An American National Standard

Standard Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 300 keV and 25 MeV[1]

This standard is issued under the fixed designation ISO/ASTM 51649; 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 outlines dosimetric procedures to be followed in installation qualification (IQ), operational qualification (OQ) and performance qualifications (PQ), and routine processing at electron beam facilities.

1.2 The electron beam energy range covered in this practice is between 300 keV and 25 MeV, although there are some discussions for other energies.

1.3 Dosimetry is only one component of a total quality assurance program for adherence to good manufacturing practices used in radiation processing applications. Other measures besides dosimetry may be required for specific applications such as health care product sterilization and food preservation.

1.4 Specific standards exist for the radiation sterilization of health care products and the irradiation of food. For the radiation sterilization of health care products, see ISO 11137-1 (Requirements) and ISO 11137-3 (Guidance on dosimetric aspects). For irradiation of food, see ISO 14470. In those areas covered by these standards, they take precedence. Information about effective or regulatory dose limits for food products is not within the scope of this practice (see ASTM Guides F1355, F1356, F1736, and F1885).

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 ISO/ASTM 52628, "Practice for Dosimetry in Radiation Processing".

NOTE 1—For guidance in the calibration of routine dosimetry systems, see ISO/ASTM Practice 51261. For further guidance in the use of specific dosimetry systems, see relevant ISO/ASTM Practices. For discussion of radiation dosimetry for pulsed radiation, see ICRU Report 34.

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 requirements 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

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

F1736 Guide for Irradiation of Finfish and Aquatic Invertebrates Used as Food to Control Pathogens and Spoilage Microorganisms

F1885 Guide for Irradiation of Dried Spices, Herbs, and Vegetable Seasonings 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

51539 Guide for the Use of Radiation-Sensitive Indicators

51608 Practice for Dosimetry in an X-Ray (Bremsstrahlung) Facility for Radiation Processing

51702 Practice for Dosimetry in a Gamma Facility for Radiation Processing

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing

51818 Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 80 and 300 keV

52628 Practice for Dosimetry in Radiation Processing

[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 and ISO/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.

52701 Guide for Performance Characterization of Dosimeters and Dosimetry Systems for Use in Radiation Processing

2.3 *ISO Standards:*[3]

ISO 11137-1 Sterilization of Health Care Products–Radiation – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices

ISO 11137-3 Sterilization of Health Care Products–Radiation – Part 3: Guidance on dosimetric aspects

ISO 14470 Food Irradiation – Requirements for the development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food

ISO 10012 Measurement Management Systems – Requirements for Measurement Processes and Measuring Equipment

ISO/IEC 17025 General Requirements for the Competence of Calibration and Testing Laboratories

2.4 *International Commission on Radiation Units and Measurements (ICRU) Reports:*[4]

ICRU Report 34 The Dosimetry of Pulsed Radiation

ICRU Report 35 Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV

ICRU Report 37 Stopping Powers for Electrons and Positrons

ICRU Report 80 Dosimetry for Use in Radiation Processing

ICRU Report 85a Fundamental Quantities and Units for Ionizing Radiation

2.5 *Joint Committee for Guides in Metrology (JCGM) Reports:*[5]

JCGM 100:2008, GUM 1995 , with minor corrections, Evaluation of measurement data – Guide to the expression of uncertainty in measurement

3. Terminology

3.1 *Definitions:*

3.1.1 *absorbed dose (D)*—quantity of ionizing radiation energy imparted per unit mass of a specified material.

3.1.1.1 *Discussion—(1)* The SI unit of absorbed dose is the gray (Gy), where 1 gray is equivalent to the absorption of 1 joule per kilogram in 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. (See ICRU Report 85a.)

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

3.1.1.2 *Discussion—(2)* Absorbed dose is sometimes referred to simply 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.

3.1.2.1 *Discussion*—A recognized national metrology institute or other calibration laboratory accredited to ISO/IEC 17025 or its equivalent should be used for issue of reference standard dosimeters or irradiation of dosimeters in order to ensure traceability to a national or international standard. A calibration certificate provided by a laboratory not having formal recognition or accreditation will not necessarily be proof of traceability to a national or international standard.

3.1.3 *average beam current*—time-averaged electron beam current; for a pulsed accelerator, the averaging shall be done over a large number of pulses (see Fig. 1).

3.1.4 *beam length*—dimension of the irradiation zone along the direction of product movement at a specified distance from the accelerator window (see Fig. 2).

3.1.4.1 *Discussion*—Beam length is therefore perpendicular to beam width and to the electron beam axis. In case of product that is stationary during irradiation, 'beam length' and 'beam width' may be interchangeable.

3.1.5 *beam width (W_b)*—dimension of the irradiation zone perpendicular to the direction of product movement at a specified distance from the accelerator window (see Fig. 2).

3.1.5.1 *Discussion*—For a radiation processing facility with a conveyor system, the beam width is usually perpendicular to the direction of motion of the conveyor (see Fig. 2). Beam width is the distance between two points along the dose profile, which are at a defined level from the maximum dose region in the profile (see Fig. 3). Various techniques may be employed to produce an electron beam width adequate to cover the processing zone, for example, use of electromagnetic scanning of a pencil beam (in which case beam width is also referred to as scan width), defocussing elements, and scattering foils.

3.1.6 *compensating dummy*—see *simulated product*.

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

3.1.7.1 *Discussion*—Typical distributions along the beam axis in homogeneous materials produced by a normally incident monoenergetic electron beam are shown in Annex A2.

3.1.8 *dose uniformity ratio (DUR)*—ratio of the maximum to the minimum absorbed dose within the irradiated product.

3.1.8.1 *Discussion*—The concept is also referred to as the max/min dose ratio.

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

3.1.10 *electron beam energy*—kinetic energy of the accelerated electrons in the beam. Unit: J

3.1.10.1 *Discussion*—Electron volt (eV) is often used as the unit for electron beam energy where 1 eV = $1.602 \cdot 10^{-19}$ J. In radiation processing, where beams with a broad electron energy spectrum are frequently used, the terms *most probable energy* (E_p) and *average energy* (E_a) are common. They are

[3] Available from International Organization for Standardization, 1 Rue de Varembé, Case Postale 56, CH-1211 Geneva 20, Switzerland.

[4] 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/WG 1). Available free of charge at the BIPM website (http://www.bipm.org).

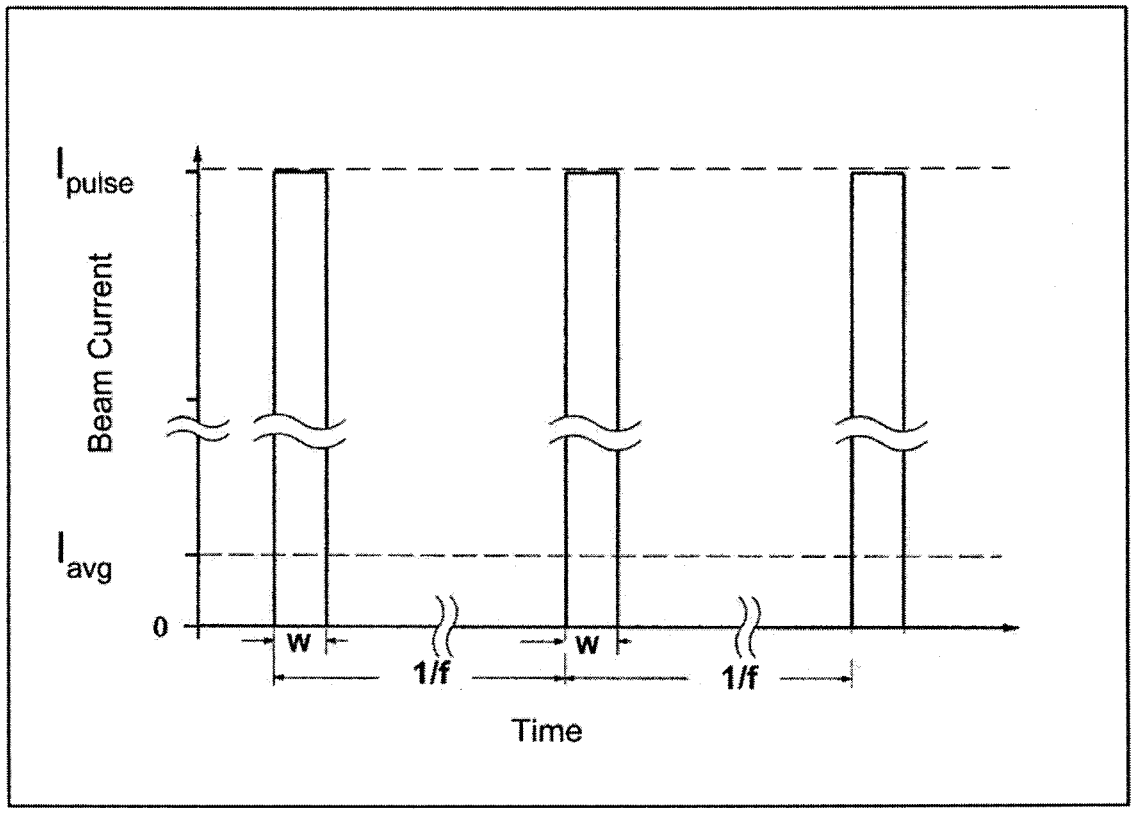


FIG. 1 Example showing pulse beam current (I_{pulse}), average beam current (I_{avg}), (pulse width (W) and repetition rate (f) for a pulsed accelerator

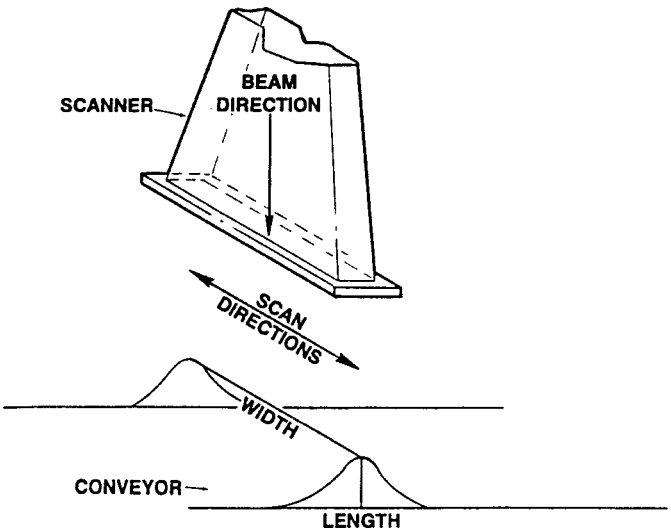


FIG. 2 Diagram showing beam length and beam width for a scanned beam using a conveyor system

linked to the *practical electron range* R_p and *half-value depth* R_{50} by empirical equations (see Fig. 4 and Annex A4).

3.1.11 *electron beam facility*—establishment that uses energetic electrons produced by particle accelerators to irradiate product.

3.1.12 *electron energy spectrum*—particle fluence distribution of electrons as a function of energy.

3.1.13 *installation qualification (IQ)*—process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification.

3.1.14 *operational qualification (OQ)*—process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

3.1.15 *performance qualification (PQ)*—process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification.

3.1.16 *process load*—volume of material with a specified product loading configuration irradiated as a single entity.

3.1.17 *production run*—series of process loads consisting of materials or products having similar radiation-absorption characteristics, that are irradiated sequentially to a specified range of absorbed dose.

3.1.18 *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.

3.1.19 *reference plane*—selected plane in the radiation zone that is perpendicular to the electron beam axis.

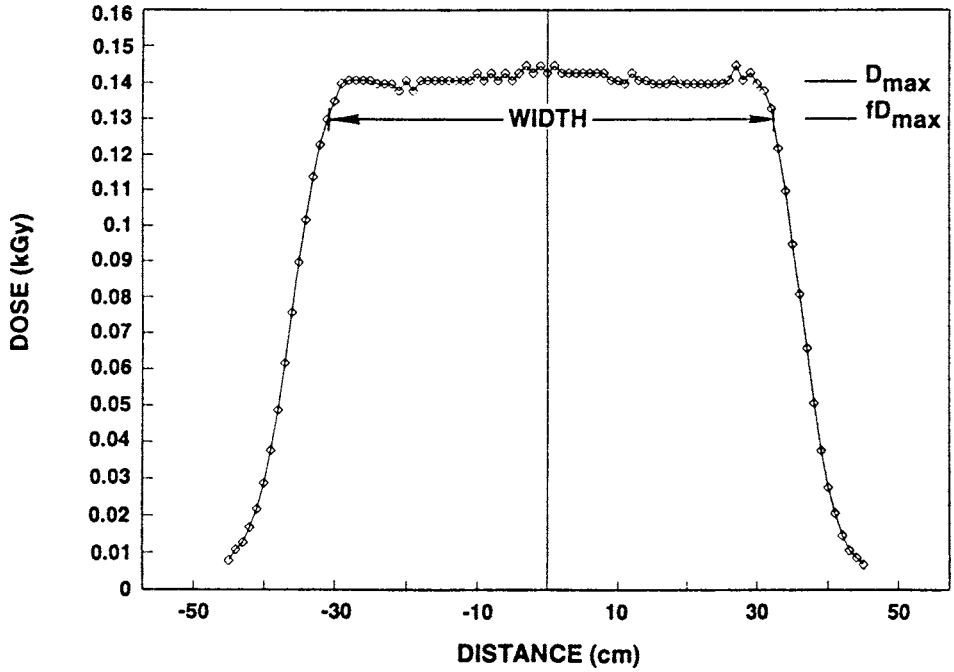
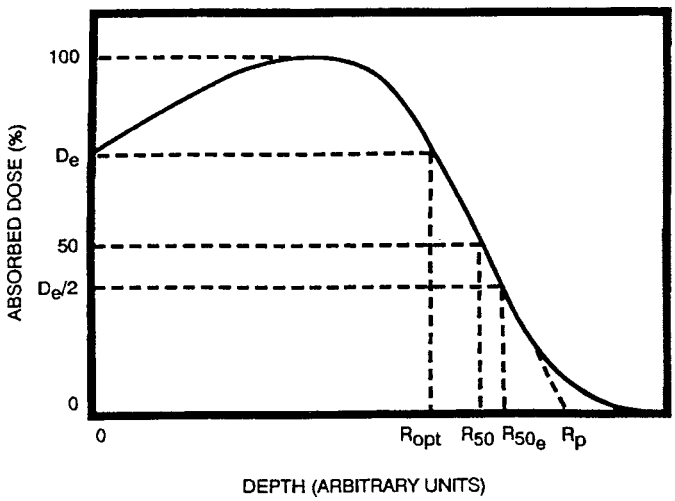


FIG. 3 Example of electron-beam dose distribution along the scan direction, where the beam width is specified at a defined fractional level *f* of the average maximum dose D_{max}



D_e: Dose at entrance surface
R_{opt}: Depth at which dose at descending part of curve equals D_e
R_{50}: Depth at which dose has decreased to 50 % of its maximum value
R_{50e}: Depth at which dose has decreased to 50 % of D_e
R_p: Depth where extrapolated straight line of descending curve meets depth axis

FIG. 4 A typical depth-dose distribution for an electron beam in a homogeneous material

3.1.20 *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.

3.1.20.1 *Discussion*—This position may be a location of minimum or maximum dose in the process load or it may be an alternate convenient location in, on or near the process load where the relationship of the dose at this position with the minimum and maximum dose has been established.

3.1.21 *simulated product*—material with radiation absorption and scattering properties similar to those of the product, material or substance to be irradiated.

3.1.21.1 *Discussion*—Simulated product is used during irradiator characterization as a substitute for the actual product, material or substance to be irradiated. When used in routine production runs in order to compensate for the absence of product, simulated product is sometimes referred to as compensating dummy. When used for absorbed-dose mapping, simulated product is sometimes referred to as phantom material.

3.1.22 *standardized depth (z)*—thickness of the absorbing material expressed as the mass per unit area, which is equal to the product of depth in the material t and density ρ.

3.1.22.1 *Discussion*—If m is the mass of the material beneath area A of the material through which the beam passes, then:

$$z = m/A = t\rho$$

The SI unit of z is in kg/m^2, however, it is common practice to express t in centimetres and ρ in grams per cm^3, then z is in grams per square centimetre. Standardized depth may also be referred to as surface density, area density, mass-depth or mass-thickness.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *beam power*—product of the average electron beam energy and the average beam current.

3.2.2 *beam spot*—shape of the unscanned electron beam incident on the reference plane.

3.2.3 *continuous-slowing-down-approximation (CSDA) range (r_0)*—average pathlength traveled by a charged particle

as it slows down to rest, calculated in the continuous-slowing-down-approximation method.

3.2.3.1 *Discussion*—In this approximation, the rate of energy loss at every point along the track is assumed to be equal to the total stopping power. Energy-loss fluctuations are neglected. The CSDA range is obtained by integrating the reciprocal of the total stopping power with respect to energy. Values of r_0 for a wide range of electron energies and for many materials can be obtained from ICRU Report 37.

3.2.4 *duty cycle (for a pulsed accelerator)*—fraction of time the beam is effectively on.

3.2.4.1 *Discussion*—Duty cycle is the product of the pulse width (w) in seconds and the pulse rate (f) in pulses per second.

3.2.5 *electron beam range*—penetration distance in a specific, totally absorbing material along the beam axis of the electrons incident on the material.

3.2.6 *extrapolated electron range (R_{ex})*—depth in homogeneous material to the point where the tangent at the steepest point (the inflection point) on the almost straight descending portion of the depth-dose distribution meets the depth axis (see Fig. A2.6 in Annex A2).

