BS EN ISO 16645:2019

BSI Standards Publication

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

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Full document details: BS EN ISO 16645:2019

National foreword

This British Standard is the UK implementation of EN ISO 16645:2019. It is identical to ISO 16645:2016.

The UK participation in its preparation was entrusted to Technical Committee NCE/2, Radiation protection and measurement.

A list of organizations represented on this committee can be obtained on request to its secretary.

BSI, as a member of CEN, is obliged to publish EN ISO 16645:2019 as a British Standard. However, attention is drawn to the fact that during the development of this European Standard, the UK committee voted against its approval.

The UK committee was of the opinion that ISO 16645:2016 should not have been approved as a European standard because the defined requirements are only at the level of guidelines (very similar to, for example, NCRP 151). Instead of an analytical and unambiguous step-by-step approach to obtaining clearly defined wall and labyrinth dimensions for shields, ISO 16645:2016 merely provides an overview of the calculation methods and references to other reports and guidelines.

The UK committee considers that future versions of ISO 16645 should be developed in accordance with EU Directive 2013/59/Euratom.

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Published by BSI Standards Limited 2020

ISBN 978 0 539 05736 2

ICS 13.280

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 January 2020.

Amendments/corrigenda issued since publication

Date	Text affected

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 16645

June 2019

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)

This European Standard was approved by CEN on 8 March 2019.

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European foreword

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Endorsement notice

The text of ISO 16645:2016 has been approved by CEN as EN ISO 16645:2019 without any modification.

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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.

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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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4.2 Shielding design assumptions

A radiotherapy facility that uses the assumption proposed 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 60601-2-1[1] 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 45°. For a square f m x f m field, the minimum value of w is given by:

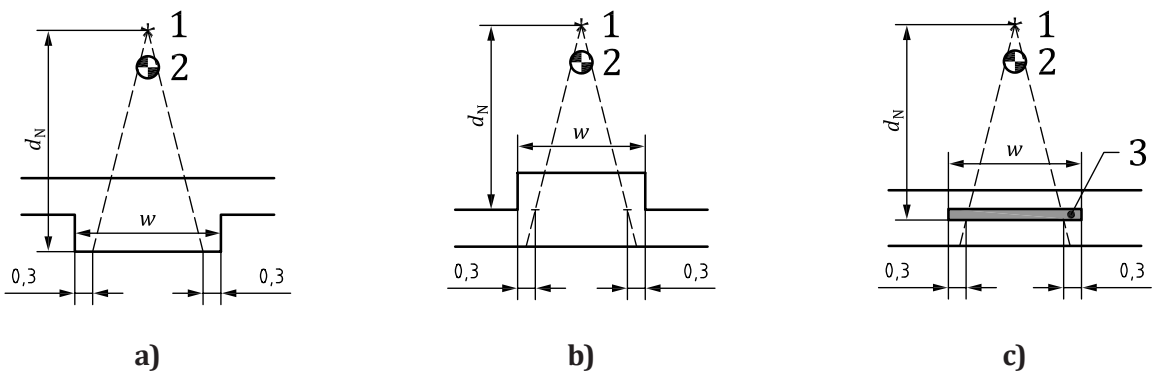
$$w = \left(f \,/\, 1\ \text{m}\right)\sqrt{2}d_{\text{N}} + 0,6\ \text{m} \tag{1}$$

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

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.

Dimensions in metres



Key

1 target

2 isocentre

3 metal

Figure 1 — Primary barrier width

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5 Role of the manufacturers, of the radiation protection officer or qualified expert and interactions between stakeholders

5.1 General

Ensuring adequate protection for both the facility workers and the general public from linear accelerator radiation is a cooperative effort. Clause 5 provides general guidance on the roles, responsibilities, and interaction among the various stakeholders involved in this process.

