

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE

**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**

**Appareils électromédicaux –**

**Partie 2-1: Exigences particulières pour la sécurité de base et les performances  
essentielles des accélérateurs d'électrons dans la gamme de 1 MeV à 50 MeV**



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INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

COMMISSION  
ELECTROTECHNIQUE  
INTERNATIONALE

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ICS 11.040.60

ISBN 978-2-8322-8942-6

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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 subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This fourth edition cancels and replaces the third edition published in 2009 and Amendment 1:2014. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- a) alignment with the new relevant collateral standards;
- b) addition of computer interface and control;
- c) addition of new technologies in RADIOTHERAPY, including
  - BEAM GATING, and
  - ADAPTIVE RADIOTHERAPY.

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

|              |                  |
|--------------|------------------|
| FDIS         | Report on voting |
| 62C/770/FDIS | 62C/785/RVD      |

Full information on the voting for the approval of this document 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 document, 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 document, 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this document, 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 Clause 7 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 document;
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (\*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

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 document will remain unchanged until the stability date indicated on the IEC website under "<http://webstore.iec.ch>" in the data related to the specific document. At this date, the document will be

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

NOTE The attention of users of this document is drawn to the fact that equipment MANUFACTURERS and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

## INTRODUCTION

The use of ELECTRON ACCELERATORS for RADIOTHERAPY purposes may expose PATIENTS to danger if the ME EQUIPMENT fails to deliver the required dose distribution to the PATIENT, or if the ME EQUIPMENT design fails to meet the requirements of BASIC SAFETY and ESSENTIAL PERFORMANCE. The ME EQUIPMENT may also cause danger to persons in the vicinity if the ME EQUIPMENT itself fails to contain the RADIATION adequately 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.

Clauses 201.10, 201.103, 201.104, 201.105 and 201.108 contain limits beyond which INTERLOCKS prevent, INTERRUPT or TERMINATE IRRADIATION in order to insure ESSENTIAL PERFORMANCE is maintained to avoid an unsafe condition. In this document, the information in Clause 201.10 has either been reorganized or moved to other clauses in order to better reflect current usage and broaden the applicability of certain clauses to always apply to the ME EQUIPMENT when IRRADIATION is being produced and not just when a PATIENT is being treated. Annex AA provides a table showing the relationship between the clauses in IEC 60601-2-1:2009 and IEC 60601-2-1:2009/AMD1:2014 and the clauses in this document.

TYPE TESTS that are performed by the MANUFACTURER, 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 RESPONSIBLE ORGANIZATION.

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

IEC 60601-2-1 was first published in 1981. It was amended in 1984 and 1990. A second edition was published in 1998 and amended in 2002. The third edition was prompted by the need to align IEC 60601-2-1 with the third edition of the general standard, IEC 60601-1:2005, and was amended in 2014. This fourth edition is prompted by the need to update IEC 60601-2-1 for the technology that is in current use as well as to bring it into alignment with IEC 60601-1:2005 and IEC 60601-2-1/AMD1:2012. This prompted the relabelling and organization of Clause 201.10 as well as the addition of Clauses 201.102 through 201.109.

IEC 60976:2007 and IEC TR 60977:2008 are closely related to the third edition of this document. 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 performance standard but suggests performance values, measured per the methods specified in IEC 60976, that could be achievable with technology available at the time of publication. Until IEC 60976:2007 and IEC TR 60977:2008 are updated to match this document, it is suggested that MANUFACTURERS replace the word "ISOCENTRE" with "EQUIPMENT REFERENCE POINT" when reading the test methods.

When a stated requirement does not apply to a given piece of equipment because the function involved does not exist on that equipment, compliance with that requirement is not necessary. However, when that stated requirement addresses a RISK that could be caused by a substantially similar function of the equipment, the MANUFACTURER needs to address the RISK caused by that similar function in the RISK MANAGEMENT FILE.

## 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<sup>1</sup> applies, except as follows:

##### 201.1.1 Scope

*Replacement:*

This part of IEC 60601 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.

NOTE 1 While ELECTRON ACCELERATORS used for TREATMENT of PATIENTS are always ME EQUIPMENT, there are times in this document where they are referred to as EXTERNAL BEAM EQUIPMENT (EBE). Usage of EBE does not remove the requirements placed on the ME EQUIPMENT but is meant to clarify that the ME EQUIPMENT being discussed is the EBE and not some other ME EQUIPMENT that may be part of the system configuration.

This particular standard, with the inclusion of TYPE TESTS and SITE TESTS, applies to the manufacture and some installation aspects of ELECTRON ACCELERATORS and their included equipment used to increase the precision, accuracy and volumetric targeting of the TREATMENT delivery

- intended for RADIOTHERAPY in medical practice, including those in which the selection and DISPLAY of TREATMENT 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 or ELECTRON RADIATION having
  - NOMINAL ENERGY in the range 1 MeV to 50 MeV,
  - maximum ABSORBED DOSE RATES between  $0,001 \text{ Gy} \times \text{s}^{-1}$  and  $1 \text{ Gy} \times \text{s}^{-1}$  at the ERP from the RADIATION SOURCE, and
  - REFERENCE TREATMENT DISTANCES (RTDs) between 0,5 m and 2 m from the RADIATION SOURCE;

and

- intended to be
  - for NORMAL USE, operated under the authority of the RESPONSIBLE ORGANIZATION by QUALIFIED PERSONS appropriately licensed or having the required skills for a particular medical application, for particular SPECIFIED clinical purposes,
  - maintained in accordance with the recommendations given in the INSTRUCTIONS FOR USE, and
  - subject to regular QUALITY ASSURANCE performance and calibration checks by a QUALIFIED PERSON.

<sup>1</sup> The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

NOTE 2 In this particular standard, all references to installation refer to installation in the RESPONSIBLE ORGANIZATION's premises.

NOTE 3 In this particular standard, all references to ABSORBED DOSE refer to ABSORBED DOSE in water.

NOTE 4 The limits on maximum ABSORBED DOSE RATES are included for two reasons. The first is due to requirements related to time in this document. This restriction limits the total dose that could be delivered during a SPECIFIED time (examples: timer, TIME TO INTERRUPT or TERMINATE, LATENCY). The second is to limit the amount of RADIATION damage that can occur during the time required to take action (often as a follow up to an INTERRUPTION or TERMINATION OF IRRADIATION). Wherever requirements were made to limit the amount of dose delivered before action is taken, the RADIATION damage was considered to be independent of the dose rate and only dependent on the dose. This would largely hold true if the dose rate stayed within the range stated above.

IEC 61217 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 60976:2007 specifies methods of testing and disclosure of functional performance of medical ELECTRON ACCELERATORS and is intended to facilitate comparisons of accelerator-based ME EQUIPMENTS of different manufacture. IEC 60976:2007 contains no safety requirements, and is not required to show compliance with this document. Until IEC 60976:2007 and IEC TR 60977:2008 are updated to match this document, it is suggested that MANUFACTURERS replace the word "ISOCENTRE" with "EQUIPMENT REFERENCE POINT" when reading the test methods.

IEC TR 62926 provides guidance for integration of ELECTRON ACCELERATORS with other equipment.

IEC TR 63183 provides guidance on the construction of error and warning messages.

### 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 document helps to ensure that the ME EQUIPMENT

- maintains PATIENT safety during ME EQUIPMENT movements and failure of the SUPPLY MAINS,
- maintains OPERATOR and general public safety during ME EQUIPMENT NORMAL USE and failure of the SUPPLY MAINS,
- delivers the pre-selected RADIATION TYPE, NOMINAL ENERGY, and ABSORBED DOSE, and
- delivers the RADIATION in accordance with the pre-selected relationship of the RADIATION BEAM to the PATIENT, without causing unnecessary RISK to the PATIENT, the OPERATOR, other persons or the environment.

### 201.1.3 Collateral standards

#### *Addition:*

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

IEC 60601-1-2:2014 applies. IEC 60601-1-6:2010 and IEC 60601-1-6:2010/AMD1:2013 apply as modified in Clause 206. IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-9:2007 and IEC 60601-1-9:2007/AMD1:2013, IEC 60601-1-10:2007 and IEC 60601-1-10:2007/AMD1:2013, IEC 60601-1-11 and IEC 60601-1-12 do not apply, and all other collateral standards in the IEC 60601-1 series do not apply.

#### 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.

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

For brevity, IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 are referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document 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 addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard and applicable collateral standards 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 3.147, additional definitions in this document 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, for example 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

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

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

## 201.2 Normative references

NOTE Informative references are listed in the Bibliography.

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

*Replacement:*

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*  
IEC 60601-1-6:2010/AMD1:2013

*Addition:*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*  
IEC 60601-1:2005/AMD1:2012

IEC 60601-2-68:2014, *Medical electrical equipment – Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment*

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

IEC 61000-4-3, *Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test*

IEC 61217:2011, *Radiotherapy equipment – Coordinates, movements and scales*

CISPR 11, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*

## 201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC TR 60788:2004 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

NOTE An index of defined terms is found beginning on page 111.

*Addition:*

### 201.3.201

#### ADAPTIVE RADIOTHERAPY

RADIOTHERAPY that monitors PATIENT anatomy or physiology and, based upon the monitored information, allows changes to TREATMENT PARAMETERS throughout the course of TREATMENT

Note 1 to entry: IMAGE-GUIDED RADIATION THERAPY (IGRT) is one form of ADAPTIVE RADIOTHERAPY.

### 201.3.202

#### AMBIENT DOSE EQUIVALENT

$H^*(10)$

DOSE EQUIVALENT at the point of interest in the actual RADIATION FIELD defined as DOSE EQUIVALENT that would be produced by the corresponding aligned and expanded RADIATION FIELD at a depth of 10 mm in the ICRU sphere on the radius opposing the direction of the aligned RADIATION FIELD

Note 1 to entry: 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 to entry: See also ICRU definition of AMBIENT DOSE EQUIVALENT in ICRU Report 39.

### 201.3.203

#### BEAM GATING

allowance or inhibition of IRRADIATION and related equipment movements according to the status provided by a BEAM GATING SIGNAL

[SOURCE: IEC 60601-2-64:2014, 201.3.204]

### 201.3.204

#### BEAM GATING SIGNAL

signal generated for the purpose of BEAM GATING

EXAMPLE Examples include a respiratory spirometer, electrocardiogram, optical sensor, etc.

[SOURCE: IEC 60601-2-64:2014, 201.3.205]

### 201.3.205

#### BEAM GATING LATENCY

time between the assertion of the BEAM GATING SIGNAL and the inhibition or enabling of IRRADIATION

Note 1 to entry: The inhibition or enabling of IRRADIATION is measured at 90 % of dose rate change.

### 201.3.206

#### BEAM HOLD

condition, during IRRADIATION, in which the ME EQUIPMENT has minimized the TREATMENT IRRADIATION output

Note 1 to entry: BEAM HOLD is not the same as INTERRUPTION OF IRRADIATION where the ME EQUIPMENT is changed to the beam off state.

Note 2 to entry: BEAM HOLD is a subcondition of IRRADIATION for the purpose of rapid transition to intended TREATMENT IRRADIATION output.

Note 3 to entry: BEAM HOLD approximates the IRRADIATION off condition by inhibiting the IRRADIATION output.

Note 4 to entry: This is commonly used during gating, INTENSITY-MODULATED RADIATION THERAPY (IMRT), etc.

### 201.3.207

#### BEAM LIMITING DEVICE

BLD

<RADIOTHERAPY> structure, fixed or movable, intended to block or collimate IONIZING RADIATION, resulting in shielding the TREATMENT region from unintended X-RADIATION or ELECTRON RADIATION

Note 1 to entry: Examples are non-adjustable primary collimators, adjustable collimators, JAWS, MLCs, cones (non-adjustable BLD), etc.

