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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

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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.

ISO/ASTM 51818:2020(E)



Standard Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 80 and 300 keV¹

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 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: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 measurement⁵

JCGM 200:2012, VIM International vocabulary of metrology – Basic and general concepts and associated terms⁶

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.

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>).



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 a measurement result whereby the result can be related to a reference through a documented unbroken chain of 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 budget*—statement of a measurement uncertainty, of the components of that measurement uncertainty, and of their calculation and combination (VIM).

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.

4. Significance and use

4.1 A variety of irradiation processes 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

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

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 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 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 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 and to measure doses with 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 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 ISO/ASTM 52628 identifies requirements for selection of dosimetry systems. For 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 minimized (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 52701). One such influence quantity might be irradiation atmosphere, and some low-energy accelerator applications involve irradiation in oxygen-free 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. 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 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) 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) will likely lead to dose gradients through the thickness of the dosimeter. When the dosimeter response is measured, this will lead to a dose value (an apparent dose, D_{app}) that is 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_w and is independent of the dosimeter thickness (1). [Annex A2](#) describes the application of this principle for dose measurements carried out during calibration.

NOTE 5—Dose gradient within a dosimeter is most pronounced in dosimeters with thicknesses that represent a significant fraction of the electron range (see [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 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—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 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. This is achieved through irradiator dose mapping.

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, 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 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:

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

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](#) ($\text{Gy} \cdot \text{m}^2 / (\text{A} \cdot \text{s})$).

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

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*—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 (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 variability of measured doses. It is often difficult to separate effect of operating parameter variability and dosimeter reproducibility and thus the measured variability will often be a combination of the two (2).

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

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 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 ISO/ASTM 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 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.

7.3 OQ dose mapping can in some cases be used as PQ dose mapping. For example, this might be the case for irradiation treatment of wide webs (roll-to-roll). In other cases, such as sterilization of complex product, it might be required to carry out specific PQ product dose mapping.

7.4 During PQ dose mapping the locations and magnitudes of minimum and maximum doses, as well as the dose at a routine monitoring position, should be determined.

7.5 The relationship between minimum and maximum doses and the dose at a routine monitoring position is determined.

7.6 PQ dose mapping measurements shall be repeated a sufficient number of times (at least three) to allow statistical evaluation and characterization of the dose distribution data.

7.7 Based on the measured uncertainties of this relationship (see 7.5) process target doses measured at the routine monitoring position(s) and their acceptable limits of variation might be determined (2).

7.8 Repeat of PQ dose mapping shall be considered if product is changed (thus affecting dose distribution), or if the OQ status of the irradiation facility is changed.

8. Routine process control

8.1 *Monitoring of Operating Parameters*—The operating parameters (beam energy, beam current, beam width and conveying speed) shall be monitored and recorded continuously during the process or at intervals specified by the operator of the facility. The intervals shall be chosen to provide assurance that the irradiator is consistently operating within specifications.

NOTE 16—Beam energy, beam current and beam width are usually not measured directly, but are obtained through indirect measurements. The relationship between measured and actual values should be documented.

8.2 *Measurement of Routine Dose*—The dose at the routine monitoring position should be measured at intervals specified by the operator of the facility. The intervals should be chosen to verify the irradiator operated within limits, and thereby ensuring that the process specifications were achieved. The rationale for the interval should be documented.

8.3 *Process Control Limits*—Acceptance limits for the variation of the monitored process parameters (8.1) and measured routine monitoring dose (8.2) should be selected based on the process variability and measured uncertainties (see 6.2.3 and 7.6). The selection of acceptance limits can be based on the principles for statistical process control (2).

9. Measurement uncertainty

9.1 All dose measurements shall be accompanied by an estimate of uncertainty. Appropriate procedures are recommended in ISO/ASTM Guide 51707 (see also (GUM)).

9.2 All components of uncertainty should be included in the estimate, including those arising from calibration, dosimetry system reproducibility, instrument performance stability, and the effect of influence quantities. A full quantitative analysis of components of uncertainty is referred to as an uncertainty budget, and is often presented in the form of a table. Typically, the uncertainty budget will identify all significant components of uncertainty, together with their methods of estimation, statistical distributions and magnitudes.

