SVENSK STANDARD
SS-ISO/ASTM 51818:2020

Praxis för dosimetri vid anläggning med elektronstråle för bestrålning vid energier mellan 80 och 300 keV (ISO/ASTM 51818:2020, IDT)

Practice for dosimetry in an electron beam facility for radiation processing at energies between 80 and 300 keV (ISO/ASTM 51818:2020, IDT)

Svenska Institutet för Standarder

Språk: engelska/English

Utgåva: 2

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Fastställd: 2020-07-07
ICS: 17.240

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Den internationella standarden ISO/ASTM 51818:2020 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av ISO/ASTM 51818:2020.

Denna standard ersätter SS-ISO/ASTM 51818:2018, utgåva 1.

The International Standard ISO/ASTM 51818:2020 has the status of a Swedish Standard. This document contains the official English version of ISO/ASTM 51818:2020.

This standard supersedes the Swedish Standard SS-ISO/ASTM 51818:2018, edition 1.

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Foreword

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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).

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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.

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.

Standard Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 80 and 300 keV[1]

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.

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*

[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.

Current edition approved March 2020. Published June 2020. Originally published as ASTM E1818–96. The present Fourth Edition of International Standard ISO/ASTM 51818:2020(E) is a major revision of the Third Edition of ISO/ASTM 51818:2013(E).

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:*[2]

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:*[2]

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:*[3]

ICRU Report 80 Dosimetry Systems for Use in Radiation Processing

ICRU Report 85a Fundamental Quantities and Units for Ionizing Radiation

2.4 *ISO Standards:*[4]

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[5]

JCGM 200:2012, VIM International vocabulary of metrology – Basic and general concepts and associated terms[6]

3. Terminology

3.1 *Definitions:*

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

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

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.

[2] For referenced 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.

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

[4] 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.

[5] 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).

[6] 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).