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.

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. In those areas covered by ISO 11137, that standard takes precedence. For food irradiation, see ISO 14470:2011. 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. It is intended to be read in conjunction with ASTM E2232, "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 and health practices and determine the applicability of regulatory limitations prior to use.*

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

E2303 Guide for Absorbed-Dose Mapping in Radiation Processing Facilities

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 Practice for Irradiation of Fresh and Frozen Red 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

2.3 *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

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

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

2.4 *International Commission on Radiation Units and Measurements (ICRU) Report:*[4]
ICRU Report 85a Fundamental Quantities and Units for Ionizing Radiation
ICRU Report 80 Dosimetry Systems for Use in Radiation Processing

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 d*m*, where $d\bar{\varepsilon}$ is the mean incremental energy imparted by ionizing radiation to matter of incremental mass d*m*.

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

3.1.6 *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.

3.1.7 *dosimetry system*—system used for determining absorbed dose, consisting of dosimeters, measurement instruments and their associated reference standards, and procedures for the system's use.

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

3.1.9 *traceability*—property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

3.1.10 *uncertainty*—parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand or derived quantity (see ISO/ASTM Guide 51707).

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)**.[5]

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.

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

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 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. 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 for a dosimetry system to be effective in low-energy electron irradiation applications and to measure doses with an acceptable level of uncertainty, it is necessary to calibrate the dosimetry system under irradiation conditions that

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

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

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 dose measurement 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 E2628 identifies requirements for selection of dosimetry systems. For use with low-energy electron beam facilities consideration should specifically be given to the limited range of such electrons which might give rise to dose gradients through the thickness of the dosimeter. By choosing thin film dosimeters this problem can be limited (see 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 E2701). One such influence quantity is irradiation atmosphere, and some low-energy accelerator applications involve irradiation in oxygen-free conditions.

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 methods are given in ISO/ASTM 51261.

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 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 2—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 lead to dose gradients through the thickness of the dosimeter. When the dosimeter response is measured, this will lead to an apparent dose that is related to the dose distribution. 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 absorbing material. This is given the symbol D_{μ} and is independent of the dosimeter thickness (**1**). The dose estimate for the calibration is carried out by the approved laboratory that issues the transfer standard dosimeters (5.2.2), and this dose can be given in terms of D_{μ} (see Annex A2).

NOTE 3—Some applications may not require dose measurements to be traceable to a national standard (see Annex A4).

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 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.

NOTE 4—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, 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 E2303.

NOTE 5—Some applications may not require OQ dose measurements to be traceable to a national standard (see Annex A4).

NOTE 6—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, and corrections applied to the OQ dose measurements as needed.

6.2.1 The performance of the low-energy electron beam facility depends on the energy of the electrons. It may 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:

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

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 · m^2) / (A · 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.

6.2.2.2 *Beam Width*—The beam width is measured by placing 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*—The beam penetration 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).

6.2.2.4 *Dose Distribution on Reference Material*—It may be needed to measure the distribution of dose on or in 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 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) to allow determination of the operating parameter variability based on a statistical evaluation of the dose measurements.

NOTE 7—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 of measured doses. It is often difficult to separate operating parameter variability and dosimeter reproducibility and the 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.

6.2.5 *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.

6.2.6 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 8—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 demonstrate 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 E2303.

NOTE 9—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, 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).

7.3 OQ dose mapping can in some cases be used as PQ dose mapping. For example, this is the case for irradiation treatment of wide webs of infinite length. In other cases, such as sterilization of complex product, it may 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 are 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 (three or more) to allow statistical evaluation and characterization of the dose distribution data.

7.7 Based on the measured uncertainties of this relationship (see 7.5) acceptable limits for variation of the dose at the routine monitoring position to be measured during process irradiations can be determined (**2**).

7.8 Repeat of PQ dose mapping shall be considered if product is changed (thus affecting dose or 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 11—Beam energy, beam current and beam width are usually not measured directly, but are obtained through indirect measurements.

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

NOTE 12—Some applications may not require routine dose measurements to be traceable to a national standard (see Annex A4).

8.3 *Process Control Limits*—Acceptance limits for the variation of the monitored process parameters (8.1) and measured routine dose (8.2) should be selected based on the 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 (**3**)).

9.2 All components of uncertainty should be included in the estimate, including those arising from calibration, dosimeter reproducibility, instrument reproducibility, 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.

9.3 The expanded uncertainty for dose to product in a low-energy electron process depends on the facility and product variabilities, and on the combined uncertainty of the dosimetry system.

