
Guide for absorbed-dose mapping in radiation processing facilities

Guide pour la cartographie de dose absorbée du rayonnement des installations de traitement



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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

ASTM International, 100 Barr Harbor Drive, PO Box C700,
West Conshohocken, PA 19428-2959, USA
Tel. +610 832 9634
Fax +610 832 9635
E-mail khoooper@astm.org
Web www.astm.org

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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 52303 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 first edition cancels and replaces ASTM E2303-11, which has been technically revised.



Standard Guide for Absorbed-Dose Mapping in Radiation Processing Facilities¹

This standard is issued under the fixed designation ISO/ASTM 52303; 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 document provides guidance in determining absorbed-dose distributions (mapping) in products, materials or substances irradiated in gamma, X-ray (bremsstrahlung) and electron beam facilities.

NOTE 1—For irradiation of food and the radiation sterilization of health care products, specific ISO and ISO/ASTM standards containing dose mapping requirements exist. See ISO/ASTM Practices 51431, 51608, 51649, 51702 and 51818 and ISO 11137-1. Regarding the radiation sterilization of health care products, in those areas covered by ISO 11137-1, that standard takes precedence.

1.2 This guide is one of a set of standards that provides recommendations for properly implementing dosimetry in radiation processing. It is intended to be read in conjunction with ISO/ASTM 52628.

1.3 Methods of analyzing the dose map data are described. Examples are provided of statistical methods that may be used to analyze dose map data.

1.4 Dose mapping for bulk flow processing and fluid streams is not discussed.

1.5 Dosimetry is an element of a total quality management system for an irradiation facility. Other controls besides dosimetry may be required for specific applications such as medical device sterilization and food preservation.

1.6 *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 requirements prior to use.*

2. Referenced Documents

2.1 ASTM Standards:²

E170 Terminology Relating to Radiation Measurements and Dosimetry

¹ This guide 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.

E178 Practice for Dealing With Outlying Observations

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

2.2 ISO/ASTM Standards:²

51261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing

51431 Practice for Dosimetry in Electron Beam and X-Ray (Bremsstrahlung) Irradiation Facilities for Food Processing

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 MeV

51702 Practice for Dosimetry in a Gamma Irradiation 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 80 and 300 keV

52628 Practice for Dosimetry in Radiation Processing

2.3 International Commission on Radiation Units and Measurements Reports:³

ICRU Report 85a Fundamental Quantities and Units for Ionizing Radiation

2.4 International Organization for Standardization: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:

JCGM 100:2008 GUM 1995, with minor corrections, Evaluation of measurement data – Guide to the expression of uncertainty in measurement⁵

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

⁴ Available from International Organization for Standardization (ISO), 1 rue de Varembe, Case postale 56, CH-1211, Geneva 20, Switzerland.

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>).