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**Practice for dosimetry in an electron  
beam facility for radiation processing  
at energies between 80 and 300 keV**

*Pratique de la dosimétrie dans une installation de traitement par  
irradiation utilisant un faisceau d'électrons d'énergies comprises  
entre 80 et 300 keV*

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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.

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 (see [www.iso.org/directives](http://www.iso.org/directives)).

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For an explanation of 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 [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by ASTM Committee E61, *Radiation processing* (as ASTM E1818-96), and drafted in accordance with its editorial rules. It was assigned to Technical Committee ISO/TC 85, *Nuclear energy, nuclear technologies and radiation protection*, and adopted under the "fast-track procedure".

This fourth edition cancels and replaces the third edition (ISO/ASTM 51818:2013), which has been technically revised.

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](http://www.iso.org/members.html).

## ISO/ASTM 51818:2020(E)



# Standard Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 80 and 300 keV<sup>1</sup>

This standard is issued under the fixed designation ISO/ASTM 51818; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision.

## INTRODUCTION

Low energy electron beams, typically 80 – 300 keV, are used in several industrial processes, from curing of prints and crosslinking of plastic foils to surface sterilization of containers for pharmaceuticals and medical devices. These different applications are addressed through IQ, OQ, PQ and routine dose monitoring, although radiation curing and crosslinking might only require that reproducibility of dose delivery during execution of the process can be demonstrated.

This standard practice describes the dose measurements that might be required for full documentation of a low energy electron beam sterilization process. The dose measurement requirements for sterilization using low energy electron beams are derived from the international standard for radiation sterilization ISO 11137-1.

Not all low energy e-beam applications require dose measurement documentation with traceability to national standards. For radiation curing or crosslinking processes, for example, it might not be a requirement that calibration of the dosimetry system is established and maintained with traceability to national or international standards. The user must decide whether or not measurement traceability is required for the specific irradiation process, and it is the user who therefore accepts responsibility for reproducibility and documentation of the process.

## 1. Scope

1.1 This practice covers dosimetric procedures to be followed in installation qualification, operational qualification and performance qualification (IQ, OQ, PQ), and routine processing at electron beam facilities to ensure that the product has been treated with an acceptable range of absorbed doses. Other procedures related to IQ, OQ, PQ, and routine product processing that may influence absorbed dose in the product are also discussed.

1.2 The electron beam energy range covered in this practice is between 80 and 300 keV, generally referred to as low energy.

1.3 Dosimetry is only one component of a total quality assurance program for an irradiation facility. Other measures may be required for specific applications such as medical device sterilization and food preservation.

<sup>1</sup> 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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1.4 Other specific ISO and ASTM standards exist for the irradiation of food and the radiation sterilization of health care products. For the radiation sterilization of health care products, see ISO 11137-1. In those areas covered by ISO 11137-1, that standard takes precedence. For food irradiation, see ISO 14470. Information about effective or regulatory dose limits for food products is not within the scope of this practice (see ASTM F1355 and F1356).

1.5 This document is one of a set of standards that provides recommendations for properly implementing dosimetry in radiation processing, and describes a means of achieving compliance with the requirements of ISO/ASTM 52628. It is intended to be read in conjunction with ISO/ASTM 52628.

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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.7 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the*



Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

## 2. Referenced documents

### 2.1 ASTM Standards:<sup>2</sup>

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

**E3083** Terminology Relating to Radiation Processing: Dosimetry and Applications

**F1355** Guide for Irradiation of Fresh Agricultural Produce as a Phytosanitary Treatment

**F1356** Guide for Irradiation of Fresh, Frozen or Processed Meat and Poultry to Control Pathogens and Other Microorganisms

