IEC 60601-2-68

Edition 2.0 2025-02
REDLINE VERSION

INTERNATIONAL STANDARD

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

IEC 60601-2-68:2025-02 RLV(en)

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INTERNATIONAL
ELECTROTECHNICAL
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at https://patents.iec.ch. IEC shall not be held responsible for identifying any or all such patent rights.

This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition IEC 60601-2-68:2014. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

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 ~~may~~ can extend over many days, during which the TARGET VOLUME/PATIENT ~~may~~ can shrink or grow ~~and/~~or move. Hence, the exact location of the TARGET VOLUME/critical structures ~~may~~ 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 ~~AND/~~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 ~~and/~~or other reference features, to compensate for anatomical changes including internal organ motions ~~and/~~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, ~~medical~~ 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.

~~This particular standard applies to X-ray based IGRT equipment used in-room for IGRT purposes. This particular standard does not apply to standard CT scanners, which are not used for IGRT. However if a CT scanner is used in-room with a linear (electron) accelerator (linac) for IGRT then this particular standard applies.~~

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 ~~may or may~~ does not ~~require~~ 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 60976, *Medical electrical equipment – Medical electron accelerators – Functional performance characteristics*~~

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

– IEC 60601-2-1

– IEC 60601-2-44

– IEC 60601-2-64

– IEC 62083

– IEC 61217

– IEC 62274

~~This particular standard may give rise to amendments to some of the above standards.~~

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 –

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

201.1 Scope, object and related standards

Clause 1 of ~~the general standard[1]~~ 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 ~~known~~ 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 ~~EXTERNAL BEAM~~ EBE SYSTEM ~~(X-IGRT EBS)~~. 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.

~~[1] The general standard is IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*~~

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 ~~appropriately licensed or~~ the RESPONSIBLE ORGANIZATION by QUALIFIED PERSONS ~~by OPERATORS~~ having the required skills for a particular medical application, for particular specified clinical purposes, e.g., STATIONARY RADIOTHERAPY or MOVING BEAM RADIOTHERAPY,
- maintained in accordance with the recommendations given in the INSTRUCTIONS FOR USE, 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.

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

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.

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

The numbering of 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.~~139~~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

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

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-2-1:~~2009~~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 60601-2-44:2012, *Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography*~~

~~IEC 60731:2011, *Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy*~~

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

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

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 61223-3-5:2004, *Evaluation and routine testing in medical imaging departments – Part 3-5: Acceptance tests – Imaging performance of computed tomography X-ray equipment*~~

~~IEC 61262-7:1995, *Medical electrical equipment – Characteristics of electro-optical X-ray image intensifiers – Part 7: Determination of the modulation transfer function*~~

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

~~IEC 62274:2005, *Medical electrical equipment – Safety of radiotherapy record and verify systems*~~

~~IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*~~

~~IEC 62396-1:2012, *Process management for avionics – Atmospheric radiation effects – Part 1: Accommodation of atmospheric radiation effects via single event effects within avionics electronic equipment*~~

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*

~~NOTE Informative references are listed in the bibliography beginning on page 58.~~

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:

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

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

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

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

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

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

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.~~5~~6.2);

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

$D_{Ref}(y)$ 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.~~5~~6.2) for $(N \times T)_{Ref}$;

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

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

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 x N x 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.

~~Note 9 to entry: The note to entry concerning the origin of the abbreviation *CTDI* APPLIES TO THE FRENCH TEXT ONLY.~~

[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*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

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

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~~, but not less than 100 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.

~~Note 2 to entry: The note to entry concerning the origin of the abbreviation CNR APPLIES TO THE FRENCH TEXT ONLY.~~

[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)

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

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.

~~Note 6 to entry: The note to entry concerning the origin of the abbreviation DLP APPLIES TO THE FRENCH TEXT ONLY.~~

[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~~/AMD1:2012~~, 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.~~207~~208
EXTERNAL BEAM EQUIPMENT
EBE
external RADIATION EQUIPMENT utilizing ELECTRON ACCELERATORS, light ion beam medical electrical equipment or RADIONUCLIDE BEAM THERAPY EQUIPMENT

~~Note 1 to entry: The note to entry concerning the origin of the abbreviation EBE APPLIES TO THE FRENCH TEXT ONLY.~~

201.3.~~208~~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.~~209~~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 note to entry concerning the origin of the abbreviation IGRT APPLIES TO THE FRENCH TEXT ONLY.~~

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.~~210~~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.~~211~~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.~~212~~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.~~213~~216
KILOVOLTAGE X-IGRT EQUIPMENT
X-IGRT EQUIPMENT using kilovoltage X-RADIATION

201.3.~~214~~217
MEGAVOLTAGE X-IGRT EQUIPMENT
X-IGRT EQUIPMENT using megavoltage X RADIATION

201.3.~~215~~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.

~~Note 2 to entry: The note to entry concerning the origin of the abbreviation MTF APPLIES TO THE FRENCH TEXT ONLY.~~

[SOURCE: ~~IEC 62220-1:2003, 3.9~~ 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.~~216~~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.~~217~~221
OFFLINE IGRT
IGRT for the purpose of PATIENT setup ~~and/~~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 ~~positioning device~~ POSITIONER and is immobile during and in-between imaging and TREATMENT.

201.3.~~219~~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]

~~**201.3.220**~~
~~**PROTOCOL ELEMENT**~~
~~set of the particular CBCT CONDITIONS OF OPERATION necessary to perform a scan~~

~~Note 1 to entry: The following modes are examples of different types of scan: helical, axial, axial series, scanning without movement of the patient support 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 "PROTOCOL ELEMENT", e.g., "scan", "scan group", "scan series", "presets", "CBCT modes" etc., which actually means "PROTOCOL ELEMENT"~~

~~Note 3 to entry: A PROTOCOL ELEMENT is typically associated with a IGRT task, anatomical region, and/or age or size group.~~

~~[SOURCE: IEC 60601-2-44:2009/AMD1:2012, 201.3.216, modified – The reference to "CT" in the original definition has been replaced by a reference to "CBCT" and Notes 2 and 3 to entry have been changed.]~~

201.3.~~221~~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.~~222~~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.~~223~~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.~~224~~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 ~~may~~ 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.~~225~~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~~/AMD1:2012~~, 201.3.207]

201.3.~~226~~229
SPATIAL RESOLUTION
resolution also known as HIGH-CONTRAST RESOLUTION and described by the MODULATION TRANSFER FUNCTION

201.3.~~227~~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 — ~~the term incorporates the context of an image display system~~ Addition of Note 1 to entry.]

201.3.~~228~~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.~~229~~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 ~~CT CONDTIONS OF OPERATION~~ 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 × Δd.

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 × Δd.

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>

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

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 ~~CT CONDTIONS~~ 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 × N × 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 ~~CT CONDITIONS OF OPERATION~~ 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.~~230~~233
WEIGHTED $CTDI_{100}$
$CTDI_W$
value defined as

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

where

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

$CTDI_{100(peripheral)}$ is the average of the four values of $CTDI_{100}$ measured around the dosimetry PHANTOM periphery according to ~~201.102.1.5.2.1.1~~ 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.~~231~~234
X-IGRT EBE SYSTEM
system comprising of X-IGRT EQUIPMENT and EXTERNAL BEAM EQUIPMENT

201.3.~~232~~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.~~233~~236
X-IGRT IMAGING COMPONENT
part of the X-IGRT EQUIPMENT that performs the imaging function

~~**201.3.234**~~
~~**X-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 should also state its latency time from receiving the signal to providing the correction.~~

~~Note 2 to entry: The X-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 user. Network transfer latency therefore is not considered as part of the X-IGRT LATENCY time.~~

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 ~~ME EQUIPMENT~~ 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 ~~ME EQUIPMENT~~ 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 ~~ME EQUIPMENT~~ MEE.

– TYPE TEST/SITE TEST grade C: Functional test or measurement of the ~~ME EQUIPMENT~~ 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 ~~ME EQUIPMENT~~ MEE, the test ~~should~~ 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 ~~DOCUMENTS~~ 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 ~~DOCUMENTS~~ 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 ~~DOCUMENTS~~ 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 ~~DOCUMENTS~~ DOCUMENTATION for all non-adjustable BEAM LIMITING DEVICES (BLDs).

For adjustable devices, the range of the GEOMETRICAL RADIATION FIELD at the NOMINAL REFERENCE ~~plane~~ DISTANCE shall be specified in the ACCOMPANYING ~~DOCUMENTS~~ 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 ~~its~~ the distal end to the ~~nominal reference distance~~ 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 ~~DOCUMENTS~~ 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 ~~of an X-IGRT EQUIPMENT~~

~~a) where a mechanical scale, numerical readout or a status indicator aligns with an IEC 61217 axis, then the IEC 61217 axis shall be used for each available IEC 61217 movement;~~

~~NOTE 1 This does not apply to a value for a movement that is not defined by IEC 61217~~

~~b) a means shall be provided to align the PATIENT with respect to the reference point of the X-IGRT EQUIPMENT (e.g. LIGHT FIELD, lasers etc.);~~

~~NOTE 2 For X-IGRT EQUIPMENT that share the same REFERENCE POINT as the EBE then the means to align can be the same as the EBE.~~

~~c) a means shall be provided to determine the distance from the X-IGRT EQUIPMENT RADIATION SOURCE and RADIATION DETECTOR to the reference point (e.g. scale, numerical indication or lasers) for X-IGRT EQUIPMENT with adjustable distances from the RADIATION SOURCE or RADIATION DETECTOR to the reference point .~~

~~D) the distances from the RADIATION SOURCE and the RADIATION DETECTOR to a reference point shall be stated in the ACCOMPANYING DOCUMENTS for X-IGRT EQUIPMENT with both a fixed source and fixed RADIATION DETECTOR to reference point distance(s).~~

~~e) 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 3 The distance for a kilovoltage RADIATION SOURCE is measured from its focal spot.~~

~~NOTE 4 For isocentric equipment, the reference point is the ISOCENTRE for that piece of equipment.~~

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 ~~by inspection~~ 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 ~~may require~~ 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, ~~may~~ 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.~~104~~103	~~a) d)~~ e)	f)		a) b) c) ~~e) f) g)~~ d)	

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
201.9.7.101		†			
201.9.8.101	a) b)				
201.9.8.102	b)				
201.10.1.2.101~~.11~~	†				
201.10.1.2.~~105~~102	a)		b)	b)	
201.11.~~101~~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)		~~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.~~5~~6.1	a) b)				
201.102.~~5~~6.2.2.1	†				
201.102.~~5~~6.2.2.2	†				
201.102.~~5~~6.2.2.3	†				
201.102.~~5~~6.2.2.4	†				
201.102.~~5~~6.2.2.5	†	†			
201.102.~~5~~6.2.2.6	†				
201.102.~~5~~6.2.2.7		†			
201.103.1	a) b) ~~c)~~				
201.103.2	a) b) c)				
201.103.3.1	†	†		†	
201.103.3.2	†	†		†	
201.103.3.3	†	†		†	
201.104	a) d)			b) c) e) f)	

~~NOTE~~
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~~ DOCUMENTS~~ 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 ~~DOCUMENTS~~ DOCUMENTATION, INSTRUCTIONS FOR USE and the technical description

~~CHECK REFERENCE~~	~~ACCOMPANYING DOCUMENTS~~	~~INSTRUCTIONS FOR USE~~	~~TECHNICAL DESCRIPTION~~
~~1~~	~~201.2~~		
~~2~~			~~201.5.1.101~~
~~3~~	~~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~~	~~201.7.9.2.5~~	
~~12~~			~~201.7.9.2.15~~
~~13~~			~~201.8.11.1~~
~~14~~	~~201.9.2.4.101~~		
~~15~~	~~201.9.2.101~~	~~201.9.2.101~~	
~~16~~		~~201.9.2.102~~	
~~17~~		~~201.9.2.103~~	
~~18~~	~~201.9.2.104~~		
~~19~~	~~201.9.8.101~~		
~~20~~	~~201.9.101~~		
~~21~~	~~201.10.1.2.105~~		~~201.10.1.2.105~~
~~22~~		~~201.11.101~~	
~~23~~		~~201.14.101~~	
~~24~~	~~201.17.101~~		
~~25~~	~~201.101.1~~		~~201.101.1~~
~~26~~		~~201.101.5~~	
~~27~~	~~201.101.6~~		
~~28~~	~~201.101.7~~		
~~29~~			~~201.101.8~~
~~30~~	~~201.101.9.1~~		
~~31~~		~~201.101.9.2~~	
~~32~~		~~201.102.2~~	
~~33~~	~~201.102.4~~		~~201.102.4~~
~~34~~	~~201.102.5.1~~		~~201.102.5.1~~
~~35~~	~~201.102.5.2.2.1~~		
~~36~~	~~201.102.5.2.2.2~~		
~~37~~	~~201.102.5.2.2.3~~		
~~38~~	~~201.102.5.2.2.4~~		
~~39~~	~~201.102.5.2.2.5~~		

~~CHECK REFERENCE~~	~~ACCOMPANYING DOCUMENTS~~	~~INSTRUCTIONS FOR USE~~	~~TECHNICAL DESCRIPTION~~
~~40~~	~~201.102.5.2.2.6~~		
~~41~~		~~201.103.1~~	~~201.103.1~~
~~42~~		~~201.103.2~~	~~201.103.2~~
~~43~~	~~201.103.3.1~~	~~201.103.3.1~~	
~~44~~	~~201.103.3.2~~	~~201.103.3.2~~	
~~45~~	~~201.103.3.3~~	~~201.103.3.3~~	
~~46~~	~~203.4.1~~		
~~47~~	~~203.6.3.2~~		
~~48~~	~~203.8.4~~		
~~49~~	~~203.10.2~~	~~203.10.2~~	
~~NOTE The check reference is given as an aid for checking the availability of compliance documentation.~~			

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		
29	201.101.1		201.101.1

Check reference	ACCOMPANYING DOCUMENTATION	INSTRUCTIONS FOR USE	Technical description
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 ~~DOCUMENTS~~ DOCUMENTATION shall describe the ~~X-IGRT EQUIPMENT~~ devices or systems supplied or recognized by the X-IGRT EBE SYSTEM MANUFACTURER for use with the X-IGRT EBE SYSTEM.

The ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION shall warn that any ~~X-IGRT EQUIPMENT~~ 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 ~~DOCUMENTS~~ DOCUMENTATION shall contain a cautionary statement regarding the potential detrimental interaction of the imaging and therapeutic RADIATION with active implantable medical devices ~~and~~ 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 ~~X-~~IGRT LATENCY time of the X-IGRT EQUIPMENT to perform its function shall be stated in the ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION. The conditions used to determine the ~~X-~~IGRT LATENCY time shall also be stated in the ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION. Where the time between images is not operator determined, the time between images shall also be stated.

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

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

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

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 geometry of the X-ray imaging beam shall be defined in the technical description~~ 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 ~~may~~ 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. ~~Where installation prevents a test, a hazard analysis shall be conducted instead.~~ 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

~~CT SCANNERS~~ 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 ~~associated with PATIENT scanning~~.

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 ~~ME EQUIPMENT~~ 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 ~~might~~ 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 ~~CT SCANNERS~~ 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 ~~by inspection and test~~ 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, do not 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 ~~may~~ 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 ~~should~~ 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 ~~are to~~ 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 ~~is to~~ 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 ~~are to~~ 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 ~~is to~~ 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 ~~should to~~ 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 ~~ME EQUIPMENT~~ MEE or externally in as many places as ~~may be considered~~ 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 ~~ME EQUIPMENT~~ MEE parts automatically to the positions required for the start of a PATIENT TREATMENT or imaging. This includes when pre-programed movements are initiated by the operator.

NOTE 102 The term 'pre-programmed movements' is used where movement of ~~ME EQUIPMENT~~ 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

~~For the PATIENT SUPPORT system, 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 IEC 60601-1:2012 FIGURE A.19.~~

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 ~~to be~~ incorporated on site by the RESPONSIBLE ORGANIZATION, the requirements and SITE TEST procedures shall be SPECIFIED in the ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION and the results ~~should~~ 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 ~~DOCUMENTS~~ DOCUMENTATION, and by inspection and measurement of stopping distances and disconnection times using suitable measuring ~~instruments~~ 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 GANTRY, RADIATION HEAD and PATIENT SUPPORT system**~~

~~a) General~~

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

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

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

~~4) For automatic set-up and for the checks of pre-programmed movements before start of imaging, the overshoot shall not exceed 2° for rotational displacements 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.~~

~~5) Additional means shall be provided for avoiding any collision and the ACCOMPANYING DOCUMENTS shall include a statement to evoke cautions, if the angle or distance required for stopping movement exceeds the values specified in 201.9.2.101 b) and c).~~

~~6) Where the possibility exists that failure of a powered movement during NORMAL USE might result in the PATIENT becoming trapped, means shall be provided to permit release of the PATIENT; these means shall be described in the INSTRUCTIONS FOR USE.~~

~~b) Rotational movements~~

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

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

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

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

c) Linear movements

1) The minimum speed available for displacements 20, 21, 22 and 23 as specified in IEC 61217, Figure 13c of the RADIATION FIELD edges, and displacements 9, 10 and 11 as specified in Figure 201.101 of the PATIENT SUPPORT system shall not exceed $10 \text{ mm} \cdot s^{-1}$.

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

3) The distance between the position of the moving part, at the instant of operating any control to stop the movement, and its final position shall not exceed 10 mm for any speed greater than $25 \text{ mm} \cdot s^{-1}$, and 3 mm for speeds not exceeding $25 \text{ mm} \cdot s^{-1}$ unless it can be shown through RISK MANAGEMENT that the distances achieved do not pose an unacceptable RISK to the equipment, PATIENT or OPERATOR.

Exception – Requirement 1) and 2) above does not apply to the BEAM LIMITING SYSTEM (BLS).

Compliance is checked as follows:

1) by inspection of the instructions for use and the facilities provided;

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

3) by inspection and measurement.

201.9.2.101 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°. 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° × 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° × 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°. For speeds faster than 1° × 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° × s^{-1} around the axis of rotation.

– No speed shall exceed 7° × s^{-1} around the axis of rotation.

– When rotating at the speed nearest to, but not exceeding, 1° × 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°. For speeds faster than 1° × 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 mm × s^{-1}.

– 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}.

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° × 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° × 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°. For speeds faster than 1° × 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 ~~ME EQUIPMENT~~ MEE parts that ~~may~~ 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 ~~may~~ 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 ~~ME EQUIPMENT~~ 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 ~~injury~~ or OPERATOR.

c) The switches required in a) and b) above shall be operable sufficiently close to the PATIENT ~~SUPPORT system~~ 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 ~~control panel~~ TCP or a pre-programmed movement is included in the TREATMENT ~~prescription~~ PLAN, with the PATIENT ~~finally positioned~~ in position for TREATMENT, a check of all intended or planned movements should be made by the OPERATOR before leaving the TREATMENT ROOM.

~~*Compliance is checked by inspection.*~~

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 ~~ME EQUIPMENT~~ MEE parts have been set up automatically ~~and/~~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 ~~support device~~ POSITIONER motion to re-align the TARGET VOLUME to the planned location in relation to the EBE delivery system. In that case, movement ~~may~~ can instead cause BEAM HOLD or INTERRUPTION OF IRRADIATION.

~~NOTE "Pre-programmed" includes planned movements of the ME EQUIPMENT in response to PATIENT position; e.g. respiratory tracking, TARGET VOLUME movement, etc. during PATIENT treatment.~~

c) For ~~ME EQUIPMENT~~ 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 ~~support device~~ POSITIONER motion to re-align the TARGET VOLUME to the planned location in relation to the EBE delivery system. In that case, movement ~~may~~ can instead cause BEAM HOLD or INTERRUPTION OF IRRADIATION.

d) For ~~ME EQUIPMENT~~ 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 ~~support device~~ POSITIONER motion to re-align the TARGET VOLUME to the planned location in relation to the EBE delivery system, then the movement ~~may~~ 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 ~~ME EQUIPMENT~~ MEE parts in motion to be stopped within the limits given in 201.9.2.101.

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

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.*

~~201.9.2.104 Operation of movements of ME EQUIPMENT parts from outside the facility~~

~~The X-IGRT EQUIPMENT may be provided with the capability for electronic access (e.g. via the Internet) to the control system for the purpose of diagnostic evaluation of the equipment. Such evaluation may necessitate operation of equipment capabilities. For example, the TCP may be controlled by a remote site for such purposes. When functions and controls are accessed remotely from outside the facility:~~

~~a) a means shall be provided at the TCP to enable control by a remote operator;~~

~~b) the equipment must require an action at the TCP at the time a connection is established and before any functions or movements are controlled remotely;~~

~~c) the TCP shall indicate whenever a remote connection is established; and~~

~~d) any movements shall comply with the provisions of subclause 201.9.2.101.~~

~~In addition, it shall be impossible through remote access to:~~

~~e) violate or override any of the provisions of subclauses 201.9.2.102 and 201.9.2.103; or~~

~~f) allow the remote OPERATOR to bypass interlocks that could result in injury to any person; or~~

~~g) allow the remote OPERATOR to turn on any RADIATION SOURCES.~~

~~*Compliance tests:*~~

~~*a) TYPE TEST Grade A – Inspection of ACCOMPANYING DOCUMENTS.*~~

~~*b) SITE TEST* Grade B: attempt to connect from a remote site to the *X-IGRT EBE SYSTEM* without first providing action at the TCP and verify that control cannot be established.~~

~~*c) SITE TEST Grade B – Demonstrate that the display indicates remote operation under remote control.*~~

~~*d) TYPE TEST* Grade A: Inspection of *ACCOMPANYING DOCUMENTS.*~~

~~e), f), and g) *SITE TEST* Grade B: demonstrate function of remote diagnostic capability.~~

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.

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

b) The ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION shall contain maintenance requirements and define the conditions and limits of use for the ACCESSORIES supplied; they ~~should~~ 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.*

~~*Additional subclause:*~~

201.9.~~101~~8.102 Relative movement between immobilisation devices and ~~PATIENT SUPPORT~~ **system** 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 ~~PATIENT SUPPORT system~~ 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 ~~PATIENT SUPPORT system~~ TABLE TOP or chair becoming loose or undone.

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

b) The ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION shall contain maintenance requirements and define the limits of use for the immobilisation devices supplied by the MANUFACTURERS of IGRT EQUIPMENT.

The ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION shall warn that any immobilisation device or PATIENT ~~SUPPORT system~~ 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:~~2009~~2020 and amended as follows:

NOTE The exceptions defined for ~~ME EQUIPMENT~~ 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~~.11~~ Starting conditions

~~*Replacement:*~~

NOTE Item f) of 201.14.101 from IEC 60601-2-1:~~2009~~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 ~~201.10.1.2.101.10a)~~ 201.10.101.1.14 a) 1) in IEC 60601-2-1:~~2009~~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.~~105~~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.

~~NOTE 1 It is expected that the input signal will not be capable of a false correct functioning signal.~~

~~The ACCOMPANYING DOCUMENTS shall state the typical imaging doses for the supplied X-IGRT protocols.~~

~~Where no protocols are supplied, clinical examples of imaging dose should be illustrated.~~

~~The MANUFACTURER'S ACCOMPANYING DOCUMENTS shall specify what the optimal alignment and tolerances are 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 ~~CONDITIONS OF OPERATION~~ IGRT IMAGING PROTOCOL shall be required prior to the initiation of another ~~scan~~ 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:~~2010~~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 the general standard does not apply.~~

~~NOTE 1 Accuracy of controls and instruments (12.1 of the general standard) does not apply as it is covered by 201.9 and 201.10.~~

~~NOTE 2 12.2 of the general standard (USABILITY) does not apply as it is covered by Clause 206.~~

~~NOTE 3 12.3 of the general standard (ALARM SYSTEMS) does not apply as these systems use interlocks for safety controls.~~

~~NOTE 4 12.4 of the general standard (Protection against hazardous output) does not apply as it is covered by 201.10.~~

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) ~~Control software and firmware~~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 ~~conditions~~ SITUATIONS, make the ~~ME EQUIPMENT~~ 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 ~~ME EQUIPMENT~~ 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 ~~ME EQUIPMENT~~ 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 ~~may~~ can be those of RESPONSIBLE ORGANIZATIONS or of the MANUFACTURER. Any allowances made shall be justified and included in the ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION.

The requirements for compliance shall be those applying to PERMANENTLY INSTALLED ~~ME EQUIPMENT~~ 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 ~~ME EQUIPMENT~~ 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 ~~ME EQUIPMENT~~ 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 ~~ME EQUIPMENT~~ 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 ~~DOCUMENTS~~ 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 ~~ME EQUIPMENT~~ MEE, the MANUFACTURER shall state the required parameters for the REFERENCE IMAGES in the ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION.

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

~~NOTE If, as in the case of an isocentric gantry based system, the X-IGRT EQUIPMENT shares the same geometric reference as the EBE, then stating such in the ACCOMPANYING DOCUMENTS is deemed to be in compliance with the geometric reference requirement.~~

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 ~~should~~ shall conform to the SI unit. The prefix "centi" ~~may~~ can be used. For example, units of RADIATION quantities ~~may~~ 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 ~~and/~~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.

SITE TEST grade B – Procedure: Attempt to enter data elements outside the stated limits.

201.101.6 * Conformance of data bounds from X-IGRT EQUIPMENT to EBE

Means shall be provided to allow the user to set maximum bounds for control parameters transmitted from the X-IGRT EQUIPMENT to the EBE unless the RISK ASSESSMENT shows an increase to RISK.

When the maximum bounds are exceeded, therapeutic IRRADIATION shall be inhibited, and the OPERATOR shall be informed.

The allowable range of these bounds shall be described in the ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding maximum bounds for control parameters transmitted from the X-IGRT EQUIPMENT to the EBE.

SITE TEST grade B – Procedure: Attempt to start IRRADIATION with maximum bounds exceeded; the therapeutic irradiation is inhibited, and the OPERATOR is informed.

201.101.7 Verification of data coherence and selection of TREATMENT PARAMETERS

a) Consistency, correctness and completeness of the imported data set or data being loaded shall be checked by the X-IGRT EQUIPMENT before it can be accepted for IGRT.

b) In the case of inconsistency, incorrectness or incompleteness of the imported data set or data being loaded, IGRT shall not be allowed to commence without:

   1) explicit display of the identified deficiencies to the OPERATOR, and

   2) ability of the OPERATOR to change or accept the identified deficiencies.

c) In the case of abnormal termination of the X-IGRT IMAGING COMPONENT, the image data shall be recorded.

   NOTE 1 In the case of abnormal termination it ~~may not~~ can be ~~possible~~ impossible to record all of the image data normally available in non-abnormal termination conditions.

   In the case of restarting after abnormal termination, the consistency, correctness and completeness of the data set required for completing the IGRT shall be checked by the X-IGRT EQUIPMENT before it can be accepted for IGRT.

d) MANUFACTURER shall state in ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION the data set required by the X-IGRT EQUIPMENT.

