

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –

Part 2-68: 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

Appareils électromédicaux –

Partie 2-68: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de radiothérapie à rayonnement X assistée par imagerie médicale, destinés à être utilisés avec les accélérateurs d'électrons, les appareils de thérapie par faisceau d'ions légers et les appareils de thérapie par faisceau de radionucléides



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-68: 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

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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IEC 60601-2-68 has been prepared by IEC subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

This second edition cancels and replaces the first edition published in 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 editions of the relevant standards:
 - IEC 60601-2-1:2020;

- IEC 60601-2-44:2009, IEC 60601-2-44:2009/AMD1:2012 and IEC 60601-2-44:2009/AMD2:2016;
- IEC 60601-2-64:2014;
- b) clarification of the use of IEC 60601-2-68 for CT SCANNERS, X-RAY EQUIPMENT for RADIOGRAPHY and RADIOSCOPY used in the same room with an EXTERNAL BEAM EQUIPMENT (EBE);
- c) introduction of updated requirements related to MECHANICAL HAZARDS, RADIATION HAZARDS, PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS), ACCOMPANYING DOCUMENTATION of an ME SYSTEM, and REMOTE OPERATION.

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

Draft	Report on voting
62C/927/FDIS	62C/941/RVD

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

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, AND IEC 60601-1:2005/AMD2:2020, IN THIS DOCUMENT 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 document 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, 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 webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

INTRODUCTION

Modern RADIOTHERAPY practices utilize information from various imaging modalities, acquired prior to initiating administration of the therapy, to plan the TREATMENT. The imaging provides information about the location of the TARGET VOLUME and other anatomical features so that a TREATMENT PLAN can be developed that provides an optimal dose distribution to have the best chance of achieving the intended effect of TREATMENT while minimizing side effects.

However, difficulties arise when trying to administer the RADIATION, since TARGET VOLUMES/critical structures are constantly moving within the body. For example, in parts of the body moving with respiration, the TARGET VOLUMES/critical structures may change position or shape during the RADIATION BEAM delivery throughout any given fraction. Furthermore, a course of therapy can extend over many days, during which the TARGET VOLUME/PATIENT can shrink or grow or move. Hence, the exact location of the TARGET VOLUME/critical structures can change between the time of TREATMENT PLANNING imaging and the actual administration of a TREATMENT.

IMAGE-GUIDED RADIOTHERAPY (IGRT) combines planar or volumetric imaging during the course of RADIOTHERAPY to adjust the TREATMENT delivery based on the PATIENT anatomy and PATIENT position. This enables the OPERATOR or EXTERNAL BEAM EQUIPMENT (EBE) to adjust the RADIATION BEAM delivery based on the imaging information, such as the position of the TARGET VOLUME, critical organs or other reference features, to compensate for anatomical changes including internal organ motions or TREATMENT setup uncertainties. The increased accuracy and precision achieved allows higher doses of RADIATION to be delivered to the TARGET VOLUME and a reduction in the margin of healthy cells affected by the RADIATION. This is often used in conjunction with other monitoring equipment.

This document establishes requirements to be complied with by MANUFACTURERS in the design and construction of X-RAY IGRT EQUIPMENT (X-IGRT).

This document covers safety aspects of kilovoltage (kV) and megavoltage (MV) X-ray imaging devices in a known geometrical relationship with an EXTERNAL BEAM EQUIPMENT such as an ELECTRON ACCELERATOR, LIGHT ION BEAM MEDICAL ELECTRICAL EQUIPMENT or RADIONUCLIDE BEAM THERAPY EQUIPMENT, for the purpose of IGRT. It covers aspects of communication and relationships between the EXTERNAL BEAM EQUIPMENT and X-ray imaging devices, attached or not directly attached to, but in the same RADIATION shielded area as, and dedicated for use only with, the EXTERNAL BEAM EQUIPMENT.

When performing a HAZARD ANALYSIS, the MANUFACTURER should consider relevant diagnostic standards. For example, the IMAGE DISPLAY DEVICE quality is specified in IEC documents in regard to diagnostic use (e.g., IEC 62563-1:2009). However, since IGRT usage does not necessarily have such high requirements, it is left to the MANUFACTURER to specify what is required for use with their X-IGRT EQUIPMENT.

This document deals with the safety aspect of image acquisitions, image analysis, data transfer and TREATMENT replanning or EBE/PATIENT repositioning.

This document deals with equipment for OFFLINE X-IGRT, ONLINE X-IGRT, and REAL-TIME X-IGRT.

X-IGRT EQUIPMENT is also related to the following current publications:

- IEC 60601-2-1
- IEC 60601-2-44
- IEC 60601-2-64
- IEC 62083
- IEC 61217
- IEC 62274

This document will focus on the safety aspects of the primary function of X-IGRT. It will not focus on emerging technologies within the field so as to not hinder progress, yet it will define a safe way of achieving X-IGRT.

MEDICAL ELECTRICAL EQUIPMENT –

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201.1 Scope, object and related standards

Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.1.1 * Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of X-ray based IMAGE-GUIDED RADIOTHERAPY equipment for use with EXTERNAL BEAM EQUIPMENT (EBE).

This document covers safety aspects of kilovoltage (kV) and megavoltage (MV) X-ray imaging devices integrated in a specified geometrical relationship with EBE for the purpose of IGRT. It covers aspects of communication and relationships between the EXTERNAL BEAM EQUIPMENT and X-ray imaging devices, attached or not directly attached to, but in the same RADIATION shielded area as, and dedicated for use only with, the EXTERNAL BEAM EQUIPMENT.

This document deals with equipment for OFFLINE X-IGRT, ONLINE X-IGRT and REAL-TIME X-IGRT. It covers procedures to reduce the risk of over-reliance on the X-IGRT EBE SYSTEM. For example, in the case of ONLINE X-IGRT, the MANUFACTURER will provide an interactive interface for user interaction with the correction suggested by the system.

This document does not apply to CT SCANNERS, X-RAY EQUIPMENT for RADIOGRAPHY, and X-RAY EQUIPMENT for RADIOSCOPY, that are not intended for use for IGRT.

Requirements that are being tested according to another standard can be identified by the manufacturer. If these requirements are equivalent, retesting is not required, but instead evidence can refer to the CT SCANNER, X-RAY EQUIPMENT for RADIOGRAPHY, or X-RAY for RADIOSCOPY manufacturer's compliance statements or test reports.

If the X-IGRT EQUIPMENT is combined with an MEE, any requirement that is the same for the X-IGRT EQUIPMENT and the MEE, such as a PATIENT POSITIONER, is not required to be tested twice, but can be accepted as tested by the MEE.

This document applies to X-RAY EQUIPMENT for RADIOGRAPHY, RADIOSCOPY, and COMPUTER TOMOGRAPHY used for IGRT.

If a clause or subclause is specifically intended to be applicable to X-IGRT EBE SYSTEMS, the content of that clause or subclause will say so. Where that is not the case, the clause or subclause applies only to X-IGRT EQUIPMENT.

This document, with the inclusion of TYPE TESTS and SITE TESTS, applies respectively to the MANUFACTURER and some installation aspects of X-IGRT EBE SYSTEMS intended to be

- for NORMAL USE, operated under the authority of the RESPONSIBLE ORGANIZATION by QUALIFIED PERSONS having the required skills for a particular medical application, for particular specified clinical purposes, e.g., STATIONARY RADIOTHERAPY or MOVING BEAM RADIOTHERAPY,
- maintained in accordance with the recommendations given in the INSTRUCTIONS FOR USE, and
- subject to regular quality assurance performance and calibration checks by a QUALIFIED PERSON.

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

201.1.2 Object

Replacement:

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for X-IGRT EQUIPMENT and X-IGRT EBE SYSTEMS.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and Clause 201.2 of this document.

IEC 60601-1-3 and IEC 60601-1-6 apply as modified in Clause 203 and Clause 206 respectively. IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10 and IEC 60601-1-11 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

The numbering of clauses and subclauses of this document corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this document addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

"Replacement" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is replaced completely by the text of this document.

"Addition" means that the text of this document is additional to the requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard.

"Amendment" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.154, 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, any applicable collateral standards and this document taken together.

Where there is no corresponding clause or subclause in this document, the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

NOTE Informative references are listed in the bibliography.

Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

Replacement:

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*

IEC 60601-1-3:2008/AMD1:2013

IEC 60601-1-3:2008/AMD2:2021

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 60601-1:2005/AMD2:2020

IEC 60601-2-1:2020, *Medical electrical equipment – Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV*

IEC 60601-2-4:2010, *Medical electrical equipment – Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators*

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*

IEC 62563-1:2009, *Medical electrical equipment – Medical image display systems – Part 1: Evaluation methods*

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 60601-2-1:2020, IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020, and IEC TR 60788:2004 apply, except as follows:

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

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

*Additional terms and definitions:***201.3.201****COMPUTED TOMOGRAPHY DOSE INDEX 100** **$CTDI_{100}$**

integral of the DOSE PROFILE representative of a single axial scan along a line perpendicular to the TOMOGRAPHIC PLANE divided by $N \times T$ according to the following:

for $N \times T$ less than or equal to 40 mm

$$CTDI_{100} = \int_{-50\text{mm}}^{+50\text{mm}} \frac{D(y)}{N \times T} dy$$

for $N \times T$ greater than 40 mm (all IGRT IMAGING PROTOCOL except collimation are kept the same for these measurements)

$$CTDI_{100} = \int_{-50\text{mm}}^{+50\text{mm}} \frac{D_{\text{Ref}}(y)}{(N \times T)_{\text{Ref}}} dy \times \frac{CTDI_{\text{free air, } N \times T}}{CTDI_{\text{free air, Ref}}}$$

where

$D(y)$ is the DOSE PROFILE representative of a single axial scan along a line perpendicular to the TOMOGRAPHIC PLANE, where dose is reported as ABSORBED DOSE in air and is evaluated within a polymethylmethacrylate (PMMA) dosimetry PHANTOM (see 201.102.6.2);

$(N \times T)_{\text{Ref}}$ is a specific $N \times T$ of 20 mm or the largest $N \times T$ available not greater than 20 mm;

$D_{\text{Ref}}(y)$ is the DOSE PROFILE representative of a single axial scan along a line perpendicular to the TOMOGRAPHIC PLANE, where dose is reported as ABSORBED DOSE in air and is evaluated within a polymethylmethacrylate (PMMA) dosimetry PHANTOM (see 201.102.6.2) for $(N \times T)_{\text{Ref}}$;

$CTDI_{\text{free air, } N \times T}$ is the $CTDI_{\text{free air}}$ (201.3.202) for a specific value of $N \times T$;

$CTDI_{\text{free air, Ref}}$ is the $CTDI_{\text{free air}}$ (201.3.202) for $(N \times T)_{\text{Ref}}$;

N is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-ray source;

T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS.