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 at 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 beam accelerator; ionizing radiation; radiation crosslinking; radiation curing; radiation processing; radiation sterilization

ANNEXES

(Mandatory Information)

A1. DOSE MEASUREMENTS FOR OPERATIONAL QUALIFICATION

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

NOTE A1.1—Multiple beam systems can be characterized individually or as the combined 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 calibration 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:

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

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 (Gy · m^2) / (A · s)

(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.

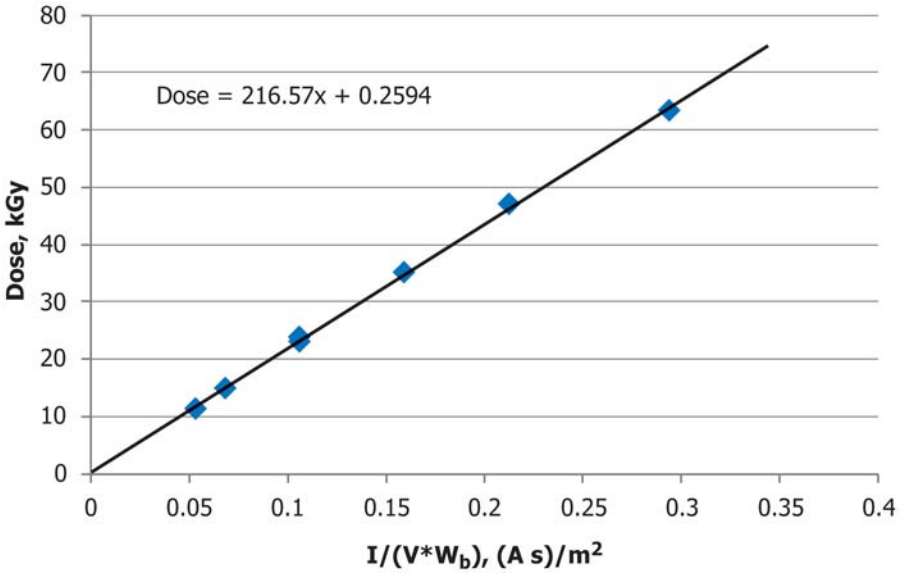


FIG. A1.1 Example of measurement of dose as function of average beam current *I*, conveying speed *V* and beam width W_b. Measured at an electron accelerator with beam energy 110 keV.
K = 216.57 (kGy · m^2) / (A · s)

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

A1.3 Beam width

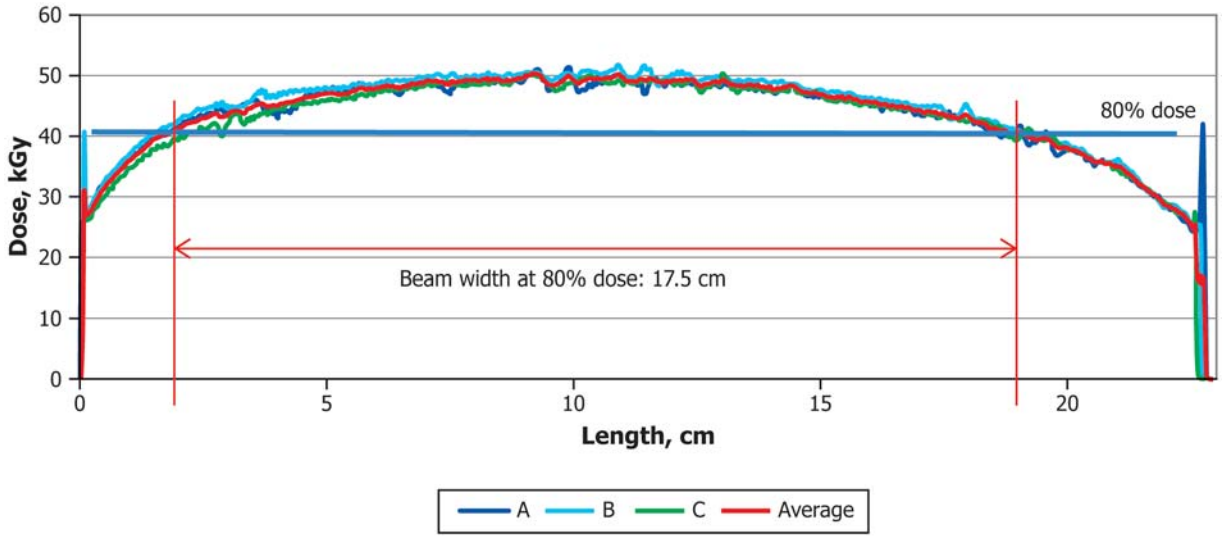
A1.3.1 Beam width is measured by placing strips of dosimeter film or arrays of single dosimeters across the width of the electron beam. Using arrays of single dosimeters, more dosimeters might be placed in zones of expected high dose gradients, and less where dose distribution is expected to be uniform.

