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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 dans une installation de traitement par irradiation utilisant un faisceau d'électrons d'énergies comprises entre 300 keV et 25 MeV

Reference number
ISO/ASTM 51649:2005(E)

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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.

ASTM International is one of the world's largest voluntary standards development organizations with global participation from affected stakeholders. ASTM technical committees follow rigorous due process balloting procedures.

A project between ISO and ASTM International has been formed to develop and maintain a group of ISO/ASTM radiation processing dosimetry standards. Under this project, ASTM Subcommittee E10.01, Dosimetry for Radiation Processing, is responsible for the development and maintenance of these dosimetry standards with unrestricted participation and input from appropriate ISO member bodies.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. Neither ISO nor ASTM International shall be held responsible for identifying any or all such patent rights.

International Standard ISO/ASTM 51649 was developed by ASTM Committee E10, Nuclear Technology and Applications, through Subcommittee E10.01, and by Technical Committee ISO/TC 85, Nuclear energy.

This second edition cancels and replaces the first edition (ISO/ASTM 51649:2002), which has been technically revised.

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 covers dosimetric procedures to be followed in Installation Qualification, Operational Qualification and Performance Qualifications (IQ, OQ, PQ), and routine processing at electron beam facilities to ensure that the product has been treated with an acceptable range of absorbed doses. Other procedures related to IQ, OQ, PQ, and routine product processing that may influence absorbed dose in the product are also discussed.

NOTE 1—For guidance in the selection and calibration of dosimeters, see ISO/ASTM Guide 51261. For further guidance in the use of specific dosimetry systems, and interpretation of the measured absorbed dose in the product, also see ISO/ASTM Practices 51275, 51276, 51431, 51607, 51631, 51650, and 51956. For use with electron energies above 5 MeV, see Practice E 1026, and ISO/ASTM Practices 51205, 51401, 51538, and 51540 for discussions of specific large volume dosimeters. For discussion of radiation dosimetry for pulsed radiation, see ICRU Report 34.

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 an irradiation facility. Other measures besides dosimetry may be required for specific applications such as medical device sterilization and food preservation.

1.4 Other specific ISO and ASTM standards exist for the irradiation of food and the radiation sterilization of health care products. For food irradiation, see ISO/ASTM Practice 51431. For the radiation sterilization of health care products, see ISO 11137. In those areas covered by ISO 11137, that standard takes precedence.

1.5 *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]

E 170 Terminology Relating to Radiation Measurements and Dosimetry

E 1026 Practice for Using the Fricke Reference Standard Dosimetry System

E 2232 Guide for Selection and Use of Mathematical Methods for Calculating Absorbed Dose in Radiation Processing Applications

E 2303 Guide to Dose Mapping in Radiation Processing Facilities

2.2 *ISO/ASTM Standards:*[2]

51205 Practice for Use of a Ceric-Cerous Sulfate Dosimetry System

51261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing

51275 Practice for Use of a Radiochromic Film Dosimetry System

51276 Practice for Use of a Polymethylmethacrylate Dosimetry System

51400 Practice for Characterization and Performance of a High-Dose Radiation Dosimetry Calibration Laboratory

51401 Practice for Use of a Dichromate Dosimetry System

51431 Practice for Dosimetry in Electron and X-ray (Bremsstrahlung) Irradiation Facilities for Food Processing

51538 Practice for Use of an Ethanol-Chlorobenzene Dosimetry System

51539 Guide for the Use of Radiation-Sensitive Indicators

51540 Practice for Use of a Radiochromic Liquid Solution Dosimetry System

51607 Practice for Use of the Alanine–EPR Dosimetry System

51631 Practice for Use of Calorimetric Dosimetry Systems for Electron Beam Measurements and Dosimeter Calibrations

51650 Practice for Use of a Cellulose Triacetate Dosimetry System

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing

[1] This practice is under the jurisdiction of ASTM Committee E10 on Nuclear Technology and Applications and is the direct responsibility of Subcommittee E10.01 on Dosimetry for Radiation Processing, and is also under the jurisdiction of ISO/TC 85/WG 3.

Current edition approved by ASTM June 1, 2004. Published May 15, 2005. Originally published as E 1649–94. Last previous ASTM edition E 1649–00. ASTM E 1649–94$^{\epsilon 1}$ was adopted by ISO in 1998 with the intermediate designation ISO 15569:1998(E). The present International Standard ISO/ASTM 51649:2005(E) is a major revision of the last previous edition ISO/ASTM 51649:2002(E), which replaced ISO 15569.