3.2.7 *half-entrance depth (R_{50e})*—depth in homogeneous material at which the absorbed dose has decreased to 50 % of its value at the entrance surface of the material (see Fig. 4).

3.2.8 *half value depth (R_{50})*—depth in homogeneous material at which the absorbed dose has decreased to 50 % of its maximum value (see Fig. 4).

3.2.9 *optimum thickness (R_{opt})*—depth in homogeneous material at which the absorbed dose equals its value at the entrance surface of the material (see Fig. 4).

3.2.10 *practical electron range (R_p)*—depth in homogeneous material to the point where the tangent at the steepest point (the inflection point) on the almost straight descending portion of the depth-dose distribution curve meets the extrapolated X-ray background (see Fig. 4 and Fig. A2.6 in Annex A2).

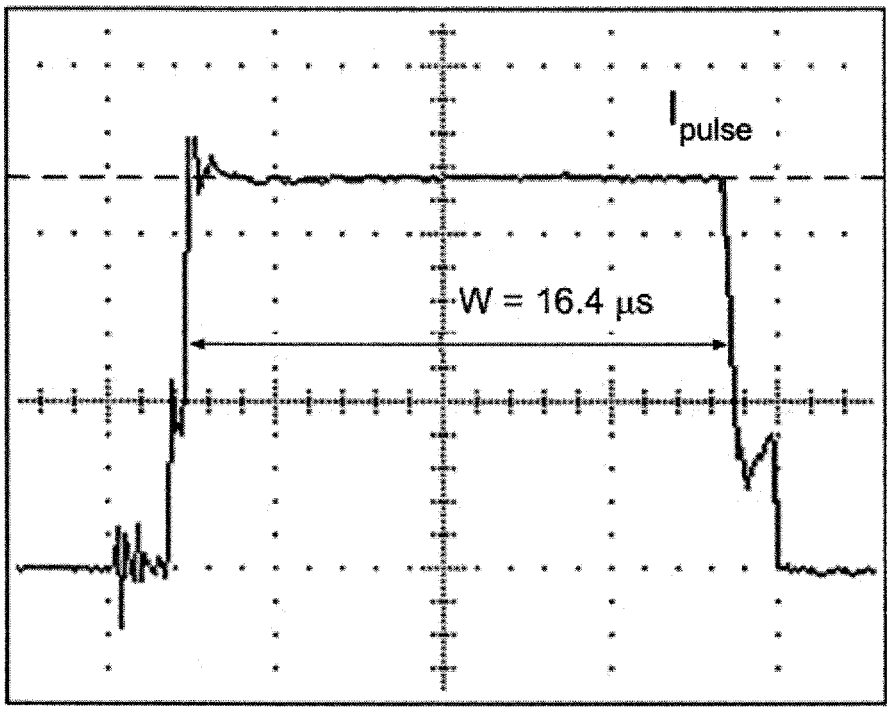
3.2.10.1 *Discussion*—Penetration can be measured from experimental depth-dose distributions in a given material. Other forms of electron range are found in the dosimetry literature, for example, extrapolated range derived from depth-dose data and the continuous-slowing-down-approximation range. Electron range is usually expressed in terms of mass per unit area ($kg \cdot m^{-2}$), but sometimes in terms of thickness (m) for a specified material.

3.2.11 *pulse beam current, for a pulsed accelerator*—beam current averaged over the top ripples (aberrations) of the pulse current waveform.

3.2.11.1 *Discussion*—Its value may be calculated as I_{avg}/wf, where I_{avg} is the average beam current, w is the pulse width, and f is the pulse rate (see Fig. 5).

3.2.12 *pulse rate (for a pulsed accelerator) (f)*—pulse repetition frequency in hertz, or pulses per second.

3.2.12.1 *Discussion*—This is also referred to as the repetition (rep) rate.



Horizontal axis: Time, µs
Vertical axis: Pulse beam current, mA

FIG. 5 Typical pulse current waveform from an S-Band linear accelerator

3.2.13 *pulse width (for a pulsed accelerator) (w)*—time interval between two points on the leading and trailing edges of the pulse current waveform where the current is 50 % of its peak value (see Fig. 5).

3.2.14 *scanned beam*—electron beam that is swept back and forth with a varying magnetic field.

3.2.14.1 *Discussion*—This is most commonly done along one dimension (beam width), although two-dimensional scanning (beam width and length) may be used with high-current electron beams to avoid overheating the beam exit window of the accelerator or product under the scan horn.

3.2.15 *scan frequency*—number of complete scanning cycles per second.

3.2.16 *scan uniformity*—degree of uniformity of the dose measured along the scan direction.

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

4. Significance and use

4.1 Various products and materials are routinely irradiated at pre-determined doses at electron beam facilities to preserve or modify their characteristics. Dosimetry requirements may vary depending on the radiation process and end use of the product. A partial list of processes where dosimetry may be used is given below.

4.1.1 Polymerization of monomers and grafting of monomers onto polymers,

4.1.2 Cross-linking or degradation of polymers,

4.1.3 Curing of composite materials,

4.1.4 Sterilization of health care products,

4.1.5 Disinfection of consumer products,

4.1.6 Food irradiation (parasite and pathogen control, insect disinfestation, and shelf-life extension),

4.1.7 Control of pathogens and toxins in drinking water,

4.1.8 Control of pathogens and toxins in liquid or solid waste,

4.1.9 Modification of characteristics of semiconductor devices,

4.1.10 Color enhancement of gemstones and other materials, and

4.1.11 Research on radiation effects on materials.

4.2 Dosimetry is used as a means of monitoring the irradiation process.

NOTE 2—Dosimetry with measurement traceability and known uncertainty is required for regulated radiation processes such as sterilization of health care products (see ISO 11137-1 and Refs (**1-3**[6])) and preservation of food (see ISO 14470 and Ref (**4**)). It may be less important for other processes, such as polymer modification, which may be evaluated by changes in the physical and chemical properties of the irradiated materials. Nevertheless, routine dosimetry may be used to monitor the reproducibility of the treatment process.

NOTE 3—Measured dose is often characterized as absorbed dose in water. Materials commonly found in single-use disposable medical devices and food are approximately equivalent to water in the absorption of ionizing radiation. Absorbed dose in materials other than water may be determined by applying conversion factors (**5**, **6**).

4.3 An irradiation process usually requires a minimum absorbed dose to achieve the desired effect. There may also be a maximum dose limit that the product can tolerate while still meeting its functional or regulatory specifications. Dosimetry is essential, since it is used to determine both of these limits during the research and development phase, and also to confirm that the product is routinely irradiated within these limits.

4.4 The dose distribution within the product depends on process load characteristics, irradiation conditions, and operating parameters.

4.5 Dosimetry systems must be calibrated with traceability to national or international standards and the measurement uncertainty must be known.

4.6 Before a radiation facility is used, it must be characterized to determine its effectiveness in reproducibly delivering known, controllable doses. This involves testing and calibrating the process equipment, and dosimetry system.

4.7 Before a radiation process is commenced it must be validated. This involves execution of Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ), based on which process parameters are established that will ensure that product is irradiated within specified limits.

4.8 To ensure consistent and reproducible dose delivery in a validated process, routine process control requires that documented procedures are established for activities to be carried out before, during and after irradiation, such as for ensuring consistent product loading configuration and for monitoring of critical operating parameters and routine dosimetry.

5. Radiation source characteristics

5.1 Electron sources considered in this practice are either direct-action (potential-drop) or indirect-action (Radio Frequency (RF) or microwave-powered accelerators. These are discussed in Annex A1.

6. Documentation

6.1 Documentation for the irradiation facility must be retained in accordance with the requirements of a quality management system. Typically, all facility related documentation is retained for the life of the facility, and product related documentation is related for the life of the product.

7. Dosimetry system selection and calibration

7.1 *Selection of dosimetry systems:*

7.1.1 ISO/ASTM 52628 identifies requirements for selection of dosimetry systems. Consideration shall specifically be given to the limited range of electrons which might give rise to dose gradients through the thickness of the dosimeter. By choosing thin film dosimeters this problem can be minimized.

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

7.1.2 When selecting a dosimetry system, consideration shall be given to effects of influence quantities on the response of the dosimeter (see ISO/ASTM 52701).

7.1.3 Different dosimetry systems may be selected for different dose measurement tasks due to different requirements on, for example, dosimetry systems for dose mapping and dosimetry systems for routine monitoring.

7.2 *Dosimetry system calibration:*

7.2.1 The dosimetry system shall be calibrated in accordance with ISO/ASTM 51261, and the user's procedures, which should specify details of the calibration process and quality assurance requirements.

7.2.2 The dosimetry system calibration is part of a measurement management system.

8. Installation qualification

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

8.2 The specification of the electron beam facility shall be documented in the agreement between the supplier and the operator of the facility. This agreement shall contain details concerning the following:

8.2.1 Operating procedures for the irradiator and associated conveyor system.

8.2.2 Test and verification procedures for process and ancillary equipment, including associated software, to verify operation to design specifications. The test method(s) shall be documented and the results shall be recorded.

8.2.3 Any modifications made to the irradiator during installation.

8.2.4 The characteristics of the electron beam (such as electron energy, average beam current, beam width and beam uniformity) shall be determined and recorded.

8.2.5 Specification for equipment for conveying product through the irradiation zone.

NOTE 4—The dose measurements carried out during IQ will often be the same as the ones carried out during Operational Qualification (OQ). Details of these dose measurements are given under OQ.

8.2.6 IQ typically involves measurements of beam penetration, beam width and beam width uniformity that can be used to estimate process throughput to verify the equipment performance specifications.

8.2.7 A dosimetry system calibration curve obtained by dosimeter irradiation at another facility with similar operating characteristics might be used for these dose measurements, but in order to ensure that the dose measurements are reliable, the calibration curve must be verified for the actual conditions of use.

NOTE 5—Calibration under the approximate conditions of use can only be accomplished after installation qualification and after establishment of process operating settings and appropriate process control procedures.

9. Operational qualification

9.1 Operational qualification (OQ) is carried out to characterize the performance of the irradiation equipment with respect to reproducibility of dose to product.

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.

NOTE 7—Multiple beam systems can be characterized individually or as the combined facility.

9.2 The relevant OQ dose measurements are described in more detail in Annex A2 – Annex A9. They typically include the following:

9.2.1 *Depth-dose distribution and electron beam energy estimation*—The depth-dose distribution is measured by irradiating dosimeters in a stack of plates of homogeneous material or by placing dosimeters or a dosimeter strip at an angle through a homogeneous absorber. See Annex A2 and Annex A3. Electron beam energy can be determined using established relationships between beam energy and depth-dose distribution parameters. The method used for energy calculation must be specified. See Annex A4.

9.2.2 *Dose as function of average beam current, beam width and conveyor speed*—Dose to the product irradiated in an electron beam facility is proportional to average beam current (I), and inversely proportional to conveyor speed (V) and to beam width (W_b), for a given electron beam energy. This relationship is valid for product that is conveyed through the radiation zone perpendicular to the beam width. This is expressed as:

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

where:

D = Absorbed dose (Gy),
I = Average beam current (A),
V = Conveyor speed (m s^{-1}),
Wb = Beam width (m), and
K = Slope of the straight line relationship in Eq 1 (Gy * m^2)/(A * 2).

In order to determine the relationship, dose shall be measured at a specific location and for a specific irradiation geometry using a number of selected parameter sets of beam current, conveyor speed and beam width to cover the operating range of the facility. See Annex A5.

9.2.3 *Beam width*—The beam width is measured by placing dosimeter strips or discrete dosimeters at selected intervals over the full beam width and at defined distance from the beam window. See Annex A6.

9.2.4 *Beam homogeneity:*

9.2.4.1 For scanned beams it shall be ensured that there is sufficient overlap between scans at the highest expected product speeds through the irradiation zone.

9.2.4.2 For scanned and pulsed beams it shall be ensured that there is sufficient overlap between beam pulses in the scan direction at the highest expected scan frequency and lowest expected pulse frequency.

9.2.4.3 For a pulsed and scanned beam it is necessary to have information about the beam diameter, because degree of overlap between scans and pulses can be calculated if the size and the shape of the beam spot are known. The beam spot can be measured by irradiating dosimeters or sheets of dosimeter film at defined distance from the beam window. See Annex A7.

9.2.5 *Dose distribution in reference material*—The distribution of dose in a homogeneous reference material shall be measured by placing dosimeters in a specified pattern within the material. See Annex A8.

9.2.6 *Process interruption*—A process interruption can be caused by, for example, failure of beam current delivery or the conveyor stoppage. The effect of a process interruption shall be determined, so that decisions about possible product disposition can be made. See Annex A9.

9.3 The measurements in 9.2 shall be repeated a sufficient number of times (three or more) to estimate the extent of the operating parameter variability based on a statistical evaluation of the dose measurements.

NOTE 8—An estimate of operating parameter variability can be obtained from the scatter between repeated dose measurements made at different times using identical operating parameter settings. This measured dose variability has two sources: dosimetry uncertainty and operating parameter variability, and it is generally difficult to separate these two components. Thus, the measured dose variability will often be a combination of the two.

9.3.1 Based on the estimated variability of the operating parameters, it can be determined if their specifications are met.

NOTE 9—The specifications may be adjusted as data from repeated OQ studies are accumulated.

9.4 *Requalification*—OQ measurements shall be repeated at intervals specified by the user's documented procedure, and following changes that might affect dose or dose distribution. The intervals shall be chosen to provide assurance that the facility 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 irradiator has changed from previous OQ measurements, then PQ might have to be repeated.

9.4.1 See Annex A11 for examples of changes that might lead to repeat of OQ.

10. Performance qualification

10.1 Performance Qualification (PQ) uses specific 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. Therefore, the objective of performance qualification is to establish all process parameters that will satisfy absorbed dose requirements. This is accomplished by establishing the dose distribution throughout the process load for a specific product loading pattern. Key process parameters include electron beam energy, beam current, material handling system parameters (conveyor speed or irradiation time), beam width, process load characteristics and irradiation conditions.

10.2 PQ dose mapping is carried out to demonstrate that product can be irradiated to doses required for the intended effect and the maximum acceptable dose. For PQ product dose mapping guidance, see ASTM Guide E2303.

NOTE 10—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. This may be allowed provided that the linear relationship in 9.2.2 has been demonstrated.

10.3 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 or in the case where no more than a single process load at a given time is processed at the facility. In most other cases, such as medical device sterilization, it is required to carry out specific PQ product dose mapping.

10.4 A loading pattern for product irradiation shall be established for each product type. The specification includes:

10.4.1 dimensions and bulk density of the process load,

10.4.2 composition of product and all levels of packaging,

10.4.3 orientation of the product within its package, and

10.4.4 orientation of the product with respect to the material handling system and beam direction.

10.5 Dosimeters shall be placed throughout the volume of interest (see ASTM Guide E2303). Placement patterns that can most probably identify the locations of the dose extremes shall be selected. Dosimeters shall be concentrated in areas expected to receive maximum and minimum doses, while fewer dosimeters might be placed in areas likely to receive intermediate absorbed dose. In addition, dosimeters are placed at the monitoring position(s) to be used in routine processing.

10.6 Dosimeters used for dose mapping shall be able to detect doses and dose gradients likely to occur within irradiated products. Dosimeter films in sheets or strips may be useful for obtaining this information.

NOTE 11—Irradiation of complex product, such as many medical devices, often produces dose gradients where dose may change by a factor of 10 or more within millimetre distances, such as for dose mapping small metal components. It is necessary to use dosimeter systems that can measure dose correctly under these conditions. This may involve use of thin film dosimeters that are analyzed on measurement equipment with high spatial resolution.

10.7 Some dosimeters are provided in protective packaging. For dose mapping it might be needed to use dosimeters without the protective packaging in order for the dosimeters to be placed in close proximity to product surfaces.

10.7.1 Using dosimeters without protective packaging may result in irradiation of the dosimeters under conditions that are different from the conditions of calibration. For such cases, it is essential to verify the validity of the calibration curve.

10.7.2 Verification of the calibration curve can be carried out by irradiating such un-packaged dosimeters and reference standard dosimeters together during dose mapping. It must be ensured that the two dosimeters received the same dose through the use of appropriate irradiation phantoms.

10.7.3 A correction factor to be applied to dose map results is determined from analysis of the irradiated dose map dosimeters and reference standard dosimeters.

10.8 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.

10.9 The ratio between maximum and minimum doses (dose uniformity ratio, DUR) should be calculated. If a routine monitoring location is used for process monitoring, then the ratios between the maximum and minimum dose and the dose

at the monitoring position should be calculated and documented. This ratio is used during process control (see 11.1.3).

10.10 PQ dose mapping measurements shall be repeated for a sufficient number of process loads to allow statistical evaluation and characterization of the dose distribution data.

NOTE 12—"A sufficient number of process loads" is often interpreted as a minimum of three. However, a higher degree of confidence in the measurement result is obtained by using a greater number of measurements.

10.11 For partially-loaded process loads, additional performance qualification shall be carried out as for fully-loaded process loads.

10.11.1 Variations to the dose distribution from partial loading may in some cases be minimized by filling the process load with simulated product.

NOTE 13—If simulated product is used, procedures must be in place to separate this from product after irradiation.

10.12 For irradiators used in a bulk flow mode, absorbed-dose mapping as described above may not be feasible. In this case, absorbed dose extremes may be estimated by using an appropriate number of dosimeters mixed with and carried by the product through the irradiation zone. Enough dosimeters should be used to obtain statistically significant results. Calculation of the absorbed dose extremes may be an appropriate alternative **(7, 8)**.