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 may 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



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 (4)

or conveyor passing the beam zone. An example of such a measurement is shown in Fig. A1.3.

A1.4 Depth-dose distribution

A1.4.1 Typical depth-dose distribution curves for low energy electrons are shown in Figs. A1.4 and A1.5.

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.

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

A1.4.4 The dosimeters for measurement of beam penetration should be placed on a suitable backing material.

A1.4.5 Depth-dose distribution depends on 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. 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 of measured beam penetration.

NOTE A1.2—Reproducibility of beam penetration might be determined as the reproducibility of the extrapolated range. It is, however, often not possible to provide a measure of extrapolated range, because only an insufficient part of the depth-dose distribution can be measured.

NOTE A1.3—Energy-range relationships are not established for low energy electron irradiation. However, comparison between calculated depth-dose distributions and measured depth-dose distributions might be used to estimate the electron energy.

A1.4.7 See ASTM E2232 and its references for information related to the application of mathematical modeling methods.

A1.5 Dose distribution on reference material

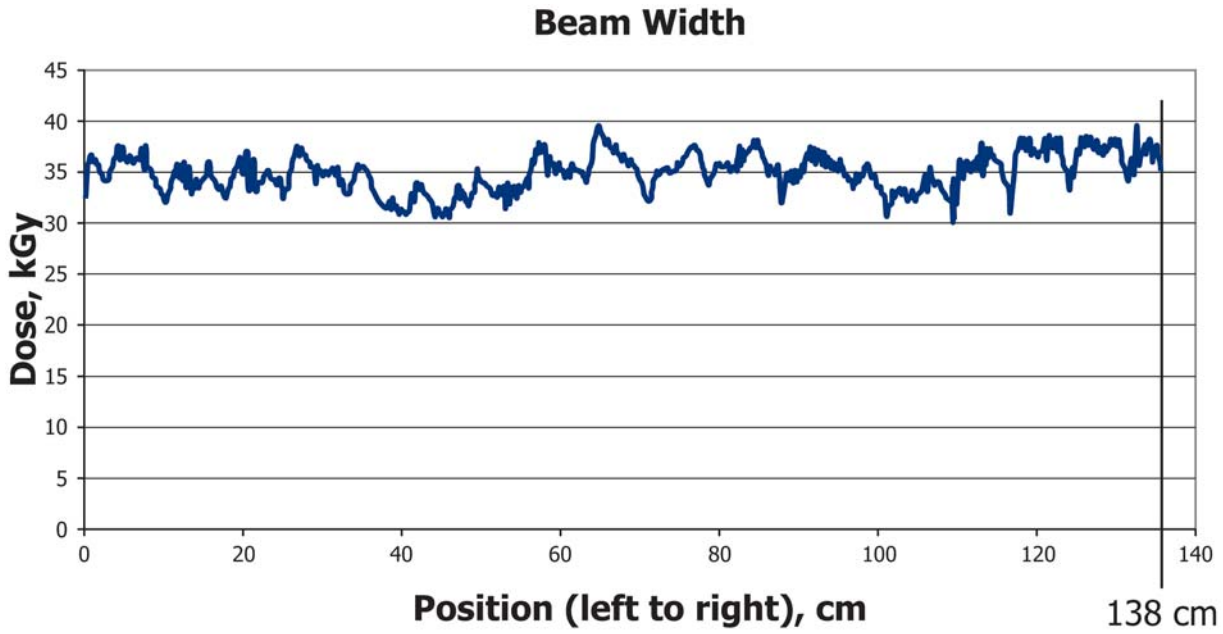
A1.5.1 The irradiation process may involve irradiation of complex product geometries, e.g., for surface sterilization of medical devices or of containers for pharmaceutical products. In this case a more simple reference material can be used for measurement of the reproducibility of the dose distribution.