[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.

51956 Practice for Thermoluminescence Dosimetry (TLD) Systems for Radiation Processing

2.3 *ISO Standard:*[3]

ISO 11137 Sterilization of Health Care Products–Requirements for Validation and Routine Control–Radiation Sterilization

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 60 Fundamental Quantities and Units for Ionizing Radiation

3. Terminology

3.1 *Definitions:*

3.1.1 *absorbed dose (D)*—quantity of ionizing radiation energy imparted per unit mass of a specified material. The SI unit of absorbed dose is the gray (Gy), where 1 gray is equivalent to the absorption of 1 joule per kilogram in the specified material (1 Gy = 1 J/kg). The mathematical relationship is the quotient of $d\bar{\epsilon}$ by dm, where $d\bar{\epsilon}$ is the mean incremental energy imparted by ionizing radiation to matter of incremental mass dm.

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

3.1.1.1 *Discussion*—The discontinued unit for absorbed dose is the rad (1 rad = 100 erg/g = 0.01 Gy). Absorbed dose is sometimes referred to simply as dose.

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

3.1.3 *beam length*—dimension of the irradiation zone, perpendicular to the beam width and direction of the electron beam at a specified distance from the accelerator window (see Fig. 2).

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

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

3.1.6 *beam width*—dimension of the irradiation zone in the direction that the beam is scanned, perpendicular to the beam length and direction of the electron beam at a specified distance from the accelerator window (see Fig. 2).

3.1.6.1 *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. 2). Beam width is the distance between two points along the dose profile, which

[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.

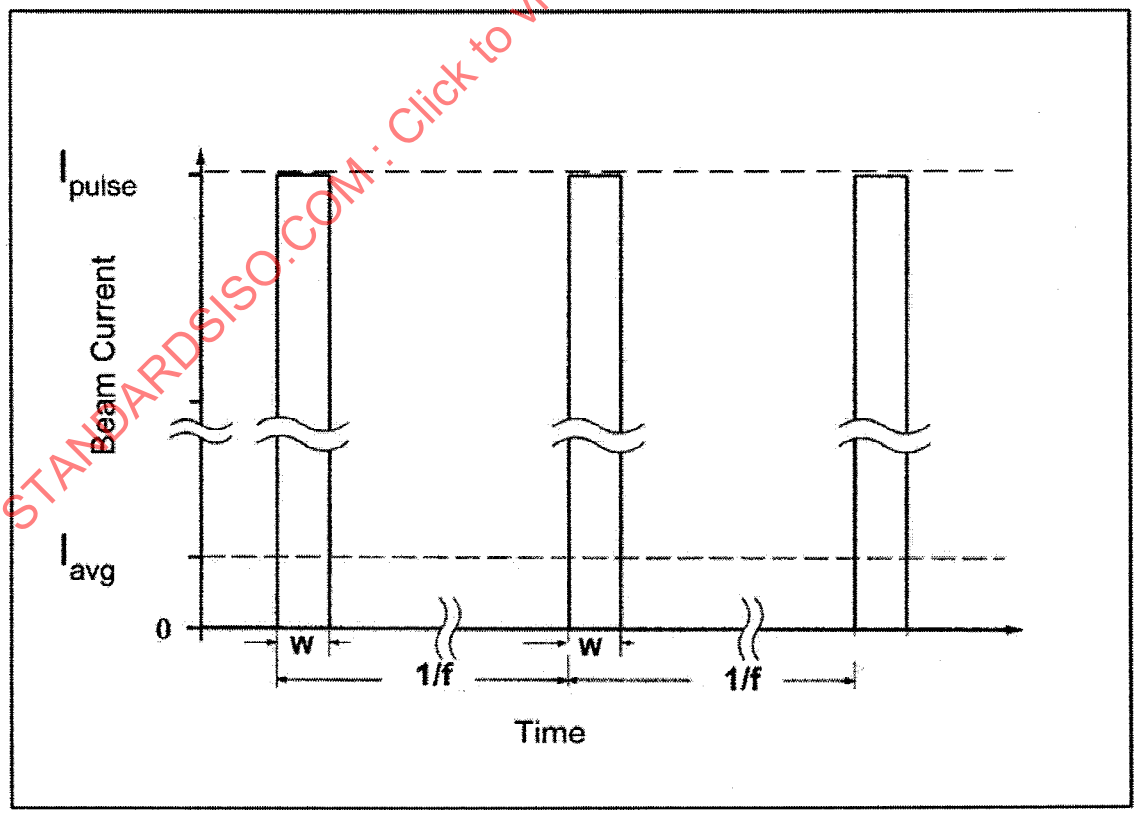


FIG. 1 Example pulse current (I_{pulse}), average beam current (I_{avg}), pulse width (W) and repetition rate (f) for a pulsed accelerator

