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Radiological protection — Medical electron accelerators — Requirements and recommendations for shielding design and evaluation

Radioprotection — Accélérateurs médicaux d'électrons — Exigences et recommandations pour la conception et l'évaluation du blindage

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Contents

Page

Foreword ..... **v**

Introduction ..... **vi**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **1**
3.1 Quantities 1
3.2 Definitions 4

4 Shielding design goals and other design criteria **6**
4.1 Shielding design goals 6
4.2 Shielding design assumptions 7

5 Role of the manufacturers, of the radiation protection officer or qualified expert and interactions between stakeholders **8**
5.1 General 8
5.2 Linear accelerator manufacturer 8
5.3 Shielding material vendor 9
5.4 Architectural firm/general contractor 10
5.5 Radiation protection officer or qualified expert 10
5.6 The licensee 11

6 Radiation fields around a linear electron accelerator **11**
6.1 General 11
6.2 X-ray radiation 11
6.2.1 Primary X-ray beam 11
6.2.2 Primary electron beam bremsstrahlung 12
6.2.3 Secondary X-ray radiation 12
6.2.4 Tertiary X-ray radiation 13
6.3 Neutron radiation 13
6.3.1 General 13
6.3.2 Direct neutron radiation 14
6.3.3 Scattered and thermal neutron radiation 14
6.3.4 Primary barrier neutron radiation 15
6.4 γ radiation 15
6.4.1 General 15
6.4.2 Maze γ radiation 15
6.4.3 Door γ radiation 15
6.4.4 Primary barrier γ radiation 15
6.4.5 Air γ radiation 16

7 Shielding materials and transmission values **16**

8 General formalism for shielding calculation **18**

9 Shielding calculation for conventional devices **20**
9.1 General 20
9.2 Primary barriers 20
9.2.1 Radiation components 20
9.2.2 Barrier with a unique material 21
9.2.3 Barrier with multiple layers 21
9.3 Secondary barriers 22
9.3.1 Radiation components 22
9.3.2 Barrier with a unique material 23
9.3.3 Barriers with multiple layers 24

10 Doors and mazes **24**
10.1 General 24

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10.2 Radiation components 25
10.3 Standard maze 25
10.3.1 Maze X-ray scatter calculations 25
10.3.2 X-ray direct Leakage 30
10.3.3 Maze neutron and capture gamma calculations 31
10.4 Two legged maze 33
10.5 No maze - Direct-shielded doors 34
10.5.1 General 34
10.5.2 Shielding at the far side of a direct-shielded door entrance 35
10.5.3 Shielding at the near side of a direct-shielded door entrance 37
10.6 No door at maze entrance 39
10.7 Door Calculations 40
10.7.1 General 40
10.7.2 Maze door calculations 40
10.7.3 Direct Shielded Door Calculations 41

11 Shielding calculations for special devices 41
11.1 General 41
11.2 Robotic arm accelerator 41
11.3 Helical intensity modulated radiotherapy 42
11.4 Dedicated device for intra operative radiotherapy with electrons 42

12 Ducts 43
12.1 Duct impact on radiation protection 43
12.2 Recommended location and geometry 43
12.3 Additional shielding 44
12.3.1 General 44
12.3.2 Neutron and capture gamma radiation passing through the interior of the shielded duct 44
12.3.3 X scattered radiation passing through the interior of the shielded duct 45
12.3.4 Scattered radiation passing through the walls of the duct shielding 46
12.3.5 Dose equivalent at HVAC duct exterior opening 46

13 Special considerations 46
13.1 Skyshine 46
13.1.1 General 46
13.1.2 X-ray skyshine radiation 46
13.1.3 Neutron skyshine radiation 48
13.2 Groundshine radiations 49
13.3 Joints and junctions 49

14 Shielding evaluation (experimental verification) 49
14.1 General 49
14.2 Measuring equipment and methodology 50
14.3 Evaluation 50

15 Indication, warning signs, interlocks 52

Annex A (informative) **Tenth value layers for the most common shielding materials 53**

Annex B (informative) **Supporting data for shielding calculations 66**

Annex C (informative) **Example of calculation for conventional device and standard maze 68**

Bibliography 75

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 85, *Nuclear energy, nuclear technologies, and radiological protection*, Subcommittee SC 2, *Radiological protection*.

