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Practice for dosimetry in an electron-beam facility for radiation processing at energies between 300 keV and 25 MeV

Pratique de la dosimétrie utilisant des faisceaux d'énergie comprise entre 300 keV et 25 MeV

Reference number
ISO 15569:1998(E)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 15569 was prepared by the American Society for Testing and Materials (ASTM) Subcommittee E10.01 (as E 1649-94) and was adopted, under a special "fast-track procedure", by Technical Committee ISO/TC 85, *Nuclear energy*, in parallel with its approval by the ISO member bodies.

A new ISO/TC 85 Working Group WG 3, *High-level dosimetry for radiation processing*, was formed to review the voting comments from the ISO "Fast-track procedure" and to maintain these standards. The USA holds the convenership of this working group.

International Standard ISO 15569 is one of 20 standards developed and published by ASTM. The 20 fast-tracked standards and their associated ASTM designations are listed below:

ISO Designation	ASTM Designation	Title
15554	E 1204-93	*Practice for dosimetry in gamma irradiation facilities for food processing*
15555	E 1205-93	*Practice for use of a ceric-cerous sulfate dosimetry system*
15556	E 1261-94	*Guide for selection and calibration of dosimetry systems for radiation processing*
15557	E 1275-93	*Practice for use of a radiochromic film dosimetry system*
15558	E 1276-96	*Practice for use of a polymethylmethacrylate dosimetry system*
15559	E 1310-94	*Practice for use of a radiochromic optical waveguide dosimetry system*
15560	E 1400-95a	*Practice for characterization and performance of a high-dose radiation dosimetry calibration laboratory*
15561	E 1401-96	*Practice for use of a dichromate dosimetry system*

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15562	E 1431-91	*Practice for dosimetry in electron and bremsstrahlung irradiation facilities for food processing*
15563	E 1538-93	*Practice for use of the ethanol-chlorobenzene dosimetry system*
15564	E 1539-93	*Guide for use of radiation-sensitive indicators*
15565	E 1540-93	*Practice for use of a radiochromic liquid dosimetry system*
15566	E 1607-94	*Practice for use of the alanine-EPR dosimetry system*
15567	E 1608-94	*Practice for dosimetry in an X-ray (bremsstrahlung) facility for radiation processing*
15568	E 1631-96	*Practice for use of calorimetric dosimetry systems for electron beam dose measurements and dosimeter calibrations*
15569	E 1649-94	*Practice for dosimetry in an electron-beam facility for radiation processing at energies between 300 keV and 25 MeV*
15570	E 1650-94	*Practice for use of cellulose acetate dosimetry system*
15571	E 1702-95	*Practice for dosimetry in a gamma irradiation facility for radiation processing*
15572	E 1707-95	*Guide for estimating uncertainties in dosimetry for radiation processing*
15573	E 1818-96	*Practice for dosimetry in an electron-beam facility for radiation processing at energies between 80 keV and 300 keV*

For the purposes of this International Standard, the following amendments to the ASTM text apply.

Page 1, subclause 1.2, note 2, and subclause 1.3

Replace note 2 and subclause 1.3 by the following.

1.3 Dosimetry is only one component of a total quality assurance program for an irradiation facility. Other controls besides dosimetry may be required for specific applications such as medical device sterilization and food preservation.

1.4 For the irradiation of food and the radiation sterilization of health care products, other specific ISO standards exist. For food irradiation, see ISO 15562:1998, *Practice for dosimetry in electron and bremsstrahlung irradiation facilities for food processing* (ASTM Practice E 1431). For the radiation sterilization of health care products, see ISO 11137:1995, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization*. In those areas covered by ISO 11137, that standard takes precedence.

Page 1, subclause 1.4

Renumber this subclause as 1.5.

Designation: E 1649 – 94

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If not listed in the current combined index, will appear in the next edition.

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 E 1649; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This practice covers dosimetric procedures to be followed in facility characterization, process qualification, and routine processing using electron beam radiation to ensure that the entire product has been treated with an acceptable range of absorbed doses. Other procedures related to facility characterization (including equipment documentation), process qualification, and routine product processing that may influence and may be used to monitor absorbed dose in the product are also discussed.

NOTE 1—For guidance in the selection and calibration of dosimeters, see Guide E 1261. For further guidance in the selection, calibration, and use of specific dosimeters, and interpretation of absorbed dose in the product from dosimetry, also see Practices E 668, E 1275, E 1276, E 1431, E 1607, E 1631, and E 1650. For use with electron energies above 5 MeV, see Practices E 1026, E 1205, E 1401, E 1538, and E 1540 for discussions of specific large volume dosimeters. For discussion of radiation dosimetry for pulsed radiation, see ICRU Report 34. When considering a dosimeter type, be cautious of influences from dose rates and accelerator pulse rates and widths (if applicable).

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

NOTE 2—For application of dosimetry in the characterization and operation of electron beam and X-ray (bremsstrahlung) irradiation facilities for food processing, see Practice E 1431. For application of dosimetry in the characterization and operation of irradiation facilities using X-ray radiation (bremsstrahlung), see Practice E 1608.

1.3 Dosimetry is one component of a total quality assurance program for adherence to good manufacturing practices. Specific applications of electron beam radiation processing may require additional controls.

1.4 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

E 170 Terminology Relating to Radiation Measurements and Dosimetry[2]

E 668 Practice for the Application of Thermoluminescence-Dosimetry (TLD) Systems for Determining Absorbed Dose in Radiation-Hardness Testing of Electronic Devices[2]

E 1026 Practice for Using the Fricke Reference Standard Dosimetry System[2]

E 1205 Practice for Use of a Ceric-Cerous Sulfate Dosimetry System[2]

E 1261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing[2]

E 1275 Practice for Use of a Radiochromic Film Dosimetry System[2]

E 1276 Practice for Use of a Polymethylmethacrylate Dosimetry System[2]

E 1401 Practice for Use of a Dichromate Dosimetry System[2]

E 1431 Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing[2]

E 1538 Practice for Use of an Ethanol-Chlorobenzene Dosimetry System[2]

E 1539 Guide for the Use of Radiation-Sensitive Indicators[2]

E 1540 Practice for Use of a Radiochromic Liquid Solution Dosimetry System[2]

E 1607 Practice for Use of the Alanine–EPR Dosimetry System[2]

E 1608 Practice for Dosimetry in an X-Ray (Bremsstrahlung) Irradiation Facility for Radiation Processing[2]

E 1631 Practice for Use of Calorimetric Dosimetry Systems for Electron Beam Measurements and Dosimeter Calibrations[2]

E 1650 Practice for Use of a Cellulose Acetate Dosimetry System[2]

2.2 *International Commission on Radiation Units and Measurements (ICRU) Reports:*

ICRU Report 33 Radiation Quantities and Units[3]

ICRU Report 34 The Dosimetry of Pulsed Radiation[3]

ICRU Report 35 Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV[3]

ICRU Report 37 Stopping Powers for Electrons and Positrons[3]

3. Terminology

3.1 *Definitions*—Other terms used in this practice may be found in Terminology E 170 and ICRU Report 33.

3.2 *Descriptions of Terms Specific to This Standard:*

3.2.1 *absorbed dose, D*—the quotient of $d\bar{\varepsilon}$ by dm, where $d\bar{\varepsilon}$ is the mean energy imparted by ionizing radiation to the

[1] This practice is under the jurisdiction of ASTM Committee E-10 on Nuclear Technology and Applications and is the direct responsibility of Subcommittee E10.01 on Dosimetry for Radiation Processing.
Current edition approved Nov. 15, 1994. Published February 1995.

[2] *Annual Book of ASTM Standards*, Vol 12.02.

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

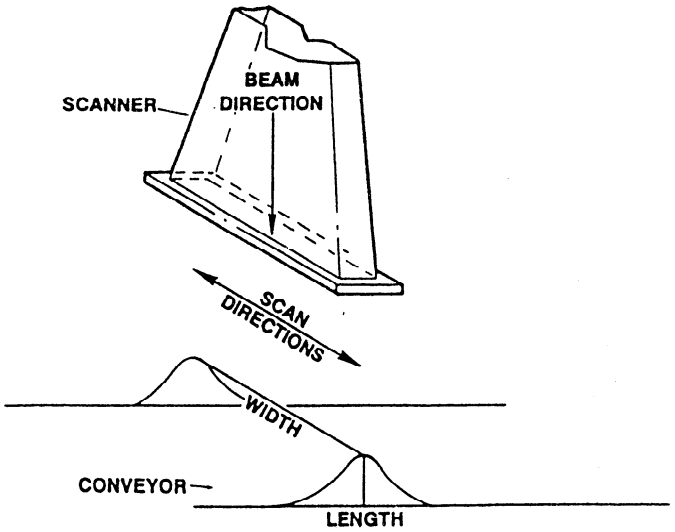


FIG. 1 Diagram Showing Beam Length and Width for a Scanned Beam Using a Conveyor Material Handling System

matter of mass *dm* (see ICRU Report 33).

$$D = \frac{d\bar{e}}{dm}$$

The special name of the unit for absorbed dose is the gray (Gy):

$$1\ \text{Gy} = 1\ \text{J}\cdot\text{kg}^{-1}$$

Formerly, the special unit for absorbed dose was the rad:

$$1\ \text{rad} = 10^{-2}\ \text{J}\cdot\text{kg}^{-1} = 10^{-2}\ \text{Gy}$$

and:

$$1\ \text{Mrad} = 10\ \text{kGy}$$

3.2.2 *average beam current*—time-averaged electron beam current; for a pulsed machine, the averaging shall be done over a large number of pulses.

