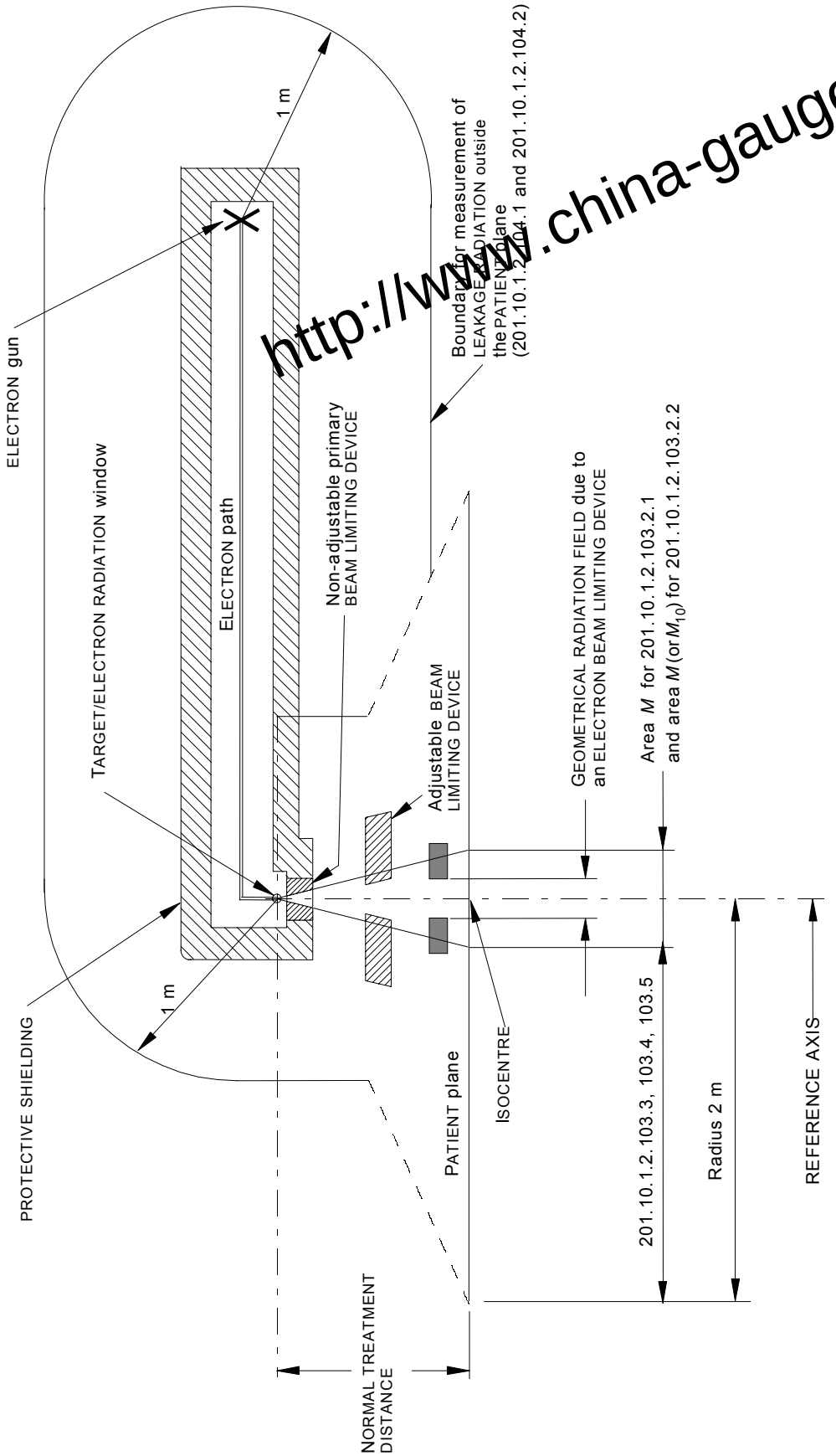