Note 1 to entry: The dose is reported as ABSORBED DOSE to air, but for practical purposes the evaluation of ABSORBED DOSE to air within a PMMA dosimetry PHANTOM is well approximated by measurement of the AIR KERMA.

Note 2 to entry: This definition assumes that the DOSE PROFILE is centred on $y = 0$.

Note 3 to entry: A single axial scan is typically a 360° rotation of the X-ray source. For CBCT partial rotations are still considered as a single axial scan.

Note 4 to entry: When the TOMOGRAPHIC SECTIONS overlap, e.g., in CT SCANNERS with a "y-flying FOCAL SPOT" or with CBCT modes that merge multiple scans, the denominator of the integral needs to be replaced by the total nominal width along y of overlapping tomographic sections. For example, if the percentage of overlap is 50 %, then the denominator would be replaced with $0,5 \times N \times T$.

Note 5 to entry: Typically, the y -axis is the axis of rotation (the y -axis corresponds to the z -axis in the DICOM coordinate system).

Note 6 to entry: The $CTDI_{100}$ is designed to include most of the scattered RADIATION.

Note 7 to entry: See IEC 60601-2-44:2009/AMD1:2012, Annex CC for more explanation.

Note 8 to entry: It is assumed for MV CBCT that an appropriate calibrated pencil chamber is used.

[SOURCE: IEC 60601-2-44:2009/AMD1:2012, 201.3.203, modified – Notes 3, 4 and 5 to entry have been extended, and Note 8 to entry added.]

201.3.202

COMPUTED TOMOGRAPHY DOSE INDEX FREE-IN-AIR

$CTDI_{\text{free air}}$

integral of the DOSE PROFILE representative of a single axial scan along a line through the ISOCENTRE and perpendicular to the TOMOGRAPHIC PLANE divided by $N \times T$ according to the following

$$CTDI_{\text{free air}} = \int_{-L/2}^{+L/2} \frac{D(y)}{N \times T} dy$$

where

$D(y)$ is the DOSE PROFILE representative of a single axial scan along a line through ISOCENTRE and perpendicular to the TOMOGRAPHIC PLANE, where dose is reported as ABSORBED DOSE in air and is evaluated free-in-air in the absence of a PHANTOM and the PATIENT SUPPORT;

N is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-ray source;

T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS;

L is at least $(N \times T) + 40$ mm.

Note 1 to entry: This definition assumes that the DOSE PROFILE is centred on $y = 0$. The y axis corresponds to the z axis in the DICOM coordinate system.

Note 2 to entry: When the TOMOGRAPHIC SECTIONS overlap, e.g., in CT SCANNERS with a "y-flying FOCAL SPOT" or with CBCT modes that merges multiple scans, the denominator of the integral needs to be replaced by the total nominal width along y of overlapping tomographic sections. For example, if the percentage of overlap is 50 %, then the denominator would be replaced by $0,5 \times N \times T$.

Note 3 to entry: Typically, a RADIATION DETECTOR of length L or longer is used. Annex DD provides an example for alternate measurements.

Note 4 to entry: For CBCT, the imaging is not slice based and $N \times T$ is the scan length along a line perpendicular to the TOMOGRAPHIC PLANE with the NOMINAL collimation.

Note 5 to entry: It is assumed for MV CBCT that an appropriate calibrated pencil chamber or ion chamber, and a build-up cap is used.

[SOURCE: IEC 60601-2-44:2009/AMD1:2012, 201.3.215, modified – Note 1 and 2 to entry have been extended and Notes 4 and 5 to entry added.]

201.3.203

CONE BEAM COMPUTED TOMOGRAPHY

CBCT

computed tomography performed using a cone beam of X-RADIATION

201.3.204

CONTRAST TO NOISE RATIO

CNR

physical quantity describing the ability to distinguish between various contrast objects of a digital image and the inherent noise within the image, defined as the difference of mean pixel values of the contrast objects and image background, and divided by the standard deviation of the image background pixel value

Note 1 to entry: $C = \frac{|S_A - S_B|}{\sigma_0}$

S_A and S_B are signal intensities for the signal producing structures A and B in the region of interest and σ_0 is the standard deviation of the image noise. The MANUFACTURER specifies the structures defining A and B.

[SOURCE: IEC 61223-3-2:2007, 3.8, modified – Two notes to entry have been added.]

201.3.205

DOSE-LENGTH PRODUCT

DLP

index characterizing the product of the $CTDI_{vol}$ and the total length scanned

- a) For axial scanning

$$DLP = CTDI_{vol} \times \Delta d \times n$$

where

Δd is the PATIENT SUPPORT travel in y-direction between consecutive scans;

n is the number of scans in the series.

- b) For helical scanning

$$DLP = CTDI_{vol} \times L$$

where

L is the table travel during the entire LOADING, adjusted for dynamic collimation modes where applicable.

Note 1 to entry: L might be longer than the programmed scan length.

Note 2 to entry: The time weighted average of $CTDI_{vol}$ is to be used if $CTDI_{vol}$ is variable.

Note 3 to entry: A way for obtaining L could be to use the FWHM along a line perpendicular to the TOMOGRAPHIC PLANE at isocentre of the free-in-air DOSE PROFILE for the entire scan. In the absence of dynamic collimation this is approximately equivalent to table travel during the entire LOADING.

- c) For scanning without movement of the PATIENT SUPPORT

$$DLP = CTDI_{vol} \times N \times T$$

where

N is the number of TOMOGRAPHIC SECTIONS PRODUCED in a single axial scan of the X-ray source;

T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS.

Note 4 to entry: For CBCT, usually only c) is applicable where $N \times T$ is the scan length along a line perpendicular to the TOMOGRAPHIC PLANE with the NOMINAL collimation.

Note 5 to entry: Typically, the y-axis is the axis of rotation. The y axis corresponds to the z axis in the DICOM coordinate system.

- d) For axial scanning without gaps and helical scanning, both involving back-and-forth PATIENT SUPPORT movement between two positions (shuttle mode)

$$DLP = CTDI_{vol} \times ((N \times T) + R)$$

where

N is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-ray source;

T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS;

R is the distance between the two positions.

[SOURCE: IEC 60601-2-44:2009 and IEC 60601-2-44:2009/AMD1:2012, 201.3.214, modified – Notes 4 and 5 to entry have been added.]

201.3.206

DOSE PROFILE

representation of the dose as a function of position along a line

[SOURCE: IEC 60601-2-44:2009, 201.3.205]

201.3.207

EQUIPMENT REFERENCE POINT

ERP

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

201.3.208

EXTERNAL BEAM EQUIPMENT

EBE

external RADIATION EQUIPMENT utilizing ELECTRON ACCELERATORS, light ion beam medical electrical equipment or RADIONUCLIDE BEAM THERAPY EQUIPMENT

201.3.209

IGRT EQUIPMENT

ME EQUIPMENT that provides IGRT functionality

201.3.210

*** IGRT LATENCY**

time from initiation of image acquisition to output signal by X-IGRT EQUIPMENT to the EBE

Note 1 to entry: It is expected that the EBE can also state its latency time from receiving the signal to providing the correction.

Note 2 to entry: The IGRT LATENCY includes the hardware and software latencies.

Note 3 to entry: Network transfer times vary from one installation to another as there are too many factors involved that are supplied by the RESPONSIBLE ORGANIZATION. Network transfer latency therefore is not considered as part of the IGRT LATENCY time.

201.3.211

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 beam to TARGET VOLUME

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

[SOURCE: IEC 60976:2007, 3.8, modified — Addition of Note 1 to entry.]

201.3.212

IMAGING PROTOCOL

set of parameters necessary to perform imaging

Note 1 to entry: The following modes are examples of different types of imaging: radiography, radioscopy, helical, axial, axial series, scanning without movement of the PATIENT POSITIONER and shuttle mode.

Note 2 to entry: To maintain consistency with their respective user interfaces and documentation, various X-IGRT EQUIPMENT might use terminology different from "IMAGING PROTOCOL", e.g., "scan", "scan group", "scan series", "presets", "CBCT modes" etc.

Note 3 to entry: An IMAGING PROTOCOL is typically associated with a IGRT task, anatomical region, age or size group.

201.3.213

IMAGE RECONSTRUCTION

method to process acquired data into an image data set that can be used for analysis

Note 1 to entry: The analysis of the reconstructed image data set can be for the purpose of IMAGE REGISTRATION against reference data.

201.3.214

IMAGE REGISTRATION

method for mapping or registering corresponding points from one image data set to another

Note 1 to entry: IMAGE REGISTRATION can be rigid or deformable.