   NOTE 2 Data set consists of the correct combinations of RTPS information e.g., CT images, machine model, etc. that are needed for correct treatment delivery.

Compliance is checked as follows:

a) TYPE TEST grade B – Procedure: Attempt to import a data set, that is 1) not consistent, 2) not correct and 3) not complete and try to commence.

b) SITE TEST grade B – Procedure: Attempt to import a data set containing faults and try to commence. If the design is such that a data set with a fault cannot be created on-site, then this test shall be a TYPE TEST.

c) SITE TEST grade B – Procedure: Causation of termination of imaging and causation of TERMINATION OF IRRADIATION by specified means; inspect the data set recorded.

SITE TEST grade B – Procedure: Attempt to import the recorded data set and confirm that complete data were imported.

d) TYPE TEST grade A – Statement regarding the data set required by the X-IGRT EQUIPMENT.

201.101.8 Correctness of data transfer

a) Data transferred to or from other devices to or from the X-IGRT EBE SYSTEM shall use a communication protocol that verifies error-free data transmission. The MANUFACTURER shall specify these protocols in the technical description.

NOTE Example: communication protocol DICOM.

b) If data are transferred to or from another device, other than closed communication within an X-IGRT EBE SYSTEM ~~and/~~or an integrated RTPS that has been type tested by the MANUFACTURER, then,

– the format of the transferred data shall be included in the technical description, including (but not limited to) identification of all data elements, data types, and data limits; and

– the data output shall include the date on which the data was written and any relevant identifiers for the PATIENT, X-IGRT EBE SYSTEM and TREATMENT PLAN.

Compliance is checked as follows:

a) TYPE TEST grade A – Statement regarding communication protocol specifications.

b) TYPE TEST grade A – Statement regarding format of the transferred data, including identification of all data elements, data types, and data limits;

SITE TEST grade B – Procedure: Transfer data from device and check output information.

201.101.9 Confidence in correctness of supplied geometry

201.101.9.1 Correlation of imaging system and treatment system frames of reference

~~Relationships between imaging geometries and the treatment geometry of the IGRT EQUIPMENT TO THE EBE shall be described as a diagram in the ACCOMPANYING DOCUMENTS.~~

~~Design offset between the imaging system and treatment frames of reference shall be defined in the ACCOMPANYING DOCUMENTS in accordance with IEC 61217.~~

The relationship between the imaging coordinate system and treatment coordinate system shall be defined in the ACCOMPANYING DOCUMENTATION in accordance with IEC 61217.

The X-IGRT EQUIPMENT ~~may~~ can have an alternative scheme of coordinates selectable by the RESPONSIBLE ORGANIZATION if that coordinate system matches the one on the receiving EXTERNAL BEAM EQUIPMENT.

If the coordinate system is not in accordance with IEC 61217 the MANUFACTURER shall state in its ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION a transformation method from these coordinates into IEC 61217 coordinates.

Compliance is checked as follows:

– *TYPE TEST grade A – ~~Statement regarding relationships between imaging geometries and the treatment geometry of the X-IGRT EBE SYSTEM.~~ Checking the ACCOMPANYING DOCUMENTATION.*

– *SITE TEST grade ~~C~~ B – Principle: Targeting test to show the correlation between the imaging and TREATMENT geometry are within the manufacturer's specifications.*

201.101.9.2 Correlation of ~~reference and treatment~~ the PATIENT orientation with the REFERENCE IMAGES

When the REFERENCE IMAGE is displayed, the PATIENT orientation in the REFERENCE IMAGE shall also be displayed.

When exported, X-IGRT images shall include the coordinates and PATIENT orientation in the X-IGRT images.

If scales are displayed, the method by which the scale is displayed shall be explained in the INSTRUCTIONS FOR USE.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding the method of display of scales.

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

201.101.9.3 Geometric relationship

The relationship between X-IGRT EQUIPMENT and EBE geometries shall be specified in the ACCOMPANYING DOCUMENTATION including accuracy and technique of measurement establishing this.

NOTE This is an example of some items to consider:

Detailing limits on how these relationships ~~may~~ can change with time:

- Long term e.g., mechanical drift;
- Short term e.g., during fraction (rotation etc.);
- With user activity e.g., fitting accessories, removing/deploying hardware;
- With machine geometry;
- With IGRT technique.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding the relationship between X-IGRT EQUIPMENT and TREATMENT EQUIPMENT geometries including accuracy, technique of measurement and importance of periodic reassessment.

201.102 X-IGRT imaging

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).

201.102.1 Saving data

201.102.1.1 Image identification

If an image acquisition is initiated, the following shall be saved:

- date and time of the image acquisition;
- data sufficient to allow determination of dose;
- identification of OPERATOR;
- identification of PATIENT;
- the X-IGRT EQUIPMENT hardware model and revision at the time of acquisition; and
- the X-IGRT EQUIPMENT software version used at the time of acquisition.

NOTE As long as the above information is saved to allow association with the acquired image, it is not required that the information all exist on the X-IGRT EQUIPMENT.

Compliance is checked as follows:

SITE TEST grade B – Procedure: Perform an image acquisition and inspect the saved data.

201.102.1.2 Image approval information

When an image is saved, it shall be unambiguously associated with the image identification. Where an image approval is required, the following information shall be additionally saved:

- time and date when the image was approved; and
- identification of the approval authority.

NOTE As long as the above information is saved to allow association with the acquired image, it is not required that the information all exist on the X-IGRT EQUIPMENT.

Compliance is checked as follows:

SITE TEST grade B – Procedure: Inspect the saved data.

201.102.2 Action before X-IGRT

When an OPERATOR retrieves information pertaining to a PATIENT TREATMENT, the following information shall be displayed to the OPERATOR to identify that information as being unique for that TREATMENT session:

~~This shall include at a minimum:~~

- identification of PATIENT; and
- identification of TREATMENT PLAN.

When the following information is provided to the MEE through electronic means, the following information shall also be displayed to the OPERATOR:

- the fraction number of the sequence of fractions defined in the TREATMENT PLAN; and
- the PATIENT orientation.

NOTE Only the information in the data set needed to identify the PATIENT treatment can be displayed.

Approval by the OPERATOR shall be recorded by the X-IGRT EBE SYSTEM or where such capability is not provided, the MANUFACTURER shall include in the INSTRUCTIONS FOR USE a recommendation that the RESPONSIBLE ORGANIZATION ensure that such information is recorded by another system. This information shall include the identification of the OPERATOR.

~~NOTE Not all the information contained in the data set need be displayed but only that information in the data set needed to identify the PATIENT treatment as being unique for that treatment.~~

Compliance is checked as follows:

SITE TEST grade B – Procedure: Perform a visual inspection.

201.102.3 Abnormal termination

In the event of abnormal termination of IGRT, the X-IGRT EQUIPMENT shall display to the user a warning or error depending on impact to IGRT.

A warning shall be displayed when the workflow is valid but ~~may~~ can be prone to errors.

An error shall be displayed when the workflow is invalid and cannot be used.

In the case of abnormal termination of the X-IGRT EQUIPMENT the image data shall be recorded.

In the case of restarting after abnormal termination, the consistency, correctness and completeness of the data set required for completing the IGRT shall be checked by the X-IGRT EBE SYSTEM before it can be accepted for IGRT.

In the case of inconsistency, incorrectness or incompleteness of the data set being loaded, IGRT shall not be allowed to commence without:

- explicit display of the identified deficiencies to the OPERATOR; and
- ability of the OPERATOR to change or accept the identified deficiencies.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding warnings given of potential HAZARDOUS SITUATIONS.

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

SITE TEST grade B – Attempt to import a data set that fails the consistency, correctness and completeness test and verify that IGRT cannot commence. If the design is such that a data set with a fault cannot be created on-site, then this test shall be a TYPE TEST.

201.102.4 Image quality

The image quality and the method of measurement of the X-IGRT IMAGING COMPONENT shall be specified in the technical description. Where applicable, the method used to measure image quality in NORMAL USE of the X-IGRT IMAGING COMPONENT shall be described directly or by reference to a published reference.

The quality of the IMAGE DISPLAY DEVICE for the IGRT images shall be specified in the ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION. This shall at a minimum state the CONTRAST and SPATIAL RESOLUTION of the IMAGE DISPLAY SYSTEM.

When the IMAGE DISPLAY DEVICE quality is less than that stated by IEC 62563-1:2009, the MANUFACTURER shall use HAZARD ANALYSIS to justify the image display quality needed.

NOTE The IMAGE DISPLAY DEVICE quality is specified in IEC documents in regard to diagnostic use (e.g., IEC 62563-1: 2009); since IGRT usage ~~may or may not require~~ can imply such high requirements, it is left to the MANUFACTURER to specify what is required for use with their X-IGRT EQUIPMENT.

The image quality shall be defined in terms of:

- CONTRAST TO NOISE RATIO;
- spatial resolution (MTF or cut-off frequency, expressed e.g., as line pairs per cm); and
- uniformity throughout the clinical field of view.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding image quality and the method of measurement of the X-IGRT IMAGING COMPONENT.

201.102.5 Image artefacts

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

– whether an artefact could be mistaken for detail that could result in an incorrect TREATMENT; and

– whether an artefact would be obvious to an OPERATOR.

Compliance is checked by:

TYPE TEST grade A – Statement in the ACCOMPANYING DOCUMENTATION regarding known possible artefacts and their effect.

201.102.~~5~~6 Imaging dose

201.102.~~5~~6.1 Display and ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION for planar imaging

a) The expected typical imaging dose for predefined protocols shall be stated in the ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION. ~~If the actual imaging dose is known prior to imaging, it shall be displayed to the OPERATOR prior to imaging.~~ The units for the expected imaging dose shall be based upon the specifications of the protocol used. Where no protocols are supplied, clinical examples of imaging dose shall be illustrated in the ACCOMPANYING DOCUMENTATION.

b) The technical description supplied by the MANUFACTURER shall define the methods used for measuring the imaging dose referring to the specific standards for the planar imaging modality.

NOTE A dose area meter is not required for dose monitoring.

~~For fan-beam imaging on a CT imaging device, *CTDI* measurements can be conducted as defined in IEC 60601-2-44:2011~~

Compliance is checked as follows:

a) TYPE TEST grade A – Statement regarding expected typical imaging dose for predefined protocols.

b) *TYPE TEST grade A – Statement regarding the methods used for measuring the imaging dose*.

201.102.~~5~~6.2 Display and ACCOMPANYING DOCUMENTATION for CBCT

201.102.~~5~~6.2.1 Dosimetry PHANTOM

The dosimetry PHANTOM shall consist of a PMMA cylinder of density (1,19 ± 0,01) g/cm^3, of diameter 160 mm for all head PROTOCOL ELEMENTS and 320 mm for all body PROTOCOL ELEMENTS. The length of the PHANTOM shall be at least 140 mm. The PHANTOM shall be longer than the length of the sensitive volume of the RADIATION DETECTOR used for the measurements. The PHANTOM shall contain holes just large enough to accept the RADIATION DETECTOR. These holes shall be parallel to the axis of symmetry of the PHANTOM, and the centres of the holes shall be located at the centre and 10 mm below the surface of the PHANTOM at 90° intervals. For the holes not used during a measurement, properly fitting insert parts of the same material as the PHANTOM shall be used.

~~If applicable,~~ The method used to provide RADIATION dose indication in NORMAL USE of the ~~ME EQUIPMENT~~ MEE shall be described ~~directly~~ in the ACCOMPANYING DOCUMENTATION or by reference to a published reference.

NOTE The PHANTOM definition is based on IEC 60601-2-44:2009/~~AMD1:2012~~AMD2:2016, 203.108.

201.102.~~5~~6.2.2 Dose statements

201.102.~~5~~6.2.2.1 $CTDI_{100}$

The following dose information shall be obtained by using the dosimetry PHANTOM for CBCT. Separate dose information shall be provided for each application (e.g., head and body) in the ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION. All dose measurements shall be performed with the dosimetry PHANTOM placed on the PATIENT SUPPORT without additional attenuating material present. The dosimetry PHANTOM appropriate for the application shall be centred in the scan field and on the axis of rotation of the X-IGRT EQUIPMENT.

The following information shall be given in the ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION for each application.

a) The $CTDI_{100}$ and the corresponding CBCT MODES OF OPERATION at the following locations in the dosimetry PHANTOM SPECIFIED IN 201.102.~~5~~6.2.1. The CBCT MODES OF OPERATION shall be the typical values suggested by the MANUFACTURER.
   1) Along the axis of rotation of the PHANTOM ($CTDI_{100}$ (centre)).
   2) Along a line parallel to the axis of rotation and 10 mm interior to the surface of the PHANTOM, with the PHANTOM positioned so that the $CTDI_{100}$ is the maximum obtainable at this depth.
   3) Along a line parallel to the axis of rotation and 10 mm interior to the surface of the PHANTOM at positions 90°, 180° and 270° from the position in item a) 2) of this subclause. The location of the position where the $CTDI_{100}$ is maximum as specified in item a) 2) of this subclause shall be given by the MANUFACTURER with respect to the gantry or other readily identifiable part of the X-IGRT EQUIPMENT in such a manner as to permit placement of the dosimetry PHANTOM in this orientation.
   4) $CTDI_{100}$ (peripheral) as the average of the four values of $CTDI_{100}$ measured around the dosimetry PHANTOM periphery according to 201.102.~~5~~6.2.~~1~~2.1 a) 2) and 3) above.
b) The $CTDI_{100}$ in the centre location of the dosimetry PHANTOM for each selectable CBCT MODE OF OPERATION that varies the $CTDI_{100}$ (centre) value. This $CTDI_{100}$ (centre) shall be presented as a value that is normalized to the $CTDI_{100}$ in the centre location of the dosimetry PHANTOM from item a) of this subclause, with the $CTDI_{100}$ (centre) of item a) of this subclause having a value of 1. As a single CBCT MODE OF OPERATION is changed, all other independent CBCT MODES OF OPERATION shall be maintained at the typical values described in item a) of this subclause. These data shall encompass the range of each CBCT MODE OF OPERATION stated by the MANUFACTURER as appropriate. When more than three selections of a CBCT MODES OF OPERATION are available, the normalized $CTDI_{100}$ shall be provided, at least for the minimum, maximum and one mid-range value of the CBCT MODES OF OPERATION.
c) For scans using partial rotations used typically with CBCT, the same trajectory shall be used for all $CTDI_{100}$ measurements.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding the $CTDI_{100}$ and the corresponding CBCT MODES OF OPERATION and the MANUFACTURER's test results.

NOTE 201.102.~~5~~6.2.2.1 has been ~~adopted~~ adapted from IEC 60601-2-44:2009/~~AMD1:2012~~AMD2:2016, 203.109.1.

201.102.~~5~~6.2.2.2 $CTDI_{free\ air}$

$CTDI_{free\ air}$ and the corresponding CBCT MODES OF OPERATION shall be provided in the ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION. $CTDI_{free\ air}$ shall be measured along a line perpendicular to the TOMOGRAPHIC PLANE at the ISOCENTRE of the X-IGRT EQUIPMENT in the absence of any dosimetry PHANTOM and PATIENT SUPPORT.

For MV CBCT appropriate build-up shall be used.

For scans using partial rotations used typically with CBCT, the same trajectory shall be used as for the $CTDI_{100}$ measurements.

A statement of the maximum deviation from the values shall be given. Deviations shall not exceed these limits.

The following data shall be included in the ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION:

- $CTDI_{free\ air}$ at typical NOMINAL beam collimations for all CBCT MODES OF OPERATION ~~shall be maintained~~ at the typical ~~conditions of operation~~ IGRT IMAGING PROTOCOL;
- $CTDI_{free\ air}$ at typical settings for all CBCT MODES OF OPERATION ~~shall be maintained~~ at the typical ~~conditions of operation~~ IGRT IMAGING PROTOCOL; see Table 203.101 as an example below; and
- $CTDI_{free\ air}$ at the typical ~~conditions of operation~~ IGRT IMAGING PROTOCOL for each additional shaped or flat FILTER.

If a build-up cap is required to perform MV beam measurements, it shall be documented in the ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION.

NOTE 1 NOMINAL beam collimation is equal to nominal, pre-set collimator field sizes of the CBCT mode. It usually is the same as the scan length along a line perpendicular to the TOMOGRAPHIC PLANE of a CBCT scan.

~~NOTE 2 Only one measurement is required for any given scan length.~~

NOTE 2 An alternative method to measure CTDI ($CTDI_{100}$ or $CTDI_{free\ air}$) is based on measurement of the DOSE PROFILE and integration of the profile over the desired range. The dose profile can be measured with a RADIATION DETECTOR that fulfils IEC 61674, e.g., with a small dosimeter.

NOTE 3 Table 201.103 provides an example test pattern for $CTDI_{free\ air}$ for kV.

Table 201.103 – Example test pattern for $CTDI_{free\ air}$ for kV

		Variation of the NOMINAL beam collimation				
		Collimation 1	**Collimation 2**	**Collimation 3**	**Collimation 4 (typical)**	**Collimation 5**
Variation of kV	**kV1**				Y	
	kV2 (typical)	Y	Y	Y	Y	Y
	kV3				Y	

NOTE 4 201.102.~~5~~6.2.2.2 has been ~~adopted~~ adapted from IEC 60601-2-44:2009/~~AMD1:2012~~AMD2:2016, 203.109.2.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding the $CTDI_{free\ air}$ and the corresponding CBCT MODES OF OPERATION and the MANUFACTURER's test results.

201.102.6.2.2.3 DOSE PROFILE statement

A graphical presentation of the DOSE PROFILE along a line perpendicular to the TOMOGRAPHIC PLANE and centred at the ISOCENTRE, determined in free air for one axial scan, in the centre location of the head-dosimetry PHANTOM, and the centre location of the body-dosimetry PHANTOM shall be given in the ACCOMPANYING ~~DOCUMENTS for each selectable~~ DOCUMENTATION for minimum and maximum value of $N \times T$. ~~When more than three different values of $N \times T$ are~~

~~available, the information shall be provided for at least the minimum, maximum and one mid-range value.~~

For X-IGRT EQUIPMENT with a single detector row along the line perpendicular to the TOMOGRAPHIC PLANE, the DOSE PROFILE shall be presented on the same graph and to the same scale as the corresponding SENSITIVITY PROFILE required by ~~203.111~~ 201.102.6.2.2.4. For X-IGRT EQUIPMENT with multiple detector rows along the line perpendicular to the TOMOGRAPHIC PLANE, two vertical line segments separated by the width $N \times T$ shall be presented on the same graph centred within the DOSE PROFILE.

The graphical presentation shall cover a range along the y-direction that extends to at least the full width at one-tenth maximum of the DOSE PROFILE.

NOTE 1 For CBCT $N \times T$ is NOMINAL beam collimation.

NOTE 2 201.102.~~5~~6.2.2.3 has been ~~adopted~~ adapted from IEC 60601-2-44:2009/~~AMD1:2012~~AMD2:2016, 203.110.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding DOSE PROFILE.

201.102.~~5~~6.2.2.4 SENSITIVITY PROFILE statement

A graphical representation of the associated SENSITIVITY PROFILE in air shall be given in the ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION as follows:

a) One SENSITIVITY PROFILE for each available axial NOMINAL TOMOGRAPHIC SECTION THICKNESS shall be plotted. Where there are more than three NOMINAL TOMOGRAPHIC SECTION THICKNESS, plot the SENSITIVITY PROFILE for at least the minimum, the maximum and one mid-range value.

b) For X-IGRT EQUIPMENT with a single detector row along the line perpendicular to the TOMOGRAPHIC PLANE, the SENSITIVITY PROFILE associated with the configuration slide thickness T shall be presented on the same graph, placed about the same central location, to the same scale as that of the corresponding DOSE PROFILE required by 201.102.~~5~~6.2.1, for the head-dosimetry PHANTOM and for the body-dosimetry PHANTOM.

NOTE 201.102.~~5~~6.2.2.4 has been ~~adopted~~ adapted from IEC 60601-2-44:2009/~~AMD1:2012~~AMD2:2016, 203.111.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding SENSITIVITY PROFILE.

201.102.~~5~~6.2.2.5 Display and recording of $CTDI_{vol}$ and DLP

The values for $CTDI_{vol}$ expressed in units of mGy or cGy and DLP expressed in units of mGy·cm or cGy·cm, both quantities reflecting the PROTOCOL ELEMENT selected, shall be displayed on the CONTROL PANEL prior to initiation of a scanning sequence. Additionally, the PHANTOM diameter on which $CTDI_{vol}$ values are based shall be displayed.

The units selected ~~must~~ shall conform to other radiation units per 201.101.3.

The ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION shall contain the conversion from the $CTDI_{vol}$ based on the 32 cm phantom to the $CTDI_{vol}$ based on the 16 cm phantom. This conversion shall be provided for all relevant combinations of ~~CBCT CONDITIONS OF OPERATION~~ IGRT IMAGING PROTOCOL. The ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION shall contain guidance on how to specify whether a PROTOCOL ELEMENT is a head or body PROTOCOL ELEMENT.

If any of the ~~CBCT CONDITIONS OF OPERATION~~ IGRT IMAGING PROTOCOL are intended to vary within a scanning sequence, corresponding expected values of $CTDI_{vol}$ and *DLP* shall be displayed prior to exposure. Each value shall represent an anticipated time-weighted average over the scanning sequence.

For scanning without pre-programmed movement of the PATIENT SUPPORT, when calculating $CTDI_{vol}$ per ~~201.3.229 c)~~ 201.3.232.3 for display, *n* is equal to the maximum number of pre-programmed rotations. Where the number of rotations is not pre-programmed, during the scan the $CTDI_{vol}$ ~~per second~~ shall be displayed in units ~~of mGy~~ as defined in 201.101.3.

Following a sequence of scanning (e.g., with CBCT modes that merges multiple scans) the mean values of $CTDI_{vol}$ and *DLP* shall be displayed on the CONTROL PANEL, where these values are calculated as time-weighted averages over the scanning sequence.

The post-scan mean values of $CTDI_{vol}$ and *DLP* along with the PHANTOM type shall be recorded according to the DICOM ~~CT~~ RADIATION dose structured report (SR) ~~templates of ISO 12052~~.

The accuracy of the displayed and recorded values of $CTDI_{vol}$ and *DLP* shall be specified in the ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION.

NOTE 1 The displayed and recorded $CTDI_{vol}$ and *DLP* given by the MANUFACTURER ~~may~~ can be a representative figure for that model and not the value measured on the ~~particular~~ X-IGRT EQUIPMENT.

The ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION shall contain the method used for adjusting *L* as defined in 201.3.205 b).

NOTE 2 201.102.~~5~~6.2.2.5 has been ~~adopted~~ adapted from IEC 60601-2-44:~~2012~~2009/AMD2:2016, 203.112.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding $CTDI_{vol}$ *and* DLP.

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

201.102.~~5~~6.2.2.6 TOMOGRAPHIC SECTION THICKNESS accuracy

A statement about the TOMOGRAPHIC SECTION THICKNESS accuracy shall be provided in the ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION for all CBCT MODES OF OPERATION used to provide the information required by 201.102.~~5~~6.2.

TYPE TEST grade A – Statement regarding TOMOGRAPHIC SECTION THICKNESS ACCURACY.

201.102.~~5~~6.2.2.7 Post-exposure display of changed ~~CBCT CONDITIONS OF OPERATION~~ IGRT IMAGING PROTOCOL for kV CBCT

For kV CBCT, following a sequence of scanning in which the TUBE CURRENT was selected to vary, the time weighted average of the TUBE CURRENT over the scanning sequence shall be displayed.

Compliance is checked as follows:

TYPE TEST GRADE *B – Procedure: Inspect DISPLAY and output information.*

201.103 IGRT analysis and correction

201.103.1 Algorithm description

a) Description of all algorithms used for IMAGE RECONSTRUCTION and IMAGE REGISTRATION shall be included in the technical description. This shall include a description of the factors accounted by the algorithm, the class of algorithms forming the basis of the calculation, the limits applied to all variables used in the equations, and details of how algorithms handle different artefacts.

b) Where a choice of algorithms is provided for a particular calculation, the INSTRUCTIONS FOR USE shall discuss the relative advantages and disadvantages of the different algorithms.

~~c) The technical description shall include a description of artefacts.~~

Compliance is checked as follows:

a) TYPE TEST grade A – Statement regarding algorithms used for IMAGE RECONSTRUCTION and IMAGE REGISTRATION.

b) TYPE TEST grade A – Statement regarding relative advantages and disadvantages of the different algorithms.

~~*c) TYPE TEST grade A – Statement regarding artefacts.*~~

201.103.2 Accuracy of algorithms

a) For each algorithm used for IMAGE RECONSTRUCTION and IMAGE REGISTRATION, the technical description shall state the accuracy of the result(s) of the algorithm relative to the displayed calculated PATIENT shift for at least one set of pre-defined conditions. The predefined conditions shall be chosen to simulate the conditions for NORMAL USE. Where predefined conditions are available in a published report or standard, these ~~should~~ shall be used.

NOTE For each type of input as well as limitations in the algorithm, there is an associated resolution limitation. This requirement is looking for the final uncertainty in the calculated value due to these resolution limitations.

b) The technical description shall include all descriptions and data necessary for the RESPONSIBLE ORGANIZATION to reproduce the pre-defined conditions, or suitable references where these conditions are publicly available. It shall also include test procedures that permit convenient testing by the RESPONSIBLE ORGANIZATION to show that the expected results are achieved with the provided input data.

c) The INSTRUCTIONS FOR USE shall provide cautionary notes for the OPERATOR concerning the limitations of IMAGE REGISTRATION and the need for visual inspection of accuracy and fitness for purpose.

Compliance is checked as follows:

a) TYPE TEST grade A – Statement regarding the accuracy of the algorithm relative to measured data for at least one set of pre-defined conditions.

b) TYPE TEST grade A – Statement regarding the required description and data necessary for the RESPONSIBLE ORGANIZATION to reproduce the pre-defined conditions.

c) TYPE TEST grade A – Statement regarding the limitations of registration and the need for visual inspection of accuracy and fitness.

201.103.3 * Image-guided adjustment and correction

201.103.3.1 OFFLINE IGRT

The following items shall be ~~available to the X-IGRT EBE SYSTEM~~ provided and either recorded by the X-IGRT EQUIPMENT or communicated to an external system:

– the positional corrections calculated ~~by~~ from IMAGE REGISTRATION;

~~– the OPERATOR performing IMAGE REGISTRATION~~

– IGRT ~~calculated~~ adjustment(s) to PATIENT position or TREATMENT PLAN; and

NOTE 1 The IGRT calculated adjustment(s) ~~may not~~ can be different from the correction applied by the EBE.

– the OPERATOR performing approval and the approved adjustment(s) where adjustments are approved at the X-IGRT EQUIPMENT.

If neither recording nor communicating capability is provided, the MANUFACTURER shall include in the INSTRUCTIONS FOR USE a recommendation that the RESPONSIBLE ORGANIZATION ensures that such information is recorded by another system.