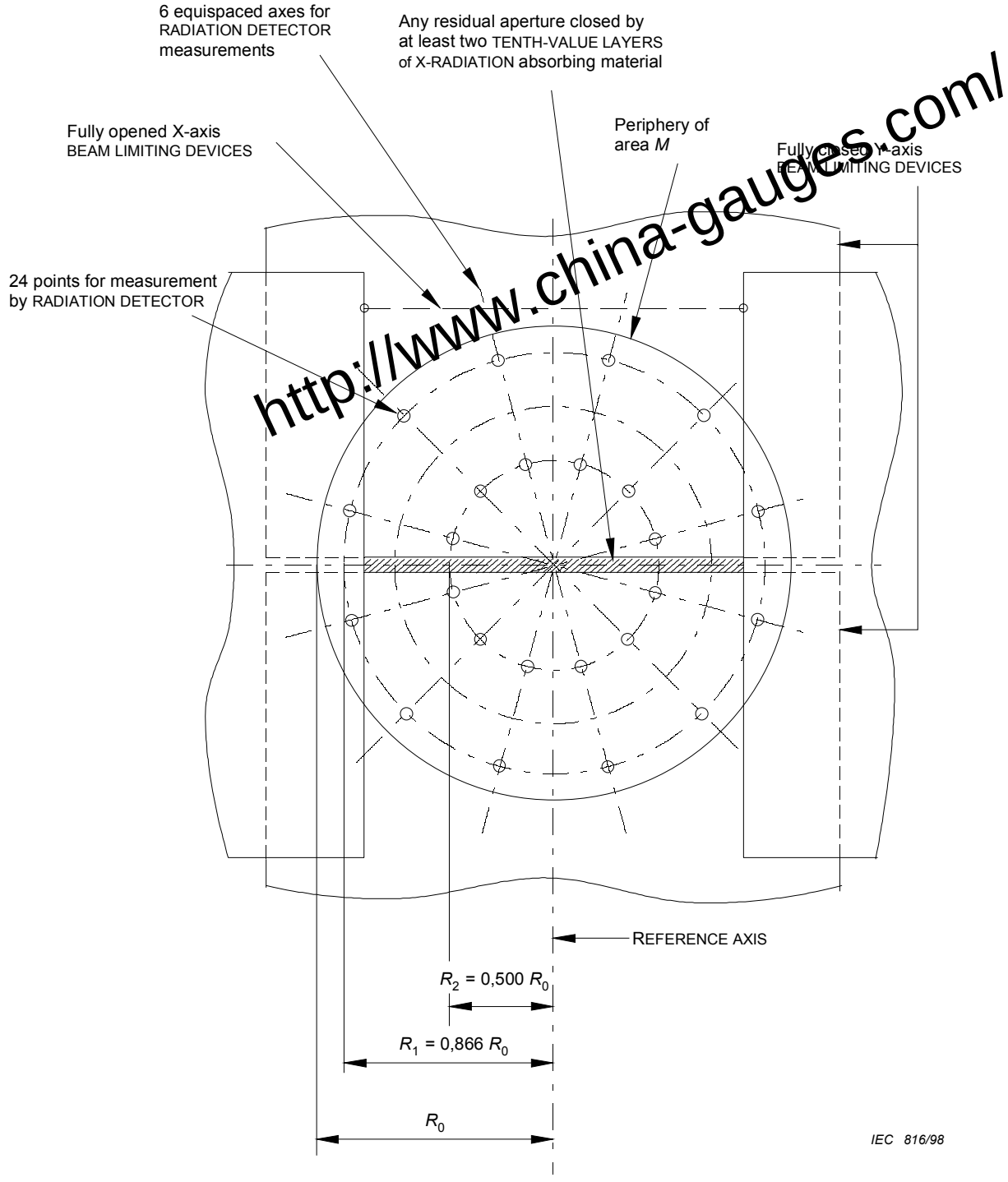