[SOURCE: IEC 60976:2007, 3.2, modified – Note added.]

### **201.3.208**

#### **BEAM LIMITING SYSTEM**

##### **BLS**

entirety of parts and their geometrical configuration contributing to the limitation of the RADIATION BEAM

[SOURCE: IEC 60601-1-3:2008, 3.12, modified – Abbreviated term "BLS" added.]

### **201.3.209**

#### **CONTROL POINT**

##### **CP**

point in TREATMENT delivery sequence representing the geometric or radiological parameters at a particular time or state of the delivery device

Note 1 to entry: The time separation between CONTROL POINTS can be determined by a trigger other than time (e.g. GANTRY position, DOSE MONITOR UNITS).

Note 2 to entry: CONTROL POINT 0 ( $CP_0$ ) defines the initial setup where all applicable parameters are defined.

Note 3 to entry: For  $n > 0$ ,  $CP_n$  defines the parameters that change relative to  $CP_{(n-1)}$ .

### **201.3.210**

#### **CONTROLLING TIMER**

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

### **201.3.211**

#### **DOSE MONITOR UNIT**

parameter, reported by the DOSE MONITORING SYSTEM, from which, through a calibration procedure and with additional information, the ABSORBED DOSE delivered can be calculated

Note 1 to entry: The DOSE MONITOR UNIT reported by the DOSE MONITORING SYSTEM is related to the amount of IRRADIATION produced by the ME EQUIPMENT.

[SOURCE: IEC 60601-2-64:2014, 201.3.207, modified – Note added.]

### **201.3.212**

#### **DOSE MONITORING SYSTEM**

system of devices for the measurement and DISPLAY of a RADIATION QUANTITY directly related to the ABSORBED DOSE

Note 1 to entry: It may include means for TERMINATION OF IRRADIATION when a pre-selected value is reached.

[SOURCE: IEC TR 60788:2004, rm-33-01]

### **201.3.213**

#### **ELECTRON BEAM APPLICATOR**

device that, on its own or in combination with an interchangeable aperture, is a BEAM LIMITING DEVICE for ELECTRON RADIATION beams

### **201.3.214**

#### **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

[SOURCE: IEC 60976:2007, 3.5, modified – Note deleted.]

**201.3.215****ELECTRONIC PORTAL IMAGING DEVICE****EPID**

device consisting of a two-dimensional RADIATION DETECTOR and associated electronics, placed 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 to entry: 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.

[SOURCE: IEC 60976:2007, 3.6]

**201.3.216****EQUIPMENT REFERENCE AXES**

coordinate axes defined in the EQUIPMENT REFERENCE COORDINATE SYSTEM

**201.3.217****EQUIPMENT REFERENCE COORDINATE SYSTEM**

cartesian right-handed coordinate system with its origin at the ERP and the Z axis vertically upward when all coordinate system angles are set to zero

Note 1 to entry: The EQUIPMENT REFERENCE COORDINATE SYSTEM is identical to the fixed reference system in IEC 61217.

**201.3.218****EQUIPMENT REFERENCE POINT****ERP**

point in space used for referencing dimensions and positions of equipment and performing dosimetry measurements

Note 1 to entry: Typically the EQUIPMENT REFERENCE POINT is coincident with the ISOCENTRE. If the beam delivery equipment is not ISOCENTRIC, then the centre of the PATIENT alignment system may be used.

[SOURCE: IEC 60601-2-64:2014, 201.3.212, modified – Words "and positions" added in the definition, and Note 2 deleted.]

**201.3.219****EXTERNAL BEAM EQUIPMENT****EBE**

external RADIATION equipment utilizing ELECTRON ACCELERATORS, LIGHT ION BEAM equipment or RADIONUCLIDE BEAM THERAPY EQUIPMENT

[SOURCE: IEC 60601-2-68:2014, 201.3.207, modified – Note deleted.]

**201.3.220****EXTERNAL MONITORING DEVICE**

device that can be connected to ME EQUIPMENT and monitors PATIENT anatomy or physiology

**201.3.221****FLUENCE RATE**

quotient of  $d\Phi$  by  $dt$ , where  $d\Phi$  is the increment of the fluence in the time interval  $dt$

Note 1 to entry: The unit of FLUENCE RATE is  $\text{m}^{-2}\text{s}^{-1}$ .

[SOURCE: ICRU Report 60:1998, modified – Rephrased to follow IEC term format.]

**201.3.222****GANTRY**

part of the ME EQUIPMENT supporting the RADIATION HEAD

Note 1 to entry: The GANTRY is any mechanical device that supports the RADIATION HEAD regardless of movement limitations.

### **201.3.223**

#### **GEOMETRICAL RADIATION FIELD**

geometrical projection of the aperture formed at the distal end of the BEAM LIMITING DEVICE on a plane orthogonal to the REFERENCE AXIS at the EQUIPMENT REFERENCE POINT, as seen from the centre of the front surface of the TARGET/ELECTRON RADIATION window

### **201.3.224**

#### **HARD-WIRED**

condition of a system where its features can be modified only by physically removing and re-routing physically linked wires

### **201.3.225**

#### **IMAGE-GUIDED RADIOTHERAPY**

##### **IGRT**

RADIOTHERAPY process by which the location of a RADIOTHERAPY beam relative to the intended TARGET VOLUME within a PATIENT's anatomy is determined by imaging of the TARGET VOLUME and surrounding anatomical structures at the time of TREATMENT, so as to enable any necessary positional corrections to the intended relative location of the beam to the TARGET VOLUME

Note 1 to entry: The time period of "at the time of TREATMENT" is specified in the definitions of REAL-TIME IGRT, ONLINE IGRT and OFFLINE IGRT.

[SOURCE: IEC 60601-2-68:2014, 201.3.209 modified – Note 1 replaced.]

### **201.3.226**

#### **INTENSITY-MODULATED 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

[SOURCE: IEC 60976:2007, 3.9, modified – Words "of the external beam" added in the definition, and note deleted.]

### **201.3.227**

#### **INTERRUPTION OF IRRADIATION**

stopping of IRRADIATION and movements with the possibility of continuing without reselecting operating conditions

### **201.3.228**

#### **JAW**

BLD used to collimate the primary RADIATION BEAM to form a single simple geometric shape of adjustable size

Note 1 to entry: Examples of shapes are rectangles and circles.

### **201.3.229**

#### **LATENCY**

time interval between occurrence or initiation of an event and its detection or effect

### **201.3.230**

#### **MULTILEAF COLLIMATOR**

##### **MLC**

multi-element BLD capable of defining RADIATION FIELDS of irregular shapes

Note 1 to entry: The positions of the individual elements can either be static or can be changed dynamically during IRRADIATION.

**201.3.231****NOMINAL ENERGY**

numerical value stated by the MANUFACTURER to identify the RADIATION BEAM

**201.3.232****OFFLINE ADAPTIVE RADIOTHERAPY**

process wherein the PATIENT setup or TREATMENT PLAN is adjusted for application in subsequent TREATMENT delivery sessions

**201.3.233****ONLINE ADAPTIVE RADIOTHERAPY**

process wherein the PATIENT setup or TREATMENT PLAN is adjusted immediately prior to or during the therapeutic IRRADIATION session requiring OPERATOR initiated adjustments.

Note 1 to entry: The PATIENT stays on the PATIENT POSITIONER and is immobile during and in-between adaptive calculations and TREATMENT.

**201.3.234****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

**201.3.235****PATIENT POSITIONER**

<RADIOTHERAPY> assembly of equipment upon which the PATIENT is placed and positioned for RADIOTHERAPY

Note 1 to entry: The PATIENT POSITIONER includes the TABLE TOP and TABLE TOP SUPPORT.

**201.3.236****PREPARATORY STATE**

state of equipment for setting essential operating conditions, if in the STAND-BY STATE the setting of these conditions is not possible

[SOURCE: IEC TR 60788:2004, rm-84-04]

**201.3.237****PRIMARY DOSE MONITORING SYSTEM**

DOSE MONITORING SYSTEM which is intended to TERMINATE IRRADIATION when a pre-selected value is reached

[SOURCE: IEC TR 60788:2004, rm-33-03]

**201.3.238****PROGRAMMABLE WEDGE FIELD****PWF**

generation of a RADIATION FIELD with a wedge-shaped DOSE PROFILE, with or without the use of a fixed metal WEDGE FILTER placed in the X-ray beam, where the programmed wedge DOSE PROFILE may be generated by controlling the relationship between the beam intensity and a moveable BEAM LIMITING DEVICE

[SOURCE: IEC 60976:2007, 3.18, modified – Words "a RADIATION FIELD with" added in the definition.]

**201.3.239****QUALIFIED PERSON**

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

[SOURCE: IEC TR 60788:2004, rm-85-04, modified – Word "specified" replaced by "particular" in the definition.]

### **201.3.240**

#### **QUALITY ASSURANCE**

##### **QA**

part of quality management focused on providing confidence that quality requirements will be fulfilled

Note 1 to entry: Unless given requirements fully reflect the needs of the RESPONSIBLE ORGANIZATION, QUALITY ASSURANCE will not be complete.

Note 2 to entry: For effectiveness, QUALITY ASSURANCE requires a continuing evaluation of factors that affect the adequacy of the design or specification for intended applications as well as VERIFICATIONS and audits of production, installation and inspection operations. Providing confidence can involve producing evidence.

Note 3 to entry: Within an organization, QUALITY ASSURANCE also serves to provide confidence in the supplier.

[SOURCE: IEC TR 61258:2008, 2.5]

### **201.3.241**

#### **RADIATION HEAD**

structure from which the RADIATION BEAM emerges

[SOURCE: IEC TR 60788:2004, rm-20-06]

### **201.3.242**

#### **RADIATION TYPE**

nature of the waves or corpuscles comprising the RADIATION

EXAMPLE RADIATION is X-RADIATION or ELECTRON RADIATION

### **201.3.243**

#### **REAL-TIME ADAPTIVE RADIOTHERAPY**

RADIOTHERAPY that, throughout therapeutic IRRADIATION, monitors PATIENT anatomy or physiology and based upon that information, allows autonomous adjustments of TREATMENT PARAMETERS throughout the therapeutic IRRADIATION without OPERATOR intervention