NOTE 2 Another system can be e.g., a RECORD AND VERIFY SYSTEM that is in communication with the X-IGRT EBE SYSTEM.

All IGRT correction values shall be in SI units and shall be in the IEC 61217 coordinate system.

NOTE 3 This applies to the values recorded and shown to the user. An alternate set of units for use during transfer ~~is allowed~~ can be used as long as it is part of a standard communication protocol (i.e., DICOM).

The X-IGRT EQUIPMENT ~~may~~ can have an alternative scheme of coordinates selectable by the RESPONSIBLE ORGANIZATION if that coordinate system matches the one on the receiving EXTERNAL BEAM EQUIPMENT.

~~The corrections to be sent to the EBE shall be tolerance checked against pre-established limits defined and documented by the MANUFACTURER in its ACCOMPANYING DOCUMENTS.~~

Compliance is checked as follows:

~~TYPE TEST *grade A – Statement regarding pre-established limits.*~~

TYPE TEST grade B – Procedure: Perform IGRT workflow and check recorded data and communication to external system.

SITE TEST grade B – Procedure: Perform IGRT workflow and check recorded data and communication to external system.

201.103.3.2 ONLINE IGRT

The following items shall be displayed on the X-IGRT EQUIPMENT or X-IGRT EBE SYSTEM:

– IGRT calculated adjustment(s) to PATIENT position or TREATMENT; and

– IGRT correction sent to the EBE or other external system, where different from the calculated adjustment(s).

The following items shall either be ~~available on the X-IGRT EQUIPMENT and either~~ recorded by the X-IGRT EBE SYSTEM or provided by the X-IGRT EQUIPMENT as output data to an external system:

– the adjustment(s) calculated by image analysis;

– IGRT calculated adjustment(s) to PATIENT position or TREATMENT;

– IGRT correction sent to the EBE or other external system and the date and time this occurs; and

NOTE 1 The IGRT correction sent to the EBE ~~may not~~ can be different from the correction applied by the EBE.

– the OPERATOR performing the IGRT calculated correction or overriding actual correction.

If the X-IGRT EBE SYSTEM provides the above items as output data to an external system, the MANUFACTURER shall include in the INSTRUCTIONS FOR USE a recommendation that the RESPONSIBLE ORGANIZATION ensures that such information is recorded by another system.

NOTE 2 Another system can be e.g., a RECORD AND VERIFY SYSTEM that is in communication with the X-IGRT EBE SYSTEM.

~~If the X-IGRT image data is used for monitoring during therapeutic IRRADIATION, then the X-IGRT EQUIPMENT shall have the ability to display the reference data during therapeutic IRRADIATION.~~

All IGRT correction values shall be in SI units and shall be in the IEC 61217 coordinate system.

NOTE 3 This applies to the values recorded and shown to the user. An alternate set of units for use during transfer ~~is allowed~~ can be used as long as it is part of a standard communication protocol (i.e., DICOM).

The X-IGRT EQUIPMENT ~~may~~ can have an alternative scheme of coordinates selectable by the RESPONSIBLE ORGANIZATION if that coordinate system matches the one on the receiving EXTERNAL BEAM EQUIPMENT.

The corrections to be sent to the EBE shall be tolerance checked by the X-IGRT EQUIPMENT against pre-established limits defined and documented by the MANUFACTURER in its ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION.

Means shall be provided for the OPERATOR to override the calculated corrections from the X-IGRT EBE SYSTEM at any time before the corrections are sent to the EBE.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding pre-established limits.

TYPE TEST grade B – Procedure: Perform IGRT workflow and check recorded data and communication to external system.

SITE TEST grade B – Procedure: Perform IGRT workflow and check recorded data and communication to external system.

201.103.3.3 REAL-TIME IGRT

The corrections to be sent to the EBE shall be tolerance checked against pre-established limits defined and documented by the MANUFACTURER in its ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION.

The X-IGRT EQUIPMENT shall have a function to transmit an interlock signal(s) for inhibiting, interrupting or terminating the therapeutic IRRADIATION by the EBE.

The X-IGRT EQUIPMENT shall have a function to automatically terminate X-RAY RADIATION for imaging upon receipt of an interlock signal from the EBE indicating a system fault, data values out of bounds or INTERLOCK.

The images acquired shall be displayed to the OPERATOR during the entire IRRADIATION along with the REFERENCE IMAGES or reference data used for comparison until such time that new images for IGRT calculated corrections are acquired unless the images are acquired at a rate faster than 24 per second. For images acquired at rates faster than 24 per second, the displayed frame rate ~~may~~ can be 24 per second.

Means shall be provided for the OPERATOR to send an INTERRUPT and TERMINATE signal to the EBE from the X-IGRT EQUIPMENT at any time during therapeutic IRRADIATION.

The following items shall be available and either recorded by the IGRT EQUIPMENT or provided by the IGRT EQUIPMENT as output data to external equipment each time the IGRT correction is sent to the EBE:

– the OPERATOR initiating the REAL-TIME IGRT;
– adjustment(s) calculated by image analysis and the associated images;

– IGRT calculated adjustment(s) to PATIENT position or TREATMENT;

– IGRT correction sent to the EBE;

NOTE 1 The IGRT correction sent to the EBE ~~may not~~ can be different from the correction applied by the EBE.

– the OPERATOR performing manual adjustment or overriding correction; and

– the application time of the alignment correction.

If the IGRT EQUIPMENT provides the above items as output data to an external system, the MANUFACTURER shall include in the INSTRUCTIONS FOR USE a recommendation that the RESPONSIBLE ORGANIZATION ensure that such information is recorded by another system.

NOTE 2 Another system can be e.g., a RECORD AND VERIFY SYSTEM that is in communication with the IGRT EQUIPMENT.

All IGRT correction values shall be in SI units and shall be in the IEC 61217 coordinate system. An alternate set of units for use during transfer is allowed as long as it is part of a standard communication protocol (i.e., DICOM).

The X-IGRT EQUIPMENT ~~may~~ can have an alternative scheme of coordinates selectable by the RESPONSIBLE ORGANIZATION if that coordinate system matches the one on the receiving EXTERNAL BEAM EQUIPMENT.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding pre-established limits.

TYPE TEST grade B – Procedure: Perform IGRT workflow and check recorded data and communication to external system.

SITE TEST grade B – Procedure: Perform IGRT workflow and check recorded data and communication to external system.

201.104 Operation of ME EQUIPMENT parts from outside the facility

The X-IGRT EQUIPMENT can be provided with the capability for electronic access (e.g., via the Internet) to the control system for the purpose of diagnostic evaluation of the equipment. Such evaluation is performed to correctly operate the device. For example, the TCP can be controlled from a remote location for this purpose.

When functions and controls are accessed remotely from outside the facility:

a) a means shall be provided at the TCP to enable control by a remote operator;

b) the MEE shall require an action at the TCP at the time a connection is established and before any functions or movements are controlled remotely, or before any files on the MEE are remotely modified;

c) the TCP shall indicate whenever a remote connection is established; and

d) any movements shall comply with the provisions of 201.9.2.101.

In addition, it shall be impossible through remote access to:

e) violate or override any of the provisions of 201.9.2.102 and 201.9.2.103;

f) allow the remote OPERATOR to bypass interlocks that could result in injury to any person; or

g) allow the remote OPERATOR to INITIATE IRRADIATION for any RADIATION SOURCES.

Compliance tests:

a) TYPE TEST grade A – Inspection of ACCOMPANYING DOCUMENTATION.

b) *SITE TEST grade B: attempt to connect from a remote site to the X-IGRT EBE SYSTEM without first providing action at the TCP and verify that control cannot be established.*

c) SITE TEST grade B – Demonstrate that the display indicates remote operation under remote control.

d) *TYPE TEST grade A: Inspection of ACCOMPANYING DOCUMENTATION.*

e), f), and g) *SITE TEST grade B: demonstrate function of remote diagnostic capability.*

203 RADIATION protection in diagnostic X-RAY EQUIPMENT

For 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 Annex AA).

IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013, and IEC 60601-1-3:2008/AMD2:2021 apply for KILOVOLTAGE X-IGRT EQUIPMENT, except as follows:

203.4 General requirements

203.4.1 Statement of compliance

Replacement:

If for an X-IGRT EQUIPMENT, or a sub-assembly thereof, compliance with ~~IEC 60601-1-3~~ IEC 60601-2-68 is to be stated, the statement shall be given in the ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION:

X-IGRT EQUIPMENT... ++) IEC 60601-2-68:~~2013~~2025

++) MODEL OR TYPE REFERENCE

Compliance is checked by inspection of the ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION*.*

203.6 RADIATION management

203.6.2 Initiation and TERMINATION OF IRRADIATION

203.6.2.1 Normal initiation and TERMINATION OF IRRADIATION

Replacement:

The first LOADING of an IMAGING SESSION shall be initiated by means of a control requiring action by the OPERATOR. It shall be possible for the OPERATOR to terminate the LOADING at any time.

Any control by which the LOADING of an X-RAY TUBE can be initiated shall be protected against unintended actuation using means compatible with the INTENDED USE of the X-RAY EQUIPMENT.

Compliance is checked by inspection and by the appropriate functional tests.

203.6.3 Radiation dose and RADIATION QUALITY

~~*Replacement:*~~

203.6.3.1 Adjustment of RADIATION dose and RADIATION QUALITY

Replacement:

It shall be possible to restrict the RADIATION dose to the PATIENT in line with the INTENDED USE of the X-RAY EQUIPMENT. It shall be possible to adjust the RADIATION QUALITY over a suitable range in line with the INTENDED USE of the X-RAY EQUIPMENT.

Compliance is checked by inspection and functional tests.

203.6.3.2 Reproducibility of the RADIATION output

Replacement:

The ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION shall state the reproducibility of the RADIATION output.

Compliance is checked by inspection of the ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION.

203.6.4 Indication of operational states

203.6.4.1 Indication of the X-RAY SOURCE ASSEMBLY selected

Replacement:

Where X-RAY EQUIPMENT has provisions to select more than one X-RAY SOURCE ASSEMBLY ~~and/~~or X-RAY IMAGING ARRANGEMENT, an indication of the X-RAY SOURCE ASSEMBLY ~~and/~~or X-RAY IMAGING ARRANGEMENT selected shall be provided on the CONTROL PANEL prior to the LOADING of the X-RAY SOURCE ASSEMBLY.

Compliance is checked by inspection.

203.8 Limitation of the extent of the X-RAY BEAM and relationship between X-RAY FIELD and IMAGE RECEPTION AREA

203.8.4 Confinement of EXTRA-FOCAL RADIATION

Replacement:

The contribution of EXTRA-FOCAL RADIATION to the X-RAY IMAGE RECEPTOR and to the PATIENT dose shall be limited to an acceptable level. Acceptable levels of EXTRA-FOCAL RADIATION shall be determined by the RISK MANAGEMENT and stated in the ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION.

NOTE One of the most important means of decreasing the EXTRA-FOCAL RADIATION is to limit the RADIATION BEAM close to the FOCAL-SPOT.

Compliance is checked by inspection.

203.10 ATTENUATION of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR

203.10.2 Information in the ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION

Replacement:

The ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION shall state the maximum value of the ATTENUATION EQUIVALENT of each item interposed between the PATIENT and the X-RAY IMAGE RECEPTOR and forming part of the X-RAY EQUIPMENT.

For X-IGRT EQUIPMENT specified to be used in combination with ACCESSORIES or other items not forming part of the same or other X-IGRT EQUIPMENT, the instructions for use shall include a statement drawing attention to the possible adverse effects arising from materials located in the X-RAY BEAM (e.g., parts of the PATIENT SUPPORT device).

Compliance is checked by examination of the ACCOMPANYING ~~DOCUMENTS~~ DOCUMENTATION.

203.11 Protection against RESIDUAL RADIATION

Clause 11 of ~~the collateral standard~~ IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013, and IEC 60601-1-3:2008/AMD2:2021 does not apply.

203.13 Protection against STRAY RADIATION

Clause 13 of ~~the collateral standard~~ IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013, and IEC 60601-1-3:2008/AMD2:2021 does not apply.

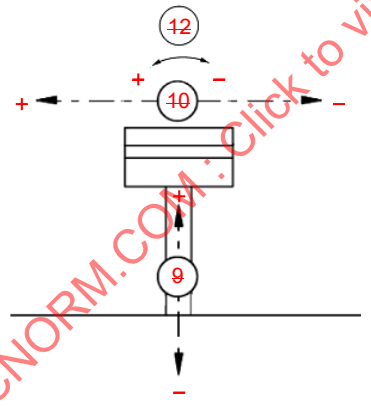
206 Usability

IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 apply, except as follows:

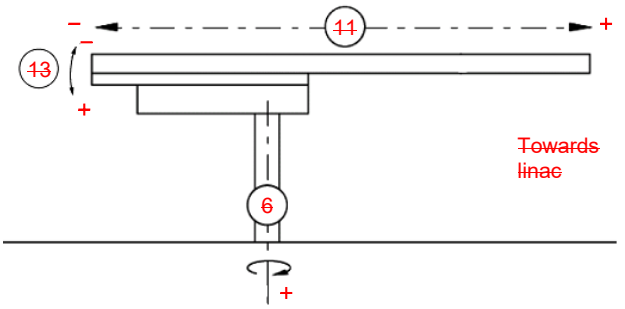
Addition:

NOTE Although it will not be possible to apply IEC 60601-1-6:2010 retroactively to existing ~~ME EQUIPMENT~~ MEE and to those that have passed beyond the stage identified above, examination of the available design and process control data ~~may~~ can provide substantial verification.

~~Viewed from linac base~~



~~Viewed from side~~



~~Linear displacements~~

~~9 Vertical displacement of the PATIENT SUPPORT~~

~~10 Lateral displacement of the PATIENT SUPPORT~~

~~11 Longitudinal displacement of the PATIENT SUPPORT~~

~~Rotational displacements~~

~~6 ISOCENTRIC rotational of the PATIENT SUPPORT (yaw)~~

~~12 Roll displacement of the PATIENT SUPPORT~~

~~13 Pitch displacement of the PATIENT SUPPORT~~

~~NOTE For continuity, the numbered labels correspond to those used in IEC 60601-2-1:2009, Figure 201.108.~~

~~Figure 201.101 – PATIENT SUPPORT movements~~

Annexes

The annexes of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 apply, except as follows:

~~Annex B~~
~~(informative)~~

~~Sequence of testing~~

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

~~B.1 General~~

~~*Addition:*~~

~~The MANUFACTURER should state the sequence of testing if it differs from the sequence shown in this annex.~~

Annex A
(informative)

Sequence of testing

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

A.1 General

Addition:

The MANUFACTURER shall state the sequence of testing where it differs from the sequence shown in this annex.

Annex I
(informative)

ME SYSTEMS aspects

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

Additional annexes:

Annex AA
(informative)

Particular guidance and rationale

The following are rationales for specific subclauses in this document, with subclause numbers parallel to those in the body of the document.

Subclause 201.1.1 – Scope

In this document CT SCANNER, X-RAY EQUIPMENT for RADIOGRAPHY, or X-RAY EQUIPMENT for RADIOSCOPY used for X-IGRT are addressed as X-IGRT IMAGING COMPONENT as defined in 201.3.236 of this document.

The scope defines that requirements being tested according to other standard(s) can be identified by the manufacturer and if equivalent, do not require retesting, instead, evidence can refer to corresponding compliance statement or test report.

Table AA.1 lists the clauses of this document with the corresponding equivalent clauses of IEC 60601-2-44 for CT SCANNERS, and of IEC 60601-2-54 for X-RAY EQUIPMENT for RADIOGRAPHY and X-RAY EQUIPMENT for RADIOSCOPY.

Table AA.1 – Clauses of the standard that contain requirements for X-IGRT IMAGING COMPONENTS and related clauses of IEC 60601-2-44 and IEC 60601-2-54 with equivalent requirements for CT SCANNER, X-RAY EQUIPMENT for RADIOGRAPHY, and X-RAY EQUIPMENT for RADIOSCOPY

IEC 60601-2-68:2024	IEC 60601-2-44:2009, IEC 60601-2-44:2009/AMD1:2012 and IEC 60601-2-44:2009/AMD2:2016	IEC 60601-2-54:2009	Description
201.8.8.3	201.8.8.3	201.8.8.3	Dielectric strength
201.10	201.10 and 203.107	201.10 and 203	Safety measures against excessive X-RADIATION
201.102	203	203	X-IGRT IMAGING and dose indications
203	203	203	RADIATION protection in diagnostic X-RAY EQUIPMENT

Subclause 201.3.210 – IGRT LATENCY

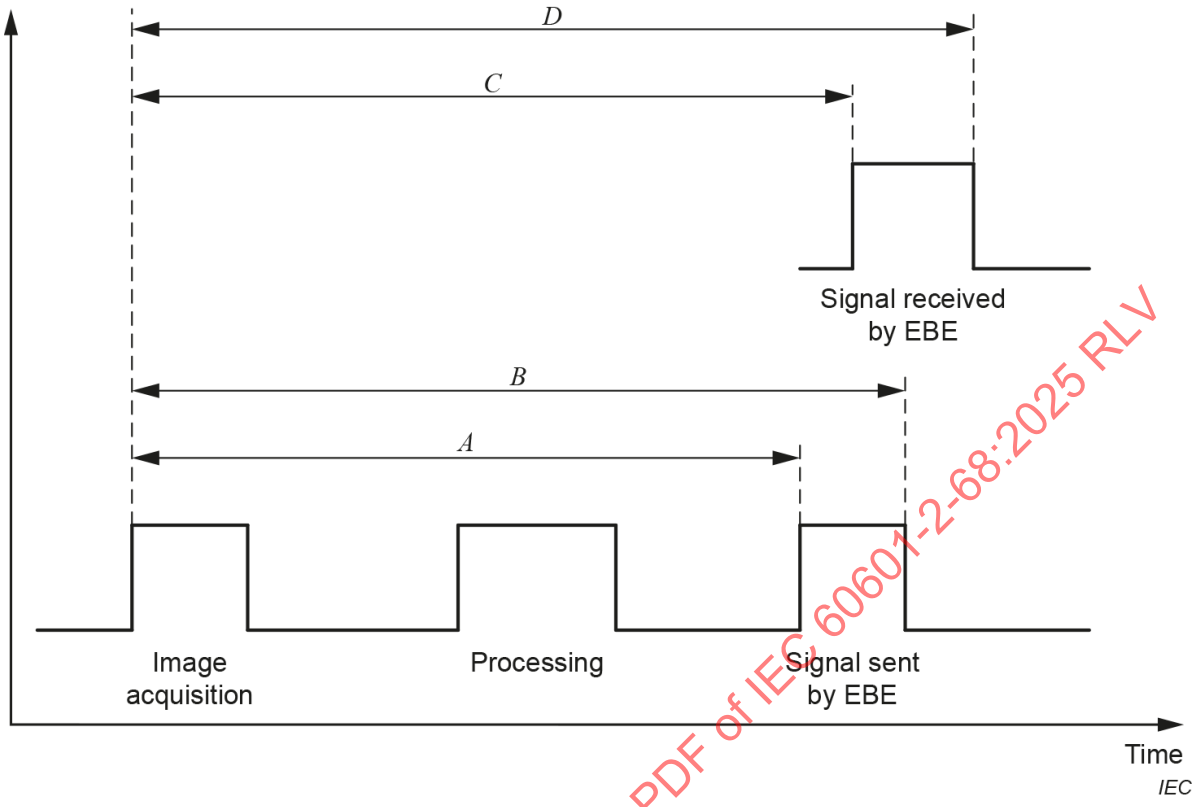


Figure AA.1 – Signals related to IGRT LATENCY

For the definition of IGRT LATENCY, the time of initiation of image acquisition is understood by the time the trigger starts the image acquisition. That can be by pressing a hand switch or set by a software command. The output signal by IGRT EQUIPMENT to the EBE is depending on the actual implementation of the IGRT EQUIPMENT. The signal can have a raising and a falling edge, as shown in Figure AA.1 with A and B, and the IGRT LATENCY is related to either one of these cases. The IGRT LATENCY does not consider the signal received at the EBE, the transmission time is not part of the IGRT LATENCY.

Subclause 201.101.6 – Conformance of data bounds from X-IGRT EQUIPMENT to EBE

Increasingly, RADIATION TREATMENT machines have the ability to vary TREATMENT PARAMETERS as TREATMENTS are progressing. For example, ~~couch~~ PATIENT POSITIONER speed, field size, dose rate, etc. ~~may~~ can be varied during TREATMENT. With the introduction of PATIENT monitoring systems that track PATIENT movement during TREATMENT, and cause TREATMENT PARAMETERS to be varied during TREATMENT to compensate for that movement, the increased RISK to the PATIENT should be considered if these monitoring systems do not operate as intended. In particular, the need to establish real-time secondary level bounds checking should be considered for parameters that are varied during TREATMENT.

Two types of position errors are worth illustrating:

1) Normal discrepancy between planned and actual position of moving parts

   An example case is a PATIENT POSITIONER that is movable during the PATIENT TREATMENT. As with any real-time position control system, there will always be a finite discrepancy between the planned and the actual position of the positioner. Typical real-time positioning software will establish an acceptable error band, and the TREATMENT will be terminated if the position of the table falls outside the pre-determined error limits.

2) Position error caused by unexpected condition or position control algorithm flaw

Consider an X-ray based imaging system that is monitoring the PATIENT position and has the ability to change a TREATMENT PARAMETER, such as field width, to compensate for PATIENT movement. Suppose that the imaging system receives an unexpected input, for example an image artefact, and mistakenly decides that based on this input, the field should be enlarged to the maximum possible size at a time when a very small field was desired. This could cause significant dose error, as this condition would not necessarily be caught by a cumulative type of dose monitoring system located upstream of the field limiting device. To help guard against this possibility, some sort of bounds check (or "sanity check") at TREATMENT time is required to make sure parameter settings that are obviously incorrect cannot be made. In this example, the X-IGRT EBE SYSTEM should check the value against a predetermined allowable change and INTERRUPT the delivery and ask the operator if it is safe to proceed before continuing.

In conclusion, the increasing reliance on complex ~~software~~ algorithms to modify TREATMENT PARAMETERs in real-time during TREATMENT calls for some checks and constraints on the values of those parameters. These constraints could be determined at planning time and transferred to the TREATMENT system just before TREATMENT. This allows the TREATMENT system to monitor for any attempts by the software to set TREATMENT PARAMETERs outside the pre-established safe range, and halt the TREATMENT if the safe range is exceeded. This sort of secondary sanity check should be performed in addition to the traditional primary position error band check used in real-time control systems.

Subclause 201.103.3 – Image-guided adjustment and correction

Modes of operation of X-IGRT have been categorised in 3 types, OFFLINE X-IGRT, ONLINE X-IGRT and REAL-TIME X-IGRT. Clauses applicable to X-IGRT with 3 spatial dimensions and time (4D X-IGRT) are covered by the modes of operation, OFFLINE X-IGRT, ONLINE X-IGRT and REAL-TIME X-IGRT.

The following are examples of 4D X-IGRT classified by mode.

Example 1: OFFLINE X-IGRT

4D CT image acquisition of the patient during the TREATMENT is carried out. The image analysis is performed offline where the position of the TARGET VOLUME is determined from the 4D CT set, using this 4D information the range of motion of the TARGET VOLUME is determined and a mean position is calculated. This ~~may~~ can be done on several sessions. Future sessions can adjust the setup to incorporate the range of motion.

Example 2: ONLINE X-IGRT

4D CT image acquisition of the patient immediately prior to TREATMENT is acquired. This 4D information is used to determine the range of motion of the TARGET VOLUME and determine its mean position. A shift of the patient is performed prior to the commencement of the TREATMENT to ensure the mean position is at the planned TREATMENT position.

Example 3: ONLINE X-IGRT

Image and respiratory information of the patient are acquired immediately prior to the TREATMENT. Analysis is performed to correlate image and respiratory information in 4D. This information is used to determine range of motion of the TARGET VOLUME. During the TREATMENT the respiratory monitoring is continued to calculate the position of the TARGET VOLUME. The EBE is sent the signal to correct for the change of the TARGET VOLUME position continuously.

This is ONLINE X-IGRT as the IGRT only performed a pre-TREATMENT model and the real-time aspects are dealt with by the correlation model which is fixed during TREATMENT.

Example 4: REAL-TIME X-IGRT

Images are continuously acquired using multiple kV X-ray sources at different angles during the TREATMENT. The images are continuously analysed to determine the 3D position of the TARGET VOLUME. The EBE is sent to the signal to correct for the change of the TARGET VOLUME position or correlation model throughout the therapeutic IRRADIATION.

Annex BB
(informative)

Measuring $CTDI_{free\ air}$

Free-in-air measurements of *CTDI* are useful in understanding the X-RAY BEAM characteristics of a CBCT scan on an IGRT EQUIPMENT. Since there is not a scattering medium, these measurements characterize the X-RAY BEAM output emanating from the collimators, quantifying the dosimetric effects of the tube, the inherent filtration, the filtration of the central ray and the effects of over-beaming and penumbra. In order to measure $CTDI_{free\ air}$, it is necessary to integrate the DOSE PROFILE along the y-axis for the entire extent of the X-ray field. In order to ensure that the entire y-extent is captured, the integration length (*L*) should be at least 40 mm longer than the nominal beam collimation.

One method of measuring $CTDI_{free\ air}$ is to use a RADIATION DETECTOR (e.g., an IONIZATION CHAMBER) positioned along the axis of rotation of the IGRT EQUIPMENT and translated (stepped) through the ISOCENTRE using the PATIENT SUPPORT to cover the entire integration length.

NOTE 1 As another method the DOSE PROFILE can be measured with a RADIATION DETECTOR that fulfils IEC 61674, e.g., with a point DOSIMETER uniformly translated through the ISOCENTRE using a helical scan protocol.

1) Attach IONIZATION CHAMBER to a long, minimally attenuating support such as a metre stick or plastic rod.
2) Attach support with IONIZATION CHAMBER to the PATIENT SUPPORT using a weighted stand or other means so that the chamber apparatus will move with the PATIENT SUPPORT. Ensure that the active length of the IONIZATION CHAMBER extends a distance greater than half the integration length (*L*/2) beyond the end of the PATIENT SUPPORT so that the PATIENT SUPPORT does not interact with the primary beam during measurements.
3) Ensure that the centre of the IONIZATION CHAMBER is positioned at the ISOCENTRE of the IGRT EQUIPMENT, and that the IONIZATION CHAMBER is aligned with the IGRT EQUIPMENT y-axis; set the PATIENT SUPPORT location to 0.
4) Using the PATIENT SUPPORT, move the IONIZATION CHAMBER in the negative y-direction by *X* mm where

$$X = \frac{L - W}{2}$$

and where

L is the integration length in mm;

W is the chamber length in mm.