A1.5.2 Dose distribution on 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

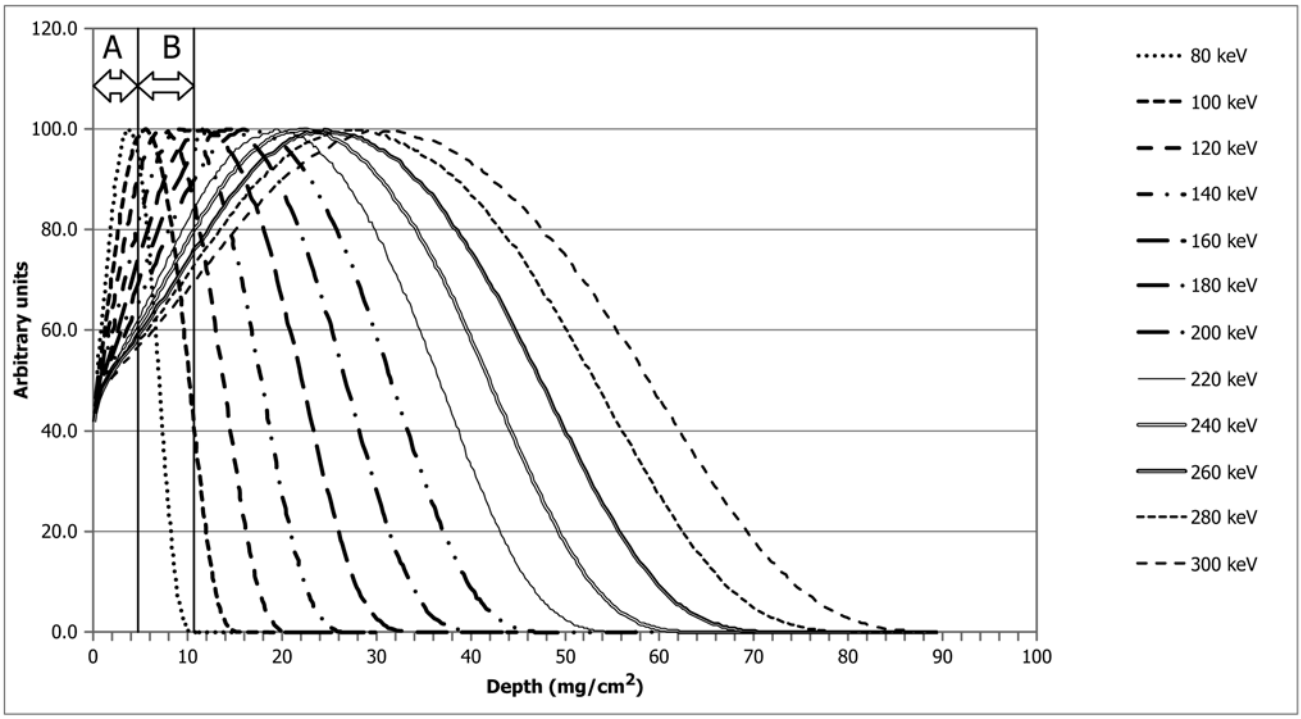
A1.6.1 The irradiation process can be interrupted for a number of reasons, either fault in the electron accelerator(s) or in the conveying system. Faults in the ancillary systems (e.g., coating system or filling line) can also lead to interruption of the irradiation process.

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



Actual beam width cannot be measured because it exceeds the width over which it is possible to place dosimeters. **(4)**
The parameters of the accelerator were:
Electron energy: 125 keV
Beam current: 100 mA
Nominal beam width: 165 cm
Beam width obtained by elongated electrode (no scanning).
Average Dose 34.94 kGy
St dev 1.80 kGy 5.1 %