NOTE 14—In case the required doses are not met with the values of the operating parameters used for the dose map study, the parameters may be scaled in order to achieve the required doses provided that the linear relationship in 9.2.2 has been demonstrated. There may be cases where values of operating parameters for dose mapping are intentionally chosen to fit a specific dosimetry system.

10.13 Repeat of PQ dose mapping is needed if product is changed, thus affecting dose or dose distribution significantly, or if OQ measurements show that the irradiation facility is changed. The rationale for decisions taken shall be documented.

10.14 *Dose Mapping for Irradiation at High or Low Temperatures:*

10.14.1 Some applications require irradiation at temperatures different from the dosimeter calibration temperature, such as irradiation of frozen food or irradiation of pharmaceutical products at liquid nitrogen in order to reduce adverse radiation effects on the product.

10.14.2 For these applications, absorbed-dose mapping may be performed with simulated or real product at a temperature where dosimetry results will not be affected.

NOTE 15—This requires that there be no change in any parameter (other than temperature) that may affect the absorbed dose during processing of the heated or cooled product.

10.14.3 During routine processing of product where product is maintained at higher or lower temperatures during irradiation, dosimeters are only placed at a routine monitoring position that is insulated from the effects of temperature of the product.

10.14.4 Dose mapping of a product may be performed at the actual product temperature, using a dosimetry system that is calibrated at the intended processing temperature.

10.15 *Unacceptable Dose Uniformity Ratio:*

10.15.1 If the dose mapping reveals that the minimum or maximum, or both, doses during processing will be unacceptable, it may be possible to change the process parameters to reduce the dose uniformity ratio to an acceptable level. Alternatively, it may be necessary to change the product configuration within the process load or the shape, size, or flow pattern of the process load itself.

10.15.2 Changing the beam characteristics, for example, by optimizing the electron beam energy, can change the dose extremes. Other means to change the dose extremes may be employed, such as use of attenuators, scatterers and reflectors.

10.15.3 Irradiation from two sides is often used to achieve an acceptable dose distribution. For two-sided irradiation, the magnitudes and locations of dose extremes are usually quite different from those for single-sided irradiation. Slight fluctuations in density or thickness of product within the process load or fluctuations in electron beam energy may cause more pronounced changes in absorbed dose and its distribution within the product for two-sided irradiation as compared to single-sided irradiation.

10.15.4 Irradiation from more than two sides may be used to further reduce the dose uniformity ratio.

10.15.5 For some cases, a redesign of the process load may be needed to achieve an acceptable dose uniformity ratio.

11. Routine process control

11.1 For routine product processing, process parameters shall be selected as established during performance qualification. The average beam current *I* and the conveyor speed *V* may be set in such a way that the quotient *I/V* has the same value in performance qualification and routine product processing.

NOTE 16—This means that if, for example, the beam current is lowered by 20 % the process speed has to be decreased by the same percentage in order to deliver the same absorbed dose.

11.1.1 The operating parameters (beam energy, beam current, beam width and conveyor speed) shall be monitored and recorded during the process. The measuring intervals shall be chosen to provide assurance that the facility is consistently operating within specifications.

NOTE 17—Electron beam energy, electron beam current and beam width are usually not routinely measured directly, but are obtained through indirect measurements.

11.1.2 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 that the irradiator operates within specifications, and thereby ensuring that the product specifications were achieved.

NOTE 18—It is common practice to place dosimeters – as a minimum – at start and end of a production run. More frequent placement of dosimeters during the production run may reduce the risk of discarding product should some operational failure arise.

NOTE 19—Some processes, such as the modification of material properties, may not require dosimetry.

11.1.3 Acceptance limits for the variation of the monitored operating parameters (11.1.2) and measured routine dose (11.1.3) shall be established.

11.2 Procedures shall be in place describing actions to be taken in case monitored operating parameters or measured routine doses exceed specifications.

11.3 For some types of bulk-flow irradiators (for example, where fluids or grains continuously flow during irradiation), it is not feasible to place dosimeters at the locations of minimum or maximum absorbed dose or at defined routine monitoring position during routine processing. In these cases, several dosimeters shall be added to the product stream at the beginning, the middle, and near the end of the production run. Each set of absorbed-dose measurements requires several dosimeters to ensure, within a specified level of confidence, that the minimum (and maximum, if a prescribed limit) absorbed dose has been delivered. This procedure requires that the rate of flow and flow pattern of the dosimeters are the same as those of the product.

NOTE 20—In case it is not feasible to utilize dosimeters during the routine processing of bulk materials, it may be acceptable to rely on operating parameter control or product end point analysis. For some processes, it may be sufficient to determine the average dose and the maximum and minimum doses in process experiments using samples of the material to be irradiated or dummy products. Calculation of dose extremes may also be acceptable. The consistency of the dose distribution can be ensured by monitoring all of the critical operating parameters and by repeating the performance qualification procedure at appropriate intervals.

11.4 *Radiation-Sensitive Indicators*—Radiation-sensitive indicators can be used for quality control and for inventory purposes. For multiple irradiations, one indicator may be affixed before each pass on the side facing the electron beam to give visual evidence of the number of passes the process load has traversed. However, the use of radiation-sensitive indicators is not a substitute for dosimetry. For information on use of radiation-sensitive indicators, see ISO/ASTM Guide 51539.

11.5 *Process Interruption*—If there is a planned or unplanned process interruption, for example due to power loss, its implication on the process (for example, dose uniformity) and the product (for example, impact of time delay) shall be evaluated.

12. Certification

12.1 *Documentation:*

12.1.1 *Equipment Documentation*—Record or reference the calibration and maintenance of equipment and instrumentation used to control and measure the absorbed doses delivered to the product.

12.1.2 *Process Parameters*—Record the values of the process parameters (see 11.1) affecting absorbed dose together with sufficient information identifying these parameters with specific production runs.

12.1.3 *Dosimetry Data*—Record and document all dosimetry results for installation qualification, operational qualification, performance qualification, and routine product processing. Include date, time, product type, product loading diagrams, and absorbed doses for all products processed.

12.1.4 *Dosimetry Uncertainty*—Include estimates of the measurement uncertainty of absorbed dose (see Section 13) in records and reports, as appropriate.

12.1.5 *Facility Log*—Record the date the product lot is processed and the starting and the ending times of the irradiation run. Record the name of the operator, as well as any special conditions of the irradiator or the facility that could affect the absorbed dose to the product.

12.1.6 *Product Identification*—Ensure that each product lot that is processed bears an identification that distinguishes it from all other lots in the facility. This identification shall be used on all lot documents.

12.2 *Review and Certification:*

12.2.1 Prior to release of product, review routine dosimetry results and recorded values of the operating parameters to verify compliance with specifications.

12.2.2 Approve and certify the absorbed dose to the product for each production run, in accordance with an established facility quality assurance program. Certification shall be performed by authorized personnel, as documented in the quality assurance program.

12.2.3 Audit all documentation at time intervals specified in the quality assurance program to ensure that records are accurate and complete. If deficiencies are found, ensure that corrective actions are taken.

12.3 *Retention of Records:*

12.3.1 File all information pertaining to each production lot together, for example, copies of the shipping document, certificates of irradiation, and the records of the irradiation control record. Retain the files for the period of time specified in the quality assurance program and have the files available for inspection as needed.

13. Measurement uncertainty

13.1 All dose measurements need to be accompanied by an estimate of uncertainty (JCGM 100, 1995). Appropriate procedures are recommended in ISO/ASTM Guide 51707 and Practice 51261.

13.1.1 All components of uncertainty shall be included in the estimate, including those arising from calibration, dosimeter variability, 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.

14. Keywords

14.1 absorbed dose; dose mapping; dosimeter; dosimetry system; electron beam; ionizing radiation; irradiation; irradiator characterization; radiation; radiation processing

ANNEXES

(informative)

A1. TYPES OF ELECTRON BEAM FACILITIES

A1.1 *Electron Beam Facility Design*:

A1.1.1 The design of an irradiation facility affects the delivery of absorbed dose to a product. Therefore, the facility design should be considered when performing the absorbed-dose measurements required for IQ, OQ, PQ and routine monitoring.

A1.1.2 An electron beam facility includes the electron beam accelerator system, material handling systems, a radiation shield with personnel safety system, product staging, loading and storage areas; auxiliary equipment for power, cooling, ventilation, etc., equipment control room, laboratories for dosimetry and product testing, and personnel offices. The electron beam accelerator system consists of the radiation source, equipment to disperse the beam on product, control system, and associated equipment (**1**).

A1.1.3 *Type of Accelerator:*

A1.1.3.1 Commonly used industrial electron accelerators may be classified as direct action or indirect action accelerators. Direct action (also called potential drop) accelerators can deliver beams typically up to 5 MeV. Indirect action accelerators, such as microwave or radio frequency powered accelerators, extend to higher energies.

A1.1.4 *Characteristics of Microwave-powered Accelerators* (**9-15**)*:*

A1.1.4.1 Electrons are introduced into an accelerator structure (also referred to as an "accelerating waveguide") from an injector. The electrons are accelerated to the final energy through the accelerating structure. Power for beam acceleration is provided by a pulsed microwave, high-frequency generator. The resonant frequency of the accelerator structure is usually in the 1300 to 3000 MHz range. Microwave power is usually provided by a klystron amplifier.

A1.1.4.2 The accelerating structure is a high-power microwave waveguide with resonating cavities where the phase velocity of the microwaves is less than the speed of light.

A1.1.4.3 The electron beam energy depends upon the microwave power level, and the injected electron beam current.

A1.1.4.4 The electron beam is typically pulsed.

NOTE A1.1—For pulsed accelerators using a scanned beam, the relationship between the beam pulse rate frequency, the scan frequency, and the transport speed may affect the distribution of the delivered dose. Improper coordination of these parameters can cause unacceptable dose variation (see 9.2.4 and Annex A7).

A1.1.5 *Characteristics of Radio-Frequency-Powered Accelerators* (**16, 17**)*:*

A1.1.5.1 Electrons are introduced into the accelerator from an injector. The electrons are accelerated to the final energy by passing through the accelerating structure. Power for beam acceleration is provided by a pulsed or continuous-wave (cw) radio-frequency (rf) generator using a vacuum tube, that is, a triode or a tetrode.

A1.1.5.2 The accelerating structure is usually a single resonant cavity, but more than one cavity can be used to achieve higher electron energy. The electrons can also gain higher energy by passing repeatedly through the same cavity. The resonant frequency is usually in the 100 to 200 MHz range.

A1.1.5.3 The electron beam energy depends upon the strength of the rf electric field, the rf power level and the injected electron beam current. Electron energies commonly produced by rf powered accelerators are in the range of 1 to 10 MeV.

A1.1.6 *Characteristics of Potential-drop Accelerators* (**14, 15**)*:*

A1.1.6.1 Electrons are introduced into the accelerator from an injector. The electrons are accelerated to the final energy through a potential (voltage) difference. The injector is located in a terminal held at a negative potential corresponding to the final electron energy. The electrons are accelerated toward ground potential.

A1.1.6.2 The electron beam may consist of constant direct current (dc) or pulsed current.

A1.1.6.3 The energy of the electrons is primarily controlled by the potential on the terminal produced by dc or pulsed high-voltage generators to create strong electric fields. Electron energies commonly produced by potential drop accelerators in use today for radiation processing are 5 MeV and less, although electrostatic accelerators can produce energies up to 25 MeV.

A1.1.6.4 The injector, high-voltage terminal, and terminal charging equipment are located in a large pressure vessel, which is filled with insulating gas or liquid to prevent electrical breakdown. The most powerful systems utilize cascaded rectifier circuits to convert low-voltage alternating current (ac) to high-voltage direct current (dc) power.

A1.1.7 *Material Handling:*

A1.1.7.1 Absorbed dose distributions within product may be affected by the material handling system. Examples of systems commonly used are:

A1.1.7.2 *Conveyors or Carriers*—Material is placed upon carriers or conveyors for passage through the electron beam. The speed of the conveyor or carriers is controlled in conjunction with the electron beam current and beam width so that the required dose is applied. The dose is also dependent on the number of passes the product goes through the beam.

A1.1.7.3 *Roll-to-Roll Feed System*—Roll-to-roll (also referred to as reel-to-reel) feed systems are used for tubing, wire, cable, and continuous web products. The speed of the system is controlled in conjunction with the electron beam current and beam width so that the required dose is applied. Dose is also dependent on the way product is configured during irradiation and the number of times the product goes through the beam.

A1.1.7.4 *Bulk-flow System*—For irradiation of liquids or particulate materials like grain or plastic pellets, bulk-flow transport through the irradiation zone may be used. Because

the flow velocity of the individual pieces of the product cannot be controlled, the average velocity of the product in conjunction with the beam characteristics and beam dispersion parameters determines the average absorbed dose.

A1.1.7.5 *Stationary*—For high-dose processes, the material may be placed under the beam and not moved. Cooling may be required to dissipate the heat accumulated by the product during processing. The irradiation time is controlled in conjunction with the electron beam current, beam length, and beam width to achieve the required dose.

A1.1.7.6 For facilities utilizing continuously-moving conveyors (including, for example, roll-to-roll feed systems and bulk flow systems to transport product through the irradiation zone), conveyor or product speed determines the irradiation time. Therefore, when other operating parameters are held constant, conveyor speed determines the absorbed dose to the product.

NOTE A1.2—The conveyor speed and the beam current may be linked so that a variation in one causes a corresponding change in the other to maintain a constant value of the absorbed dose.

A1.1.7.7 For those facilities that irradiate products while they are stationary in the irradiation zone, irradiation time determines the absorbed dose to the product when other operating parameters are held constant.

A1.1.8 *Conditions Affecting Absorbed Dose*—The absorbed dose within a process load depends in part on the operating parameters: beam characteristics, beam dispersion parameters, material handling, and their inter-relationships. It also depends on process load characteristics and irradiation conditions. These operating parameters are controlled by various accelerator and other facility parameters.

A1.1.9 *Beam Characteristics:*

A1.1.9.1 The two principal beam characteristics that affect absorbed dose are the electron energy spectrum, and average beam current. The electron energy spectrum affects the depth-dose distribution within the product (see Annex A2). The average beam current, in addition to several other operating parameters, affects the average dose rate.

A1.1.9.2 Beam characteristics of importance include:

(1) Electron beam energy,
(2) Average beam current,
(3) Peak beam current (for pulsed accelerators),
(4) Average beam power,
(5) Peak beam power (for pulsed accelerators),
(6) Duty cycle (for pulsed accelerators),
(7) Pulse (or repetition or rep) rate,
(8) Pulse width (for pulsed accelerators), and
(9) Beam dimensions.

NOTE A1.3—The electron energy spectrum of the incident electron beam may be characterized by the average electron beam energy (E_a) and the most probable electron beam energy (E_p) (see Annex A3). An energy-analyzing magnet may be used for a detailed analysis of the energy spectrum.

NOTE A1.4—The energy spectrum of the beam delivered to the product may be further influenced by an electromagnet which bends the beam at a specific angle for a specific current supplied to the electromagnet. Electrons outside the acceptable energy range are absorbed by collimators in the bending system.

A1.1.10 *Beam Dispersion:*

A1.1.10.1 Dispersion of the electron beam spot to obtain a beam width to adequately cover the processing zone may be achieved by various techniques. These include electromagnetic scanning of a pencil beam or use of defocussing elements or scattering foils.

A1.1.10.2 Beam dispersion measurements of importance include:

(1) Beam width,
(2) Beam length,
(3) Variation of dose along the beam width and length, and
(4) Beam centering with respect to the irradiation zone.

NOTE A1.5—The beam width, in addition to several other operating parameters, affects the dose rate. For a pulsed accelerator, scanning of a pencil beam can produce pulsed dose at points along the beam width. This can influence the dosimeters' performance when they are sensitive to dose rate variations (see Annex A2).

A1.1.11 *Facility Description*—The following should be included in a description of an electron beam facility:

A1.1.11.1 The accelerator specifications and characteristics.

A1.1.11.2 Description of the construction and the operation of any associated material handling equipment.

A1.1.11.3 Description of the process control system and personnel safety system.

A1.1.11.4 Description of the location of the irradiator within the operator's premises.

A1.1.11.5 Description of the means for segregation of non-irradiated products from irradiated products, if required.

A1.1.11.6 Description of the construction materials and dimensions of containers used to hold products during irradiation, if used.

A1.1.11.7 Irradiator operating procedures.

A1.1.12 *Temperature Rise:*

A1.1.12.1 Irradiation causes the temperature of the treated material to increase. In high-dose processes with high-power electron beams, the temperature rise may have to be controlled by cooling the material during continuous irradiation or by multiple irradiations with cooling between each irradiation.

A1.1.12.2 Neglecting energy transformations from chemical reactions and any convective, conductive, or radiant cooling, the adiabatic temperature increase in the irradiated product ΔT is given by:

$$\Delta T = D_a / c \qquad \text{(A1.1)}$$

where, D_a is the average dose [Gy] for the irradiated material, and c is the specific heat capacity of the material [J/(kg·K)]. Most plastics and metals have lower specific heat capacity than water, so their temperature rise will be greater than that for water for the same dose.

A2. ELECTRON BEAM DEPTH-DOSE DISTRIBUTIONS

A2.1 Scope

A2.1.1 This annex describes depth-dose distribution in homogeneous materials for different electron beam energies.