5.2 Linear accelerator manufacturer

The manufacturer of the linear accelerator shall provide detailed technical documents containing at least the following information:

a) dimension sheets containing:

— the dimensions of the linear accelerator;

— the minimum treatment room dimensions (length, width and height) for the accelerator itself but also for allowing full extension of the treatment couch in any direction. For isocentric equipment, the isocentre-to-wall clearance, minimum clearance from the treatment room floor to the ceiling shall be defined. For non isocentric equipment, the possible primary beam orientation shall be described; the isocentre height and the distance from the isocentre to the rear wall need to be specified;

— minimum dimensions, location and requirements for control room. Specification, and location, inside or outside the treatment room, of technical rooms which may contain parts of the associated equipment necessary for accelerator;

— information on ducting requirements for electrical cables, waterpipes, heating and air-conditioning ventilation ducts etc. necessary to operate the equipment in the treatment room.

b) Functional performance characteristics

The protective shielding design shall take into account the different types of radiation emitted by the accelerator according to the data provided by the manufacturer which shall contain at least the following:

— the reference distance, in m, defined as for:

— X-radiation: specified distance measured along the axis of the beam from the source of X-radiation (front surface of the X-radiation target) to the isocentre or to a specified plane for non-isocentric equipment;

— electron radiation: specified distance measured along the axis of the beam from the virtual source of electrons to the isocentre or to a specified plane for non-isocentric equipment;

— the available nominal energies of the beam and the available associated absorbed dose rates at reference distance under conditions of maximum build-up in a phantom (maximum dose) for reference field, (10x10) cm^2 or specified reference field size, and the maximum radiation fields for both X-radiation and electron radiation.

In addition to the nominal energy of the beam, the way to achieve a uniform dose for clinical X-radiation beams shall be mentioned: flattening filter (FF) or flattening filter free (FFF). The FF scatter photons are one of the major sources of linear accelerator head scatter. The FFF operating mode results in an increase in dose rate, softening of X-ray spectra, reduction in head scattered radiation, therefore the rate of photo-neutron generation for both the FF and FFF modes are substantially equivalent.

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For the purposes of this International Standard, it is assumed that the dose rate at the reference distance may be obtained for larger distances in accordance with the inverse square law.

— the dimensioned shape of the maximum geometric radiation fields at the reference distance for X-radiation and electron radiation for every radiation type available;

— the highest absorbed dose rate to water of the neutron radiation contamination in X-ray and electron beams to the extent that they are required for radiation protection measures against neutrons;

— the highest absorbed dose rate to water of the X-ray radiation contamination in the electron beam;

— the distribution of the maximum leakage radiation (x-radiation and neutron); the spatial distribution of the absorbed dose rate of the radiation emerging from the radiation source assembly outside the maximum radiation beam cross-section for the operating state and the operating parameters at which the highest dose rates outside the radiation beam occur;

This distribution may, for example, be specified in the form of isodose sheets or by an analytical expression from which the highest dose rate can be determined for every surrounding area.

— availability of a beamstopper and description of geometric characteristics (largest primary beam and angle of scattered radiation intercepted, distance from reference point…), nature and thickness of the shielding material and attenuation factor for primary beam.

5.3 Shielding material vendor

The shielding vendor is responsible for providing accurate drawings and information describing their products for use in the shielding evaluation.

The usual materials for radiation shielding are normal or high density concrete, steel, or lead for which the attenuation properties (*TVL*) are well known and related to density.

Most published data assume a density for concrete of 2350 $kg.m^{-3}$ but variation according to the used aggregate have been shown. Any concrete with a density higher than 3000 $kg.m^{-3}$ can be considered as high density concrete. The increased density is achieved by adding various higher density aggregates to increase photon attenuation. Common among these are iron ores and minerals (haematite, limonite, magnetite …).

The shielding material supplier should:

— specify the overall density and composition of the shielding material. If Monte Carlo calculations are to be performed, further information about the composition nature by weight for the different component of the mix (aggregate, cement, additional material, water in %) and atomic composition for different elements (Ca, Fe, H, O, Si… in %) relevant to evaluate the shielding properties shall be provided;

— ensure, in collaboration with the structural engineer, quality control of produced concrete in order to respect the required density otherwise adjustment is needed to determine the required barrier thickness to achieve the shielding goal.