10. Documentation

10.1 Data and measurement results shall be recorded and stored in accordance with the operator's measurement management system. Data to be recorded and stored include:



10.1.1 Data from initial IQ and from any changes to the irradiation facility.

10.1.2 Data from maintenance of the irradiation facility.

10.1.3 Data from OQ of the irradiation facility.

10.1.4 Data from PQ for products irradiated at the facility.

10.1.5 Process control data.

10.1.6 Calibration data for the dosimetry system(s) used.

10.1.7 Calibration data for measurement systems used as process control of the irradiation facility.

10.2 *Review and Approval*—All data and dosimetry records shall be reviewed in accordance with the operator's measurement management system.

11. Keywords

11.1 absorbed dose; dosimeter; dosimetry system; electron beam; electron accelerator; ionizing radiation; radiation cross-linking; radiation curing; radiation processing; radiation sterilization

ANNEXES

A1. DOSE MEASUREMENTS FOR OPERATIONAL QUALIFICATION

A1.1 This annex describes dose measurements that can be carried out in connection with operational qualification of a low-energy electron beam facility.

A1.2 Dose as function of beam current, beam width and conveying speed

A1.2.1 Absorbed dose to product depends on average beam current, beam width, conveying speed and beam energy. Measurement of dose as a function of these parameters constitutes effectively a characterization of the electron beam facility. There is no simple relationship between dose and energy, and measurement of dose as a function of the three other parameters should therefore be made for each operating energy.

A1.2.1.1 The relationship is expressed as:

$$D = (K \cdot I) / (V \cdot W_b) \quad (\text{A1.1})$$

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 A1.1 ($\text{Gy} \cdot \text{m}^2$) / ($\text{A} \cdot \text{s}$). The value of K is specific to a specific electron accelerator and to specific irradiation conditions.

(1) D is dose at the point of measurement. It would often be the surface dose at the center of the beam. It can be expressed as D_μ , see Annex A2.

(2) I is the average beam current as monitored by the facility. This monitored current is often the current going to the emitting cathode(s), while the beam current reaching the product is less.

(3) V is the speed of product through the irradiation zone.

(4) W_b is the width of the beam at a specified fraction of dose at the center of the beam (see A1.3).

A1.2.1.2 See Fig. A1.1 for example of measurement of Dose = $f(I, V, W_b)$.

A1.2.2 Dose depends on beam window thickness, distance between the beam window and the product surface, and on the

composition and temperature of the gas between the beam window and the product surface. These should therefore be kept constant during the measurements.

A1.2.3 The relationship in Eq A1.1 can be established by dose measurements with different combinations of the parameters I , V , and W_b . Showing that this relationship is a straight line passing through (0,0)—within uncertainties—proves that the facility operates as expected, and that at a given beam energy dose can be selected by appropriate choice of these parameters.

NOTE A1.1—A line that deviates significantly from the expected straight line or deviates significantly from (0,0) might be an indication for erroneous measurement of one or more of the parameters in Eq A1.1.

NOTE A1.2—By re-arranging the terms in Eq A1.1 the equation can be used to calculate, for example, the required beam current with the other parameters constant.

A1.2.4 Dose should be measured a sufficient number of times (at least three) for the same values of the key parameters in order to allow determination of the measurement repeatability.

A1.3 Beam width

A1.3.1 Beam width is measured by irradiating strips of dosimeter film or arrays of individual dosimeters across the width of the electron beam. Using arrays of single dosimeters, more dosimeters might be placed in zones of expected high dose gradients (e.g. near beam width extremes), and less where dose distribution is expected to be uniform (e.g. near the center).

A1.3.2 Beam width is measured at a specified distance between beam window and product surface.

A1.3.3 Beam width is often defined at a specified fraction of the dose at the center of the extended beam (see Fig. A1.2).

A1.3.4 Beam width should be measured a sufficient number of times to determine the repeatability of the measured beam width.