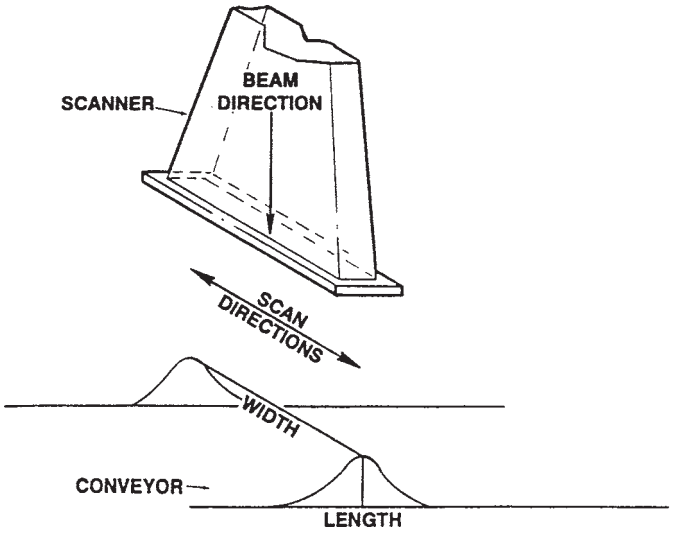


FIG. 2 Diagram showing beam length and width for a scanned beam using a conveyor system

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.

3.1.7 *compensating dummy*—simulated product used during routine production runs in process loads that contain less product than specified in the documented product-loading configuration, or simulated product used at the beginning or end of a production run, to compensate for the absence of product.

3.1.7.1 *Discussion*—Simulated product or phantom material may be used during irradiator characterization as a substitute for the actual product, material or substance to be irradiated.

3.1.8 *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-aproximation method.

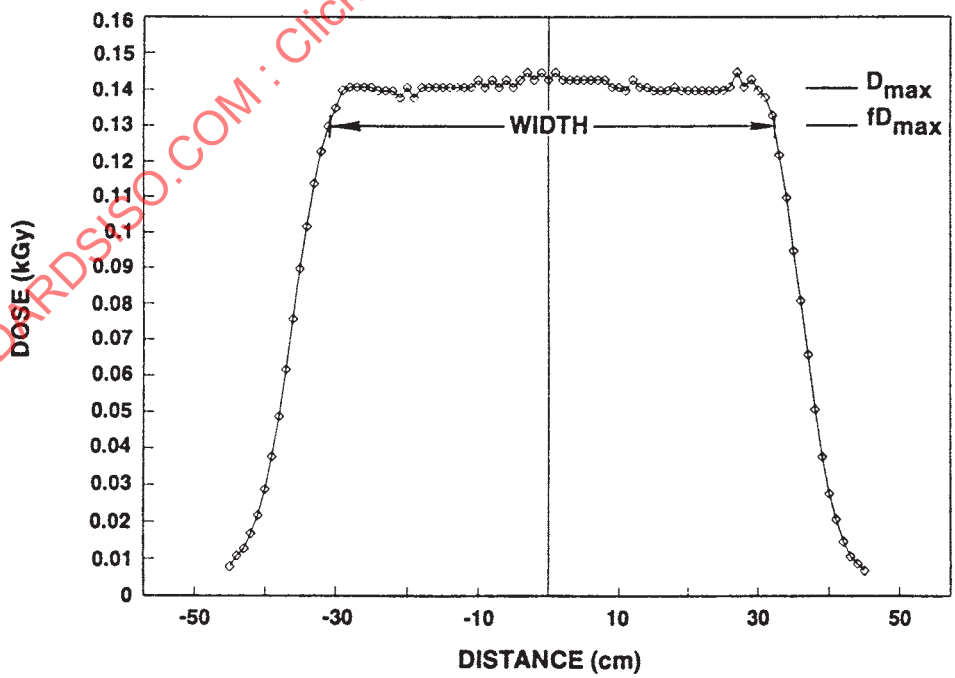
3.1.8.1 *Discussion*—In this approximation, the rate of energy loss at every point along the track is assumed to be equal to the total stopping power. Energy-loss fluctuations are neglected. The CSDA range is obtained by integrating the reciprocal of the total stopping power with respect to energy. Values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