A2.2 Depth-dose distribution

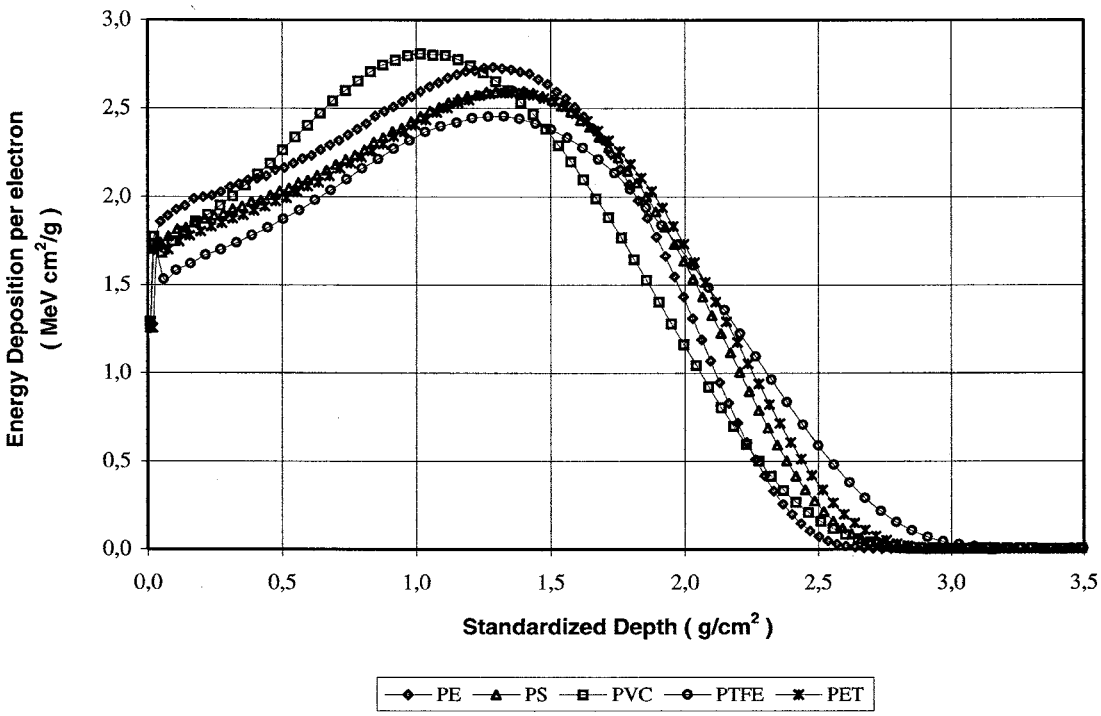
A2.2.1 Depth-dose distributions presented in this annex, except where noted, are calculated for monoenergetic electron beams. Experimentally determined distributions may differ from these calculated ones, because the electron beam may not be monoenergetic. Additionally, scanned electron beams may exhibit varying energy spectra along the scan direction.

A2.2.2 Electron beam irradiation of homogeneous materials produces depth-dose distributions that tend to rise with increasing depth within the material to about the midpoint of the electron range and then rapidly fall to low values. The shape of the depth-dose distribution is determined by collisions of primary and secondary electrons with atomic electrons and nuclei in the absorbing material. So, the shape is dependent on the atomic composition of the material (**18-21**). This is illustrated in Figs. A2.1 and A2.2 which present theoretically calculated depth-dose distributions for polyethylene (PE), polystyrene (PS), polyvinylchloride (PVC), polytetrafluoroethylene (PTFE), Polyethylene therapthalate (PET), carbon (C), aluminum (Al), iron (Fe) and Tantalum (Ta) with 5 MeV monoenergetic electrons (**19, 21**).

A2.2.3 The depth of penetration (electron range) is nearly proportional to the incident electron beam energy. This is shown in Figs. A2.3-A2.5 which present the Monte Carlo calculated depth-dose distributions for polystyrene irradiated with monoenergetic electrons from 300 keV to 12 MeV. The vertical axis in Figs. A2.1-A2.6 shows the energy deposition per incident electron in units of MeV per unit thickness in g/cm^2. These are the units used in the output data file of the Monte Carlo program (**19**). When the electron beam current and the area throughput rate of an irradiation process are known, these physical units can be converted to practical absorbed dose units (Gy). For details see Appendix 4.8 of Guide E2232. The equivalent thicknesses of the beam window and the intervening air space are also shown on the depth coordinates. The effects of the window and air space are important below 1 MeV, but become insignificant as the energy increases.

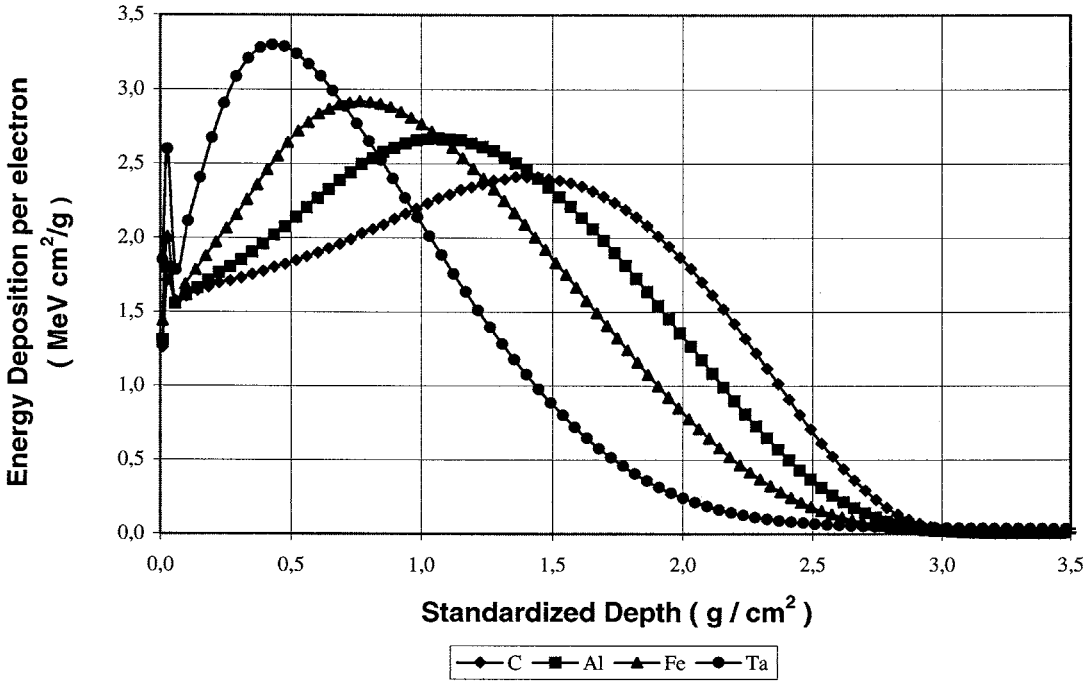
NOTE A2.1—The depth-dose distributions in Figs. A2.1-A2.6 have been calculated for normal incidence of monoenergetic electrons on flat sheets of homogeneous materials using the ITS 3 Monte Carlo Transport Code (**19**). Other simpler programs can also be used for this purpose (**22, 23**). The use and selection of mathematical models for calculating absorbed dose in radiation processing applications is discussed in ASTM Guide E2232.

A2.2.4 X-radiation (bremsstrahlung) is created when electrons are decelerated in material. This radiation contributes to



NOTE 1—The window is assumed to be 4 × 10^{-5} m thick titanium (0.018 g/cm^2) followed by 0.15 m of air (0.018 g/cm^2). The first Monte Carlo calculated data point of each curve represents the energy deposition in the titanium window and the second data point of each curve represents the energy deposition in the air space. The third data points correspond to the energy desposition at the surface of the irradiated material.

FIG. A2.1 Calculated depth-dose distributions in various homogeneous polymers for normally incident 5.0 MeV (monoenergetic) electrons using the Program ITS3 (19, 21)



NOTE 1—The window is assumed to be 4×10^{-5} m thick titanium (0.018 g/cm^2) followed by 0.15 m of air (0.018 g/cm^2). The first Monte Carlo calculated data point of these curves represents the energy deposition in the titanium window and the second set of data points represents the energy deposition in the air space. The third data points correspond to the energy deposition at the surface of the irradiated material.

FIG. A2.2 Calculated depth-dose distributions in various homogeneous materials for normally incident 5.0 MeV (monoenergetic) electrons using the Program ITS3 (19, 21)

the depth-dose distribution. Fig. A2.6 illustrates the X-ray contribution in the tail of the Monte Carlo calculated curve (**24**). For electrons with energies below 10 MeV which are incident on materials with low atomic numbers, for example, organic compounds, this effect is usually insignificant. In such cases R_{ex} and R_p are essentially the same, and R_p is commonly used to express both quantities.

A2.2.5 The maximum thickness of homogeneous material that can be treated at a given electron energy depends on the acceptable value of dose uniformity ratio within the material. For electron treatment from one side of the material, the optimum thickness R_{opt} will give an exit dose equal to the entrance dose, provided that the backing material has similar composition (see A2.2.8). For treatment from two opposite sides, the maximum thickness may be more than twice R_{opt} for the same dose uniformity ratio because of the overlapping tails of the depth-dose curves (refer to Figs. 29–31 of Ref (**4**) for additional information).

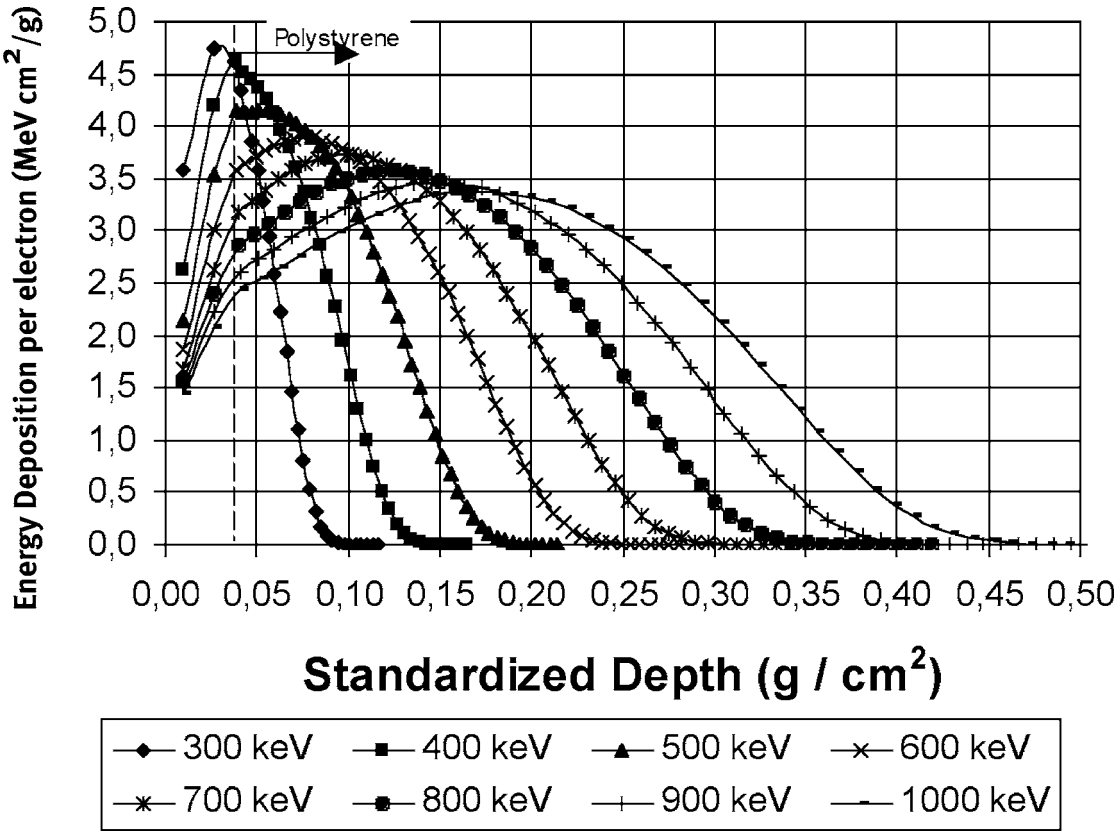
NOTE A2.2—If the material thickness is twice the optimum thickness, R_{opt}, for single-sided treatment, then the total dose in the middle of the material with double-sided treatment will be almost twice the entrance dose (see Fig. A2.7).

NOTE A2.3—If the material thickness is twice the half-value depth, R_{50} (an exit dose equal to half the maximum dose with single-sided treatment), then the total dose in the middle of the material with double-sided treatment will be approximately equal to the maximum dose with single-sided treatment (see Fig. A2.7).

NOTE A2.4—If the material thickness is twice the half-entrance depth, R_{50e} (an exit dose equal to half the entrance dose with single-sided treatment), then the total dose in the middle with double-sided treatment will be nearly equal to the entrance dose (see Fig. A2.7). For thicknesses greater than two times R_{50e}, the dose uniformity ratio will dramatically increase with increasing thickness as the dose at the center will progressively decrease.

A2.2.6 The correlations between the incident electron beam energy and various range parameters, such as optimum thickness R_{opt}, half-value depth R_{50}, half-entrance depth R_{50e}, and the practical range R_p are shown in Figs. A2.8 and A2.9 (**20**). These values have been obtained from the calculated depth-dose distribution curves for polystyrene shown in Figs. A2.3-A2.5. The energy dependence of these thickness parameters is nearly linear from 1 to 12 MeV.

A2.2.7 Fig. A2.10 presents measured depth-dose distributions for two nominal 10 MeV electron beams incident on homogeneous polystyrene (**26, 27**). These curves are provided by accelerator manufacturers and electron beam facility operators. Important parameters influencing the curves are presented in Table A2.1. There are noticeable differences between these measured curves and the theoretical 10 MeV curve presented in Fig. A2.5. This illustrates the caution that must be taken when comparing theoretical curves to measured curves. Characteristics of the measured curves are influenced, for example, by the accuracy of the dosimetry system used, energy spectrum of the electron beam, and accuracy of the estimated nominal electron beam energy. The broad electron energy spectrum of typical linear accelerators causes the peak dose and the half-value dose to occur at slightly reduced depths in comparison to a monoenergetic beam. However, the practical or extrapolated range values are less affected by a broader energy spectrum. See ICRU Report 35.



NOTE 1—The window is assumed to be 4×10^{-5} m thick titanium (0.018 g/cm^2) followed by 0.15 m of air (0.018 g/cm^2). The first Monte Carlo calculated data point of these curves represents the energy deposition in the titanium window and the second set of data points represents the energy deposition in the air space. The third data points correspond to the energy deposition at the surface of the irradiated material.

FIG. A2.3 Calculated depth-dose distributions in polystyrene for normally incident electrons at monoenergetic energies from 300 to 1000 keV using the Program ITS3 (19, 20)

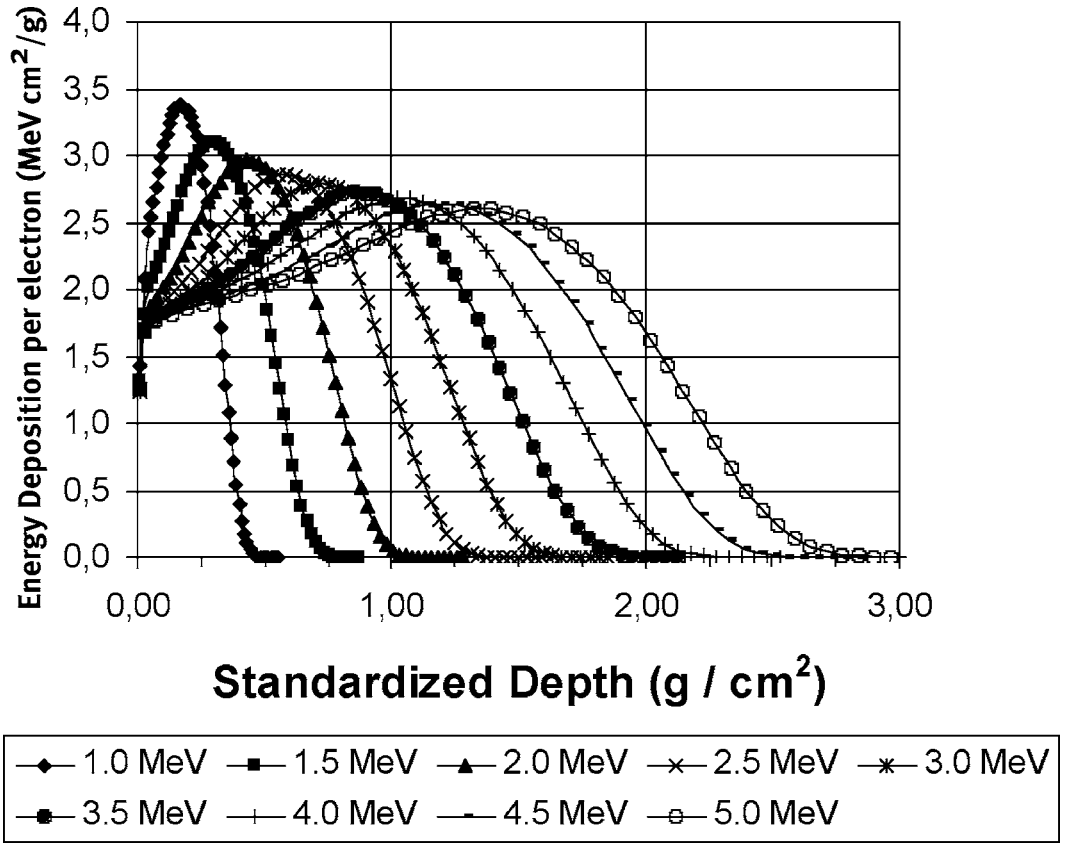
A2.2.8 If the material thickness is less than the maximum range of the electrons, the dose near the exit surface is affected by the composition of the backing material. This is caused by backscattering of electrons from the backing material. This effect can be measured or it can be estimated with the EDMULT program (**22, 23**) or Monte Carlo programs (**19, 28, 29**).