This corrected version of ISO 16645:2016 incorporates the correction of Tables A.9 and C.6.

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Introduction

Radiotherapy uses external beam radiation to kill cancer cells and shrink tumours. The use of electron linear accelerators to administer external beam radiation has spread during recent decades and is now common throughout the world. These accelerators deliver high energy electron and photon beams with increasingly high dose rates. Although the use of radiotherapy is well established, irradiation techniques have continued to evolve and are becoming increasingly complex. Examples include modulation of beam intensity, availability of high dose rate modes, arctherapy, helical intensity modulated radiotherapy, robotic arm accelerators, and dedicated devices for intra-operative radiotherapy. The shielding design of treatment rooms has been evolving with these changes. The higher radiation workload associated with most of these techniques can impact the shielding materials used. The irradiation technique can also impact the geometry to be considered in the shielding calculations.

IEC 60601-2-1 relates to the design and the construction of the accelerators in order to ensure the safety of their operation[1]. In addition, several national[2][3] or international (IAEA Safety Reports Series Report No. 47, 2006) reports propose recommendations concerning the installation and the exploitation of these accelerators, the safety devices, the design and the calculation of protections, the radiological control and monitoring. National standards have been established in certain countries[4] [5]. Moreover national regulations impose particular rules of protection against radiation, in particular relating to the definition of the controlled areas and the calculation of shielding.

Taking into account the developments of new irradiation techniques and of new designs of treatment room facilities on the one hand, and the variety of guides or normative documents on the other hand, it appeared judicious to establish an international standard to be used as a general framework. This standard is intended to be complementary to the other international standards (IEC and IAEA).

The following items are discussed in the standard:

— types of accelerators: conventional accelerators with and without flattening filter (FF and FFF operating modes), devices for helical intensity modulated radiotherapy and robotic arm accelerator, dedicated machines for intra-operative radiotherapy;

— radiation fields: electrons, X photons and neutrons (direct, scattered, leakage), neutron capture gamma rays;

— Treatment room geometry: maze without and with door, no maze with direct door;

— materials of protection: concrete (ordinary or high density), metals, laminated barriers (concrete and metal), hydrogenated materials, earth and others;

— design of the radiotherapy facility:

— calculation methods of the shielding, including neutrons, various types of installations and shielding geometries;

— evaluation of the impact of the maze and calculation of the protection of the entrance door;

— evaluation of the impact of the ducts (ventilation and air-conditioning, high voltage and fluids) and additional protections;

— shielding design assumption and goals;

— Radiation survey of the completed installation to ensure national requirements have been met and the shielding and design is fit for purpose after installation of the accelerator.

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Radiological protection — Medical electron accelerators — Requirements and recommendations for shielding design and evaluation

1 Scope

This International Standard is applicable to medical electron linear accelerators i.e. linear accelerators with nominal energies of the beam ranging from 4 MV to 30 MV, including particular installations such as robotic arm, helical intensity modulated radiotherapy devices and dedicated devices for intra operative radiotherapy (IORT) with electrons.

The cyclotrons and the synchrotrons used for hadrontherapy are not considered.

The radiation protection requirements and recommendations given in this International Standard cover the aspects relating to regulations, shielding design goals and other design criteria, role of the manufacturers, of the radiation protection officer or qualified expert and interactions between stakeholders, radiations around a linear accelerator, shielding for conventional and special devices (including shielding materials and transmission values, calculations for various treatment room configurations, duct impact on radiation protection) and the radiological monitoring (measurements).

NOTE 1 Annex A provides transmission values for the most common shielding materials.

NOTE 2 Annex B provides supporting data for shielding calculation.