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

3.1.9.1 *Discussion*—Typical distributions in homogeneous materials produced by an electron beam along the beam axis are shown in Figs. A1.1 and A1.2. See Annex A1.

3.1.10 *dose uniformity ratio*—ratio of the maximum to the minimum absorbed dose within the process load. The concept is also referred to as the max/min dose ratio.

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



NOTE—McKeown, J., AECL Accelerators, private communication, 1993. Example of a beam width profile of an AECL Impela accelerator.

FIG. 3 Example of electron-beam dose distribution along the beam width with the width noted at some defined fractional level *f* of the average maximum dose D_{max}

3.1.12 *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.

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

3.1.13.1 *Discussion*—Electron volt (eV) is often used as the unit for electron beam energy where 1 eV = $1.602 \cdot 10^{-19}$ J (approximately). 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 linked to the *practical electron range* R_p and *half-value depth* R_{50} by empirical equations.

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

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

3.1.16 *electron range*—penetration distance in a specific, totally absorbing material along the beam axis of the electrons incident on the material (equivalent to practical electron range, R_P).

3.1.16.1 *Discussion*—R_P 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 (the calculated pathlength traversed by an electron in a material in the course of completely slowing down). 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.

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

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

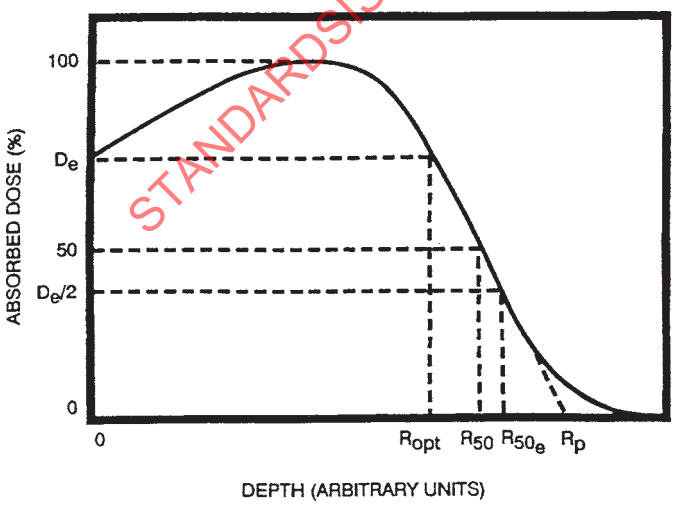


FIG. 4 A typical depth-dose distribution for an electron beam in a homogeneous material

3.1.19 *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 (see Fig. 4).

3.1.20 *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. A1.6 in Annex A1).

3.1.21 *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 curve meets the depth axis (see Fig. A1.6 in Annex A1).

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

3.1.23 *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.

3.1.24 *pulse beam current, for a pulsed accelerator*—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 (see Fig. 5).

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

3.1.26 *pulse width, for a pulsed accelerator*—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).

3.1.27 *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 of dose delivery.

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

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

3.1.29.1 *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.

3.1.30 *scan frequency*—number of complete scanning cycles per second expressed in Hz.

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

3.1.32 *simulated product*—mass of material with attenuation and scattering properties similar to those of the product, material or substance to be irradiated.

3.1.32.1 *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, it is sometimes referred to as compensating

