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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

Reference number
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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11

Email: copyright@iso.org
Website: www.iso.org

ASTM International
100 Barr Harbor Drive, PO Box C700
West Conshohocken, PA 19428-2959, USA
Phone: +610 832 9634
Fax: +610 832 9635
Email: khooper@astm.org
Website: www.astm.org

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

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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.

ISO/ASTM 51818:2020(E)

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.

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