A1.3.5 It might not be possible to place dosimeters to measure the total beam width of some low-energy electron beam facilities, because the beam width is wider than the web

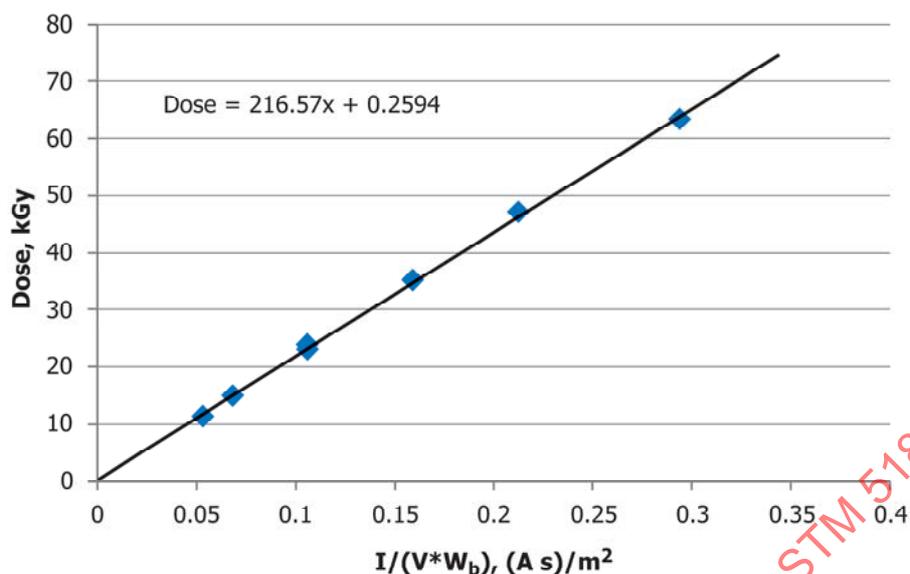
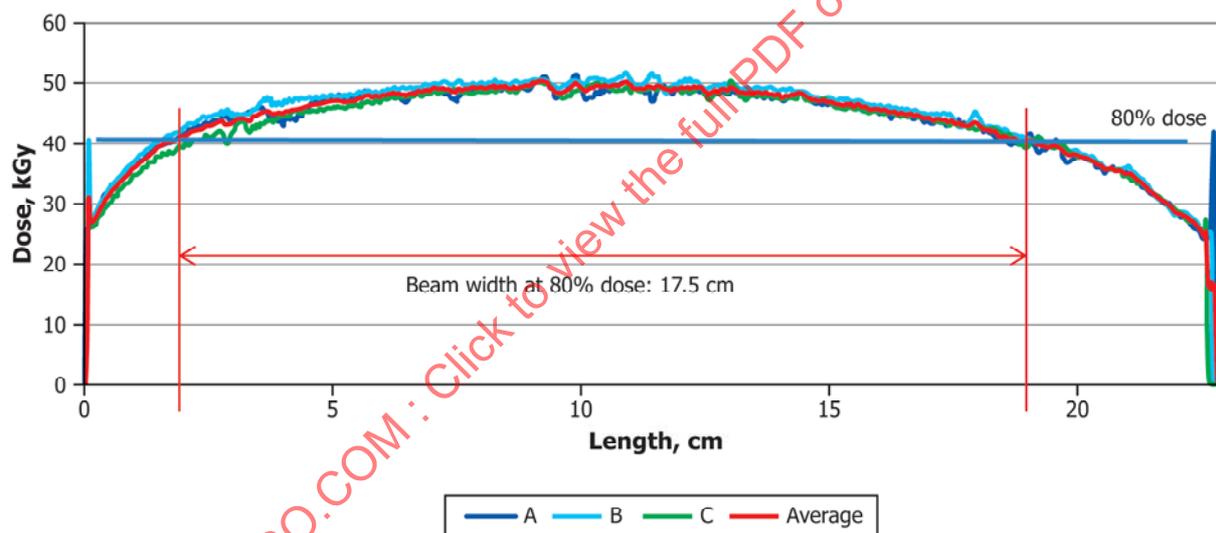


FIG. A1.1 Example of measurement of dose as function of average beam current I , conveying speed V and beam width W_b . Measured at an electron accelerator with beam energy 110 keV.
 $K = 216.57 \text{ (kGy} \cdot \text{m}^2) / (\text{A} \cdot \text{s})$



The parameters of the accelerator were:
 Electron energy: 150 keV
 Beam current: 1 mA
 Beam width obtained by elongated electrode (no scanning).
 Beam width was measured to be 17.5 cm at 80 % dose level.