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

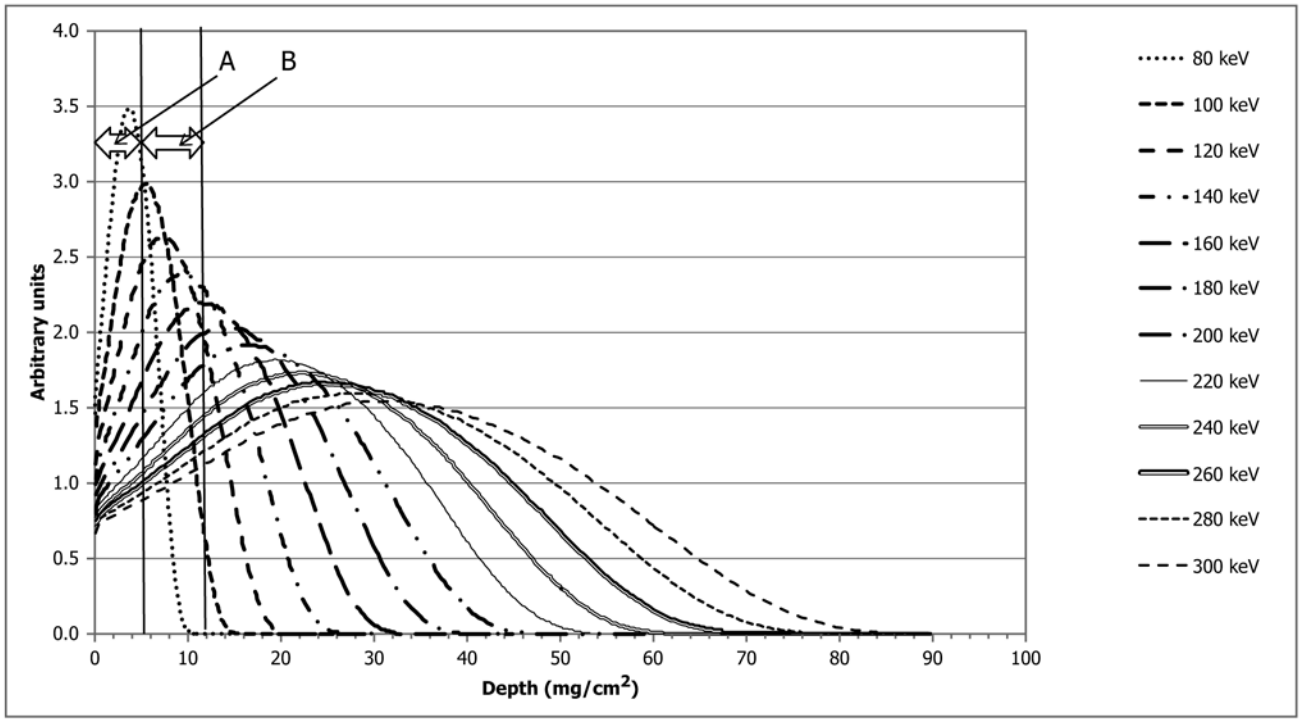


The curves are normalized to 100 % relative dose.
Monte Carlo code: EGSnrc, DOSRZnrc, (5) Cut-off energy 1 keV.
Examples of beam window and air gap thicknesses are shown.
A: 10 µm Ti beam window
B: 5 cm air gap
10 mg/cm^2 equals 100 µm in water (specific density 1 g/cm^3)

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

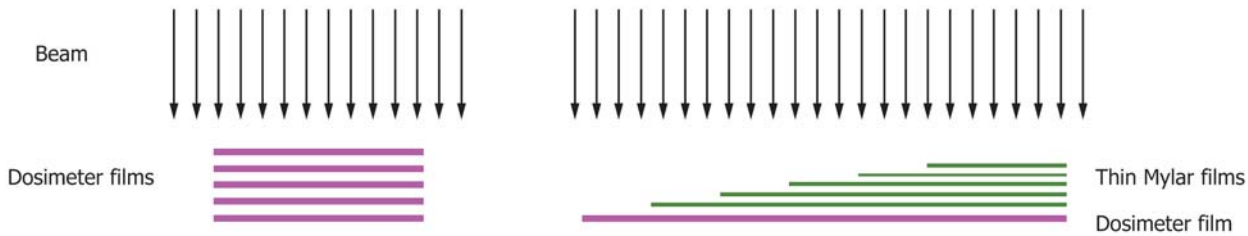
A1.6.3 Measurement of dose variations as a consequence of a process interruption can be measured by placing dosimeters along the direction of product movement, and interrupting the irradiation process manually followed by a re-start.

A1.6.4 Dose to product may exceed the specifications as a consequence of process interruption and the subsequent re-start. Such product must be identified so it can be segregated for disposition.



The curves are normalized to electron fluence.
Monte Carlo code: EGSnrc, DOSRZnrc **(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
10 mg/cm^2 equals 100 µm in water (specific density 1 g/cm^3)