A2.2.8.1 With backing materials of higher effective atomic number than the irradiated material, the exit dose will be higher than that indicated by the depth-dose distribution curves for thick absorbers. This is illustrated in Fig. A2.11 which presents measured depth-dose distributions with 400 keV electrons in stacks of cellulose acetate films backed with wood, aluminum, and iron (**30**). The effective atomic numbers of wood (cellulose), aluminum and iron are 6.7, 13, and 26, respectively.

A2.2.8.2 With backing materials of lower effective atomic number than the irradiated material, the exit dose will be lower than indicated by the depth-dose distributions for thick absorbers (**31**).

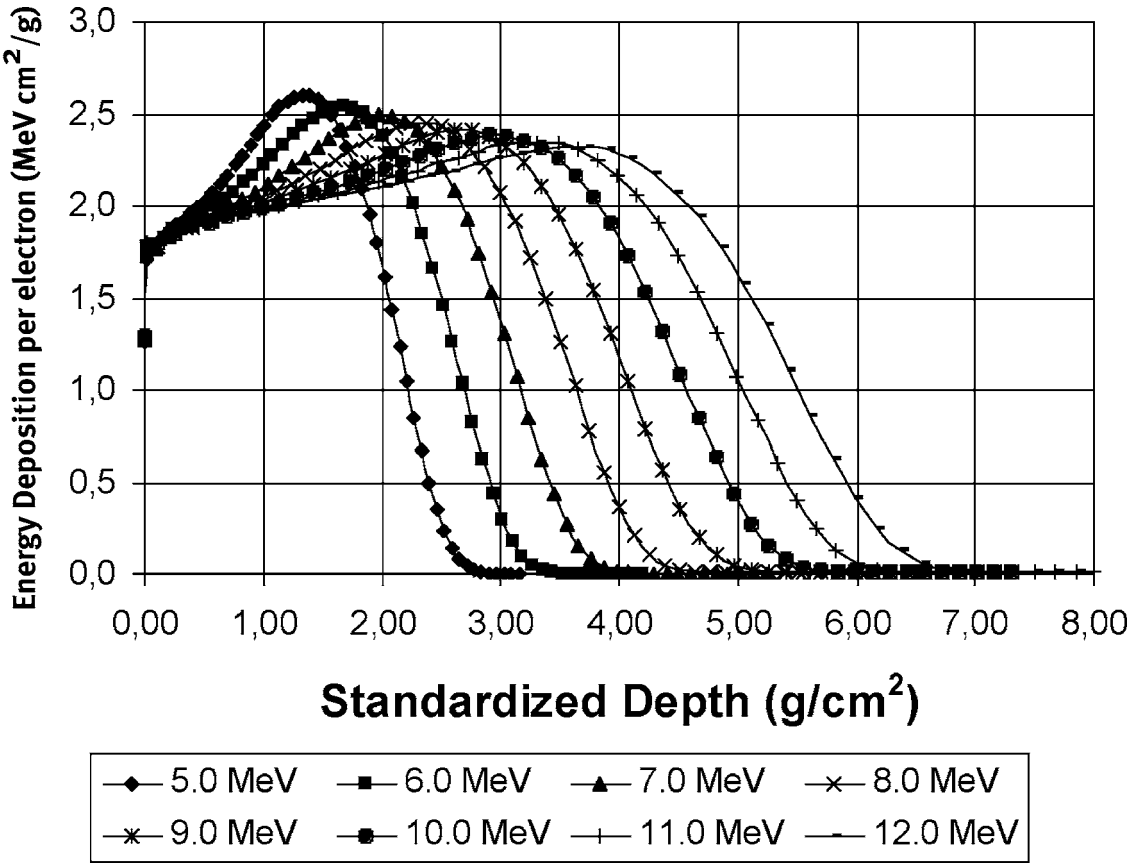
A2.2.9 If the incident angle of the electron beam is not normal (perpendicular) to the surface of the material, then the shape of the depth-dose distribution curve will be modified. This is shown in Fig. A2.12 which presents measured depth-dose distribution curves with 2 MeV electrons incident on polystyrene absorbers at angles of 0°, 15°, 30°, 45°, 60°, and 75° from the normal direction. With each incident angle, the depth-dose distributions were measured in a direction perpendicular to the entrance surface of the material (**31**).

A2.2.10 With heterogeneous materials, such as medical devices or molded parts, the dose distributions will be affected by the shapes and orientations of the objects and by the air spaces between them. Therefore, the relationships given above for homogeneous materials are not applicable in such cases and the dose distributions must be measured using the procedures described in Section 10.



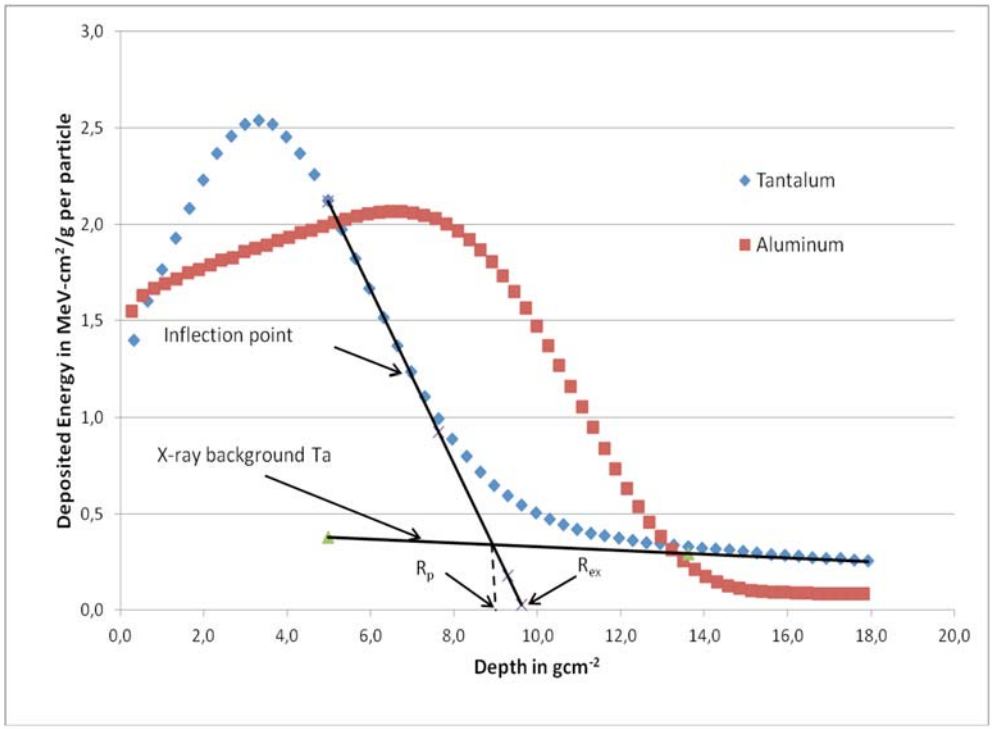
NOTE 1—The window is assumed to be 4×10^{-5} m thick titanium (0.018 g/cm^2) followed by 0.15 m of air (0.018 g/cm^2). The first Monte Carlo calculated data point of these curves represents the energy deposition in the titanium window and the second set of data points represents the energy deposition in the air space. The third data points correspond to the energy deposition at the surface of the irradiated material.

FIG. A2.4 Calculated depth-dose distributions in polystyrene for normally incident electrons at monoenergetic energies from 1.0 to 5.0 MeV using the program ITS3 (19, 20)



NOTE 1—The window is assumed to be 4×10^{-5} m thick titanium (0.018 g/cm^2) followed by 0.15 m of air (0.018 g/cm^2). The first data point of these curves represents the energy deposition in the titanium window and the second set of data points represents the energy deposition in the air space. The third data points correspond to the energy deposition at the surface of the irradiated material.

FIG. A2.5 Calculated depth-dose distributions in polystyrene for normally incident electrons at monoenergetic energies from 5.0 to 12.0 MeV using the program ITS3 (19, 20)



NOTE 1—The X-ray background and the definitions of electron range R_{ex} and R_p using the tangent through the inflection point are illustrated.

FIG. A2.6 Calculated depth-dose distributions in Al and Ta for normally incident electrons at a monoenergetic energy of 25 MeV using the program ITS3 (19, 24)

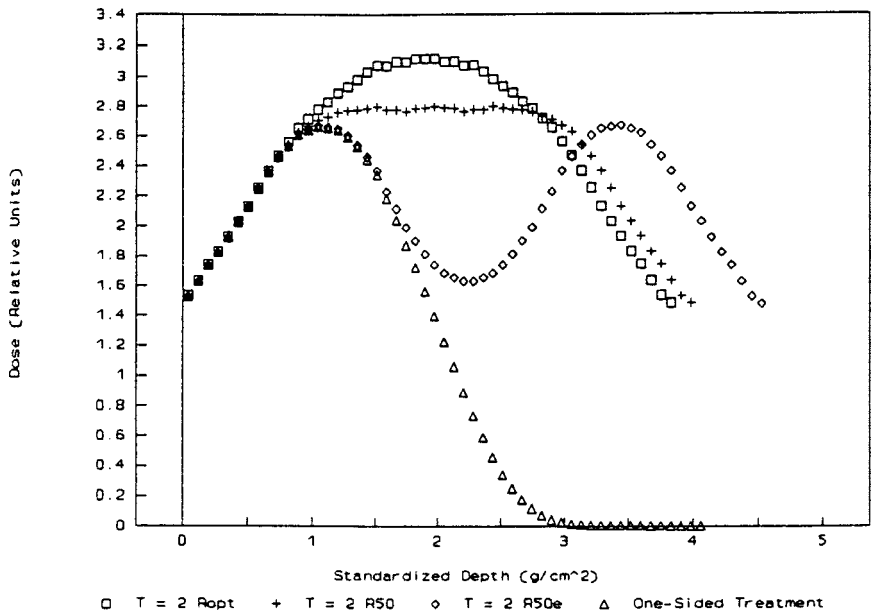
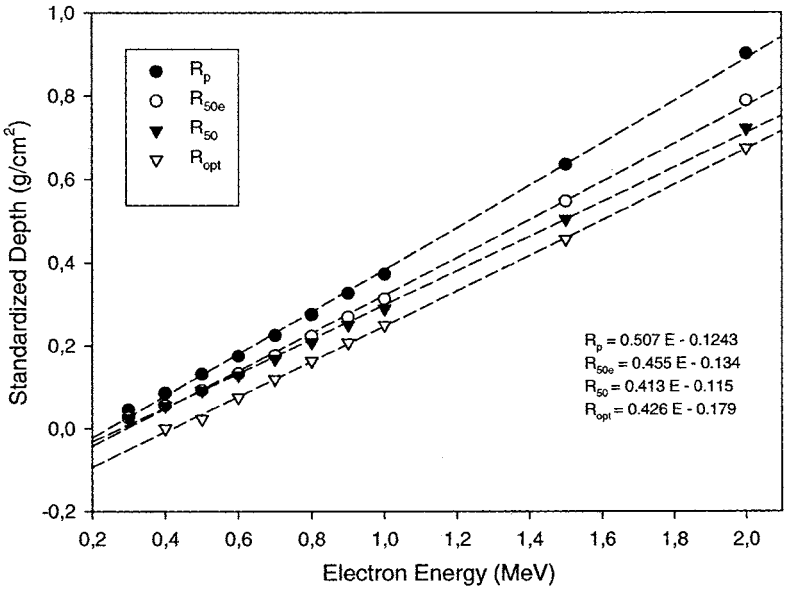


FIG. A2.7 Superposition of calculated depth-dose distributions for aluminum irradiated with 5-MeV monoenergetic electrons from both sides with different thicknesses (*T*) and from one side using experimental data presented in Refs (18 and 25) (see Notes A2.2-A2.4)



NOTE 1—Nearly equivalent relationships may be expected for water.

FIG. A2.8 Calculated correlations between incident electron beam energy and optimum thickness R_{opt}, half-value depth R_{50}, half-entrance depth R_{50e}, and practical range R_p for polystyrene using data from Fig. A2.3 and Fig. A2.4 (see Table A4.1)

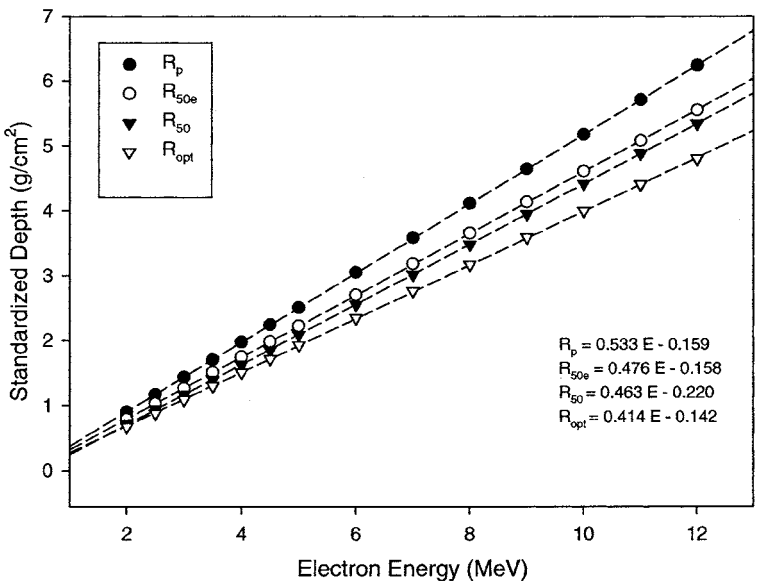
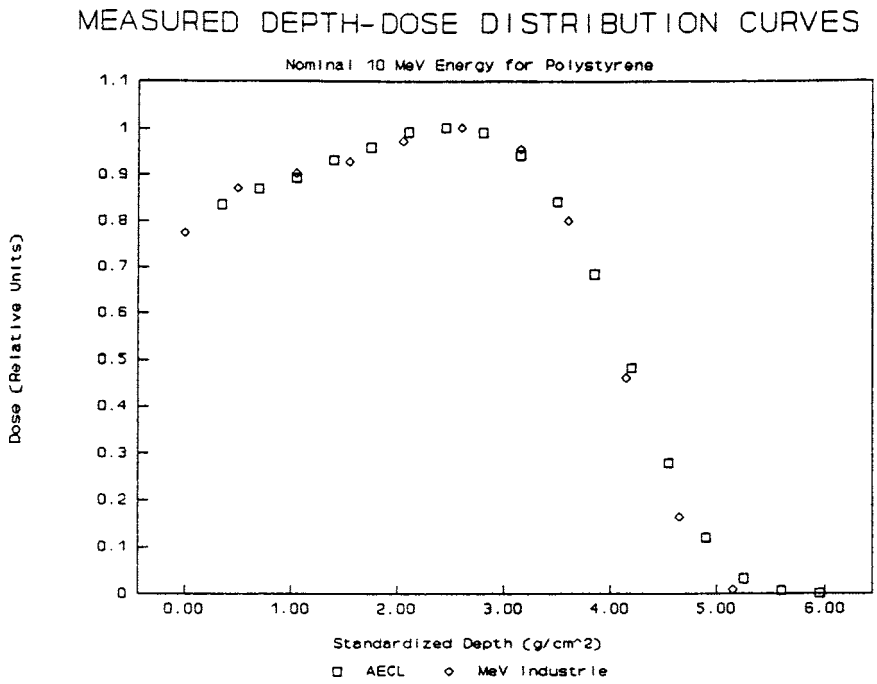


FIG. A2.9 Calculated correlations between incident electron beam energy and optimum thickness R_{opt}, half-value depth R_{50}, half-entrance depth R_{50e}, and practical range R_p, for polystyrene using data from Figs. A2.4 and A2.5 (see Table A4.1)



□ Example of a depth-dose distribution using a 10 MeV IMPELA linear accelerator.
♦ Example of a depth-dose distribution for nominal 10 MeV electrons incident on polystyrene using a CIRCE linear accelerator at Societe des Proteines Industrielles (SPI), Berric, France.

NOTE 1—See Table A2.1 for key parameters.

FIG. A2.10 Measured depth-dose distributions for nominal 10 MeV electron beams incident on polystyrene for two electron beam facilities (26, 27)

TABLE A2.1 Key parameters for measured depth-dose distribution curves presented in Fig. A2.10

	MeV industrie CIRCE[A]	AECL Impela[B]
Nominal beam energy (MeV)	10	10
Energy spectrum	unknown	unknown
Window Material	Ti	Ti
Window Thickness (m)	1.0×10^{-4}	1.3×10^{-4}
Air distance from window to energy measurement device (m)	0.463	1.02

[A] Installed at Société des Protéines Industrielles, Berric, France (26).
[B] Installed at E-Beam Services, Cranbury, NJ (27).

