ISO/FDIS 24427:2025(en)

ISO/TC 85/SC 2/WG 23

Secretariat: AFNOR

Date: 2025-05-20xx

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

Radioprotection — Accélérateurs médicaux de protons — Exigences et recommandations pour la conception et l'évaluation du blindage

FDIS stage

Style Definition ...
Formatted: Font: Bold, French (France)
Formatted: zzCover large
Formatted: Left: 1.5 cm, Right: 1.5 cm, Section start: New page, Header distance from edge: 1.27 cm, Footer distance from edge: 1.27 cm
Formatted: French (France)
Formatted ...
Formatted: Cover Title_A1
Formatted: Left

ISO copyright office
CP 401 • Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. Phone: + 41 22 749 01 11

Fax + 41 22 749 09 47

E-mail: copyright@iso.org
Website: www.iso.org

Published in Switzerland www.iso.org

Formatted: HeaderCentered
Formatted: Font: Bold
Commented [eXtyles1]: The reference "ISO 2025" is to a withdrawn standard
Formatted: Adjust space between Latin and Asian text, Adjust space between Asian text and numbers
Formatted: Default Paragraph Font
Formatted: Default Paragraph Font
Formatted: French (France)
Formatted: zzCopyright address, Adjust space between Latin and Asian text, Adjust space between Asian text and numbers
Formatted: French (France)
Formatted: Font: 11 pt
Formatted: FooterPageRomanNumber, Space Before: 0 pt, Line spacing: single, Tab stops: Not at 17.2 cm

Formatted: Font: Bold

Formatted: HeaderCentered

Contents

Formatted: Font: 10 pt

Formatted: FooterCentered, Left, Space Before: 0 pt, Tab stops: Not at 17.2 cm

Formatted: Font: 11 pt

Formatted: FooterPageRomanNumber, Left, Space After: 0 pt, Tab stops: Not at 17.2 cm

Foreword

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

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

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at ~~www.iso.org/patents~~www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: ~~www.iso.org/iso/foreword.html~~www.iso.org/iso/foreword.html.

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at ~~www.iso.org/members.html~~www.iso.org/members.html.

Formatted: HeaderCentered
Formatted: Font: Bold
Commented [eXtyles2]: The URL https://www.iso.org/directives has been redirected to http://www.iso.org/directives-and-policies.html. Please verify the URL.
Commented [eXtyles3]: The URL https://www.iso.org/patents has been redirected to http://www.iso.org/iso-standards-and-patents.html. Please verify the URL.
Commented [eXtyles4]: The URL https://www.iso.org/iso/foreword.html has been redirected to http://www.iso.org/foreword-supplementary-information.html. Please verify the URL.
Commented [eXtyles5]: The URL https://www.iso.org/members.html has been redirected to http://www.iso.org/about/members. Please verify the URL.
Formatted: Font: 11 pt
Formatted: FooterPageRomanNumber, Space Before: 0 pt, Line spacing: single, Tab stops: Not at 17.2 cm

Introduction

Protons deliver most of their energy at a prescribed, programmable distance inside the body, known as the Bragg Peak. With this feature, proton therapy is used to treat many cancers and is particularly appropriate in situations where treatment options are limited and conventional radiotherapy using photon beam presents unacceptable risks to patients. The use of proton accelerators to administer external beam radiation has been evolving and the proton therapy centres are rising worldwide.

A typical large proton therapy centre consists of an injector, a cyclotron or synchrotron to accelerate the particles, high-energy beam selection and transport system, several treatment rooms (fixed beam and/or gantry) and, occasionally, a research room. Strong secondary radiation, particularly high energy neutrons, is produced at locations where beam losses occur. Such losses may occur in the cyclotron or synchrotron along the beam transport system during acceleration, extraction, energy degradation and transport of the protons to the treatment room, and in the treatment and research nozzles. In addition, the production of proton beam interactions in the patient, beam stop, or dosimetry phantom also results in stray radiation production. As a result, meters-thick barriers are generally used around the entire accelerator system. The radiation shielding of proton therapy centre is quite complex and become one of the key elements to commission a proton therapy centre, in the perspective of both capital and time consumed.

IEC 60601-2-64 relates to the design and the construction of the light ion, including proton, accelerators to ensure the safety of their operation.[1] Several national[2][3] or international[4][5][6] Several national or international reports propose recommendations concerning the installation, the commissioning, and the operation of these accelerators, the safety devices, the design and the calculation of protection barriers, the radiological control and monitoring. National standards[7][8][9][10] have been established in certain countries. Moreover, national regulations generally impose rules of protection against radiation, in particular relating to the definition of the controlled area and supervised area and the calculation of shielding.