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

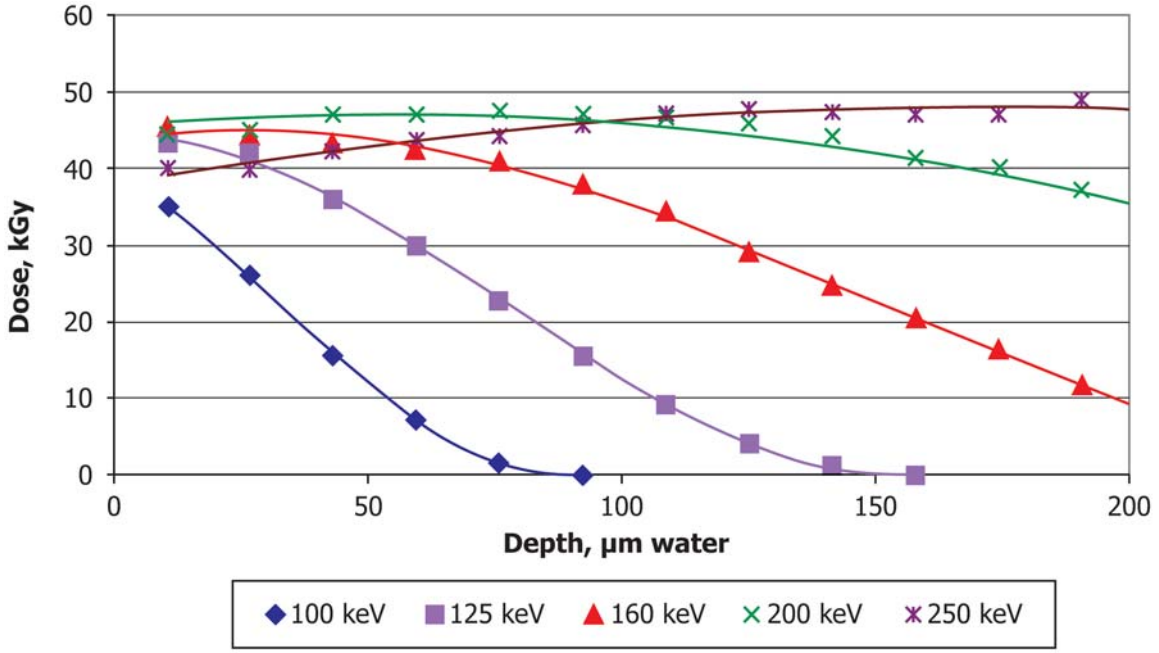


FIG. A1.7 Examples of measurements of depth dose distributions at the same electron beam facility, but at different beam energies

A2. D_μ

A2.1 Measurement traceability must be established by irradiating transfer standard dosimeters at the user's facility together with the user's dosimeters. 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 to 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—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 now irradiated at a 125 keV electron accelerator.

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 the calibration curve for the transfer standard dosimetry system.

A2.4 When the dosimeter response is measured and converted to dose using a calibration curve based on a 10 MeV irradiation, the obtained dose is referred to as the apparent dose (D_{app}). The apparent dose will be a function of the depth-dose distribution within the dosimeter and the shape of the calibration curve.

A2.5 The relationship between apparent dose D_{app} and D_μ is expressed as:

$$D_\mu = \frac{k_{water/dosimeter}}{k_\mu \cdot \eta} D_{app} \qquad \text{(A2.1)}$$

A2.6 The dose gradient correction factor k_μ corrects for the dose distribution over the thickness of the dosimeter. Calculation of the value of k_μ is based on a measured depth-dose distribution. k_μ is smaller than 1 in most low-energy applications, but at energies greater than approximately 200 keV k_μ may exceed 1.

A2.7 The sensitivity correction factor η corrects for the fact that the calibration curves of the dosimetry system are not linear. The dose distribution over the thickness of the dosimeter leads to different parts of the dosimeter being irradiated with different doses. The relative response of the dosimeter decreases as the dose increases because of the non-linear calibration curve, and the measured response therefore does not correspond to the average dose. The calculation of the value of

