~~ISO/ASTM 51818:2013(E)~~

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]

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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.~~11137-1. In those areas covered by ISO ~~11137,~~11137-1, that standard takes precedence. For food irradiation, see ISO ~~14470:2011.~~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 ~~and utilizing~~ dosimetry in radiation ~~processing.~~ processing, and describes a means of achieving compliance with the requirements of ISO/ASTM 52628. It is intended to be read in conjunction with ~~ASTM~~ISO/ASTM ~~E2232~~52628~~, "Practice for Dosimetry in Radiation Processing"~~.

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

[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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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:*[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

E2303E3083 Guide for Absorbed-Dose Mapping in Radiation Processing FacilitiesTerminology Relating to Radiation Processing: Dosimetry and Applications

E2628 Practice for Dosimetry in Radiation Processing

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

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 Standards:*[3]

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

17025:2005 General requirements for the competence of testing and calibration laboratories

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 85a Fundamental Quantities and Units for Ionizing Radiation

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]

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[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.

[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.

[3] Available from International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, CP 56, CH-1211 Geneva 20, Switzerland, http://www.iso.org.

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

[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).

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 $d\bar{\varepsilon}$ by dm, where $d\bar{\varepsilon}$ is the mean ~~incremental~~ energy imparted by ionizing radiation to matter of incremental mass ~~dm.~~ 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*—~~system~~ interrelated elements used for ~~determining~~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.

3.1.10 *measurement uncertainty*—non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used (VIM).

3.1.11 *metrological traceability*—property of ~~the result of~~ a measurement ~~or the value of a standard whereby it~~ result whereby the result can be related to ~~stated references, usually national or international standards, through an~~ a reference through a documented unbroken chain of ~~comparisons all having stated uncertainties.~~calibrations, each contributing to the measurement uncertainty (VIM).

3.1.12 *reference material*—homogeneous material of known radiation absorption and scattering properties used to establish characteristics of the irradiation process, such as scan uniformity, depth-dose distribution, and reproducibility of dose delivery.

3.1.13 *routine monitoring position*—position where absorbed dose is monitored during routine processing to ensure that the product is receiving the absorbed dose specified for the process.

3.1.14 ~~*uncertainty*—~~*uncertainty budget*—~~parameter associated with the result~~ statement of a measurement ~~that characterizes the dispersion~~ uncertainty, of the ~~values that could reasonably be attributed to the measurand or derived quantity (see ISO/ASTM Guide~~ components of that measurement uncertainty, and of their calculation and combination (VIM).~~51707)~~.

3.1.14.1 *Discussion*—

An uncertainty budget should include the measurement model, estimates, and measurement uncertainties associated with the quantities in the measurement model, covariances, type of applied probability density functions, degrees of freedom, type of evaluation of measurement uncertainty, and any coverage factor.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 D_{μ}—absorbed dose to water in the first micrometer of water equivalent absorbing material (**1**).[7]

3.2.1.1 *Discussion*—

D_{μ} is a term used by an approved laboratory to specify reported surface dose values of transfer standard dosimeters based on adjustments made to account for user site specific calibration irradiation conditions.

3.2.2 *linear process rate*—product length irradiated per unit time to deliver a given dose.

3.2.3 *mass process rate*—product mass irradiated per unit time to deliver a given dose.

3.2.4 *area process rate*—product area irradiated per unit time to deliver a given dose.

NOTE 1—Definitions of other terms used in this standard that pertain to radiation measurement and dosimetry may be found in ISO/ASTM 52628, ASTM Terminology E3083, and ISO 12749-4. Definitions in these documents are compatible with ICRU Report 85a, and therefore, may be used as alternative references. Where appropriate, definitions used in this standard have been derived from, and are consistent with, general metrological definitions given in the VIM.

~~3.3 Definitions of other terms used in this standard that pertain to radiation measurement and dosimetry may be found in Terminology E170. Definitions in Terminology E170 are compatible with ICRU Report 85a; that document, therefore, may be used as an alternative reference.~~

4. Significance and use

4.1 A variety of irradiation processes ~~uses~~use low energy electron beam facilities to modify product characteristics. Dosimetry requirements, the number and frequency of measurements, and record keeping requirements will vary depending on the type and end use of the products being processed. Dosimetry is often used in conjunction with physical, chemical, or biological testing of the product, to help verify specific treatment parameters.

