SLOVENSKI STANDARD
SIST EN ISO 16645:2019

01-september-2019

Radiološka zaščita - Medicinski elektronski pospeševalniki - Zahteve in priporočila za snovanje in ocenjevanje zaščitnih zaslonov (ISO 16645:2016)

Radiological protection - Medical electron accelerators - Requirements and recommendations for shielding design and evaluation (ISO 16645:2016)

Strahlenschutz - Medizinische Elektronenbeschleuniger-Anlagen - Anforderungen und Empfehlungen an die Ausführung der Abschirmung und deren Bewertung (ISO 16645:2016)

Radioprotection - Accélérateurs médicaux d'électrons - Exigences et recommandations pour la conception et l'évaluation du blindage (ISO 16645:2016)

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13.280	Varstvo pred sevanjem	Radiation protection

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 16645

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ICS 13.280

English Version

Radiological protection - Medical electron accelerators - Requirements and recommendations for shielding design and evaluation (ISO 16645:2016)

Radioprotection - Accélérateurs médicaux d'électrons - Exigences et recommandations pour la conception et l'évaluation du blindage (ISO 16645:2016)

Strahlenschutz - Medizinische Elektronenbeschleuniger-Anlagen - Anforderungen und Empfehlungen an die Ausführung der Abschirmung und deren Bewertung (ISO 16645:2016)

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European foreword

The text of ISO 16645:2016 has been prepared by Technical Committee ISO/TC 85 "Nuclear energy, nuclear technologies, and radiological protection" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 16645:2019 by Technical Committee CEN/TC 430 "Nuclear energy, nuclear technologies, and radiological protection" the secretariat of which is held by AFNOR.

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INTERNATIONAL STANDARD

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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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Foreword

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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.

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.

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

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

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

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*).