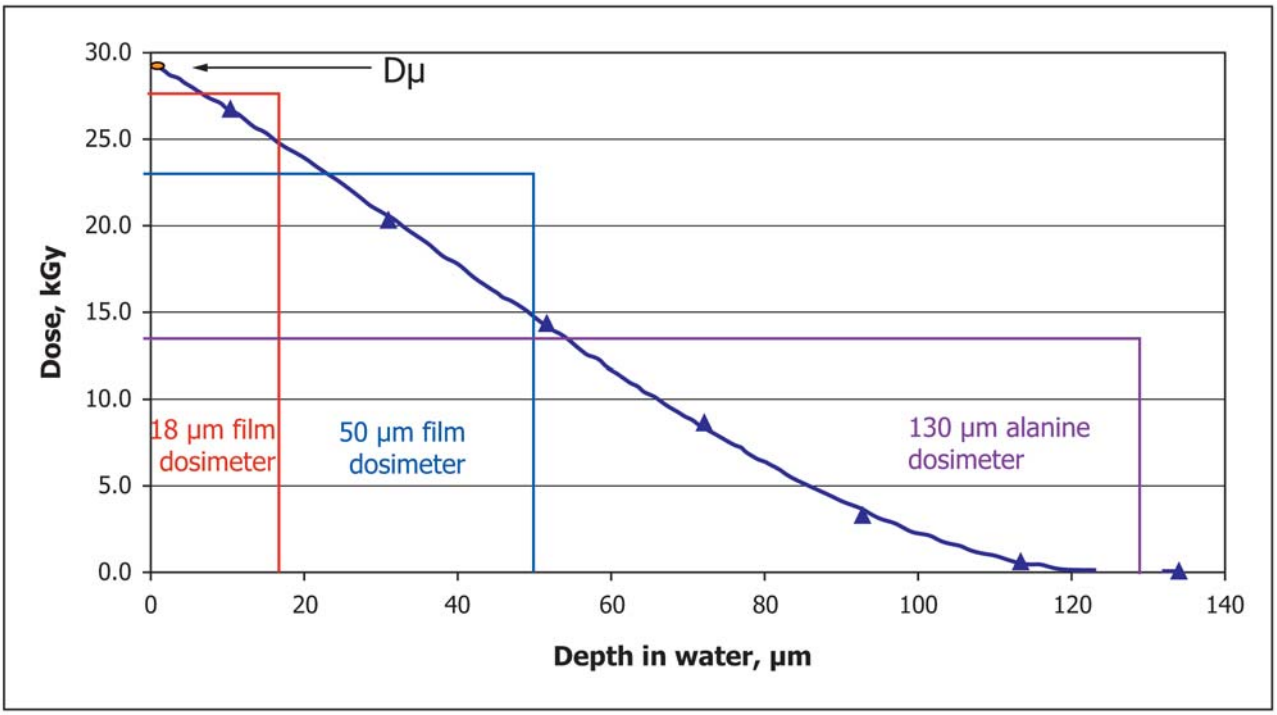


FIG. A2.1 Average dose measured with three dosimeters (18 μm RCD film dosimeter; 50 μm RCD film dosimeter; 130 μm alanine film dosimeter) all calibrated by irradiation at a 10 MeV electron accelerator, and now irradiated at a 125 keV electron accelerator. Depth dose distribution measured at Risø HDRL 125 keV electron accelerator.

η is based on the measured depth-dose distribution and the calibration curve of the dosimetry system. A calibration curve obtained via irradiation with high energy electrons or via gamma radiation can be used for this purpose. η is always equal to or less than 1 for the dosimeters used for low energy dosimetry.

A2.8 The backscatter correction factor $k_{water/dosimeter}$ is found by Monte-Carlo calculations. It corrects for differences in backscattered electrons from the different materials upon which the dosimeter might be placed. By applying $k_{water/dosimeter}$ it is assured that the dose measured by the dosimeter is expressed as dose to water as if the dosimeter was placed on water. The value of $k_{water/dosimeter}$ is close to 1 when low atomic number materials are used as backing materials, and in most practical situations it can be ignored.

A2.9 During in-plant calibration routine dosimeters are irradiated together with transfer standard dosimeters (5.2.2). The dose to the routine dosimeters is given by the dose measured with the transfer standard dosimeters in terms of D_μ having applied the correction factors given above.

A2.10 The calibration curve for the routine dosimetry system is established in terms of response as a function of D_μ, and the routine dosimetry system therefore measures dose in terms of D_μ. This applies when the irradiation conditions of the calibration are the same as the irradiation conditions of actual use.

A2.11 In some applications the irradiation conditions of the calibration cannot be maintained during actual use. This may be the case, for example, for dose mapping of complex product where the distance between beam window and dosimeter is not maintained at the same value as used during calibration. Increased distance may lead to a different dose distribution within the dosimeter, and hence a difference between the apparent dose D_{app} and D_μ compared to what it was during calibration. The actual surface dose may therefore be greater than D_μ, and thus—in case of radiation sterilization—any error will be conservative and safe.

A3. PRODUCT THROUGHPUT CALCULATION

A3.1 This annex describes methods for calculation of product throughput.

A3.2 Linear process rate

A3.2.1 The linear process rate is the conveying speed V at which a given surface dose can be delivered to product.

A3.2.2 The linear process rate V can be calculated from re-arrangement of Eq A1.1:

$$V = (K \cdot I)/(D \cdot W_b)\ [\mathrm{m \cdot s^{-1}}] \quad (A3.1)$$

A3.3 Area process rate

A3.3.1 The area process rate is the product area that can be irradiated at a given dose per unit of time.

A3.3.2 The area process rate can be calculated by multiplying the linear process rate by the beam width:

$$\text{Area process rate} = V \cdot W_b = (K \cdot I)/D \quad [\mathrm{m^2 \cdot s^{-1}}] \quad (A3.2)$$

A3.3.3 The area process rate refers to the maximum area that can be irradiated. The actual area that is irradiated at a given dose per time unit is reduced if the product width is less than the beam width.