5) Take an axial scan with the desired parameters and record the exposure value.
6) Increment the table in the positive y-direction by an amount equal to the length of the ion chamber.
7) Repeat steps 5) and 6) for a total of *Y* exposures, until the entire integration length is covered, where

$$X = \frac{L}{W}$$

and where

L is the integration length in mm;

W is the chamber length in mm.

8) Sum the *Y* different exposure values to compute the $CTDI_{free\ air}$ for the given IGRT equipment configuration.

NOTE 2 More precise estimations of $CTDI_{free\ air}$ could be obtained by employing step sizes much smaller than the chamber length or by uniformly translating the entire chamber through the beam.

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Index of defined terms used in this document

IEC 60601-2-68

Edition 2.0 2025-02

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

IEC 60601-2-68:2025-02(en-fr)

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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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9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at https://patents.iec.ch. IEC shall not be held responsible for identifying any or all such patent rights.

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 –

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

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

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

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

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

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);
$(N \times T)_{\mathrm{Ref}}$	is a specific $N \times T$ of 20 mm or the largest N x T available not greater than 20 mm;
$D_{\mathrm{Ref}}(y)$	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 $(N \times T)_{\mathrm{Ref}}$;
$CTDI_{\mathrm{free\ air,\ } N \times T}$	is the $CTDI_{\mathrm{free\ air}}$ (201.3.202) for a specific value of $N \times T$;
$CTDI_{\mathrm{free\ air,\ Ref}}$	is the $CTDI_{\mathrm{free\ air}}$ (201.3.202) for $(N \times T)_{\mathrm{Ref}}$;
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 x N x 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: $C = \dfrac{|S_A - S_B|}{\sigma_0}$

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)

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

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*$_{\mathbf{W}}$
***CTDI*$_{\mathbf{vol}}$**
<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 × Δd.

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 × Δd.

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>

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

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 × N × 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

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

where

$CTDI_{100(centre)}$ is the value of $CTDI_{100}$ measured in the centre of a dosimetry PHANTOM;
$CTDI_{100(peripheral)}$ 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, do not

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-programed 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°. 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° × 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° × 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°. For speeds faster than 1° × 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° × s^{-1} around the axis of rotation.

– No speed shall exceed 7° × s^{-1} around the axis of rotation.

– When rotating at the speed nearest to, but not exceeding, 1° × 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°. For speeds faster than 1° × 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 mm × s^{-1}.
- 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}.

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° × 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° × 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°. For speeds faster than 1° × 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.

SITE TEST grade B – Procedure: Attempt to enter data elements outside the stated limits.

201.101.6 * Conformance of data bounds from X-IGRT EQUIPMENT to EBE

Means shall be provided to allow the user to set maximum bounds for control parameters transmitted from the X-IGRT EQUIPMENT to the EBE unless the RISK ASSESSMENT shows an increase to RISK.

When the maximum bounds are exceeded, therapeutic IRRADIATION shall be inhibited, and the OPERATOR shall be informed.

The allowable range of these bounds shall be described in the ACCOMPANYING DOCUMENTATION.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding maximum bounds for control parameters transmitted from the X-IGRT EQUIPMENT to the EBE.

SITE TEST grade B – Procedure: Attempt to start IRRADIATION with maximum bounds exceeded; the therapeutic irradiation is inhibited, and the OPERATOR is informed.

201.101.7 Verification of data coherence and selection of TREATMENT PARAMETERS

a) Consistency, correctness and completeness of the imported data set or data being loaded shall be checked by the X-IGRT EQUIPMENT before it can be accepted for IGRT.

b) In the case of inconsistency, incorrectness or incompleteness of the imported data set or data being loaded, IGRT shall not be allowed to commence without:

   1) explicit display of the identified deficiencies to the OPERATOR, and

   2) ability of the OPERATOR to change or accept the identified deficiencies.

c) In the case of abnormal termination of the X-IGRT IMAGING COMPONENT, the image data shall be recorded.

   NOTE 1 In the case of abnormal termination it can be impossible to record all of the image data normally available in non-abnormal termination conditions.

   In the case of restarting after abnormal termination, the consistency, correctness and completeness of the data set required for completing the IGRT shall be checked by the X-IGRT EQUIPMENT before it can be accepted for IGRT.

d) MANUFACTURER shall state in ACCOMPANYING DOCUMENTATION the data set required by the X-IGRT EQUIPMENT.

   NOTE 2 Data set consists of the correct combinations of RTPS information e.g., CT images, machine model, etc. that are needed for correct treatment delivery.

Compliance is checked as follows:

a) TYPE TEST grade B – Procedure: Attempt to import a data set, that is 1) not consistent, 2) not correct and 3) not complete and try to commence.

b) SITE TEST grade B – Procedure: Attempt to import a data set containing faults and try to commence. If the design is such that a data set with a fault cannot be created on-site, then this test shall be a TYPE TEST.

c) SITE TEST grade B – Procedure: Causation of termination of imaging and causation of TERMINATION OF IRRADIATION by specified means; inspect the data set recorded.

SITE TEST grade B – Procedure: Attempt to import the recorded data set and confirm that complete data were imported.

d) TYPE TEST grade A – Statement regarding the data set required by the X-IGRT EQUIPMENT.

201.101.8 Correctness of data transfer

a) Data transferred to or from other devices to or from the X-IGRT EBE SYSTEM shall use a communication protocol that verifies error-free data transmission. The MANUFACTURER shall specify these protocols in the technical description.

NOTE Example: communication protocol DICOM.

b) If data are transferred to or from another device, other than closed communication within an X-IGRT EBE SYSTEM or an integrated RTPS that has been type tested by the MANUFACTURER, then,

– the format of the transferred data shall be included in the technical description, including (but not limited to) identification of all data elements, data types, and data limits; and

– the data output shall include the date on which the data was written and any relevant identifiers for the PATIENT, X-IGRT EBE SYSTEM and TREATMENT PLAN.

Compliance is checked as follows:

a) TYPE TEST grade A – Statement regarding communication protocol specifications.

b) TYPE TEST grade A – Statement regarding format of the transferred data, including identification of all data elements, data types, and data limits;

SITE TEST grade B – Procedure: Transfer data from device and check output information.

201.101.9 Confidence in correctness of supplied geometry

201.101.9.1 Correlation of imaging system and treatment system frames of reference

The relationship between the imaging coordinate system and treatment coordinate system shall be defined in the ACCOMPANYING DOCUMENTATION in accordance with IEC 61217.

The X-IGRT EQUIPMENT can have an alternative scheme of coordinates selectable by the RESPONSIBLE ORGANIZATION if that coordinate system matches the one on the receiving EXTERNAL BEAM EQUIPMENT.

If the coordinate system is not in accordance with IEC 61217 the MANUFACTURER shall state in its ACCOMPANYING DOCUMENTATION a transformation method from these coordinates into IEC 61217 coordinates.

Compliance is checked as follows:

– *TYPE TEST grade A – Checking the ACCOMPANYING DOCUMENTATION.*

– *SITE TEST grade B – Principle: Targeting test to show the correlation between the imaging and TREATMENT geometry are within the manufacturer's specifications.*

201.101.9.2 Correlation of the PATIENT orientation with the REFERENCE IMAGES

When the REFERENCE IMAGE is displayed, the PATIENT orientation in the REFERENCE IMAGE shall also be displayed.

When exported, X-IGRT images shall include the coordinates and PATIENT orientation in the X-IGRT images.

If scales are displayed, the method by which the scale is displayed shall be explained in the INSTRUCTIONS FOR USE.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding the method of display of scales.

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

201.101.9.3 Geometric relationship

The relationship between X-IGRT EQUIPMENT and EBE geometries shall be specified in the ACCOMPANYING DOCUMENTATION including accuracy and technique of measurement establishing this.

NOTE This is an example of some items to consider:

Detailing limits on how these relationships can change with time:

- Long term e.g., mechanical drift;
- Short term e.g., during fraction (rotation etc.);
- With user activity e.g., fitting accessories, removing/deploying hardware;
- With machine geometry;
- With IGRT technique.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding the relationship between X-IGRT EQUIPMENT and TREATMENT EQUIPMENT geometries including accuracy, technique of measurement and importance of periodic reassessment.

201.102 X-IGRT imaging

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).

201.102.1 Saving data

201.102.1.1 Image identification

If an image acquisition is initiated, the following shall be saved:

- date and time of the image acquisition;
- data sufficient to allow determination of dose;
- identification of OPERATOR;
- identification of PATIENT;
- the X-IGRT EQUIPMENT hardware model and revision at the time of acquisition; and
- the X-IGRT EQUIPMENT software version used at the time of acquisition.

NOTE As long as the above information is saved to allow association with the acquired image, it is not required that the information all exist on the X-IGRT EQUIPMENT.

Compliance is checked as follows:

SITE TEST grade B – Procedure: Perform an image acquisition and inspect the saved data.

201.102.1.2 Image approval information

When an image is saved, it shall be unambiguously associated with the image identification. Where an image approval is required, the following information shall be additionally saved:

- time and date when the image was approved; and

- identification of the approval authority.

NOTE As long as the above information is saved to allow association with the acquired image, it is not required that the information all exist on the X-IGRT EQUIPMENT.

Compliance is checked as follows:

SITE TEST grade B – Procedure: Inspect the saved data.

201.102.2 Action before X-IGRT

When an OPERATOR retrieves information pertaining to a PATIENT TREATMENT, the following information shall be displayed to the OPERATOR to identify that information as being unique for that TREATMENT session:

- identification of PATIENT; and
- identification of TREATMENT PLAN.

When the following information is provided to the MEE through electronic means, the following information shall also be displayed to the OPERATOR:

- the fraction number of the sequence of fractions defined in the TREATMENT PLAN; and
- the PATIENT orientation.

NOTE Only the information in the data set needed to identify the PATIENT treatment can be displayed.

Approval by the OPERATOR shall be recorded by the X-IGRT EBE SYSTEM or where such capability is not provided, the MANUFACTURER shall include in the INSTRUCTIONS FOR USE a recommendation that the RESPONSIBLE ORGANIZATION ensure that such information is recorded by another system. This information shall include the identification of the OPERATOR.

Compliance is checked as follows:

SITE TEST grade B – Procedure: Perform a visual inspection.

201.102.3 Abnormal termination

In the event of abnormal termination of IGRT, the X-IGRT EQUIPMENT shall display to the user a warning or error depending on impact to IGRT.

A warning shall be displayed when the workflow is valid but can be prone to errors.

An error shall be displayed when the workflow is invalid and cannot be used.

In the case of abnormal termination of the X-IGRT EQUIPMENT the image data shall be recorded.

In the case of restarting after abnormal termination, the consistency, correctness and completeness of the data set required for completing the IGRT shall be checked by the X-IGRT EBE SYSTEM before it can be accepted for IGRT.

In the case of inconsistency, incorrectness or incompleteness of the data set being loaded, IGRT shall not be allowed to commence without:

- explicit display of the identified deficiencies to the OPERATOR; and
- ability of the OPERATOR to change or accept the identified deficiencies.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding warnings given of potential HAZARDOUS SITUATIONS.

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

SITE TEST grade B – Attempt to import a data set that fails the consistency, correctness and completeness test and verify that IGRT cannot commence. If the design is such that a data set with a fault cannot be created on-site, then this test shall be a TYPE TEST.

201.102.4 Image quality

The image quality and the method of measurement of the X-IGRT IMAGING COMPONENT shall be specified in the technical description. Where applicable, the method used to measure image quality in NORMAL USE of the X-IGRT IMAGING COMPONENT shall be described directly or by reference to a published reference.

The quality of the IMAGE DISPLAY DEVICE for the IGRT images shall be specified in the ACCOMPANYING DOCUMENTATION. This shall at a minimum state the CONTRAST and SPATIAL RESOLUTION of the IMAGE DISPLAY SYSTEM.

When the IMAGE DISPLAY DEVICE quality is less than that stated by IEC 62563-1:2009, the MANUFACTURER shall use HAZARD ANALYSIS to justify the image display quality needed.

NOTE The IMAGE DISPLAY DEVICE quality is specified in IEC documents in regard to diagnostic use (e.g., IEC 62563-1: 2009); since IGRT usage can imply such high requirements, it is left to the MANUFACTURER to specify what is required for use with their X-IGRT EQUIPMENT.

The image quality shall be defined in terms of:

- CONTRAST TO NOISE RATIO;
- spatial resolution (MTF or cut-off frequency, expressed e.g., as line pairs per cm); and
- uniformity throughout the clinical field of view.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding image quality and the method of measurement of the X-IGRT IMAGING COMPONENT.

201.102.5 Image artefacts

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

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

Compliance is checked by:

TYPE TEST grade A – Statement in the ACCOMPANYING DOCUMENTATION regarding known possible artefacts and their effect.

201.102.6 Imaging dose

201.102.6.1 Display and ACCOMPANYING DOCUMENTATION for planar imaging

a) The expected typical imaging dose for predefined protocols shall be stated in the ACCOMPANYING DOCUMENTATION. The units for the expected imaging dose shall be based upon the specifications of the protocol used. Where no protocols are supplied, clinical examples of imaging dose shall be illustrated in the ACCOMPANYING DOCUMENTATION.

b) The technical description supplied by the MANUFACTURER shall define the methods used for measuring the imaging dose referring to the specific standards for the planar imaging modality.

NOTE A dose area meter is not required for dose monitoring.

Compliance is checked as follows:

a) TYPE TEST grade A – Statement regarding expected typical imaging dose for predefined protocols.

b) *TYPE TEST grade A – Statement regarding the methods used for measuring the imaging dose*.

201.102.6.2 Display and ACCOMPANYING DOCUMENTATION for CBCT

201.102.6.2.1 Dosimetry PHANTOM

The dosimetry PHANTOM shall consist of a PMMA cylinder of density (1,19 ± 0,01) g/cm^3, of diameter 160 mm for all head PROTOCOL ELEMENTS and 320 mm for all body PROTOCOL ELEMENTS. The length of the PHANTOM shall be at least 140 mm. The PHANTOM shall be longer than the length of the sensitive volume of the RADIATION DETECTOR used for the measurements. The PHANTOM shall contain holes just large enough to accept the RADIATION DETECTOR. These holes shall be parallel to the axis of symmetry of the PHANTOM, and the centres of the holes shall be located at the centre and 10 mm below the surface of the PHANTOM at 90° intervals. For the holes not used during a measurement, properly fitting insert parts of the same material as the PHANTOM shall be used.

The method used to provide RADIATION dose indication in NORMAL USE of the MEE shall be described in the ACCOMPANYING DOCUMENTATION or by reference to a published reference.

NOTE The PHANTOM definition is based on IEC 60601-2-44:2009/AMD2:2016, 203.108.

201.102.6.2.2 Dose statements

201.102.6.2.2.1 *CTDI*$_{100}$

The following dose information shall be obtained by using the dosimetry PHANTOM for CBCT. Separate dose information shall be provided for each application (e.g., head and body) in the ACCOMPANYING DOCUMENTATION. All dose measurements shall be performed with the dosimetry PHANTOM placed on the PATIENT SUPPORT without additional attenuating material present. The dosimetry PHANTOM appropriate for the application shall be centred in the scan field and on the axis of rotation of the X-IGRT EQUIPMENT.

The following information shall be given in the ACCOMPANYING DOCUMENTATION for each application.

a) The CTDI$_{100}$ and the corresponding CBCT MODES OF OPERATION at the following locations in the dosimetry PHANTOM SPECIFIED IN 201.102.6.2.1. The CBCT MODES OF OPERATION shall be the typical values suggested by the MANUFACTURER.

   1) Along the axis of rotation of the PHANTOM (*CTDI*$_{100}$ (centre)).

   2) Along a line parallel to the axis of rotation and 10 mm interior to the surface of the PHANTOM, with the PHANTOM positioned so that the *CTDI*$_{100}$ is the maximum obtainable at this depth.

   3) Along a line parallel to the axis of rotation and 10 mm interior to the surface of the PHANTOM at positions 90°, 180° and 270° from the position in item a) 2) of this subclause. The location of the position where the *CTDI*$_{100}$ is maximum as specified in item a) 2) of this subclause shall be given by the MANUFACTURER with respect to the gantry or other readily identifiable part of the X-IGRT EQUIPMENT in such a manner as to permit placement of the dosimetry PHANTOM in this orientation.

4) $CTDI_{100}$ (peripheral) as 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) above.

b) The $CTDI_{100}$ in the centre location of the dosimetry PHANTOM for each selectable CBCT MODE OF OPERATION that varies the $CTDI_{100}$ (centre) value. This $CTDI_{100}$ (centre) shall be presented as a value that is normalized to the $CTDI_{100}$ in the centre location of the dosimetry PHANTOM from item a) of this subclause, with the $CTDI_{100}$ (centre) of item a) of this subclause having a value of 1. As a single CBCT MODE OF OPERATION is changed, all other independent CBCT MODES OF OPERATION shall be maintained at the typical values described in item a) of this subclause. These data shall encompass the range of each CBCT MODE OF OPERATION stated by the MANUFACTURER as appropriate. When more than three selections of a CBCT MODES OF OPERATION are available, the normalized $CTDI_{100}$ shall be provided, at least for the minimum, maximum and one mid-range value of the CBCT MODES OF OPERATION.

c) For scans using partial rotations used typically with CBCT, the same trajectory shall be used for all $CTDI_{100}$ measurements.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding the $CTDI_{100}$ and the corresponding CBCT MODES OF OPERATION and the MANUFACTURER's test results.

NOTE 201.102.6.2.2.1 has been adapted from IEC 60601-2-44:2009/AMD2:2016, 203.109.1.

201.102.6.2.2.2 $CTDI_{free\ air}$

$CTDI_{free\ air}$ and the corresponding CBCT MODES OF OPERATION shall be provided in the ACCOMPANYING DOCUMENTATION. $CTDI_{free\ air}$ shall be measured along a line perpendicular to the TOMOGRAPHIC PLANE at the ISOCENTRE of the X-IGRT EQUIPMENT in the absence of any dosimetry PHANTOM and PATIENT SUPPORT.

For MV CBCT appropriate build-up shall be used.

For scans using partial rotations used typically with CBCT, the same trajectory shall be used as for the $CTDI_{100}$ measurements.

A statement of the maximum deviation from the values shall be given. Deviations shall not exceed these limits.

The following data shall be included in the ACCOMPANYING DOCUMENTATION:

- $CTDI_{free\ air}$ at typical NOMINAL beam collimations for all CBCT MODES OF OPERATION at the typical IGRT IMAGING PROTOCOL;
- $CTDI_{free\ air}$ at typical settings for all CBCT MODES OF OPERATION at the typical IGRT IMAGING PROTOCOL; see Table 203.101 as an example below; and
- $CTDI_{free\ air}$ at the typical IGRT IMAGING PROTOCOL for each additional shaped or flat FILTER.

If a build-up cap is required to perform MV beam measurements, it shall be documented in the ACCOMPANYING DOCUMENTATION

NOTE 1 NOMINAL beam collimation is equal to nominal, pre-set collimator field sizes of the CBCT mode. It usually is the same as the scan length along a line perpendicular to the TOMOGRAPHIC PLANE of a CBCT scan.

NOTE 2 An alternative method to measure CTDI ($CTDI_{100}$ or $CTDI_{free\ air}$) is based on measurement of the DOSE PROFILE and integration of the profile over the desired range. The dose profile can be measured with a RADIATION DETECTOR that fulfils IEC 61674, e.g., with a small dosimeter.

NOTE 3 Table 201.103 provides an example test pattern for $CTDI_{free\ air}$ for kV.

Table 201.103 – Example test pattern for $CTDI_{free\ air}$ for kV

		Variation of the NOMINAL beam collimation				
		Collimation 1	Collimation 2	Collimation 3	Collimation 4 (typical)	Collimation 5
Variation of kV	kV1				Y	
	kV2 (typical)	Y	Y	Y	Y	Y
	kV3				Y	

NOTE 4 201.102.6.2.2.2 has been adapted from IEC 60601-2-44:2009/AMD2:2016, 203.109.2.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding the $CTDI_{free\ air}$ and the corresponding CBCT MODES OF OPERATION and the MANUFACTURER's test results.

201.102.6.2.2.3 DOSE PROFILE statement

A graphical presentation of the DOSE PROFILE along a line perpendicular to the TOMOGRAPHIC PLANE and centred at the ISOCENTRE, determined in free air for one axial scan, in the centre location of the head-dosimetry PHANTOM, and the centre location of the body-dosimetry PHANTOM shall be given in the ACCOMPANYING DOCUMENTATION for minimum and maximum value of $N \times T$.

For X-IGRT EQUIPMENT with a single detector row along the line perpendicular to the TOMOGRAPHIC PLANE, the DOSE PROFILE shall be presented on the same graph and to the same scale as the corresponding SENSITIVITY PROFILE required by 201.102.6.2.2.4. For X-IGRT EQUIPMENT with multiple detector rows along the line perpendicular to the TOMOGRAPHIC PLANE, two vertical line segments separated by the width $N \times T$ shall be presented on the same graph centred within the DOSE PROFILE.

The graphical presentation shall cover a range along the y-direction that extends to at least the full width at one-tenth maximum of the DOSE PROFILE.

NOTE 1 For CBCT $N \times T$ is NOMINAL beam collimation.

NOTE 2 201.102.6.2.2.3 has been adapted from IEC 60601-2-44:2009/AMD2:2016, 203.110.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding DOSE PROFILE.

201.102.6.2.2.4 SENSITIVITY PROFILE statement

A graphical representation of the associated SENSITIVITY PROFILE in air shall be given in the ACCOMPANYING DOCUMENTATION as follows:

a) One SENSITIVITY PROFILE for each available axial NOMINAL TOMOGRAPHIC SECTION THICKNESS shall be plotted. Where there are more than three NOMINAL TOMOGRAPHIC SECTION THICKNESS, plot the SENSITIVITY PROFILE for at least the minimum, the maximum and one mid-range value.

b) For X-IGRT EQUIPMENT with a single detector row along the line perpendicular to the TOMOGRAPHIC PLANE, the SENSITIVITY PROFILE associated with the configuration slide thickness T shall be presented on the same graph, placed about the same central location, to the same scale as that of the corresponding DOSE PROFILE required by 201.102.6.2.1, for the head-dosimetry PHANTOM and for the body-dosimetry PHANTOM.

NOTE 201.102.6.2.2.4 has been adapted from IEC 60601-2-44:2009/AMD2:2016, 203.111.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding SENSITIVITY PROFILE.

201.102.6.2.2.5 Display and recording of $CTDI_{vol}$ and DLP

The values for $CTDI_{vol}$ expressed in units of mGy or cGy and DLP expressed in units of mGy·cm or cGy·cm, both quantities reflecting the PROTOCOL ELEMENT selected, shall be displayed on the CONTROL PANEL prior to initiation of a scanning sequence. Additionally, the PHANTOM diameter on which $CTDI_{vol}$ values are based shall be displayed.

The units selected shall conform to other radiation units per 201.101.3.

The ACCOMPANYING DOCUMENTATION shall contain the conversion from the $CTDI_{vol}$ based on the 32 cm phantom to the $CTDI_{vol}$ based on the 16 cm phantom. This conversion shall be provided for all relevant combinations of IGRT IMAGING PROTOCOL. The ACCOMPANYING DOCUMENTATION shall contain guidance on how to specify whether a PROTOCOL ELEMENT is a head or body PROTOCOL ELEMENT.

If any of the IGRT IMAGING PROTOCOL are intended to vary within a scanning sequence, corresponding expected values of $CTDI_{vol}$ and *DLP* shall be displayed prior to exposure. Each value shall represent an anticipated time-weighted average over the scanning sequence.

For scanning without pre-programmed movement of the PATIENT SUPPORT, when calculating $CTDI_{vol}$ per 201.3.232.3 for display, *n* is equal to the maximum number of pre-programmed rotations. Where the number of rotations is not pre-programmed, during the scan the $CTDI_{vol}$ shall be displayed in units as defined in 201.101.3.

Following a sequence of scanning (e.g., with CBCT modes that merges multiple scans) the mean values of $CTDI_{vol}$ and *DLP* shall be displayed on the CONTROL PANEL, where these values are calculated as time-weighted averages over the scanning sequence.

The post-scan mean values of $CTDI_{vol}$ and *DLP* along with the PHANTOM type shall be recorded according to the DICOM RADIATION dose structured report (SR).

The accuracy of the displayed and recorded values of $CTDI_{vol}$ and *DLP* shall be specified in the ACCOMPANYING DOCUMENTATION.

NOTE 1 The displayed and recorded $CTDI_{vol}$ and *DLP* given by the MANUFACTURER can be a representative figure for that model and not the value measured on the X-IGRT EQUIPMENT.

The ACCOMPANYING DOCUMENTATION shall contain the method used for adjusting *L* as defined in 201.3.205 b).

NOTE 2 201.102.6.2.2.5 has been adapted from IEC 60601-2-44:2009/AMD2:2016, 203.112.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding $CTDI_{vol}$ and DLP.

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

201.102.6.2.2.6 TOMOGRAPHIC SECTION THICKNESS accuracy

A statement about the TOMOGRAPHIC SECTION THICKNESS accuracy shall be provided in the ACCOMPANYING DOCUMENTATION for all CBCT MODES OF OPERATION used to provide the information required by 201.102.6.2.

TYPE TEST grade A – Statement regarding TOMOGRAPHIC SECTION THICKNESS ACCURACY.

201.102.6.2.2.7 Post-exposure display of changed IGRT IMAGING PROTOCOL for kV CBCT

For kV CBCT, following a sequence of scanning in which the TUBE CURRENT was selected to vary, the time weighted average of the TUBE CURRENT over the scanning sequence shall be displayed.

Compliance is checked as follows:

TYPE TEST GRADE *B – Procedure: Inspect DISPLAY and output information.*

201.103 IGRT analysis and correction

201.103.1 Algorithm description

a) Description of all algorithms used for IMAGE RECONSTRUCTION and IMAGE REGISTRATION shall be included in the technical description. This shall include a description of the factors accounted by the algorithm, the class of algorithms forming the basis of the calculation, the limits applied to all variables used in the equations, and details of how algorithms handle different artefacts.

b) Where a choice of algorithms is provided for a particular calculation, the INSTRUCTIONS FOR USE shall discuss the relative advantages and disadvantages of the different algorithms.

Compliance is checked as follows:

a) TYPE TEST grade A – Statement regarding algorithms used for IMAGE RECONSTRUCTION and IMAGE REGISTRATION.

b) TYPE TEST grade A – Statement regarding relative advantages and disadvantages of the different algorithms.

201.103.2 Accuracy of algorithms

a) For each algorithm used for IMAGE RECONSTRUCTION and IMAGE REGISTRATION, the technical description shall state the accuracy of the result(s) of the algorithm relative to the displayed calculated PATIENT shift for at least one set of pre-defined conditions. The predefined conditions shall be chosen to simulate the conditions for NORMAL USE. Where predefined conditions are available in a published report or standard, these shall be used.