FIG. A1.2 Example of beam width measurement (3 measurements and their average are shown). Beam width was measured on a low-energy accelerator installed in an electron beam tunnel for an aseptic filling line (3)

or conveyor passing the beam zone. An example of such a measurement is shown in Fig. A1.3. Actual beam width could not be measured because it exceeds the width over which it is possible to place dosimeters.

A1.4 Depth-dose distribution

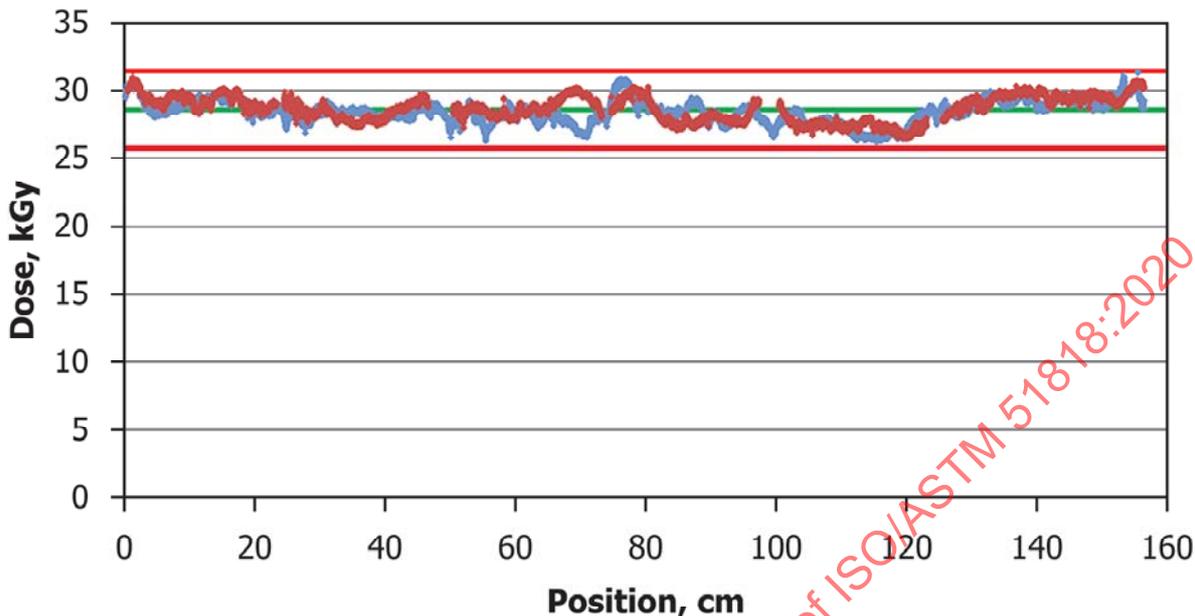
A1.4.1 Typical calculated depth-dose distribution curves for low energy electrons are shown in Fig. A1.4 and Fig. A1.5. (4)

A1.4.2 For high energy electrons, measurements of depth-dose distributions are carried out by placing dosimeters at

increasing depth in a homogeneous absorber. For low-energy electrons, dosimeters are often used as the homogeneous absorber, and the depth-dose distribution can be measured in a stack of dosimeter films (Fig. A1.6 left).

