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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

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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.

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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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

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