Instead of concrete, pre-moulded high density interlocking blocks of different density are commercially available or specific patented building methods such as dry mineral filling between thin prefabricated concrete walls are also used.

If the above data needed are not available, the supplier shall provide radiation attenuation characteristics such as *TVL* for X-rays or neutrons in the energy range of the accelerator and all relevant data available. For therapy installations operating above 8 MV, activation of material within the shielding shall be considered and available data provided.

Linear accelerators operating with nominal energies of the beam above 8 MV may require door shielding for neutrons and photons; the door supplier shall provide any relevant data to assess attenuation property: thicknesses and composition of layers.

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5.4 Architectural firm/general contractor

To ensure that the facility is built according to the intent of the licensee, the contract between the architectural firm and general contractor should specify the following responsibilities.

The architectural firm is responsible for researching the existing structure (if any). This includes providing information on the existing and planned usage of the space around the linear accelerator. The architect shall also prepare drawings that accurately show the installed linear accelerator location, along with the location and nature of the shielding surrounding the linear accelerator. The architectural firm is also responsible to review the shielding evaluation report to ensure the shielding described in that report is incorporated into the design. In some cases, some or the entire role of the architect may be performed by a general contractor or a shielding vendor.

The general contractor has responsibility to ensure the facility is constructed with shielding that is consistent with the shielding evaluation report. The general contractor shall also ensure that the radiation protection officer or qualified expert has accurate drawings and other relevant information needed to have an accurate understanding of the structure. The general contractor has the responsibility to coordinate with the radiation protection officer or qualified expert any situation arising during construction that may compromise the shielding. In particular, shielding for locations where structural constraints exist shall be coordinated between stakeholders.

5.5 Radiation protection officer or qualified expert

The radiation protection officer or qualified expert for the electron accelerator installation shall provide, in closed collaboration with the other stakeholders (medical physicist, radiation oncologists…) detailed documents containing the specifications essential for construction and the intended operation. The shielding plan should use conservative shielding assumptions to reach the facility's shielding goal although these shielding assumptions also should be realistic.

The documents shall contain information according to national regulation. They shall at least contain the following specifications:

— drawings of the buildings, rooms and external facilities belonging to the radiation therapy department and of any neighbouring buildings, rooms and traffic areas from which the dimensions and distances required for radiation protection computations can be derived;

— data on existing building structure (material, thickness);

— the division of the rooms within the radiation therapy department and their use;

— workplaces and occupied areas within the radiation therapy department;

— specifications regarding the intended demarcation of supervised, controlled or prohibited areas;

— type and use of areas outside the radiation therapy department and related occupancy factors T for uncontrolled areas on basis of conservative assumption;

— details of the intended operating modes [combination of radiation type, radiation energy including FF and FFF mode, beam direction and as consequence determination of orientation or use factor U, possible positions of the radiation head, intensity modulated radiation therapy (IMRT) and the frequency of use];

— the maximum number of each type of intended treatment and the related mean dose at the reference point during the reference period defined for achieving the shielding goal. (workload);

— specific requirements regarding type of treatments planned to be realized and their impact on dimensions of the treatment room. For example, a total body irradiation (TBI) procedure requires a larger treatment distance to one wall. For intra-operative procedures (IORT) that require extensive support staff and equipment, the room may need to be larger.

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The radiation protection officer or qualified expert should provide a shielding evaluation report that demonstrates the barriers in the structure (material type, thickness, and location) provide adequate protection for the staff and general public. A clear statement of all assumptions used to generate the shielding design shall be included in the report. He shall ensure that a radiation survey after machine installation is performed and that a report is provided demonstrating the dose rate outside the structure housing the linear accelerator is suitable for occupancy by the staff and, for locations with uncontrolled access, the general public.