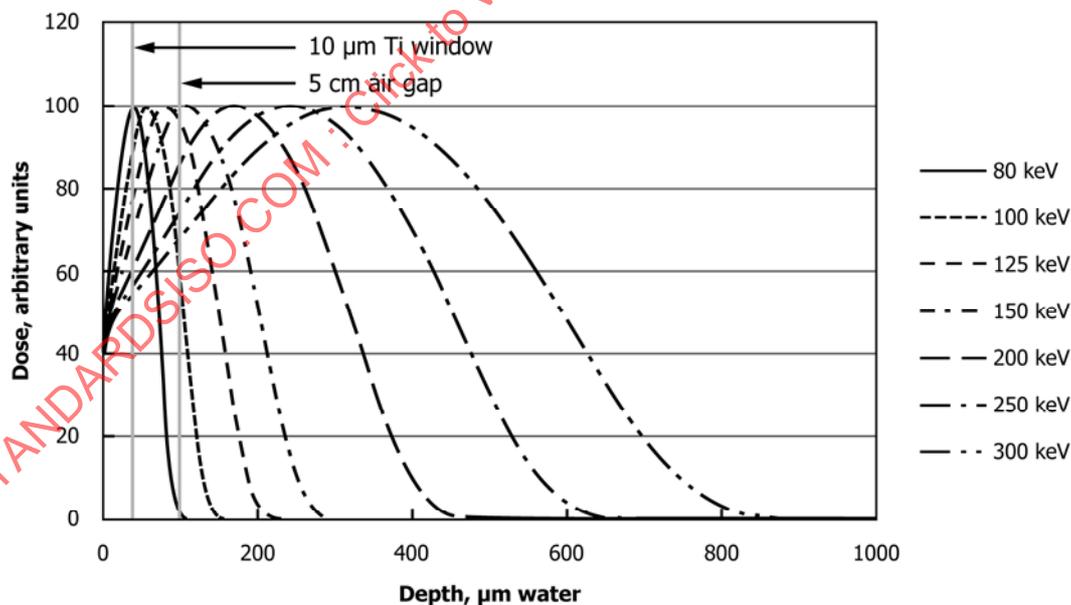
A1.4.3 Placing a dosimeter under increasing layers of thin plastic film can also be used for measurement of the depth-dose distribution (see Fig. A1.6 right).

Beam Width - 155 cm



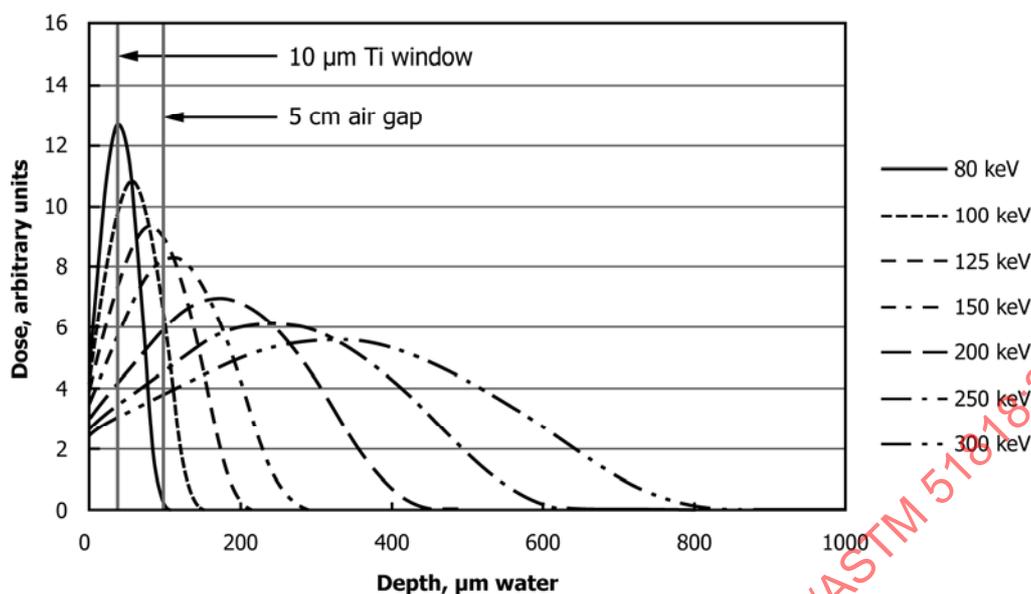
The parameters of the accelerator were:
 Electron energy: 175 keV
 Beam current: 140 mA
 Nominal beam width: 165 cm
 Beam width obtained by elongated electrode (no scanning).
 Average Dose 28.7 kGy
 St dev 0.9 kGy 3.1 %
 Horizontal lines represent average dose $\pm 10\%$
 Figure courtesy of Buergofol, Siegenburg, Germany

FIG. A1.3 Example of beam width measurement at a low-energy electron accelerator facility for curing purpose