### 2.2 ISO/ASTM Standards:<sup>2</sup>

**51261** Practice for Calibration of Routine Dosimetry Systems for Radiation Processing

**51275** Practice for Use of a Radiochromic Film Dosimetry System

**51607** Practice for Use of an Alanine-EPR Dosimetry System

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

**51650** Practice for Use of a Cellulose Triacetate Dosimetry System

**51707** Guide for Estimating Uncertainties in Dosimetry for Radiation Processing

**52303** Guide for Absorbed-Dose Mapping in Radiation Processing Facilities

**52628** Practice for Dosimetry in Radiation Processing

**52701** Guide for Performance Characterization of Dosimeters and Dosimetry Systems for Use in Radiation Processing

### 2.3 International Commission on Radiation Units and Measurements (ICRU) Report:<sup>3</sup>

**ICRU Report 80** Dosimetry Systems for Use in Radiation Processing

**ICRU Report 85a** Fundamental Quantities and Units for Ionizing Radiation

### 2.4 ISO Standards:<sup>4</sup>

**11137-1:2006** Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

**14470:2011** Food irradiation – Requirements for the development, validation and routine control of the ionizing radiation used for the treatment of food

**17025:2017** General requirements for the competence of testing and calibration laboratories

**12749-4** Nuclear energy, nuclear technologies, and radiological protection – Vocabulary – Part 4: Dosimetry for radiation processing

**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 measurement<sup>5</sup>

**JCGM 200:2012, VIM** International vocabulary of metrology – Basic and general concepts and associated terms<sup>6</sup>

## 3. Terminology

### 3.1 Definitions:

**3.1.1 absorbed dose (*D*)**—quotient of  $d\bar{\epsilon}$  by  $dm$ , where  $d\bar{\epsilon}$  is the mean energy imparted by ionizing radiation to matter of incremental mass  $dm$  (ICRU-85a), thus

$$D = d\bar{\epsilon} / dm$$

**3.1.1.1 Discussion**—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).

**3.1.1.2 Discussion**—Throughout this practice, “absorbed dose” is referred to as “dose”.

**3.1.2 approved laboratory**—laboratory that is a recognized national metrology institute; or has been formally accredited to ISO/IEC 17025; or has a quality system consistent with the requirements of ISO/IEC 17025.

**3.1.3 average beam current**—time-averaged electron beam current.

**3.1.4 beam width**—dimension of the irradiation zone perpendicular to the direction of product movement, at a specified distance from the accelerator window.

**3.1.5 calibration curve**—expression of the relation between indication and corresponding measured **quantity value** (VIM).

**3.1.5.1 Discussion**—In radiation processing standards, the term ‘**dosimeter response**’ is generally used for ‘indication.’

**3.1.6 depth-dose distribution**—variation of absorbed dose with depth from the incident surface of a material exposed to a given radiation.

**3.1.7 dosimeter**—device that, when irradiated, exhibits a quantifiable change that can be related to absorbed dose in a given material using appropriate measurement instruments and procedures.

**3.1.8 dosimetry system**—interrelated elements used for measuring absorbed dose, consisting of dosimeters, measurement instruments and their associated reference standards, and procedures for the system’s use.

**3.1.9 electron beam energy**—kinetic energy of the accelerated electrons in the beam.

<sup>2</sup> For referenced ASTM standards, visit the ASTM website, [www.astm.org](http://www.astm.org), or contact ASTM Customer Service at [service@astm.org](mailto:service@astm.org). For *Annual Book of ASTM Standards* volume information, refer to the standard’s Document Summary page on the ASTM website.

<sup>3</sup> Available from the International Commission on Radiation Units and Measurements, 7910 Woodmont Ave., Suite 800, Bethesda, MD 20814, U.S.A.

<sup>4</sup> Available from International Organization for Standardization (ISO), ISO Central Secretariat, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, <http://www.iso.org>.

<sup>5</sup> Document produced by Working Group 1 of the Joint Committee for Guides in Metrology (JCGM WG1), Available free of charge at the BIPM website (<http://www.bipm.org>).

<sup>6</sup> Document produced by Working Group 2 of the Joint Committee for Guides in Metrology (JCGM WG2), Available free of charge at the BIPM website (<http://www.bipm.org>).