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Practice for dosimetry in an X-ray (bremsstrahlung) facility for radiation processing at energies between 50 KeV and 7.5 MeV

Pratique de la dosimétrie dans une installation de traitement par des rayons X (bremsstrahlung) entre 50 KeV et 7,5 MeV

Reference number
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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.

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.

ASTM International is one of the world's largest voluntary standards development organizations with global participation from affected stakeholders. ASTM technical committees follow rigorous due process balloting procedures.

A project between ISO and ASTM International has been formed to develop and maintain a group of ISO/ASTM radiation processing dosimetry standards. Under this project, ASTM Committee E61, Radiation Processing, is responsible for the development and maintenance of these dosimetry standards with unrestricted participation and input from appropriate ISO member bodies.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. Neither ISO nor ASTM International shall be held responsible for identifying any or all such patent rights.

International Standard ISO/ASTM 51608 was developed by ASTM Committee E61, Radiation Processing, through Subcommittee E61.03, Dosimetry Application, and by Technical Committee ISO/TC 85, Nuclear energy, nuclear technologies and radiological protection.

This third edition cancels and replaces the second edition (ISO/ASTM 51608:2005), which has been technically revised.

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An American National Standard

Standard Practice for Dosimetry in an X-Ray (Bremsstrahlung) Facility for Radiation Processing at Energies between 50 keV and 7.5 MeV[1]

This standard is issued under the fixed designation ISO/ASTM 51608; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision.

1. Scope

1.1 This practice outlines the dosimetric procedures to be followed during installation qualification, operational qualification, performance qualification and routine processing at an X-ray (bremsstrahlung) irradiator. Other procedures related to operational qualification, performance qualification and routine processing that may influence absorbed dose in the product are also discussed.

NOTE 1—Dosimetry is only one component of a total quality assurance program for adherence to good manufacturing practices used in radiation processing applications.

NOTE 2—ISO/ASTM Practices 51649, 51818 and 51702 describe dosimetric procedures for electron beam and gamma facilities for radiation processing.

1.2 For radiation sterilization of health care products, see ISO 11137-1, *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*. In those areas covered by ISO 11137-1, that standard takes precedence.

1.3 For irradiation of food, see ISO 14470, *Food irradiation – Requirements for development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food*. In those areas covered by ISO 14470, that standard takes precedence.

1.4 This document is one of a set of standards that provides recommendations for properly implementing and utilizing dosimetry in radiation processing. It is intended to be read in conjunction with ISO/ASTM Practice 52628, "Practice for Dosimetry in Radiation Processing".

1.5 In contrast to monoenergetic gamma radiation, the X-ray energy spectrum extends from low values (about 35 keV) up to the maximum energy of the electrons incident on the X-ray target (see Section 5 and Annex A1).

1.6 Information about effective or regulatory dose limits and energy limits for X-ray applications is not within the scope of this practice.

1.7 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced documents

2.1 *ASTM Standards:*[2]

E170 Terminology Relating to Radiation Measurements and Dosimetry

E2232 Guide for Selection and Use of Mathematical Methods for Calculating Absorbed Dose in Radiation Processing Applications

E2303 Guide for Absorbed-Dose Mapping in Radiation Processing Facilities

2.2 *ISO/ASTM Standards:*[2]

51261 Practice for Calibration of Routine Dosimetry Systems for Radiation Processing

51539 Guide for Use of Radiation-Sensitive Indicators

51649 Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 300 keV and 25 MeV

51702 Practice for Dosimetry in a Gamma Facility for Radiation Processing

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing

51818 Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 80and 300 keV

52628 Practice for Dosimetry in Radiation Processing

[1] This practice is under the jurisdiction of ASTM Committee E61 on Radiation Processing and is the direct responsibility of Subcommittee E61.03 on Dosimetry Application, and is also under the jurisdiction of ISO/TC 85/WG 3.

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[2] For referenced ASTM or ISO/ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

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