NOTE For each type of input as well as limitations in the algorithm, there is an associated resolution limitation. This requirement is looking for the final uncertainty in the calculated value due to these resolution limitations.

b) The technical description shall include all descriptions and data necessary for the RESPONSIBLE ORGANIZATION to reproduce the pre-defined conditions, or suitable references where these conditions are publicly available. It shall also include test procedures that permit convenient testing by the RESPONSIBLE ORGANIZATION to show that the expected results are achieved with the provided input data.

c) The INSTRUCTIONS FOR USE shall provide cautionary notes for the OPERATOR concerning the limitations of IMAGE REGISTRATION and the need for visual inspection of accuracy and fitness for purpose.

Compliance is checked as follows:

a) TYPE TEST grade A – Statement regarding the accuracy of the algorithm relative to measured data for at least one set of pre-defined conditions.

b) TYPE TEST grade A – Statement regarding the required description and data necessary for the RESPONSIBLE ORGANIZATION to reproduce the pre-defined conditions.

c) TYPE TEST grade A – Statement regarding the limitations of registration and the need for visual inspection of accuracy and fitness.

201.103.3 * Image-guided adjustment and correction

201.103.3.1 OFFLINE IGRT

The following items shall be provided and either recorded by the X-IGRT EQUIPMENT or communicated to an external system:

– the positional corrections calculated from IMAGE REGISTRATION;

– IGRT adjustment(s) to PATIENT position or TREATMENT PLAN; and

NOTE 1 The IGRT calculated adjustment(s) can be different from the correction applied by the EBE.

– the OPERATOR performing approval and the approved adjustment(s) where adjustments are approved at the X-IGRT EQUIPMENT.

If neither recording nor communicating capability is provided, the MANUFACTURER shall include in the INSTRUCTIONS FOR USE a recommendation that the RESPONSIBLE ORGANIZATION ensures that such information is recorded by another system.

NOTE 2 Another system can be e.g., a RECORD AND VERIFY SYSTEM that is in communication with the X-IGRT EBE SYSTEM.

All IGRT correction values shall be in SI units and shall be in the IEC 61217 coordinate system.

NOTE 3 This applies to the values recorded and shown to the user. An alternate set of units for use during transfer can be used as long as it is part of a standard communication protocol (i.e., DICOM).

The X-IGRT EQUIPMENT can have an alternative scheme of coordinates selectable by the RESPONSIBLE ORGANIZATION if that coordinate system matches the one on the receiving EXTERNAL BEAM EQUIPMENT.

Compliance is checked as follows:

TYPE TEST grade B – Procedure: Perform IGRT workflow and check recorded data and communication to external system.

SITE TEST grade B – Procedure: Perform IGRT workflow and check recorded data and communication to external system.

201.103.3.2 ONLINE IGRT

The following items shall be displayed on the x-IGRT EQUIPMENT or X-IGRT EBE SYSTEM:

– IGRT calculated adjustment(s) to PATIENT position or TREATMENT; and

– IGRT correction sent to the EBE or other external system, where different from the calculated adjustment(s).

The following items shall either be recorded by the X-IGRT EBE SYSTEM or provided by the X-IGRT EQUIPMENT as output data to an external system:

– the adjustment(s) calculated by image analysis;

– IGRT calculated adjustment(s) to PATIENT position or TREATMENT;

– IGRT correction sent to the EBE or other external system and the date and time this occurs; and

NOTE 1 The IGRT correction sent to the EBE can be different from the correction applied by the EBE.

– the OPERATOR performing the IGRT calculated correction or overriding actual correction.

If the X-IGRT EBE SYSTEM provides the above items as output data to an external system, the MANUFACTURER shall include in the INSTRUCTIONS FOR USE a recommendation that the RESPONSIBLE ORGANIZATION ensures that such information is recorded by another system.

NOTE 2 Another system can be e.g., a RECORD AND VERIFY SYSTEM that is in communication with the X-IGRT EBE SYSTEM.

All IGRT correction values shall be in SI units and shall be in the IEC 61217 coordinate system.

NOTE 3 This applies to the values recorded and shown to the user. An alternate set of units for use during transfer can be used as long as it is part of a standard communication protocol (i.e., DICOM).

The X-IGRT EQUIPMENT can have an alternative scheme of coordinates selectable by the RESPONSIBLE ORGANIZATION if that coordinate system matches the one on the receiving EXTERNAL BEAM EQUIPMENT.

The corrections to be sent to the EBE shall be tolerance checked by the X-IGRT EQUIPMENT against pre-established limits defined and documented by the MANUFACTURER in its ACCOMPANYING DOCUMENTATION.

Means shall be provided for the OPERATOR to override the calculated corrections from the X-IGRT EBE SYSTEM at any time before the corrections are sent to the EBE.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding pre-established limits.

TYPE TEST grade B – Procedure: Perform IGRT workflow and check recorded data and communication to external system.

SITE TEST grade B – Procedure: Perform IGRT workflow and check recorded data and communication to external system.

201.103.3.3 REAL-TIME IGRT

The corrections to be sent to the EBE shall be tolerance checked against pre-established limits defined and documented by the MANUFACTURER in its ACCOMPANYING DOCUMENTATION.

The X-IGRT EQUIPMENT shall have a function to transmit an interlock signal(s) for inhibiting, interrupting or terminating the therapeutic IRRADIATION by the EBE.

The X-IGRT EQUIPMENT shall have a function to automatically terminate X-RAY RADIATION for imaging upon receipt of an interlock signal from the EBE indicating a system fault, data values out of bounds or INTERLOCK.

The images acquired shall be displayed to the OPERATOR during the entire IRRADIATION along with the REFERENCE IMAGES or reference data used for comparison until such time that new images for IGRT calculated corrections are acquired unless the images are acquired at a rate faster than 24 per second. For images acquired at rates faster than 24 per second, the displayed frame rate can be 24 per second.

Means shall be provided for the OPERATOR to send an INTERRUPT and TERMINATE signal to the EBE from the X-IGRT EQUIPMENT at any time during therapeutic IRRADIATION.

The following items shall be available and either recorded by the IGRT EQUIPMENT or provided by the IGRT EQUIPMENT as output data to external equipment each time the IGRT correction is sent to the EBE:

– the OPERATOR initiating the REAL-TIME IGRT;
– adjustment(s) calculated by image analysis and the associated images;
– IGRT calculated adjustment(s) to PATIENT position or TREATMENT;
– IGRT correction sent to the EBE;

NOTE 1 The IGRT correction sent to the EBE can be different from the correction applied by the EBE.

– the OPERATOR performing manual adjustment or overriding correction; and
– the application time of the alignment correction.

If the IGRT EQUIPMENT provides the above items as output data to an external system, the MANUFACTURER shall include in the INSTRUCTIONS FOR USE a recommendation that the RESPONSIBLE ORGANIZATION ensure that such information is recorded by another system.

NOTE 2 Another system can be e.g., a RECORD AND VERIFY SYSTEM that is in communication with the IGRT Equipment.

All IGRT correction values shall be in SI units and shall be in the IEC 61217 coordinate system. An alternate set of units for use during transfer is allowed as long as it is part of a standard communication protocol (i.e., DICOM).

The X-IGRT EQUIPMENT can have an alternative scheme of coordinates selectable by the RESPONSIBLE ORGANIZATION if that coordinate system matches the one on the receiving EXTERNAL BEAM EQUIPMENT.

Compliance is checked as follows:

TYPE TEST grade A – Statement regarding pre-established limits.

TYPE TEST grade B – Procedure: Perform IGRT workflow and check recorded data and communication to external system.

SITE TEST grade B – Procedure: Perform IGRT workflow and check recorded data and communication to external system.

201.104 Operation of ME EQUIPMENT parts from outside the facility

The X-IGRT EQUIPMENT can be provided with the capability for electronic access (e.g., via the Internet) to the control system for the purpose of diagnostic evaluation of the equipment. Such evaluation is performed to correctly operate the device. For example, the TCP can be controlled from a remote location for this purpose.

When functions and controls are accessed remotely from outside the facility:

a) a means shall be provided at the TCP to enable control by a remote operator;
b) the MEE shall require an action at the TCP at the time a connection is established and before any functions or movements are controlled remotely, or before any files on the MEE are remotely modified;
c) the TCP shall indicate whenever a remote connection is established; and
d) any movements shall comply with the provisions of 201.9.2.101.

In addition, it shall be impossible through remote access to:

e) violate or override any of the provisions of 201.9.2.102 and 201.9.2.103;

f) allow the remote OPERATOR to bypass interlocks that could result in injury to any person; or

g) allow the remote OPERATOR to INITIATE IRRADIATION for any RADIATION SOURCES.

Compliance tests:

a) TYPE TEST grade A – Inspection of ACCOMPANYING DOCUMENTATION.

b) *SITE TEST grade B: attempt to connect from a remote site to the X-IGRT EBE SYSTEM without first providing action at the TCP and verify that control cannot be established.*

c) SITE TEST grade B – Demonstrate that the display indicates remote operation under remote control.

d) *TYPE TEST grade A: Inspection of ACCOMPANYING DOCUMENTATION.*

e), f), and g) *SITE TEST grade B: demonstrate function of remote diagnostic capability.*

203 RADIATION protection in diagnostic X-RAY EQUIPMENT

For 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 Annex AA).

IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013, and IEC 60601-1-3:2008/AMD2:2021 apply for KILOVOLTAGE X-IGRT EQUIPMENT, except as follows:

203.4 General requirements

203.4.1 Statement of compliance

Replacement:

If for an X-IGRT EQUIPMENT, or a sub-assembly thereof, compliance with IEC 60601-2-68 is to be stated, the statement shall be given in the ACCOMPANYING DOCUMENTATION:

X-IGRT EQUIPMENT... ++) IEC 60601-2-68:2025

++) MODEL OR TYPE REFERENCE

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTATION.

203.6 RADIATION management

203.6.2 Initiation and TERMINATION OF IRRADIATION

203.6.2.1 Normal initiation and TERMINATION OF IRRADIATION

Replacement:

The first LOADING of an IMAGING SESSION shall be initiated by means of a control requiring action by the OPERATOR. It shall be possible for the OPERATOR to terminate the LOADING at any time.

Any control by which the LOADING of an X-RAY TUBE can be initiated shall be protected against unintended actuation using means compatible with the INTENDED USE of the X-RAY EQUIPMENT.

Compliance is checked by inspection and by the appropriate functional tests.

203.6.3 Radiation dose and RADIATION QUALITY

203.6.3.1 Adjustment of RADIATION dose and RADIATION QUALITY

Replacement:

It shall be possible to restrict the RADIATION dose to the PATIENT in line with the INTENDED USE of the X-RAY EQUIPMENT. It shall be possible to adjust the RADIATION QUALITY over a suitable range in line with the INTENDED USE of the X-RAY EQUIPMENT.

Compliance is checked by inspection and functional tests.

203.6.3.2 Reproducibility of the RADIATION output

Replacement:

The ACCOMPANYING DOCUMENTATION shall state the reproducibility of the RADIATION output.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTATION.

203.6.4 Indication of operational states

203.6.4.1 Indication of the X-RAY SOURCE ASSEMBLY selected

Replacement:

Where X-RAY EQUIPMENT has provisions to select more than one X-RAY SOURCE ASSEMBLY or X-RAY IMAGING ARRANGEMENT, an indication of the X-RAY SOURCE ASSEMBLY or X-RAY IMAGING ARRANGEMENT selected shall be provided on the CONTROL PANEL prior to the LOADING of the X-RAY SOURCE ASSEMBLY.

Compliance is checked by inspection.

203.8 Limitation of the extent of the X-RAY BEAM and relationship between X-RAY FIELD and IMAGE RECEPTION AREA

203.8.4 Confinement of EXTRA-FOCAL RADIATION

Replacement:

The contribution of EXTRA-FOCAL RADIATION to the X-RAY IMAGE RECEPTOR and to the PATIENT dose shall be limited to an acceptable level. Acceptable levels of EXTRA-FOCAL RADIATION shall be determined by the RISK MANAGEMENT and stated in the ACCOMPANYING DOCUMENTATION.

NOTE One of the most important means of decreasing the EXTRA-FOCAL RADIATION is to limit the RADIATION BEAM close to the FOCAL-SPOT.

Compliance is checked by inspection.

203.10 ATTENUATION of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR

203.10.2 Information in the ACCOMPANYING DOCUMENTATION

Replacement:

The ACCOMPANYING DOCUMENTATION shall state the maximum value of the ATTENUATION EQUIVALENT of each item interposed between the PATIENT and the X-RAY IMAGE RECEPTOR and forming part of the X-RAY EQUIPMENT.

For X-IGRT EQUIPMENT specified to be used in combination with ACCESSORIES or other items not forming part of the same or other X-IGRT EQUIPMENT, the instructions for use shall include a statement drawing attention to the possible adverse effects arising from materials located in the X-RAY BEAM (e.g., parts of the PATIENT SUPPORT device).

Compliance is checked by examination of the ACCOMPANYING DOCUMENTATION.

203.11 Protection against RESIDUAL RADIATION

Clause 11 of IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013, and IEC 60601-1-3:2008/AMD2:2021 does not apply.

203.13 Protection against STRAY RADIATION

Clause 13 of IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013, and IEC 60601-1-3:2008/AMD2:2021 does not apply.

206 Usability

IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 apply, except as follows:

Addition:

NOTE Although it will not be possible to apply IEC 60601-1-6:2010 retroactively to existing MEE and to those that have passed beyond the stage identified above, examination of the available design and process control data can provide substantial verification.

Annexes

The annexes of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 apply, except as follows:

Annex A
(informative)

Sequence of testing

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

A.1 General

Addition:

The MANUFACTURER shall state the sequence of testing where it differs from the sequence shown in this annex.

Annex I
(informative)

ME SYSTEMS aspects

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

Additional annexes:

Annex AA
(informative)

Particular guidance and rationale

The following are rationales for specific subclauses in this document, with subclause numbers parallel to those in the body of the document.

Subclause 201.1.1 – Scope

In this document CT SCANNER, X-RAY EQUIPMENT for RADIOGRAPHY, or X-RAY EQUIPMENT for RADIOSCOPY used for X-IGRT are addressed as X-IGRT IMAGING COMPONENT as defined in 201.3.236 of this document.

The scope defines that requirements being tested according to other standard(s) can be identified by the manufacturer and if equivalent, do not require retesting, instead, evidence can refer to corresponding compliance statement or test report.

Table AA.1 lists the clauses of this document with the corresponding, equivalent clauses of IEC 60601-2-44 for CT SCANNERS, and of IEC 60601-2-54 for X-RAY EQUIPMENT for RADIOGRAPHY and X-RAY EQUIPMENT for RADIOSCOPY.

Table AA.1 – Clauses of the standard that contain requirements for X-IGRT IMAGING COMPONENTS and related clauses of IEC 60601-2-44 and IEC 60601-2-54 with equivalent requirements for CT SCANNER, X-RAY EQUIPMENT for RADIOGRAPHY, and X-RAY EQUIPMENT for RADIOSCOPY

IEC 60601-2-68:2024	IEC 60601-2-44:2009, IEC 60601-2-44:2009/AMD1:2012 and IEC 60601-2-44:2009/AMD2:2016	IEC 60601-2-54:2009	Description
201.8.8.3	201.8.8.3	201.8.8.3	Dielectric strength
201.10	201.10 and 203.107	201.10 and 203	Safety measures against excessive X-RADIATION
201.102	203	203	X-IGRT IMAGING and dose indications
203	203	203	RADIATION protection in diagnostic X-RAY EQUIPMENT

Subclause 201.3.210 – IGRT LATENCY

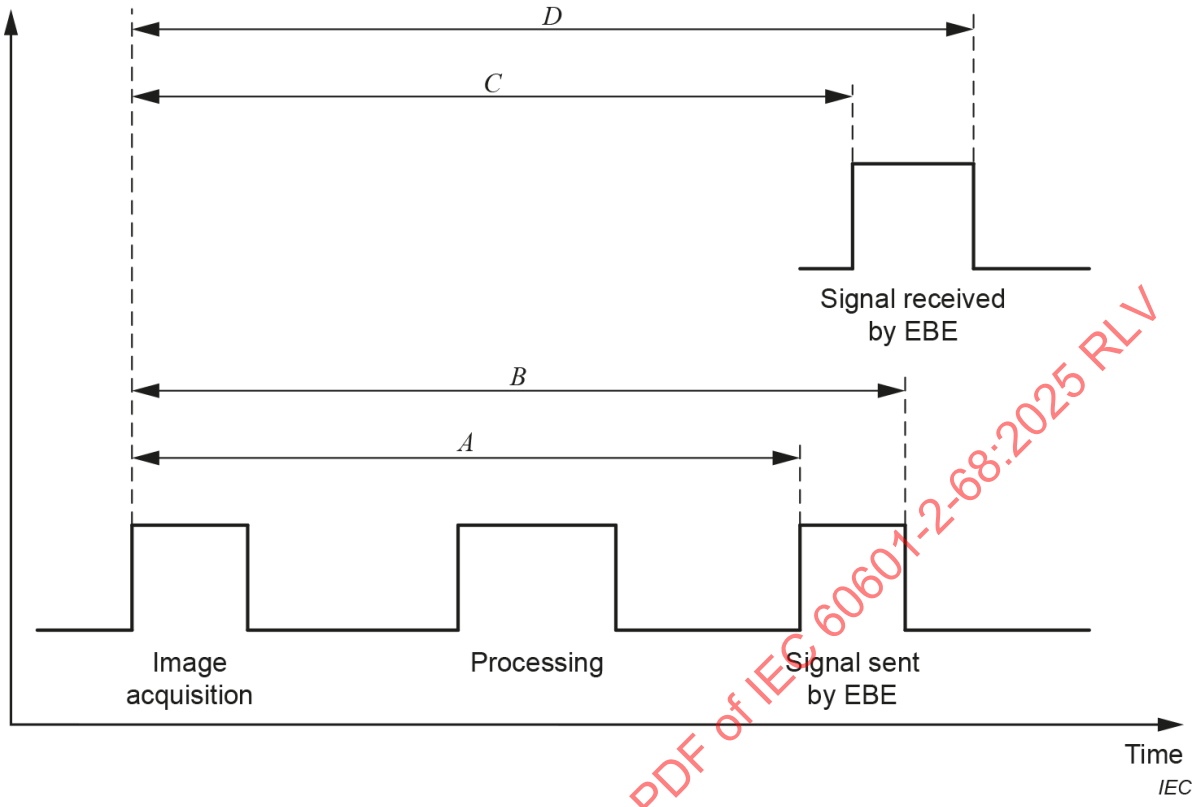

Figure AA.1 – Signals related to IGRT LATENCY

For the definition of IGRT LATENCY, the time of initiation of image acquisition is understood by the time the trigger starts the image acquisition. That can be by pressing a hand switch or set by a software command. The output signal by IGRT EQUIPMENT to the EBE is depending on the actual implementation of the IGRT EQUIPMENT. The signal can have a raising and a falling edge, as shown in Figure AA.1 with A and B, and the IGRT LATENCY is related to either one of these cases. The IGRT LATENCY does not consider the signal received at the EBE, the transmission time is not part of the IGRT LATENCY.

Subclause 201.101.6 – Conformance of data bounds from X-IGRT EQUIPMENT to EBE

Increasingly, RADIATION TREATMENT machines have the ability to vary TREATMENT PARAMETERS as TREATMENTS are progressing. For example, PATIENT POSITIONER speed, field size, dose rate, etc. can be varied during TREATMENT. With the introduction of PATIENT monitoring systems that track PATIENT movement during TREATMENT, and cause TREATMENT PARAMETERS to be varied during TREATMENT to compensate for that movement, the increased RISK to the PATIENT should be considered if these monitoring systems do not operate as intended. In particular, the need to establish real-time secondary level bounds checking should be considered for parameters that are varied during TREATMENT.

Two types of position errors are worth illustrating:

1) Normal discrepancy between planned and actual position of moving parts

   An example case is a PATIENT POSITIONER that is movable during the PATIENT TREATMENT. As with any real-time position control system, there will always be a finite discrepancy between the planned and the actual position of the positioner. Typical real-time positioning software will establish an acceptable error band, and the TREATMENT will be terminated if the position of the table falls outside the pre-determined error limits.

2) Position error caused by unexpected condition or position control algorithm flaw

Consider an X-ray based imaging system that is monitoring the PATIENT position and has the ability to change a TREATMENT PARAMETER, such as field width, to compensate for PATIENT movement. Suppose that the imaging system receives an unexpected input, for example an image artefact, and mistakenly decides that based on this input, the field should be enlarged to the maximum possible size at a time when a very small field was desired. This could cause significant dose error, as this condition would not necessarily be caught by a cumulative type of dose monitoring system located upstream of the field limiting device. To help guard against this possibility, some sort of bounds check (or "sanity check") at TREATMENT time is required to make sure parameter settings that are obviously incorrect cannot be made. In this example, the X-IGRT EBE SYSTEM should check the value against a predetermined allowable change and INTERRUPT the delivery and ask the operator if it is safe to proceed before continuing.

In conclusion, the increasing reliance on complex algorithms to modify TREATMENT PARAMETERS in real-time during TREATMENT calls for some checks and constraints on the values of those parameters. These constraints could be determined at planning time and transferred to the TREATMENT system just before TREATMENT. This allows the TREATMENT system to monitor for any attempts by the software to set TREATMENT PARAMETERS outside the pre-established safe range, and halt the TREATMENT if the safe range is exceeded. This sort of secondary sanity check should be performed in addition to the traditional primary position error band check used in real-time control systems.

Subclause 201.103.3 – Image-guided adjustment and correction

Modes of operation of X-IGRT have been categorised in 3 types, OFFLINE X-IGRT, ONLINE X-IGRT and REAL-TIME X-IGRT. Clauses applicable to X-IGRT with 3 spatial dimensions and time (4D X-IGRT) are covered by the modes of operation, OFFLINE X-IGRT, ONLINE X-IGRT and REAL-TIME X-IGRT.

The following are examples of 4D X-IGRT classified by mode.

Example 1: OFFLINE X-IGRT

4D CT image acquisition of the patient during the TREATMENT is carried out. The image analysis is performed offline where the position of the TARGET VOLUME is determined from the 4D CT set, using this 4D information the range of motion of the TARGET VOLUME is determined and a mean position is calculated. This can be done on several sessions. Future sessions can adjust the setup to incorporate the range of motion.

Example 2: ONLINE X-IGRT

4D CT image acquisition of the patient immediately prior to TREATMENT is acquired. This 4D information is used to determine the range of motion of the TARGET VOLUME and determine its mean position. A shift of the patient is performed prior to the commencement of the TREATMENT to ensure the mean position is at the planned TREATMENT position.

Example 3: ONLINE X-IGRT

Image and respiratory information of the patient are acquired immediately prior to the TREATMENT. Analysis is performed to correlate image and respiratory information in 4D. This information is used to determine range of motion of the TARGET VOLUME. During the TREATMENT the respiratory monitoring is continued to calculate the position of the TARGET VOLUME. The EBE is sent the signal to correct for the change of the TARGET VOLUME position continuously.

This is ONLINE X-IGRT as the IGRT only performed a pre-TREATMENT model and the real-time aspects are dealt with by the correlation model which is fixed during TREATMENT.

Example 4: REAL-TIME X-IGRT

Images are continuously acquired using multiple kV X-ray sources at different angles during the TREATMENT. The images are continuously analysed to determine the 3D position of the TARGET VOLUME. The EBE is sent to the signal to correct for the change of the TARGET VOLUME position or correlation model throughout the therapeutic IRRADIATION.

Annex BB
(informative)

Measuring $CTDI_{free\ air}$

Free-in-air measurements of *CTDI* are useful in understanding the X-RAY BEAM characteristics of a CBCT scan on an IGRT EQUIPMENT. Since there is not a scattering medium, these measurements characterize the X-RAY BEAM output emanating from the collimators, quantifying the dosimetric effects of the tube, the inherent filtration, the filtration of the central ray and the effects of over-beaming and penumbra. In order to measure $CTDI_{free\ air}$, it is necessary to integrate the DOSE PROFILE along the y-axis for the entire extent of the X-ray field. In order to ensure that the entire y-extent is captured, the integration length (L) should be at least 40 mm longer than the nominal beam collimation.

One method of measuring $CTDI_{free\ air}$ is to use a RADIATION DETECTOR (e.g., an IONIZATION CHAMBER) positioned along the axis of rotation of the IGRT EQUIPMENT and translated (stepped) through the ISOCENTRE using the PATIENT SUPPORT to cover the entire integration length.

NOTE 1 As another method the DOSE PROFILE can be measured with a RADIATION DETECTOR that fulfils IEC 61674, e.g., with a point DOSIMETER uniformly translated through the ISOCENTRE using a helical scan protocol.

1) Attach IONIZATION CHAMBER to a long, minimally attenuating support such as a metre stick or plastic rod.
2) Attach support with IONIZATION CHAMBER to the PATIENT SUPPORT using a weighted stand or other means so that the chamber apparatus will move with the PATIENT SUPPORT. Ensure that the active length of the IONIZATION CHAMBER extends a distance greater than half the integration length (L/2) beyond the end of the PATIENT SUPPORT so that the PATIENT SUPPORT does not interact with the primary beam during measurements.
3) Ensure that the centre of the IONIZATION CHAMBER is positioned at the ISOCENTRE of the IGRT EQUIPMENT, and that the IONIZATION CHAMBER is aligned with the IGRT EQUIPMENT y-axis; set the PATIENT SUPPORT location to 0.
4) Using the PATIENT SUPPORT, move the IONIZATION CHAMBER in the negative y-direction by X mm where

$$X = \frac{L - W}{2}$$

and where

L is the integration length in mm;

W is the chamber length in mm.

5) Take an axial scan with the desired parameters and record the exposure value.
6) Increment the table in the positive y-direction by an amount equal to the length of the ion chamber.
7) Repeat steps 5) and 6) for a total of Y exposures, until the entire integration length is covered, where

$$X = \frac{L}{W}$$

and where

L is the integration length in mm;

W is the chamber length in mm.

8) Sum the Y different exposure values to compute the $CTDI_{free\ air}$ for the given IGRT equipment configuration.

NOTE 2 More precise estimations of $CTDI_{free\ air}$ could be obtained by employing step sizes much smaller than the chamber length or by uniformly translating the entire chamber through the beam.

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[1] This publication was withdrawn and replaced with IEC 60522-1:2020

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Index of defined terms used in this document

SOMMAIRE

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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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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L'IEC 60601-2-68 a été établie par le sous-comité 62C: Appareils de radiothérapie, de médecine nucléaire et de dosimétrie du rayonnement, du comité d'études 62 de l'IEC: Équipement médical, logiciels et systèmes médicaux. Il s'agit d'une Norme internationale.