3.2.3 *beam length*—dimension of the irradiation zone perpendicular to the beam width and direction of the electron beam specified at a specified distance from the accelerator window.

DISCUSSION—See Fig. 1.

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

3.2.5 *beam width*—dimension of the irradiation zone perpendicular to the beam length and direction of the electron beam specified at a specific distance from where the beam exits the accelerator.

DISCUSSION—For a radiation processing facility with a conveyor system, the beam width is usually perpendicular to the flow of motion of the conveyor (see Fig. 1). Beam width is the distance between the points along the dose profile which are at a defined level from the maximum dose region in the profile (see Fig. 2). Various techniques may be employed to produce an electron beam width adequate to cover the processing zone, for example, use of electromagnetic scanning of pencil beam (in which case beam width is also referred to as scan width), defocussing elements, and scattering foils.

3.2.6 *compensating dummy*—simulated product used during routine production runs with irradiation units containing less product than specified in the product loading configuration or at the beginning and end of a production run to compensate for the absence of product.

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

DISCUSSION—A typical distribution in homogeneous material produced by an electron beam along the beam axis is shown in Fig. 3. See

[4] McKeown, J., AECL Accelerators, private communication, 1993. Example of a beam width profile of an AECL Impela accelerator.

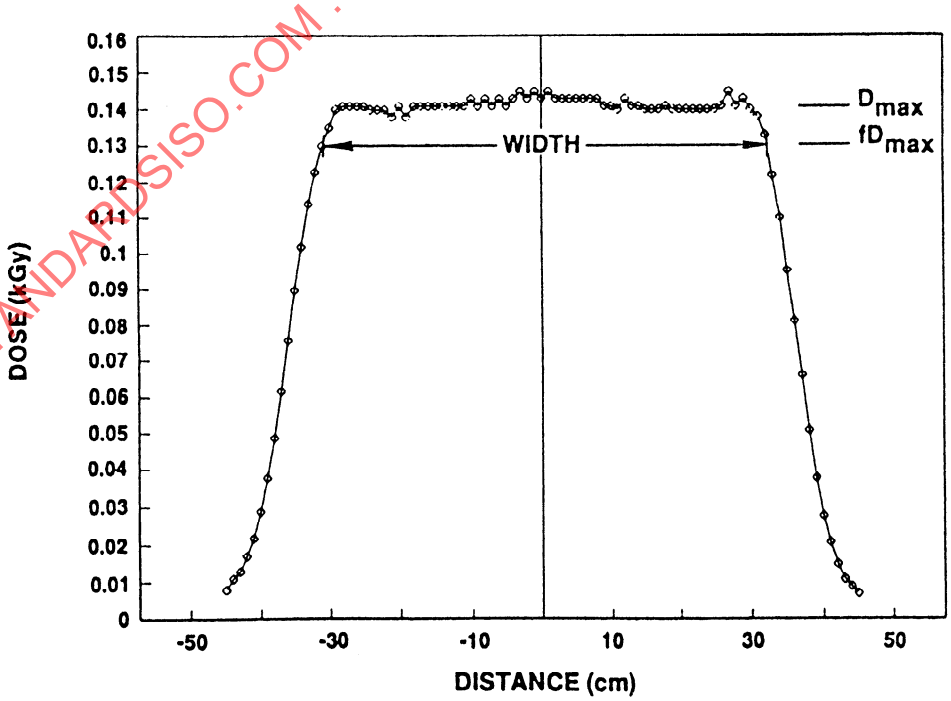


FIG. 2 Example of Electron-beam Dose Distribution Along the Beam Width[4] with the Width Noted at Some Defined Fractional Level *f* of the Average Maximum Dose D_{max}

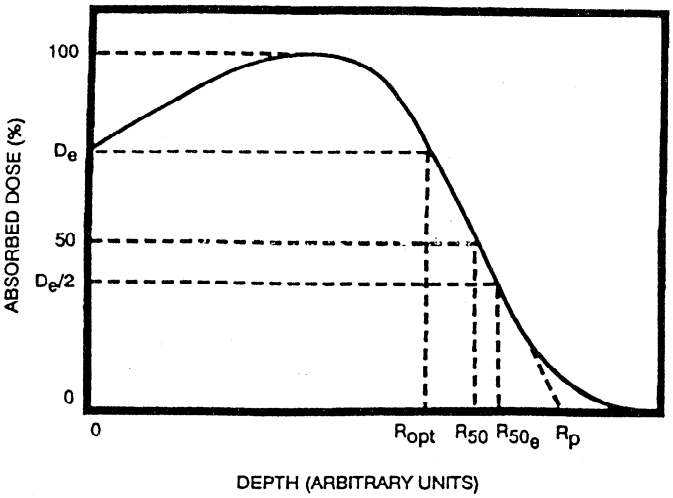


FIG. 3 A Typical Depth-Dose Distribution for an Electron Beam

Appendix X1.

3.2.8 *dose uniformity ratio*—ratio of the maximum to the minimum absorbed dose within the irradiation unit; it is a measure of the degree of uniformity of the absorbed dose; the concept is also referred to as the max/min dose ratio.

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

3.2.10 *duty cycle*—for a pulsed accelerator, the fraction of time the beam is effectively on; it is the product of the pulse width in seconds and the pulse rate in pulses per second.

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

3.2.12 *electron energy*—kinetic energy of electron (unit: electron volt (eV))

3.2.13 *electron energy spectrum*—frequency or energy distribution of electrons as a function of energy; the energy spectrum of the electron beam impinging on the product depends on the type of the accelerator and the conditions of the irradiation process.

3.2.14 *electron range*—penetration distance along the beam axis of electrons within homogeneous material.

DISCUSSION—Several range parameters may be defined to describe the characteristics of the electron beam. For more information, refer to ICRU Report 35.

3.2.15 *half-entrance depth* (R_{50e})—depth in homogeneous material at which the absorbed dose has decreased 50 % of the absorbed dose at the surface of the material.

DISCUSSION—See Fig. 3.

3.2.16 *half-value depth* (R_{50})—depth in homogeneous material at which the absorbed dose has decreased 50 % of its maximum value.

DISCUSSION—See Fig. 3.

3.2.17 *irradiation unit*—a volume of product with a specified loading configuration processed as a single entity; this term is not relevant to bulk-flow processing.

3.2.18 *optimum thickness* (R_{opt})—depth in homogeneous material at which the absorbed dose equals the absorbed dose at the surface where the electron beam enters.

DISCUSSION—See Fig. 3.

3.2.19 *practical range* (R_p)—distance from the surface of homogeneous material where the electron beam enters 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 depth axis.

DISCUSSION—See Fig. 3.

3.2.20 *production run*—series of irradiation units containing the same product, and irradiated sequentially to the same absorbed dose.

3.2.21 *pulse beam current*—for a pulsed accelerator, the beam current averaged over the top ripples (aberrations) of the pulse current waveform; this is equal to I_{avg}/wf, where I_{avg} is the average beam current, w is the pulse width, and f is the pulse rate.

DISCUSSION—See Fig. 4.

3.2.22 *pulse rate*—for a pulsed accelerator, the pulse current repetition frequency in hertz, or pulses per second; this is also referred to as the repetition (rep) rate.

3.2.23 *pulse width*—for a pulsed accelerator, the time interval between the half peak beam current amplitude points on the leading and falling edges of the pulse beam current waveform.

DISCUSSION—See Fig. 4.

3.2.24 *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, throughput rate, and reproducibility.

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

3.2.26 *scanned beam*—an electron beam which is swept back and forth with a varying magnetic field.

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.

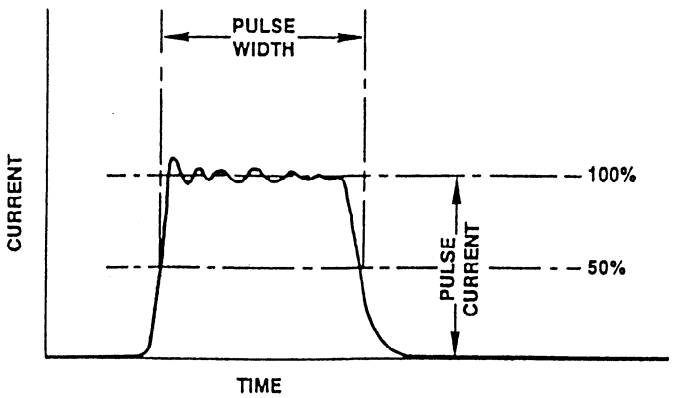


FIG. 4 Typical Pulse Current Waveform with Pulse Current and Pulse Width Noted

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

3.2.28 *simulated product*—a mass of material with attenuation and scattering properties similar to those of a particular material or combination of materials; this material is sometimes referred to as dummy product or phantom.

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 upon the radiation process and end use of the product. For example, a partial list of processes where dosimetry may be used is:

4.1.1 Cross-linking or degradation of polymers and elastomers,

4.1.2 Polymerization of monomers and grafting of monomers onto polymers,

4.1.3 Sterilization of medical devices,

4.1.4 Disinfection of consumer products,

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

4.1.6 Control of pathogens in liquid or solid waste,

4.1.7 Modification of characteristics of semiconductor devices,

4.1.8 Color enhancement of gemstones and other materials, and

4.1.9 Research on materials effects.

NOTE 3—Dosimetry is required for regulated radiation processes such as the sterilization of medical devices (**1, 2, 3**)[5] and the preservation of food. 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.