201.3.215

IMAGING SESSION

length of continuous time that images are taken of the PATIENT while the PATIENT remains on the PATIENT positioning device

Note 1 to entry: If the PATIENT is removed from the PATIENT positioning device, the imaging session is ended.

201.3.216

KILOVOLTAGE X-IGRT EQUIPMENT

X-IGRT EQUIPMENT using kilovoltage X-RADIATION

201.3.217

MEGAVOLTAGE X-IGRT EQUIPMENT

X-IGRT EQUIPMENT using megavoltage X RADIATION

201.3.218

MODULATION TRANSFER FUNCTION

MTF

modulus of the generally complex OPTICAL TRANSFER FUNCTION, expressed as a function of SPATIAL FREQUENCIES u and v

Note 1 to entry: The MTF can be determined in several ways, e.g., from the Fourier transforms of the point spread function (PSF), the line spread function (LSF) and the edge spread function (ESF). Any method is acceptable if performed correctly.

[SOURCE: IEC 62220-1-1:2015, 3.10, modified – A note to entry has been added, and the symbol for the term has been changed.]

201.3.219

NOMINAL REFERENCE DISTANCE

<X-RADIATION> SPECIFIED distance along the REFERENCE AXIS, which is for X-RADIATION, from the TARGET surface of the exiting beam to a SPECIFIED plane containing the EQUIPMENT REFERENCE POINT of the X-IGRT EQUIPMENT

201.3.220

NORMAL USE

operation, including routine inspection and adjustments by any OPERATOR, and STAND-BY, according to the INSTRUCTIONS FOR USE

Note 1 to entry: NORMAL USE should not be confused with INTENDED USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, transport, etc. as well.

Note 2 to entry: NORMAL USE is all functions performed by the OPERATOR. This includes warmup, calibration, and other testing "physics" modes.

[SOURCE: IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.71, modified – Note 2 has been added.]

201.3.221

OFFLINE IGRT

IGRT for the purpose of PATIENT setup or TREATMENT PLAN adjustment to be applied in subsequent TREATMENT delivery

201.3.222

ONLINE IGRT

IGRT for the purpose of PATIENT setup or TREATMENT PLAN adjustment 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 imaging and TREATMENT.

201.3.223

OPTICAL TRANSFER FUNCTION

OTF

two-dimensional Fourier transform of the imaging system's point spread function.

Note 1 to entry: See ISO 9334:2012.

Note 2 to entry: For the OPTICAL TRANSFER FUNCTION to have significance, it is essential that the imaging system is working in its LINEAR RANGE, and that an ISOPLANATIC REGION is considered.

[SOURCE: IEC 61262-7:1995, 3.1.14]

201.3.224

RADIOGRAPHY

technique for obtaining, recording and optionally processing directly or after TRANSFER, information contained in an X-RAY PATTERN at an IMAGE RECEPTION AREA intended to be analysed during a time independent from the IRRADIATION time

[SOURCE: IEC 60601-1-3:2008, 3.64]

201.3.225

RADIOSCOPY

technique for obtaining continuously or periodically a sequence of X-RAY PATTERNS and presenting them directly or through a TRANSFER and optional processing simultaneously and continuously as visible images, intended to provide real-time guidance to an ongoing action

[SOURCE: IEC 60601-1-3:2008, 3.69]

201.3.226

REAL-TIME IGRT

IGRT that images throughout therapeutic IRRADIATION and based upon that information, allows automatic adjustments of TREATMENT PARAMETERS throughout the therapeutic IRRADIATION without OPERATOR intervention

201.3.227**REFERENCE IMAGE**

an image related to the TREATMENT PLAN to which subsequent images will be compared to align the PATIENT or adjust the TREATMENT PLAN

Note 1 to entry: REFERENCE IMAGES could be acquired during the first or subsequent TREATMENT fraction from an ELECTRONIC PORTAL IMAGING DEVICE.

Note 2 to entry: There can be more than one REFERENCE IMAGE.

Note 3 to entry: Examples of REFERENCE IMAGES can be digital reconstructed radiographs generated by the planning system for comparison to 2D images taken at time of TREATMENT or TREATMENT planning CT images used for CBCT registration, or the image generated by IGRT based on the CT and the TREATMENT PLAN.

201.3.228**SENSITIVITY PROFILE**

relative response of a system for COMPUTED TOMOGRAPHY as a function of position along a line perpendicular to the TOMOGRAPHIC PLANE

[SOURCE: IEC 60601-2-44:2009, 201.3.207]

201.3.229**SPATIAL RESOLUTION**

resolution also known as HIGH-CONTRAST RESOLUTION and described by the MODULATION TRANSFER FUNCTION

201.3.230**SPATIAL RESOLUTION OF AN IMAGE DISPLAY SYSTEM**

measure of the ability of an image display system to distinguish spatial features of interest within an image

Note 1 to entry: Systems designed with adequate spatial resolution characteristics are necessary to assure that spatial details of interest are preserved when a medical image is displayed. Portraying image data on an image display device with insufficient resolution will compromise the accuracy of the radiological interpretation.

[SOURCE: IEC 62563-1:2009, 3.1.20, modified – Addition of Note 1 to entry.]

201.3.231**USABILITY**

characteristic of the OPERATOR interface that establishes effectiveness, efficiency, ease of OPERATOR learning and OPERATOR satisfaction

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.136, modified – The definition was rephrased.]

201.3.232.1**VOLUME $CTDI_W$** **$CTDI_{vol}$**

<axial scanning>

$$CTDI_{vol} = \frac{N \times T}{\Delta d} CTDI_W$$

where

N is the number of tomographic sections produced in a single axial scan of the X-ray source;

T is the nominal tomographic section thickness;

Δd is the patient support travel in y-direction between consecutive scans.

Note 1 to entry: For the selected IGRT IMAGING PROTOCOL, but irrespective of any scanning length that may be used clinically, the VOLUME $CTDI_W$ ($CTDI_{vol}$) is an index of dose based on a convention of 100 mm range of integration

along the y-axis. For axial scanning, $CTDI_{vol}$ corresponds to the average dose that would accrue in the PHANTOM central section of volume equal to the cross-sectional area $\times \Delta d$.

Note 2 to entry: For axial scanning with a total table travel of less than $N \times T$, $CTDI_{vol}$ as defined overestimates the average dose that would accrue in the PHANTOM central section of volume equal to the cross-sectional area $\times \Delta d$.

Note 3 to entry: Typically, the y-axis is the axis of rotation. The y axis corresponds to the z axis in the DICOM coordinate system.

[SOURCE: IEC 60601-2-44:2009/AMD1:2012, 201.3.212, modified – Modification of notes to entry.]

201.3.232.2

VOLUME $CTDI_W$

$CTDI_{vol}$

<helical scanning>

$$CTDI_{vol} = \frac{CTDI_W}{CT \text{ pitchfactor}}$$

Note 1 to entry: CT PITCH FACTOR will be a function of time when Δd is variable during the exposure.

Note 2 to entry: For the selected X-IGRT CONDITIONS OF OPERATION, but irrespective of any scanning length that may be used clinically, the VOLUME $CTDI_W$ ($CTDI_{vol}$) is an index of dose based on a convention of 100 mm range of integration along the y-axis. For helical scanning, $CTDI_{vol}$ corresponds to the average dose that would accrue in the centre of a 100 mm scan length.

Note 3 to entry: For helical scanning, when the product a small number of rotations times the table travel per rotation is much less than $N \times T$ $CTDI_{vol}$ as defined overestimates the average dose that would accrue in the centre of a 100 mm scan length.

Note 4 to entry: Typically, the y-axis is the axis of rotation. The y axis corresponds to the z axis in the DICOM coordinate system.

[SOURCE: IEC 60601-2-44:2009/AMD1:2012, 201.3.212, modified – Modification of notes to entry.]

201.3.232.3

VOLUME $CTDI_W$

$CTDI_{vol}$

<scanning without movement of the PATIENT SUPPORT>

$$CTDI_{vol} = n \times CTDI_W$$

where n is equal to the number of rotations.

Note 1 to entry: 201.3.232.3 includes situations where the PATIENT SUPPORT may be moved manually, for example, during an interventional procedure.

Note 2 to entry: For scanning without movement of the PATIENT SUPPORT and for situations where the PATIENT SUPPORT may be moved manually, this definition overestimates the dose as it includes assumed scatter contribution from adjacent slices.

Note 3 to entry: For scanning without movement of the PATIENT SUPPORT, $CTDI_{vol}$ corresponds to the dose that would accrue in the PHANTOM central section of volume equal to the cross-sectional area $\times N \times T$ were there n congruent sequences of contiguous scanning, each sequence of length 100 mm.

Note 4 to entry: For CBCT, usually only 201.3.232.3 is applicable.

Note 5 to entry: Typically, the y-axis is the axis of rotation. The y axis corresponds to the z axis in the DICOM coordinate system.

Note 6 to entry: For CBCT n is typically 1 and for partial rotations n is considered as 1.

[SOURCE: IEC 60601-2-44:2009/AMD1:2012, 201.3.212, modified – Notes to entry 3, 7, 11, 12 and 13 have been added, and Notes to entry 1 and 2 are slightly modified.]

201.3.232.4

VOLUME $CTDI_W$

$CTDI_{vol}$

<axial scanning without gaps and helical scanning, both involving back-and-forth PATIENT SUPPORT movement between two positions (shuttle mode)>

$$CTDI_{vol} = n \frac{N \times T}{(N \times T) + R} CTDI_W$$

where

N is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-ray source;

T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS;

n is equal to the total number of rotations for the entire scan series;

R is the distance between the two positions;

$CTDI_W$ is the weighted $CTDI_{100}$.

Note 1 to entry: Seen Figure 201.102 in IEC 60601-2-44:2009/AMD1:2012.