Cette deuxième édition annule et remplace la première édition parue en 2014. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente:

a) alignement sur les nouvelles éditions des normes pertinentes:
   – IEC 60601-2-1:2020;
   – IEC 60601-2-44:2009, IEC 60601-2-44:2009/AMD1:2012 et IEC 60601-2-44:2009/AMD2:2016;
   – IEC 60601-2-64:2014;
b) clarification de l'utilisation de l'IEC 60601-2-68 pour les TOMODENSITOMETRES, les APPAREILS A RAYONNEMENT X pour la RADIOGRAPHIE et la RADIOSCOPIE utilisés dans la même salle avec un APPAREIL DE RADIOTHERAPIE EXTERNE (EBE);
c) introduction d'exigences actualisées relatives aux DANGERS MECANIQUES, aux DANGERS DUS AU RAYONNEMENT, aux SYSTEMES ELECTROMEDICAUX PROGRAMMABLES (SEMP), à la DOCUMENTATION D'ACCOMPAGNEMENT d'un SYSTEME EM, et au FONCTIONNEMENT A DISTANCE.

Le texte de cette Norme internationale est issu des documents suivants:

Projet	Rapport de vote
62C/927/FDIS	62C/941/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à son approbation.

La langue employée pour l'élaboration de cette Norme internationale est l'anglais.

Ce document a été rédigé selon les Directives ISO/IEC, Partie 2, il a été développé selon les Directives ISO/IEC, Partie 1 et les Directives ISO/IEC, Supplément IEC, disponibles sous www.iec.ch/members_experts/refdocs. Les principaux types de documents développés par l'IEC sont décrits plus en détail sous www.iec.ch/publications.

Dans le présent document, les caractères d'imprimerie suivants sont utilisés:

– exigences et définitions: caractères romains;
– *modalités d'essais: caractères italiques;*
– indications de nature informative qui apparaissent hors des tableaux, comme les notes, les exemples et les références: petits caractères. Le texte normatif à l'intérieur des tableaux est également en petits caractères;
– TERMES DEFINIS A L'ARTICLE 3 DE L'IEC 60601-1:2005, L'IEC 60601-1:2005/AMD1:2012 ET L'IEC 60601-1:2005/AMD2:2020, DANS LE PRESENT DOCUMENT OU COMME CELA EST NOTE: PETITES MAJUSCULES.

Concernant la structure du présent document, le terme:

– "article" désigne l'une des dix-sept sections numérotées dans la table des matières, avec toutes ses subdivisions (par exemple, l'Article 7 inclut les paragraphes 7.1, 7.2, etc.);
– "paragraphe" désigne une subdivision numérotée d'un article (par exemple, le 7.1, le 7.2 et le 7.2.1 sont tous des paragraphes de l'Article 7).

Dans le présent document, les références à des articles sont précédées du mot "Article" suivi du numéro de l'article concerné. Dans le présent document, les références aux paragraphes utilisent uniquement le numéro du paragraphe concerné.

Dans le présent document, la conjonction "ou" a la valeur d'un "ou inclusif". Ainsi, un énoncé est vrai si une combinaison des conditions, quelle qu'elle soit, est vraie.

Les formes verbales utilisées dans le présent document sont conformes à l'usage donné à l'Article 7 des Directives ISO/IEC, Partie 2. Pour les besoins du présent document:

– le verbe "devoir" signifie que la conformité à une exigence ou à un essai est obligatoire pour assurer la conformité au présent document;
– l'expression "il convient" signifie que la conformité à une exigence ou à un essai est recommandée, mais n'est pas obligatoire pour assurer la conformité au présent document;
– le verbe "pouvoir" est utilisé afin de décrire un moyen admissible pour assurer la conformité à exigence ou à un essai.

Lorsqu'un astérisque (*) est utilisé comme premier caractère devant un titre ou au début d'un titre d'alinéa ou de tableau, il indique l'existence de recommandations ou d'une justification à consulter à l'Annexe AA.

Une liste de toutes les parties des séries IEC 60601, publiées sous le titre général *Appareils électromédicaux*, se trouve sur le site web de l'IEC.

Le comité a décidé que le contenu de ce document ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous webstore.iec.ch dans les données relatives au document recherché. À cette date, le document sera

- reconduit,
- supprimé, ou
- révisé.

INTRODUCTION

Les pratiques de RADIOTHERAPIE modernes utilisent des informations issues de différentes modalités d'imagerie, acquises avant de lancer la thérapie, afin de planifier le TRAITEMENT à engager. L'imagerie fournit des informations sur l'emplacement du VOLUME CIBLE et d'autres caractéristiques anatomiques, de manière à pouvoir établir un PLAN DE TRAITEMENT qui permet une distribution optimale de la dose afin de réunir au mieux les conditions d'obtention de l'effet de TRAITEMENT prévu, tout en réduisant le plus possible les effets secondaires.

Des difficultés surgissent cependant lorsqu'il s'agit d'appliquer le RAYONNEMENT, du fait du mouvement constant des VOLUMES CIBLES/structures critiques à l'intérieur du corps. Par exemple, dans les parties du corps mobiles en phase de respiration, la position ou la forme des VOLUMES CIBLES/structures critiques peut varier au cours de l'application du FAISCEAU DE RAYONNEMENT sur toute fraction donnée. De plus, un programme de thérapie peut se prolonger sur plusieurs jours, au cours desquels le VOLUME CIBLE/PATIENT peut rétrécir, croître ou bouger. De ce fait, l'emplacement exact du VOLUME CIBLE/des structures critiques peut être modifié entre le cycle d'imagerie de PLANIFICATION des TRAITEMENTS et l'administration réelle d'un TRAITEMENT.

La RADIOTHERAPIE ASSISTEE PAR IMAGERIE MEDICALE (IGRT, *Image-Guided RadioTherapy*) combine image planaire ou volumétrique au cours du programme de RADIOTHERAPIE pour ajuster l'administration du TRAITEMENT en fonction de l'anatomie du PATIENT et de sa position. Ceci permet à l'OPERATEUR ou à l'APPAREIL DE RADIOTHERAPIE EXTERNE (EBE) d'ajuster l'application du FAISCEAU DE RAYONNEMENT en fonction des informations d'imagerie, telles que la position du VOLUME CIBLE, les organes critiques ou d'autres caractéristiques de référence, afin de compenser les changements anatomiques, y compris les déplacements d'organes internes ou les incertitudes liées à la définition du TRAITEMENT. Les plus grandes exactitude et précision obtenues permettent d'appliquer des doses plus élevées de RAYONNEMENT au VOLUME CIBLE et de réduire la proportion de cellules saines affectées par le RAYONNEMENT. Cette pratique est souvent associée à d'autres appareils de surveillance.

Le présent document définit les exigences auxquelles les FABRICANTS sont tenus de satisfaire dans la conception et la construction des APPAREILS DE RADIOTHERAPIE A RAYONNEMENT X ASSISTEE PAR IMAGERIE MEDICALE (X-IGRT).

Le présent document couvre les aspects de sécurité des dispositifs d'imagerie à rayonnement X sous kilotension (kV) et sous mégatension (MV) dans une relation géométrique connue avec un APPAREIL DE RADIOTHERAPIE EXTERNE tel qu'un ACCELERATEUR D'ELECTRONS, un APPAREIL ELECTROMEDICAL PAR FAISCEAU D'IONS LEGERS ou un APPAREILS DE THERAPIE PAR FAISCEAU DE RADIONUCLEIDES, à des fins de RADIOTHERAPIE ASSISTEE PAR IMAGERIE MEDICALE. Il couvre les aspects de communication et les relations entre les APPAREILS DE RADIOTHERAPIE EXTERNES et les dispositifs d'imagerie à rayonnement X fixés ou non directement fixés, mais présents dans la même zone protégée contre le RAYONNEMENT que les APPAREILS DE RADIOTHERAPIE EXTERNES, et destinés à être utilisés uniquement avec ces appareils.

Il convient que le FABRICANT tienne compte des normes de diagnostic pertinentes lorsqu'il effectue une ANALYSE DE DANGER. Par exemple, la qualité des DISPOSITIFS DE VISUALISATION DES IMAGES est spécifiée dans les documents IEC concernant l'application pratique des diagnostics (par exemple, IEC 62563-1:2009). Toutefois, dans la mesure où l'application de la RADIOTHERAPIE ASSISTEE PAR IMAGERIE MEDICALE n'implique pas nécessairement des exigences si sévères, la spécification de ce qu'exige l'utilisation des APPAREILS X-IGRT incombe à leur FABRICANT.

Le présent document traite des aspects de sécurité liés aux acquisitions et à l'analyse des images, ainsi qu'au transfert de données et à la replanification des TRAITEMENTS, ou au repositionnement des APPAREILS DE RADIOTHERAPIE EXTERNES/du PATIENT.

Le présent document traite des APPAREILS DE RADIOTHERAPIE A RAYONNEMENT X ASSISTEE PAR IMAGERIE MEDICALE HORS LIGNE, EN LIGNE et EN TEMPS REEL.

Les APPAREILS DE RADIOTHERAPIE A RAYONNEMENT X ASSISTEE PAR IMAGERIE MEDICALE sont également associés aux publications actuelles suivantes:

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

Le présent document cible les aspects de sécurité liés à la fonction principale de la RADIOTHERAPIE A RAYONNEMENT X ASSISTEE PAR IMAGERIE MEDICALE. Il ne cible pas les nouvelles technologies du domaine de manière à ne pas entraver leur évolution, mais définit cependant une méthode sûre de réalisation de la RADIOTHERAPIE A RAYONNEMENT X ASSISTEE PAR IMAGERIE MEDICALE.

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

201.1 Domaine d'application, objet et normes connexes

L'Article 1 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.1.1 * Domaine d'application

Remplacement:

La présente partie de l'IEC 60601 s'applique à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des APPAREILS DE RADIOTHERAPIE A RAYONNEMENT X ASSISTEE PAR IMAGERIE MEDICALE destinés à être utilisés avec les APPAREILS DE RADIOTHERAPIE EXTERNES (EBE).

Le présent document couvre les aspects de sécurité des dispositifs d'imagerie à rayonnement X sous kilotension (kV) et sous mégatension (MV) intégrés dans une relation géométrique spécifiée avec les EBE à des fins de RADIOTHERAPIE ASSISTEE PAR IMAGERIE MEDICALE. Il couvre les aspects de communication et les relations entre les APPAREILS DE RADIOTHERAPIE EXTERNES et les dispositifs d'imagerie à rayonnement X fixés ou non directement fixés, mais présents dans la même zone protégée contre le RAYONNEMENT que les APPAREILS DE RADIOTHERAPIE EXTERNES, et destinés à être utilisés uniquement avec ces appareils.

Le présent document traite des APPAREILS DE RADIOTHERAPIE A RAYONNEMENT X ASSISTEE PAR IMAGERIE MEDICALE HORS LIGNE, EN LIGNE et EN TEMPS REEL. Il couvre les procédures de réduction du risque de confiance excessive envers le SYSTEME EBE X-IGRT. Par exemple, dans le cas d'une RADIOTHERAPIE A RAYONNEMENT X ASSISTEE PAR IMAGERIE MEDICALE EN LIGNE, le FABRICANT fournit une interface interactive destinée à l'interaction des utilisateurs avec la correction proposée par le système.

Le présent document ne s'applique pas aux TOMODENSITOMETRES, aux APPAREILS A RAYONNEMENT X pour la RADIOGRAPHIE et aux APPAREILS A RAYONNEMENT X pour la RADIOSCOPIE, qui ne sont pas conçus pour être utilisés pour la RADIOTHERAPIE ASSISTEE PAR IMAGERIE MEDICALE.

Les exigences soumises à l'essai conformément à une autre norme peuvent être identifiées par le fabricant. Lorsque ces exigences sont équivalentes, de nouveaux essais ne sont pas exigés, mais la conformité peut être prouvée par les déclarations de conformité ou les rapports d'essai relatifs aux TOMODENSITOMETRES, aux APPAREILS A RAYONNEMENT X pour la RADIOGRAPHIE ou aux APPAREILS A RAYONNEMENT X pour les APPAREILS DE RADIOSCOPIE fournis par le fabricant.

Lorsqu'un APPAREIL DE RADIOTHERAPIE A RAYONNEMENT X ASSISTEE PAR IMAGERIE MEDICALE est combiné à un APPAREIL ELECTROMEDICAL, toutes les exigences communes à l'APPAREIL DE RADIOTHERAPIE A RAYONNEMENT X ASSISTEE PAR IMAGERIE MEDICALE et à l'APPAREIL ELECTROMEDICAL (par exemple, un POSITIONNEUR DE PATIENT) n'ont pas besoin d'être soumises à l'essai deux fois, mais peuvent être admises comme ayant été soumises à l'essai par l'APPAREIL ELECTROMEDICAL.

Le présent document s'applique aux APPAREILS A RAYONNEMENT X pour la RADIOGRAPHIE, la RADIOSCOPIE et la TOMODENSITOMETRIE utilisées pour la RADIOTHERAPIE ASSISTEE PAR IMAGERIE MEDICALE.

Si un article ou un paragraphe est destiné spécifiquement à s'appliquer aux SYSTEMES EBE X-IGRT, le contenu de cet article ou de ce paragraphe l'indique de manière explicite. Si tel n'est pas le cas, l'article ou le paragraphe s'applique uniquement aux APPAREILS X-IGRT.

Le présent document, y compris les ESSAIS DE TYPE et les ESSAIS SUR LE SITE, s'applique respectivement au FABRICANT et à certains aspects d'installation des SYSTEMES EBE X-IGRT destinés à être

- pour une UTILISATION NORMALE, manipulés, sous la responsabilité de l'ORGANISME RESPONSABLE, par des PERSONNES QUALIFIEES qui disposent des compétences exigées pour une application médicale particulière, à des fins cliniques spécifiées particulières, par exemple RADIOTHERAPIE A CHAMP FIXE ou RADIOTHERAPIE CINETIQUE,
- entretenus selon les recommandations données dans les INSTRUCTIONS D'UTILISATION, et
- vérifiés périodiquement par une PERSONNE QUALIFIEE selon un programme d'assurance qualité qui porte sur le contrôle des performances et de l'étalonnage.

NOTE Dans le présent document, toutes les références à l'installation se rapportent à l'installation dans les locaux de l'ORGANISME RESPONSABLE.

201.1.2 Objet

Remplacement:

L'objet du présent document est d'établir des exigences particulières pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES des APPAREILS X-IGRT et des SYSTEMES EBE X-IGRT.

201.1.3 Normes collatérales

Addition:

Le présent document fait référence aux normes collatérales applicables énumérées à l'Article 2 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 et à l'Article 201.2 du présent document.

L'IEC 60601-1-3 et l'IEC 60601-1-6 s'appliquent telles qu'elles sont modifiées à l'Article 203 et à l'Article 206, respectivement. Les normes IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10 et IEC 60601-1-11 ne s'appliquent pas. Toutes les autres normes collatérales publiées de la série IEC 60601-1 s'appliquent, telles que publiées.

Toutes les autres normes collatérales publiées de la série IEC 60601-1 s'appliquent, telles que publiées.

201.1.4 Normes particulières

Remplacement:

Dans la série IEC 60601, des normes particulières peuvent modifier, remplacer ou supprimer des exigences contenues dans l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 et dans les normes collatérales en fonction de l'APPAREIL EM concerné. Elles peuvent également ajouter des exigences supplémentaires pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES.

Une exigence d'une norme particulière prévaut sur l'exigence correspondante de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020.

La numérotation des articles et des paragraphes du présent document correspond à celle de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 avec le préfixe "201" (par exemple, le 201.1 du présent document concerne le contenu de l'Article 1 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020) ou à celle de la norme collatérale applicable avec le préfixe "20x", où x représente le ou les derniers chiffres du numéro de document de la norme collatérale (par exemple, le 202.4 du présent document concerne le contenu de l'Article 4 de la norme collatérale IEC 60601-1-2, le 203.4 du présent document concerne le contenu de l'Article 4 de la norme collatérale IEC 60601-1-3, etc.). Les modifications apportées au texte de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 sont précisées en utilisant les termes suivants:

"*Remplacement*" signifie que l'article ou le paragraphe de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable est remplacé complètement par le texte du présent document.

"*Addition*" signifie que le texte du présent document vient s'ajouter aux exigences de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable.

"*Amendement*" signifie que l'article ou le paragraphe de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable est modifié comme cela est indiqué par le texte du présent document.

Les paragraphes, figures ou tableaux qui sont ajoutés à ceux de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 sont numérotés à partir de 201.101. Toutefois, en raison du fait que les définitions dans l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 sont numérotées de 3.1 à 3.154, les définitions qui sont ajoutées dans le présent document sont numérotées à partir de 201.3.201. Les annexes qui sont ajoutées sont notées AA, BB, etc., et les éléments qui sont ajoutés aa), bb), etc.

Les paragraphes, figures ou tableaux qui s'ajoutent à ceux d'une norme collatérale sont numérotés à partir de 20x, où "x" est le chiffre de la norme collatérale, par exemple 202 pour l'IEC 60601-1-2, 203 pour l'IEC 60601-1-3, etc.

L'expression "le présent document" est utilisée pour se référer à l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, à toutes les normes collatérales applicables et au présent document, pris en compte ensemble.

Lorsque le présent document ne comprend pas d'article ou de paragraphe correspondant, l'article ou le paragraphe de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable, bien qu'il puisse être sans objet, s'applique sans modification; lorsqu'il est demandé qu'une partie quelconque de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable, bien que potentiellement pertinente, ne s'applique pas, cela est expressément mentionné dans le présent document.

201.2 Références normatives

NOTE Une liste des références informatives est donnée dans la bibliographie.

L'Article 2 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

Remplacement:

IEC 60601-1-3:2008, *Appareils électromédicaux – Partie 1-3: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Radioprotection dans les appareils à rayonnement X de diagnostic*
IEC 60601-1-3:2008/AMD1:2013
IEC 60601-1-3:2008/AMD2:2021

Addition:

IEC 60601-1:2005, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-2-1:2020, *Appareils électromédicaux – Partie 2-1: Exigences particulières de sécurité de base et de performances essentielles pour les accélérateurs d'électrons dans la gamme de 1 MeV à 50 MeV*

IEC 60601-2-4:2010, *Appareils électromédicaux – Partie 2-4: Exigences particulières pour la sécurité de base et les performances essentielles des défibrillateurs cardiaques*

IEC TR 60788:2004, *Medical electrical equipment – Glossary of defined terms* (disponible en anglais seulement)

IEC 61000-4-3, *Compatibilité électromagnétique (CEM) – Partie 4-3: Techniques d'essai et de mesure – Essai d'immunité aux champs électromagnétiques rayonnés aux fréquences radioélectriques*

IEC 61217:2011, *Appareils utilisés en radiothérapie – Coordonnées, mouvements et échelles*

IEC 62563-1, *Appareils électromédicaux – Systèmes d'imagerie médicale – Partie 1: Méthodes d'évaluation*

CISPR 11, *Appareils industriels, scientifiques et médicaux – Caractéristiques de perturbations radioélectriques – Limites et méthodes de mesure*

201.3 Termes et définitions

Pour les besoins du présent document, les termes et définitions de l'IEC 60601-2-1:2020, l'IEC 606011:2005, l'IEC 60601-1:2005/AMD1:2012, l'IEC 60601-1:2005/AMD2:2020 et l'IEC/TR 60788:2004 s'appliquent, avec les exceptions suivantes:

L'ISO et l'IEC tiennent à jour des bases de données terminologiques destinées à être utilisées en normalisation, consultables aux adresses suivantes:

- IEC Electropedia: disponible à l'adresse https://www.electropedia.org/
- ISO Online browsing platform: disponible à l'adresse https://www.iso.org/obp

Termes et définitions supplémentaires:

201.3.201
INDICE 100 DE DOSE TOMODENSITOMÉTRIQUE
***CTDI*$_{100}$**
intégrale du PROFIL DE DOSE correspondant à un balayage axial unique, le long d'une ligne perpendiculaire au PLAN TOMOGRAPHIQUE, divisée par $N \times T$ conformément à ce qui suit:

pour $N \times T$ inférieur ou égal à 40 mm

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

pour $N \times T$ supérieur à 40 mm (tous les PROTOCOLES D'IMAGERIE IGRT à l'exception de la collimation restent les mêmes pour ces mesures)

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

où

$D(y)$	est le PROFIL DE DOSE correspondant à un balayage axial unique le long d'une ligne perpendiculaire au PLAN TOMOGRAPHIQUE, où la dose utilisée est la DOSE ABSORBEE dans l'air et est évaluée à l'intérieur d'un FANTOME de dosimétrie en polyméthacrylate de méthyle (PMMA) (voir 201.102.6.2);
$(N \times T)_{\text{Réf}}$	est une valeur de $N \times T$ spécifique de 20 mm ou la valeur de $N \times T$ disponible la plus grande non supérieure à 20 mm;
$D_{\text{Réf}}(y)$	est le PROFIL DE DOSE correspondant à un balayage axial unique le long d'une ligne perpendiculaire au PLAN TOMOGRAPHIQUE, où la dose utilisée est la DOSE ABSORBEE dans l'air et est évaluée à l'intérieur d'un FANTOME de dosimétrie en polyméthacrylate de méthyle (PMMA) (voir 201.102.6.2) pour $(N \times T)_{\text{Réf}}$;
$CTDI_{\text{air libre, } N \times T}$	est le $CTDI_{\text{air libre}}$ (201.3.202) pour une valeur spécifique de $N \times T$;
$CTDI_{\text{air libre, Réf}}$	est le $CTDI_{\text{air libre}}$ (201.3.202) pour $(N \times T)_{\text{Réf}}$;
N	est le nombre de COUPES TOMOGRAPHIQUES produites en un seul balayage axial de la source de rayonnement X;
T	est l'EPAISSEUR NOMINALE DE COUPE TOMOGRAPHIQUE

Note 1 à l'article: La dose utilisée est la DOSE ABSORBÉE dans l'air, mais pour des raisons pratiques, l'évaluation de la DOSE ABSORBÉE dans l'air à l'intérieur d'un FANTÔME dosimétrique PMMA est correctement approchée par la mesure du KERMA DANS L'AIR.

Note 2 à l'article: Cette définition suppose que le PROFIL DE DOSE est centré sur $y = 0$.

Note 3 à l'article: Un seul balayage axial représente généralement une rotation de 360° de la source de rayonnement X. Pour la CBCT, les rotations partielles sont encore considérées comme un seul balayage axial.

Note 4 à l'article: Lorsque les COUPES TOMOGRAPHIQUES se chevauchent, par exemple dans les TOMODENSITOMETRES avec un "FOYER flottant en y" ou avec les modes CBCT qui regroupent plusieurs balayages, il est nécessaire de remplacer le dénominateur de l'intégrale par la largeur nominale totale le long de l'axe y des coupes tomographiques qui se chevauchent. Par exemple, pour un pourcentage de chevauchement de 50 %, le dénominateur serait donc remplacé par 0,5 x N x T.

Note 5 à l'article: L'axe y est généralement l'axe de rotation (l'axe y correspond à l'axe z dans le système de coordonnées DICOM).

Note 6 à l'article: Le $CTDI_{100}$ est conçu de manière à inclure la plus grande partie du RAYONNEMENT diffusé.

Note 7 à l'article: Voir l'Annexe CC de l'IEC 60601-2-44:2009/AMD1:2012 pour des explications plus détaillées.

Note 8 à l'article: Pour la CBCT sous MV, il est admis par hypothèse qu'une chambre à faisceau-crayon appropriée étalonnée est utilisée.

[SOURCE: IEC 60601-2-44:2009/AMD1:2012, 201.3.203, modifié – Les Notes 3, 4 et 5 à l'article ont été développées, et la Note 8 à l'article a été ajoutée.]

201.3.202
INDICE DE DOSE TOMODENSITOMETRIQUE A L'AIR LIBRE
***CTDI*$_{\text{air libre}}$**
iintégrale du PROFIL DE DOSE correspondant à un balayage axial unique, le long d'une ligne traversant l'ISOCENTRE et perpendiculaire au PLAN TOMOGRAPHIQUE, divisée par $N \times T$ conformément à ce qui suit:

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

où

D(y) est le PROFIL DE DOSE correspondant à un balayage axial unique le long d'une ligne y traversant l'ISOCENTRE et perpendiculaire au PLAN TOMOGRAPHIQUE, où la dose utilisée est la DOSE ABSORBEE dans l'air et est évaluée à l'air libre en l'absence de FANTOME et du SUPPORT DU PATIENT;

N est le nombre de COUPES TOMOGRAPHIQUES produites en un seul balayage axial de la source de rayonnement X;

T est l'EPAISSEUR NOMINALE DE COUPE TOMOGRAPHIQUE;

L est au moins égale à $(N \times T)$ +40 mm.

Note 1 à l'article: Cette définition suppose que le PROFIL DE DOSE est centré sur $y = 0$. L'axe y correspond à l'axe z dans le système de coordonnées DICOM.

Note 2 à l'article: Lorsque les COUPES TOMOGRAPHIQUES se chevauchent, par exemple dans les TOMODENSITOMETRES avec un "FOYER flottant en y" ou avec les modes CBCT qui regroupent plusieurs balayages, il est nécessaire de remplacer le dénominateur de l'intégrale par la largeur nominale totale le long de l'axe *y* des coupes tomographiques qui se chevauchent. Par exemple, pour un pourcentage de chevauchement de 50 %, le dénominateur serait donc remplacé par $0,5 \times N \times T$.

Note 3 à l'article: Un DÉTECTEUR DE RAYONNEMENT de longueur *L* ou supérieure est généralement utilisé. L'Annexe DD fournit un exemple d'autres mesures.

Note 4 à l'article: Pour la CBCT, la formation d'images ne se fait pas par tranches et $N \times T$ est la longueur de balayage le long d'une ligne perpendiculaire au PLAN TOMOGRAPHIQUE avec la collimation NOMINALE.

Note 5 à l'article: Pour la CBCT SOUS MV, il est admis par hypothèse qu'une chambre à faisceau-crayon appropriée étalonnée ou une chambre d'ionisation et un capuchon d'équilibre électronique sont utilisés.

[SOURCE: IEC 60601-2-44:2009/AMD1:2012, 201.3.215, modifié – Les Notes 1 et 2 à l'article ont été développées, et les Notes 4 et 5 à l'article ont été ajoutées.]

201.3.203
TOMODENSITOMETRIE A FAISCEAU CONIQUE
CBCT
tomodensitométrie qui utilise un faisceau conique de RAYONNEMENT X

Note 1 à l'article: L'abréviation "cbct" est dérivée du terme anglais développé correspondant "cone beam computed tomography".

201.3.204
RAPPORT CONTRASTE/BRUIT
CNR
grandeur physique décrivant l'aptitude à faire la distinction entre divers objets de contraste d'une image numérique et le bruit inhérent à l'intérieur de l'image, définie comme la différence des valeurs moyennes de pixels des objets de contraste et du fond de l'image, et divisée par l'écart-type de la valeur de pixel du fond de l'image

Note 1 à l'article: $C = \frac{|S_A - S_B|}{\sigma_0}$

S_A and S_B sont des intensités de signal pour les structures de production de signal A et B dans la région concernée et σ_0 est l'écart-type du bruit d'image. Le FABRICANT spécifie les structures qui définissent A et B.

Note 2 à l'article: L'abréviation "cnr" est dérivée du terme anglais développé correspondant "contrast to noise ratio".