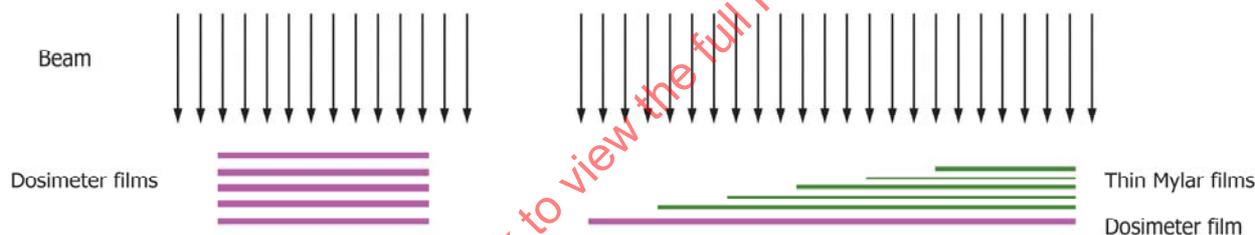
The curves are normalized to 100 % relative dose.
 Monte Carlo code: EGSnrc (5) Cut-off energy 1 keV.
 Examples of beam window and air gap thicknesses are shown.
 A: 10 µm Ti beam window
 B: 5 cm air gap

FIG. A1.4 Calculated depth-dose distribution in water (specific density 1 g cm⁻³)



The curves are normalized to electron fluence.
 Monte Carlo code: EGSnrc (5), Cut-off energy 1 keV.
 Examples of beam window and air gap thicknesses are shown.
 A: 10 μm Ti beam window
 B: 5 cm air gap

FIG. A1.5 Calculated depth-dose distribution in water (specific density 1 g cm^{-3})



Left: A stack of thin dosimeter films.
 Right: A dosimeter film under increasing layers of thin plastic (Mylar) films.

FIG. A1.6 Methods for measurement of depth-dose distribution

A1.4.4 The dosimeters for measurement of depth-dose distribution should be placed on a suitable backing material, preferably a material that has similar radiation absorption properties as the dosimeter. The backing material should be thicker than the range of the accelerated electrons.

A1.4.5 Depth-dose distribution depends on several parameters, such as beam energy, beam window thickness, distance between beam window and product surface, and on the composition and temperature of the gas between beam window and product surface. Measurements should therefore be repeated for the selected combinations of these operating parameters as they are used during actual processing. See Fig. A1.7 for examples of measurements of depth-dose distributions.

A1.4.6 Depth-dose distribution should be measured a sufficient number of times to allow determination of the uncertainty.

NOTE A1.3—Reproducibility of depth-dose distribution might be determined as the reproducibility of the extrapolated range such as it might be done for high energy electron beams. (See ISO/ASTM 51649.) It is, however, often not possible to provide such a measure of extrapolated

range, because only an insufficient part of the depth-dose distribution can be measured, the major part of the energy deposition happening in the beam window and the air gap between window and absorbing material.

NOTE A1.4—Simple mathematical relationships between electron energy and electron range are not established for low-energy electron irradiation such as they are for high energy. However, comparison between calculated depth-dose distributions and measured depth-dose distributions might be used to estimate the electron energy.

A1.5 Dose distribution on or in reference material

A1.5.1 The irradiation process may involve irradiation of complex product geometries, e.g., for surface sterilization of medical devices or of containers for pharmaceutical products. In this case a more simple reference material can be used for measurement of the reproducibility of the dose distribution.

A1.5.2 Dose distribution at the surface of the reference material should be measured a sufficient number of times to allow determination of the variability of the measured dose.

A1.6 Process interruption

A1.6.1 The irradiation process can be interrupted for a number of reasons, either fault in the electron accelerator(s) or