NOTE 3 Annex C provides an example of calculation for conventional device and standard maze.

2 Normative references

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

IEC 60976, *Medical electrical equipment — Medical electron accelerators — Functional performance characteristics*

IAEA Safety Reports Series Report No. 47, *Radiation protection in the Design of Radiotherapy Facilities (2006)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60976 and the following apply.

3.1 Quantities

3.1.1
absorbed dose
D
quotient of $d\bar{\varepsilon}$ by *dm*, where $d\bar{\varepsilon}$ is the mean energy imparted to matter of mass *dm* thus

$$D = \frac{d\bar{\varepsilon}}{dm}$$

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Note 1 to entry: In this document, the absorbed dose is defined for radiation produced by a linear accelerator at a specific location: the absorbed dose to water at the isocentre (at 1 m from the source for conventional devices) at a reference depth in water in electron equilibrium conditions (for example at the depth of maximum absorbed dose).

Note 2 to entry: The unit of absorbed dose is joule per kilogram ($J \cdot kg^{-1}$), and its special name is gray (Gy).

[SOURCE: ISO 12749-2:2013, 4.1.6.7][6]

3.1.2
absorbed dose rate
output rate
DR_O
dose absorbed per unit of time

Note 1 to entry: In this International Standard, in the absence of specific indication, the absorbed dose rate is defined for radiation produced by a linear accelerator at a specific location: the absorbed dose rate to water at the isocentre (at 1 m from the source for conventional devices) at a reference depth in water in electron equilibrium conditions (for example at the depth of maximum absorbed dose).

Note 2 to entry: The unit of absorbed dose rate is gray per second ($Gy \cdot s^{-1}$). The usual unit for medical accelerators is gray per hour ($Gy \cdot h^{-1}$).

3.1.3
dose equivalent
H
product of D and Q at a point in tissue, where D is the absorbed dose (3.1.1) and Q is the quality factor for the specific radiation at this point, thus: $H = D \times Q$

Note 1 to entry: The unit of dose equivalent is joule per kilogram ($J \cdot kg^{-1}$), and its special name is sievert (Sv).

[SOURCE: ISO 12749-2:2013, 4.1.6.8][6]

3.1.4
IMRT ratio
C_I
ratio of the average monitor unit per unit prescribed absorbed dose needed for IMRT (MU_{IMRT}) and the monitor unit per unit absorbed dose for conventional treatment (MU_{conv})

$$C_I = \frac{MU_{IMRT}}{MU_{CONV}}$$

3.1.5
instantaneous dose-equivalent rate
IDR
"ambient/personal" dose-equivalent rate ($Sv \cdot h^{-1}$) as measured with the linear accelerator operating at the absorbed dose rate DR_O ($Gy \cdot h^{-1}$)

Note 1 to entry: This is the direct reading of the ratemeter that gives a stable reading in dose-equivalent per hour. *IDR* is specified at a reference point (30 cm) beyond the penetrated barrier.

3.1.6
effective dose
E
summation of all the tissue equivalent doses, each multiplied by the appropriate tissue weighting factor

3.1.7
occupancy factor
T
fraction of time the areas adjacent to the treatment room are occupied by an individual or group during linear accelerator operation

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3.1.8
orientation or use factor
U
fraction of the time during which the radiation under consideration is directed at a particular barrier

3.1.9
reflection coefficient
α
fraction of radiation (e.g., fluence, energy fluence) expressed by the ratio of the amount backscattered to that incident

3.1.10
shielding design goal
P
practical values of dose equivalent, for a single radiotherapy source or set of sources, evaluated at a reference point beyond a protective barrier

Note 1 to entry: The shielding design goals ensure that the respective annual values for effective dose limit defined by national regulation or IAEA/ICRP for controlled and uncontrolled areas are not exceeded.

3.1.11
(patient) scatter fraction
***a*(*θ*)**
ratio of absorbed dose at 1 m from a tissue-equivalent scattering object to the absorbed dose measured at the isocentre with the object removed

Note 1 to entry: This quantity is a function of the scatter angle (θ), incident beam quality, and beam area. A scattering phantom is typically a water-equivalent volume representing a standard human being.