4.2 As a means of (quality) control of the radiation process, dosimeters are used to relate the calibrated response to radiation to the absorbed dose in the material or product being irradiated.

NOTE 4—Measured dose is often characterized as absorbed dose in water because materials commonly found in 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 in accordance with Guide E 1261.

4.3 A beneficial irradiation process is usually specified by a minimum absorbed dose to achieve the desired effect and a maximum dose limit that the product can tolerate and still be functional. Since it is used to determine these limits, dosimetry is essential in the evaluation and control of the radiation process.

4.4 The dose distribution within the product depends on irradiation unit characteristics, irradiation conditions, and operating parameters. The operating parameters consist of beam characteristics (such as energy and beam current), beam dispersion parameters, and product material handling. These critical parameters must be controlled to obtain reproducible results.

4.5 Before a radiation process can be used, the facility must be qualified to demonstrate its ability to deliver known, controllable doses in a reproducible manner. This involves testing the process equipment, calibrating the equipment and dosimetry system, and characterizing the magnitude, distribution, and reproducibility of the dose absorbed by a reference material.

4.6 To ensure that products are irradiated with reproducible doses, routine process control requires documented product handling procedures before, during, and after the irradiation, consistent orientation of the products during irradiation, monitoring of critical process parameters, routine product dosimetry, and documentation of the required activities and functions.

5. Radiation Source Characteristics

5.1 Radiation sources for electrons with energies greater than 300 keV considered in this practice are either direct-action (potential-drop) or indirect-action (microwave-powered) accelerators. These are further discussed in Appendix X2.

6. Types of Irradiation Facility

6.1 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; a laboratory for dosimetry and product testing; and personnel offices. The electron beam accelerator system consists of the radiation source (see Appendix X2), equipment to disperse the beam on product, and associated equipment (**4**).

6.2 *Process Parameters:*

6.2.1 There are various process parameters that play essential roles in determining and controlling the absorbed dose in radiation processing at an irradiation facility. They should, therefore, be considered when performing the absorbed-dose measurements required in Sections 8, 9, and 10.

6.2.2 Process parameters include irradiation unit characteristics (for example, size, bulk density, and heterogeneity), irradiation conditions (for example, processing geometry, multi-sided exposure, and number of passes through the beam), and operating parameters.

6.2.3 Operating parameters include beam characteristics (controlled by accelerator parameters: for example, energy, average beam current, and pulse rate), performance characteristics of material handling (see 6.3), and beam dispersion parameters (for example, beam width and frequency at which scanned beam is swept across product). Operating parameters are measurable, and their values depend on the facility controlling parameters. During irradiation facility qualification (see Section 8), absorbed dose characteristics over the expected range of the operating parameters are established for a reference material.

6.2.4 Process parameters for a radiation process are established during process qualification (see Section 9) to achieve the absorbed dose within the specified limits.

6.2.5 During routine product processing (see Section 10), the facility operating parameters are controlled and monitored to maintain all values that were set during process qualification.

[5] The boldface numbers in parentheses refer to a list of references at the end of this practice.

6.2.6 Different product types may require different operating and process parameters.

6.3 *Configuration of Material Handling*—The absorbed dose distributions within product may be affected by the material handling system. Examples of systems commonly used are:

6.3.1 *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.

6.3.2 *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.

6.3.3 *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.

6.3.4 *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 amount of irradiation time is controlled in conjunction with the electron beam current, beam length, and beam width to achieve the required dose.

7. Dosimetry Systems

7.1 Dosimetry systems are used to determine absorbed dose and consist of the dosimeter, the calibration curve or function, reference standards, appropriate instrumentation, and procedures for the system's use.

7.2 It is important that the dosimeter be evaluated for those parameters which may influence the dosimeter's response; for example, electron energy, average and peak absorbed dose rate (particularly for pulsed accelerators), and environmental conditions (for example, temperature, humidity, and light). Guidance as to desirable characteristics and selection criteria for dosimetry systems can be found in Guide E 1261, Practices E 1026, E 1205, E 1275, E 1276, E 1401, E 1538, E 1540, E 1607, E 1631, and E 1650.

7.3 The dosimetry system should be properly calibrated using a calibration service traceable to national standards. Guidance for calibration can be found in Guide E 1261.

8. Irradiation Facility Qualification

8.1 *Objective*—The purpose of qualifying an electron beam facility is to establish baseline data for evaluating the ability of the facility to accurately and reproducibly deliver doses over the range of conditions at which the facility will operate **(4)**. For example, dosimetry can be used (*1*) to establish relationships between measured absorbed dose distributions in reference materials in given geometries and operating parameters of the facility, and (*2*) to characterize dose variations when these conditions fluctuate statistically and through normal operations **(5)**.

8.2 *Equipment Documentation*—Document the irradiator qualification program that demonstrates that the irradiator, operating within specified limits, will consistently produce an absorbed-dose distribution in a given product to prerequisite specification. Such documentation shall be retained for the life of the irradiator, and include:

8.2.1 The irradiator specifications and characteristics,

8.2.2 A description of the location of the irradiator within the operator's premises in relation to the means provided for the segregation of non-irradiated products from irradiated products, if required,

8.2.3 A description of the construction and the operation of any associated material handling equipment,

8.2.4 The dimensions and the description of the materials and the construction of containers used to hold products during irradiation, if used,

8.2.5 A description of the manner of operating the irradiator, and

8.2.6 Any modifications made during and after installation.

8.3 *Equipment Testing and Calibration*—The absorbed dose within an irradiation unit depends in part on the operating parameters: beam characteristics, material handling, beam dispersion parameters, and their inter-relationships. It also depends on irradiation unit characteristics and irradiation conditions. These operating parameters are controlled by various accelerator and other facility parameters.

8.3.1 *Beam Characteristics:*

8.3.1.1 The three principal beam characteristics that affect dosimetry are the electron energy spectrum, average beam current, and pulse beam current. The electron energy spectrum affects the depth-dose distribution within the product (see Appendix X1). The average and pulse beam currents, in addition to several other operating parameters, affect the average and peak dose rates, respectively.

NOTE 5—Indirect-action (microwave-powered) accelerators may deliver higher dose rates while the beam current is actually on compared to direct-action (potential-drop) accelerators with the same average beam current. These higher dose rates in a pulsed mode may affect the dosimeter response.

NOTE 6—The electron energy spectrum of the accelerated electron beam may be characterized by the average electron energy (E_a) and the most probable electron energy (E_p) (see Appendix X3). An energy analyzing magnet may be used for more detailed analysis.

8.3.2 *Material Handling:*

8.3.2.1 For facilities utilizing continuously-moving conveyors (including, for example, roll-to-roll feed systems for tubing, wire, cable, and continuous web products) to transport product through the irradiation zone, conveyor speed determines the irradiation time. Therefore, when other operating parameters are held constant, conveyor speed governs the absorbed dose in the product.

NOTE 7—The conveyor speed and the beam current may be linked for some types of accelerators so that a variation in one causes a corresponding change in the other to maintain a constant value of the absorbed dose (also see Note 8).

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

8.3.3 *Beam Dispersion Parameters:*

8.3.3.1 Dispersion of the electron beam to produce a beam width adequate to 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.

8.3.3.2 The beam width, in addition to several other operating parameters, affects the dose rate. 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.

8.3.3.3 See Appendix X4 for determination of beam width and dose uniformity across the beam width.

8.4 *Irradiator Characterization:*

8.4.1 The dose on the surface of the product facing the beam is primarily related to the beam characteristics, the beam dispersion, electron scatter conditions at the surface, and material handling (see 8.3). Over the expected range of these operating parameters, establish the absorbed dose characteristics in a reference material using appropriate dosimetry.

NOTE 8—Electron beam irradiators generally utilize continuously-moving conveyors. Dose uniformity in a reference plane is strongly influenced by the coordination of the beam spot dimensions, conveyor speed, beam width, and scan frequency (for those irradiators that employ beam scanning). For a pulsed-beam accelerator, all these parameters must also be coordinated with the pulse width and repetition rate. Improper coordination of these parameters can cause unacceptable dose variation in the reference plane.

8.4.2 Using appropriate dosimetry, establish the depth-dose distribution within a reference material (see Appendixes X1 and X3). The exact shape of the distribution will be different for different facilities since it depends on the energy spectrum of the electron beam and the irradiation geometry (**6**). The depth of penetration depends on electron energy. Increasing the electron energy increases the half-value depth (R_{50}), the practical range (R_p), and the optimum thickness (R_{opt}).

8.4.3 Establish the capability of the facility to deliver a reproducible constant dose in a reference geometry. Measure the fluctuations in the values of the operating parameters that may cause variation in absorbed dose. Estimate the magnitude of these dose variations, for example, by passing dosimeters in the reference geometry through the irradiation zone on the product conveyor at time intervals appropriate to the frequency of the parameter fluctuations. The reference geometry for the irradiated material is selected so that the placement of the dosimeters on and within the material will not affect the reproducibility of the measurements.

9. Process Qualification

9.1 *Objective*—Absorbed dose requirements vary depending upon the process and type of product being irradiated. A radiation process is usually associated with a minimum absorbed dose requirement and sometimes a maximum absorbed dose requirement. For a given process, one or both of these limits may be prescribed by regulations. Therefore, the objective of process qualification is to ensure that absorbed dose requirements are satisfied. This is accomplished by mapping the dose distribution throughout the irradiation unit for a specific product loading pattern. This procedure also establishes all the process parameters, for example, electron energy, beam current, material handling parameters (conveyor speed or irradiation time), beam width, irradiation unit characteristics and irradiation conditions necessary to achieve the absorbed dose for the set requirements (see, for example, Refs **4**, **7**, and **8**).