Note 2 to entry: $CTDI_W$ is evaluated as the time weighed $CTDI_W$ reflecting the varying IGRT IMAGING PROTOCOL.

[SOURCE: IEC 60601-2-44:2009/AMD1:2012, 201.3.212, modified – Notes to entry 3, 7, 11, 12 and 13 have been added, and Notes to entry 1 and 2 are slightly modified.]

201.3.233

WEIGHTED $CTDI_{100}$

$CTDI_W$

value defined as

$$CTDI_W = \frac{1}{3} CTDI_{100(\text{centre})} + \frac{2}{3} CTDI_{100(\text{peripheral})}$$

where

$CTDI_{100(\text{centre})}$ is the value of $CTDI_{100}$ measured in the centre of a dosimetry PHANTOM;

$CTDI_{100(\text{peripheral})}$ is the average of the four values of $CTDI_{100}$ measured around the dosimetry PHANTOM periphery according to 201.102.6.2.2.1 a) 2) and 3)

[SOURCE: IEC 60601-2-44:2009, 201.3.211, modified – Reference is made to this standard rather than the source document.]

201.3.234

X-IGRT EBE SYSTEM

system comprising of X-IGRT EQUIPMENT and EXTERNAL BEAM EQUIPMENT

201.3.235

X-IGRT EQUIPMENT

ME EQUIPMENT that provides IGRT functionality when X-rays are used for imaging

Note 1 to entry: The IGRT functionality can be provided by a different part of the X-IGRT EBE SYSTEM than the X-ray imaging, e.g., a CT SCANNER provides the X-ray images, and another equipment provides the positional correction calculation.

201.3.236

X-IGRT IMAGING COMPONENT

part of the X-IGRT EQUIPMENT that performs the imaging function

201.4 General requirements

Clause 4 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies except as follows:

201.5.1 TYPE TESTS

Additional subclause:

201.5.1.101 Test grades

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

- TYPE TEST/SITE TEST grade A: An analysis of MEE 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 MEE. The test shall be in accordance with the procedure SPECIFIED in this document and shall be based on operating states, including fault condition states that are achievable only without interference with the circuitry or construction of the MEE.
- TYPE TEST/SITE TEST grade C: Functional test or measurement of the MEE. The test shall be in accordance with the principle SPECIFIED in this document. 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 MEE, the test shall be performed by, or under the direct supervision of, the MANUFACTURER or his agent.

201.5.4 Other conditions

Item 5.4 a) of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 does not apply.

Replacement of item 5.4 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 requirements for testing.

201.5.9 Determination of APPLIED PARTS and ACCESSIBLE PARTS**201.5.9.2.1 Test finger***Addition:*

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

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.7.1.1 USABILITY of the identification, marking and documents*Addition:*

All sub-assemblies and components of X-IGRT EQUIPMENT 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; and
- that interchangeable devices are individually distinguishable to the OPERATOR both in NORMAL USE and for the purpose of obtaining replacements.

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts**201.7.2.4 ACCESSORIES***Addition:*

The dimensions of the GEOMETRICAL RADIATION FIELD at the NOMINAL REFERENCE DISTANCE shall be clearly legible on the outside of all manually interchangeable and non-adjustable BEAM LIMITING DEVICES (BLDs).

The dimensions of the GEOMETRICAL RADIATION FIELD at the nominal reference distance shall be clearly stated in the ACCOMPANYING DOCUMENTATION for all non-adjustable BEAM LIMITING DEVICES (BLDs).

For adjustable devices, the range of the GEOMETRICAL RADIATION FIELD at the NOMINAL REFERENCE DISTANCE shall be specified in the ACCOMPANYING DOCUMENTATION.

For all ACCESSORIES supplied by the MANUFACTURER, the limitations of each device shall be specified in the ACCOMPANYING DOCUMENTATION.

EXAMPLE A limitation is a smaller field of view due to collimation.

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

All X-IGRT EQUIPMENT ACCESSORIES supplied by the MANUFACTURER that could present a collision RISK when attached to the X-IGRT EQUIPMENT shall be clearly marked on the outside with the distance from the distal end to the ERP.

Compliance is checked by inspection.

201.7.2.15 Cooling conditions

Addition:

The cooling requirements for the safe operation of an X-IGRT EQUIPMENT, or a sub-assembly thereof, shall be indicated in the ACCOMPANYING DOCUMENTATION, including as appropriate the maximum heat dissipation.

201.7.2.20 Removable protective means

Addition:

Where the requirements of the subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 are wholly or partly met by the nature of the installation, compliance at installation shall be checked by inspection; the results shall 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 X-IGRT EQUIPMENT X-ray source

Removal of the covers of the X-IGRT EQUIPMENT X-ray source(s) shall expose safety sign 10 of Table D.2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 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 shall be provided:

- a) a means to align the PATIENT with respect to the ERP of the X-IGRT EQUIPMENT (e.g., LIGHT FIELD, lasers etc.);

NOTE 1 For X-IGRT EQUIPMENT that share the same ERP as the EBE then the means to align can be the same as the EBE.

- b) for X-IGRT EQUIPMENT with adjustable distances from the RADIATION SOURCE or RADIATION DETECTOR to the ERP, a means to determine the distance from the X-IGRT EQUIPMENT RADIATION SOURCE and RADIATION DETECTOR to the ERP (e.g., scale, numerical indication or lasers);
- c) for X-IGRT EQUIPMENT with both a fixed source and fixed RADIATION DETECTOR to ERP distance(s), the distances from the RADIATION SOURCE and the RADIATION DETECTOR to an ERP shall be stated in the ACCOMPANYING DOCUMENTATION;

- d) all mechanical scales, numerical read outs or status indicators that the MANUFACTURER'S HAZARD ANALYSIS indicates shall be available to the OPERATOR, shall be presented to the OPERATOR;

NOTE 2 The distance for a kilovoltage RADIATION SOURCE is measured from its focal spot.

NOTE 3 For isocentric equipment, the ERP is the ISOCENTRE for that piece of equipment.

- e) The designation, direction of increasing value, and zero position of the indications used in the display of images and movements shall either comply with IEC 61217 or where the equipment used is not IEC 61217 compliant, the ACCOMPANYING DOCUMENTATION shall state the coordinate transformation to IEC 61217 coordinates; and

NOTE 4 This does not apply to displays of movements and scales of MEE that are not used for X-IGRT.

- f) a statement indicating the accuracy of each scale or numerical indication of the MEE shall be provided in the ACCOMPANYING DOCUMENTATION.

For OPERATOR set values, the values of the X-IGRT EQUIPMENT shall be capable of being provided to the OPERATOR in the same units and coordinate system as the device the values are applied to.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding accuracy of each scale or numerical indication of the TREATMENT geometry of the MEE.

TYPE TEST grade A – Compliance is checked by inspection of the ACCOMPANYING DOCUMENTATION.

201.7.8 Indicator lights and controls

201.7.8.1 Colours of indicator lights

Replacement:

Where indicators (lights or displays) on X-IGRT EQUIPMENT are used on the TREATMENT CONTROL PANEL (TCP) or other control panels associated with the EBE, 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 X-IGRT EBE SYSTEM cannot automatically correct for misalignment, for REAL-TIME IGRT the colour red shall be used as this represents an urgent action required by the OPERATOR.

NOTE 101 In the TREATMENT ROOM or at other locations, these states can indicate urgent action or caution; different colours, as given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020, Table 2, can therefore be used in such locations.

Compliance is checked by inspection.

201.7.9 ACCOMPANYING DOCUMENTS

Addition:

Data required in the technical description to support TYPE TEST and SITE TEST compliance in Clauses 201.7, 201.9, 201.10, 201.11, 201.14, 201.101, 201.102, 201.103, and 201.104 is given in Table 201.101.

Table 201.101 – Data required in the technical description

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
201.7.4.101	†				
201.8.7.3	†		†		
201.9.2.4.101		†			
201.9.2.5	†	†			
201.9.2.101	†	†			
201.9.2.102	†				
201.9.2.103	e)	f)		a) b) c) d)	
201.9.7.101		†			
201.9.8.101	a) b)				
201.9.8.102	b)				
201.10.1.2.101	†				
201.10.1.2.102	a)		b)	b)	
201.11.1.4	†		†		
201.14.101	†				†
201.101.1	†				
201.101.2				†	
201.101.3				†	
201.101.4				†	
201.101.5	†			†	
201.101.6	†			†	
201.101.7	d)	a)		b) c)	
201.101.8	a) b)			b)	
201.101.9.1	†				†
201.101.9.2	†			†	
201.101.9.3	†				
201.102.1.1				†	
201.102.1.2				†	
201.102.2				†	
201.102.3	†			†	†
201.102.4	†				
201.102.5	†				
201.102.6.1	a) b)				
201.102.6.2.2.1	†				
201.102.6.2.2.2	†				
201.102.6.2.2.3	†				
201.102.6.2.2.4	†				
201.102.6.2.2.5	†	†			
201.102.6.2.2.6	†				
201.102.6.2.2.7		†			
201.103.1	a) b)				
201.103.2	a) b) c)				
201.103.3.1	†	†		†	

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
201.103.3.2	†	†		†	
201.103.3.3	†	†		†	
201.104	a) d)			b) c) e) f)	
Key † denotes requirement of subclause having no other SPECIFIC identification.					

Clauses and subclauses in this document that require the provision of information in the ACCOMPANYING DOCUMENTATION, INSTRUCTIONS FOR USE and the technical description are given in Table 201.102.

