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**Practice for dosimetry in a gamma
facility for radiation processing**

*Pratique pour la dosimétrie dans les installations pour
l'irradiation gamma*

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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 pilot project between ISO and ASTM International has been formed to develop and maintain a group of ISO/ASTM radiation processing dosimetry standards. Under this pilot 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 51702 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.



Standard Practice for Dosimetry in a Gamma Facility for Radiation Processing¹

This standard is issued under the fixed designation ISO/ASTM 51702; 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 installation qualification program for an irradiator and the dosimetric procedures to be followed during operational qualification, performance qualification, and routine processing in facilities that process products with ionizing radiation from radionuclide gamma sources to ensure that product has been treated within a predetermined range of absorbed dose. 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 51818 and 51649 describe dosimetric procedures for low and high energy electron beam facilities for radiation processing and ISO/ASTM Practice 51608 describes procedures for X-ray (bremsstrahlung) facilities for radiation processing.

1.2 For the radiation sterilization of health care products, see ISO 11137-1. In those areas covered by ISO 11137-1, that standard takes precedence.

1.3 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 ASTM Practice E2628.

1.4 *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

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 and 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.

E2303 Guide for Absorbed-Dose Mapping in Radiation Processing Facilities

E2628 Practice for Dosimetry in Radiation Processing

E2701 Guide for Performance Characterization of Dosimeters and Dosimetry Systems for Use in Radiation Processing

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

51608 Practice for Dosimetry in an X-Ray (Bremsstrahlung) Facility for Radiation Processing

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

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 80 and 300 keV

2.3 International Commission on Radiation Units and Measurements (ICRU) Reports:³

ICRU Report 85a Fundamental Quantities and Units for Ionizing Radiation

2.4 ISO Standards:⁴

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

2.5 Joint Committee for Guides in Metrology (JCGM) Reports:⁵

JCGM 100:2008, GUM 1995, with minor corrections, Evaluation of measurement data – Guide to the Expression of Uncertainty in Measurement

3. Terminology

3.1 Definitions:

3.1.1 *absorbed dose, D*—quantity of ionizing radiation energy imparted per unit mass of a specified material. The SI unit of absorbed dose is the gray (Gy), where 1 gray is equivalent to the absorption of 1 joule per kilogram of the specified material (1 Gy = 1 J/kg). The mathematical relationship is the quotient of $d\bar{\epsilon}$ by dm , where $d\bar{\epsilon}$ is the mean

³ Available from the International Commission on Radiation Units and Measurements, 7910 Woodmont Ave., Suite 800, Bethesda, MD 20814, USA.

⁴ Available from International Organization for Standardization (ISO), 1 rue de Varembe, Case postale 56, CH-1211, Geneva 20, Switzerland, <http://www.iso.ch>.

⁵ Document produced by Working Group 1 of the Joint Committee for Guides in Metrology (JCGM/WG 1). Available free of charge at the BIPM website (<http://www.bipm.org>).