NOTE 9—In conjunction with dose distribution measurements, it is usually necessary to do testing of the product to ensure compatibility with the electron beam treatment. It is recommended that this testing be done at doses higher than the maximum absorbed dose attained during routine processing.

9.2 *Determination of Product Loading Pattern*—A loading pattern for irradiation shall be established for each product type. The specification for this loading pattern shall document the following:

9.2.1 Description of the product with specifications that influence the absorbed dose distribution (such as dimensions and composition) and, if applicable, description of the orientation of the product within its package, and

9.2.2 Orientation of the product with respect to the material handling. This may include a further description of the orientation of the product within another container used during irradiation.

9.3 *Irradiation Unit Absorbed-Dose Mapping* (**9**):

NOTE 10—The irradiation of tubing, wire, cable, and continuous web products may not require absorbed dose mapping studies. Desired effects from absorbed dose may be attained through control of the operating parameters and monitoring the desired effects themselves.

9.3.1 Establish the locations of absorbed dose extremes for the selected product loading pattern. This can be accomplished by placing dosimeters throughout the volume of interest for several irradiation units. Select placement patterns that can most probably identify the locations of the dose extremes; concentrate dosimeters in those areas, with fewer dosimeters placed in areas likely to receive intermediate absorbed dose. Dosimeters used for dose mapping must be selected to be able to detect doses and dose gradients likely to occur within irradiated products. For electron irradiation, dosimeter films in sheets or strips may be most useful for obtaining this information. Because of variations in packaging geometry or product distribution, dosimeters placed in similar locations in several irradiation units may produce a range of absorbed dose measurements. Select a sufficient number of irradiation units for mapping to determine the variability of the distributions among irradiation units.

9.3.2 Ensure that values of the process parameters that affect the absorbed dose in the product are the same during both mapping and routine production runs. This requirement is necessary to avoid altering the magnitudes (and perhaps locations) of absorbed dose extremes because a change in process parameters might cause the doses to lie outside the prescribed absorbed dose requirements. Dose mapping may need to be repeated whenever one or more of the process parameters are changed.

9.3.3 If process parameters are changed that could affect the magnitudes or locations of absorbed dose extremes, repeat the dose mapping to the extent necessary to establish the effects.

9.3.4 If the locations of absorbed dose extremes identified during the dose mapping procedure of 9.3.1 are not readily accessible during production runs, alternative external or internal positions may be used for routine product processing dosimetry. The relationships between the absorbed doses at these alternative reference positions and the ab-

sorbed dose extremes shall be established, shown to be reproducible, and documented.

9.3.5 Results from the dose mapping measurements will govern the dose to be delivered to the product to ensure that prescribed dose requirements within the product are achieved. The uncertainties of the dosimetry system, the uncertainties from the measurement of the dose distribution, and the variations of the radiation process lead to an overall uncertainty of the minimum and maximum doses within the product. This uncertainty must be taken into account when the process parameters are chosen. Generally, the parameters must be chosen so that the probability of irradiating the product or part of the product with doses lower than the required minimum or higher than the allowed maximum is known and documented **(7, 8)**.

9.3.6 For irradiators being used in a bulk flow mode, absorbed-dose mapping as described in 9.3.1 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 **(10, 11)**. Calculation of the absorbed dose extremes may be an appropriate alternative **(8)**.

9.3.7 If the dose mapping procedure of 9.3.1 reveals that the measured dose extremes are unacceptable, it may be possible to alter these values by changing the operating parameters. Alternatively, it may be necessary to change the product within the irradiation unit or the shape, size, or flow pattern of the irradiation unit itself.

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

9.3.7.2 Depending upon the density, thickness, and inhomogeneity of an irradiation unit and beam energy of the irradiator, many processes require double-sided irradiation to achieve an acceptable dose distribution. For double-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 irradiation unit may cause much more pronounced changes in absorbed dose within the product for double-sided irradiation as compared to single-sided irradiation.

10. Routine Product Processing (Ref 4)

10.1 *Process Parameters:*

10.1.1 For routine product processing, set the operating parameters as established during process qualification.

10.1.2 Control, monitor and document the operating parameters to ensure that each irradiation unit that passes through the irradiator is processed in accordance with specifications.

10.1.3 If these parameters deviate outside the processing limits prescribed from process qualification, take appropriate actions, for example, immediate interruption of the process to evaluate and correct the cause of the deviations.

NOTE 11—Monitoring of operating parameters alone may not be adequate for some radiation processes (for example, sterilization and food irradiation). For these situations, dosimetry is required during routine product processing.

10.2 *Routine Production Dosimetry*—Ensure that the product receives the absorbed dose within prescribed limits by employing proper dosimetry procedures, with appropriate statistical controls and documentation. These procedures involve the use of routine in-plant dosimetric measurements performed as follows:

NOTE 12—Some processes, such as the modification of material properties, may not require routine dosimetry (see Notes 3 and 11).

10.2.1 *Dosimeter Location*—Place dosimeters either within or on the selected irradiation units at predetermined locations of the minimum (and maximum, if a prescribed limit) absorbed dose (see 9.3.1), or at the reference positions determined in 9.3.4.

10.2.2 *Placement Frequency*—Place dosimeters at locations described in 10.2.1. Always place dosimeters at the start of the run. For long production runs, place dosimeters at or near the middle of the run, at the end of the run, and at other intervals as appropriate.

NOTE 13—More frequent placement of dosimeters during the production run could result in less product rejection should some operational uncertainty or failure arise.

10.2.3 *Partial Loading*—If processing partially-loaded irradiation units is necessary, follow the same process qualification requirements as for fully-loaded irradiation units. Perform the dose mapping procedures of 9.3 to ensure that the absorbed-dose distributions are adequately characterized and are acceptable. Variations to the dose distribution from a partial loading may in some cases be minimized by the use of compensating dummy material placed at appropriate locations within the irradiation unit.

10.2.4 *Bulk-flow*—For some types of bulk-flow irradiators (for example, where fluids or grains continuously flow during irradiation), where it may not be feasible during routine production to place dosimeters at the locations of minimum and maximum absorbed dose, add several dosimeters 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 is known. This procedure requires that the total irradiation time and rate of flow of the dosimeters are the same as those of the product.

NOTE 14—In case it is not feasible to utilize dosimeters during the routine processing of bulk materials, it may be acceptable to rely on process 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 process parameters and by repeating the process qualification procedure at appropriate intervals.

10.2.5 *Environmental Changes*—A change in the environment (for example, temperature or humidity) of a dosimeter during the irradiation process may affect its response. If required, correct the dosimeter response for any such effect (see Guide E 1261).

10.3 *Radiation-Sensitive Indicators*—For some dose levels, radiation-sensitive indicators may be available that

can be used for process control and for inventory purposes. A radiation-sensitive indicator may be affixed on each irradiation unit to help ensure that the unit has passed through the irradiation zone. For multiple irradiation, one indicator may be affixed before each pass on each side facing the electron beam to give visual evidence of the number of passes the irradiation unit has traversed. However, the use of radiation-sensitive indicators is not a substitute for the dosimetry procedures described in 10.2. See Guide E 1539.

11. Certification

11.1 *Documentation Accumulation:*

11.1.1 *Irradiation Control and Dosimetry Record:*

11.1.1.1 Record and document all dosimetry data for irradiator facility qualification, process qualification, and routine production processing. Include date, time, product type, loading diagrams, and absorbed doses for all products processed (see Guide E 1261).

11.1.1.2 Record the values of the process parameters affecting absorbed dose together with sufficient information identifying these parameters with specific production runs.

11.1.1.3 Record or reference the calibration and maintenance of equipment and instrumentation used to control or measure the absorbed doses delivered to the product (see Guide E 1261).

11.1.2 *Facility Log:*

11.1.2.1 Ensure that each lot of product that is processed bears a distinct identification that distinguishes it from all other lots in the facility. This identification shall be used on all lot documents (see 11.1.1).

11.1.2.2 Record the date the product is processed and the starting and the ending times of the irradiation. 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.

11.2 *Review and Approval:*

11.2.1 Certify, for each production run, in accordance with an established quality assurance program, the delivery of the dose to the product. Certification shall be performed by authorized personnel as documented in the quality assurance program.

11.2.2 Audit all documentation periodically to ensure that records are accurate and complete.

11.3 *Retention of Records:*

11.3.1 File all information pertaining to each production run (copies of receiving and shipping documents, dose calibration documents for the run, certificate of irradiation, dosimetry measurements, and the irradiation control record; see 11.1.1).

11.3.2 Retain the files at the facility and have them available for inspection as needed. Keep the files for a period of time specified by relevant authorities.

12. Precision and Bias

12.1 For many applications, it is essential to know the accuracy of the absorbed dose measurement. In most applications, there are specific absorbed dose limits. Because of the statistical nature of dose measurements, variations of irradiation unit characteristics, irradiation conditions, and operating parameters, it must be anticipated that some measurement may fall outside a dose limit. The process must be set so that this can only occur at some acceptable level of probability (7, 8).

12.2 Records and reports shall include estimates of the measurement uncertainty of absorbed dose that include both precision and bias at a specified confidence level (see Guide E 1261).

12.3 The level of uncertainty that is acceptable shall satisfy regulatory and commercial requirements pertaining to the specific product being irradiated.

