

# 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**

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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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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

## MEDICAL ELECTRICAL EQUIPMENT –

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

## FOREWORD

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International standard IEC 60601-2-68 has been prepared by IEC subcommittee 62C Equipment for radiotherapy, nuclear medicine and radiation dosimetry of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62C/595/FDIS	62C/602/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

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

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

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

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

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

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

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

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

## INTRODUCTION

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 extend over many days, during which the TARGET VOLUME/PATIENT may shrink or grow and/or move. Hence, the exact location of the TARGET VOLUME/critical structures may 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 in order 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 particular standard establishes requirements to be complied with by MANUFACTURERS in the design and construction of X-RAY IGRT EQUIPMENT (X-IGRT).

This particular standard 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 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, IMAGE DISPLAY DEVICE quality is specified in IEC documents in regards to diagnostic use (e.g. IEC 62563-1:2009, Ed. 1.0). However, since IGRT usage may or may not require such high requirements it is left to the MANUFACTURER to specify what is required for use with their X-IGRT EQUIPMENT.

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

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

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

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

- IEC 61217, *Radiotherapy equipment – Coordinates, movements and scales*
- IEC 62274, *Medical electrical equipment – Safety of radiotherapy record and verify systems*
- 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.*

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

This particular standard 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.

## **iTeh STANDARD PREVIEW** **(standards.iteh.ai)**

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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

#### 201.1 Scope, object and related standards

Clause 1 of the general standard<sup>1</sup> applies, except as follows:

##### 201.1.1 Scope

###### *Replacement:*

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

This particular standard covers safety aspects of kilovoltage (kV) and megavoltage (MV) X-ray imaging devices in a known 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 particular standard deals with equipment for REAL-TIME X-IGRT, ONLINE X-IGRT and OFFLINE X-IGRT. It covers procedures to reduce the risk of over-reliance on the X-IGRT EXTERNAL BEAM SYSTEM (X-IGRT EBS). For example the manufacturer will provide an interactive interface for user interaction with the correction suggested by the system.

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. If that is not the case, the clause or subclause applies only to X-IGRT EQUIPMENT.

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

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

##### 201.1.2 Object

###### *Replacement:*

<sup>1</sup> 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*

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

IEC60601-1-3 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.

### 201.1.4 Particular standards

*Replacement:*

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

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

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

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

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

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

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

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

## 201.2 Normative references

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

*Amendment:*

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 60601-1-6:2010, *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:*

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

IEC 60601-1:2005/AMD1:2012 [IEC 60601-2-68:2014](https://standards.iteh.ai/catalog/standards/sist/2b8a2746-daa0-4fec-a9b2-dc36662b2802/iec-60601-2-68-2014)  
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IEC 60601-2-1:2009, *Medical electrical equipment – Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV*

IEC 60601-2-4:2010, *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 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*

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

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

Addition:

#### 201.3.201

##### COMPUTED TOMOGRAPHY DOSE INDEX 100

##### CTDI<sub>100</sub>

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

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

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

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

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

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 201.102.5.2);

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

$D_{\text{Ref}}(y)$  is the DOSE PROFILE representative of a single axial scan along a line perpendicular to the TOMOGRAPHIC PLANE, where dose is reported as ABSORBED DOSE in air and is evaluated within a polymethylmethacrylate (PMMA) dosimetry PHANTOM (see 201.102.5.2) for  $(N \times T)_{\text{Ref}}$ ;

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

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

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

$T$  is the NOMINAL TOMOGRAPHIC SECTION THICKNESS.

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

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

Note 3 to entry: A single axial scan is typically a  $360^\circ$  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 by  $0,5 \times N \times T$ .

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

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

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

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

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

#### $CTDI_{\text{free air}}$

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

<https://standards.iteh.ai/catalog/standards/sist/2b8a2746-daa0-4fec-a9b2-dc36662b2802/iec-60601-2-68-2014>

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

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, but not less than 100 mm.

Note 1 to entry: This definition assumes that the DOSE PROFILE is centered 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  $\sigma_0$  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.]

STANDARD PREVIEW  
(standards.iteh.ai)

**201.3.205**

**DOSE-LENGTH PRODUCT**

**DLP**

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

IEC 60601-2-68:2014

<http://product.standards.iteh.ai/catalog/standards/sist/60601-2-68-2014/dc36662b2802/iec-60601-2-68-2014>

a) For axial scanning

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

where

$\Delta d$  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 if 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 isocenter of the free-in-air DOSE PROFILE for the entire scan. In the absence of dynamic collimation this is approximately equivalent to table travel during the entire LOADING.

c) For scanning without movement of the PATIENT SUPPORT

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

where

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

$T$  is the NOMINAL TOMOGRAPHIC SECTION THICKNESS.

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

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

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

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

where

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

$T$  is the NOMINAL TOMOGRAPHIC SECTION THICKNESS;

$R$  is the distance between the two positions.

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/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: 60601-2-44:2009/AMD1:2012, 201.3.205]

### 201.3.207

#### EXTERNAL BEAM EQUIPMENT

##### EBE

external RADIATION EQUIPMENT utilizing ELECTRON ACCELERATORS, light ion beam 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

#### IGRT EQUIPMENT

ME EQUIPMENT that provides IGRT functionality

### 201.3.209

#### 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.

[SOURCE: IEC 60976:2007, 3.8]