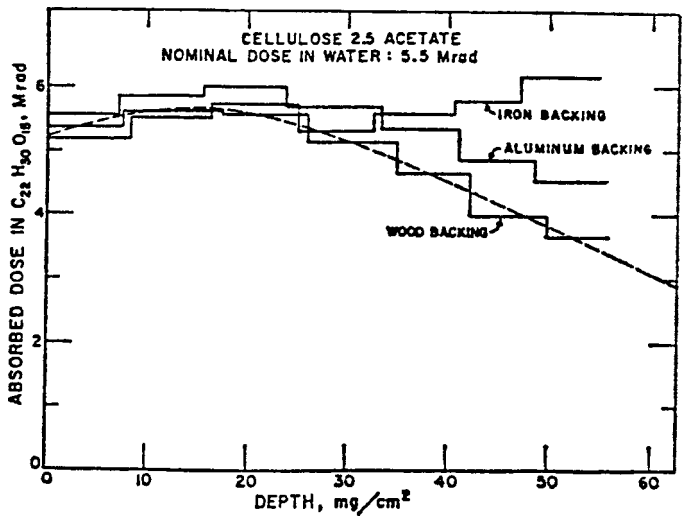


FIG. A2.11 Depth-dose distributions in stacks of cellulose acetate films backed with wood, aluminum, and iron for incident electrons with 400 keV energy (30)

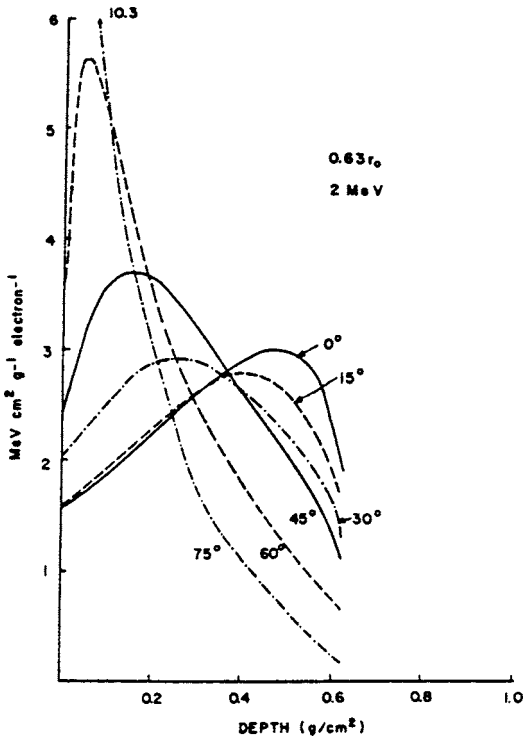


FIG. A2.12 Depth-dose distributions with 2 MeV electrons incident on polystyrene absorbers at various angles from the normal direction (31)

A3. MEASUREMENT OF DEPTH-DOSE DISTRIBUTION

A3.1 *General Considerations*:

A3.1.1 This annex describes apparatus and procedures for measuring depth-dose distribution in homogeneous materials for different electron energies.

A3.1.2 Two different types of measurement devices, referred to as a stack and a wedge, in conjunction with a film dosimetry system, may be used to measure the depth-dose distributions in a homogeneous reference material. Details of the construction of the devices and methods of loading the dosimeters are presented below.

A3.1.3 Aluminum, as well as low density materials such as polyethylene, polystyrene, graphite, polymethylemethacrylate (PMMA), and nylon may be used for the reference material. Relevant properties of some of these materials are given in Table A3.1.

NOTE A3.1—The purity and density of the homogeneous material in which depth-dose distributions are measured may affect the measured depth-dose distribution. This must be taken into account when using the measured electron ranges for energy calculations (see Annex A4).

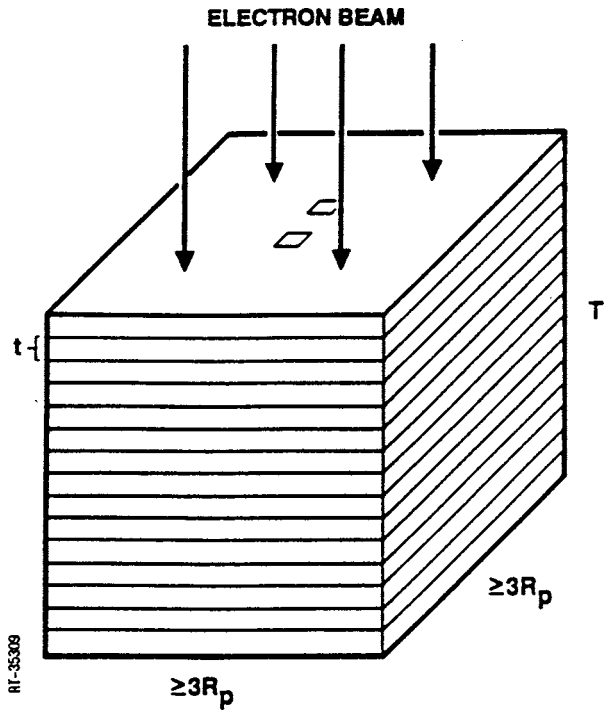
A3.2 *Stack*:

A3.2.1 For electron energies of a few MeV, depth-dose distribution measurements with a stack of thin polystyrene plates are commonly used to determine the electron beam energy. For these energies, the dosimeters may be a significant part of the total absorber thickness. Thus, it may be advantageous to choose materials that are similar in composition to the dosimeters in order to minimize their effects on the depth-dose distribution.

A3.2.2 In the energy range above a few MeV, aluminum absorbers may be used for electron beam energy determination, as described in Annex A4. In this range, the thickness of the dosimeters may be much less than the aluminum, so the difference in their composition may not be significant.

A3.2.3 A stack of plates of a suitable reference material should be assembled interleaved with dosimeter films (or a stack of dosimeter films alone) (see Fig. A3.1).

A3.2.4 The nominal plate thickness should be 1/12 th of the anticipated R_p or less to ensure an adequate number of data points for establishing the depth-dose distribution. The lateral dimensions of the stack should be at least 3 R_p by 3 R_p to avoid the influence of edge effects on the dose distribution. The total thickness of the stack should be at least 1.5 R_p. The stack thickness includes the thickness of the interleaved dosimeter films.



NOTE 1—Plate thickness $t \leq R_p/12$ and the stack height $T \geq 1.5\ R_p$, where R_p is the anticipated practical range of the electron beam in the stack material. At least two film dosimeters should be placed on the top (shown in drawing) and between the plates along the center of the stack.

FIG. A3.1 Stack measurement device

A3.2.5 Thin dosimeters, such as radiochromic film dosimeters (see ISO/ASTM Practice 51275), are most suitable for the measurement. At least two dosimeters should be placed on the top surface of the top plate and other sets of at least two dosimeters between the remaining plates. The dosimeters should be located close together along the middle of the stack away from the edge of the stack.

A3.3 *Wedge*:

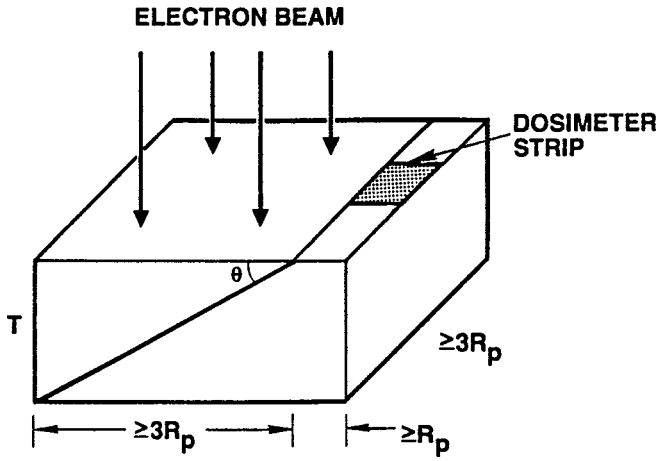
A3.3.1 The wedge should be made of electrically conducting material to avoid possible effect of charge accumulation on the measured depth-dose distribution (**32**, **33**). The most commonly used materials for the wedge measurement device are aluminum and graphite because of their easy availability. It may be constructed by stacking two wedges together to form a rectangular block (see Fig. A3.2).

A3.3.2 The wedge should be at least 3 R_p by 3 R_p to avoid the influence of edge effects on the dosimeter strip with a minimum thickness at least 1.5 times the anticipated practical range R_p of the electron beam. Additionally, the width of the wedge should extend at least R_p beyond the protrusion of the dosimeter strip, as shown in Fig. A3.2, to provide proper

TABLE A3.1 Some relevant properties of common reference materials

Reference Material	Density (g/cm^3)	CSDA Range[A] r_o for 5 MeV	CSDA Range[A] r_o for 10 MeV	CSDA Range[A] r_o for 25 MeV
Aluminum	2.699	3.092	5.859	12.60
Graphite	1.700	2.906	5.657	12.84
PMMA	1.190	2.641	5.158	11.77
Polyethylene	0.940	2.461	4.833	11.16
Polystyrene	1.060	2.635	5.155	11.82
Water	1.000	2.547	4.963	11.27

[A] Continuous-Slowing-Down-Approximation range in g/cm^2 (ICRU Report 37).



NOTE 1—Height $T \geq 1.5\ R_p$, where R_p is the anticipated practical range of the electron beam in the wedge material (for example, aluminum). θ is no larger than 30°. A film dosimeter strip is placed along the sloping surface between the two wedges.

FIG. A3.2 Wedge measurement device

scattering conditions for the dosimeter. The angle of the wedge should be no larger than 30°.

NOTE A3.2—An array of individual dosimeters may be used in place of a continuous dosimeter strip.

A3.3.3 The dosimeter strip should be placed along the center of the sloping surface between the two wedges. This should cover the full length of the sloping surface with a short piece protruding at the electron entry surface. A narrow mark should be made on the dosimeter strip at the point where the strip enters the sloping section of the wedge. The mark can also be placed elsewhere at a known position on the dosimeter strip allowing the possibility for a consistency check: the surface dose should be constant before the strip enters the sloping section of the wedge.

A3.4 Procedure for measurement of depth-dose distribution

A3.4.1 *General Considerations*—The measurement device should be placed at the center of the conveyor. If a container, such as a tray or tote, is used to hold this measurement device, it should be placed away from the side or walls of the container. If possible, a flat tray without sides should be used to avoid effects of scattering of electrons from the sides of the container into the measurement device during irradiation. The device should be located far enough from the beam exit window so that the electron beam incident on the device approaches a broad parallel beam. However, with low energy beams, the distance may need to be limited to avoid excessive energy loss in the air space. Preferably, the distance should be the same as that for a typical product during routine processing.

NOTE A3.3—The effects of the exit window thickness and air-space become more pronounced as the electron energy decreases. For electron energies greater than a few MeV, these effects may be negligible.

A3.4.2 The measurement device should be irradiated by moving the conveyor at a constant speed through the radiation zone. The scan width should be greater than the device to ensure that the surface dose is uniform. The scan width, beam current, and conveyor speed should be selected so the absorbed dose is within the useful range of the dosimetry system.

NOTE A3.4—The maximum absorbed dose within the measurement device should be limited to reduce temperature effects on the dosimeter response.

NOTE A3.5—The incident angle of the electron beam should be perpendicular to the surface of the device, otherwise the depth-dose distribution curve within the device will be affected by the incident angle of the electron beam (see A2.2.9).

A3.4.3 *Stacks:*

A3.4.3.1 The average dose values for each set of dosimeters at the surface of the stack and between the stack plates are measured.

A3.4.3.2 The depth-dose distribution is plotted as a function of distance from the surface of the stack. To determine the distance, the thickness of each plate must be measured and its density known.

NOTE A3.6—Alternatively, the depth-dose distribution may be plotted as function of standardized depth z (see 3.1.22 for a definition of standardized depth). R_p in Eq A4.9 and Eq A4.13 should be replaced by $z_p = \rho^* R_p$.

NOTE A3.7—The thickness of the interleaved dosimeter films may affect the measurement. Corrections for this effect may be approximated by adding the standardized depth of the films to the standardized depth of the stack material.

A3.4.4 *Wedge:*

A3.4.4.1 The wedge should be placed on the conveyor such that the dosimeter strip, or linear array of film dosimeters, is parallel to the direction of product travel (perpendicular to the scan direction).

A3.4.4.2 The dose values along the entire length of the dosimeter strip are measured. The depth may be calculated by multiplying the distance along the dosimeter strip from the entrance of the wedge (identified by the mark on the film) by the sine of θ, the angle between the incident wedge surface and the plane of the dosimeter film (see Fig. A3.2).

A3.4.5 *Electron Beam Energy Calculation:*

A3.4.5.1 From the depth-dose distribution, the practical range R_p, extrapolated range R_{ex} and half-value depth R_{50} for the reference material of the energy measurement device are determined. Depending on the reference material used, the electron energy is calculated following guidelines provided in Annex A4.

NOTE A3.8—It is common practice to use the practical range R_p for the purpose of determining the electron beam energy.

A4. CALCULATION OF ELECTRON BEAM ENERGY BASED ON MEASURED DEPTH-DOSE DISTRIBUTION

A4.1 *General*:

A4.1.1 The extent to which electrons penetrate into a given material is nearly proportional to their initial energy. This relationship can be exploited to determine the energy of the electron beam.

A4.1.2 This annex describes methods that use depth-dose distribution measurements in homogeneous materials to determine the electron beam energy. As noted throughout this annex, there may be differences in the energies determined through the use of the various equations presented. These equations and energy measurement techniques can be used for quality assurance and control of the electron beam energy, provided the same equation and technique are consistently used. In this way, the constancy of the beam energy at the facility over time can be determined.

A4.1.3 Formulas for calculation of energy based on electron range measurements are given in ICRU 35. These formulas are derived from measurements on medical electron accelerators used in cancer therapy. Other formulas are given in this annex that are based on Monte Carlo calculations. It is necessary that the user specifies the method used for electron beam energy calculation and its applicable energy range.

A4.2 Energy and range correlations

A4.2.1 The energy equations presented in this annex exhibit varying levels of accuracy. This is caused by differences in the energy spectra of the beams measured compared to the spectra upon which the equations are based (in some cases, the equations are based on monoenergetic electrons, as noted). Additionally, scanned non-monoenergetic beams exhibit different energy spectra across the beam width.

A4.2.2 *Empirically derived Correlations for Water and Aluminum:*

A4.2.2.1 For water, the empirically derived relationships (see ICRU Report 35) between the most probable electron beam energy E_p and the average (mean) electron beam energy E_a at the entrance surface of water and the range parameters R_p and R_{50} (see Fig. 4) are:

$$E_p\,(\text{MeV}) = 0.22 + 1.98\,R_p + 0.0025\,R_p^{\,2} \qquad \text{(A4.1)}$$

$$1\ \text{MeV} < E_p < 50\ \text{MeV}$$

$$E_a\,(\text{MeV}) = 2.33\,R_{50} \qquad \text{(A4.2)}$$

$$5\ \text{MeV} < E_a < 35\ \text{MeV}$$

where R_p and R_{50} are the practical range and half-value depth, respectively, in water (both in cm). If the material in which the range parameters are measured is nearly water equivalent (effective atomic number and atomic weight nearly the same as water), then the practical range and half-value depth may be adjusted by:

$$R_w = R_m \frac{(r_{0,w} \times \rho_m)}{(r_{0,m} \times \rho_m)} \qquad \text{(A4.3)}$$

where ρ is the density, r_0 is the CSDA range, and subscripts w and m refer to water and the material under use (see Table A3.1 and ICRU Reports 35 and 37). This adjustment is not appropriate for other materials, such as aluminum, with atomic numbers and atomic weights substantially greater than water.

A4.2.2.2 For aluminum, the empirically derived relationships (see ICRU Report 35 and Ref **34**) between the most probable electron energy E_p and the average (mean) energy E_a at the entrance surface of aluminum, and the parameters R_p and R_{50} (see Fig. 3) are:

$$E_p\,(\text{MeV}) = 0.20 + 5.09\,R_p \qquad \text{(A4.4)}$$

$$5\ \text{MeV} < E_p < 25\ \text{MeV}$$

$$E_a = 6.2\,R_{50} \qquad \text{(A4.5)}$$

$$10\ \text{MeV} < E_a < 25\ \text{MeV}$$

where R_p is the practical range and R_{50} is the half-value depth, respectively, in aluminum (both in cm).

A4.2.3 *Monte Carlo-derived Correlations for Polystyrene:*

A4.2.3.1 If the electron beam is monoenergetic, then the most probable energy and the average energy at the surface of an absorbing material may be considered to be the same. This value E may be correlated to the optimum thickness R_{opt}, half-value depth R_{50}, half entrance depth R_{50e}, and practical range R_p (see Fig. 4). For polystyrene, these correlations have been calculated from the Monte-Carlo depth-dose distributions discussed in Annex A2, section A2.2, and are given by the following equations for electron energies between 0.3 MeV and 12 MeV (**20**):

$$0.3\ \text{MeV} < E < 2.0\ \text{MeV}$$

$$E = 2.347\,R_{opt} + 0.420 \qquad \text{(A4.6)}$$

$$E = 2.421\,R_{50} + 0.278 \qquad \text{(A4.7)}$$

$$E = 2.198\,R_{50e} + 0.295 \qquad \text{(A4.8)}$$

$$E = 1.972\,R_p + 0.245 \qquad \text{(A4.9)}$$

$$2.0\ \text{MeV} < \text{E} < 12\ \text{MeV}$$

$$E = 2.415\,R_{opt} + 0.343 \qquad \text{(A4.10)}$$

$$E = 2.160\,R_{50} + 0.475 \qquad \text{(A4.11)}$$

$$E = 2.101\,R_{50e} + 0.332 \qquad \text{(A4.12)}$$

$$E = 1.876\,R_p + 0.298 \qquad \text{(A4.13)}$$

The range values are given as standardized depths (g/cm^2) and E is in MeV. The values of optimum thickness R_{opt}, half-value depth R_{50}, entry half-value depth R_{50e} and practical range R_p, in polystyrene for various electron energies E have been obtained from the Monte Carlo depth-dose distributions (**20**). These values are listed in Table A4.1.