5.6 The licensee

As required by local or national regulations, the radiation survey report shall be submitted by a representative of the licensee to the appropriate regulatory authority for approval prior to the start of clinical commissioning.

6 Radiation fields around a linear electron accelerator

6.1 General

There are various radiation components that contribute to the ambient dose equivalent rate at a given point outside the treatment room:

- X-ray radiation
  - primary X-ray beam;
  - primary electron beam bremsstrahlung;
  - leakage X-ray radiation;
  - scattered X-ray radiation;
  - tertiary X-ray radiation;
- neutron radiation (primary X-ray > 8 MV)
  - direct neutron radiation;
  - scattered and thermal neutron radiation;
  - primary barrier neutron radiation;
- γ radiation (primary X-ray > 8 MV)
  - maze γ radiation;
  - door γ radiation;
  - primary barrier γ radiation.

6.2 X-ray radiation

6.2.1 Primary X-ray beam

The primary X-ray beam is the collimated X-ray radiation produced in the head of the accelerator and used to treat the patients. It is a bremsstrahlung radiation generated by the slowing down of the accelerated electrons in a thick target of high atomic number (tungsten, gold). The selection of the transmission curves to be used for shielding calculations for the primary barriers shall account for the polyenergetic nature of the spectrum and the broad beam geometry[8][9]. The term “nominal energy” used by the manufacturers doesn’t refer necessarily to the accelerating voltage, it refers to BJR 11 or BJR 17 definitions[10][11].

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Care should be taken with the definition of the nominal energy of the beam, because it has changed with time, corresponding to different energy spectra (see Table 1)[12]. When considering published data for primary X-ray transmission calculations, check the energy definition related to the data and the energy definition of the accelerator to be installed. By default, a conservative approach is to use data related to BJR 11 energy definition.

Table 1 — Comparison of BJR 11 and BJR 17 MV definitions

BJR 11 (MV)	4	6	10	15	18	20	24
BJR 17 (MV)	4	6	10	16	23	25	30

Generally linear electron accelerators produce X-ray beams with a single nominal energy (typically 6 MV) or with multiple nominal energies (between 6 MV and 18 MV).

6.2.2 Primary electron beam bremsstrahlung

Linear electron accelerators also produce electron beams used for the treatment of patients, with generally 5 or 6 possible energies (from 4 MeV to about 20 MeV). For conventional accelerators, broad electron beams are generated by scattering foils.

The primary electron beam is contaminated with bremsstrahlung X-rays, with two different components:

— X-rays present in the electron beam;

— X-rays generated by the electron beam outside the linac (i.e. in the air, in the patient and in the primary shielding barriers).

Since the shielding thickness against the bremsstrahlung generated by the electron beam is in any case greater than the electron range, it suffices to calculate the shielding requirements for the bremsstrahlung (no separate shielding is required for the primary electrons).

6.2.3 Secondary X-ray radiation

The secondary X-ray component is made of two components: leakage radiation and scattered radiation.

Leakage X-ray component is bremsstrahlung radiation created in the head of the linear accelerator and transmitted through the head shielding, outside the region defined by the beam limiting device.

The energy spectrum of the leakage radiation is softened as compared to the primary X-ray beam, leading to different transmission values[8]. This should be taken into account for shielding calculations, but a conservative approach is to consider the leakage component with the same transmission values as the primary beam.

IEC 60601-2-1[1] specifies design requirements for linear accelerators in order to limit the exposure due to leakage X-rays, and gives the maximum allowed contribution to the dose equivalent around the linear accelerator.

Scattered radiation that originates from the impact areas of the primary X-ray beam:

— secondary X-rays scattered from the patient;

— secondary X-rays scattered from a primary barrier.

The energy spectrum of the scattered photons is degraded as compared to the primary photon beam, with the mean energy decreasing as the scattering angle increases. This leads to different transmission values for different scattering angles.