3.1.12
tenth-value distance
TVD
distance that a specified radiation travels under broad beam condition in order to reduce the radiation field intensity to one-tenth of its original value

3.1.13
tenth-value layer
TVL
thickness of a specific material that reduces a specified radiation field intensity by a factor of 10 of its original value, under broad beam condition

Note 1 to entry: *TVL* is expressed in m or cm of a defined material or in kg/m^2 (thickness × density).

Note 2 to entry: TVL_1 and TVL_2 are the first and the second tenth-value layer thicknesses, respectively.

Note 3 to entry: TVL_e is the equilibrium tenth-value layer, thickness for each subsequent tenth-value layer in the region in which the directional and spectral distributions of the radiation field are practically independent of thickness.

Note 4 to entry: TVL_c is the cumulative tenth-value layer, approximate value based on large attenuation measurements: for a given thickness t, $TVL_c = -t/\log(B)$.

3.1.14
time averaged dose-equivalent rate
TADR
barrier attenuated dose-equivalent rate averaged over a specified period of accelerator operation

Note 1 to entry: *TADR* is proportional to instantaneous dose-equivalent rate (*IDR*), and depends on the values of workload (*W*) and orientation or use factor (*U*).

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3.1.15
transmission factor (or barrier transmission)
B
ratio of radiation field intensity at a location behind the barrier on which radiation is incident to the field intensity at the same location without the presence of the shield, for a given radiation type and quality

Note 1 to entry: *B* is a measure of the shielding effectiveness of the barrier.

3.1.16
workload
W
average absorbed dose to water of radiation produced by a linear accelerator, at the isocentre at a reference depth in water in electron equilibrium conditions, over a specified period averaged over a year

Note 1 to entry: The workload is specified in Gray (Gy).

Note 2 to entry: The time period should be consistent between shielding design goals and workload.

Note 3 to entry: The isocentre is at 1 m from the source for conventional devices.

Note 4 to entry: The reference depth in water is for example the depth of maximum absorbed dose.

3.2 Definitions

3.2.1
barrier (or protective barrier)
protective wall of radiation attenuating material(s) used to reduce the dose equivalent on the side beyond the radiation source to an acceptable level compatible with national legislation or international guidance

3.2.2
primary barrier
wall, ceiling, floor or other structure designed to attenuate the direct radiation emitted from the target or source that passes though the collimator opening (useful beam) to an acceptable level compatible with national legislation or international guidance

3.2.3
secondary barrier
wall, ceiling, floor or other structure not struck by the primary beam and designed to attenuate the leakage and scattered radiations to an acceptable level compatible with national legislation or international guidance

3.2.4
controlled area
defined area in which specific protection measures and safety provisions are or could be required for controlling exposures or preventing the spread of contamination in normal working conditions, and preventing or limiting the likelihood and magnitude of potential exposures

Note 1 to entry: This implies that access, occupancy, and working conditions are controlled for radiation protection purposes.

[SOURCE: IAEA BSS][7]

3.2.5
geometrical field size
geometrical projection as seen from the centre of the front surface of the radiation source on a plane perpendicular to the axis of the beam of the distal end of the beam limiting device or collimator

Note 1 to entry: The field is thus of the same shape as the aperture of the beam limiting device.

Note 2 to entry: The projected field size is specified at a particular distance from the target, e.g. at the isocentre 1 m from the target or at the reference distance of the device.

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[SOURCE: IEC 60976:2007]

3.2.6
helical intensity modulated radiotherapy
radiotherapy using a linear accelerator that delivers treatment with a slit beam adjustable by a multileaf collimator (MLC) and that rotates continuously around patient with geometry resembling diagnostic computed tomography (CT), with concomitant motion of the couch

Note 1 to entry: Helical intensity modulated radiotherapy is often called tomotherapy.