A4.2.3.2 Eq A4.6-A4.13 are less accurate for materials with chemical compositions different from polystyrene. As the energy decreases, the beam window and air space become more important (see Fig. A2.3) and their effects on the depth-dose distributions in the irradiated material must be taken into account.

TABLE A4.1 Half-value depth R_{50}, half-entrance depth R_{50e}, optimum thickness R_{opt} and practical range R_p in polystyrene for monoenergetic electron energies E from 0.3 to 12 MeV derived from Monte Carlo calculations (20)

E (MeV)	R_{50} (g/cm^2)	R_{50e} (g/cm^2)	R_{opt} (g/cm^2)	R_p (g/cm^2)	Ratio R_p/R_{50}
0,3	0,0254	0,0254	0,0000	0,0451	1,7774
0,4	0,0554	0,0554	0,0000	0,0851	1,5360
0,5	0,0923	0,0924	0,0231	0,1310	1,4203
0,6	0,1290	0,1326	0,0754	0,1747	1,3544
0,7	0,1679	0,1762	0,1192	0,2240	1,3339
0,8	0,2085	0,2218	0,1632	0,2746	1,3171
0,9	0,2501	0,2687	0,2072	0,3258	1,3030
1	0,2888	0,3121	0,2491	0,3717	1,2873
1,5	0,5043	0,5477	0,4565	0,6357	1,2605
2	0,7217	0,7890	0,6738	0,9011	1,2485
2,5	0,9454	1,0282	0,8833	1,1692	1,2367
3	1,1708	1,2672	1,0920	1,4373	1,2276
3,5	1,4004	1,5079	1,3026	1,7069	1,2189
4	1,6283	1,7483	1,5125	1,9766	1,2139
4,5	1,8573	1,9871	1,7211	2,2445	1,2085
5	2,0914	2,2270	1,9333	2,5091	1,1997
6	2,5549	2,7070	2,3496	3,0494	1,1936
7	3,0215	3,1847	2,7677	3,5817	1,1854
8	3,4843	3,6579	3,1759	4,1123	1,1803
9	3,9505	4,1333	3,5915	4,6427	1,1752
10	4,4146	4,6057	3,9967	5,1744	1,1721
11	4,8835	5,0782	4,4008	5,7041	1,1680
12	5,3445	5,5470	4,7964	6,2336	1,1663

NOTE 1—The window is assumed to be 4×10^{-5} m thick titanium (0.018 g/cm^2) followed by 0.15 m of air (0.018 g/cm^2).

NOTE A4.1—When the practical range values R_p are used, Eq A4.1 is consistent within 2 % with Eq A4.13 for higher energies from 2.0 MeV to 12 MeV, provided that Eq A4.3 is used to convert the polystyrene ranges to the equivalent water values. However, the deviation increases as the energy decreases. At 1.0 MeV, Eq A4.1 gives energy values about 4 percent less than Eq A4.13. When the half-value depths R_{50} are used, Eq A4.2 is consistent within 2 percent with Eq A4.11 for higher energies from 8.0 MeV to 12 MeV, but the deviation increases as the energy decreases. At 5 MeV, Eq A4.2 gives energy values about 6 percent less than Eq A4.11. Eq A4.1 and Eq A4.2 were empirically determined using measured depth-dose distribution curves in water. The validity of the Monte Carlo method for electron energies below 2.0 MeV has been demonstrated by the data presented in Ref (**18**).The comparisons between the Monte Carlo equations and ICRU equations indicate that Eq A4.1 should not be used below 2.0 MeV, and that Eq A4.2 should not be used below 8.0 MeV. The Monte Carlo equations for polystyrene provide an accurate method for measuring electron beam energies below 2.0 MeV. Determination of electron beam energy from measured depth-dose distribution curves using Eq A4.6 through Eq A4.13 may deviate from the actual energy if the electron beam has a broad energy spread. The accuracy of the energy values from these equations is influenced by the differences in electron beam energy spectra in the measured beam and the mono-energetic beams used to create the Monte Carlo equations (**20, 35, 36**).

A4.2.4 *Monte Carlo-derived Correlations for Aluminum:*

A4.2.4.1 Depth dose distributions in aluminum with density of 2.7 g/cm^3 have been calculated for energies from 2.5 MeV to 25 MeV. The calculations simulate the geometry of a moving block of aluminum in air, 15 cm away from a 50 μm thick titanium window. The resulting dose distributions were recorded in three dimensions and they take scatter effects in the titanium window into account.

A4.2.4.2 The values of half-value depth R_{50}, practical range R_p, and extrapolated range R_{ex} in aluminum for various electron beam energies E have been obtained from the Monte Carlo data in Ref (**25**). These values are listed in Table A4.2.

A4.2.4.3 The incident electron energy values E(MeV) can be correlated to the R_p and R_{50} range values for aluminum (cm) given in Table A4.2 with second order equations as follows (for electron energies between 2.5 MeV and 25 MeV):

$$E = 0.423 + 4.69 \cdot R_p + 0.0532 \cdot R_p^2 \quad \text{(A4.14)}$$

$$E = 0.394 + 4.77 \cdot R_{ex} + 0.0287 \cdot R_{ex}^2 \quad \text{(A4.15)}$$

$$E = 0.734 + 5.78 \cdot R_{50} + 0.0504 \cdot R_{50}^2 \quad \text{(A4.16)}$$

A4.2.4.4 Density for different aluminum alloys may vary. A correction shall be applied such that R_p, R_{ex}, R_{50} in the equations above are replaced by the respective measured values multiplied by the density ratio. The following equation applies only for small differences in density:

$$R = R_{measured} \cdot \rho_{alloy} / 2.7 \text{ g cm}^{-3} \quad \text{(A4.17)}$$

NOTE A4.2—When the practical range values R_p are used, Eq A4.4 is consistent within 2 percent with Eq A4.14 from 2.5 MeV to 25 MeV. When the half-value depths R_{50} are used, Eq A4.5 is consistent within 2 percent with the Eq A4.16 from 10 MeV to 25 MeV, but the deviation increases as the energy decreases. At 7.5 MeV, Eq A4.5 gives energy values about 4 percent less than Eq A4.16, while at 5.0 MeV, Eq A4.5 gives energy values about 9 percent less than Eq A4.16.

A4.2.4.5 The ratio of R_p/R_{50} in aluminum given in Table A4.2 is slightly dependent on the electron energy E. In a practical situation, if the measured value of this ratio is found to be greater than the calculated value in Table A4.2, the beam may not be monoenergetic. A broad energy spectrum reduces R_{50} more than R_p; thus, this ratio is an indication of the energy spread in the beam (see ICRU Report 35).

TABLE A4.2 Half-value depth R_{50}, practical range R_p and extrapolated range R_{ex} in aluminum for monoenergetic electron energy E from 2.5 to 25 MeV derived from Monte Carlo calculations (25)

E (MeV)	R_{50} (cm)	R_p (cm)	R_{ex} (cm)	Ratio R_p/R_{50}
2.5	0.3046	0.4386	0.4404	1.4398
3	0.3906	0.5440	0.5446	1.3928
4	0.5622	0.7541	0.7526	1.3414
5	0.7333	0.9633	0.9601	1.3137
6	0.9038	1.1714	1.1671	1.2961
7	1.0739	1.3787	1.3736	1.2838
7.5	1.1588	1.4819	1.4767	1.2789
8	1.2435	1.5849	1.5796	1.2746
9	1.4126	1.7903	1.7851	1.2674
10	1.5812	1.9947	1.9901	1.2615
12	1.9170	2.4009	2.3986	1.2525
15	2.4171	3.0036	3.0077	1.2427
20	3.2415	3.9913	4.0134	1.2313
25	4.0548	4.9591	5.0077	1.2230

NOTE 1—The window is assumed to be 5×10^{-5} m thick titanium (0.018 g/cm^2) followed by 0.15 m of air (0.018 g/cm^2).

A5. ABSORBED DOSE AS FUNCTION OF BEAM CURRENT, BEAM WIDTH AND CONVEYOR SPEED

A5.1 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 electron beam energy, and measurement of dose as a function of the three other parameters should therefore be made for each operating energy. The relationship is expressed as:

$$D = (K * I) / (V * W_b) \quad \text{(A5.1)}$$

where:

D = Absorbed dose (Gy),
I = Average beam current (A),
V = Conveyor speed (m s^{-1}),
W_b = Beam width (m), and
K = Slope of the straight line relationship in Eq A5.1 (Gy * m^2) / (A * s).

D is dose at the point of measurement. It might be the surface dose at the center of the beam, or the dose measured at the routine monitoring position. The value of K will depend on the point of measurement.

I is the average beam current as monitored by the facility.
V is the speed of product through the irradiation zone.
W_b is the width of the beam at a specified fraction of dose at the center of the beam, see Annex A6.

See Fig. A5.1 for example of measurement of Dose = $f(I, V, W_b)$.

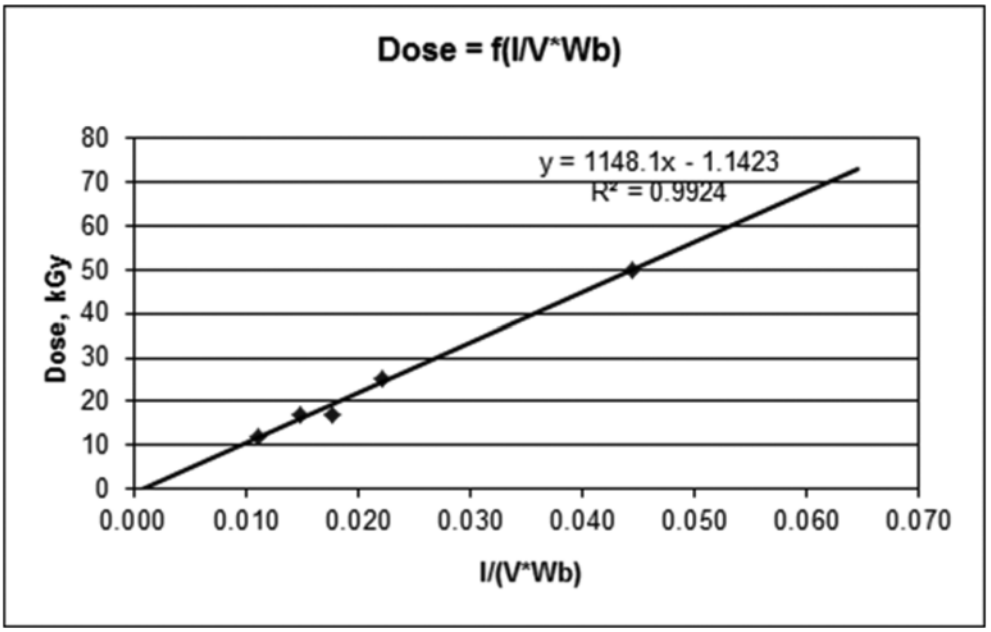


FIG. A5.1 Example of dose as function of average beam current (I), conveyor speed (V) and beam width (W_b)

A5.2 Dose also depends on beam exit window thickness, and distance between the beam window and the point of measurement.

A5.3 The relationship in Eq A5.1 should 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.

A5.4 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 and stability of the operating parameters.

A5.5 Information about machine variability σ_{mach} can be obtained from residual values for the straight line fit for $D = f(I/(V*W_b))$.

A5.6 Estimates of material processing rates can be based on Eq A5.1, see Annex A10.

A6. MEASUREMENT OF BEAM WIDTH AND DOSE UNIFORMITY ALONG SCAN DIRECTION

A6.1 Scope

A6.1.1 There are various methods for determining the beam width and the dose uniformity along the scan direction. This annex describes methods that use dosimetry to measure the dispersion and uniformity of dose for facilities using conveyors or carrier systems. Fig. 2 shows beam length and beam width for a scanned beam using a conveyor system. Fig. 3 is an example of measured dose distribution along the scan direction.

A6.1.2 Dose distribution along the scan direction is measured by placing strips of dosimeter film or arrays of single dosimeters in the scan direction. Using arrays of single dosimeters, more dosimeters might be placed in zones of expected high dose gradients (such as at the extremes of scan), and less where dose distribution is expected to be uniform.

A6.1.3 Beam width is measured at a specified distance from the beam window.

A6.1.4 Beam width is defined at a specified fraction of the dose at the center of the scanned beam (see Fig. 3).

A6.1.5 Beam width should be measured a sufficient number of times to determine the repeatability of the measured beam width.

A6.2 Measurement Procedure

A6.2.1 An array of dosimeters or long strips of dosimeter film are mounted on a fixture with homogeneous backing material (use of individual dosimeters will limit the spatial resolution of the measurement).

NOTE A6.1—The thickness of the backing material should be large enough to prevent backscattered electrons affecting the measurement result.

A6.2.2 Whenever possible, dosimeters should also be placed beyond the expected beam width to identify the limits of the full beam width. The fixture should be reproducibly mounted onto the conveyor or carrier at a defined distance from the beam exit window.

A6.2.3 A backing material such as polystyrene or polyethylene should be used. Metals with low specific heat should not be used because of excessive temperature rise due to absorbed dose.

A6.2.4 The dosimeter fixture is irradiated by passing it through the electron beam using a known set of operating parameters. The center line of the dosimeter array should correspond to the expected center line of the beam width. The overall width of the dosimeter array should be large enough to compensate for any possible differences in centering. The dose uniformity may be influenced by interactions between the following parameters:

A6.2.4.1 beam width,

A6.2.4.2 scan frequency,

A6.2.4.3 beam spot size and shape,

A6.2.4.4 pulse width (for pulsed accelerators),

A6.2.4.5 pulse repetition rate (for pulsed accelerators),

A6.2.4.6 conveyor speed, and

A6.2.4.7 distance of the dosimeter fixture from the beam exit window and from the conveyor or carrier.

A6.2.4.8 The effects of these parameters are considered in more detail in Annex A7.

A6.2.5 Dose values are plotted as a function of measurement location. Location must be referenced to normal product flow for the operating parameters used, such as the center of the product flow.

A6.2.6 Beam width and the variation of the measured dose along the scan direction are determined. Beam width is the distance between the points along the dose profile which are at a defined fractional level from the maximum dose region in the profile (see Fig. 3). The fractional level should be specified.

A6.2.7 The measured beam width should adequately cover the expected process load width.

A7. DOSE DISTRIBUTIONS FOR SCANNED AND PULSED BEAMS

A7.1 For scanned electron beams special attention must be paid ensuring that product moving through the irradiation zone is homogeneously irradiated. It must thus be ensured that the scanning arrangement does not leave any areas non-irradiated. Fig. A7.1 shows different scanning arrangements (scan magnet current versus time) with type A being the most common.

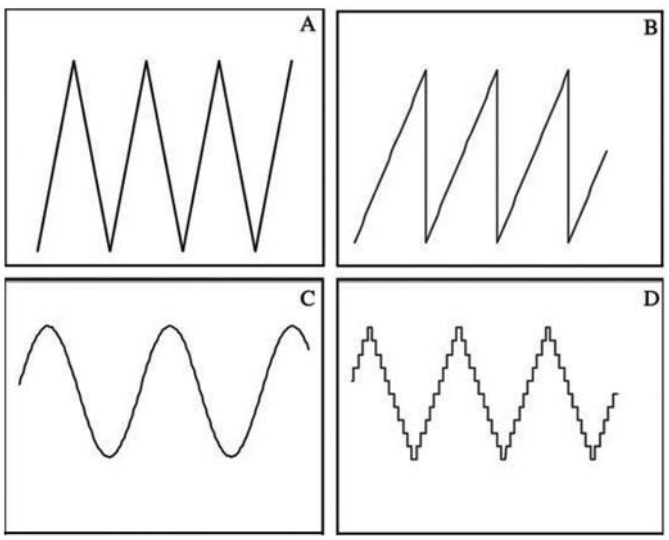
A7.2 It must be ensured that product has not moved so far during the time of one scan cycle that the beam does not overlap on the product surface from one scan cycle to the next.

A7.3 For pulsed and scanned beam it must be ensured that one beam pulse overlaps with the next beam pulse.

A7.4 It is essential to know the shape and size of beam spot. The size is usually expressed by the width in terms of its Full Width at Half Maximum (FWHM), and it may often be assumed that the beam spot is rotationally symmetric. In case rotational symmetry does not exist, then further analysis might be needed.

A7.5 Measurement of the beam spot size and shape can be carried out by irradiating a sheet of dosimeter film without scanning the beam and without movement of conveyor.

NOTE A7.1—Care must be exercised for this type of measurement, because of the risk of beam window damage when the scanner is not operating.



NOTE 1—Includes complex scanning patterns, to produce an optimal distribution of dose at the surface of the product. *(A)* Linear saw-tooth, *(B)* linear saw-tooth for scanning of the beam in one direction, with a fast "fly-back" in the other direction, *(C)* sinusoidal scanning of the beam giving rise to increased doses at the edge of the scan, and *(D)* step scanning function sometimes used with pulsed beams. the pulse frequency and scanning frequency are synchronized, and each step can be adjusted to give an optimal dose distribution. (Source: ICRU Report No. 80)

FIG. A7.1 Different scan characteristics used for electron beams

A7.6 The following parameters must be known:

Beam spot width (FWHM):	d	(measured)
Scan width = Beam width:	W_b	(measured)
Scan frequency:	f_{scan}	(selected parameter)
Pulse frequency:	f_{pulse}	(selected parameter)

From f_{pulse} is calculated t_{pulse}, time interval between pulses.
From f_{scan} is calculated t_{scan}, time for one scan cycle.

