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

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

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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.

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO 16645 was prepared by Technical Committee ISO/TC 85, *Nuclear energy, nuclear technologies, and radiological protection*, Subcommittee SC 2, *Radiological protection*.

This second/third/... edition cancels and replaces the first/second/... edition (), [clause(s) / subclause(s) / table(s) / figure(s) / annex(es)] of which [has / have] been technically revised.

Introduction

Radiotherapy is a major method for treating cancer. The use of electron linear accelerators was spread during these last decades and became the technique of irradiation privileged in the industrialized countries. These accelerators deliver high energy electron and photon beams (until approximately 30 MeV) with increasingly high dose rates (up to around 25 Gy per minute at 1 m distance from the source). The irradiation techniques are diversifying and becoming increasingly complex (modulation of beam intensity, modulation of the dose rate, arctherapy, tomotherapy, robotic arm, dedicated devices for intra-operative radiotherapy). The design of the treatment room facilities also changes (geometry and materials).

IEC 60601-2-1 relates to the design and the construction of the accelerators in order to ensure the safety of their operation. In addition, several national (NCRP report No 151, 2005; IPEM report No 75, 2002) or international (IAEA Safety Report 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 (Ordinance of the DFI, Switzerland; DIN 6847-2, Germany). Moreover national regulations impose particular rules of protection against radiation (France), 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 being used as general framework. It intends 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 tomotherapy and robotic arm, dedicated machines for intra-operative radiotherapy;

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

— geometries of the treatment room: with standard maze, with two-legged maze, with short maze or without maze, with maze but without door;

— materials of protection: concrete (ordinary or heavy), 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;

— radiological goals;

— control (radiation protection) of the shielding after installation of the accelerator;

— ambient monitoring.

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

1 Scope

This standard is applicable to medical electron linear accelerators with energies ranging from 4 to 30 MeV, including particular installations such as robotic arm, helical intensity modulated radiotherapy (tomotherapy) 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 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 medical electron accelerator, biological shielding for conventional and special devices (including shielding materials and transmission values, calculations for various bunker configurations, duct impact on radiation protection) and the radiological monitoring (measurements).

2 Normative references

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

ISO 14152, *Neutron radiation protection shielding — Design principles and considerations for the choice of appropriate materials*

ISO 12749-2, *Nuclear energy, nuclear technologies, and radiological protection — Vocabulary — Part 2: Radiological protection*

NCRP Report No. 151, *Structural shielding design and evaluation for megavoltage X- and gamma-ray radiotherapy facilities (2005)*

NCRP Report No. 79, *Neutron contamination from medical electron accelerators (1984*)

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

IAEA Safety Standards, *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements* (2014)

Ordonnance du DFI sur la radioprotection s'appliquant aux accélérateurs délectrons utilisés à des fins médicales (2004)

DIN 6847-2, *Medical electron accelerators — Part 2: Rules for construction of structural radiation protection Accélérateurs médicaux d'électrons (2014)*

IPEM report No. 75, *The design of Radiotherapy Treatment Room Facilities (2002)*

IEC 60601-2-1, *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 60976 Ed. 2 B, *Medical electrical equipment — Medical electron accelerators — Functional performance characteristics*

IEC/TR 61859, *Guidelines for radiotherapy treatment rooms design*

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

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

Note 1 to entry: The unit of absorbed dose is joule per kilogram (J kg^{-1}). The special name for the unit of absorbed dose is gray (Gy).

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

3.1.2
absorbed dose rate
output rate
$\boldsymbol{DR_o}$
the absorbed dose rate (Gy h^{-1}) of radiation produced by a linear accelerator at a specific location: the absorbed dose rate to water from photons (or electrons for an electron beam) 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)

3.1.3
dose equivalent
H
the product of absorbed dose (D) and the radiation weighting factor at a specified point of interest in tissue

Note 1 to entry: The unit for H is joule per kilogram (J kg^{-1}), with the special name sievert (Sv).

3.1.4
instantaneous dose-equivalent rate
IDR
the “ambient/personal” dose-equivalent rate (Sv h^{-1}) as measured with the accelerator operating at the absorbed dose rate DR_o (Gy 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.

3.1.5
occupancy factor
T
the fraction of time the areas adjacent to the treatment room are occupied by an individual or group during machine operation

3.1.6
orientation or use factor
U
fraction of the radiation workload during which the useful beam radiation under consideration is directed at a particular barrier, is pointed toward the area in question

3.1.7
reflection coefficient
α
the fraction of radiation (e.g., fluence, energy, absorbed dose) expressed by the ratio of the amount backscattered to that incident

3.1.8
shielding design goal
P
practical values, for a single radiotherapy source or set of sources, that are 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.

3.1.9
(patient) scatter fraction
a **(*θ*)**
the ratio of absorbed dose of photons 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.

3.1.10
tenth-value distance
TVD
the distance that radiation traverses in order to reduce the radiation field quantity to one-tenth of its original value

3.1.11
tenth-value layer
TVL
the thickness of a specific material that reduces a specified radiation field quantity 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/m² (thickness x 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, $TVL_c = -t/\log(B)$.