Figure 201.103 – Elevation view – Application of LEAKAGE RADIATION requirements (201.10.1.2.103 and 201.10.1.2.104)



NOTE 1 Area $M = \pi R_o^2$; M is defined in Note 2 of 201.10.1.2.103.2.

NOTE 2 Dimensions relate to the PATIENT plane at NORMAL TREATMENT DISTANCE.

NOTE 3 The second set of measurements is made with the X-axis BEAM LIMITING DEVICES fully closed and the Y-axis fully opened.

NOTE 4 Area M is centred on REFERENCE AXIS and is perpendicular to it.

Figure 201.104 – 24 measurement points for averaging LEAKAGE RADIATION during X-RADIATION (201.10.1.2.103.2.1)

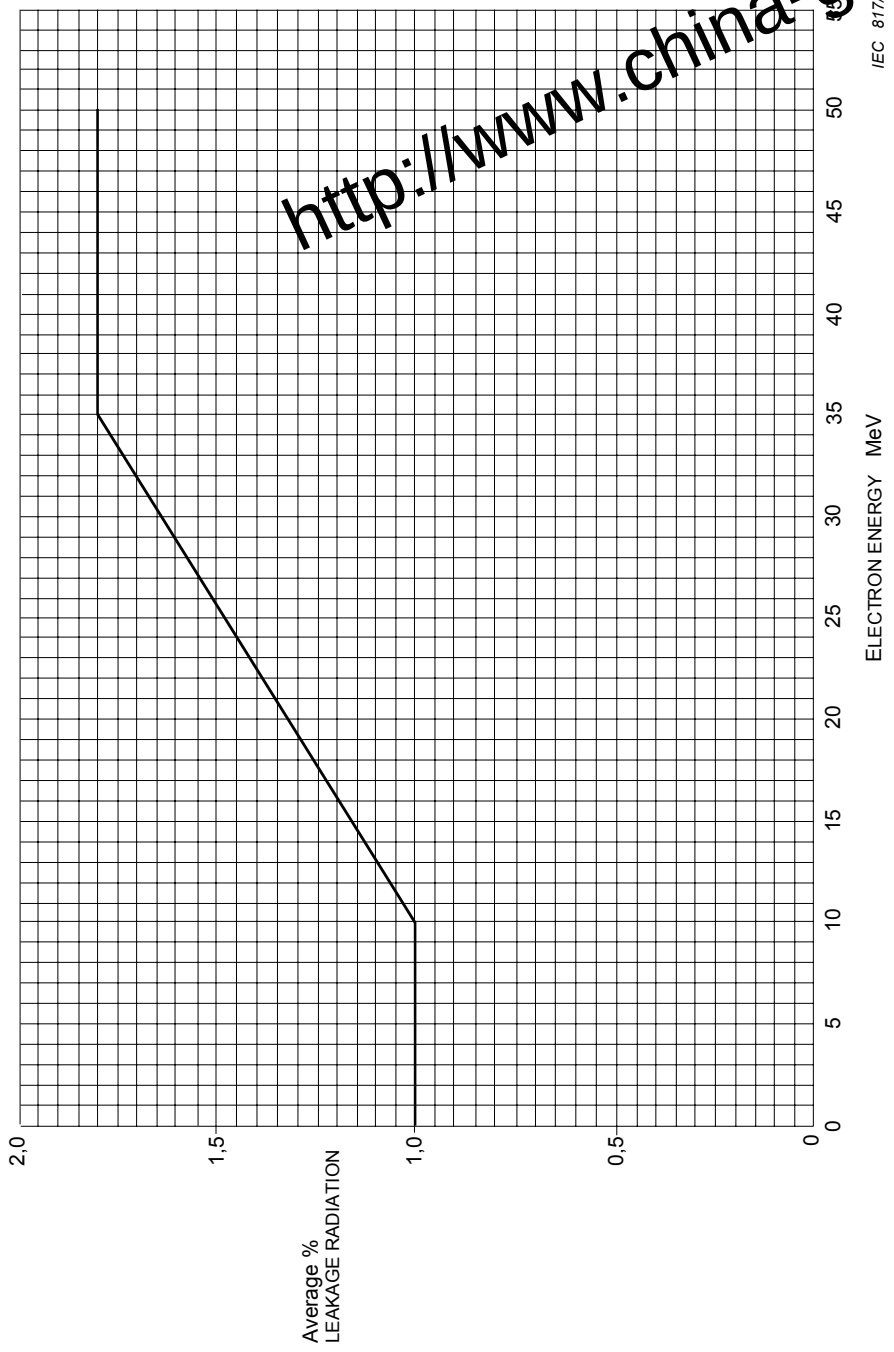
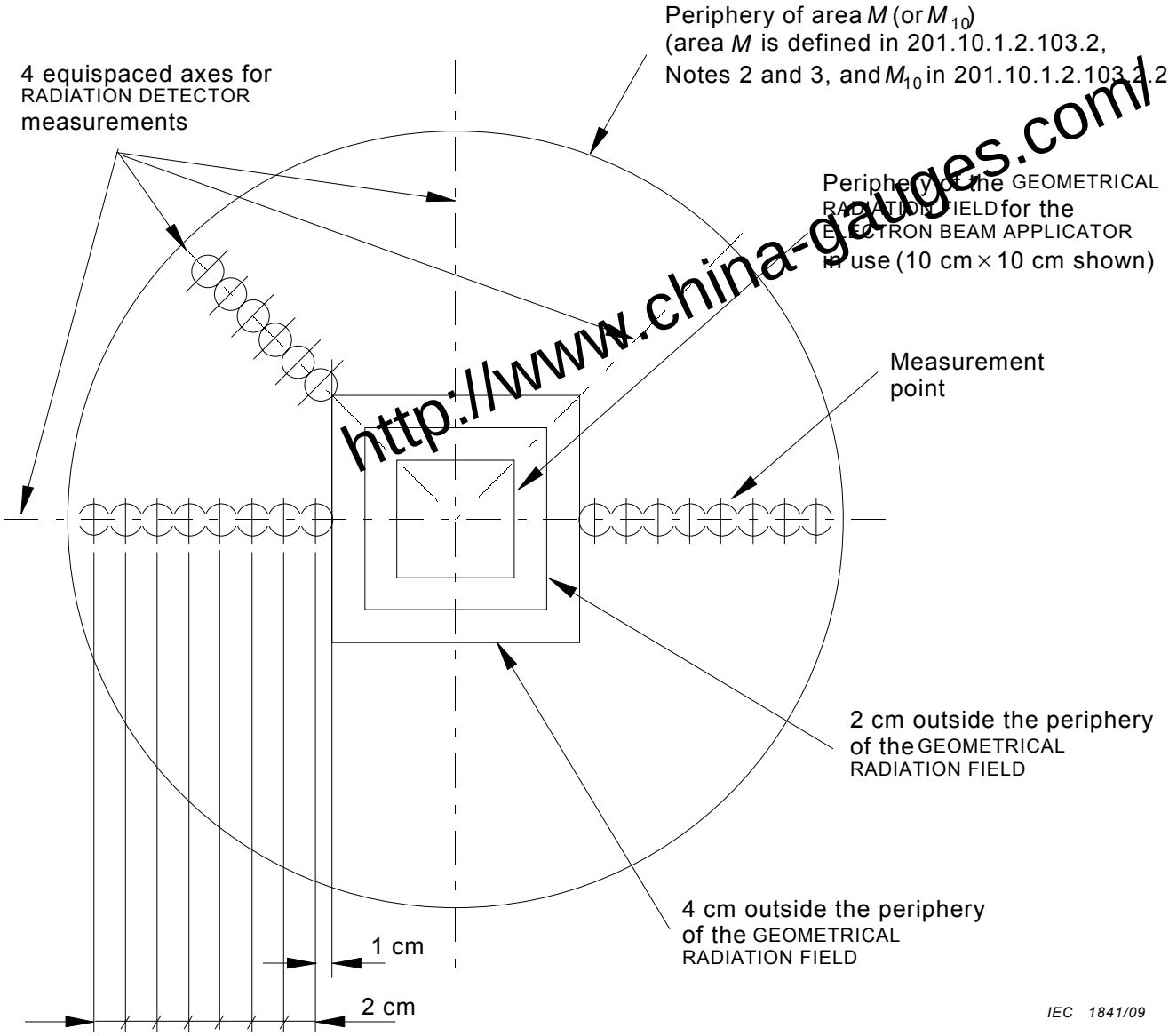
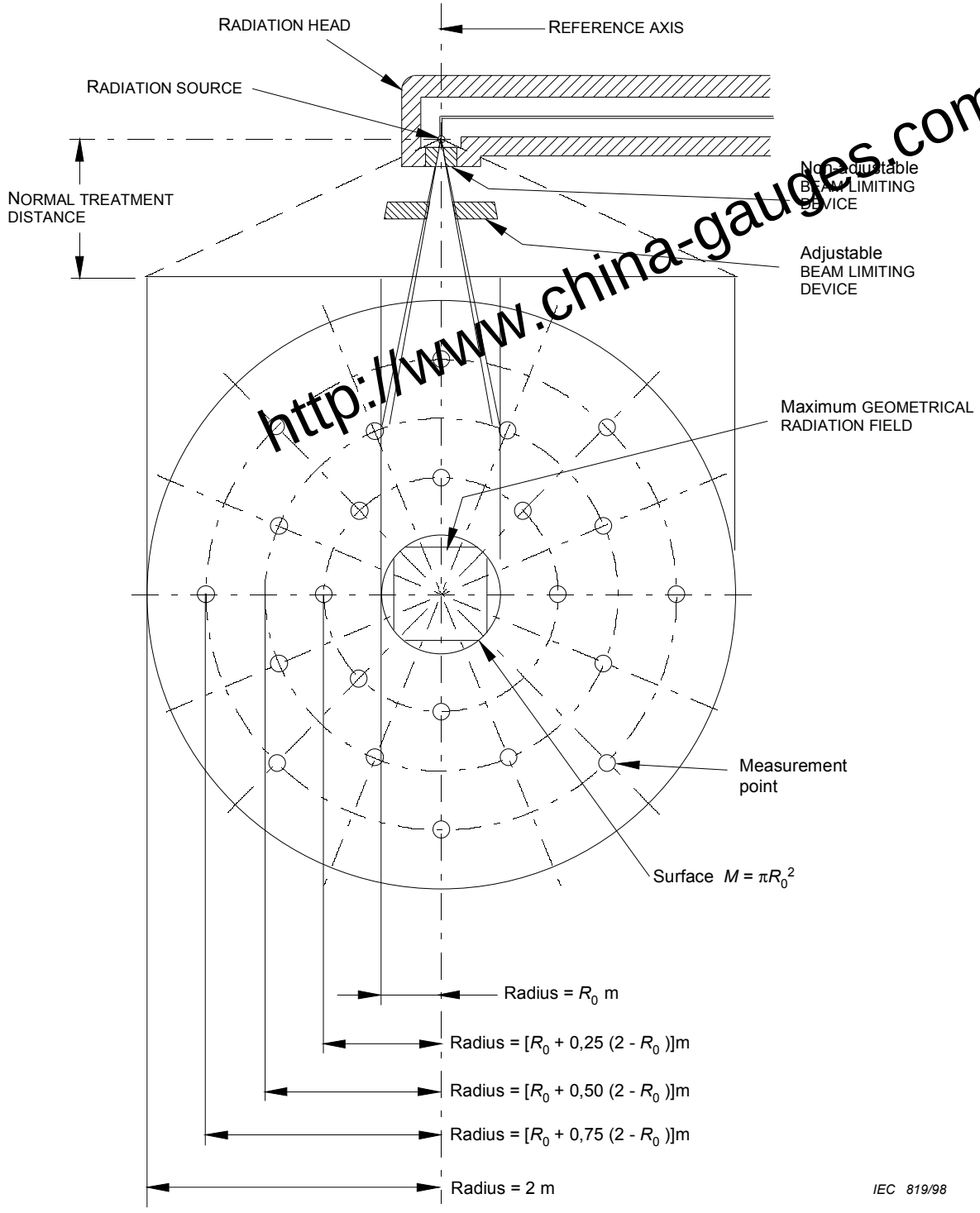