The scattered radiation intensity depends on the energy of the primary beam, on the scattering angle and, for photons scattered by a barrier, on the incident angle and on the barrier material (wall reflection coefficient).

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— scattered by patient: fraction, energy and *TVL*: [IAEA SRS 47][2][13];

— scattered by barrier: wall reflection coefficients: [IAEA SRS 47][2][14].

These effects should be taken into account for shielding calculations. A conservative approach is to consider, for small scattering angles, that the scattered component has the same transmission values as the primary beam.

6.2.4 Tertiary X-ray radiation

Tertiary X-ray radiation originates from the impact areas of secondary X-ray radiation as well as from the impact area of the primary electron beam bremsstrahlung. In case of facilities with a maze, the tertiary X-ray component reaches the entrance door and should be calculated for shielding evaluation at the entrance.

The energy of the tertiary radiation is degraded as compared to the primary photon beam and this point has to be taken into account for shielding calculations.

6.3 Neutron radiation

6.3.1 General

X-rays above a given energy incident on a nucleus (atomic number Z, mass number A) produce photonuclear reactions according to:

$$X + Z^{A} \rightarrow Z^{(A-1)} + n \text{ or } Z^{A}\,(X, n)\,Z^{(A-1)}$$

For this to take place, the photon energy shall be higher than the binding energy of the least bound nucleon. The value of this threshold energy is dependent on the atomic number Z (see Table 2)[15][16].

In practice, the photoneutron production becomes significant regarding radiation protection issues when the nominal energy of the primary X-ray beam is higher than 8 MV. Neutrons are produced in the head of the linac and also in the primary barrier.

In the energy range of linear accelerators, the dominant mechanism of photoneutron production is giant dipole resonance. As a consequence:

— the emission of neutrons can be considered as isotropic[17];

— the energy spectrum is described by a Maxwellian distribution, with an average energy of about 1-2 MeV for heavy nuclei[14] and the average neutron energy can be considered as independent from the nominal energy of the X-ray beam[18];

— the photoneutron yield increases with increasing nominal energy of the beam[2][19][20].

For a given nominal energy, the photoneutron yield depends on the linac model because the X-ray spectrum can vary strongly from one model to another[9][21][22].For a given model, the neutron fluence depends on the secondary and tertiary collimation settings[23][24].

Neutron production in electron operating mode is much lower than in photon mode principally because direct production of neutrons by electron-nuclear reactions is at least two orders of magnitude lower than photonuclear production.

The above characteristics of neutron production shall be considered for radiation protection purposes around a linear accelerator.

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Table 2 — Threshold energies and photonuclear reaction cross sections for typical nuclides[15][16]

Element	Mass number A	Abundance %	E_{th} MeV	σ_{max} mb
C	12	98,9	18,7	< 10
N	14	99,6	10,6	≅ 15
O	16	99,8	15,7	≅ 10
Cr	52	83,8	12,0	≅ 70
	53	9,5	7,9	≅ 70
Mn	55	100	10,2	≅ 70
Fe	56	91,7	11,2	≅ 60
Ni	58	68,1	12,2	≅ 25
	60	26,2	11,4	≅ 70
Cu	63	69,2	10,8	≅ 80
	65	30,8	9,9	≅ 90
W	182	26,3	8,1	≅ 400
	183	14,3	6,2	≅ 450
	184	30,7	7,4	≅ 400
	186	28,6	7,2	≅ 400
Au	197	100	8,1	≅ 550
Pb	206	24,1	8,1	≅ 600
	207	22,1	6,7	≅ 600
	208	52,4	7,4	≅ 650

6.3.2 Direct neutron radiation

Direct neutron radiation is the neutron component produced in the head of the linac. Neutron production in the head is mainly due to (γ,n) reactions in tungsten materials (flattening filter, primary collimator, jaws, MLC…).