13. Keywords

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

APPENDIXES

(Nonmandatory Information)

X1. ELECTRON BEAM DEPTH-DOSE DISTRIBUTIONS, MATERIAL PROCESSING RATES, AND TEMPERATURE RISE DURING RADIATION TREATMENT

X1.1 This appendix describes the distribution of absorbed dose in homogeneous materials at different electron energies, methods to estimate processing rates for different absorbed doses, and temperature increase within material as a consequence of absorbing dose adiabatically.

X1.2 Depth-Dose Distribution

NOTE X1.1—Depth dose-distributions curves presented in this section and conclusions drawn from these curves, except where noted, are theoretically calculated based upon monoenergetic electron beams and may exhibit varying levels of inaccuracy. Practical measurements of these curves may deviate from the figures because the electron beam is usually not monoenergetic. Additionally, scanned electron beams will exhibit changing energy spectra along the width of the scanned beam.

X1.2.1 Electron beam treatment of homogeneous materials produces absorbed 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 curve 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. This is illustrated in Fig. X1.1 which presents theoretically calculated depth-dose curves for polyethylene (PE), polystyrene (PS), polytetrafluoroethylene (PTFE), polyvinylchloride (PVC), aluminum (Al) and iron (Fe) with 5 MeV monoenergetic electrons.

X1.2.2 The depth of penetration (electron range) is nearly

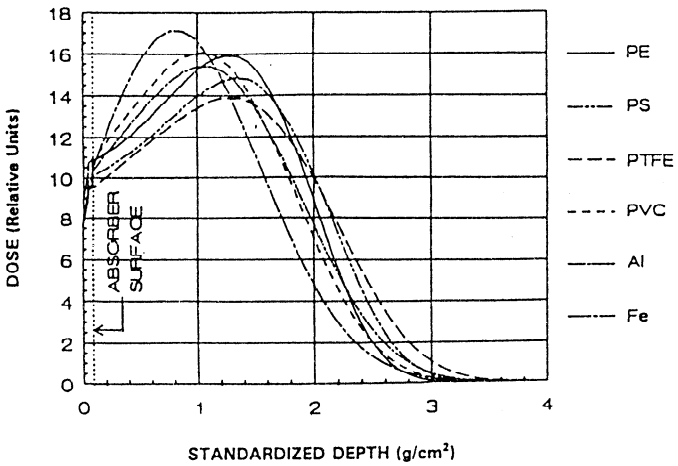


FIG. X1.1 Calculated Depth-Dose Distribution Curves in Various Homogeneous Materials for Normally Incident Monoenergetic Electrons at 5.0 MeV Using the Program EDMULT (12, 13)

proportional to the incident electron energy. This is shown in Figs. X1.2 through X1.4 which present the depth-dose distribution curves for polystyrene with monoenergetic electron energies from 400 keV to 12 MeV. 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 1.0 MeV, but become insignificant as the energy increases.

NOTE X1.2—The depth-dose distribution curves in Figs. X1.1 through X1.4 have been calculated for normal incidence of monoenergetic electrons on flat sheets of homogeneous polystyrene using the EDMULT program for three-layer absorbers. This program can be used for any combination of materials in the energy range from 0.1 MeV to 20 MeV **(12, 13)**. More complex Monte Carlo programs can also be used for this purpose **(14)**.[6]

NOTE X1.3—The thickness of the absorbing material is usually referred to as standardized depth and is expressed as the mass per unit area z, which is the depth in the material t times the density ρ. If m is the mass of the material and A is the area of the material through which the beam passes, then:

$$z = m/A = t\rho, \qquad \text{(X1.1)}$$

If t is in centimetres and ρ in grams per cubic centimetre, then z is in grams per square centimetre. This is the depth unit used in Figs. X1.1 through X1.4.

NOTE X1.4—In Fig. X1.1 the beam window is assumed to be 10^{-4} m thick titanium (0.045 g/cm²) followed by 0.3 m of air (0.036 g/cm²). The surface of the polystyrene begins after the electron beam has passed through a total standardized depth of 0.081 g/cm². In Figs. X1.2 through X1.4, the window is assumed to be 4×10^{-5} m thick titanium (0.018 g/cm²) followed by 0.15 m of air (0.018 g/cm²). The surface of the polystyrene begins after the electron beam has passed through a total standardized depth of 0.036 g/cm².

X1.2.3 The maximum thickness of homogeneous material that can be treated at a given electron energy depends on the acceptable level of dose uniformity given as the ratio of the maximum to minimum absorbed dose (max to min ratio) within the material. For single 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 X1.2.6). For double treatment from opposite sides, the thickness may be more than twice R_{opt} because of the overlapping tails of the depth-dose curves.

NOTE X1.5—For example, 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. X1.5).

NOTE X1.6—For example, 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. X1.5). For thicknesses greater than this, the dose uniformity ratio will dramatically increase with increasing thickness.

NOTE X1.7—For example, 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. X1.5).

NOTE X1.8—Figure X1.5 is derived from theoretical calculations at monoenergetic electron energy and presents examples only. Practical measurements of these curves may deviate from the examples because the electron beam is usually not monoenergetic. Additionally, scanned electron beams will exhibit changing energy spectra along the width of the scanned beam.

X1.2.4 The correlations between optimum thickness R_{opt}, half-value depth R_{50}, half entrance depth R_{50e}, and the practical range R_p, and the incident electron energy are shown in Fig. X1.6. These values have been obtained from the depth-dose distribution curves for polystyrene shown in Figs. X1.3 and X1.4. The energy dependences of these thickness criteria are nearly linear from 1 to 12 MeV.

X1.2.5 Figure X1.7 presents measured depth-dose distribution curves for nominal 10 MeV electron beams incident on homogeneous polystyrene. These curves are provided by various accelerator manufacturers and electron beam facilities. Important parameters influencing the curves are presented in Table X1.1.

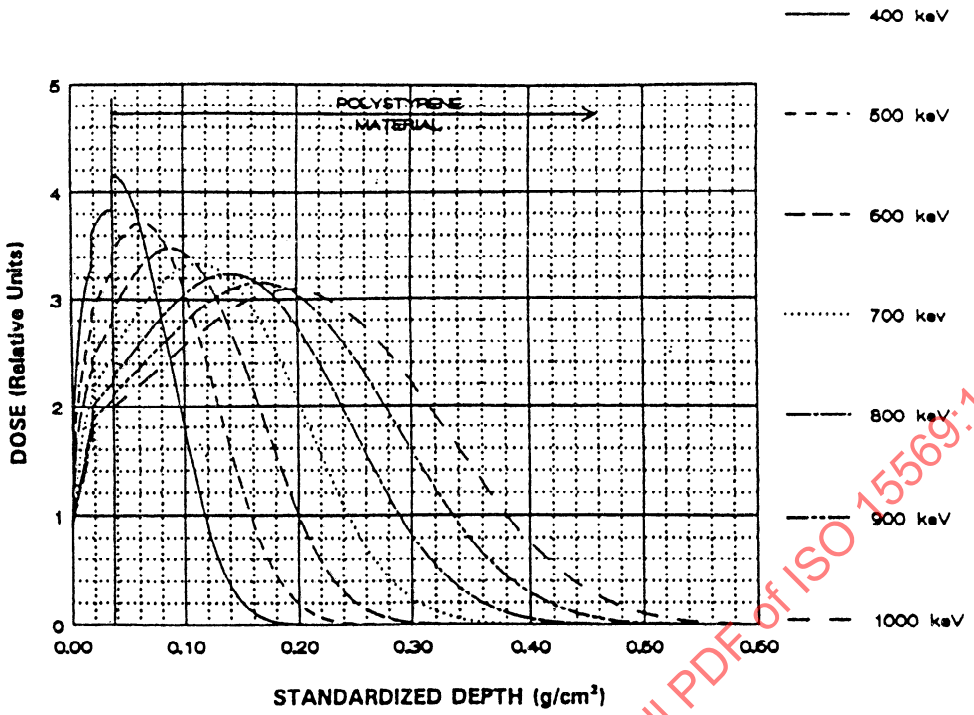
X1.2.5.1 There are noticeable differences between these curves and the theoretical calculated curve presented in Fig. X1.4. This illustrates the caution that must be taken when comparing the theoretical curves to measured curves. Properties of the measured curves are influenced, for example, by the accuracy of the dosimetry used to create the curves, energy spectrum of the electron beam, and accuracy of the estimated nominal electron beam energy.

X1.2.6 If the material thickness is less than the maximum range of the electrons, then the dose at the exit surface will be affected by the composition of the backing material. This is caused by reflection or backscattering of electrons by the backing material. This effect can be estimated with the EDMULT program **(12, 13)** or Monte Carlo programs **(14)**.[6]

X1.2.6.1 With backing materials of higher effective atomic number and atomic weight 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. X1.8 which presents measured depth-dose distributions with 400 keV electrons in stacks of cellulose acetate films backed with wood, aluminum, and iron **(15)**.