NOTE 2—In many cases dosimetry results can be related to other quantitative product properties; for example, gel fraction, melt flow, elastic modulus, molecular weight distribution, or ~~cure analysis tests.~~degree of cure.

4.2 Radiation processing specifications usually include a minimum or maximum absorbed dose limit, or both. For a given application these limits may be set by government regulation or by limits inherent to the product itself.

4.3 Critical ~~process~~operating parameters must be controlled to obtain reproducible dose distribution in processed materials. The electron beam energy, beam current, beam width and process line speed (conveying speed) affect absorbed dose.

4.4 Before any electron beam facility can be routinely utilized, it must be ~~validated to determine its effectiveness.~~ characterized to determine the relationship between dose to product and the main operating parameters. This involves testing of the process equipment, calibrating the measuring instruments and the dosimetry system, and demonstrating the ability to consistently deliver the required dose within predetermined specifications.

4.5 In order to establish metrological traceability for a dosimetry system ~~to be effective in low-energy electron irradiation applications~~ and to measure doses with ~~an acceptable~~a known level of uncertainty, it is necessary to calibrate the dosimetry system under irradiation conditions that are consistent with those encountered in routine use. For example, a dosimetry system calibration conducted using penetrating gamma radiation or high energy electrons may result in ~~significantly inaccurate~~ significant dose measurement errors when the dosimetry system is used at low energy electron beam facilities. Details of calibration are discussed in Section 5.

5. Selection and calibration of the dosimetry system

5.1 *Selection of Dosimetry Systems:*

5.1.1 ~~ASTM~~ISO/ASTM ~~E2628~~52628 identifies requirements for selection of dosimetry systems. For ~~use with~~dosimetry at low-energy electron beam facilities consideration should specifically be given to the limited range of such electrons which might give rise to significant dose gradients through the thickness of the dosimeter. By choosing thin film dosimeters this problem can be ~~limited (see~~ minimized ~~Note 2)~~ (**1**).

5.1.2 When selecting a dosimetry system, consideration should be given to effects of influence quantities on the response of the dosimeter (see ISO/ASTM ~~E2701~~52701). One such influence quantity ~~is~~ might be irradiation atmosphere, and some low-energy accelerator applications involve irradiation in oxygen-free ~~conditions.~~conditions which might influence dosimeter response.

5.2 *Calibration of the Dosimetry System:*

5.2.1 The dosimetry system shall be calibrated prior to use and at intervals thereafter in accordance with the user's documented procedure that specifies details of the calibration process and quality assurance requirements. ~~Calibration~~ General conditions for calibration methods are given in ISO/ASTM 51261.

NOTE 3—For some applications it might not be a requirement that calibration of the dosimetry system is established and maintained with traceability

[7] The boldface numbers in parentheses refer to the bibliography at the end of this standard.

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. For more information on relative dose measurements see Annex A4.

5.2.2 The calibration irradiation may be performed by irradiating the dosimeters at *(a)* an approved laboratory or *(b)* ~~a production irradiator under actual production irradiation conditions~~ an irradiator where the normal irradiation conditions are used for calibration irradiation of routine dosimeters together with transfer standard dosimeters issued and analyzed by an approved laboratory. In case of option *(a)*, the resulting calibration curve shall be verified for the actual conditions of use (see ISO/ASTM 51261). The same applies for option *(b)* if irradiation conditions different from the actual production conditions have been used for the calibration irradiation.