### **201.3.244**

#### **REDUNDANT DOSE MONITORING SYSTEM**

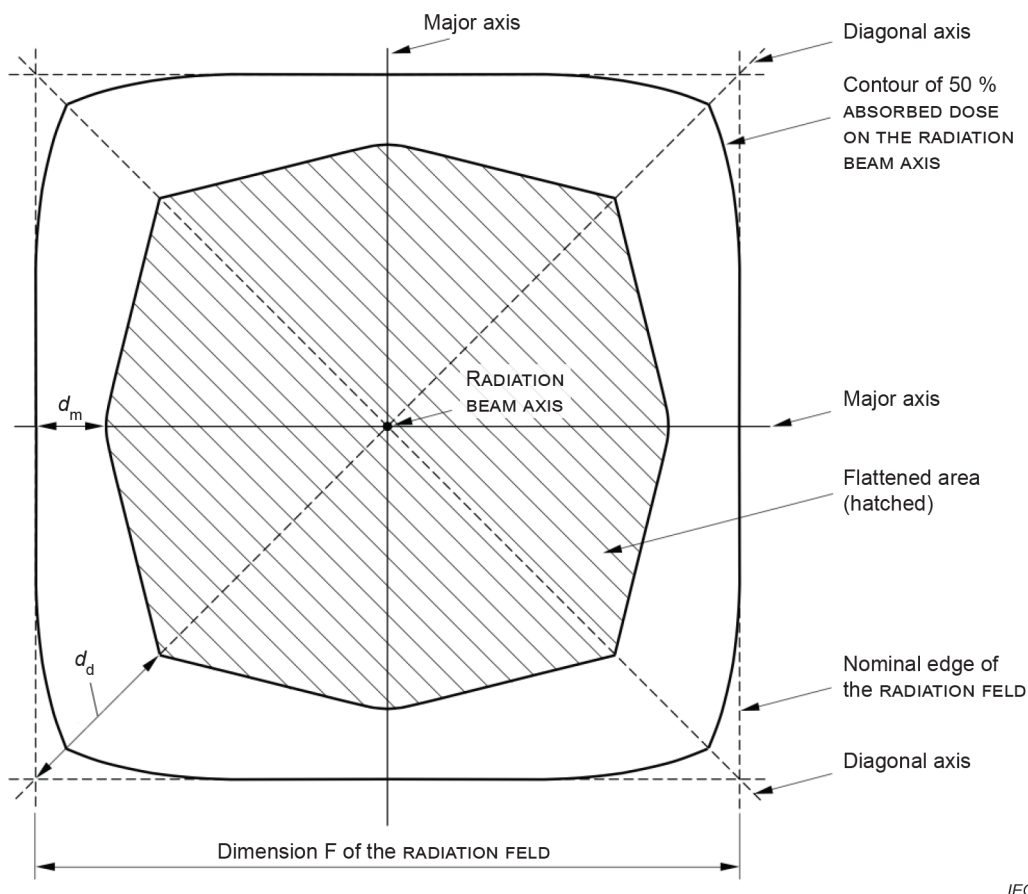
utilization of two DOSE MONITORING SYSTEMS where both systems are arranged to TERMINATE IRRADIATION according to the pre-selected number of DOSE MONITOR UNITS

[SOURCE: IEC 60976:2007, 3.21, modified – The words "be the PRIMARY DOSE MONITORING SYSTEM" have been replaced by "TERMINATE IRRADIATION according to the pre-selected number of DOSE MONITOR UNITS".]

### **201.3.245**

#### **REFERENCE ABSORBED DOSE**

area-weighted averaged ABSORBED DOSE within the hatched area as shown in Figure 201.101 and measured at the REFERENCE TREATMENT DISTANCE at a depth containing the maximum ABSORBED DOSE measured on the REFERENCE AXIS, whose measurement area is defined by the dimensions in Table 201.101



IEC

**Figure 201.101 – Flattened area within the RADIATION FIELD****Table 201.101 – Dimensions defining the flattened area according to Figure 201.101**

| Square RADIATION FIELD<br>$F$<br>$c_m$ | Dimensions defining the measurement area |         |
|----------------------------------------|------------------------------------------|---------|
|                                        | $d_m$                                    | $d_d$   |
| $5 \leq F \leq 10$                     | 1 cm                                     | 2 cm    |
| $10 < F \leq 30$                       | $0,1 F$                                  | $0,2 F$ |
| $30 < F$                               | 3 cm                                     | 6 cm    |

Note 1 to entry: As an alternative, measurement points arranged in an equidistant square pattern and with each point no more than 1 cm from any other point may be used.

Note 2 to entry: Area-weighted averages are defined as follows:

$$\bar{D}_{\text{area}} = \frac{1}{\text{area}} \int_{\text{area}} D(x, y) dx dy, \bar{D}_{\text{area}} = \frac{1}{\text{area}} \int_{\text{area}} D(r, \varphi) r dr d\varphi, \bar{D}_{\text{area}} = \sum_{i=1}^n D_i A_i / \sum_{i=1}^n A_i$$

**201.3.246****REFERENCE AXIS**

line through the centre of a RADIATION SOURCE in the direction perpendicular to the plane of either the front surface of the TARGET if X-RADIATION, or the ELECTRON RADIATION window if ELECTRON RADIATION

### **201.3.247**

#### **REFERENCE CONDITIONS**

conditions under which all influence quantities and instrument parameters have their reference values

[SOURCE: IEC TR 60788:2004, rm-70-12]

### **201.3.248**

#### **REFERENCE TREATMENT DISTANCE**

##### **RTD**

SPECIFIED distance measured along the REFERENCE AXIS which is, for ELECTRON RADIATION, measured from the ELECTRON RADIATION window to the distal end of the ELECTRON BEAM APPLICATOR or to a SPECIFIED plane containing the EQUIPMENT REFERENCE POINT, or for X-RADIATION, from the TARGET surface of the exiting beam to a SPECIFIED plane containing the EQUIPMENT REFERENCE POINT

Note 1 to entry: The REFERENCE TREATMENT DISTANCE replaces the use of NORMAL TREATMENT DISTANCE in previous editions of IEC 60601-2-1.

### **201.3.249**

#### **REFERENCE TREATMENT PLANE**

##### **RTP**

plane containing the EQUIPMENT REFERENCE POINT and which is perpendicular to the therapeutic REFERENCE AXIS

### **201.3.250**

#### **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 water or a water-equivalent PHANTOM with its surface at a SPECIFIED distance

### **201.3.251**

#### **SECONDARY DOSE MONITORING SYSTEM**

DOSE MONITORING SYSTEM which is intended to TERMINATE IRRADIATION in the event of failure of the PRIMARY DOSE MONITORING SYSTEM

[SOURCE: IEC TR 60788:2004, rm-33-04]

### **201.3.252**

#### **SEGMENT**

span between two consecutive CONTROL POINTS

### **201.3.253**

#### **SITE TEST**

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

Note 1 to entry: It is understood that SITE TESTS shall be performed but may or may not be performed by the MANUFACTURER, per the agreement between the MANUFACTURER and the RESPONSIBLE ORGANIZATION.

### **201.3.254**

#### **TABLE TOP**

device attached to the TABLE TOP SUPPORT to which registration or immobilization devices are attached and upon which the PATIENT is placed

Note 1 to entry: The TABLE TOP can be exchangeable.

[SOURCE: IEC 60601-2-64:2014, 201.3.238, modified – Words "an exchangeable device attached to the patient positioner" have been replaced by "device attached to the TABLE TOP SUPPORT", and note added.]

**201.3.255****TABLE TOP SUPPORT**

device used in conjunction with the TABLE TOP to support and position the PATIENT during RADIOTHERAPY

**201.3.256****TERMINATION OF IRRADIATION**

stopping of IRRADIATION and movements, with no possibility of restarting without the reselection of all operating conditions

Note 1 to entry: I.e. returning to the PREPARATORY STATE.

Note 2 to entry: Events that TERMINATE IRRADIATION and stop movements include the following:

- normal TERMINATION OF IRRADIATION:
  - when the pre-selected value of DOSE MONITOR UNITS is reached;
  - when the pre-selected value of elapsed time is reached;
  - when the pre-selected value of an angular or linear dimension is reached;
- abnormal termination of IRRADIATION:
  - a deliberate manual act;
  - the operation of an INTERLOCK which is not due to a pre-selected value being reached;
  - when the pre-selected value of an angular or linear dimension is exceeded.

**201.3.257****TRANSMISSION DETECTOR**

RADIATION DETECTOR through which the RADIATION BEAM passes

**201.3.258****TREATMENT PARAMETER**

factor that describes one aspect of the IRRADIATION of a PATIENT during RADIOTHERAPY

Note 1 to entry: Examples of a TREATMENT PARAMETER include such values as RADIATION ENERGY, SOURCE STRENGTH and TREATMENT TIME.

[SOURCE: IEC 60601-2-17:2013, 201.3.214, modified – Information in the new note moved from the definition.]

**201.3.259****TREATMENT VOLUME**

<RADIOTHERAPY> region, in the PATIENT, to which the prescribed ABSORBED DOSE is delivered

**201.4 General requirements**

Clause 4 of the general standard applies.

**201.5 General requirements for testing ME EQUIPMENT**

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

**201.5.1 TYPE TESTS**

*Addition:*

**201.5.1.101 Test grades**

Three grades of TYPE TEST and three of SITE TEST procedures are SPECIFIED as follows, and used throughout this document:

- TYPE TEST/SITE 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**

Item a) does not apply.

*Replacement of item d):*

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

*Addition:*

The MANUFACTURER shall state in the ACCOMPANYING DOCUMENTATION any additional requirement for testing.

#### **201.5.9.2.1 Test finger**

*Addition:*

Where the nature of the installation renders parts inaccessible to 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 DOCUMENTATION 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:

#### **201.7.1.1 USABILITY of the identification, marking and documents**

*Addition:*

All sub-assemblies, components and ACCESSORIES of ELECTRON ACCELERATORS that can be removed in NORMAL USE, and are relevant to compliance with this document, shall be marked to ensure

- that they can be identified readily and correlated with their ACCOMPANYING DOCUMENTATION;
- that interchangeable devices are individually distinguishable to the OPERATOR both in NORMAL USE and for the purpose of obtaining replacements.

#### **201.7.2.4 ACCESSORIES**

*Addition:*

For all interchangeable and non-adjustable BEAM LIMITING DEVICES (BLDs) and ELECTRON BEAM APPLICATORS, the dimensions of the GEOMETRICAL RADIATION FIELD at the REFERENCE TREATMENT DISTANCE (RTD) and the distance from the distal end to RTD shall be clearly legible on the outside of the device.

The dimensions of the GEOMETRICAL RADIATION FIELD at the RTD shall be clearly stated in the ACCOMPANYING DOCUMENTATION for all non-adjustable BLDs.

For adjustable devices, the minimum and maximum size of the GEOMETRICAL RADIATION FIELD at the REFERENCE TREATMENT PLANE shall be SPECIFIED in the ACCOMPANYING DOCUMENTATION.

For any ACCESSORY supplied by the MANUFACTURER, the limitations of each device shall be SPECIFIED in the ACCOMPANYING DOCUMENTATION.

Each manually interchangeable RADIATION FILTER and BLD shall be clearly marked to establish its identity.

Any ACCESSORY that could present collision RISK when attached to the ME EQUIPMENT shall be clearly marked on its outside with the distance along the REFERENCE AXIS from its distal end to the REFERENCE TREATMENT DISTANCE.

*Compliance is checked by inspection*

#### **201.7.2.20 Removable protective means**

*Addition:*

Where the requirements of 7.2.20 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**

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".

#### **201.7.4 Marking of controls and instruments**

*Additional subclause:*

##### **201.7.4.101 PROVISION OF SCALES AND INDICATIONS FOR MOVING PARTS**

The following non- X-ray based means shall be provided:

- a) a means to align the PATIENT with respect to the EQUIPMENT REFERENCE POINT of the ME EQUIPMENT (e.g. LIGHT FIELD, lasers, imaging systems);

NOTE For ISOCENTRIC equipment, the EQUIPMENT REFERENCE POINT is the ISOCENTRE of the ME EQUIPMENT.

- b) a means to determine RADIATION SOURCE TO SKIN DISTANCE (e.g. scale, numerical indication, lasers, imaging systems).

For a) and b) above, if the ME EQUIPMENT only allows ON-LINE X-IGRT TREATMENTS, the use of an X-ray based imaging system may be the only means provided.

A statement indicating the accuracy of each scale or numerical indication of the TREATMENT geometry of the ME EQUIPMENT shall be provided in the ACCOMPANYING DOCUMENTATION.