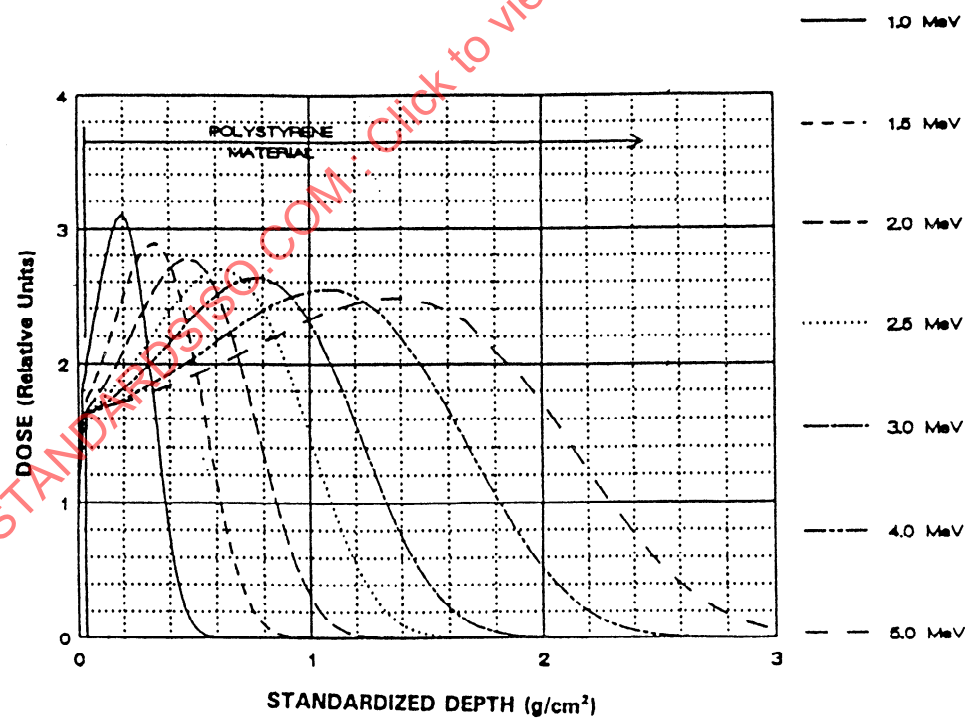
X1.2.6.2 With backing materials of lower effective atomic number and atomic weight than the irradiated material, the exit dose will be lower than indicated by the depth-dose

[6] CCC-107/ETRAN, CCC-331/EGS4, and CCC-467/ITS. These Monte Carlo codes are available from the Radiation Shielding Information Center (RISC), Oak Ridge National Laboratory, P.O. Box 2008, Oak Ridge, TN 37831.



NOTE—The window is assumed to be 4×10^{-5} m thick titanium (0.018 g/cm²) followed by 0.15 m of air (0.018 g/cm²). See Note X1.3 for further discussion of the determination of standardized depth.

FIG. X1.2 Calculated Depth-Dose Distribution Curves in Polystyrene for Normally Incident, Plane Parallel Incident Electrons at Monoenergetic Energies from 400 to 1000 keV Using the Program EDMULT (12, 13)

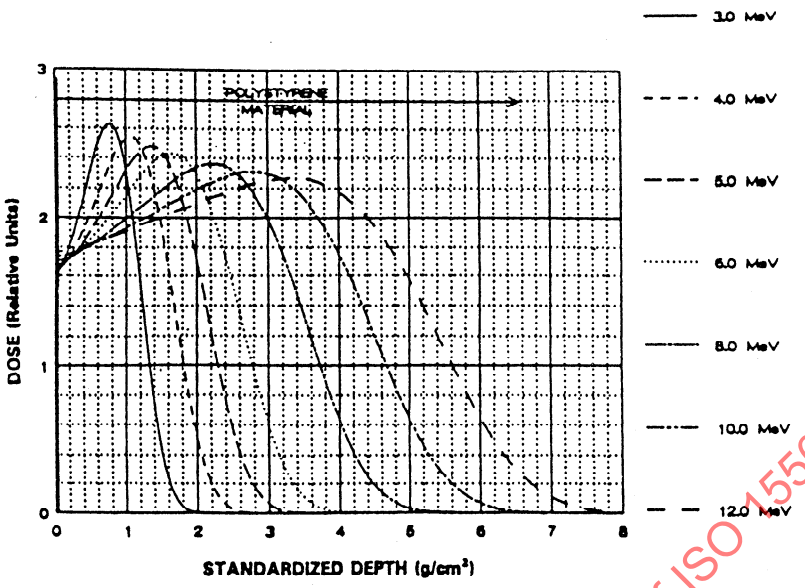


NOTE—The window is assumed to be 4×10^{-5} m thick titanium (0.018 g/cm²) followed by 0.15 m of air (0.018 g/cm²). See Note X1.3 for further discussion of the determination of standardized depth.

FIG. X1.3 Calculated Depth-Dose Distribution Curves in Polystyrene for Normally Incident, Plane Parallel Incident Electrons at Monoenergetic Energies from 1.0 to 5.0 MeV Using the Program EDMULT (12, 13)

distribution curves for thick absorbers (16).

X1.2.7 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



NOTE—The window is assumed to be 4 × 10^{-5} m thick titanium (0.018 g/cm²) followed by 0.15 m of air (0.018 g/cm²). See Note X1.3 for further discussion of the determination of standardized depth.

FIG. X1.4 Calculated Depth-Dose Distribution Curves in Polystyrene for Normally Incident, Plane Parallel Incident Electrons at Monoenergetic Energies from 3.0 to 12.0 MeV Using the Program EDMULT (12, 13)

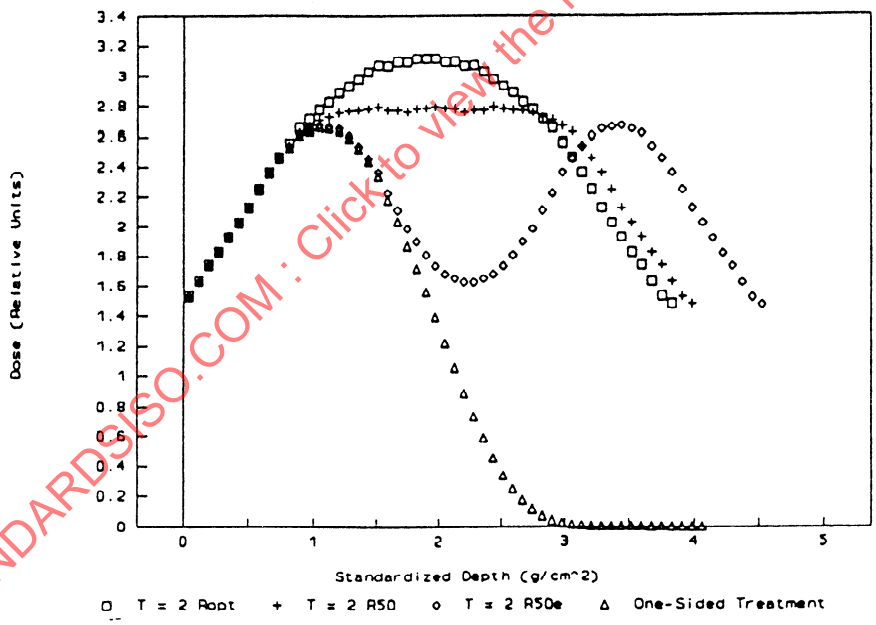


FIG. X1.5 Superposition of Theoretically Calculated Depth-Dose Distribution Curves for Aluminum Irradiated with 5 MeV Monoenergetic Electrons from Both Sides with Different Thicknesses (T) and from One Side Using Data Presented in Ref. 16 (see Note X1.8)

modified. This is shown in Fig. X1.9 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 (**16**).

X1.2.8 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 9.3.

X1.3 Area Processing Rate

X1.3.1 Area 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. All product surfaces facing and normal to the beam will receive approximately the same dose if the materials are of similar composition and density. The quantities A/T and F_i can be evaluated for the product conveyor rather than the individual objects on the conveyor.