NOTE 4—While 5.2.2 is valid for most dosimeter calibration irradiations, it must be recognized that the irradiation of various dosimeters with low energy electrons (less than 300 keV) ~~may~~ will likely lead to dose gradients through the thickness of the dosimeter. When the dosimeter response is measured, this will lead to ~~an apparent dose~~a dose value (an apparent dose, D_{app}) that is ~~related to the dose distribution. For~~ based on the assumption that there are no dose gradients within the dosimeter. However, if dose gradients exist within the dosimeter, then for a given set of irradiation conditions, the apparent dose will depend on the thickness of the dosimeter, i.e., dosimeters with different thickness will measure different apparent doses. One solution to overcome this problem is that all dose measurements are specified as dose to water in the first micrometer of the water equivalent absorbing material. This is given the symbol D_{μ} and is independent of the dosimeter thickness (**1**).Annex A2 ~~The dose estimate for the calibration is carried out by the approved laboratory that issues the transfer standard dosimeters~~ (describes the application of this principle for dose measurements carried out during calibraton.~~5.2.2), and this dose can be given in terms of D_{μ} (see Annex A2).~~

NOTE 5—~~Some applications may not require dose measurements to be traceable to a national standard~~ Dose gradient within a dosimeter is most pronounced in dosimeters with thicknesses that represent a significant fraction of the electron range (see ~~Annex A4~~Fig. A2.1). Using thin dosimeters, e.g. in the order of 10 µm, will reduce the gradient and hence the difference between dose at the front and the back of the dosimeter.

5.3 *Measurement Instrument Calibration and Performance Verification*—For the calibration of the instruments, and for the verification of instrument performance between calibrations, ISO/ASTM 51261, the ~~corresponding~~relevant ISO/ASTM or ASTM standard for the dosimetry system, and/or instrument-specific operating manuals should be consulted.

6. Installation and operational qualification

6.1 Installation qualification (IQ) is carried out to demonstrate that the irradiation equipment and any ancillary items have been supplied and installed in accordance with their specifications.

6.1.1 IQ typically involves measurement of depth-dose distribution and dose uniformity that can be used to calculate estimates of process throughput to verify the equipment performance specifications.

NOTE 6—The dosimetric measurements to be carried out during IQ depend on the agreement between supplier and user of the facility. They might be similar to the ones carried out during Operational Qualification (OQ).

NOTE 7—~~The dosimetric measurements carried out during IQ will often be the same as the ones carried out during Operational Qualification (OQ). IQ typically involves the use of dosimetric measurements of beam penetration and dose uniformity that can be used to calculate estimates of process throughput to verify the equipment performance specifications.~~ A dosimetry system calibration curve obtained by dosimeter irradiation at another facility might be used for these dose measurements, but in order to ensure that the dose measurements are ~~traceable to national standards,~~ valid, the calibration curve must be verified for the actual conditions of use.

6.2 Operational qualification (OQ) is carried out to characterize the performance of the irradiation equipment with respect to reproducibility of dose to product. ~~For OQ product dose mapping guidance, see ASTM~~ This is achieved through irradiator dose mapping.~~E2303~~.

NOTE 8—Some applications may not require OQ dose measurements to be traceable to a national standard (see Annex A4).

NOTE 9—Dose measurements for OQ may have to be carried out using a dosimetry system calibration curve obtained by irradiation at another facility. This calibration curve should be ~~verified as soon as possible,~~ verified, and corrections applied to the OQ dose measurements as needed.

NOTE 10—Distance between beam window and dosimeter should be specified for dose measurements carried out during OQ.

6.2.1 The performance of the low-energy electron beam facility depends primarily on the ~~energy of the electrons. It may~~electron beam energy. It might therefore be necessary to carry out separate OQ measurements for each energy selected for the operation of the facility.

6.2.2 The relevant dosimetric OQ measurements are described in more detail in Annex A1. They typically include the following:

6.2.2.1 *Dose as Function of Average Beam Current, Beam Width and Conveying Speed*—Dose to the product irradiated in an electron beam facility is proportional to average beam current (I), inversely proportional to conveying speed (V), and inversely proportional to beam width (W_b). The last relationship is valid for product that is conveyed through the beam zone perpendicular to the beam width. This is expressed as:

~~$$\text{Dose} = (K \cdot I)/(V \cdot W_b) \quad (1)$$~~

$$D = (K \cdot I)/(V \cdot W_b) \quad (1)$$

where:

D = absorbed dose (Gy),
I = average beam current (A),
V = conveying speed (m s^{-1}),
W_b = beam width (m), and

K = slope of the straight line relationship in Eq 1 $(Gy \cdot m^2) / (A \cdot s)$.