Table 201.102 – Clauses and subclauses in this document 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		201.1.1	
2			201.5.1.101
3	201.5.4		201.5.4
4	201.5.9.2.1		
5	201.7.1.1		
6	201.7.2.4		
7	201.7.2.15		
8	201.7.4.101		
9	201.7.9.2.2		
10	201.7.9.2.2.101		
11	201.7.9.2.5		
12	201.7.9.2.5.101		
13		201.7.9.2.5.102	
14		201.7.9.2.15	201.7.9.2.15
15	201.7.9.2.17		
16	201.8.7.3		
17			201.8.11.1
18	201.9.2.4.101		
19	201.9.2.5	201.9.2.5	
20	201.9.2.101	201.9.2.101	
21		201.9.2.102	
22		201.9.2.103	
23	201.9.8.101		
24	201.9.8.102		
25	201.10.1.2.102		201.10.1.2.102
26		201.11.1.4	
27	201.14.101	201.14.101	201.14.101
28	201.17.101		

Check reference	ACCOMPANYING DOCUMENTATION	INSTRUCTIONS FOR USE	Technical description
29	201.101.1		201.101.1
30		201.101.5	
31	201.101.6		
32	201.101.7		
33			201.101.8
34	201.101.9.1		
35		201.101.9.2	
36	201.101.9.3		
37		201.102.2	
38	201.102.4		201.102.4
39	201.102.5		
40	201.102.6.1		201.102.6.1
41	201.102.6.2.2.1		
42	201.102.6.2.2.2		
43	201.102.6.2.2.3		
44	201.102.6.2.2.4		
45	201.102.6.2.2.5		
46	201.102.6.2.2.6		
47		201.103.1	201.103.1
48		201.103.2	201.103.2
49	201.103.3.1	201.103.3.1	
50	201.103.3.2	201.103.3.2	
51	201.103.3.3	201.103.3.3	
52	201.104		
53	203.4.1		
54	203.6.3.2		
55	203.8.4		
56	203.10.2	203.10.2	
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 X-IGRT EBE SYSTEM MANUFACTURER for use with the X-IGRT EBE SYSTEM.

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

Additional subclause:

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 with active implantable medical devices or body worn active medical devices and indicating that the MANUFACTURER of such devices should be contacted for more information and that such said device should be checked for correct operation after the IRRADIATION.

201.7.9.2.5 ME EQUIPMENT description

Addition:

The MANUFACTURER shall state in the ACCOMPANYING DOCUMENTATION the function of the X-IGRT EQUIPMENT.

The accuracy of the X-IGRT EQUIPMENT geometry shall be described in the ACCOMPANYING DOCUMENTATION.

The accuracy of the relationship of all axes of the X-IGRT 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 geometrical stability of the X-IGRT EQUIPMENT to the EBE's ERP and EQUIPMENT REFERENCE COORDINATE SYSTEM in relationship to the X-IGRT EQUIPMENT at the time of calibration and the recommended frequency of 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 (rotation, etc.);
- changes related to OPERATOR activity e.g., fitting accessories, detracting/deploying hardware;
- changes related to machine position and configuration.

Additional subclauses:

201.7.9.2.5.101 REAL-TIME IGRT

In the case of REAL-TIME IGRT, the IGRT LATENCY time of the x-IGRT EQUIPMENT to perform its function shall be stated in the ACCOMPANYING DOCUMENTATION. The conditions used to determine the IGRT LATENCY time shall also be stated in the ACCOMPANYING DOCUMENTATION. Where the time between images is not operator determined, the time between images shall also be stated.

When the IGRT LATENCY is compensated by a prediction model or another method, the method of compensation shall be described in the ACCOMPANYING DOCUMENTATION.

If the method of compensation also includes an assumed latency of the EBE in addition to the IGRT LATENCY of the x-IGRT EQUIPMENT, then that method shall also be included in the ACCOMPANYING DOCUMENTATION.

201.7.9.2.5.102 kV X-IGRT EQUIPMENT

For X-IGRT EQUIPMENT using a kV X-RAY TUBE, electric output data shall be stated in the INSTRUCTIONS FOR USE in terms of LOADING FACTORS as required in IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021, 6.4.3.

For X-IGRT EQUIPMENT in which part of the HIGH-VOLTAGE GENERATOR is integrated with the X-RAY TUBE ASSEMBLY (for example X-RAY TUBE HEADS) the stated values shall refer to the complete device.

The following combinations and data shall be stated in the INSTRUCTIONS FOR USE for kV X-RAY TUBES:

- a) the corresponding NOMINAL X-RAY TUBE VOLTAGE together with the highest X-RAY TUBE CURRENT obtainable from the HIGH-VOLTAGE GENERATOR when operated at that X-RAY TUBE VOLTAGE;
- b) the corresponding highest X-RAY TUBE CURRENT together with the highest X-RAY TUBE VOLTAGE, obtainable from the HIGH-VOLTAGE GENERATOR when operating at that X-RAY TUBE CURRENT;
- c) the corresponding combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT that results in the highest electric output power; and
- d) the NOMINAL ELECTRIC POWER given as the highest constant electric output power in kilowatts that the HIGH-VOLTAGE GENERATOR can deliver, for a LOADING TIME corresponding to the maximum clinical load time or 4 s whichever is shorter at an X-RAY TUBE VOLTAGE of 120 kV, or where these values are not selectable, with an X-RAY TUBE VOLTAGE nearest to 120 kV.

The NOMINAL ELECTRIC POWER shall be given together with the combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT and the LOADING TIME which are used with kV X-IGRT EQUIPMENT.

201.7.9.2.10 Messages

Replacement:

All system messages, error messages, and fault messages required by 7.9.2.10 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 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 MEE or MEE parts that can exhibit RADIOACTIVITY.

201.7.9.2.17 ME EQUIPMENT emitting RADIATION

Replacement:

To assist the RESPONSIBLE ORGANIZATION's radiological protection adviser, the following information of the X-ray imaging beam shall be defined in the ACCOMPANYING DOCUMENTATION.

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

For each X-RADIATION NOMINAL ENERGY:

- maximum electron energy striking the TARGET and corresponding maximum ABSORBED DOSE RATES at NOMINAL REFERENCE DISTANCE under conditions of NORMAL USE, with and without any ADDED FILTER where NORMAL USE is possible in both these states;
- dimensioned shape of the maximum RADIATION FIELDS at NOMINAL REFERENCE DISTANCE for X-RADIATION;
- location(s), referenced to accessible points on the RADIATION HEAD, of the front surface of the TARGET, and
- available directions of the RADIATION BEAM.

For each X-RADIATION NOMINAL ENERGY, where a RADIATION BEAM shield is incorporated, its transmission factor shall be provided in the ACCOMPANYING DOCUMENTATION.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.8.4 Limitation of voltage, current or energy

201.8.4.2 ACCESSIBLE PARTS and APPLIED PARTS

Addition to item d):

The requirements of 8.4.2 d) of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 do not apply where the installation prevents the test with the test rod and pin. The ACCOMPANYING DOCUMENTATION shall state when these conditions apply.

Additional subclauses:

201.8.4.101 Limitation of high voltage to the nominal X-ray tube voltage

kV X-IGRT EQUIPMENT shall be designed so as not to deliver a voltage higher than the NOMINAL X-RAY TUBE VOLTAGE for the X-RAY TUBE ASSEMBLY in NORMAL USE.

NOTE This clause has been adapted from IEC 60601-2-44.

Compliance is checked by inspection of the MANUFACTURER'S data for the component, by inspection of the MEE, and where necessary, by functional test.

201.8.4.102 Detachable high-voltage cable connections

Detachable high voltage cable connections to the X-RAY TUBE ASSEMBLY shall be designed so that the use of tools is required to disconnect them or to remove their protective covers.

NOTE This clause has been adapted from IEC 60601-2-54.

Compliance is checked by inspection.

201.8.4.103 Unacceptably high voltage in the MAINS PART

For kV X-IGRT EQUIPMENT provision shall be made to prevent the appearance of an unacceptably high voltage in the MAINS PART or in any other low-voltage circuit.

NOTE 1 Achieved for example:

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

NOTE 2 This clause has been adapted from IEC 60601-2-44.

Compliance is checked by inspection of design data and construction.

201.8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

201.8.7.1 General requirements

Addition to item b):

- with the X-IGRT 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 1 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 X-IGRT EQUIPMENT that is supplied by its own exclusive connection to the SUPPLY MAINS or to a central connection point, where the latter is fixed and PERMANENTLY INSTALLED.

A fixed and PERMANENTLY INSTALLED central PROTECTIVE EARTH TERMINAL can be provided inside the outer ENCLOSURE or cover of the X-IGRT EQUIPMENT. When 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 can 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 MEE 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 201.7.9.3.1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020.

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

Addition to item e):

For PERMANENTLY INSTALLED kV X-IGRT EQUIPMENT, 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:

TYPE TEST grade A: Inspection of the ACCOMPANYING DOCUMENTATION.

201.8.8.3 Dielectric strength

CT SCANNERS, X-RAY EQUIPMENT for RADIOGRAPHY, or X-RAY EQUIPMENT for RADIOSCOPY, where the following requirements are equivalent and tested according to another standard, shall

require retesting and can refer to the corresponding compliance statement or test report (see also Annex AA).

Amendment to the TYPE TEST for high-voltage circuit:

The high-voltage circuit of the kV X-IGRT imaging component is tested by applying no more than half the test voltage, and then the test voltage is gradually raised over a period of 10 s to the full value, which is maintained for 3 min in radiography and computed tomography and 15 min in radioscopy.

Addition to the test conditions for high-voltage circuit:

The test for the high-voltage circuit shall be made without a kV X-ray tube assembly connected and with a test voltage of 1,2 times the nominal kV X-ray tube voltage of the X-IGRT EQUIPMENT. If the X-IGRT IMAGING COMPONENT can be tested only with the kV X-ray tube assembly connected and if the kV X-ray tube does not allow the X-IGRT IMAGING COMPONENT to be tested with a test voltage of 1,2 times the nominal kV X-ray tube voltage, the test voltage can be lower but not less than 1,1 times that voltage.