3.1.12
time averaged dose-equivalent rate
TADR
the barrier attenuated dose-equivalent rate averaged over a specified time or 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 use factor (U).

3.1.13
transmission factor (or barrier transmission)
B
ratio of any radiation field quantity at a location behind the barrier on which radiation is incident to the field quantity 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.

3.1.14
workload
W
the average absorbed dose of radiation produced by a linear accelerator over a specified time (the time period should be consistent between shielding design goals and workload) at a specific location: the absorbed dose to water from photons (or electrons for an electron beam) 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) over the defined period averaged over a year if necessary. The workload is specified in Gray (Gy)

3.2 Definitions

3.2.1
barrier (or protective barrier)
a protective wall of radiation attenuation material(s) used to reduce the equivalent dose on the side beyond the radiation source

3.2.2
primary barrier
a 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 the required degree

3.2.3
secondary barrier
a wall, ceiling, floor or other structure designed to attenuate the leakage and scattered radiations to the required degree

3.2.4
controlled area
a limited-access area in which the occupational exposure of personnel to radiation is under the supervision of an individual in charge of radiation protection

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

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

[SOURCE: IEC 60976]

3.2.6
helical intensity modulated radiotherapy
a helical intensity modulated radiotherapy system uses a linear accelerator that delivers treatment with a slit beam that is adjustable by a MLC and rotates continuously around patient with geometry resembling diagnostic CT. Couch motion while radiation head is rotating is an integral part of the treatment

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]

3.2.8
IMRT ratio
C_I
intensity modulated radiation therapy (IMRT) procedures often use small beams produced by multileaf collimators or cones with narrow openings. Due to the small field sizes of the large number of beamlets used, the total accelerator monitor units (MU) required are much higher than would have been required for conventional radiotherapy for the same absorbed dose to the patient. The 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}) is called the IMRT ratio C_I.

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

MU_{IMRT} = the average total monitor unit required to deliver a unit prescribed absorbed dose per fraction (D_{pre}) for the "i" cases.

$$MU_{IMRT} = \sum_I \frac{MU_i}{(D_{pre})_i}$$

MU_{conv} = the monitor unit required to deliver the same unit absorbed dose to a phantom at the reference depth at 100 cm source-to-isocentre distance, using field size 10 cm × 10 cm.

3.2.9
isocentre
the point defined by intersection of the gantry axis of rotation and the beam centerline of a medical accelerator

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

3.2.10
leakage radiation
all 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 protective source housing as specified by IEC-60601-2-1-AM1.

3.2.11
members of the public
all 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.

3.2.12
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 endpoint energy of a bremsstrahlung spectrum, while “MeV” is used when referring to monoenergetic photons or electrons

[SOURCE: IEC 60976]

3.2.13
occupied area
any 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

3.2.14
radiation protection officer
a 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]

3.2.15
qualified expert
an 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]

3.2.16
robotic radiosurgery system
device composed by a linear particle accelerator with 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 to which robot and imaging calibration is defined.

3.2.17
scattered radiation
radiation that, during passage through matter, is changed in direction, and the change is usually accompanied by a decrease in energy

3.2.18
secondary radiation
all radiation produced by scattering from the impact areas of the primary X-ray beam or leakage through the protective source housing of the treatment unit

3.2.19
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

3.2.20
tertiary radiation
all radiation produced by scattering from the impact areas of 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 and associated to definition and provision for different regulated areas.

The P value (Sv) chosen or recommended by national authorities should be a fraction of dose limits for workers or for members of the public. They are expressed most often 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 could be used.

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

4.2 Shielding design assumptions

A radiotherapy facility that uses the P values given above would produce effective dose values lower than the regulation statements for supervised, controlled and public areas. This is the result of the conservatively safe nature of the shielding design methodology recommended.

Some design assumption should be made:

— the minimum distance to the occupied area from a shielded wall (or barrier) is assumed to be 0,3 m (considered as representative for whole body exposure);

— attenuation of the primary beam by the patient should be neglected;

— calculations of recommended barrier thickness for primary barrier assume perpendicular incidence of the radiation except for robotic arm accelerator for which oblique incidence should be considered;

— leakage radiation from radiotherapy equipment is assumed to be at the maximum value recommended by IEC (2002) for the radiotherapy device, although in practice the leakage radiation is often less than this value;

— the primary barrier width (w) shall be sufficient to extend at least 0,3 m beyond the edge of a geometrical field of maximum size rotated 45º. For a square f cm x f cm field, the minimum value of w is given by (m):

$$w = \left(f / 100\,\text{cm}\right)\sqrt{2}\,d_{\text{N}} + 0{,}6\,\text{m} \qquad (1)$$

where d_{N} is the distance from the target to the far side of the most narrow part of the barrier, in metre.

The distance from the target to the narrow point of the primary barrier should be measured at the top of the barrier, not at the same height as isocentre.

Figure 1 illustrates the typical locations for the narrowest point of the barrier.