Due to the intrinsic shielding of the head (W or Pb), characteristics of the neutron field outside the region defined by the non-adjustable beam limiting device (leakage neutrons) are different from those of the in-field neutrons: the energy spectrum is degraded by inelastic scattering and (n, 2n) reactions and the fluence is reduced by a factor of about 2[15][23][25]. As the maximum solid angle defined by the primary collimator and the maximum adjustable field size is only 1 % of 4π, it is possible to take as a good approximation, the hypothesis that all the direct neutrons are leakage neutrons.

Although there are different locations of neutron production within the linear accelerator head, it is justified to approximate it by using the point of divergence of the primary X-ray beam as sole origin of neutrons from the linac head. Fluence of the direct neutron component as a function of the distance from the source can be described by an inverse square law.

6.3.3 Scattered and thermal neutron radiation

Direct neutrons are scattered from the walls, the floor and the ceiling of the treatment room and a part of them are thermalized. As a consequence, the neutron energy spectrum around linear accelerator is softened as compared to the direct neutron spectrum: it is the combination of direct, scattered and thermalized neutrons[15].

Fluence of the indirect neutron component cannot be described by an inverse square law as a function of the distance from the source[15][26].

In a facility with a maze, a part of the neutrons produced in the treatment room reach the entrance door and this neutron component shall be calculated for shielding evaluation at the entrance.

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6.3.4 Primary barrier neutron radiation

When the nominal energy of the photon beam is higher than 8 MV, neutrons are also produced in the barriers hit by the primary X-ray beam. Depending on the composition and the thickness of the barriers, those neutrons can significantly contribute or not to the exposure outside the treatment vault.

For concrete barriers (normal or high density concretes), neutron production within the barrier is strongly compensated by self-attenuation, leading to insignificant contribution outside the vault[15].

When a barrier contains a high proportion of metallic constituents, neutron production in the barrier can be significant and not compensated by self-attenuation. In this case, neutron radiation generated in the barrier should be taken in consideration for shielding calculations. This is especially the case when walls or ceilings are reinforced by one or more lead or steel layers[27][28].

6.4 γ radiation

6.4.1 General

When the nominal energy of the primary X-ray beam is higher than 8 MV, secondary γ radiation is produced together with neutrons. The γ component results from the two following processes:

— slow neutron capture (see Table 3):

$$n_{slow} + Z^{A} \rightarrow Z^{(A+1)} + \gamma \text{ or } Z^{A}\ (n_{slow}, \gamma)\ Z^{(A+1)}$$

— photonuclear reaction, with de-excitation of the new nucleus[2]:

$$X + Z^{A} \rightarrow Z^{*(A-1)} + n \text{ and } Z^{*(A-1)} \rightarrow Z^{(A-1)} + \gamma$$

6.4.2 Maze γ radiation

Slow neutron capture occurs principally in shielding materials situated in the maze. Normal or high density concretes contain elements that have non negligible neutron capture cross sections: Si, Ca, S, Fe, Ba. For ordinary concrete, the average energy of emitted γ rays is 3,6 MeV and maximum energy is about 10 MeV[15][29].

The γ component reaching the entrance door shall be calculated for shielding evaluation at the entrance[2].

6.4.3 Door γ radiation

Slow neutron capture also occurs in the door, especially when it contains borated polyethylene (BPE). Usually, doors have a multilayer structure made of successive layers of hydrogen-rich material (paraffin, polyethylene or borated polyethylene) and metal (steel (Fe, Ni, Cr) or lead), or made of three layers of metal, hydrogen-rich material, and metal.

The γ component generated in the door shall be taken into account in the construction of the door (composition, thickness and order of the different layers). The energy of the neutron capture γ radiation produced in BPE is 478 keV[2].

6.4.4 Primary barrier γ radiation

In primary barriers, neutron capture occurs in the concrete. In addition, if the barrier is reinforced with metal layer, photonuclear reactions with γ emission take place in the metal (steel, lead).

The γ component generated in the primary barrier should be taken into account for shielding calculations. For concrete barriers, some neutron transmission values include it implicitly[2][30]. For

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barriers reinforced with metal slabs, the additional dose equivalent due to metal capture γ rays should be evaluated[2][31].