[SOURCE: IEC 61223-3-2:2007, 3.8, modifié – Deux notes à l'article ont été ajoutées.]

201.3.205
PRODUIT DOSE-LONGUEUR
DLP
indice caractérisant le produit du $CTDI_{vol}$ et de la longueur totale balayée

a) Pour le balayage axial

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

où

Δd est la course du SUPPORT DU PATIENT dans la direction y entre des balayages consécutifs.

n est le nombre de balayages en série.

b) Pour le balayage hélicoïdal

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

où

L est la course de la table au cours de la CHARGE complète, ajustée pour les modes de collimation dynamique le cas échéant.

Note 1 à l'article: L pourrait être supérieure à la longueur de balayage programmée.

Note 2 à l'article: La moyenne pondérée dans le temps de $CTDI_{vol}$ doit être utilisée si $CTDI_{vol}$ est variable.

Note 3 à l'article: Une méthode de détermination de L peut consister à utiliser le LMH le long d'une ligne perpendiculaire au PLAN TOMOGRAPHIQUE à l'isocentre du PROFIL DE DOSE à l'air libre pour le balayage complet. En l'absence de collimation dynamique, cela est approximativement équivalent à la course de la table au cours de la CHARGE complète.

c) Pour le balayage sans mouvement du SUPPORT DU PATIENT

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

où

N est le nombre de COUPES TOMOGRAPHIQUES produites en un seul balayage axial de la source de rayonnement X;

T est l'EPAISSEUR NOMINALE DE COUPE TOMOGRAPHIQUE.

Note 4 à l'article: Pour la CBCT, généralement seul le point c) est applicable lorsque $N \times T$ est la longueur de balayage le long d'une ligne perpendiculaire au PLAN TOMOGRAPHIQUE avec la collimation NOMINALE.

Note 5 à l'article: Généralement, l'axe y est l'axe de rotation. L'axe y correspond à l'axe z dans le système de coordonnées DICOM.

d) Pour un balayage axial sans "trous" et un balayage hélicoïdal, les deux impliquant un mouvement de va-et-vient du SUPPORT DU PATIENT entre deux positions (mode navette)

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

où

N est le nombre de COUPES TOMOGRAPHIQUES produites en un seul balayage axial de la source de rayonnement X;

T est l'EPAISSEUR NOMINALE DE COUPE TOMOGRAPHIQUE;

R est la distance entre les deux positions.

Note 6 à l'article: L'abréviation "dlp" est dérivée du terme anglais développé correspondant "dose-length product".

[SOURCE: IEC 60601-2-44:2009 et IEC 60601-2-44:2009/AMD1:2012, 201.3.214, modifié – Les Notes 4 et 5 à l'article ont été ajoutées.]

201.3.206
PROFIL DE DOSE
représentation de la dose comme une fonction de la position le long d'une ligne

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

201.3.207
POINT DE RÉFÉRENCE DES APPAREILS
ERP
point dans l'espace utilisé pour référencer les dimensions et les positions des appareils et effectuer les mesurages de dosimétrie

Note 1 à l'article: L'abréviation "erp" est dérivée du terme anglais développé correspondant "equipment reference point".

201.3.208
APPAREIL DE RADIOTHERAPIE EXTERNE
EBE
APPAREIL à RAYONNEMENT externe qui utilise des ACCELERATEURS D'ELECTRONS, des appareils électromédicaux par faisceau d'ions légers ou des APPAREILS DE THERAPIE PAR FAISCEAU DE RADIONUCLEIDES

Note 1 à l'article: L'abréviation "ebe" est dérivée du terme anglais développé correspondant "external beam equipment".

201.3.209
APPAREIL IGRT
APPAREIL EM qui fournit une fonctionnalité IGRT

201.3.210
*** LATENCE IGRT**
temps qui s'écoule entre le début du processus d'acquisition des images et le signal de sortie, et ce, entre l'APPAREIL X-IGRT et l'APPAREIL DE RADIOTHERAPIE EXTERNE

Note 1 à l'article: Il est prévu que l'EBE puisse également indiquer son temps de latence entre la réception du signal et l'application de la correction.

Note 2 à l'article: La LATENCE IGRT inclut les latences matérielles et logicielles.

Note 3 à l'article: Les temps de transfert de réseaux varient d'une installation à l'autre, du fait du trop grand nombre de paramètres impliqués fournis par l'ORGANISME RESPONSABLE. La latence de transfert de réseaux n'est par conséquent pas considérée comme partie intégrante du temps de LATENCE IGRT.

201.3.211
RADIOTHERAPIE ASSISTEE PAR IMAGERIE MEDICALE
IGRT
processus de radiothérapie par lequel le positionnement d'un faisceau de radiothérapie par rapport au VOLUME CIBLE prévu dans l'anatomie du patient est déterminé par l'imagerie du VOLUME CIBLE et des structures anatomiques environnantes au moment du TRAITEMENT, de manière à permettre toutes corrections de position nécessaires au positionnement relatif prévu du faisceau par rapport au VOLUME CIBLE

Note 1 à l'article: La période "au moment du TRAITEMENT" est spécifiée dans les définitions de IGRT HORS LIGNE, IGRT EN LIGNE et IGRT EN TEMPS REEL.

Note 2 à l'article: L'abréviation "igrt" est dérivée du terme anglais développé correspondant "image-guided radiotherapy".

[SOURCE: IEC 60976:2007, 3.8, modifié – La Note 1 à l'article a été ajoutée.]

201.3.212
PROTOCOLE D'IMAGERIE
ensemble des paramètres nécessaires à la réalisation de l'imagerie

Note 1 à l'article: Les modes suivants sont des exemples de différents types d'imageries: radiographie, radioscopie, balayage hélicoïdal, axial, série de balayages axiaux, balayage sans mouvement de l'POSITIONNEUR DE PATIENT et en mode navette.

Note 2 à l'article: Pour préserver la compatibilité avec leurs interfaces utilisateur et leur documentation respectives, plusieurs APPAREILS X-IGRT peuvent utiliser une terminologie différente de "PROTOCOLE D'IMAGERIE", par exemple "balayage", "groupe de balayages", "série de balayages", "préréglages", "modes CBCT", etc.

Note 3 à l'article: Un PROTOCOLE D'IMAGERIE est généralement associé à une tâche IGRT, une région anatomique, un groupe d'âges ou de tailles.

201.3.213
RECONSTITUTION D'IMAGE
méthode de transformation des données acquises en un ensemble de données d'images qui peut être utilisé pour analyse

Note 1 à l'article: L'analyse de l'ensemble de données d'images reconstituées peut être destinée au CALAGE D'IMAGES par rapport aux données de référence.

201.3.214
CALAGE D'IMAGES
méthode de mappage ou de calage de points correspondants d'un ensemble de données d'images à un autre

Note 1 à l'article: Le CALAGE D'IMAGES peut être rigide ou déformable.

201.3.215
SESSION D'IMAGERIE
durée de prise continue d'images du PATIENT pendant que le PATIENT reste sur son dispositif de positionnement

Note 1 à l'article: Le retrait du PATIENT de son dispositif de positionnement met un terme à la session d'imagerie.

201.3.216
APPAREIL X-IGRT SOUS KILOTENSION
APPAREIL X-IGRT qui utilise un RAYONNEMENT X sous kilotension

201.3.217
APPAREIL X-IGRT SOUS MEGATENSION
APPAREIL X-IGRT qui utilise un RAYONNEMENT X sous mégatension

201.3.218
FONCTION DE TRANSFERT DE MODULATION
MTF
module de la FONCTION DE TRANSFERT OPTIQUE généralement complexe, exprimé en fonction des FREQUENCES SPATIALES *u* et *v*

Note 1 à l'article: La MTF peut être déterminée de plusieurs façons, par exemple à partir des transformées de Fourier de la fonction de distribution ponctuelle (PSF, *Point Spread Function*), la fonction de distribution linéaire (LSF, *Line Spread Ffunction*) et la fonction de distribution angulaire (ESF, *Edge Spread Function*). Toute méthode est acceptable si elle est appliquée correctement.

Note 2 à l'article: L'abréviation "mtf" est dérivée du terme anglais développé correspondant "modulation transfer function".

[SOURCE: IEC 62220-1-1:2015, 3.10, modifié – Une note à l'article a été ajoutée, et le symbole du terme a été modifié.]

201.3.219
DISTANCE DE REFERENCE NOMINALE
<RAYONNEMENT X> distance SPECIFIEE le long de l'AXE DE REFERENCE qui est, pour le RAYONNEMENT X, mesurée entre la surface CIBLE du faisceau de sortie et un plan SPECIFIE qui contient le POINT DE REFERENCE des APPAREILS X-IGRT

201.3.220
UTILISATION NORMALE
fonctionnement, y compris lors des vérifications périodiques et des réglages faits par un OPERATEUR, ainsi que dans l'état EN ATTENTE, selon les INSTRUCTIONS D'UTILISATION

Note 1 à l'article: Il convient de ne pas confondre UTILISATION PREVUE et UTILISATION NORMALE. Si les deux expressions intègrent le concept de l'utilisation telle qu'elle est prévue par le FABRICANT, l'UTILISATION PREVUE se concentre sur le but médical tandis que l'UTILISATION NORMALE ne se limite pas au but médical, mais englobe aussi la maintenance, le transport, etc.

Note 2 à l'article: L'UTILISATION NORMALE désigne toutes les fonctions réalisées par l'OPERATEUR. Elle comprend la mise en température, l'étalonnage et d'autres modes "physiques" d'essai.

[SOURCE: IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 3.71, modifié – La Note 2 a été ajoutée.]

201.3.221
IGRT HORS LIGNE
IGRT à des fins d'installation du PATIENT ou d'ajustement du PLAN DE TRAITEMENT à appliquer dans l'administration du TRAITEMENT ultérieur

201.3.222
IGRT EN LIGNE
IGRT à des fins d'installation du PATIENT ou d'ajustement du PLAN DE TRAITEMENT immédiatement avant ou pendant la session d'IRRADIATION thérapeutique qui exige des ajustements de l'opérateur

Note 1 à l'article: Le PATIENT reste sur l'POSITIONNEUR DE PATIENT et demeure immobile pendant et entre les phases d'imagerie et de TRAITEMENT.

201.3.223
FONCTION DE TRANSFERT OPTIQUE
FTO
transformée de Fourier en deux dimensions de la fonction de distribution ponctuelle du système de formation d'images

Note 1 à l'article: Voir l'ISO 9334:2012.

Note 2 à l'article: Pour que la FONCTION DE TRANSFERT OPTIQUE ait une signification, il est essentiel que le système de formation d'images fonctionne dans sa PLAGE LINEAIRE et qu'on considère une REGION ISOPLANETIQUE.

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

201.3.224
RADIOGRAPHIE
technique d'obtention, d'enregistrement et éventuellement de traitement direct ou après TRANSFERT, d'informations contenues dans une IMAGE RADIOLOGIQUE POTENTIELLE au niveau d'une SURFACE RECEPTRICE DE L'IMAGE destinées à être analysées pendant un temps indépendant du temps d'IRRADIATION

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

201.3.225
RADIOSCOPIE
technique d'obtention, continue ou périodique d'une séquence d'IMAGES RADIOLOGIQUES POTENTIELLES et de leur présentation directe ou après TRANSFERT et traitement optionnel, de manière simultanée et continue sous forme d'images visibles, destinées à guider en temps réel les actions en cours

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

201.3.226
IGRT EN TEMPS RÉEL
IGRT qui produit des images au cours de l'IRRADIATION thérapeutique et qui, à partir de ces informations, permet des ajustements automatiques des PARAMETRES DE TRAITEMENT pendant ladite IRRADIATION sans aucune intervention de l'OPERATEUR

201.3.227
IMAGE DE REFERENCE
image associée au PLAN DE TRAITEMENT à laquelle les images futures sont comparées en vue de l'alignement du PATIENT ou de l'ajustement du PLAN DE TRAITEMENT

Note 1 à l'article: Les IMAGES DE REFERENCE peuvent être acquises au cours de la première fraction ou de la fraction suivante du TRAITEMENT à partir d'un DISPOSITIF D'IMAGERIE PORTALE ELECTRONIQUE.

Note 2 à l'article: Il peut exister plusieurs IMAGES DE REFERENCE.

Note 3 à l'article: Les exemples d'IMAGES DE REFERENCE peuvent prendre la forme de radiogrammes numériques reconstitués générés par le système de planification en vue d'une comparaison aux images 2D prises au cours du TRAITEMENT, d'images tomodensitométriques de planification du TRAITEMENT utilisées à des fins de calage CBCT, ou d'images générées par IGRT à partir de la tomodensitométrie et du PLAN DE TRAITEMENT.

201.3.228
PROFIL DE SENSIBILITE
réponse relative d'un système de TOMODENSITOMÉTRIE en fonction de la position le long d'une ligne perpendiculaire au PLAN TOMOGRAPHIQUE

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

201.3.229
RÉSOLUTION SPATIALE
résolution également appelée RESOLUTION A CONTRASTE ELEVE et décrite par la FONCTION DE TRANSFERT DE MODULATION

201.3.230
RESOLUTION SPATIALE D'UN DISPOSITIF DE VISUALISATION DES IMAGES
mesure de la capacité d'un dispositif de visualisation des images à distinguer les caractéristiques spatiales concernées au sein d'une image

Note 1 à l'article: Des systèmes conçus avec des caractéristiques de résolution spatiale appropriées sont nécessaires pour s'assurer de la préservation des détails d'espace concernés lors de l'affichage d'une image médicale. L'affichage de données d'images sur un dispositif de visualisation des images avec une résolution insuffisante compromet l'exactitude de l'interprétation radiologique.

[SOURCE: IEC 62563-1:2009, 3.1.20, modifié – La Note 1 à l'article a été ajoutée.]

201.3.231
APTITUDE A L'UTILISATION
caractéristique de l'interface de l'OPERATEUR qui établit l'efficacité, le rendement, la simplicité d'apprentissage de l'OPERATEUR et la satisfaction de l'OPERATEUR

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.136, modifié – La définition a été reformulée.]

201.3.232.1
***CTDI*$_{W}$ VOLUMIQUE**
***CTDI*$_{vol}$**
<balayage axial>

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

où
N est le nombre de coupes tomographiques produites en un seul balayage axial de la source de rayonnement X;
T est l'épaisseur nominale de coupe tomographique;
Δd est la course du support du patient dans la direction y entre des balayages consécutifs

Note 1 à l'article: Pour le PROTOCOLE D'IMAGERIE IGRT choisi, mais quelle que soit la longueur de balayage qu'il est admis de choisir cliniquement, le $CTDI_{W}$ VOLUMIQUE ($CTDI_{vol}$) est un indice de dose fondé sur une convention de plage d'intégration de 100 mm le long de l'axe y. Pour le balayage axial, *CTDI*vol correspond à la dose moyenne qui pourrait s'accumuler dans la section centrale du FANTOME de volume égal à la section × Δd.

Note 2 à l'article: Pour le balayage axial avec une course totale de la table inférieure à $CTDI_{vol}$ tel que défini surestime la dose moyenne qui pourrait s'accumuler dans la section centrale du FANTOME de volume égal à la section × Δd.

Note 3 à l'article: Généralement, l'axe y est l'axe de rotation. L'axe y correspond à l'axe z dans le système de coordonnées DICOM.

[SOURCE: IEC 60601-2-44:2009/AMD1:2012, 201.3.212, modifié – Les notes à l'article ont été modifiées.]

201.3.232.2
***CTDI*$_W$ VOLUMIQUE**
***CTDI*$_{vol}$**
<balayage hélicoïdal>

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

Note 1 à l'article: Le FACTEUR TOMODENSITOMETRIQUE DE PAS dépendra du temps lorsque Δd est variable au cours de l'exposition.

Note 2 à l'article: Pour les CONDITIONS DE FONCTIONNEMENT X-IGRT choisies, mais quelle que soit la longueur de balayage qu'il est admis de choisir cliniquement, le *CTDI*$_W$ VOLUMIQUE (*CTDI*$_{vol}$) est un indice de dose fondé sur une convention de plage d'intégration de 100 mm le long de l'axe z. Pour le balayage hélicoïdal, *CTDI*vol correspond à la dose moyenne qui pourrait s'accumuler au centre d'une longueur de balayage de 100 mm.

Note 3 à l'article: Pour le balayage hélicoïdal, lorsque le produit d'un petit nombre de rotations par le déplacement table par tour est beaucoup plus petit que $N \times T$, le *CTDI*$_{vol}$ défini dépasse l'estimation de la dose moyenne qui se serait accumulée au centre d'une longueur de balayage de 100 mm.

Note 4 à l'article: Généralement, l'axe y est l'axe de rotation. L'axe y correspond à l'axe z dans le système de coordonnées DICOM.

[SOURCE: IEC 60601-2-44:2009/AMD1:2012, 201.3.212, modifié – Les notes à l'article ont été modifiées.]

201.3.232.3
***CTDI*$_W$ VOLUMIQUE**
***CTDI*$_{vol}$**
<balayage sans mouvement du SUPPORT DU PATIENT>

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

où n est égal au nombre de rotations

Note 1 à l'article: Le 201.3.232.3 comprend les situations dans lesquelles le SUPPORT DU PATIENT peut être déplacé manuellement, par exemple, au cours d'une procédure d'intervention.

Note 2 à l'article: Pour le balayage sans mouvement du SUPPORT DU PATIENT et pour les situations dans lesquelles il est admis que le SUPPORT DU PATIENT soit déplacé manuellement, cette définition surestime la dose dans la mesure où elle intègre la contribution de diffusion estimée provenant des tranches adjacentes.

Note 3 à l'article: Pour le balayage sans mouvement du SUPPORT DU PATIENT, *CTDI*$_{vol}$ correspond à la dose qui s'accumulerait dans la section centrale du FANTOME de volume égal à la section $\times N \times T$ s'il y avait n séquences congruentes de balayage contigu, chaque séquence ayant une longueur de 100 mm.

Note 4 à l'article: Pour la CBCT, généralement seul le 201.3.232.3 est applicable.

Note 5 à l'article: Généralement, l'axe y est l'axe de rotation. L'axe y correspond à l'axe z dans le système de coordonnées DICOM.

Note 6 à l'article: Pour la CBCT, n est généralement 1 et pour les rotations partielles n est considéré comme étant 1.

[SOURCE: IEC 60601-2-44:2009/AMD1:2012, 201.3.212, modifié – Les Notes 3, 7, 11, 12 et 13 à l'article ont été ajoutées et les Notes 1 et 2 à l'article ont été légèrement modifiées.]

201.3.232.4
***CTDI*$_W$ VOLUMIQUE**
***CTDI*$_{vol}$**
<balayage axial sans "trous" et balayage hélicoïdal, les deux impliquant un mouvement de va-et-vient du SUPPORT DU PATIENT entre deux positions (mode navette)>

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

où

N est le nombre de COUPES TOMOGRAPHIQUES produites en un seul balayage axial de la source de rayonnement X;
T est l'EPAISSEUR NOMINALE DE COUPE TOMOGRAPHIQUE;
n est égal au nombre total de rotations pour toute la série des balayages;
R est la distance entre les deux positions;
$CTDI_W$ est le $CTDI_{100}$ pondéré

Note 1 à l'article: Voir la Figure 201.102 de l'IEC 60601-2-44:2009/AMD1:2012.

Note 2 à l'article: $CTDI_W$ est évalué en tant que $CTDI_W$ pondéré dans le temps et reflétant les divers PROTOCOLES D'IMAGERIE IGRT.

[SOURCE: IEC 60601-2-44:2009/AMD1:2012, 201.3.212, modifié – Les Notes 3, 7, 11, 12 et 13 à l'article ont été ajoutées et les Notes 1 et 2 à l'article ont été légèrement modifiées.]

201.3.233
***CTDI*$_{100}$ PONDERE**
***CTDI*$_W$**
valeur définie de la façon suivante:

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

où
$CTDI_{100(centre)}$ est la valeur de $CTDI_{100}$ mesurée au centre d'un FANTOME de dosimétrie;
$CTDI_{100(périphérie)}$ est la moyenne des quatre valeurs de $CTDI_{100}$ mesurée à la périphérie du FANTOME de dosimétrie, conformément aux 201.102.6.2.2.1 a) 2) et 3)

[SOURCE: IEC 60601-2-44:2009, 201.3.211, modifié – Il est fait référence à la présente norme plutôt qu'au document d'origine.]

201.3.234
SYSTEME EBE X-IGRT
système constitué d'un APPAREIL X-IGRT et d'un APPAREIL DE RADIOTHERAPIE EXTERNE

201.3.235
APPAREIL X-IGRT
APPAREIL EM qui fournit une fonctionnalité IGRT lorsque des rayons X sont utilisés pour l'imagerie

Note 1 à l'article: La fonctionnalité IGRT peut être assurée par une partie du SYSTEME EBE X-IGRT autre que le dispositif d'imagerie à rayonnement X; par exemple, un TOMODENSITOMETRE fournit les images radiologiques et un autre appareil assure le calcul de correction de position.

201.3.236
COMPOSANTE D'IMAGERIE X-IGRT
partie de l'APPAREIL X-IGRT qui accomplit la fonction d'imagerie

201.4 Exigences générales

L'Article 4 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique.

201.5 Exigences générales relatives aux essais des APPAREILS EM

L'Article 5 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.5.1 ESSAIS DE TYPE

Paragraphe supplémentaire:

201.5.1.101 Catégories d'essais

Trois catégories de méthodes d'ESSAI DE TYPE et deux catégories de méthodes d'ESSAIS SUR LE SITE sont SPECIFIEES dans le présent document. Leurs exigences sont les suivantes:

– ESSAI DE TYPE/ESSAI SUR LE SITE de catégorie A: examen de la conception de l'APPAREIL EM, en relation avec les dispositions de sécurité radiologique SPECIFIEES, qui doit faire l'objet dans la description technique d'une déclaration qui démontre que la conformité est assurée par les principes de fonctionnement ou par la construction;

– ESSAI DE TYPE/ESSAI SUR LE SITE de catégorie B: examen visuel ou essai de fonctionnement ou mesurage de l'APPAREIL EM. L'essai doit être effectué selon la méthode SPECIFIEE dans le présent document, et doit être établi sur des conditions de fonctionnement, y compris des conditions de défaut, réalisables uniquement sans intervention dans les circuits ni dans la construction de l'APPAREIL EM;

– ESSAI DE TYPE/ESSAI SUR LE SITE de catégorie C: essai de fonctionnement ou mesurage de l'APPAREIL EM. L'essai doit être effectué selon le principe SPECIFIE dans le présent document. La méthode d'ESSAI SUR LE SITE doit être indiquée dans la description technique. Lorsque la méthode implique des conditions de fonctionnement qui exigent des interventions dans les circuits ou dans la construction de l'APPAREIL EM, l'essai doit être effectué par le FABRICANT ou son mandataire, ou sous sa surveillance directe.

201.5.4 Autres conditions

Le point 5.4 a) de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ne s'applique pas.

Remplacement du point 5.4 d):

d) Lorsque de l'eau de refroidissement est nécessaire, l'eau utilisée doit être conforme à la description technique.

Addition:

Le FABRICANT doit indiquer toute exigence supplémentaire d'essai dans la DOCUMENTATION D'ACCOMPAGNEMENT.

201.5.9 Détermination des PARTIES APPLIQUEES et des PARTIES ACCESSIBLES

201.5.9.2.1 Doigt d'essai

Addition:

Lorsque la nature de l'installation rend des parties inaccessibles selon l'essai effectué avec le doigt d'essai normalisé, et lorsqu'elles peuvent uniquement être rendues accessibles par l'utilisation d'un OUTIL, ces parties ne sont pas considérées comme des PARTIES ACCESSIBLES. La DOCUMENTATION D'ACCOMPAGNEMENT doit décrire de telles situations.

201.6 Classification des APPAREILS EM et des SYSTEMES EM

L'Article 6 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique.

201.7 Identification, marquage et documentation des APPAREILS EM

L'Article 7 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.7.1.1 APTITUDE A L'UTILISATION de l'identification, du marquage et de la documentation

Addition:

Tous les sous-ensembles et composants des APPAREILS X-IGRT qui peuvent être retirés en UTILISATION NORMALE, et qui sont concernés par la conformité au présent document, doivent être marqués pour s'assurer

– qu'ils peuvent être identifiés facilement et associés à leur DOCUMENTATION D'ACCOMPAGNEMENT; et
– que les dispositifs interchangeables peuvent être distingués individuellement par l'OPERATEUR puisse distinguer les dispositifs interchangeables en UTILISATION NORMALE et en vue de leur remplacement.

201.7.2 Marquage sur l'extérieur des APPAREILS EM ou parties d'APPAREILS EM

201.7.2.4 ACCESSOIRES

Addition:

Les dimensions du CHAMP DE RAYONNEMENT GEOMETRIQUE à la DISTANCE DE REFERENCE NOMINALE doivent être clairement lisibles sur la partie extérieure de tous les LIMITEURS DE FAISCEAU (DLF) interchangeables manuellement et non réglables.

Les dimensions du CHAMP DE RAYONNEMENT GEOMETRIQUE à la distance de référence nominale doivent être clairement mentionnées dans la DOCUMENTATION D'ACCOMPAGNEMENT concernant tous les LIMITEURS DE FAISCEAU (DLF) non réglables.

Pour les dispositifs réglables, l'étendue du CHAMP DE RAYONNEMENT GEOMETRIQUE à la DISTANCE DE REFERENCE NOMINALE doit être spécifiée dans la DOCUMENTATION D'ACCOMPAGNEMENT.

Pour tous les ACCESSOIRES fournis par le FABRICANT, les limitations de chaque dispositif doivent être spécifiées dans la DOCUMENTATION D'ACCOMPAGNEMENT.

EXEMPLE Une limitation consiste en un champ de vison plus petit en raison de la collimation.

Chaque FILTRE DE RAYONNEMENT manuellement interchangeable et chaque DLF doivent être marqués pour indiquer clairement son identité.

Tout ACCESSOIRE de l'APPAREIL X-IGRT fourni par le FABRICANT qui peut présenter un RISQUE de collision lorsqu'il est raccordé à l'APPAREIL X-IGRT doit être marqué, sur sa partie extérieure, pour indiquer clairement la distance entre l'extrémité distale et l'ERP.

La vérification est effectuée par examen.

201.7.2.15 Conditions de refroidissement

Addition:

Les exigences de refroidissement pour le fonctionnement en toute sécurité d'un APPAREIL X-IGRT, ou d'un sous-ensemble de celui-ci, doivent figurer dans la DOCUMENTATION D'ACCOMPAGNEMENT, y compris la dissipation de chaleur maximale, le cas échéant.

201.7.2.20 Moyens de protection amovibles

Addition:

Lorsque les exigences du paragraphe de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 sont en totalité ou en partie respectées par la nature de l'installation, la conformité de l'installation doit être vérifiée par examen. Les résultats obtenus doivent être consignés dans le rapport d'ESSAI SUR LE SITE.