For X-IGRT IMAGING EQUIPMENT in which the nominal kV X-ray tube voltage for radioscopy does not exceed 80 % of that for radiography, the test voltage for the high-voltage circuit shall be referred to the value for radiography, and the test shall be carried out in that mode only.

If during the dielectric strength test there is a risk of overheating a transformer under test, it is permitted to carry out the test at a higher supply frequency.

During the dielectric strength test, the test voltage in the high-voltage circuit shall be kept as close as possible to 100 % and is not to be outside the range of 100 % and 105 % of the value required.

During the dielectric strength test, slight corona discharges in the high-voltage circuit shall be disregarded if they cease when the test voltage is lowered to 110 % of the voltage to which the test condition is referred.

If according to risk assessment the gantry or patient support is an applied part or the part treated as an applied part, and the conductive gantry or patient support parts accessible to the patient are not fully covered by plastic enclosure, then such gantry or patient support parts are protected by MEANS OF PATIENT PROTECTION (MOPP). In this case, the test voltage for the dielectric strength testing of stator and stator circuits used for the operation of the rotating anode of the X-ray tube shall be referred to the voltage existing after reduction of the stator supply voltage to its steady state operating value.

Otherwise, the gantry is protected by MEANS OF OPERATOR PROTECTION (MOOP) and Table 6 and Tables 13 to 16 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 or the insulation coordination requirements of IEC 60950-1 apply.

Addition:

- aa) HIGH-VOLTAGE GENERATORS, or subassemblies thereof, that are integrated with an X-RAY TUBE ASSEMBLY shall be tested with an appropriately loaded X-RAY TUBE;
- bb) if such HIGH-VOLTAGE GENERATORS do not have separate adjustment of the X-RAY TUBE CURRENT, the duration of the dielectric strength test shall be reduced to such an extent that the allowable X-RAY TUBE LOAD at the increased X-RAY TUBE VOLTAGE will not be exceeded; or
- cc) if the high-voltage circuit is not accessible for the measurement of the test voltage applied, appropriate measures shall be taken to ensure that the values are kept as close as possible to 100 %, and is not to be outside the range of 100 % and 105 % of the value required.

NOTE These requirements are adapted from 201.8.8.3 of IEC 60601-2-54:2009.

201.8.11 MAINS PARTS, components and layout

201.8.11.1 Isolation from the SUPPLY MAINS

Replacement of item b):

- b) Means for isolation 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 MEE or externally in as many places as deemed 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.9.2 MECHANICAL HAZARDS associated with moving parts

201.9.2.1 General

Addition:

NOTE 101 The phrase 'to set-up automatically' or 'automatic set-up' is used to denote the moving of MEE parts automatically to the positions required for the start of a PATIENT TREATMENT or imaging. This includes when pre-programmed movements are initiated by the operator.

NOTE 102 The term 'pre-programmed movements' is used where movement of MEE parts takes place according to a previously planned programme, without intervention by the OPERATOR, during a PATIENT TREATMENT or imaging; the TREATMENT is referred to as a 'pre-programmed TREATMENT'.

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

201.9.2.2.5 Continuous activation

Item 9.2.2.5 b) of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 does not apply.

201.9.2.4 Emergency stopping devices

Additional subclause:

201.9.2.4.101 Emergency stop of motorized movements

Readily identifiable and accessible means for stopping all movements within the limits given in 201.9.2.101 shall be provided in HARD-WIRED circuit or have an equivalently safe switching function. These means shall be near to, or on, the PATIENT SUPPORT system and the TCP. The means provided near to, or on, the TCP shall also INTERRUPT IRRADIATION. The time to effect these disconnections shall not exceed 100 ms unless adequate safety can be demonstrated through RISK MANAGEMENT. When any of the means are incorporated on site by the RESPONSIBLE ORGANIZATION, the requirements and SITE TEST procedures shall be SPECIFIED in the ACCOMPANYING DOCUMENTATION and the results shall be incorporated in the SITE TEST report.

If a PESS is involved, then the technology shall be shown through RISK MANAGEMENT to assure freedom from unacceptable RISK to the equipment, PATIENT or OPERATOR.

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

If an interface to a third party's device is provided to send a signal to stop the motion of another EQUIPMENT, the maximum time elapsed after an indication is detected to send the signal shall be stated in the ACCOMPANYING DOCUMENTATION.

NOTE 1 A third party is not the same manufacturer.

When RISK MANAGEMENT is used to justify exceeding the limits specified in 201.9.2.101, then the limits used and the justification for them shall be stated in the ACCOMPANYING DOCUMENTATION.

Where a part of the X-IGRT EQUIPMENT is an integral part of another EBE, the respective limits can be applied as defined

- for ELECTRON ACCELERATOR (IEC 60601-2-1:2020) in Clause 201.9.2.101.
- for LIGHT ION BEAM MEDICAL ELECTRICAL EQUIPMENT (IEC 60601-2-64:2014) in Clause 201.9.2.101.
- for GAMMA BEAM THERAPY EQUIPMENT (IEC 60601-2-11:2013) in Clause 201.9.2.2.5.

NOTE 2 IEC 60601-2-17 automatically-controlled BRACHYTHERAPY AFTERLOADING equipment and IEC 60601-2-8 therapeutic X-RAY EQUIPMENT have no specific requirements beside IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020.

Where means are provided for monitoring or control by equipment other than the MEE, then the interface will contain at a minimum the ability to receive and send an emergency motor's stop as well as a signal to indicate that an emergency motors stop has occurred. Once received, the same time and motion limits listed in 201.9.2.4.101 shall apply.

Where means are provided for mitigating collision RISKS of the MEE by equipment other than the EBE, then the interface provided as a part of the MEE shall contain the ability to receive a motors emergency stop.

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

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

TYPE TEST grade B: Compliance is checked by inspection of the ACCOMPANYING DOCUMENTATION, and by 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:

- a) Under NORMAL CONDITIONS, the OPERATOR shall be able to release the PATIENT in an emergency situation within 30 s from a specified typical imaging position of the X-IGRT EQUIPMENT.

NOTE 1 The statement "to release the PATIENT" is the process of moving the PATIENT or MEE from their current position to the position where the PATIENT can be released from the impairment of the MEE.

- b) Under SINGLE FAULT CONDITION, where the possibility exists of the PATIENT becoming trapped or is unable to exit via normal routes, means shall be provided to permit release of the PATIENT; these means shall be described in the INSTRUCTIONS FOR USE.

NOTE 2 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 a bore device such as a CT SCANNER.

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. This also applies to the time required to allow the radiation level inside the room to fall to an acceptable level for entering the room, is also not included in the time requirements of this subclause.

Compliance is checked as follows:

- a) *TYPE TEST grade B: With the X-IGRT EQUIPMENT at the specified typical imaging position measure the time to move the equipment to the position where the PATIENT can be released.*
- b) *TYPE TEST grade A: Compliance is checked by inspection of the instructions for use.*

Additional subclauses:

201.9.2.101 X-ray source support system, ELECTRONIC IMAGING DEVICE (EID) support system, GANTRY, RADIATION HEAD and PATIENT POSITIONER

Throughout 201.9.2.101 for SINGLE FAULT CONDITIONS, the manufacturer shall demonstrate through risk management the safety of the system and describe the behaviour in the ACCOMPANYING DOCUMENTATION.

The requirements in 201.9.2.101 apply under NORMAL CONDITIONS.

a) General

- 1) When the X-ray source support system, EID support system, PATIENT POSITIONER, GANTRY, RADIATION HEAD, or any other part is provided with a means designed to reduce, in NORMAL USE, the RISK of collision, including with the PATIENT, the operation and limitations of each means shall be described in the INSTRUCTIONS FOR USE.
- 2) When the X-ray source support system, EID support system, PATIENT POSITIONER, GANTRY, RADIATION HEAD, or any other part (including ACCESSORY items) is not designed with a means to reduce, in NORMAL USE, the RISK of collisions, the collision RISKS shall be stated in the ACCOMPANYING DOCUMENTATION.

NOTE 1 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, e.g., some types of ELECTRON BEAM APPLICATORS.

- 3) For automatic set-up and for the checks of pre-programmed movements before start of imaging in NORMAL CONDITION, the overshoot shall not exceed 2° for rotational displacements around the ERP or 5 mm in the direction of motion past the intended stop position and 5 mm for linear displacements unless it can be shown through RISK MANAGEMENT that the distances achieved do not pose an unacceptable RISK to the equipment, PATIENT or OPERATOR.
- 4) When RISK MANAGEMENT is used to justify exceeding the limits specified in 201.9.2.101 then the limits used and the justification for them shall be stated in the ACCOMPANYING DOCUMENTATION.
- 5) Equipment contained within the RADIATION HEAD, X-ray source, or behind protective covers, where collisions are not possible, are exempt from the speed limits in 201.9.2.101 item b) and item c).
- 6) Hydraulic, pneumatic, and mechanical subsystems of the GANTRY, X-ray source support system, EID support system, RADIATION HEAD or PATIENT POSITIONER shall not cause unintended movement in SINGLE FAULT CONDITIONS.

b) X-ray source support system, EID support system, GANTRY, and RADIATION HEAD

- 1) At SINGLE FAULT CONDITION, the interruption or failure of powered movements or of the SUPPLY MAINS for the MEE shall cause any parts in motion to be stopped within the limits given in item 2), 3), and 4).
- 2) Rotational movements around the ERP
 - A low speed shall be available for each rotational movement which shall not exceed 1° s⁻¹.