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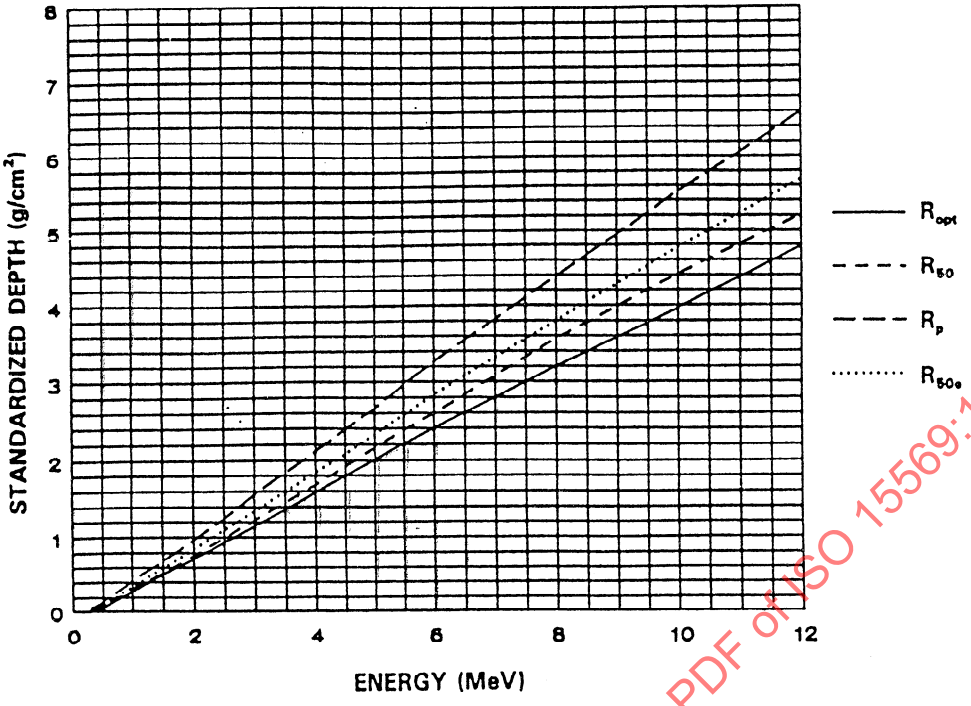
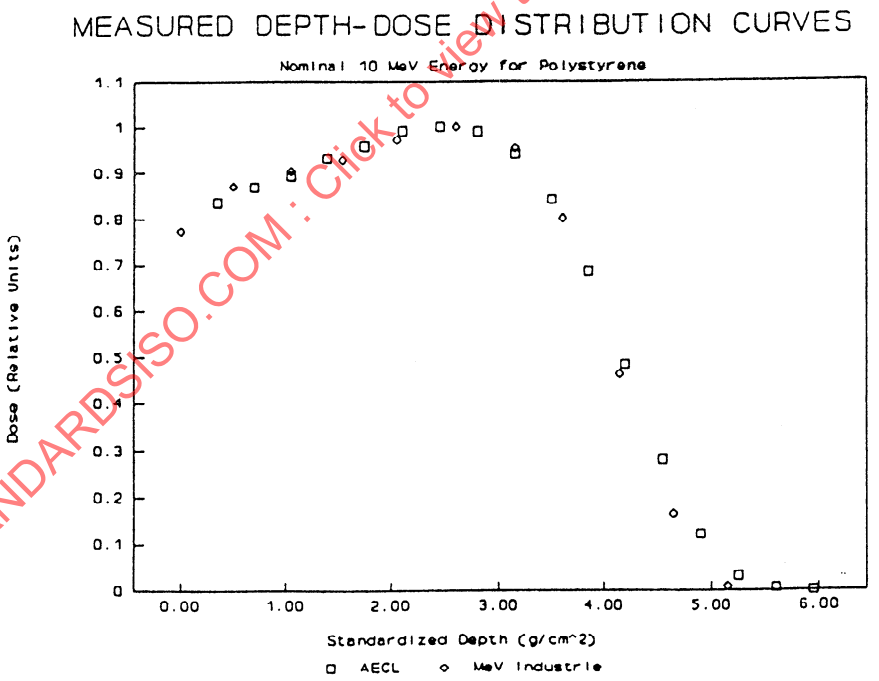


NOTE—Nearly equivalent values may be expected for water.

FIG. X1.6 Calculated Correlations Between Optimum Electron Range R_{opt}, Half-Value Depth R_{50}, Half-Entrance Depth R_{50e}, and Practical Range R_p, and Incident Electron Energy for Polystyrene Using Figs. X1.3 and X1.4



NOTE—See Table X1.1 for key parameters.

FIG. X1.7 Measured Depth-Dose Distribution Curves for Nominal 10 MeV Energy Electron Beams Incident to Polystyrene for Various Accelerator Types and Electron Beam Facilities[7,8]

[7] Morrisseau, D., Ross, A., and Sadat, T. MeV Industrie S.A., private communication, 1993. Example of depth-dose distribution curve for nominal 10-MeV energy electron beam incident on polystyrene using CIRCE accelerator at Société des Protéines Industrielles (SPI), Berric, France.

[8] Herer, A., E-Beam Services, private communication, 1993. Example of depth-dose distribution curve for nominal 10-MeV energy electron beam incident on polystyrene using AECL Impela accelerator at E-Beam Services.

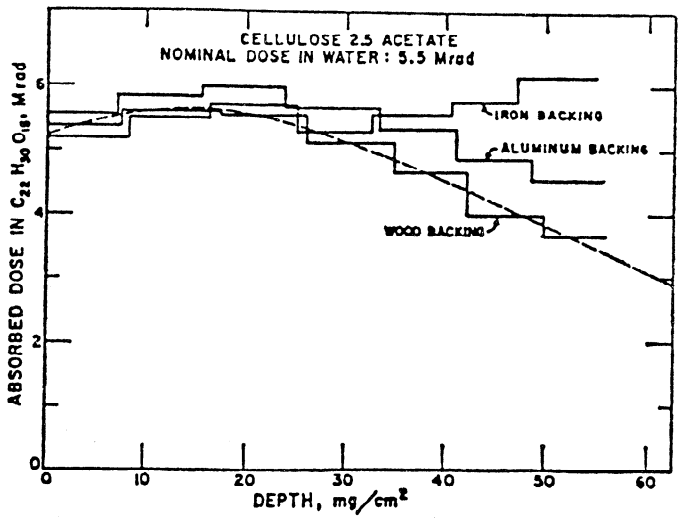


FIG. X1.8 Depth-Dose Distribution Curves in Stacks of Cellulose Acetate Films Backed with Wood, Aluminum, and Iron for Incident Electrons with 400 keV Energy (15)

TABLE X1.1 Key Parameters for Measured Depth-Dose Distribution Curves Presented in Fig. X1.7

	MeV industrie CIRCE[A,7]	AECL Impela[B,8]
Nominal beam energy (MeV)	10	10
Energy spectrum	unknown	unknown
Window Material	Ti	Ti
Window Thickness (m)	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.
[B] Installed at E-Beam Services, Cranbury, NJ.

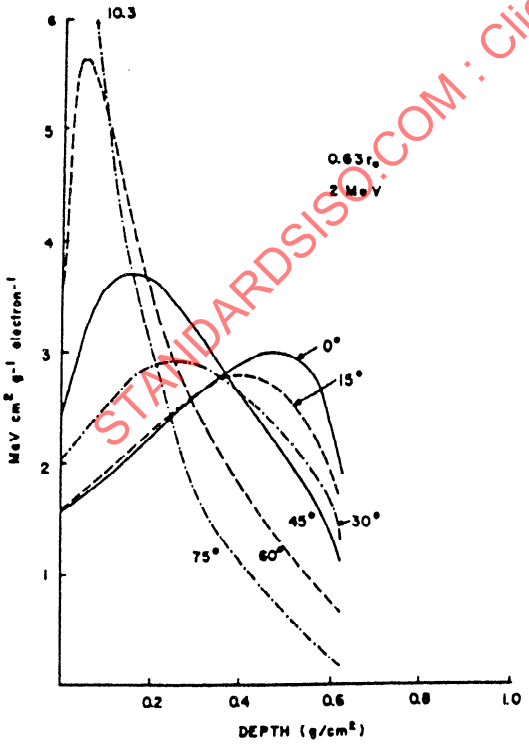
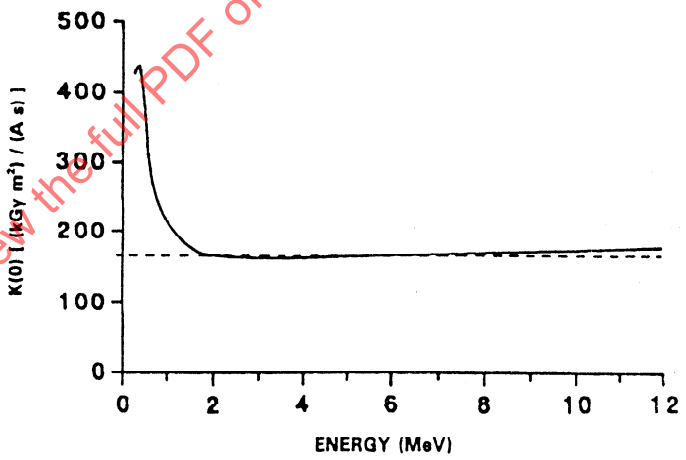


FIG. X1.9 Depth-Dose Distributions with 2 MeV Electrons Incident on Polystyrene Absorbers at Various Angles from the Normal Direction (16)



NOTE—The window is assumed to be 4×10^{-5} m thick titanium followed by 0.15 m of air.

FIG. X1.10 Area Processing Coefficient $K(0)$ at the Entrance Surface of the Material as a Function of Incident Electron Energy from 400 keV to 12 MeV

X1.3.2 The area processing rate is the area of product exposed to the electron beam per unit time. It is proportional to the beam current and inversely proportional to the absorbed dose. This relationship can be expressed as follows:

$$A/T = K(z)IF_i/D(z) \quad \text{(X1.2)}$$

where A/T is the area processing rate, I is the electron beam current, F_i is the fraction of the current that is intercepted by the irradiated material or the conveyor, and $D(z)$ is the absorbed dose at a specified depth z in the treated material. The factor $K(z)$ may be called the area processing coefficient. $K(z)$ must be evaluated at the depth where the dose is specified (17, 18).

NOTE X1.9—The absorbed dose in the irradiated material is defined as the energy imparted per unit mass (see 3.2). In an electron beam treatment process, the absorbed dose per unit electron fluence $D_e(z)$ is proportional to the energy deposition per unit mass per unit fluence at the depth z (see Note X1.10). As used here, fluence is the number of electrons incident per unit area on a small volume of material. Units of

$D_e(z)$ are MeV·m²/(kg·electron). Values of $D_e(z)$ can be calculated for flat sheets of homogeneous materials with the EDMULT program (**12, 13**). For complex product shapes and compositions, Monte Carlo methods are more appropriate (**14**).[6]

NOTE X1.10—In an electron beam treatment process, the absorbed dose $D(z)$ at the depth z can be conveniently obtained from (see Note X1.9):

$$D(z) = D_e(z)IT/A \quad \text{(X1.3)}$$

where $D(z)$ is in Gy, I is in A, A is in m², and T is in s. This equation can be rearranged to give the area processing rate as follows:

$$A/T = D_e(z)I/D(z) \quad \text{(X1.4)}$$

By comparing Eq X1.4 to Eq X1.2, the area processing coefficient $K(z)$ is given by:

$$K(z) = 10^{-3}D_e(z) \quad \text{(X1.5)}$$

So, values of $K(z)$ in Eq X1.2 are proportional to the absorbed dose per unit fluence $D_e(z)$ at the depth z in the material. If $D_e(z)$ is in MeV·m²/(kg·electron), then Eq X1.5 gives $K(z)$ in kGy·m²/(A·s).