Figure 201.105 – Limits of LEAKAGE RADIATION through the BEAM LIMITING DEVICES during ELECTRON IRRADIATION (201.10.2.103.2.2)



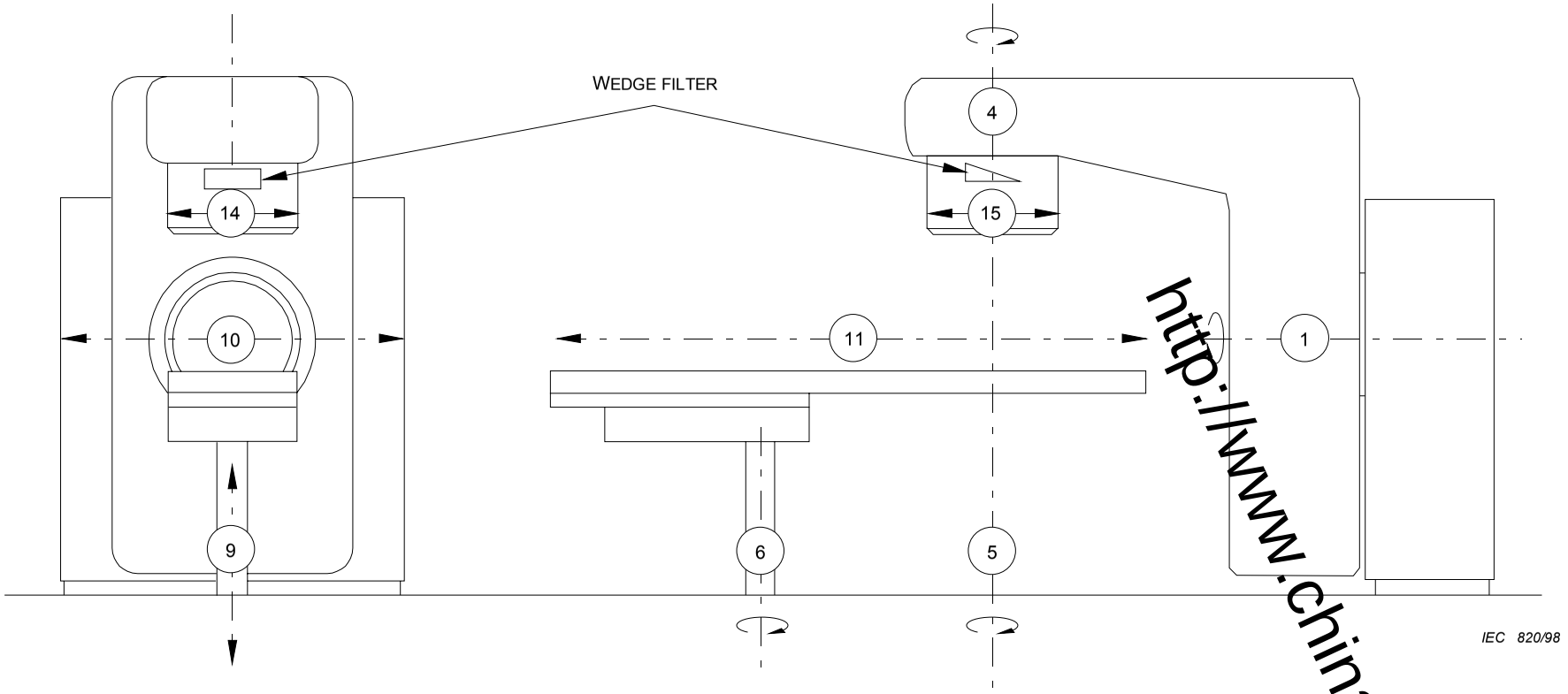
NOTE Dimensions relate to NORMAL TREATMENT DISTANCE for the ELECTRON BEAM APPLICATOR in use.