201.7.3 Marquage à l'intérieur des APPAREILS EM ou des parties d'APPAREILS EM

Paragraphe supplémentaire:

201.7.3.101 Source de rayonnement X des APPAREILS X-IGRT

Le démontage des capots de la ou des sources de rayonnement X des APPAREILS X-IGRT doit faire apparaître le signe de sécurité 10 du Tableau D.2 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, qui indique "Suivre les instructions d'utilisation".

201.7.4 Marquage des organes de commande et des instruments

Paragraphe supplémentaire:

201.7.4.101 Fourniture d'échelles et d'indications pour les parties en mouvement

Les éléments suivants doivent être fournis:

a) un moyen d'alignement de la position du PATIENT par rapport à l'ERP de l'APPAREIL X-IGRT (par exemple, CHAMP LUMINEUX, lasers, etc.);

NOTE 1 Pour les APPAREILS X-IGRT qui partagent le même ERP que les EBE, le moyen d'alignement peut être identique à celui utilisé avec les EBE.

b) pour les APPAREILS X-IGRT avec des distances réglables entre la SOURCE DE RAYONNEMENT ou le DETECTEUR DE RAYONNEMENT et l'ERP, un moyen pour déterminer la distance entre la SOURCE DE RAYONNEMENT des APPAREILS X-IGRT ou le DETECTEUR DE RAYONNEMENT et l'ERP (par exemple, échelle, indication numérique ou lasers);

c) pour les APPAREILS X-IGRT avec une source fixe et un DETECTEUR DE RAYONNEMENT fixe par rapport à la ou aux distances de l'ERP ou des ERP, les distances entre la SOURCE DE RAYONNEMENT et le DETECTEUR DE RAYONNEMENT et un ERP doivent figurer dans la DOCUMENTATION D'ACCOMPAGNEMENT;

d) toutes les échelles mécaniques et indications numériques ou tous les indicateurs d'état, dont l'ANALYSE DE DANGER du FABRICANT indique qu'ils doivent être mis à disposition de l'OPERATEUR, doivent être effectivement présentés à ce dernier;

NOTE 2 La distance applicable à une SOURCE DE RAYONNEMENT sous kilotension est mesurée à partir de son foyer.

NOTE 3 Pour les appareils isocentriques, l'ERP correspond à l'ISOCENTRE de cet appareil.

e) la désignation, le sens de la valeur croissante et la position zéro des indications utilisées dans l'affichage des images et des mouvements doivent satisfaire à l'IEC 61217 ou, lorsque l'appareil utilisé n'est pas conforme à l'IEC 61217, la DOCUMENTATION D'ACCOMPAGNEMENT doit indiquer la transformation des coordonnées en coordonnées IEC 61217; et

NOTE 4 Cette disposition ne s'applique pas aux affichages des mouvements et des échelles des APPAREILS EM qui ne sont pas utilisés pour la radiothérapie X-IGRT.

f) la DOCUMENTATION D'ACCOMPAGNEMENT doit contenir une déclaration qui indique l'exactitude de chaque échelle ou indication numérique de l'APPAREIL EM.

Pour les valeurs définies par l'OPERATEUR, les valeurs des APPAREILS X-IGRT doivent pouvoir être fournies à l'OPERATEUR dans les mêmes unités et le même système de coordonnées que le dispositif auquel les valeurs s'appliquent.

La vérification est effectuée comme suit:

ESSAI DE TYPE de catégorie A – Déclaration concernant l'exactitude de chaque échelle ou chaque indication numérique de la géométrie de TRAITEMENT de l'APPAREIL EM;

ESSAI SUR LE SITE de catégorie A – La vérification est effectuée par examen de la DOCUMENTATION D'ACCOMPAGNEMENT.

201.7.8 Voyants lumineux et organes de commande

201.7.8.1 Couleurs des voyants lumineux

Remplacement:

Lorsque des indicateurs (voyants ou dispositifs d'affichage) de l'APPAREIL X-IGRT sont utilisés au POSTE DE COMMANDE DU TRAITEMENT (TCP, *Treatment Control Panel*) ou sur d'autres postes de commande associés à l'EBE, les couleurs des voyants doivent être conformes à ce qui suit:

FAISCEAU DE RAYONNEMENT "actif"	jaune
ETAT PRET	vert
intervention urgente nécessaire en réponse à un état de fonctionnement imprévu	rouge
ETAT PREPARATOIRE	toute autre couleur

Lorsque le SYSTEME EBE X-IGRT ne peut pas corriger automatiquement tout défaut d'alignement, pour la thérapie IGRT EN TEMPS REEL, la couleur rouge doit être utilisée, dans la mesure où ceci représente une intervention urgente nécessaire de la part de l'OPERATEUR.

NOTE 101 Dans la SALLE DE TRAITEMENT ou en d'autres emplacements, ces états peuvent indiquer une intervention urgente ou une attention toute particulière; différentes couleurs, telles que celles données dans l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:202, Tableau 2, peuvent ainsi être utilisées à ce type d'emplacements.

La vérification est effectuée par examen.

201.7.9 DOCUMENTS D'ACCOMPAGNEMENT

Addition:

Le Tableau 201.101 récapitule les données de conformité aux ESSAIS DE TYPE et aux ESSAIS SUR LE SITE des Articles 201.7, 201.9, 201.10, 201.11, 201.14, 201.101, 201.102, 201.103 et 201.104 qui sont exigées dans la description technique.

Tableau 201.101 – Données exigées dans la description technique

Paragraphe de conformité	Déclaration concernant les données des ESSAIS DE TYPE de catégorie A	Détails et résultats des ESSAIS DE TYPE de catégorie B	Détails et résultats des ESSAIS DE TYPE de catégorie C	Méthodes SPECIFIQUES et conditions pour les ESSAIS SUR LE SITE de catégorie B	Méthodes SPECIFIQUES et conditions pour les ESSAIS SUR LE SITE de catégorie 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	†	†		†	

Paragraphe de conformité	Déclaration concernant les données des ESSAIS DE TYPE de catégorie A	Détails et résultats des ESSAIS DE TYPE de catégorie B	Détails et résultats des ESSAIS DE TYPE de catégorie C	Méthodes SPECIFIQUES et conditions pour les ESSAIS SUR LE SITE de catégorie B	Méthodes SPECIFIQUES et conditions pour les ESSAIS SUR LE SITE de catégorie C
201.103.3.2	†	†		†	
201.103.3.3	†	†		†	
201.104	a) d)			b) c) e) f)	
Légende Le symbole † indique que l'exigence du paragraphe n'a pas d'autre identification SPECIFIQUE.					

Le Tableau 201.102 répertorie les articles et paragraphes du présent document pour lesquels des informations doivent figurer dans la DOCUMENTATION D'ACCOMPAGNEMENT, les INSTRUCTIONS D'UTILISATION et la description technique.

Tableau 201.102 – Articles et paragraphes du présent document pour lesquels des informations doivent être indiquées dans la DOCUMENTATION D'ACCOMPAGNEMENT, les INSTRUCTIONS D'UTILISATION et la description technique

Référence de vérification	DOCUMENTATION D'ACCOMPAGNEMENT	INSTRUCTIONS D'UTILISATION	Description technique
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

Référence de vérification	DOCUMENTATION D'ACCOMPAGNEMENT	INSTRUCTIONS D'UTILISATION	Description technique
28	201.17.101		
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 La référence de vérification est donnée pour faciliter la vérification de la disponibilité de la documentation de conformité.

201.7.9.2.2 Avertissements et consignes de sécurité

Addition:

La DOCUMENTATION D'ACCOMPAGNEMENT doit décrire les dispositifs ou systèmes fournis ou reconnus par le FABRICANT de SYSTEMES EBE X-IGRT à utiliser avec le SYSTEME EBE X-IGRT.

La DOCUMENTATION D'ACCOMPAGNEMENT doit avertir du fait que les dispositifs ou systèmes non décrits par le FABRICANT de SYSTEMES EBE doivent être évalués par l'ORGANISME RESPONSABLE afin d'attester le bon fonctionnement et la sécurité du système.

Paragraphe supplémentaire:

201.7.9.2.2.101 Interaction du RAYONNEMENT avec les dispositifs médicaux actifs

La DOCUMENTATION D'ACCOMPAGNEMENT doit contenir une notice d'avertissement concernant le potentiel d'interaction néfaste du RAYONNEMENT d'imagerie et de thérapie sur les dispositifs médicaux implantables actifs ou les appareils médicaux actifs portés sur le corps et indiquant qu'il convient de contacter le FABRICANT de tels dispositifs pour plus d'informations, et qu'il convient de vérifier le bon fonctionnement de ces dispositifs après l'IRRADIATION.

201.7.9.2.5 Description de l'APPAREIL EM

Addition:

Le FABRICANT doit indiquer dans la DOCUMENTATION D'ACCOMPAGNEMENT la fonction de l'APPAREIL X-IGRT.

L'exactitude de la géométrie de l'APPAREIL X-IGRT doit être décrite dans la DOCUMENTATION D'ACCOMPAGNEMENT.

L'exactitude de la relation entre tous les axes de l'APPAREIL X-IGRT et l'ERP doit être indiquée dans la DOCUMENTATION D'ACCOMPAGNEMENT.

L'exactitude de la détermination des relations entre les axes et l'ERP et la technique de mesure utilisée pour établir ces valeurs doivent être indiquées dans la DOCUMENTATION D'ACCOMPAGNEMENT.

La stabilité géométrique attendue de l'APPAREIL X-IGRT par rapport à l'ERP de l'EBE et du SYSTEME DE COORDONNEES DE REFERENCE de l'appareil par rapport à l'APPAREIL X-IGRT au moment de l'étalonnage et la fréquence recommandée de l'AQ doivent être indiquée dans la DOCUMENTATION D'ACCOMPAGNEMENT.

NOTE Exemple d'éléments à prendre en considération:

- la dérive mécanique à long terme;
- la dérive à court terme pendant une fraction (rotation, etc.);
- les changements liés aux activités de l'OPERATEUR, par exemple montage des accessoires, déploiement/retrait du matériel;
- les changements liés à la position et à la configuration de la machine.

Paragraphes supplémentaires:

201.7.9.2.5.101 IGRT EN TEMPS REEL

Dans le cas de la thérapie IGRT EN TEMPS REEL, le temps de LATENCE IGRT de l'APPAREIL X-IGRT pour accomplir sa fonction doit figurer dans la DOCUMENTATION D'ACCOMPAGNEMENT. Les conditions qui permettent de déterminer le temps de LATENCE IGRT doivent également être indiquées dans la DOCUMENTATION D'ACCOMPAGNEMENT. Lorsque le temps entre images n'est pas déterminé par l'opérateur, ce temps doit également être indiqué.

Lorsque la LATENCE X-IGRT est compensée par un modèle de prévision ou une autre méthode, la méthode de compensation doit être décrite dans la DOCUMENTATION D'ACCOMPAGNEMENT.

Lorsque la méthode de compensation comprend également l'hypothèse d'une latence de l'EBE, en plus de la LATENCE IGRT de l'APPAREIL X-IGRT, alors cette méthode doit également figurer dans la DOCUMENTATION D'ACCOMPAGNEMENT.

201.7.9.2.5.102 APPAREIL X-IGRT sous kV

Pour les APPAREILS X-IGRT qui utilisent un TUBE RADIOGENE en kV, les données de sortie électrique doivent figurer dans les INSTRUCTIONS D'UTILISATION sous forme de PARAMETRES DE CHARGE comme cela est exigé dans l'IEC 60601-1-3:2008, l'IEC 60601-1-3:2008/AMD1:2013 et l'IEC 60601-1-3:2008/AMD2:2021, 6.4.3.

Pour les APPAREILS X-IGRT dans lesquels une partie du GENERATEUR RADIOLOGIQUE est intégrée avec la GAINE EQUIPEE (par exemple BLOCS RADIOGENES), les valeurs indiquées doivent faire référence au dispositif complet.

Les combinaisons et données suivantes doivent être indiquées dans les INSTRUCTIONS D'UTILISATION pour les TUBES RADIOGENES en kV:

a) la HAUTE TENSION RADIOGENE NOMINALE correspondante ainsi que le COURANT le plus élevé DANS LE TUBE RADIOGENE obtenus à partir du GENERATEUR RADIOLOGIQUE lorsqu'il fonctionne à cette HAUTE TENSION RADIOGENE;

b) le COURANT le plus élevé DANS LE TUBE RADIOGENE correspondant ainsi que la HAUTE TENSION RADIOGENE la plus élevée obtenus à partir du GENERATEUR RADIOLOGIQUE lorsqu'il fonctionne à ce COURANT DANS LE TUBE RADIOGENE;

c) la combinaison correspondante de la HAUTE TENSION RADIOGENE et du COURANT DANS LE TUBE RADIOGENE qui entraîne la puissance de sortie électrique la plus élevée; et

d) la PUISSANCE ELECTRIQUE NOMINALE donnée comme étant la puissance de sortie électrique constante la plus élevée en kilowatts que peut fournir le GENERATEUR RADIOLOGIQUE, pour un TEMPS DE CHARGE correspondant au temps de charge clinique maximal ou à un temps de 4 s, si celui-ci est plus court, à une HAUTE TENSION RADIOGENE de 120 kV ou, lorsque ces valeurs ne sont pas sélectionnables, à une HAUTE TENSION RADIOGENE la plus proche de 120 kV.

La PUISSANCE ELECTRIQUE NOMINALE doit être donnée de même que la combinaison de la HAUTE TENSION RADIOGENE et du COURANT DANS LE TUBE RADIOGENE et que le TEMPS DE CHARGE qui sont utilisés dans les APPAREILS X-IGRT sous kV.

201.7.9.2.10 Messages

Remplacement:

Tous les messages système, messages d'erreur et messages de défaut exigés par le 7.9.2.10 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 qui sont destinés à l'OPERATEUR pendant l'utilisation clinique et qui sont affichés au TCP doivent indiquer la raison du message et prévoir les actions possibles pour permettre à l'OPERATEUR de répondre au message de manière rapide et appropriée.

NOTE Par hypothèse, l'OPERATEUR possède toutes les informations nécessaires pour prendre une décision éclairée concernant la poursuite ou la FIN du TRAITEMENT sans nécessiter d'autres informations.

201.7.9.2.15 Protection de l'environnement

Addition:

Les INSTRUCTIONS D'UTILISATION doivent fournir des recommandations et des conseils sur les précautions à prendre en ce qui concerne l'identification, la manipulation et la mise au rebut de l'appareil em ou des parties de l'appareil em qui peuvent présenter un certain niveau de RADIOACTIVITE.

201.7.9.2.17 APPAREIL EM émettant du rayonnement

Remplacement:

Dans le but d'aider le conseiller en protection radiologique de l'ORGANISME RESPONSABLE, les informations suivantes relatives au faisceau d'imagerie à rayonnement X doivent être définies dans la DOCUMENTATION D'ACCOMPAGNEMENT.

NOTE Le conseiller en protection radiologique de l'ORGANISME RESPONSABLE est, généralement, la personne en charge de l'identification et de la mise au rebut des matériaux qui peuvent présenter une RADIOACTIVITE.

Pour chaque ENERGIE NOMINALE DE RAYONNEMENT X:

– l'énergie maximale des électrons qui touchent la CIBLE et les DEBITS DE DOSE ABSORBEE maximaux correspondants à la DISTANCE DE REFERENCE NOMINALE dans les conditions d'UTILISATION NORMALE, avec et sans FILTRE ADDITIONNEL lorsque l'UTILISATION NORMALE est possible dans ces deux états;
– le profil dimensionné des CHAMPS DE RAYONNEMENT maximaux à la DISTANCE DE REFERENCE NOMINALE pour le RAYONNEMENT X;
– l'emplacement ou les emplacements de la surface frontale de la CIBLE par rapport aux points accessibles de la TETE RADIOGENE; et
– les directions disponibles du FAISCEAU DE RAYONNEMENT.

Pour chaque ENERGIE NOMINALE DE RAYONNEMENT X, lorsqu'un bouclier de protection du FAISCEAU DE RAYONNEMENT est intégré, son facteur de transmission doit figurer dans la DOCUMENTATION D'ACCOMPAGNEMENT.

201.8 Protection contre les DANGERS d'origine électrique provenant des APPAREILS EM

L'Article 8 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.8.4 Limitation de la tension, du courant ou de l'énergie

201.8.4.2 PARTIES ACCESSIBLES et PARTIES APPLIQUÉES

Addition au point d):

Les exigences du 8.4.2 d) de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ne s'appliquent pas lorsque l'installation ne permet pas d'effectuer l'essai avec la tige et la broche d'essai. La DOCUMENTATION D'ACCOMPAGNEMENT doit indiquer le moment auquel ces conditions s'appliquent.

Paragraphes supplémentaires:

201.8.4.101 Limitation de la haute tension par rapport à la haute tension radiogène nominale

Les APPAREILS X-IGRT sous kV doivent être conçus de manière à ne pas fournir une tension supérieure à la HAUTE TENSION RADIOGENE NOMINALE pour les GAINES EQUIPEES en UTILISATION NORMALE.

NOTE Le présent article a été adapté de l'IEC 60601-2-44.

La vérification est effectuée par examen des données du FABRICANT pour le composant, par examen de l'APPAREIL EM et, le cas échéant, par un essai de fonctionnement.

201.8.4.102 Raccordements par câbles haute tension non fixés à demeure

Les raccordements à la GAINE EQUIPEE par câbles haute tension non fixés à demeure doivent être conçus de manière qu'il soit nécessaire d'utiliser des outils pour les déconnecter ou pour enlever leurs capots de protection.

NOTE Le présent article a été adapté de l'IEC 60601-2-54.

La vérification est effectuée par examen.

201.8.4.103 Haute tension inacceptable dans la PARTIE RELIEE AU RESEAU

Pour les APPAREILS X-IGRT sous kV, des dispositions doivent être prises pour éviter l'apparition d'une haute tension inacceptable dans la PARTIE RELIEE AU RESEAU ou dans tout autre circuit à basse tension.

NOTE 1 Ceci est réalisé par exemple:

- au moyen d'une couche d'enroulement ou d'un écran conducteur raccordé à la BORNE DE TERRE DE PROTECTION entre les circuits haute tension et basse tension; ou
- en prévoyant un dispositif limiteur de tension aux bornes auxquelles les dispositifs externes sont connectés et entre lesquelles une tension excessive peut apparaître si le chemin externe à la terre devient discontinu.

NOTE 2 Le présent article a été adapté de l'IEC 60601-2-44.

La vérification est effectuée par examen des données de conception et de la construction.

201.8.7 COURANTS DE FUITE et COURANTS AUXILIAIRES PATIENT

201.8.7.1 Exigences générales

Addition au point b):

– avec l'APPAREIL X-IGRT sous tension dans l'ETAT PREPARATOIRE et avec la combinaison la plus défavorable possible des mouvements motorisés simultanément.

201.8.7.3 Valeurs admissibles

Remplacement du point d):

Le COURANT DE FUITE A LA TERRE en CONDITION NORMALE et en CONDITION DE PREMIER DEFAUT ne doit pas dépasser 10 mA.

NOTE 1 La réglementation locale peut établir des limites pour les courants de terre de protection de l'installation. Voir aussi l'IEC 60364-7-710.

Les valeurs admissibles du COURANT DE FUITE A LA TERRE sont admises pour chaque sous-ensemble de l'APPAREIL X-IGRT qui est alimenté avec sa propre connexion au RESEAU D'ALIMENTATION ou à un point de connexion central, lorsque ce dernier est fixe et INSTALLE DE FAÇON PERMANENTE.

Une BORNE DE TERRE DE PROTECTION centrale fixe et INSTALLEE DE FAÇON PERMANENTE peut être fournie à l'intérieur de l'ENVELOPPE extérieure ou du capot de l'APPAREIL X-IGRT. Lorsque d'autres sous-ensembles ou APPAREILS ASSOCIES sont connectés à la BORNE DE TERRE DE PROTECTION, le COURANT DE FUITE A LA TERRE entre ce point de connexion central et le système de protection externe peut dépasser les valeurs admissibles pour chacun des dispositifs connectés.

L'utilisation d'une BORNE DE TERRE DE PROTECTION centrale est tolérée, car pour un APPAREIL EM fixe et INSTALLE DE FAÇON PERMANENTE, l'interruption du CONDUCTEUR DE TERRE DE PROTECTION n'est pas considérée comme une CONDITION DE PREMIER DEFAUT. Toutefois, dans de tels cas, les informations adéquates sur la combinaison des APPAREILS ASSOCIES doivent être fournies

conformément au 201.7.9.3.1 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020.

ESSAI DE TYPE de catégorie C: la vérification est effectuée par examen et essai.

Addition au point e):

Pour les APPAREILS X-IGRT sous kV INSTALLES DE FAÇON PERMANENTE, quelles que soient la forme d'onde et la fréquence, le COURANT DE FUITE A LA TERRE en CONDITION NORMALE et en CONDITION DE PREMIER DEFAUT ne doit pas dépasser 20 mA en valeur efficace, mesuré avec un dispositif non pondéré en fréquence.

La vérification est effectuée comme suit:

ESSAI DE TYPE de catégorie A: examen de la DOCUMENTATION D'ACCOMPAGNEMENT.

201.8.8.3 Tension de tenue

Les TOMODENSITOMETRES, les APPAREILS A RAYONNEMENT X pour la RADIOGRAPHIE ou les APPAREILS A RAYONNEMENT X pour la RADIOSCOPIE, lorsque les exigences suivantes sont équivalentes et soumises à l'essai conformément à une autre norme, n'exigent pas de nouveaux essais et il peut être fait référence à la déclaration de conformité ou au rapport d'essai correspondant (voir aussi l'Annexe AA).

Amendement à l'ESSAI DE TYPE pour un circuit haute tension:

Le circuit haute tension de la composante d'imagerie X-IGRT sous kV est soumis à l'essai en appliquant une tension maximale égale à la moitié de la tension d'essai, puis la tension d'essai est augmentée progressivement pendant une période de 10 s jusqu'à la valeur maximale, qui est maintenue pendant 3 min en radiographie et tomodensitométrie et pendant 15 min en radioscopie.

Addition aux conditions d'essai pour un circuit haute tension:

L'essai pour circuit haute tension doit être effectué sans gaine équipée sous kV connectée et avec une tension d'essai égale à 1,2 fois la haute tension radiogène en kV nominale de l'APPAREIL X-IGRT. Si la COMPOSANTE D'IMAGERIE X-IGRT peut être soumise à l'essai uniquement avec la gaine équipée sous kV connectée et si le tube radiogène sous kV ne permet pas de soumettre à l'essai la COMPOSANTE D'IMAGERIE X-IGRT avec une tension d'essai égale à 1,2 fois la haute tension radiogène en kV nominale, la tension d'essai peut être inférieure, mais non inférieure à 1,1 fois cette tension.

Pour les APPAREILS D'IMAGERIE X-IGRT dans lesquels la haute tension radiogène en kV nominale à des fins de radioscopie ne dépasse pas 80 % de celle à des fins de radiographie, la tension d'essai pour le circuit haute tension doit être désignée comme la valeur de radiographie, et l'essai doit être effectué uniquement dans ce mode.

Si, au cours de l'essai de tension de tenue, il existe un risque de surchauffe d'un transformateur en essai, il est admis d'effectuer l'essai à une fréquence d'alimentation supérieure.

Au cours de l'essai de tension de tenue, la tension d'essai appliquée dans le circuit haute tension doit être maintenue le plus près possible de 100 % et ne doit pas se situer hors de la plage de 100 % et de 105 % de la valeur exigée.

Au cours de l'essai de tension de tenue, de légers effets de couronne dans le circuit haute tension ne doivent pas être pris en compte s'ils cessent lorsque la tension d'essai est abaissée à 110 % de la tension à laquelle se réfère la condition d'essai.

Si, conformément à l'appréciation du risque, le portique ou le support du patient est une partie appliquée ou la partie traitée comme une partie appliquée, et les parties conductrices du portique ou du support du patient accessibles au patient ne sont pas couvertes entièrement par une enveloppe en plastique, de telles parties du portique ou du support du patient sont alors protégées par des MOYENS DE PROTECTION DU PATIENT (MOPP, Means Of Patient Protection). Dans ce cas, la tension d'essai pour les essais de tension de tenue du stator et des circuits statoriques utilisés pour le fonctionnement de l'anode rotative du tube radiogène doit être établie sur la tension existante après réduction de la tension d'alimentation du stator à sa valeur de fonctionnement en régime stabilisé.

Autrement, le portique est protégé par des MOYENS DE PROTECTION DE L'OPERATEUR (MOOP, Means Of Operator Protection) et les exigences du Tableau 6 et des Tableaux 13 à 16 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou les exigences de coordination de l'isolement de l'IEC 60950-1 s'appliquent.

Addition:

aa) les GENERATEURS RADIOLOGIQUES, ou leurs sous-ensembles, qui sont intégrés à une GAINE EQUIPEE doivent être soumis à l'essai avec un TUBE RADIOGENE correctement chargé;

bb) si ces GENERATEURS RADIOLOGIQUES n'ont pas de dispositif distinct pour le réglage du COURANT DANS LE TUBE RADIOGENE, la durée de l'essai de tension de tenue doit être réduite à un point tel que la CHARGE DU TUBE RADIOGENE admissible à la HAUTE TENSION RADIOGENE accrue n'est pas dépassée; ou

cc) si le circuit haute tension n'est pas accessible pour le mesurage de la tension d'essai appliquée, des mesures appropriées doivent être prises pour assurer que les valeurs sont maintenues le plus près possible de 100 %, celles-ci ne devant pas se situer hors de la plage de 100 % et 105 % de la valeur exigée.

NOTE Ces exigences sont adaptées du 201.8.8.3 de l'IEC 60601-2-54:2009.

201.8.11 PARTIES RELIEES AU RESEAU, composants et montage

201.8.11.1 Séparation du RESEAU D'ALIMENTATION

Remplacement du point b):

b) Des moyens prévus pour séparer les circuits du réseau d'alimentation, à l'exception de ceux qui doivent rester connectés pour des raisons de sécurité (pompes à vide, éclairage des locaux et certains VERROUILLAGES de sécurité, par exemple), doivent faire partie de l'APPAREIL EM ou être situés à l'extérieur en autant que cela est jugé nécessaire. Lorsque ces moyens doivent faire totalement ou partiellement partie de l'installation du site, ces exigences doivent être indiquées dans la description technique.

201.9 Protection contre les DANGERS MECANIQUES des APPAREILS EM et des SYSTEMES EM

L'Article 9 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.9.2 DANGERS MECANIQUES associés aux parties en mouvement

201.9.2.1 Généralités

Addition:

NOTE 101 L'expression "régler automatiquement" ou "réglage automatique" est utilisée pour désigner le mouvement des parties d'APPAREILS EM automatiquement sur les positions exigées pour le lancement du TRAITEMENT d'un PATIENT ou d'une formation d'images. Ceci inclut le déclenchement des mouvements préprogrammés par l'opérateur.