The following shall be provided for all ACCESSORIES attached either mechanically or electrically to the ME EQUIPMENT that are provided by the MANUFACTURER:

- c) a mechanical scale, numerical indication, or status indicator shall be presented to the OPERATOR if the MANUFACTURER'S HAZARDS ANALYSIS determines that the information is required for safe operation;
- d) when a mechanical scale, numerical read out or a status indicator aligns with an IEC 61217 axis, then the IEC 61217 axis shall be used for each available IEC 61217 movement;
- e) when a mechanical scale, numerical read out or a status indicator does not align with an IEC 61217 axis, then the MANUFACTURER shall state in its ACCOMPANYING DOCUMENTATION a transformation method from these coordinates into IEC 61217 coordinates;

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

With all linear displacements along all coordinate axes and all IEC 61217 rotational angles set to zero, the RADIATION BEAM REFERENCE AXIS shall be directed vertically downward and pass through the ERP.

*Compliance is checked as follows:*

- *TYPE TEST grade A – Statement regarding accuracy of each scale or numerical indication of the TREATMENT geometry of the ME EQUIPMENT.*
- *SITE TEST grade A – Compliance is checked by inspection of the ACCOMPANYING DOCUMENTATION.*

#### **201.7.8.1 Colours of indicator lights**

*Replacement:*

Where indicator lights (lights, DISPLAYS or icons) are used on the TREATMENT CONTROL PANEL (TCP) or other control panels associated with the ME EQUIPMENT, the colours of the lights shall accord with the following:

|                                                                        |              |
|------------------------------------------------------------------------|--------------|
| RADIATION BEAM "on"                                                    | yellow       |
| READY STATE                                                            | green        |
| Urgent action required in response to an unintended state of operation | red          |
| PREPARATORY STATE                                                      | other colour |

When the ME EQUIPMENT cannot automatically correct for misalignment during REAL-TIME ADAPTIVE RADIOTHERAPY, the colour red shall be used as this represents an urgent action required by the OPERATOR.

NOTE 1 In the TREATMENT ROOM or at other locations, these states can require urgent action or caution; different colours, as given in IEC 60601-1:2005, Table 2, can therefore be used in such locations.

NOTE 2 When computer generated, the hue of the colours stated above are determined to be correctly displayed through usability testing.

NOTE 3 Icons on a computer DISPLAY that change colours as a result of the ME EQUIPMENT states above are considered indicator lights regardless of any text that can exist with the icon.

## **201.7.9 ACCOMPANYING DOCUMENTS**

### **201.7.9.1 General**

*Addition:*

Data required in the technical description to support 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<br>from TYPE TESTS grade A | Details of, and results<br>from, TYPE TESTS grade B | Details of, and results<br>from, TYPE TESTS grade C | SPECIFIC procedures and<br>test conditions for SITE<br>TESTS grade B | SPECIFIC procedures and<br>test conditions for SITE<br>TESTS grade C |
|----------------------|-----------------------------------------------------|-----------------------------------------------------|-----------------------------------------------------|----------------------------------------------------------------------|----------------------------------------------------------------------|
| 201.7.4.101          | †                                                   |                                                     |                                                     |                                                                      |                                                                      |
| 201.7.9.2.5          | †                                                   |                                                     |                                                     |                                                                      |                                                                      |
| 201.9.2.4.101        |                                                     | †                                                   |                                                     |                                                                      |                                                                      |
| 201.9.2.5            | †                                                   |                                                     |                                                     |                                                                      |                                                                      |
| 201.110              | a) d) c)                                            |                                                     |                                                     | a) b) e) f) g)                                                       |                                                                      |
| 201.10.1.1           |                                                     |                                                     | †                                                   |                                                                      |                                                                      |
| 201.10.101.1.1.2     | b) d) e)                                            |                                                     | d)                                                  |                                                                      | a) b) c)                                                             |
| 201.10.101.1.1.3     | a) b)                                               |                                                     | b) c)                                               |                                                                      | b)                                                                   |
| 201.10.101.1.1.4     | d) f) g)                                            |                                                     |                                                     | a) b) c) d) e) f) g)                                                 |                                                                      |
| 201.10.101.1.1.5     | a) b) c) d)                                         |                                                     |                                                     |                                                                      | b) c) d)                                                             |
| 201.10.101.1.1.6     | a)                                                  |                                                     |                                                     |                                                                      | b)                                                                   |
| 201.10.101.1.7       | d) e)                                               |                                                     |                                                     | a)                                                                   | b)                                                                   |
| 201.10.101.1.8       |                                                     |                                                     |                                                     | b) c) d) e)                                                          |                                                                      |
| 201.10.101.1.9       | a) b) c) d) e)                                      | d)                                                  | b)                                                  |                                                                      | c)                                                                   |
| 201.10.101.1.10      | d) e)                                               |                                                     | f)                                                  | a) b) c) e) g)                                                       |                                                                      |
| 201.10.101.1.11      | c) e)                                               |                                                     | a)                                                  |                                                                      | b) d)                                                                |
| 201.10.101.1.12      | a) b) c) d)                                         |                                                     |                                                     |                                                                      | c) d)                                                                |
| 201.10.101.1.13      |                                                     | †                                                   |                                                     |                                                                      |                                                                      |
| 201.10.101.1.14      | e)                                                  |                                                     |                                                     | a) b) c) d) e)                                                       |                                                                      |
| 201.10.101.1.15      | †                                                   |                                                     |                                                     |                                                                      |                                                                      |
| 201.10.101.1.16      | a)                                                  |                                                     |                                                     | a) b)                                                                |                                                                      |
| 201.10.101.1.17      | a)                                                  |                                                     | d)                                                  | a) b)                                                                | c) e)                                                                |
| 201.10.101.1.18      | a) c)                                               |                                                     |                                                     | d)                                                                   | a) c)                                                                |
| 201.10.101.2.1       | †                                                   |                                                     |                                                     | †                                                                    |                                                                      |
| 201.10.101.2.2       |                                                     | †                                                   |                                                     | †                                                                    |                                                                      |
| 201.10.101.2.3       |                                                     |                                                     | †                                                   |                                                                      |                                                                      |

| 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 |
|----------------------------------------------------------------------------------|--------------------------------------------------|--------------------------------------------------|--------------------------------------------------|----------------------------------------------------------------|----------------------------------------------------------------|
| 201.10.101.3.2.1                                                                 |                                                  | a) b) c) d)                                      |                                                  | a) b) d)                                                       |                                                                |
| 201.10.101.3.2.2                                                                 | c)                                               | a) 1), a) 2), b)                                 |                                                  | a) b)                                                          | c)                                                             |
| 201.10.101.3.3                                                                   |                                                  | †                                                |                                                  |                                                                | †                                                              |
| 201.10.101.3.4                                                                   |                                                  | †                                                |                                                  |                                                                |                                                                |
| 201.10.101.3.5                                                                   | †                                                | ← grade A or grade C test →                      | †                                                |                                                                | †                                                              |
| 201.10.101.4.1                                                                   |                                                  | a) b)                                            |                                                  | a) b)                                                          |                                                                |
| 201.10.101.4.2                                                                   |                                                  |                                                  | †                                                |                                                                |                                                                |
| 201.10.101.4.3                                                                   | b)                                               | a)                                               |                                                  |                                                                |                                                                |
| 201.10.101.4.4                                                                   | †                                                |                                                  |                                                  | †                                                              |                                                                |
| 201.10.101.4.5                                                                   | c)                                               | a)                                               |                                                  | a) b)                                                          |                                                                |
| 201.10.101.5.1                                                                   | †                                                |                                                  | †                                                |                                                                | †                                                              |
| 201.10.101.5.2                                                                   | b)                                               | a) b)                                            |                                                  |                                                                |                                                                |
| 201.105.2                                                                        | f)                                               | a) b)                                            |                                                  | c) d) e)                                                       |                                                                |
| 201.105.3                                                                        |                                                  | †                                                |                                                  | †                                                              |                                                                |
| 201.106                                                                          |                                                  |                                                  |                                                  | †                                                              |                                                                |
| 201.107                                                                          | †                                                |                                                  |                                                  | †                                                              |                                                                |
| 201.108.2                                                                        | †                                                |                                                  |                                                  | †                                                              |                                                                |
| 201.108.3                                                                        | †                                                |                                                  |                                                  | †                                                              |                                                                |
| 201.14.101                                                                       | †                                                |                                                  |                                                  |                                                                | †                                                              |
| 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 DOCUMENTATION, 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 DOCUMENTATION, INSTRUCTIONS FOR USE and the technical description**

| Check reference | ACCOMPANYING DOCUMENTATION                 | INSTRUCTIONS FOR USE | Technical description      |
|-----------------|--------------------------------------------|----------------------|----------------------------|
| 1               |                                            |                      | 201.5.1.101                |
| 2               | 201.5.4                                    |                      |                            |
| 3               | 201.5.9.2.1                                |                      |                            |
| 4               | 201.7.2.4                                  |                      |                            |
| 5               |                                            | 201.7.3.101          |                            |
| 6               | 201.7.4.101, second paragraph after b), e) |                      |                            |
| 7               |                                            |                      | 201.7.9                    |
| 8               | 201.7.9.2.2                                |                      |                            |
| 9               | 201.7.9.2.2.101                            |                      |                            |
| 10              | 201.7.9.2.5                                |                      |                            |
| 11              |                                            | 201.7.9.2.15         |                            |
| 12              | 201.7.9.2.17                               |                      |                            |
| 13              | 201.8.4.2                                  |                      |                            |
| 14              |                                            |                      | 201.8.11.1                 |
| 15              | 201.9.2.4.101                              |                      |                            |
| 16              | 201.9.2.5                                  |                      |                            |
| 17              |                                            | 201.9.2.5            |                            |
| 18              |                                            | 201.9.2.101 a) 1)    |                            |
| 19              | 201.9.2.101                                | 201.9.2.101          |                            |
| 20              |                                            | 201.9.2.102          |                            |
| 21              |                                            | 201.9.2.103 e)       |                            |
| 22              | 201.110 a) c) d)                           |                      |                            |
| 23              | 201.9.8.101 b)                             |                      |                            |
| 24              | 201.9.8.102                                | 201.9.8.102          |                            |
| 25              |                                            |                      | 201.10 (see Table 201.101) |
| 26              | 201.10.101.1.1.2 c) Note                   |                      |                            |
| 27              |                                            |                      | 201.10.101.1.1.2 d)        |
| 28              |                                            |                      | 201.10.101.1.3 b), c), f)  |
| 29              |                                            |                      | 201.10.101.1.4 e)          |
| 30              |                                            | 201.10.101.1.5 b)    |                            |
| 31              | 201.10.101.1.9 e)                          |                      |                            |
| 32              |                                            |                      | 201.10.101.1.10 e)         |
| 33              | 201.10.101.1.11 c)                         |                      |                            |
| 34              |                                            | 201.10.101.1.11 c)   |                            |
| 35              |                                            | 201.10.101.1.14 e)   |                            |
| 36              |                                            | 201.10.101.1.16 a)   |                            |

| Check reference                                                                                        | ACCOMPANYING DOCUMENTATION      | INSTRUCTIONS FOR USE | Technical description |
|--------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|-----------------------|
| 37                                                                                                     |                                 | 201.10.101.1.17 a)   |                       |
| 38                                                                                                     | 201.10.101.1.17 f)              |                      |                       |
| 39                                                                                                     |                                 | 201.10.101.1.18 a)   |                       |
| 40                                                                                                     | 201.10.101.4.5                  |                      |                       |
| 41                                                                                                     |                                 | 201.10.101.5.2 b)    |                       |
|                                                                                                        | 201.10.101.5.2                  |                      |                       |
| 42                                                                                                     | 201.10.101.5.3                  |                      |                       |
| 43                                                                                                     | 201.10.101.5.4                  |                      |                       |
| 44                                                                                                     | 201.10.101.5.5                  |                      |                       |
| 45                                                                                                     | 201.103.2.3 a) b)               |                      |                       |
| 46                                                                                                     |                                 |                      | 201.10.101.4.1 b)     |
| 47                                                                                                     |                                 |                      | 201.10.101.4.3 b)     |
| 48                                                                                                     |                                 | 201.14.101 e)        |                       |
| 49                                                                                                     | 201.16.2 Note, a), b)           |                      |                       |
| 50                                                                                                     | 201.17                          |                      |                       |
| 51                                                                                                     | 201.17.101                      |                      |                       |
| 52                                                                                                     | 201.103.1                       |                      |                       |
| 53                                                                                                     | 201.103.2.3 a) b)               |                      |                       |
| 54                                                                                                     | 201.104 a) b) d) e) f) g) h) i) |                      |                       |
| 55                                                                                                     |                                 |                      | 201.105.1 a) b)       |
| 56                                                                                                     | 201.105.2 f)                    |                      |                       |
| 57                                                                                                     | 201.105.3                       | 201.106              |                       |
| 58                                                                                                     | 201.108.2                       |                      |                       |
| 59                                                                                                     | 201.108.3                       |                      |                       |
| NOTE The check reference is given as an aid for checking the availability of compliance documentation. |                                 |                      |                       |

### 201.7.9.2.2 Warning and safety notices

#### Addition:

The ACCOMPANYING DOCUMENTATION shall describe the devices or systems supplied or recognized by the ME EQUIPMENT MANUFACTURER for use with the ME EQUIPMENT.