A7.6.1 Calculations for Type A scan are given below. The calculation assumes that the following requirements must be met:

(1) Distance between two beam spot centers must not exceed the beam spot diameter (FWHM).

(2) Distance between the end point centers of two successive scans must not exceed the beam spot diameter (FWHM). The minimum pulse frequency $f_{pulse}(\min)$ that fulfills requirement *(1)* can now be calculated. From Fig. A7.2 the following relationship can be derived:

$$t_{pulse}/d = t_{scan}/2 \cdot W_b$$

that is rearranged to:

$$t_{pulse}/t_{scan} = d/2 \cdot W_b$$

and

$$f_{scan}/f_{pulse} = d/2 \cdot W_b$$

$$f_{pulse}(\min) = (f_{scan} \cdot 2 \cdot W_b)/d_{max}$$

$$= (f_{scan}\ 2 \cdot W_b)/\mathrm{FWHM}$$

(3) Maximum conveyor speed (corresponding to the minimum dose) that fulfills requirement *(2)* can be calculated:

$$V_{max} = d_{max}/t_{scan}$$

$$= FWHM \cdot f_{scan}$$

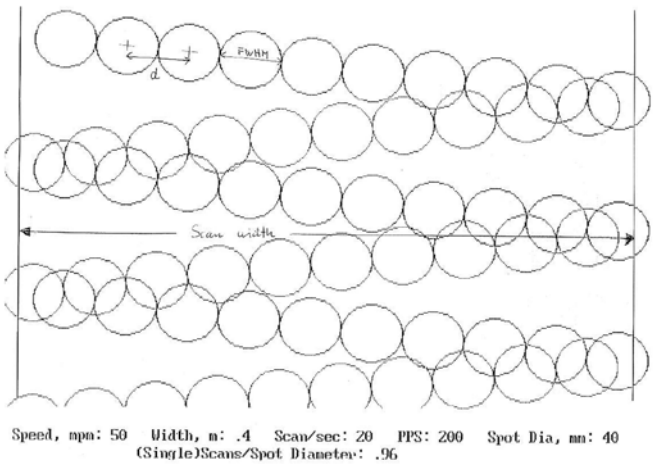


FIG. A7.2 Example of a scanned and pulsed beam with parameters needed for beam spot calculations indicated

A8. DOSE DISTRIBUTION IN REFERENCE MATERIAL

A8.1 The purpose of measuring dose distribution in a reference material is to obtain a measure of the reproducibility of dose delivery by the electron irradiation facility. Measurements of dose distribution in reference materials are generally not used to determine the irradiation conditions for real products.

A8.2 For electron beam irradiation in the energy range of this practice, it is recommended to use a homogeneous polymeric material as reference material, such as expanded polystyrene foam or expanded polyethylene foam (Ethafoam). The specific density should be selected to be similar to most products being processed at the irradiation facility. For medical device sterilization, it is suggested to use a specific density of approximately 0.1 g cm^{-3}. The reference material may be conveniently made of several layers; thickness of layers should be selected to be adequate for the required measurement resolution.

A8.3 It is not intended to irradiate the reference material in such a way as to produce a homogeneous dose distribution in the reference material. The reference material should preferably be irradiated so that the beam is completely stopped so that the range of the accelerated electrons can be measured, and whenever possible the width of the reference material should be wider than the beam width.

A8.4 It is recommended to use only single sided irradiation. Single sided irradiation is preferred for OQ dose mapping of reference material in order to obtain maximum information about consistent and stable operation of the irradiation facility. For facilities with multiple beams it is recommended to measure the dose distribution for the individual beam separately.

A8.5 Individual dosimeters should be placed in an array to cover the full cross sectional area of the reference material. More dosimeters may be placed in areas with expected high dose gradients. Alternatively, dosimeter sheets or dosimeter strips may be used. Dose distributions in the form of isodose curves may be obtained from the measurements of the irradiated dosimeters, see Fig. A8.1.

A8.6 Additional dose measurements may be carried out at the edges of the reference material (sometimes referred to as measurement of “edge effects”). Results from these dosimeters may be used to predict areas of particular interest for performance qualification dose mapping.

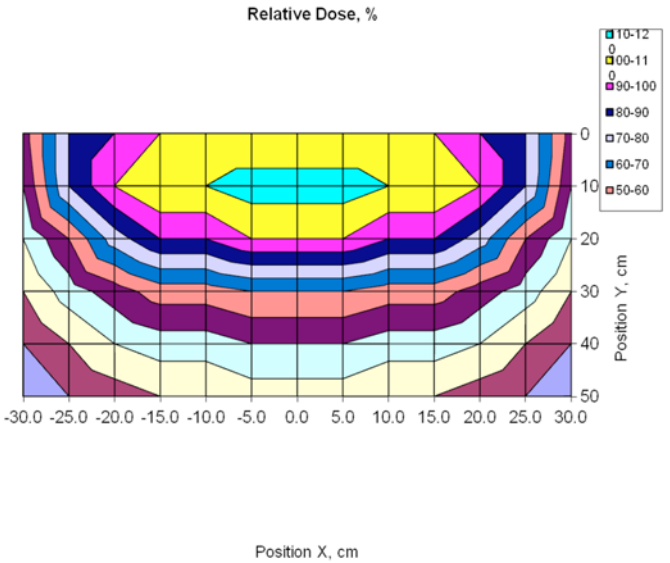


FIG. A8.1 Example of isodose curves obtained by irradiation at a 10-MeV electron accelerator of expanded polystyrene foam (specific density approximately 0.1 g/cm^3)

A9. PROCESS INTERRUPTION

A9.1 The effect on product of irradiation process interruption should be assessed.

A9.2 The irradiation process can be interrupted for a number of reasons, either fault in the electron accelerator(s) or in the conveyor system. Faults in the ancillary systems (for example, cooling or ventilation system) can also lead to interruption of the irradiation process.

NOTE A9.1—The effect of the various types or causes of a process interruption on delivered dose must be assessed in order to determine the necessary actions and procedures appropriate to respond to the various interrupt causes. The degree of process control involved in a process shutdown affects process interruption practices. Some facility designs and operating controls may necessarily require that all potentially affected products be discarded or re-processed while other process systems might be able to demonstrate that process interruptions have no effect on cause of the interruption. The potential effects of process interruptions and of the length of shutdown time associated with the interruption might have to be investigated.

A9.3 Dose variations as a consequence of a process interruption can be measured by irradiating an array of dosimeters or a strip of dosimeter film placed on the reference material along the direction of product movement, and interrupting the irradiation process manually followed by a re-start.

A9.3.1 Process interruption testing should be conducted for conditions that might be expected to have maximum effect on dose to product. This may imply testing at, for example, maximum conveyor speed, maximum process load mass or testing for multiple interruptions

A9.3.2 Dosimeters should be placed on surface of reference material facing the beam at the minimum window-to-product distance normally used for processing, where effects on dose are expected to be most pronounced.

A9.3.3 The irradiated dosimeters are measured and dose plotted as a function of product length. Analysis of dosimetry results should involve comparison against normal uninterrupted processing variability limits. Dose uniformity results obtained in OQ dose mapping may be useful for evaluation purposes. ASTM Guide E2303, Section A1.4.3, describes a statistical approach that may be used in determining a minimum detectable difference.

A9.3.4 If dose to product is outside the specified dose limits for the process as a consequence of process interruption and the subsequent re-start, then procedures must be established describing actions following a process interruption with respect to identification and segregation of affected product.

A10. MATERIAL PROCESSING RATES

A10.1 This annex describes methods for calculation of product throughput.

A10.1.1 Processing rate concepts discussed in this section are most appropriate for homogeneous materials, although they can be used to estimate processing rates for heterogeneous products, provided that the dose is specified at surfaces normal to the incident electron beam.

A10.2 *Linear processing rate*:

A10.2.1 The linear processing rate is the conveyor speed V at which a specified surface dose D can be delivered to product.

A10.2.2 The linear processing rate V can be calculated from rearrangement of Eq A5.1:

$$V = (K * I)/(D * W_b) \quad [m * s^{-1}] \qquad (A10.1)$$

A10.3 *Area processing rate*:

A10.3.1 The area processing rate is the product surface area that can be irradiated per unit time to deliver a specified dose.

A10.3.2 The area processing rate can be calculated by multiplying the linear processing rate by the beam width:

$$\text{Area processing rate} = V * W_b = (K * I)/D \quad [_m2 * s^{-1}] \qquad (A10.2)$$

A10.3.3 The area processing 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 process load width is less than the beam width.

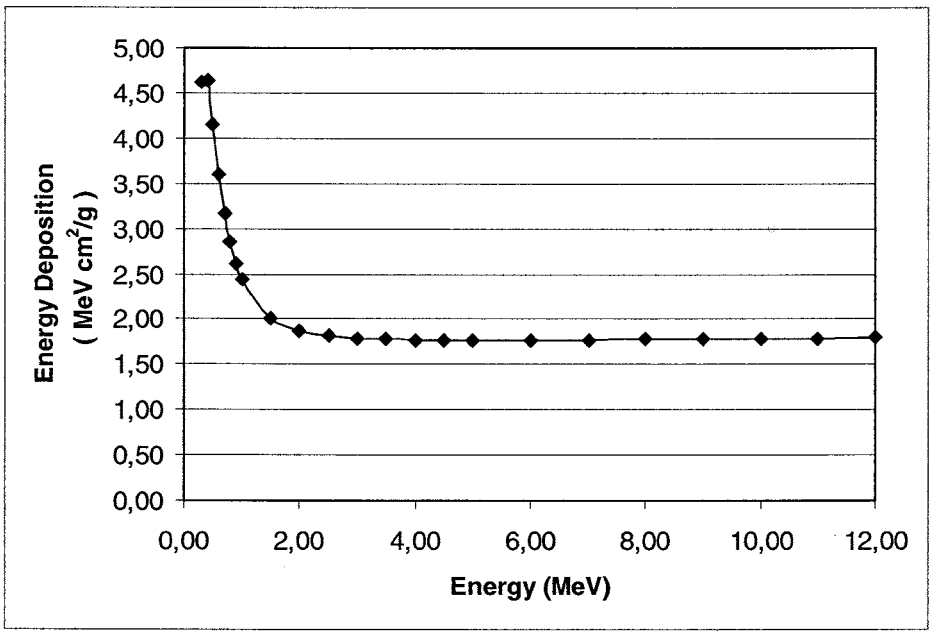
NOTE A10.1—Electron energy deposition at the entrance surface is nearly independent of the electron energy above 2 MeV. For example, with polystyrene and other hydrocarbon materials of similar atomic composition, the surface value of dose is about 0.17 MeV·m^2/kg or 1.7 MeV cm^2/g. Therefore, the surface value of K is about 170 kGy·m^2/(A·s) or 10 kGy·m^2/(mA·min). The latter value means that the surface dose will be about 10 kGy for a beam current of 1 mA and an area processing rate of 1 m^2/min. Fig. A10.1, Fig. A10.2 and Table A10.1 show the energy deposition at the entrance surface of a polystyrene absorber as a function of incident electron energy.

A10.4 *Mass processing rate*:

A10.4.1 The mass processing rate is the mass of product that can be irradiated per unit of time to deliver a specified dose.

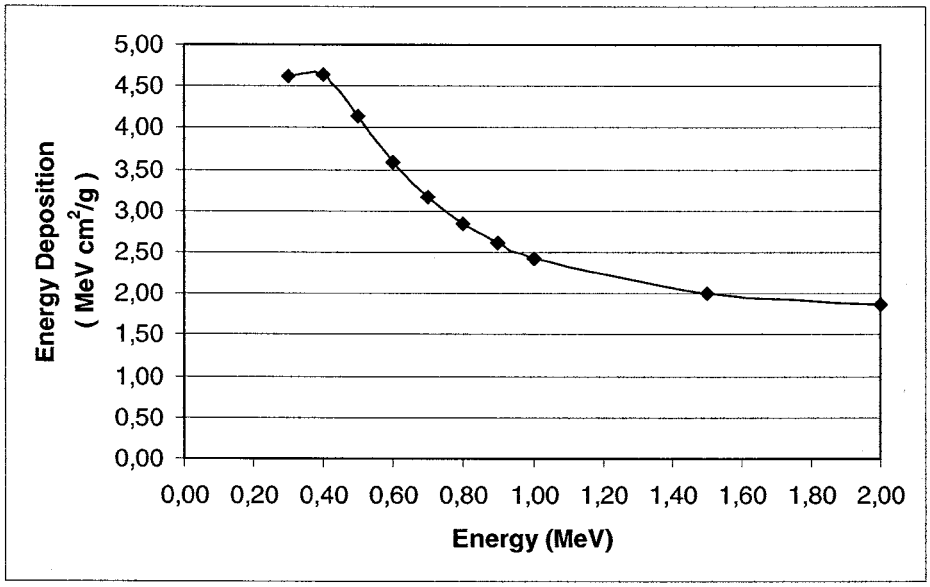
A10.4.2 The mass processing rate can be calculated by multiplying the area processing rate by the specific density ρ [kg * m^{-3}] of the product and the thickness T[m] of the product as estimated from the measured depth-dose distribution (Annex A2).The dose is the average dose through the thickness of product.

$$\text{Mass processing rate} = V * W_b * T * \rho = T * \rho * (K * I)/D \quad [\text{kg} * s^{-1}] \qquad (A10.3)$$



NOTE 1—The beam window is assumed to be 4 × 10^{-5} m titanium (0.018 g/cm^2) followed by 0.15 m of air (0.018 g/cm^2).

FIG. A10.1 Electron energy deposition at the entrance surface of a polystyrene absorber as a function of incident electron energy from 0.3 MeV to 12 MeV corresponding to the Monte Carlo calculated data shown in Figs. A2.3-A2.5



NOTE 1—The beam window is assumed to be 4×10^{-5} m titanium (0.018 g/cm^2) followed by 0.15 m of air (0.018 g/cm^2).

FIG. A10.2 Electron energy deposition at the entrance surface of a polystyrene absorber as a function of incident electron energy from 0.3 MeV to 2.0 MeV corresponding to the Monte Carlo calculated data shown in Fig. A2.3 and Fig. A2.4

TABLE A10.1 Electron energy deposition at the entrance surface of a polystyrene absorber as a function of incident electron energy from 0.3 MeV to 12 MeV corresponding to the calculated curves shown in Figs. A2.3-A2.5

Beam Energy in MeV	Energy deposited in MeV cm²/g	Beam Energy in MeV	Energy deposited in MeV cm²/g
0.3	4.627	3.5	1.776
0.4	4.640	4	1.763
0.5	4.144	4.5	1.762
0.6	3.591	5	1.761
0.7	3.174	6	1.763
0.8	2.852	7	1.767
0.9	2.612	8	1.777
1	2.432	9	1.777
1.5	2.009	10	1.786
2	1.866	11	1.790
2.5	1.813	12	1.793
3	1.789		

NOTE 1—Nearly equivalent relationships may be expected for water.

A10.4.3 The mass processing 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 penetration depth of the electron beam.

A10.4.4 A theoretical estimate of the maximum mass processing rate can be obtained from the power P of the electron beam accelerator divided by the dose D:

$$\text{Mass processing rate (max)} = P/D \quad [\text{kg}*\text{s}^{-1}] \quad \text{(A10.4)}$$

The power P[W] is the product of average beam current I[A] and average accelerating voltage E[V]. The unit of dose D is Gy = J * kg^{-1} = W * s * kg^{-1}.

A10.4.5 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 %. Eq A10.4 then becomes:

$$\text{Mass processing rate(max)} = P*f_i/D \quad [\text{kg} * s^{-1}] \quad \text{(A10.5)}$$

A11. TABLE A2 FROM ISO 11137-1

TABLE A11.1 Needs for requalification following changes of an electron beam facility

Irradiator Change	*Installation Qualification*	*Operational Qualification*			
	Installation Testing & Equipment Documentation	**Operational Testing**	**Equipment Calibration**	**Irradiator Dose Mapping**	**Type of Dose Mapping**
Accelerator mechanical alignment	✓			✓	Scan uniformity in the direction of beam scan and depth-dose in the direction of beam travel
Steering or focusing magnet systems	✓			✓	Scan uniformity in the direction of beam scan and depth-dose in the direction of beam travel
Bending magnet systems	✓		✓	✓	Scan uniformity in the direction of beam scan and depth-dose in the direction of beam travel
Beam current monitoring system	✓		✓	✓	Scan uniformity in the direction of product travel
Scanning magnet system	✓		✓	✓	Scan uniformity in the direction of beam scan
Conveyor speed monitoring and/or control circuitry	✓		✓	✓	Scan uniformity in the direction of product travel Process interruption testing
Conveyor system motors, belts, and gearing.	✓	✓			Scan uniformity in the direction of product travel Process interruption testing
NOTE OQ dose mapping results may lead to repeat of PQ					

The extent of a repeat OQ following changes that might affect dose or dose distribution will depend on the type and extent of the change in the irradiation facility (see Table A11.1). For example, an increase of the maximal designed dimensions of the process load will require a complete requalification, whereas replacement of a conveyor part could only require confirmation of the proper functioning of the conveyor including the specified orientation (with respect to overscan) of the product as conveyed through the beam.

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