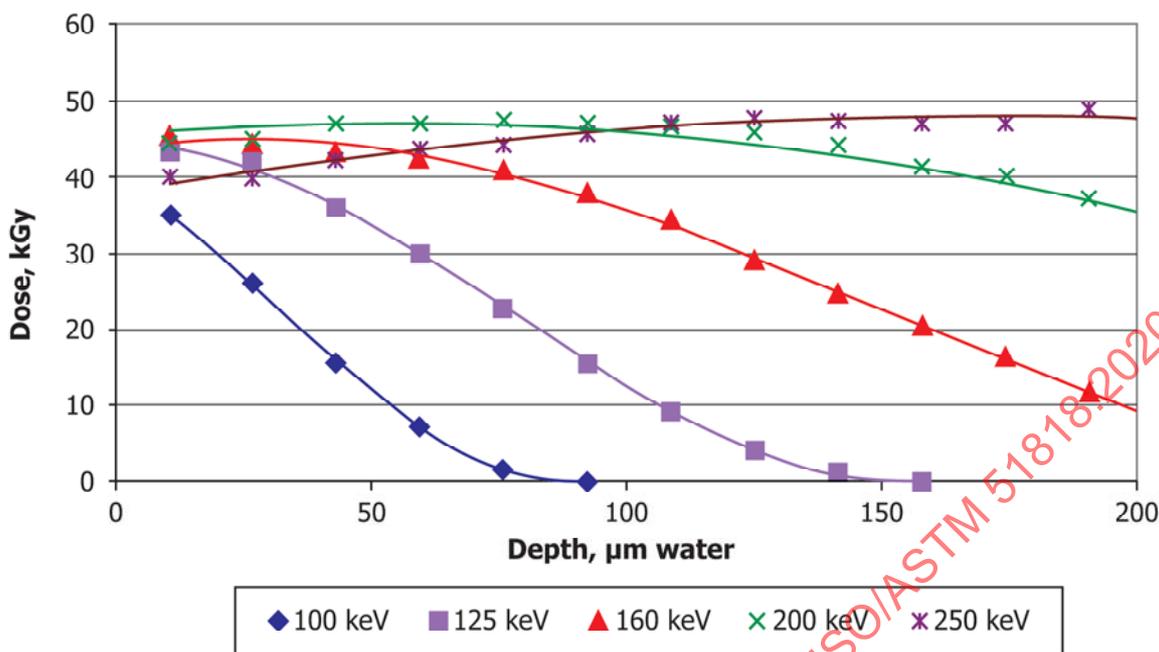


FIG. A1.7 Examples of measurements of depth-dose distributions at the same electron beam facility, but at different beam energies

in the conveying system. Faults in the ancillary systems (e.g., coating system or filling line) can also lead to interruption of the irradiation process.

NOTE A1.5—Different modes of interruption might lead to different effects on dose to product.

A1.6.2 The effect on dose to product of interrupting the irradiation process should be assessed.

A1.6.3 Measurement of dose variations as a consequence of a process interruption can be measured by placing dosimeters

along the direction of product movement, and interrupting the irradiation process manually followed by a re-start.

A1.6.4 Dose to product might be outside the specifications as a consequence of process interruptions and the subsequent re-starts. If this is so, then such product should be identified so it can be segregated, potentially for disposition.

A2. D_μ – DOSE IN FIRST MICRON

A2.1 Measurement traceability can be established during dosimetry system calibration by irradiating transfer standard dosimeters at the user’s facility together with the user’s dosimeters (in-plant/in-situ calibration). If dose gradients are generated over the thickness of the transfer standard dosimeter, then there is a need to specify the dose measured by the transfer dosimeter for a specific thickness. This annex describes the concept of D_μ and principles for its calculation and application.

A2.2 Irradiation with low-energy electrons (80–300 keV) results in dose gradients across the thickness of the dosimeters typically used for dose measurement at these energies. This leads to different doses being measured with dosimeters of different thickness irradiated at the same electron beam facility, resulting in difficulties in providing traceable dose measurements using transfer standard dosimeters. In order to overcome

these problems, a concept has been introduced for correcting all measured doses to the dose in the first micrometer of water equivalent material— D_μ (1, 6). Fig. A2.1 shows how different average doses will be measured using three dosimeters with different thickness calibrated at, for example, a 10 MeV electron irradiation and then irradiated using a 116 keV electron beam.

A2.3 D_μ is calculated for the transfer standard dosimeter used in an in-plant calibration (5.2.2). The value of D_μ is calculated from knowledge of the depth-dose distribution in the transfer dosimeter at the user’s facility (A1.4) and from a calibration curve for the transfer standard dosimetry system typically obtained at a high-energy e-beam.

NOTE A2.1—Use of a measured depth-dose distribution is preferred over a calculated curve, because often the input values for the calculations