The ACCOMPANYING DOCUMENTATION shall warn that any devices or systems not described by the ME EQUIPMENT MANUFACTURER shall be evaluated for correct system operation and safety by the RESPONSIBLE ORGANIZATION.

#### 201.7.9.2.2.101 Interaction of RADIATION with active medical devices

The ACCOMPANYING DOCUMENTATION shall contain a cautionary statement regarding the potential detrimental interaction of the imaging and therapeutic RADIATION on active implantable or body worn medical devices and indicate that:

- the MANUFACTURER of such devices should be contacted for more information,
- the device should be checked for correct operation after the IRRADIATION.

**201.7.9.2.5 ME EQUIPMENT description***Addition:*

The MANUFACTURER shall provide in the ACCOMPANYING DOCUMENTATION a method to locate the position of the ERP and EQUIPMENT REFERENCE AXES of the ME EQUIPMENT.

The accuracy of the relationship of all axes of the ME EQUIPMENT to the ERP shall be stated in the ACCOMPANYING DOCUMENTATION.

The accuracy of determining the relationships of the axes to the ERP and the technique of measurement establishing these values shall be stated in the ACCOMPANYING DOCUMENTATION.

The expected stability of the ERP and EQUIPMENT REFERENCE COORDINATE SYSTEM in relation to the ME EQUIPMENT at the time of the last calibration and the recommended frequency of QUALITY ASSURANCE (QA) shall be stated in the ACCOMPANYING DOCUMENTATION.

NOTE An example of items to consider:

- long term mechanical drift;
- short term drift during a fraction (e.g. rotation);
- changes related to OPERATOR activity, for example fitting accessories, removing/deploying hardware;
- changes related to machine position and configuration.

*Compliance is checked as follows:*

*TYPE TEST grade A – Statement regarding the TREATMENT geometry including accuracy, technique of measurement and importance of periodic reassessment.*

**201.7.9.2.10 Messages***Addition:*

All system messages, error messages, and fault messages required by 7.9.2.10 of the general standard that are intended for the OPERATOR during clinical use and are displayed at the TCP shall identify the reason for the message and provide possible actions for the OPERATOR to respond promptly and appropriately to the message.

NOTE It is intended that the OPERATOR be shown all information needed to make an informed decision concerning the continuation or TERMINATION of the TREATMENT without the need to reference other information.

**201.7.9.2.15 Environmental protection***Addition:*

The INSTRUCTIONS FOR USE shall provide guidance and advice on precautions to be taken regarding the identification, handling and disposal of ME EQUIPMENT or ME EQUIPMENT parts that may exhibit RADIOACTIVITY.

**201.7.9.2.17 ME EQUIPMENT emitting RADIATION***Replacement:*

To assist the RESPONSIBLE ORGANIZATION's RADIOLOGICAL PROTECTION adviser, the following information shall be provided in the ACCOMPANYING DOCUMENTATION:

– For each NOMINAL ENERGY:

- maximum electron energy striking the TARGET or ELECTRON WINDOW and corresponding maximum ABSORBED DOSE RATES at RTD 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 RADIATION FIELDS at RTD for X-RADIATION and ELECTRON RADIATION;
- location(s), referenced to accessible points on the RADIATION HEAD, of
  - the surface of the TARGET facing the PATIENT, and
  - the ELECTRON BEAM RADIATION window;
- available directions of the RADIATION BEAM.
- For each X-RADIATION NOMINAL ENERGY, if a primary RADIATION BEAM shield (a "beam stopper") is incorporated, its transmission factor shall be provided in the ACCOMPANYING DOCUMENTATION.

## **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 and APPLIED PARTS**

*Addition to item d):*

These requirements do not apply where the installation prevents the test rod or the test pin from being inserted into the openings concerned. The ACCOMPANYING DOCUMENTATION shall state when these conditions apply.

### **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.

#### **201.8.7.3 Allowable values**

*Replacement of item d):*

The EARTH LEAKAGE CURRENT under NORMAL CONDITION and SINGLE FAULT CONDITION shall not exceed 10 mA.

NOTE Local regulation can establish limits for protective earth currents of the installation. See also IEC 60364-7-710.

The allowable values of the EARTH LEAKAGE CURRENT are permitted for each sub-assembly of the ELECTRON ACCELERATOR that is supplied by its own exclusive connection to the SUPPLY MAINS or to a central connection point, if the latter is fixed and PERMANENTLY INSTALLED.

A fixed and PERMANENTLY INSTALLED central PROTECTIVE EARTH TERMINAL may be provided inside the outer ENCLOSURE or cover of the ELECTRON ACCELERATOR. If other sub-assemblies or ASSOCIATED EQUIPMENT are connected to the PROTECTIVE EARTH TERMINAL, the EARTH LEAKAGE CURRENT between such a central connection point and the external protective system may exceed the allowable values for any one of the single devices connected.

The provision of a central PROTECTIVE EARTH TERMINAL is acceptable, since for fixed and PERMANENTLY INSTALLED ME EQUIPMENT the interruption of the PROTECTIVE EARTH CONDUCTOR is not considered to be a SINGLE FAULT CONDITION. However, in such cases, adequate information on the combination of ASSOCIATED EQUIPMENT shall be provided in accordance with 7.9.3.1 of the general standard.

*TYPE TEST grade C: Compliance is checked by inspection and test.*

*Addition to item e):*

For PERMANENTLY INSTALLED ELECTRON ACCELERATORS, regardless of waveform and frequency, the EARTH LEAKAGE CURRENT under NORMAL CONDITION and SINGLE FAULT CONDITION shall not exceed 20 mA RMS when measured with a non-frequency-weighted device.

*Compliance is checked as follows:*

*SITE TEST grade A: Inspection of the ACCOMPANYING DOCUMENTATION*

*Compliance is checked by inspection and test.*

#### **201.8.11.1 Isolation from the SUPPLY MAINS**

*Replacement of item b):*

Means for isolation from mains power, 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 MECHANICAL HAZARDS associated with moving parts**

##### **201.9.2.1 General**

*Addition:*

NOTE 101 The term "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 whether or not the movements are initiated by the OPERATOR.

NOTE 102 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".

NOTE 103 The term "autonomous movements" is used where movement of ME EQUIPMENT parts takes place according to corrections calculated by the ME EQUIPMENT, without intervention by the OPERATOR, during a PATIENT TREATMENT.

##### **201.9.2.2.5 \* Continuous activation**

Item b) does not apply.

#### **201.9.2.4 Emergency stopping devices**

*Addition:*

##### **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 circuits or have an equivalent safety switching function. These means shall be near to, or on, the PATIENT POSITIONER 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 DOCUMENTATION and the results should be incorporated in the SITE TEST report.

If a PESS is involved, then the technology shall be shown to be free from unacceptable RISK by use of RISK MANAGEMENT.

If an interface for a third party's device is provided, the requirements for motion and the stopping limits according to 201.9.2.101 shall be stated in the ACCOMPANYING DOCUMENTATION.

If means are provided for control of motions of EBE motors by equipment other than the EBE, then the interface shall contain at a minimum the ability to receive a motors emergency stop as well as a signal to indicate if a motors emergency stop has occurred. Once received, the same time and motion limits listed in 201.9.2.4.101 shall apply.

If means are provided for monitoring collision RISKS of the ME EQUIPMENT by equipment other than the EBE, then the interface shall contain at a minimum the ability to receive a motors emergency stop as well as a signal to indicate if a motors emergency stop has occurred. Once received, the same time and motion limits listed in 201.9.2.4.101 shall apply.

If means are provided for mitigating collision RISKS of the ME EQUIPMENT by equipment other than the EBE, then the interface provided as a part of the ME EQUIPMENT shall contain the ability to receive a motors emergency stop. Once received, the same time and motion limits listed in 201.9.2.4.101 shall apply.

If means are provided for monitoring or control of equipment by the EBE, then the interface shall contain, at a minimum, the ability to send a motors emergency stop as well as the ability to receive a signal to indicate if a motors emergency stop has occurred.

If any of the interfaces in 201.9.2.4.101 are provided, the ACCOMPANYING DOCUMENTATION shall provide a description of each interface.

For the PATIENT POSITIONER, these requirements shall apply when it is unloaded and when it is loaded with a distributed mass of the maximum load of the PATIENT POSITIONER as SPECIFIED by the MANUFACTURER and distributed per Figure A.19 of IEC 60601-1:2005.

*Compliance is checked as follows:*

*SITE TEST grade A: Inspection of the ACCOMPANYING DOCUMENTATION*

*TYPE TEST grade B: Inspection and measurement of stopping distances and disconnection times using suitable measuring equipment. 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.*

### 201.9.2.5 Release of PATIENT

#### *Addition:*

Under normal operating conditions, the OPERATOR shall be able to release the PATIENT in an emergency situation within 30 s from the normal TREATMENT position.

Where the possibility exists that failure of a powered movement during NORMAL USE might result in the PATIENT becoming trapped or unable to exit via normal routes, means shall be provided to permit release of the PATIENT without the need for service personnel; these means shall be described in the INSTRUCTIONS FOR USE.

The MANUFACTURER shall state in the ACCOMPANYING DOCUMENTATION the means by which the OPERATOR can release the PATIENT within 60 s in an emergency situation when MAINS VOLTAGE has been interrupted.

NOTE 1 The statement "unable to exit via normal routes" includes the PATIENT being too high relative to the floor to exit without help, being restricted from moving due to immobilization devices and being inside of a bore device such as a CT or MRI.

NOTE 2 The statement "to release the PATIENT" is the process of removing the PATIENT from their current position to the state of being able to exit the room via the normal route.

NOTE 3 The time required for the OPERATOR to enter the TREATMENT ROOM and position themselves next to the PATIENT POSITIONER is not included in the time requirements in this subclause.