3.2.7
intensity-modulated radiation therapy
IMRT
treatment procedure requiring, in general, the coordinated control of photon or electron fluence, beam orientation relative to the patient, and beam size, either in a continuous or a discrete manner, and as pre-determined by a treatment plan

Note 1 to entry: The primary purpose of IMRT is to improve the conformity of the dose distribution to the planned target volume, while minimizing dose to surrounding healthy tissue.

[SOURCE: IEC 60976:2007]

3.2.8
isocentre
point defined by intersection of the gantry axis of rotation and the beam centerline of a linear accelerator

Note 1 to entry: For conventional linear accelerator, the isocentre is located at 1 m from the radiation source.

3.2.9
leakage radiation
radiation, except the useful beam, coming from the accelerator head and other beam-line components

Note 1 to entry: It is attenuated by shielding in the treatment head as specified by IEC 60601–2-1[1].

3.2.10
members of the public
persons who are not occupationally exposed by a source or practice under consideration

Note 1 to entry: When being irradiated as a result of medical care, patients are not considered as members of the public.

3.2.11
nominal energy
energy stated by the manufacturer to characterize the radiation beam

Note 1 to entry: “MV” is used when referring to accelerating voltages and the end point energy of a bremsstrahlung spectrum, while “MeV” is used when referring to monoenergetic photons or electrons

[SOURCE: IEC 60976:2007]

3.2.12
occupied area
room or other space, indoors or outdoors, that is likely to be occupied by any person, either regularly or periodically during the course of the person’s work, habitation or recreation, and in which an ionizing radiation field exists because of radiation sources in the vicinity

3.2.13
radiation protection officer
person technically competent in radiation protection matters relevant for a given type of practice who is designated by the registrant, licensee or employer to oversee the application of relevant requirements

[SOURCE: IAEA BSS][7]

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3.2.14
qualified expert
individual who, by virtue of certification by appropriate boards or societies, professional licence or academic qualifications and experience, is duly recognized as having expertise in a relevant field of specialization, e.g. medical physics, radiation protection, occupational health, fire safety, quality management or any relevant engineering or safety specialty

[SOURCE: IAEA BSS][7]

3.2.15
robotic arm accelerator
device composed by a linear accelerator mounted on a 6D robotic arm allowing a multi-directional delivery of the dose

Note 1 to entry: The robotic arm is referred to as 6 degrees of freedom because movements are made for 3 translational motions (X, Y and Z) and 3 rotational motions.

Note 2 to entry: The "geometric isocentre" is a reference point in the room that serves as the origin for several coordinates systems related to robot and imaging calibration.

3.2.16
scattered radiation
radiation that, during passage through matter, is changed in direction, and the change is usually accompanied by a decrease in energy and intensity

3.2.17
secondary radiation
radiation produced by scattering from the areas struck by the primary X-ray beam or leakage radiation through the treatment head of the linear accelerator

3.2.18
supervised area
defined area in which specific protection measures and safety provisions are or could be required for controlling normal exposures during normal working conditions, and preventing or limiting the extent of potential exposures

3.2.19
tertiary radiation
radiation produced by scattering from areas struck by leakage radiation, secondary radiation and primary electron beam bremsstrahlung

4 Shielding design goals and other design criteria

4.1 Shielding design goals

Shielding design goals (P) are levels of dose equivalent (H) used in the design calculations and evaluation of barriers constructed for the protection of workers or members of the public. Different shielding design goals shall be defined for supervised, controlled and public areas. They have to be in accordance with existing national regulation or if not available according to IAEA basic safety standards on radiation protection related to effective dose limits for workers and members of the public.

The P value (Sv) set by national authorities should be a fraction of dose limits for workers or for members of the public. They can be expressed as weekly values (mSv/week) since the workload (W) for a radiotherapy equipment has traditionally a weekly format. But according to national regulation, other time periods can be used.

Shielding design goals (P) are practical values that are evaluated at a reference point beyond a protective barrier for the workload W proposed by the radiotherapy department.

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