This straight-line relationship shall be determined for each energy selected for the operation of the facility. In order to determine the relationship, dose shall be measured at a specific location using a number of selected parameter sets of beam current, conveying speed and beam width to cover the operating range of the facility.

NOTE 11—Deviations from the straight-line relationship should be investigated.

6.2.2.2 *Beam Width*—The beam width is measured by ~~placing~~irradiating dosimeter strips or discrete dosimeters at selected intervals over the full beam width. Whenever possible, dosimeters should be placed beyond the expected beam width to identify the limits of the full beam width.

6.2.2.3 ~~*Beam Penetration—*~~*Depth-dose Distribution*—The ~~beam penetration~~depth-dose distribution is measured using a stack of thin dosimeters or by placing a dosimeter strip under thin layers of plastic foils.

~~*(1) Calculation Methods*—Beam penetration can be calculated using mathematical modeling (see ASTM E2232).~~

NOTE 12—Depth-dose distribution might be calculated using mathematical modeling (see ASTM E2232). Such calculations might be useful in supporting and understanding measurements.

6.2.2.4 *Dose Distribution on Reference Material*—~~It may be needed to measure the~~ The distribution of dose on or in a reference material is measured by placing dosimeters on the surface of a reference material or within a reference material.

6.2.2.5 *Process Interruption*—A process interruption can be caused by, for example, failure of beam current delivery or by the conveyor stopping. The effect of a process interruption on dose to product shall be determined, so that decisions about possible product disposition can be made.

6.2.3 The measurements in 6.2.2 shall be repeated a sufficient number of times ~~(three or more)~~(at least three) to allow determination of the operating parameter variability based on a statistical evaluation of the dose measurements.

NOTE 13—The operating parameter variability can be determined from the scatter between repeated dose measurements made at different times using identical operating parameter settings. Determination of this variability forms part of operational qualification. Operating parameter variability contributes to ~~uncertainty~~variability of measured doses. It is often difficult to separate effect of operating parameter variability and dosimeter reproducibility and thus the measured variability ~~determined~~ will often be a combination of the two (**2**).

~~6.2.4 Based on the measured variability of the operating parameters, limits for their acceptable variation can be determined.~~

6.2.4 *Requalification*—OQ measurements shall be repeated at intervals specified by the user's documented procedure. The intervals shall be chosen to provide assurance that the irradiator is consistently operating within specifications. Requalification is typically carried out on an annual cycle, with specific parts of requalification at shorter time intervals within this cycle. If requalification measurements show that the OQ status of the irradiator has changed, then PQ might have to be repeated.

6.2.5 OQ measurements shall be repeated after assessment of changes of the irradiation facility that might affect dose or dose distribution. The extent to which requalification is carried out shall be justified.

NOTE 14—Activities that might affect the OQ status of the irradiation facility include, but are not limited to:

~~replacement of accelerator emitter~~
~~replacement of accelerator window~~
~~replacement of window support grid~~
~~replacement of conveyor parts~~
~~change in electron energy~~
~~change in distance of accelerator window to product surface~~

– Replacement of accelerator emitter
– Replacement of accelerator window
– Replacement of window support grid
– Replacement of conveyor parts
– Change in electron energy
– Change in distance of accelerator window to product surface

7. Performance qualification

7.1 Performance Qualification (PQ) is the stage of validation which uses defined product to demonstrate that the facility consistently operates in accordance with predetermined criteria to deliver specified doses, thereby resulting in product that meets the specified requirements.

7.2 PQ dose mapping is carried out to ~~demonstrate~~ establish a set of operating parameters so that minimum dose to product exceeds the dose required for the intended effect and that maximum dose to product does not exceed a maximum acceptable dose. For PQ product dose mapping guidance, see ~~ASTM~~ISO/ASTM ~~E2303~~52303.

NOTE 15—Dose mapping exercises do not have to be carried out at the same dose as used for product irradiations. The use of higher ~~doses, for example,~~or lower doses can enable the dosimetry system to be used in a more accurate part of its operating range, thereby improving the overall accuracy of the dose mapping.

~~NOTE 10—Some applications may not require PQ dose measurements to be traceable to a national standard (see Annex A4).~~