6.4.5 Air γ radiation

Activation products are generated in the air by photonuclear reactions. Therefore, facility should ensure that air ventilation is adequate to remove air activation products and ozone, to meet local air quality standard.

7 Shielding materials and transmission values

Shielding materials shall be chosen not only for their radiological properties but also considering their mechanical and chemical properties, fire resistance, long time stability and cost. Activation characteristics of the materials shall be known for the type and energy of radiations to be attenuated by the shielding.

Quality control of the shielding materials shall be performed during the construction phase, before using the accelerator, in particular, control of the homogeneity (composition and density). Periodic evaluation of the shielding efficiency should be done throughout the life of the installation.

For any barrier, shielding materials shall be chosen in function of the nature of radiation components to be attenuated:

— photon components (X and γ): materials containing mainly high or medium Z elements are more effective, like: lead, iron, high density concretes (density > 3) and ordinary concretes (density around 2,3);

— neutron components: materials with a significant proportion of light elements are more effective, especially hydrogenated materials, like: paraffin, polyethylene and ordinary concretes; borated materials allow thermal neutron capture and are the most efficient materials (but expensive), like: borated polyethylene (BPE), pentahydrated Borax and colemanite-based concrete; for an extensive discussion about neutron radiation protection shielding, see ISO 14152[32], considering that the in-field neutron spectrum produced by linear electron accelerators is close to a ^{252}Cf fission spectrum[15].

For multilayer shielding with one or more metallic layers (especially reinforced primary barrier and door), neutron production has to be taken into account for nominal energies of the beam greater than 8 MV: a sufficient thickness of hydrogenated material has to be placed beyond the metallic layer.

For multilayer shielding with neutron-absorbing layer (for instance: door), γ production by neutron capture has to be taken into account: a sufficient thickness of high Z material has to be placed beyond the neutron-absorbing layer.

For any shielding material and any barrier (primary, secondary, door), information regarding photon and/or neutron attenuation properties are to be known: the data used for *TVL* values shall have been measured or determined by Monte Carlo simulations, and the materials and methods used for the *TVL* evaluation should be known. Tables of *TVL* values for the most common shielding materials and for photon components (primary, scattered and leakage X radiations) are given in Annex A. If *TVL* data are provided by the national regulatory authority in a given nation, then these shall be used in that nation. In other cases, for conservative calculations, the use of the largest *TVL* value for a given energy and a given material is recommended. Attention should be paid to the fact that for a given type of concrete (for instance ordinary concrete), manufacturing can differ significantly from one concrete to another, in particular regarding density, elemental composition (a small difference in hydrogen content can have a significant impact on neutron transmission) and homogeneity (distribution of the aggregates in the concrete).

Regarding secondary X-ray radiations, the energy of X-ray scattered by the patient decreases as the scattering angle increases and the leakage X-ray component is softened as compared to the primary X-ray radiation, so the *TVL* values of the materials used for the secondary barriers should take these

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characteristics into account (see Tables A.5 to A.8) [IAEA SRS 47]. A conservative alternative is to consider primary *TVL* values for secondary patient scattered and leakage X-ray radiations.

In presence of a maze, energy spectra of scattered X-ray and of neutron capture γ photons are softened, together with energy spectrum of scattered neutrons. The energy spectrum softening of radiations reaching the door shall be taken into account for the choice of *TVL* values of the shielding materials used at the treatment room entrance (materials used for the door and for the surrounding walls) (see Table A.9) [IAEA SRS 47].

For neutron components, *TVL* shall refer to dose equivalent attenuation and should take into account the gamma component induced in the shielding material by neutron capture. For ordinary concrete and polyethylene, neutron *TVL* for treatment room shielding and for door shielding at the end of a maze can be estimated by linear functions of the direct neutron average energy and of neutron average energy at the door, respectively[15] (see Figure A.7). For concrete, a conservative approach is to consider a *TVL* value of 25 cm for treatment room shielding [IAEA SRS 47][2][4][5][15].