Figure 201.106 – Measurement points for averaging LEAKAGE RADIATION during ELECTRON IRRADIATION (201.10.1.2.103.2.2)



NOTE Area *M* is centred on REFERENCE AXIS and is perpendicular to it.

Figure 201.107 – 24 measurement points for averaging LEAKAGE RADIATION outside area *M* (201.10.1.2.103.3)



Linear displacements

9 Vertical displacement of the PATIENT SUPPORT
10 Lateral displacement of the PATIENT SUPPORT
11 Longitudinal displacement of the PATIENT SUPPORT
14 Dimension FX of the RADIATION FIELD
15 Dimension FY of the RADIATION FIELD

Rotation axis

1 Rotation of the GANTRY
4 Rotation of the BEAM LIMITING SYSTEM
5 ISOCENTRIC rotation of the PATIENT SUPPORT
6 Eccentric rotation of the PATIENT SUPPORT

NOTE 1 For more details see Table 1 and Figures 13a, 13b and 13c of IEC 61217 of which this figure is taken.

NOTE 2 All movements are shown at their zero positions, except displacements 9 and 11.

Figure 201.108 – ME EQUIPMENT movements and scales

Annexes

The annexes of the general standard apply, except as follows:

Annex B
(informative)

Sequence of testing

Annex B of the general standard applies, except as follows:

B.1 General

Addition:

MANUFACTUREr should state the sequence of testing if differs from the sequence shown in this annex.

Annex I
(informative)

ME SYSTEMS aspects

Annex I of the general standard does not apply.

Bibliography

IEC 60976:2007, *Medical electrical equipment – Medical electron accelerators – Functional performance characteristics*

IEC/TR 60977, *Medical electrical equipment – Medical electron accelerators – Guidelines for functional performance characteristics*

IEC 62366, *Medical devices – Application of usability engineering to medical devices*

ICRP Publication 33:1982, *Protection against ionizing radiation from external sources used in medicine* (available in English only)

ICRP Publication 60:1991,1990, *Recommendations of the international commission on radiological protection* (available in English only)

ICRU Report 35:1984, *Radiation dosimetry: electron beams with energies between 1 and 50 MeV* (available in English only)

ICRU Report 39:1985, *Determination of dose equivalents resulting from external radiation sources* (available in English only)

ICRU Report 51:1993, *Quantities and units in radiation protection dosimetry* (available in English only)