*Compliance is checked as follows:*

*SITE TEST grade A: Compliance is checked by inspection of the ACCOMPANYING DOCUMENTATION.*

*TYPE TEST grade B: With the TABLE TOP positioned 10 cm below the REFERENCE TREATMENT PLANE and extended to the clinical TREATMENT position, interrupt the MAINS VOLTAGE and measure the time required to retract and lower the TABLE TOP to a height of 65 cm, or lowest achievable.*

*Additional subclauses:*

### 201.9.2.101 GANTRY, RADIATION HEAD and PATIENT POSITIONER

#### a) General

- 1) When the RADIATION HEAD, GANTRY, PATIENT POSITIONER or any other part (including ACCESSORY items) 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 means shall be described in the INSTRUCTIONS FOR USE.
- 2) When the RADIATION HEAD, GANTRY, PATIENT POSITIONER or any other part (including ACCESSORY items) is not designed with a means to reduce, in NORMAL USE, the RISK of collisions, these RISKS shall be stated in the ACCOMPANYING DOCUMENTATION.

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 HAZARDOUS SITUATION, for example some types of ELECTRON BEAM APPLICATORS.

- 3) When RISK MANAGEMENT is used to justify exceeding the limits SPECIFIED in 201.9.2.101 while showing that the new values do not pose an additional unacceptable RISK to the equipment, PATIENT or OPERATOR, then the limits used and the justification for them shall be stated in the ACCOMPANYING DOCUMENTATION.
- 4) Equipment contained within the RADIATION HEAD or behind protective covers, where collisions are not possible, are exempt from the speed limits in 201.9.2.101 b), c).
- 5) Hydraulic, pneumatic, and mechanical subsystems of the GANTRY, RADIATION HEAD or PATIENT POSITIONER shall not cause unintended movement in SINGLE FAULT CONDITIONS.

## b) GANTRY and RADIATION HEAD

- 6) For automatic set-up and for the checks of pre-programmed movements before TREATMENT, the overshoot shall not exceed  $2^\circ$  around the ERP or 5 mm in the direction of motion past the intended stop position.
- 7) 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 items 8), 9) and 10).
- 8) Rotational movements of the GANTRY or RADIATION HEAD

- A low speed shall be available for each movement of the GANTRY or RADIATION HEAD which shall not exceed  $1^\circ \times s^{-1}$  around the ERP.
- No speed shall exceed  $7^\circ \times s^{-1}$  around the ERP unless identified as an acceptable RISK, through the MANUFACTURER'S RISK ANALYSIS. The analysis shall include that the distances achieved during the time needed for the average OPERATOR to react until the ME EQUIPMENT stops do not pose an unacceptable RISK to the equipment, PATIENT, or OPERATOR.
- When rotating the GANTRY or RADIATION HEAD at the speed nearest to, but not exceeding,  $1^\circ \times s^{-1}$  around the ERP, 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  $0,5^\circ$ . For speeds faster than  $1^\circ \times s^{-1}$ , it shall not exceed  $3^\circ$ .

EXAMPLE A change in collimator angle on an ISOCENTRIC linac is not considered movement "around the ERP" while change in GANTRY position is considered movement "around the ERP".

## 9) Linear movements of the GANTRY or RADIATION HEAD

- No speed shall exceed  $100 \text{ mm} \times s^{-1}$  for a relative movement of the GANTRY or RADIATION HEAD towards the PATIENT POSITIONER unless identified as an acceptable RISK, through MANUFACTURER'S RISK ANALYSIS.
- 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 a relative movement of the GANTRY or RADIATION HEAD towards the PATIENT POSITIONER for any speed greater than  $25 \text{ mm} \times s^{-1}$ , and 3 mm for speeds not exceeding  $25 \text{ mm} \times s^{-1}$ .

## 10) Rotation of the RADIATION HEAD in relation to the point of connection to the GANTRY

- The minimum speed available for each movement shall not exceed  $1^\circ \times s^{-1}$  around the point of rotation.
- No speed shall exceed  $7^\circ \times s^{-1}$  around the point of rotation unless identified as an acceptable RISK, through the MANUFACTURER'S RISK ANALYSIS. The RISK ANALYSIS shall include at a minimum the analysis that the distances achieved during the time needed for the OPERATOR to react until the ME EQUIPMENT stops do not pose an unacceptable RISK to the equipment, PATIENT, or OPERATOR.
- When rotating at the speed nearest to, but not exceeding,  $1^\circ \times s^{-1}$  around the point of rotation, 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  $0,5^\circ$ . For speeds faster than  $1^\circ \times s^{-1}$ , it shall not exceed  $3^\circ$ .

## c) PATIENT POSITIONER

- 11) 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 14) and 15).
- 12) For the PATIENT POSITIONER, the maximum acceleration applied to the PATIENT for all linear and rotational movements shall be provided in the ACCOMPANYING DOCUMENTATION.
- 13) For the PATIENT POSITIONER, these requirements shall apply when it is unloaded and when it is loaded with a distributed mass of the maximum load of the PATIENT POSITIONER as SPECIFIED by the MANUFACTURER and distributed per Figure A.19 of IEC 60601-1:2005.

#### 14) Rotational movements

- The minimum speed available for each movement shall not exceed  $1^\circ \times s^{-1}$  around the point of rotation.
- No speed shall exceed  $7^\circ \times s^{-1}$  around the point of rotation for a relative movement of the PATIENT POSITIONER towards the RADIATION HEAD or GANTRY.
- When rotating at the speed nearest to, but not exceeding,  $1^\circ \times s^{-1}$  around the point of rotation, 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  $0,5^\circ$  for a relative movement of the PATIENT POSITIONER towards the RADIATION HEAD or GANTRY. For speeds faster than  $1^\circ \times s^{-1}$ , it shall not exceed  $3^\circ$  for a relative movement of the PATIENT POSITIONER towards the RADIATION HEAD or GANTRY.

#### 15) Linear movements

- The minimum speed available for displacements of the TABLE TOP shall not exceed  $10 \text{ mm} \times s^{-1}$ .
- No speed shall exceed  $100 \text{ mm} \times s^{-1}$  for a relative movement of the PATIENT POSITIONER towards the RADIATION HEAD or GANTRY unless identified as an acceptable RISK, through MANUFACTURER'S RISK ANALYSIS.
- 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 a relative movement of the PATIENT POSITIONER towards the RADIATION HEAD or GANTRY for any speed greater than  $25 \text{ mm} \times s^{-1}$ , and 3 mm for speeds not exceeding  $25 \text{ mm} \times s^{-1}$ .

*Compliance is checked as follows:*

*SITE TEST grade A: Inspection of the INSTRUCTIONS FOR USE, ACCOMPANYING DOCUMENTATION and the facilities provided.*

*TYPE TEST grade B: 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.*

*TYPE TEST grade B: 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 HAZARDOUS SITUATION, for example 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 unless it can be shown through RISK MANAGEMENT that the amount of motion and maximum rate of motion are sufficiently limited to avoid an unacceptable RISK to the equipment, PATIENT or OPERATOR.

- c) The switches required in a) and b) above shall be located close to the PATIENT POSITIONER, 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 as demonstrated through RISK MANAGEMENT.
- 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 PLAN, with the PATIENT in position for TREATMENT, a check of all intended or planned movements should be made by the OPERATOR before leaving the TREATMENT ROOM.

*SITE TEST Grade A – Inspection of ACCOMPANYING DOCUMENTS.*

#### **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 OPERATOR initiated automatic set-up without continuous personal action by the OPERATOR simultaneously on the automatic set-up switch and a switch common to all movements unless it can be shown by RISK MANAGEMENT that the amount of motion and maximum rate of motion is sufficiently limited to avoid PATIENT injury. Each switch, when released, shall be capable of stopping movement; at least one of the switches shall be HARD-WIRED or have an equivalently safe switching function.
- b) After ME EQUIPMENT parts have been set up either automatically or pre-programmed, it shall be impossible for the OPERATOR to adjust any movement parameter before the pre-programmed TREATMENT has been completed, without causing TERMINATION OF IRRADIATION unless that movement is restricted to PATIENT POSITIONER motion to re-align the TARGET VOLUME to the planned location in relation to the ME EQUIPMENT. In that case, movement may instead cause INTERRUPTION OF IRRADIATION.
- c) For ME EQUIPMENT that has not been pre-programmed, it shall be impossible for the OPERATOR to adjust any movement parameter during IRRADIATION without causing TERMINATION OF IRRADIATION unless that movement is restricted to PATIENT POSITIONER motion to re-align the TARGET VOLUME to the planned location in relation to the ME EQUIPMENT. In that case, movement may instead cause INTERRUPTION 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 unless it can be shown by RISK MANAGEMENT that the amount of motion and maximum rate of motion is sufficiently limited to avoid PATIENT injury. Each switch, when released, shall be capable of stopping movement; one switch shall be HARD-WIRED or have an equivalently safe switching function and shall be common to all movements. If the movement is restricted to PATIENT POSITIONER motion to re-align the TARGET VOLUME to the planned location in relation to the ME EQUIPMENT then in that case, movement may be possible during INTERRUPTION OF IRRADIATION.
- e) The INSTRUCTIONS FOR USE shall include the recommendation that the OPERATOR should have audio contact and 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 as follows:*

- a) b) c) d) *SITE TEST Grade A – Compliance is checked by inspection.*
- e) *SITE TEST Grade A – Inspection of ACCOMPANYING DOCUMENTS.*
- f) *TYPE TEST grade B – 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.

*TYPE TEST Grade B – Compliance is checked by simulation of a fault condition, operation of protective devices and measurement of stopping distances.*

## **201.9.8 MECHANICAL HAZARDS associated with support systems**

*Additional subclauses:*

### **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.

*TYPE/SITE TEST Grade A – Compliance is checked by inspection, and by consideration of design data and applied safety factors.*

- b) The ACCOMPANYING DOCUMENTATION 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.

*TYPE/SITE TEST Grade A – Compliance is checked by inspection.*

### **201.9.8.102 Relative movement between immobilisation devices and TABLE TOP**

- a) MANUFACTURERS of ME EQUIPMENT 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 TABLE TOP. This analysis shall, at a minimum, 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 TABLE TOP becoming loose or undone.

*TYPE TEST Grade A – Compliance is checked by the inspection of the RISK MANAGEMENT file.*

- b) The ACCOMPANYING DOCUMENTATION shall contain maintenance requirements, and define the limits of use for the immobilisation devices supplied by the MANUFACTURER.

The ACCOMPANYING DOCUMENTATION shall warn that any immobilisation device or PATIENT POSITIONER equipment not described by the MANUFACTURER shall be evaluated for correct operation and safety with the ME EQUIPMENT by the RESPONSIBLE ORGANIZATION.

*TYPE/SITE TEST Grade A – Compliance is checked by inspection.*

## **201.10 Protection against unwanted and excessive RADIATION HAZARDS**

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

*Addition:*

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

### **201.10.1.1 ME EQUIPMENT not intended to produce diagnostic or therapeutic X-RADIATION**

*Replacement:*

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  $\mu\text{Sv}$  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<sup>2</sup>, 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 tested in turn.*

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

*Replacement:*

Subclause 201.10.101 apply.

## **201.10.2 Alpha, beta, gamma, neutron and other particle RADIATION**

*Replacement:*

Subclause 201.10.101 apply.

*Additional subclauses:*

### **201.10.101 ME EQUIPMENT intended to produce therapeutic X-RADIATION and ELECTRON RADIATION**

#### **201.10.101.1 Protection against incorrect IRRADIATION**

##### **201.10.101.1.1 Monitoring and control of ABSORBED DOSE delivery**

###### **201.10.101.1.1.1 Types of DOSE MONITORING SYSTEMS**

Two independent DOSE MONITORING SYSTEMS shall be provided.

###### **201.10.101.1.1.2 DOSE MONITORING SYSTEMS**

The RADIATION DETECTORS SPECIFIED in 201.10.101.1.1.3 shall form part of two DOSE MONITORING SYSTEMS from whose outputs, displayed as DOSE MONITOR UNITS, the ABSORBED DOSE at a reference point under REFERENCE CONDITIONS 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 DOCUMENTATION.