When different *TVL* values are provided for a given radiation quality and a given shielding material (TLV_1, TVL_2, TVL_3, TVL_e, TVL_c), for sake of simplicity, a unique value can be used, *TVL*, which should be the more relevant one depending on the thickness t of the shielding barrier: TVL_c corresponding to thickness *t* if it is provided, and if not:

— if $t \approx TVL_1$, then $TVL = TLV_1$;

— if $t \approx TVL_1 + TVL_2$, then $TVL = (TLV_1+TVL_2)/2$;

— if $t >> TVL_1+TVL_2$:

— if $TVL_{(i+1)} > TVL_i$, then $TVL = \max(TVL_i)$;

— if $TVL_{(i+1)} < TVL_i$, then $TVL = \mathrm{mean}(TVL_i)$.

Photon thickness *TVL* values [cm] for any ordinary concrete or earth with their density ρ shall be calculated from TVL_{ref} data obtained for a reference ordinary concrete of density ρ_{ref} by applying an inverse density law:

$$\mathrm{TVL} = TVL_{ref} \times \frac{\rho_{ref}}{\rho}$$

Photon *TVL* values for a given high density concrete should be specific data obtained for that particular concrete and if such data are not provided, the thickness *TVL* values [cm] shall be calculated from data obtained for a reference ordinary concrete of density ρ_r by applying the above inverse density law. This is a conservative rule as usually, true *TVL* values of high density concretes are lower than the one obtained by the inverse density law because of pair production in high Z components at high energies.

Neutron thickness *TVL* values [cm] are considered to be equivalent for any ordinary concrete of density ρ_i. Neutron *TVL* values for a given high density concrete should be specific data obtained for that particular concrete and if such data are not provided, neutron thickness *TVL* values [cm] are considered to be similar to ordinary concrete values because the hydrogen content does not vary significantly between different concretes[30].

For primary barriers, if the accelerator produces narrow beams (radius or half-side less than to the range of secondary electrons) and is mainly used with narrow beams, transmission data for broad beams can be used. This is a conservative rule as narrow beams are less penetrating than broad beams whose scattered component enhances the dose behind a barrier (build-up effect).

For accelerators with FFF operating mode at a given end point energy, energy spectrum of the primary X-ray beam is degraded as compared to the energy spectrum of the FF operating mode. If the accelerator is exclusively used with the FFF modality, specific *TVL* values can be considered for primary and patient scattered X-ray radiations[33]. If both FF and FFF modalities are regularly used, a conservative approach should be followed, which is taking into account *TVL* values of the FF operating mode.

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8 General formalism for shielding calculation

The recommended radiation protection quantity for limitation of exposure of people is effective dose E[6]. Operational quantities such as dose equivalent H^* or dose equivalent H_p are defined by ICRU in order to estimate the effective dose[6]. As a convention, for the purpose of the document, dose equivalent represents one of these quantities chosen according to the goal of the shielding evaluation.

If a time period is not mentioned, the dose equivalent during the reference period (year, week, hour...) defined for the shielding design goal P (Sv) (see 4.1) is assumed.

For any radiation component (r) (see 6.1), the calculated shielded dose equivalent ($H_{tr,r}$), that is the transmitted dose equivalent, is given by the following equation (Sv):

$$H_{tr,r} = H_{u,r} \; B_r \tag{2}$$

where

$H_{u,r}$ is the unshielded dose equivalent related to radiation r (dose equivalent without the barrier) (Sv);

B_r is the radiation transmission factor for radiation r and the barrier.

The thickness of the barrier shall be such that $H_{tr,r} = P/T$:

$$B_r = P / \left(T \times H_{u,r}\right) \tag{3}$$

where T is the occupancy factor, to correct for the occupancy of the area.

T values depend on the countries, they should be defined by users or by national regulation. Suggested T values are given in Table 3.

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