Index of defined terms

Index of terms	Source reference
INFORMATION TECHNOLOGY EQUIPMENT, ITE	IEC 60601-1-2:2007, 3.16
INSTRUCTIONS FOR USE	IEC/TR 60788:2004, rm-82-02
INTENSITY MODULATION RADIATION THERAPY, IMRT	201.3.209
INTERLOCK, TO INTERLOCK	IEC/TR 60788:2004, rm-86-05
INTERRUPTION OF IRRADIATION, TO INTERRUPT IRRADIATION	201.3.210
IONIZING RADIATION	IEC/TR 60788:2004, rm-11-02
IRRADIATION, TO IRRADIATE	IEC/TR 60788:2004, rm-12-09
ISOCENTRE/ISOCENTRIC	IEC/TR 60788:2004, rm-37-32+
LEAKAGE CURRENT	IEC 60601-1:2005, 3.47
LEAKAGE RADIATION	IEC/TR 60788:2004, rm-11-15
LIGHT FIELD	IEC/TR 60788:2004, rm-37-09
MAINS PART	IEC 60601-1:2005, 3.49
MANUFACTURER	IEC 60601-1:2005, 3.55
ME EQUIPMENT, MEDICAL ELECTRICAL EQUIPMENT	IEC 60601-1:2005, 3.63
MEDICAL ELECTRICAL EQUIPMENT, ME EQUIPMENT	IEC 60601-1:2005, 3.63
MEDICAL ELECTRICAL SYSTEM, ME SYSTEM	IEC 60601-1:2005, 3.64
MOVING BEAM RADIOTHERAPY	201.3.211
NEUTRON RADIATION	IEC/TR 60788:2004, rm-11-01+
NOMINAL ENERGY	201.3.212
NORMAL CONDITION, NC	IEC 60601-1:2005, 3.70
NORMAL TREATMENT DISTANCE, NTD	201.3.213
NORMAL USE	IEC 60601-1:2005, 3.71
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PATIENT AUXILIARY CURRENT	IEC 60601-1:2005, 3.77
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PREPARATORY STATE	IEC/TR 60788:2004, rm-84-04
PRIMARY DOSE MONITORING SYSTEM	IEC/TR 60788:2004, rm-33-03
PRIMARY/SECONDARY DOSE MONITORING COMBINATION	201.3.216
PROGRAMMABLE ELECTRONIC SUBSYSTEM, PESS	IEC 60601-1:2005, 3.91
PROGRAMMABLE WEDGE FILTER, PWF	IEC 60976:2007, 3.18
PROTECTIVE SHIELDING	IEC/TR 60788:2004, rm-64-01
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RADIATION BEAM	IEC/TR 60788:2004, rm-37-05
RADIATION BEAM AXIS	IEC/TR 60788:2004, rm-37-06
RADIATION DETECTOR	IEC/TR 60788:2004, rm-51-01
RADIATION FIELD	IEC/TR 60788:2004, rm-37-07
RADIATION HEAD	IEC/TR 60788:2004, rm-20-06
RADIATION SOURCE	IEC/TR 60788:2004, rm-20-01
RADIATION SOURCE TO SKIN DISTANCE	IEC/TR 60788:2004, rm-37-14
RADIATION TYPE	201.3.218

Index of terms	Source reference
RADIOACTIVITY	IEC/TR 60788:2004, rm-12-13
RADIOGRAM	IEC/TR 60788:2004, rm-32-02
RADIOGRAPHIC FILM	IEC/TR 60788:2004, rm-32-32
RADIOTHERAPY	IEC/TR 60788:2004, rm-40-05
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RISK ANALYSIS	IEC 60601-1:2005, 3.103
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SECONDARY DOSE MONITORING SYSTEM	IEC/TR 60788:2004, rm-33-04
SINGLE FAULT CONDITION, SFC	IEC 60601-1:2005, 3.116
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SPECIFIED	IEC/TR 60788:2004, rm-74-02
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STEREOTACTIC RADIOTHERAPY, SRT	201.3.222
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SUPPLY MAINS	IEC 60601-1:2005, 3.120
TARGET	IEC/TR 60788:2004, rm-20-08
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TISSUE EQUIVALENT MATERIAL	IEC/TR 60788:2004, rm-35-16
TO INTERRUPT IRRADIATION, INTERRUPTION OF IRRADIATION	201.3.210
TO IRRADIATE, IRRADIATION	IEC/TR 60788:2004, rm-12-09
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TREATMENT CONTROL PANEL, TCP	IEC/TR 60788:2004, rm-33-05
TREATMENT ROOM	IEC/TR 60788:2004, rm-20-23
TREATMENT VOLUME	IEC/TR 60788:2004, rm-37-21
〈A1〉 *Text deleted* 〈A1〉	
〈A1〉 VERIFICATION	IEC 60601-1: 2005, 3.138 〈A1〉
WEDGE FILTER	IEC/TR 60788:2004, rm-35-10
X-IRRADIATION	IEC/TR 60788:2004, rm-12-09+
X-RADIATION	IEC/TR 60788:2004, rm-11-01+

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