X1.3.3 The values of $K(0)$ at the entrance surface of the material are often used to characterize an electron beam treatment process. Above 2 MeV these surface values are nearly independent of the electron energy. However, they increase substantially below 2 MeV. These trends are shown in Fig. X1.10 for polystyrene.

NOTE X1.11—Between 2 MeV and 8 MeV, the value of $K(0)$ is about 10 kGy·m²/(mA·min) for polystyrene and hydrocarbon materials with similar atomic compositions. This means that the surface dose will be about 10 kGy (1 Mrad) for a beam current of 1 mA and an area throughput rate of 1 m²/min. This relationship is sometimes called the "unity rule." The convenience of the use of this rule explains why applicable units of some of the variables used are not SI units.

X1.4 Mass Processing Rate

X1.4.1 The mass processing rate is the mass of material that can be processed per unit time. The definition of absorbed dose (3.2) is the basis of the relationship between mass processing rate and beam power, which can be expressed as follows:

$$M/T = PF_p/D_a \quad \text{(X1.6)}$$

where M/T is the mass processing rate in kg/s, P is the electron beam power in W, F_p is the fraction of the beam power absorbed by the treated material, and D_a is the dose in Gy. D_a is the average dose throughout the treated material in contrast to the dose $D(z)$ in Eq X1.2 which must be measured at a specified depth z. The average dose is usually somewhat larger than the surface dose (**17, 18**).

X1.4.2 Equation X1.6 is useful when estimating the mass processing rate for bulk treatment processes or flat sheets of homogeneous material. In such cases, the value of F_p is the ratio of the area under the depth-dose distribution curve corresponding to the material thickness to the total area under the curve compensated for beam loss because of the beam width exceeding the product width.

X1.4.2.1 With heterogeneous materials like medical devices or molded parts, it is difficult to calculate accurate values for F_p, so Eq X1.6 is not very useful for such processes.

X1.5 Temperature Rise

X1.5.1 Irradiation causes the temperature of the treated material to increase. This is the basis of the calorimetric method of dose measurement (see Practice E 1631). In high-dose processes with high-power electron beams, the temperature rise may have to be controlled by cooling the material during continuous exposure or by multiple treatments with cooling between each exposure.

X1.5.2 Neglecting energy transformations from chemical reactions and any convective, conductive, or radiant cooling, the adiabatic temperature increase ΔT is given by:

$$\Delta T = D_a/c \quad \text{(X1.7)}$$

where D_a is the average dose in Gy, and c is the specific heat capacity of the absorbing material in J/(kg·°K). Most plastics and metals have lower heat capacities than water, so their temperature rises will be greater than water.

NOTE X1.12—Temperature increases due to absorbed dose may affect the response of dosimeters placed within the material.

X2. CHARACTERISTICS OF ACCELERATORS PRODUCING ELECTRONS WITH ENERGIES > 300 keV

X2.1 Type of Accelerator

X2.1.1 Medium-energy (between 300 keV and 5 MeV) electrons are commonly produced by potential drop accelerators, whereas high-energy (>5 MeV) electrons are commonly produced using microwave powered accelerators. Electrostatic accelerators can be used to accelerate high-energy electrons, but such systems have seldom been used for radiation processing.

X2.1.2 *Characteristics of Microwave-powered Accelerators* (**19–25**):

X2.1.2.1 Electrons are introduced into an accelerating 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.

X2.1.2.2 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.

X2.1.2.3 The energy of the electron beam depends upon the RF power level and the injected electron beam current. Electron energies commonly produced by microwave powered accelerators in use today for radiation processing are greater than 5 MeV.

X2.1.2.4 The electron beam is typically pulsed.

NOTE X2.1—For pulsed accelerators using a swept beam, interactions between the beam pulse rate frequency and the sweep frequency which may affect the distribution of the delivered dose may need to be evaluated.

X2.1.3 *Characteristics of Potential-drop Accelerators* (**24, 25**):

X2.1.3.1 Electrons are introduced into the accelerator from an injector. The electrons are accelerated to the final energy through a potential difference. The injector is located in a terminal held at a high, negative potential corresponding

to the final electron energy. The electrons are accelerated toward ground potential.

X2.1.3.2 The electron beam may consist of constant direct current (dc) or pulsating current.

X2.1.3.3 The energy of the electron beam is primarily controlled by the potential (voltage) 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.

X2.1.3.4 The injector, terminal, and terminal charging equipment are located in a large tank. The tank is filled with insulating gas or liquid to prevent electrical breakdown of the high terminal voltage. The most powerful systems utilize cascaded rectifier circuits to convert low-voltage alternating current (ac) to high-voltage dc power.

X2.1.4 The beam line through which the electrons travel is under vacuum. Steering and focussing of the electron beam is accomplished with electromagnets and electrostatic fields.

X2.1.5 The energy 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.

X2.1.6 After extraction from the accelerating structure and prior to irradiation of the product, the electron beam is usually dispersed to accommodate the irradiation unit size. This is typically done by sweeping the beam back and forth across the product using an electromagnet with a varying magnetic field, although defocussing elements and scattering foils can be used.

X2.2 Beam Characteristics

X2.2.1 Electron beams are characterized by the following parameters (defined in 3.2):

X2.2.1.1 *Electron Energy*—This practice encompasses electron energies from 300 keV to 25 MeV used for radiation processing. Some accelerators are capable of providing one nominal energy whereas other accelerators can provide variable energies.

X2.2.1.2 *Average Beam Current.*

X2.2.1.3 *Beam Power.*

X2.2.1.4 *Beam Width*—The beam width must cover the profile (including positional variations and uncertainties) of the product passing through the radiation zone. For a scanned beam, the beam width defines the sweep dimension of the beam. See Appendix X4 for discussion regarding the measurement of beam width.

X2.2.1.5 *Beam Length*—Beam length is critical for processes where product is stationary under the beam; however, the beam length is not critical for products moving continuously through the beam.

X2.2.1.6 *Scan Uniformity*—See Appendix X4 for discussion regarding the measurement of dose uniformity of a scanned beam.

X2.2.2 Additional, unique characteristics (defined in 3.2) of pulsed electron beams are:

X2.2.2.1 *Duty Cycle.*

X2.2.2.2 *Pulse or Repetition (rep) Rate.*

X2.2.2.3 *Pulse Width.*

X2.2.2.4 *Pulse Beam Current.*

X3. ELECTRON ENERGY DETERMINATION THROUGH DEPTH-DOSE DISTRIBUTION

X3.1 This appendix describes methods that use depth-dose distribution measurements in homogeneous materials to determine the electron beam energy.

X3.2 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.

X3.3 Energy and Depth Relationships

NOTE X3.1—The energy equations presented in this appendix exhibit varying levels of inaccuracy. This is caused by differences in the energy spectra of the beams measured compared to the spectra upon which the equations are based (in many cases, the equations are based upon monoenergetic electron energies, as noted). Additionally, scanned beams exhibit different energy spectra across the beam scan width.

X3.3.1 For electron beams with energies of a few MeV, depth-dose distribution measurements in thin polystyrene sheets are commonly used to determine the electron beam energy. For lower energies, especially below 1 MeV, the dosimeters may be a significant part of the total absorber thickness. Then, 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.

NOTE X3.2—The correlations of the optimum thickness R_{opt}, half-value depth R_{50}, half entrance depth R_{50e}, and R_p for polystyrene and the incident monoenergetic electron energy, E, using theoretical, calculated depth-dose distributions discussed in Appendix X1, Note X1.2, are given approximately by the following equations for electron energies between 1 MeV and 12 MeV:

$$R_{opt} = (0.41\ E - 0.12)/\rho \quad \text{(X3.1)}$$

$$R_{50} = (0.46\ E - 0.20)/\rho \quad \text{(X3.2)}$$

$$R_{50e} = (0.49\ E - 0.14)/\rho \quad \text{(X3.3)}$$

$$R_p = (0.57\ E - 0.19)/\rho \quad \text{(X3.4)}$$

The approximate electron energies corresponding to these ranges are given by rearranging these equations as follows:

$$E = 2.45\ R_{opt}\ \rho + 0.29 \quad \text{(X3.5)}$$

$$E = 2.20\ R_{50}\ \rho + 0.44 \quad \text{(X3.6)}$$

$$E = 2.05\ R_{50e}\ \rho + 0.29 \quad \text{(X3.7)}$$

$$E = 1.76\ R_p\ \rho + 0.33 \quad \text{(X3.8)}$$

The range values are in centimetres, E is the electron energy in MeV, and ρ is the material density in g/cm^3.

NOTE X3.3—Equations X3.1 through X3.8 above are not suitable for energies below 1 MeV or for materials with effective atomic numbers and atomic weights different from polystyrene. As the energy decreases, the beam window and air space become more important and their effects on the depth-dose distributions in the irradiated material must be taken into account.

X3.3.2 An empirically derived relationship of the most