- d) The DOSE MONITORING SYSTEMS power supply shall be monitored for the correct output. Output outside of the SPECIFIED range shall cause TERMINATION OF IRRADIATION.
- e) The DOSE MONITORING SYSTEMS shall be arranged either as a REDUNDANT DOSE MONITORING SYSTEM or as a combination of a PRIMARY and a SECONDARY DOSE MONITORING SYSTEM. In the case of a REDUNDANT DOSE MONITORING SYSTEM, both systems shall be capable of the performance stated in the technical description. In the case of a combination of a PRIMARY and a SECONDARY DOSE MONITORING SYSTEM, at a minimum, 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.
- f) If selected circuit parameters in the DOSE MONITORING SYSTEMS are changed automatically with changes of RADIATION TYPE or NOMINAL ENERGY, the changes in one DOSE MONITORING SYSTEM shall be independent of those in the other system.
- g) The description of the INTERLOCKS provided in a) and results of the TYPE TEST performed shall be included in the ACCOMPANYING DOCUMENTATION.

*Compliance is checked as follows:*

- a) *TYPE TEST grade C – Verify the correct 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) *TYPE TEST grade C – Verify the functioning of the INTERLOCK producing TERMINATION OF IRRADIATION by simulation of failure of each common element.*
- b) *SITE TEST grade A – Inspection of the ACCOMPANYING DOCUMENTATION for a description of the INTERLOCKS and their redundancy in addition to the results of the TYPE TEST above.*
- c) *TYPE TEST grade C – Verify the functioning of the INTERLOCK producing TERMINATION OF IRRADIATION, by generation or simulation of power failure.*
- c) *SITE TEST grade A – Inspection of the ACCOMPANYING DOCUMENTATION for a description of the INTERLOCKS and their redundancy in addition to the results of the TYPE TEST above.*
- d) *TYPE TEST grade C – Verify the functioning of the INTERLOCK producing TERMINATION OF IRRADIATION when the power supply output is 10 % outside its SPECIFIED range.*
- e) *TYPE TEST grade C – Verify 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.*
- e) *TYPE TEST grade A – Statement regarding the performance of the chosen combination of DOSE MONITORING SYSTEMS.*
- f) *TYPE TEST grade A – Statement regarding the independence of systems with change of circuit parameters.*
- g) *SITE TEST grade A – Inspection of the ACCOMPANYING DOCUMENTATION for a description of the INTERLOCKS and their redundancy in addition to the results of the TYPE TEST for a).*

**201.10.101.1.1.3 RADIATION DETECTORS**

- a) Two or more 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 intended position during IRRADIATION shall TERMINATE IRRADIATION.
- c) Hermetically sealed RADIATION DETECTORS shall be sealed independently of one another. Each RADIATION DETECTOR supplied, including spares, shall be accompanied by a certificate of integrity of sealing at the date of test.

NOTE If a certificate is supplied, the RESPONSIBLE ORGANIZATION is encouraged to record the date of the integrity test when installing a replacement 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 – Verify that*
  - the displacement of each RADIATION DETECTOR, in turn, from its intended position, prevents IRRADIATION, and
  - with the RADIATION DETECTORS correctly positioned, TERMINATION OF IRRADIATION occurs at all NOMINAL ENERGIES for ELECTRON and X-RADIATION when any RADIATION DETECTOR is moved away from its intended position.
- b) *SITE TEST grade C – If the RADIATION DETECTORS are a movable type, verify the functioning of the INTERLOCKS by generation or simulation of the fault condition.*
- c) *TYPE TEST grade C – Verify the integrity of the seals.*
- c) *SITE TEST grade A – Inspection of the ACCOMPANYING DOCUMENTATION.*

**201.10.101.1.1.4 Selection and DISPLAY of DOSE MONITOR UNITS**

- a) The DISPLAYS from the DOSE MONITORING SYSTEMS shall 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.

The relationship between DOSE MONITOR UNITS and ABSORBED DOSE shall be the same for the same IRRADIATION wherever displayed by the ME EQUIPMENT and be related by a simple ratio.

- 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, the EBE shall, at a minimum, report one of the readings by one of the following methods:
  - 1) an independent back-up visual DISPLAY terminal;
  - 2) a conventional DISPLAY; or
  - 3) real-time non-volatile storage on independent removable equipment.

NOTE 1 Two DISPLAY terminals connected to the same computer are not considered independent.

- c) In the event of failure of the SUPPLY MAINS, or a component, which causes INTERRUPTION or TERMINATION OF IRRADIATION, the DOSE MONITOR UNIT or IRRADIATION time information displayed at the time of failure shall be DISPLAYED in at least one location for a minimum of 20 min.

NOTE 2 The DISPLAY required in c) can be one of the DISPLAYS required in b).

- d) Any combination of a PRIMARY DOSE MONITORING SYSTEM and a SECONDARY DOSE MONITORING SYSTEM shall have separate, clearly identified DISPLAYS.
- e) The DOSE MONITORING SYSTEM shall start counting when IRRADIATION is initiated and stop when IRRADIATION is completed.
- f) The DISPLAYS of DOSE MONITOR UNITS shall show increasing numbers and, together with the DISPLAY of the pre-selected number of DOSE MONITOR UNITS, shall maintain their readings after INTERRUPTION or TERMINATION OF IRRADIATION.
- g) 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.

NOTE 3 Selection of DOSE MONITOR UNITS can be made either manually or by data upload.

NOTE 4 A new IRRADIATION does not include continuation of IRRADIATION after an INTERRUPTION OF IRRADIATION.

- h) Means shall be provided to allow a qualified OPERATOR, as determined by the RESPONSIBLE ORGANIZATION, to set the ABSORBED DOSE to DOSE MONITOR UNIT ratio for REFERENCE CONDITIONS. When set, the ME EQUIPMENT shall record either automatically or via OPERATOR input:
  - ABSORBED DOSE to DOSE MONITOR UNIT ratio;
  - calibration reference point depth;
  - field size for which the calibration is valid;
  - RADIATION SOURCE to surface distance for which the calibration is valid.

EXAMPLE 1 1 cGy/MU at 100 cm SSD for a 10 cm × 10 cm field at a depth of 1,5 cm.

EXAMPLE 2 0,006 7 Gy/MU at 90 cm SSD for a 10 cm × 10 cm field at a depth of 10 cm.

When the ABSORBED DOSE to DOSE MONITOR UNIT ratio is set by the OPERATOR, a message shall be displayed to the OPERATOR that the information in h) shall agree with the information loaded for TREATMENT DELIVERY in order for TREATMENT in clinical mode to commence.

Means shall be provided to ensure that this information has been entered before IRRADIATION can be initiated in clinical mode.

*Compliance is checked as follows:*

- a) b) c) d) f) *SITE TEST grade B – Procedure: inspect the DISPLAYS.*
- c) f) g) *TYPE TEST grade A – Statement regarding DISPLAYS and overdose condition.*
- e) f) *SITE TEST grade B – Procedure: verify DISPLAY readings after INTERRUPTION OF IRRADIATION and after TERMINATION OF IRRADIATION.*
- g) *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.*
- c) *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 a minimum of 20 min.*
- h) *SITE TEST grade A – Inspection of the ACCOMPANYING DOCUMENTATION.*
- h) *SITE TEST grade B – Procedure: for each ENERGY and for each RADIATION TYPE and prior to setting the ABSORBED DOSE to DOSE MONITOR UNIT ratio and accompanying information, verify that INITIATION OF IRRADIATION is not possible in clinical mode.*

#### **201.10.101.1.1.5 TERMINATION OF IRRADIATION by DOSE MONITORING SYSTEM**

- a) Both DOSE MONITORING SYSTEMS shall be capable, independently, of TERMINATING IRRADIATION. Means shall be provided to test, between or prior to IRRADIATION, that each DOSE MONITORING SYSTEM can TERMINATE IRRADIATION.

- b) Both systems in a REDUNDANT DOSE MONITORING SYSTEM shall be set to TERMINATE IRRADIATION when the entire delivery of the selected pre-programmed IRRADIATION has been reached.

The PRIMARY DOSE MONITORING SYSTEM of a combination of a PRIMARY DOSE MONITORING SYSTEM and a SECONDARY DOSE MONITORING SYSTEM shall be set to terminate IRRADIATION when the pre-programmed IRRADIATION has been completed; the SECONDARY DOSE MONITORING SYSTEM shall be set to TERMINATE IRRADIATION when the pre-programmed IRRADIATION dose has been exceeded, either by not more than 5 % if a percentage margin is used, or by not more than the equivalent of 0,1 Gy ABSORBED DOSE at RTD if a fixed margin is used. Where there is a choice between fixed and percentage margins, the one providing the larger difference shall be used. Where a combination of fixed and percentage margins is used, the method used shall be described in the ACCOMPANYING DOCUMENTATION.

- 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 unless it can be shown through RISK MANAGEMENT that the design of the DOSE MONITORING SYSTEM does not allow for a SINGLE FAULT CONDITION preventing the TERMINATION OF IRRADIATION.
- d) TERMINATION OF IRRADIATION may be achieved by means other than PRIMARY DOSE MONITORING SYSTEMS (e.g. GANTRY angle, time), in which case the other means are considered as the primary TERMINATION system, and the DOSE MONITORING SYSTEM will provide secondary means of TERMINATION. The DOSE MONITORING SYSTEM shall be set to TERMINATE IRRADIATION at a dose-related value not greater than 105 % of the entire delivery of the pre-programmed IRRADIATION dose.
- e) The DOSE MONITORING SYSTEM, whether a REDUNDANT DOSE MONITORING SYSTEM or a combination of a PRIMARY DOSE MONITORING SYSTEM and a SECONDARY DOSE MONITORING SYSTEM, shall TERMINATE IRRADIATION if, between the initiation and the entire delivery of the selected pre-programmed IRRADIATION, the difference between the two DOSE MONITORING SYSTEMS exceeds either 5 % or 0,1 Gy, where the one providing the greater difference shall be used. Where a combination of fixed and percentage margin is used, the method used shall be described in the ACCOMPANYING DOCUMENTATION.

NOTE For ME EQUIPMENT delivering REAL-TIME ADAPTIVE RADIOTHERAPY, the pre-programmed IRRADIATION can be determined just prior to delivery of each SEGMENT or beam if the TREATMENT PLAN was acknowledged by the OPERATOR as a REAL-TIME ADAPTIVE RADIOTHERAPY plan before the start of PATIENT TREATMENT.

*Compliance is checked as follows:*

- a) b) c) e) *TYPE TEST grade A – Statement regarding the means used to ensure compliance.*
- b) d) *TYPE TEST grade C – Verify the functioning of TERMINATION OF IRRADIATION by each system when the other is disabled. Test at one ENERGY for each RADIATION TYPE. Verify that another IRRADIATION cannot be started.*
- c) *SITE TEST grade C – Verify the functioning of INTERLOCKS at one ENERGY for each RADIATION TYPE.*
- b) d) *Inspection of the ACCOMPANYING DOCUMENTATION for a description of the TYPE TESTS, their results, and the margins set during clinical use.*
- d) e) *TYPE TEST grade A – Statement describing the means for TERMINATION OF IRRADIATION and the margins allowed.*
- e) *SITE TEST grade C – Verify the functioning of TERMINATION OF IRRADIATION by each system when the other is disabled. Test at one ENERGY for each RADIATION TYPE. Verify that another IRRADIATION cannot be started.*

#### **201.10.101.1.1.6 Monitoring of distribution of ABSORBED DOSE**

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

- a) the RADIATION DETECTORS described in 201.10.101.1.1.3, or other RADIATION DETECTORS, shall monitor different parts of the RADIATION BEAM to detect symmetrical and non-symmetrical changes of the RADIATION BEAM, and
- b) means shall be provided to TERMINATE IRRADIATION before an additional ABSORBED DOSE of 0,25 Gy is delivered when, under REFERENCE CONDITIONS, 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 explaining how to ensure that different parts of the RADIATION BEAM are monitored by the RADIATION DETECTORS.*
- b) *SITE TEST grade C – Unless it can be shown through TYPE TEST and design analysis that it is not possible for the ABSORBED DOSE distribution to change by more than 10%, verify 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 beam profile measurements of a 10 cm × 10 cm RADIATION FIELD 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.*

#### **201.10.101.1.2 Independent termination system (ITS)**

- a) A method independent of the DOSE MONITORING SYSTEM described in 201.10.101.1.1.2 shall be available for TERMINATION OF IRRADIATION using preset values.