A3.4 Mass process rate

A3.4.1 The mass process rate is the mass of product that can be irradiated at a given dose per unit of time.

A3.4.2 The mass process rate can be calculated by multiplying the area process rate by the specific density ρ [kg · m^{-3}] of the product and the thickness T [m] of the product as estimated from the measured depth-dose distribution (A1.4).

A3.4.2.1 The dose is the average dose through the thickness of product.

$$\text{Mass process rate} = V_l \cdot W_b \cdot T \cdot \rho = T \cdot \rho \cdot (K \cdot I)/D \quad [\mathrm{kg \cdot s^{-1}}] \quad (A3.3)$$

A3.4.3 The mass process rate refers to the maximum mass that can be irradiated at the given dose. The actual mass that is irradiated at a given dose per time unit is reduced if the product width is less than the beam width, or if the product thickness is less than the electron range.

A3.4.4 A theoretical estimate of the maximum mass process rate can be obtained from the power P of the electron beam accelerator divided by the dose D:

$$\text{Mass process rate (max)} = P/D \quad [\mathrm{kg \cdot s^{-1}}] \quad (A3.4)$$

A3.4.4.1 The power P [W] is the product of average beam current I [A] and accelerating voltage E [V].

A3.4.4.2 The unit of dose D is Gy = J · kg^{-1} = W · s · kg^{-1}.

A3.4.5 The beam current that is monitored by the instrumentation of the electron accelerator facility is in practice always less than the beam current actually reaching the product. This can be expressed as the current utilization efficiency f_i, which is usually in the order of 60–80 %.

A4. NON-TRACEABLE DOSIMETRY SYSTEM CALIBRATION

A4.1 Users of industrial low energy electron applications who do not require establishment of dosimetry to be traceable to a national standard, as described in ISO/ASTM 51261, may find it practical to establish a reproducible method relating dosimeter response to dose without traceability to national standards that satisfies their own specific needs and requirements. This annex discusses such methods.

NOTE A4.1—Non-traceable dosimetry system calibrations have an unknown level of accuracy with no means of determining the uncertainty associated with the doses derived from such calibrations. These calibrations, however, may be useful in estimating so called "relative doses" but do not provide a valid means of accurately estimating dose in accordance with ISO/ASTM 51261.

A4.1.1 For example, non-traceable dose measurements may be useful in IQ/OQ irradiator qualification activities that include estimating depth-dose distribution for an electron beam or for assessing beam width and beam length dose distribution.

A4.1.2 Non-traceable dose measurements should not be used to estimate process utilization efficiency or determine so called K factors at a given set of process settings because dose measurements made with a non-traceable calibration do not take into account differences between the calibration irradiation conditions of the non-traceable calibration and the actual process conditions. Validation of a non-traceable calibration curve would necessitate performing a calibration verification audit using transfer standard dosimeters from an approved laboratory (e.g., in terms of D_μ doses) to determine the difference between the apparent dose measured and the actual dose delivered.

A4.2 A user may send representative samples of a dosimeter batch to an approved laboratory for calibration irradiation at a high energy (e.g. 10 MeV) electron accelerator facility, or at a cobalt-60 gamma facility with constant dose rate and irradiation temperature. Based on the given doses and measured response of the dosimeters a calibration curve can be established. Use of such calibrations without subsequent verification under the actual conditions of use should be expected to result in doses that can vary significantly from actual doses due to

differences between the calibration irradiation conditions and those of actual use. These differences are difficult if not impossible to assess and appropriately take into account when attempting to estimate actual absorbed dose.

A4.2.1 Dose gradients in thin film dosimeters result from irradiation energies at 80–300 keV. Measurement of dosimeter response with such dose gradients can give rise to significant differences in their values compared with the results obtained with the calibration dosimeters irradiated using fully penetrating 10 MeV electron beam or cobalt-60 gamma for calibration irradiations that have no dose gradients. These dosimeter measurements lead to an apparent dose outcome that can differ significantly from the actual dose.

A4.2.2 Dosimeter response is influenced by environmental differences (temperature, humidity, etc.) between calibration conditions and those of actual irradiation processing. This is in particular the case for unpackaged thin film dosimeters.

A4.2.3 Attempting to apply a high energy 10 MeV electron beam or gamma calibration in low energy irradiation processes may result in significant uncertainty associated with differences between irradiators (electron energy, window thickness, window material composition, air gap, nitrogen purge, etc.).

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