Considering the developments of proton therapy techniques and of new designs of proton therapy facilities on the one hand, and the variety of guidelines or normative documents on the other hand, it appeared judicious to establish an international standard to be used as a general framework. This document is intended to be complementary to the other international standards (IEC and IAEA).

The following items are discussed in this document:

— shielding design assumption and goals;

— radiation fields;

— materials for radiation shielding: concrete (ordinary or high density), steels;

— role of stakeholders;

— general formalism for shielding calculations;

— calculation methods;

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

Formatted: Font: Bold
Formatted: HeaderCentered
Commented [eXtyles6]: Not found: "IEC 60601-2-64"
Formatted: Default Paragraph Font
Formatted: Default Paragraph Font
Formatted: Default Paragraph Font
Formatted: Font: 10 pt
Formatted: FooterCentered, Left, Space Before: 0 pt, Tab stops: Not at 17.2 cm
Formatted: Font: 11 pt
Formatted: FooterPageRomanNumber, Left, Space After: 0 pt, Tab stops: Not at 17.2 cm

Radiological protection — Medical proton accelerators ~~—~~ ~~Recommendations~~ — Requirements and recommendations for shielding design and evaluation

1 Scope

This document is applicable to the radiation shielding design and evaluation work for medical proton accelerators of proton energies ranging from 70 MeV to 250 MeV, with subsystems such as beam transport system and nozzle components.

The radiation protection recommendations given in this document 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, the medical physicist, the licensee and interactions between them, sources and radiations around a proton accelerator, shielding for accelerators and its subsystems (including shielding materials and transmission values, calculations for various room configurations, duct impact on radiation protection) and the radiological measurements.

FLASH proton therapy is not covered by this document.

NOTE 1 ~~Annex A~~Annex A provides a list of the most used Monte-Carlo codes for shielding calculation.

NOTE 2 ~~Annex B~~Annex B provides the analytical methods and the corresponding necessary data for shielding calculation.

NOTE 3 ~~Annex C~~Annex C provides a set of examples on shielding calculation of barriers, maze and skyshine problems.

NOTE 4 ~~Annex D~~Annex D provides radiation shielding consideration on special topics.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

~~<std>~~ISO 12749-2~~:2022~~, Nuclear energy, nuclear technologies, and radiological protection — Vocabulary — Part 2: Radiological protection~~</std>~~

~~<std>~~ISO ~~16645:2016~~ISO 16645, Radiological protection — Medical electron accelerators — Requirements and recommendations for shielding design and evaluation~~</std>~~

~~<std>~~ISO ~~80000-10, *Quantities and units — Part 10: Atomic and nuclear physics*~~</std>~~

ISO 80000-10, *Quantities and units — Part 10: Atomic and nuclear physics*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 12749-2~~:2022~~, ISO 16645~~:2016~~, ISO 80000-10 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

Formatted: Adjust space between Latin and Asian text, Adjust space between Asian text and numbers, Tab stops: Not at 0.7 cm + 1.4 cm + 2.1 cm + 2.8 cm + 3.5 cm + 4.2 cm + 4.9 cm + 5.6 cm + 6.3 cm + 7 cm

Formatted: Adjust space between Latin and Asian text, Adjust space between Asian text and numbers

Formatted: Adjust space between Latin and Asian text, Adjust space between Asian text and numbers, Tab stops: Not at 0.7 cm + 1.4 cm + 2.1 cm + 2.8 cm + 3.5 cm + 4.2 cm + 4.9 cm + 5.6 cm + 6.3 cm + 7 cm

Formatted: Default Paragraph Font

Formatted: Default Paragraph Font

Formatted: Default Paragraph Font

Formatted: Default Paragraph Font

Formatted: Default Paragraph Font

Formatted: Adjust space between Latin and Asian text, Adjust space between Asian text and numbers

Formatted: Default Paragraph Font

Formatted: Default Paragraph Font

Formatted: Default Paragraph Font

Formatted: Default Paragraph Font

Formatted: Default Paragraph Font

Formatted: Default Paragraph Font

Formatted: Default Paragraph Font

Formatted: Default Paragraph Font

Formatted: Footer, Left, Space After: 0 pt, Tab stops: Not at 17.2 cm