NOTE The system providing the independent termination method can be a CONTROLLING TIMER.

- b) The system providing the independent method shall have a DISPLAY at the TCP and
  - 1) shall be a "count-up" type,
  - 2) shall start counting when IRRADIATION is initiated and stop when IRRADIATION is completed,
  - 3) after an INTERRUPTION or TERMINATION OF IRRADIATION, its reading shall be retained visually for a minimum period of 20 min or the next IRRADIATION, whichever comes first,
  - 4) shall require resetting to zero after TERMINATION OF IRRADIATION before a subsequent IRRADIATION is possible,
  - 5) shall be independent of any other system or subsystem controlling the TERMINATION OF IRRADIATION,
  - 6) shall protect against failure of the DOSE MONITORING SYSTEMS by TERMINATING IRRADIATION when a pre-determined quantity related to dose reaches a pre-determined number of counts, and
  - 7) shall be used for the entire delivery or each SEGMENT of the delivery depending upon the delivery type.

When a CONTROLLING TIMER is used, it may disregard the time during an IRRADIATION BEAM HOLD.

- c) The independent method shall be analysed through a RISK MANAGEMENT process. The analysis shall demonstrate that the TERMINATION OF IRRADIATION occurs within 120 % of the intended dose or an additional ABSORBED DOSE of 0,5 Gy is delivered, whichever is greater for that pre-selected IRRADIATION for that TREATMENT fraction. When the delivery is identified as REAL-TIME ADAPTIVE RADIOTHERAPY, the pre-selected value may be determined immediately before delivery of each beam or SEGMENT depending upon the delivery type.
- d) INTERLOCKS shall ensure that the ability of the ITS to TERMINATE IRRADIATION is tested between, or prior to, IRRADIATIONS unless it can be shown through RISK MANAGEMENT that the design of the ITS does not allow for a SINGLE FAULT CONDITION allowing IRRADIATION through failure of the ITS.
- e) If a CONTROLLING TIMER is used, it shall be graduated either

8) in minutes and decimals of minutes, or

9) in seconds,

but not in any combination of 8) and 9).

EXAMPLE 1 Acceptable formats: "5,1 min", "306 sec"

EXAMPLE 2 Unacceptable format: "5 min 6 sec"

*Compliance is checked as follows:*

- a) *TYPE TEST grade A – Statement regarding the means used to ensure compliance.*
- b) *TYPE TEST grade A – Statement regarding 5): independence of TERMINATION OF IRRADIATION.*
- b) *SITE TEST grade B – Procedure: at one ENERGY for each RADIATION TYPE, verify that the ITS*
  - 1) *counts up with IRRADIATION,*
  - 2) *switches on and off with IRRADIATION,*
  - 3) *retains its reading for a minimum of 20 min after INTERRUPTION or TERMINATION OF IRRADIATION,*
  - 4) *requires resetting to zero after TERMINATION OF IRRADIATION before a subsequent IRRADIATION can be initiated,*
  - 6) *TERMINATES IRRADIATION when the pre-selected value has elapsed, and*
  - 7) *is active throughout the entire delivery or SEGMENT depending on the delivery type.*
- c) *TYPE TEST grade A – Statement regarding the determination of the pre-set margin.*
- c) *SITE TEST grade C – Verify the value of the limit setting.*
- d) *TYPE TEST grade A – Statement explaining how the capability for TERMINATION OF IRRADIATION is tested between, or prior to, IRRADIATIONS.*
- d) *SITE TEST grade C – Verify the functioning of the INTERLOCKS.*
- e) *SITE TEST grade B – If a CONTROLLING TIMER is used, inspect the graduations of the CONTROLLING TIMER.*

#### **201.10.101.1.3 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 under REFERENCE CONDITIONS can be calculated. The RADIATION DETECTOR(S) described in 201.10.101.1.1.3 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 RTD 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 RTD 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 between the primary collimator and the ERP. This shall limit the excess ABSORBED DOSE allowed at any point in the RADIATION FIELD at the REFERENCE TREATMENT PLANE to less than 4 Gy. The value of the excess ABSORBED DOSE shall be given in the technical description.
- d) In ME EQUIPMENT capable of producing both X-radiation and electron radiation, the termination of irradiation shall be completed before the generation of the next pulse of radiation.

NOTE 1 a) and b) require only one DOSE RATE MONITORING SYSTEM; therefore, the second DOSE MONITORING SYSTEM can be used to meet the requirements of item c).

- e) 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 unless it can be shown through RISK MANAGEMENT that the design of the RADIATION BEAM monitoring device does not allow a SINGLE FAULT CONDITION to prevent the TERMINATION OF IRRADIATION.
- f) If the ABSORBED DOSE RATE at RTD, 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 2 During the first 10 s of IRRADIATION, the factor can differ from that associated with the remainder of the IRRADIATION.

*Compliance is checked as follows:*

- a) *SITE TEST grade B – 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 – Verify the functioning of the means for producing TERMINATION OF IRRADIATION.*
- c) *TYPE TEST grade A – Statement regarding the design of the RADIATION BEAM monitoring device and the value of the excess ABSORBED DOSE that causes TERMINATION OF IRRADIATION.*
- c) *SITE TEST grade C – Verify the functioning of the RADIATION BEAM monitoring device by generating or simulating excess ELECTRON BEAM current.*
- e) *TYPE TEST grade A – Statement regarding testing between, or prior to, IRRADIATIONS.*
- e) *SITE TEST grade C – Verify 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.*
- f) *TYPE TEST grade A – Statement regarding TERMINATION OF IRRADIATION.*
- f) *SITE TEST grade C – Verify the TERMINATION OF IRRADIATION by generation or simulation of a change of the ABSORBED DOSE RATE by the given factor.*

#### **201.10.101.1.4 Selection and DISPLAY of RADIATION TYPE**

For ME EQUIPMENT capable of both X-RADIATION and ELECTRON RADIATION, the following applies.

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

NOTE Selection of RADIATION TYPE can be made either manually or by data upload.

- 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, for example ELECTRON BEAM APPLICATORS, and shall prevent ELECTRON IRRADIATION when ACCESSORIES SPECIFIED for X-IRRADIATION are in place, for example WEDGE FILTERS.

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.

- e) When the ability exists to acquire portal images of the ELECTRON RADIATION FIELD with X-IRRADIATION, then a typical procedure and the value of any limit of associated ABSORBED DOSE shall be given in the ACCOMPANYING DOCUMENTATION.
- f) X-IRRADIATION shall be prevented when RADIATION BEAM control devices SPECIFIED for ELECTRON IRRADIATION are in place, for example ELECTRON BEAM SCATTERING FILTERS or ELECTRON RADIATION beam scanning devices. ELECTRON IRRADIATION shall be prevented when RADIATION BEAM control devices SPECIFIED for X-IRRADIATION are in place, for example X-RADIATION FIELD FLATTENING FILTERS.

*Compliance is checked as follows:*

- a) to f) *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) f) *SITE TEST grade B – Procedure: verify functioning of SPECIFIED INTERLOCKS when incorrect RADIATION BEAM modifying ACCESSORIES are fitted.*
- f) *SITE TEST grade C – Procedure: verify functioning of SPECIFIED INTERLOCKS when incorrect RADIATION BEAM control devices are in place.*

#### **201.10.101.1.5 Selection and DISPLAY of NOMINAL ENERGY**

For ME EQUIPMENT capable of multiple NOMINAL ENERGIES, the following applies.

- a) After TERMINATION OF IRRADIATION, further IRRADIATION shall be prevented until the selection of NOMINAL ENERGY has been made afresh at the TCP.

NOTE Selection of NOMINAL ENERGY can be made either manually or by data upload.

- b) ME EQUIPMENT capable of generating RADIATION BEAMS of different NOMINAL ENERGIES shall DISPLAY at the TCP, before and during IRRADIATION, the value of the selected NOMINAL ENERGY as SPECIFIED in the INSTRUCTIONS FOR USE.
- c) IRRADIATION shall be TERMINATED if the mean energy,  $E_1^2$ , of the ELECTRONS striking
  - the X-RADIATION TARGET deviates from the intended value by more than  $\pm 20\%$  during X-IRRADIATION, or
  - the ELECTRON RADIATION window deviates by more than  $\pm 20\%$  or  $\pm 2$  MeV, whichever is the lesser during ELECTRON IRRADIATION,

where the deviation shall be measured in comparison with the value of mean energy that would occur under normal operating conditions for the selected NOMINAL 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 – Verify the correct operation of the INTERLOCK with IRRADIATION, performed under conditions of the SPECIFIED mean energy deviation at all selectable NOMINAL ENERGIES and RADIATION TYPES.*

#### **201.10.101.1.6 RADIATION BEAM production and shaping systems**

##### **201.10.101.1.6.1 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, the following applies.

- a) If more than one of the same type of device is available for use at one NOMINAL 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.

<sup>2</sup> See ICRU Report 35:1984, 3.3 (Energy).

- 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 – Attempt INITIATION OF IRRADIATION with one of the INTERLOCKS disabled and with each device positioned incorrectly; repeat with the second INTERLOCK disabled.*

#### **201.10.101.1.6.2 Selection and DISPLAY of FIELD FLATTENING and BEAM SCATTERING FILTERS**

For ME EQUIPMENT incorporating movable FIELD FLATTENING or BEAM SCATTERING FILTERS, the following applies.

- a) If more than one FILTER system is available for use at one NOMINAL 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, and
  - 2) the identity of the FILTER(S) in use or the lack thereof 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 – Attempt INITIATION OF IRRADIATION with one of the INTERLOCKS disabled and 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.*

#### **201.10.101.1.7 Selection, VERIFICATION and DISPLAY of TREATMENT PARAMETERS that change during IRRADIATION**

- a) After TERMINATION OF IRRADIATION, further IRRADIATION shall be prevented until all the TREATMENT PARAMETERS have been selected afresh at the TCP.
- b) The mode of operation shall be displayed at the TCP.
- c) INITIATION OF IRRADIATION shall be prevented if the values of any of the TREATMENT PARAMETERS do not match the intended start values.

NOTE 1 The LATENCY of applying position or dose rate adjustments is covered in 201.104.

- d) For ME EQUIPMENT that has the capability to move during IRRADIATION:

- 1) GANTRY or RADIATION HEAD: for linear or rotational positions that change after the INITIATION OF IRRADIATION, the DISPLAYS of the planned and actual positions shall be updated at and between CPS during IRRADIATION;

NOTE 2 This item 1) covers the positional changes, both linear and rotational movements, of the RADIATION SOURCE.

NOTE 3 201.10.101.1.8 applies to ISOCENTRIC GANTRIES.

- 2) RADIATION HEAD: for rotational positions that change after the INITIATION OF IRRADIATION, the DISPLAYS of the planned and actual rotations shall be updated at and between CPS during IRRADIATION.