- No speed shall exceed 7° s^{-1} around the ERP unless identified as an acceptable RISK, through 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 MEE stops do not pose an unacceptable RISK to the equipment, PATIENT, or OPERATOR.
- When rotating around the ERP at the speed nearest to, but not exceeding, 1° s^{-1} , the angle between the position of the moving part at the instant of operating any control to stop the movement and its final position shall not exceed $0,5^\circ$. For speeds faster than 1° s^{-1} , it shall not exceed 3° unless it can be shown through RISK MANAGEMENT that the distances achieved do not pose an unacceptable RISK to the equipment, PATIENT or OPERATOR.

EXAMPLE 1 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".

3) Linear movements

- No speed shall exceed 100 mm s^{-1} 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 any speed greater than 25 mm s^{-1} , and 3 mm for speeds not exceeding 25 mm s^{-1} unless it can be shown through RISK MANAGEMENT that the distances achieved do not pose an unacceptable RISK to the equipment, PATIENT or OPERATOR.

4) Rotation in relation to the axis of rotation

EXAMPLE 2 The axis of rotation can be the rotation of the detector around its rotation axis of its supporting structure.

- No speed shall exceed $7^\circ \times \text{s}^{-1}$ around the axis 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 MEE stops do not pose an unacceptable RISK to the equipment, PATIENT or OPERATOR.
- When rotating at the speed nearest to, but not exceeding, $1^\circ \times \text{s}^{-1}$ around the axis 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 $1^\circ \times \text{s}^{-1}$, it shall not exceed 3° .

c) PATIENT POSITIONER

- 1) At SINGLE FAULT CONDITION, the interruption or failure of powered movements or of the SUPPLY MAINS for the MEE shall cause any parts in motion to be stopped within the limits given in item 4), 5), and 6).
- 2) For the PATIENT POSITIONER, the maximum acceleration applied to the PATIENT for all linear and rotational movements shall be provided in the ACCOMPANYING DOCUMENTATION.
- 3) 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.
- 4) Rotational movements around the ERP
 - A low speed shall be available for each movement which shall not exceed $1^\circ \times \text{s}^{-1}$ around the axis of rotation.
 - No speed shall exceed $7^\circ \times \text{s}^{-1}$ around the axis of rotation.
 - When rotating at the speed nearest to, but not exceeding, $1^\circ \times \text{s}^{-1}$ around the axis 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 $1^\circ \times \text{s}^{-1}$, it shall not exceed 3° .

5) Linear movements

- A low speed shall be available for displacements of the TABLE TOP which shall not exceed $10 \text{ mm} \times \text{s}^{-1}$.
- No speed shall exceed $100 \text{ mm} \times \text{s}^{-1}$ 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 any speed greater than $25 \text{ mm} \times \text{s}^{-1}$, and 3 mm for speeds not exceeding $25 \text{ mm} \times \text{s}^{-1}$.

6) Rotation in relation to the axis of rotation

EXAMPLE 3 The axis of rotation can be the rotation of the detector around its rotation axis of its supporting structure.

- No speed shall exceed $7^\circ \times \text{s}^{-1}$ around the axis 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 MEE stops do not pose an unacceptable RISK to the equipment, PATIENT, or OPERATOR.
- When rotating at the speed nearest to, but not exceeding, $1^\circ \times \text{s}^{-1}$ around the axis 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 $1^\circ \times \text{s}^{-1}$, it shall not exceed 3° .

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 powered movements 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.

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 MEE parts that can 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 can 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, e.g., some types of ELECTRON BEAM APPLICATORS.

- b) For MEE 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 by RISK MANAGEMENT that the amount of motion and maximum rate of motion is sufficiently limited to avoid an unacceptable RISK to the equipment, PATIENT or OPERATOR.
- c) The switches required in a) and b) above shall be operable sufficiently 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 equivalently safe switching function as demonstrated through RISK MANAGEMENT.

- d) The INSTRUCTIONS FOR USE shall contain advice that when either an intended remotely controlled movement initiated at 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.

TYPE TEST grade A – Inspection of INSTRUCTIONS FOR USE.

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

- a) It shall be impossible to initiate or maintain movements associated with automatic set-up without continuous personal action by the OPERATOR simultaneously on the automatic set-up switch and a switch common to all movements, 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 MEE parts have been set up 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 EBE delivery system. In that case, movement can instead cause BEAM HOLD or INTERRUPTION OF IRRADIATION.
- c) For MEE that has not been pre-programmed, it shall be impossible 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 EBE delivery system. In that case, movement can instead cause BEAM HOLD or INTERRUPTION OF IRRADIATION.
- d) For MEE 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 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 EBE delivery system, then the movement can be possible during BEAM HOLD or INTERRUPTION OF IRRADIATION.
- e) The INSTRUCTIONS FOR USE shall include the recommendation that the OPERATOR should have an unobstructed view of the PATIENT before and during IRRADIATION.
- f) Any INTERRUPTION OF IRRADIATION or TERMINATION OF IRRADIATION shall cause all MEE 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 B – Compliance is checked by inspection.*
- e) *TYPE TEST grade A – Inspection of INSTRUCTIONS FOR USE.*
- 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 movements shall stop from any speed within the limits SPECIFIED in 201.9.2.101.

Compliance is checked as follows:

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 modifying the imaging beam, such means shall be designed to retain those ACCESSORIES securely under all conditions of NORMAL USE.
- b) The ACCOMPANYING DOCUMENTATION shall contain maintenance requirements and define the conditions and limits of use for the ACCESSORIES supplied; they shall include guidance regarding design limits for other ACCESSORIES manufactured or commissioned by the RESPONSIBLE ORGANIZATION.

Compliance is checked as follows:

- a) *TYPE TEST grade A – Compliance is checked by inspection, and by consideration of design data and applied safety factors.*
- b) *TYPE TEST grade A – Compliance is checked by inspection.*

201.9.8.102 Relative movement between immobilisation devices and TABLE TOP

- a) MANUFACTURERS of IGRT 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., headframe) and the TABLE TOP or chair. This analysis shall include, at a minimum, 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 or chair becoming loose or undone.
- b) The ACCOMPANYING DOCUMENTATION shall contain maintenance requirements and define the limits of use for the immobilisation devices supplied by the MANUFACTURERS of IGRT EQUIPMENT.

The ACCOMPANYING DOCUMENTATION shall warn that any immobilisation device or PATIENT POSITIONER EQUIPMENT not described by the X-IGRT EBE SYSTEM MANUFACTURER shall be evaluated for correct system operation and safety by the RESPONSIBLE ORGANIZATION.

Compliance is checked as follows:

- a) *TYPE TEST grade A – Compliance is checked by the inspection of the RISK MANAGEMENT FILE.*
- b) *TYPE TEST grade A – Compliance is checked by inspection.*

201.10 Protection against unwanted and excessive radiation HAZARDS

CT SCANNERS, X-RAY EQUIPMENT for RADIOGRAPHY, or X-RAY EQUIPMENT for RADIOSCOPY, where the following requirements are equivalent and tested according to another standard, do not require retesting and can refer to the corresponding compliance statement or test report (see also Annex AA).

For MEGAVOLTAGE and KILOVOLTAGE X-IGRT EQUIPMENT, Clause 10 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as noted in IEC 60601-2-1:2020 and amended as follows:

NOTE The exceptions defined for MEE also apply to MEGAVOLTAGE and KILOVOLTAGE IGRT EQUIPMENT.

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

Replacement:

201.10.1.2.101 Starting conditions

NOTE Item f) of 201.14.101 from IEC 60601-2-1:2020 permits designated PASSWORDS as alternatives to key control when control is effected by PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS).

In the case of an operational limitation (e.g., remaining available imaging capacity) the X-IGRT EQUIPMENT shall indicate to the OPERATOR whether the chosen X-IGRT task will complete successfully.

In the case of MEGAVOLTAGE X-IGRT IMAGING EQUIPMENT, it shall be possible to start imaging IRRADIATION in NORMAL USE only by OPERATOR action at the control panel when the READY STATE is indicated and after RESPONSIBLE ORGANIZATION enablement by PASSWORD or by the dedicated mechanical key (see 201.10.101.1.14 a) 1) in IEC 60601-2-1:2020).

In the case of KILOVOLTAGE X-IGRT IMAGING EQUIPMENT:

- In NORMAL USE, it shall be possible to start imaging IRRADIATION by OPERATOR action only when the READY STATE is indicated at the imaging control panel.
- For REAL-TIME IGRT, the X-IGRT EQUIPMENT shall provide means to notify the EBE or OPERATOR if the remaining available heat capacity is not expected to be sufficient to allow completion of the TREATMENT.

Compliance is checked as follows:

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

Additional subclause:

201.10.1.2.102 Safety measures against excessive X-RADIATION

- a) X-IGRT imaging area for 2D imaging and volume for 3D imaging shall be defined in the technical description.

Means shall be provided for the X-IGRT IRRADIATION to be terminated by the EBE when the correct function of the X-IGRT EQUIPMENT is dependent on the correct function of the EBE.

The MANUFACTURER'S ACCOMPANYING DOCUMENTATION shall specify the optimal alignment and tolerances for specific protocols.

- b) The following applies for KILOVOLTAGE X-IGRT IMAGING EQUIPMENT:

- 1) means shall be provided to terminate the LOADING automatically by either de-energizing the RADIATION SOURCE or shuttering the X-RAY BEAM in the event of X-IGRT EQUIPMENT failure. Such a termination shall occur within 1 s of such a failure.
- 2) means shall be provided so that the OPERATOR can terminate the LOADING at any time during a continuous image acquisition, or series of continuous image acquisitions under X-RAY EQUIPMENT control, of greater than 0,5 s duration.

- 3) when LOADING has been terminated under circumstances covered in 1) or 2) above, a visible indication of termination shall be provided to the OPERATOR and manual resetting of the IGRT IMAGING PROTOCOL shall be required prior to the initiation of another image acquisition.

Compliance is checked as follows:

- a) *TYPE TEST grade A – Statement regarding X-IGRT imaging area for 2D imaging and X-IGRT imaging volume for 3D imaging; Statement regarding typical imaging doses of the supplied X-IGRT protocols and statement regarding optimal alignment and tolerances for specific protocols.*
- b) *1) and b)2) TYPE TEST grade C – Principle: verification of the functioning of the means to terminate the LOADING.*
- b) *3) SITE TEST grade B – Procedure: Verify visible indication after termination of LOADING and verify that manual reset is required prior to the initiation of another image acquisition.*

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies except as follows:

201.11.1 Excessive temperatures in ME EQUIPMENT

201.11.1.1 Maximum temperature during NORMAL USE

Addition:

Restrictions on allowable maximum temperature for parts in contact with oil shall not apply to parts wholly immersed in oil.

201.11.1.4 Guards

Addition:

Where certain unguarded ACCESSIBLE SURFACES of X-RAY SOURCE ASSEMBLIES can attain high temperatures, means shall be provided to make it impossible to contact such surfaces for any purposes connected with NORMAL USE.

NOTE 1 Examples of such means are covers, handles for operation etc.

Measures shall also be taken to avoid all unintentional contact. In such cases the INSTRUCTIONS FOR USE shall state information about temperatures of ACCESSIBLE SURFACES to be expected in NORMAL USE; see Table 23 of the IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020.

NOTE 2 Taken from IEC 60601-2-28:2014 and IEC 60601-2-54:2009.

Compliance is checked as follows:

TYPE TEST grade A – Inspection of INSTRUCTIONS FOR USE.

TYPE TEST grade C – Perform functional test of the means.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.12.3 ALARM SYSTEMS

Clause 12.3 does not apply.

201.13 Hazardous situations and fault conditions for ME EQUIPMENT

Clause 13 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

Additional subclause:

201.14.101 PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS)

- a) The safety provisions of this document shall apply to any PESS the failure of which can produce a HAZARD.
- b) Software control programmes shall be secured against access or modification without authorization from the MANUFACTURER.

NOTE Unauthorized access to software or firmware could create HAZARDOUS SITUATIONS, make the MEE non-compliant with the requirements of this document, and give the MANUFACTURER good reason to refute warranty claims.

- c) Prevention or TERMINATION OF IRRADIATION, and the stopping of movements, shall occur when a PESS that is part of a monitoring, measuring or control device fails to maintain its safety function.
- d) There shall be only manual control for the INITIATION OF IRRADIATION; thereafter, pre-programmed control of IRRADIATION and movements by PESS is permitted.
- e) Devices under PESS control, designed to set up or pre-position MEE parts from data supplied by a computer-based information file or other means of input, shall provide means for the comparison of the actual setting of the MEE parameters with those of the input data; IRRADIATION shall be prevented when any difference exceeds the SPECIFIED and pre-defined limits set by the RESPONSIBLE ORGANIZATION in accordance with instructions and data given in the INSTRUCTIONS FOR USE.
- f) When control is effected by PESS, designated access control, such as PASSWORDS or biometric security methods, are permitted alternatives for enabling or disabling functions where, in other types of control systems, a key control or designated (mechanical) key is required.
- g) A means to control access, such as PASSWORD or biometric security methods, or key access shall be provided to ensure that these may be controlled by an individual designated by the RESPONSIBLE ORGANIZATION. The technical description shall describe how protection is implemented and how access is controlled.
- h) Protection against unauthorized use shall provide for selective access for different functions so that the RESPONSIBLE ORGANIZATION can specify the levels of protection for SPECIFIC OPERATORS.

EXAMPLE Not all OPERATORS are qualified to perform absolute dose calibration.

- i) Where network connection is permitted by the design, the following requirements apply:
 - access to the MEE shall be provided only to authorized equipment or individuals who are authorized (for example, by a PASSWORD under the control of the RESPONSIBLE ORGANIZATION); and
 - access to calibration values, machine settings, PATIENT identifying information or TREATMENT PLANS (with or without ABSORBED DOSE distribution calculation) through the network shall be restricted so as to prevent unauthorized access.
- j) The MANUFACTURER can employ copy protection to prevent the creation of a useable duplicate MEE not intended by the MANUFACTURER to be used for TREATMENT delivery. Where copy protection is employed, it shall permit backup of data. The existence of copy protection shall be stated in the INSTRUCTIONS FOR USE.
- k) Protection against unauthorized changes to software or data (e.g., viruses) shall be employed. The MANUFACTURER shall state in the ACCOMPANYING DOCUMENTATION the means of protection employed.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding the philosophy and realisation of safe operation using PESS and application of relevant requirements of IEC 62304.

TYPE TEST grade A – Inspection of ACCOMPANYING DOCUMENTATION.

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

201.15 Construction of ME EQUIPMENT

Clause 15 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies.

201.16 ME SYSTEMS

Clause 16 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 does not apply.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies to any part that is not included in the MEEs and is required for the system integration, except as follows:

Additional subclauses:

201.17.101 Additional requirements

The requirements and tests of Clause 17 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020, with the additions given in 201.17.102 and 201.17.103 below, shall apply to imaging equipment and its integral INFORMATION TECHNOLOGY EQUIPMENT (ITE).

NOTE Integral ITE is considered as part of the MEE.

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

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

201.17.102 Radio-frequency EMISSIONS

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

Compliance is checked by measurements, made in accordance with IEC 60601-1-2 and CISPR 11, at 3 m, 10 m or 30 m from the exterior walls of the building containing the location in which the MEE has been installed.

201.17.103 IMMUNITY to radio-frequency electromagnetic fields

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

Compliance is checked by tests made in accordance with IEC 60601-1-2 and IEC 61000-4-3. The test antenna shall be placed at 3 m from the outside of the structural protection against IONIZING RADIATION. Alternatively, where the equipment is classified permanently installed large MEE and ME SYSTEMS, an alternative test method may be used as specified in IEC 60601-1-2:2014, 8.7.

NOTE To conduct tests 3 meters outside the building protection area, obtaining a local radio license can apply.

Additional clauses:

201.101 Reference data for X-IGRT

201.101.1 TREATMENT PLANNING image and data requirements

The technical description shall define the types of images that can be used as a REFERENCE IMAGE by the X-IGRT EQUIPMENT. The required parameters for the REFERENCE IMAGES shall be stated in the ACCOMPANYING DOCUMENTATION.

NOTE An example would be the DICOM conformance statement.

If the X-IGRT EQUIPMENT allows the use of REFERENCE IMAGES that are generated on other MEE, the MANUFACTURER shall state the required parameters for the REFERENCE IMAGES in the ACCOMPANYING DOCUMENTATION.

If the X-IGRT EBE SYSTEM allows data import from 3rd party systems, then data required by the X-IGRT EBE SYSTEM shall be identified in the ACCOMPANYING DOCUMENTATION and at minimum shall contain the description of the required geometrical relationship to TREATMENT PLAN.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding the types of images that can be used as a REFERENCE IMAGE; statement regarding warnings given of potential HAZARDOUS SITUATIONS and statement regarding RTPS data required by the X-IGRT EQUIPMENT.

201.101.2 Distances and linear and angular dimensions

Distance measurements and linear dimensions on the X-IGRT EBE SYSTEM shall be indicated in centimetres or in millimetres but not both. Angular dimensions shall be indicated in degrees (°). All values of distance measurements and linear and angular dimensions requested, displayed or printed shall include their units.

Compliance is checked as follows:

SITE TEST grade B – Procedure: Inspect DISPLAY and output information.

201.101.3 RADIATION quantities

- a) If RADIATION quantities are reported in the X-IGRT EBE SYSTEM, they shall be reported and displayed in consistent units.

Units of RADIATION quantities shall conform to the SI unit. The prefix "centi" can be used. For example, units of RADIATION quantities can be stated in either cGy or mGy but not in both.

- b) All values of RADIATION quantities requested, displayed or printed shall include their units.

NOTE Monitor units are not considered a unit of RADIATION quantity but are related to the dose quantity by a conversion factor.

Compliance is checked as follows:

SITE TEST grade B – Procedure: Verify that RADIATION quantities displayed or printed include their units.

201.101.4 Date and time format

When the date is displayed or printed, correct interpretation shall not depend upon the OPERATOR's interpretation of format, and a DISPLAY of the year shall be in four digits.

NOTE 1 Examples acceptable: "03 Apr 2005", "2005/04/03 (yyyy/mm/dd)".

NOTE 2 Examples not acceptable: "03/04/05", "03 Apr 05".

When the time of day is requested, displayed or printed, it shall be represented on a 24 h clock basis, or the letters "a.m." and "p.m." shall be appropriately included.

NOTE 3 By convention, noon is 12:00 p.m. and midnight is 12:00 a.m.

Measurements of time shall include units (hours, minutes, seconds or hr, min, sec).

When an amount of time is entered or printed, each denomination of time shall have its units displayed. To prevent confusion with numbers, single-letter abbreviations of time denomination shall not be used (for example h,m,s).

NOTE 4 Examples acceptable: 2,05 min; 1 hour 33 minutes; "1:43:15 (hr:min:sec)".

Compliance is checked as follows:

SITE TEST grade B – Procedure: Inspection of the DISPLAY and output information.

201.101.5 Data limits

Data elements entered by the OPERATOR or acquired from a device or network shall be compared against pre-established limits. Operation shall be prevented if the data are outside these limits unless the OPERATOR overrides a warning message prior to the start of IRRADIATION. Limits for those data elements that are entered by the OPERATOR shall be provided in the INSTRUCTIONS FOR USE or shall be provided as part of the error messages displayed when these limits are exceeded.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding limits for data elements that are entered by the OPERATOR.