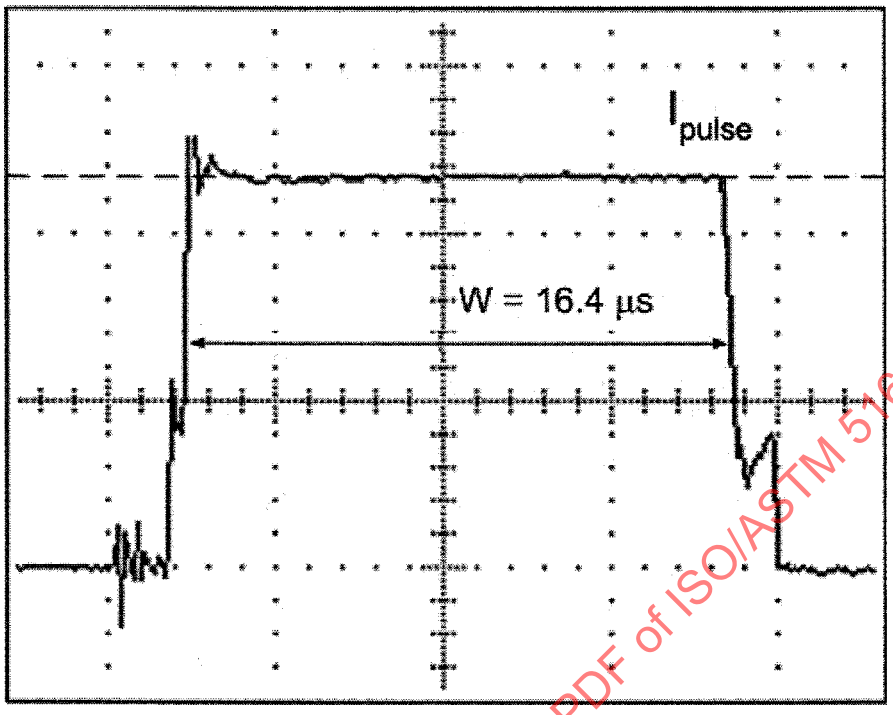


FIG. 5 Typical pulse current waveform from an S-Band linear accelerator

dummy. When used for absorbed-dose mapping, simulated product is sometimes referred to as phantom material.

3.1.33 *standardized depth (z)*—thickness of the absorbing material expressed as the mass per unit area, which is equal to the depth in the material t times the density ρ. If m is the mass of the material beneath that area and A is the area of the material through which the beam passes, then:

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

If t is in meters and ρ in kilograms per cubic meter, then z is in kilograms per square meter.

3.1.33.1 *Discussion*—It is common practice to express t in centimeters and ρ in grams per cm^3, then z is in grams per square centimeter. Standardized depth may also be referred to as surface density or area density.

3.2 *Definitions*—Definitions of other terms used in this standard that pertain to radiation measurement and dosimetry may be found in ASTM Terminology E 170. Definitions in E 170 are compatible with ICRU 60; 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. For example, 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 medical devices,

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.

NOTE 2—Dosimetry is required for regulated radiation processes such as sterilization of medical devices (see ISO 11137 and Refs **(1-4)**[5] and preservation of food (see ISO/ASTM 51431 and Ref **(5)**. 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 Dosimeters are used as a means of monitoring the radiation process.

NOTE 3—Measured dose is often characterized as absorbed dose in water to have a traceable standard reference. Moreover, 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

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

factors in accordance with ISO/ASTM Guide 51261.

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. Dosimetry is essential, since it is used to determine these limits, and dosimetry is essential in the evaluation and monitoring of the radiation process.

4.4 The dose distribution within the product depends on process load characteristics, irradiation conditions, and operating parameters. The operating parameters consist of beam characteristics (such as electron 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 facility is used, it must be qualified to demonstrate its ability to deliver specified, 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 Electron radiation sources considered in this practice are either direct-action (potential-drop) or indirect-action (RF- or microwave-powered) accelerators. These are discussed in Annex A4.

6. Types of irradiation facilities

6.1 *Irradiation Facility Design*:

6.1.1 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 in Sections 8 to 11.

6.1.2 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 (see Annex A4), equipment to disperse the beam on product, control system, and associated equipment **(2)**.

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

6.2.1 *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.

6.2.2 *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.

6.2.3 *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.

6.2.4 *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 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 *Description of Dosimeter Classes*:

7.1.1 Dosimeters may be divided into four basic classes according to their relative quality and areas of application: primary-standard, reference-standard, transfer-standard, and routine dosimeters. ISO/ASTM Guide 51261 provides information about the selection of dosimetry systems for different applications. All classes of dosimeters, except the primary standards, require calibration before their use.

7.1.1.1 *Primary-Standard Dosimeters*—Primary-standard dosimeters are established and maintained by national standards laboratories for calibration of radiation environments (fields) and other classes of dosimeters. The two most commonly used primary-standard dosimeters are ionization chambers and calorimeters.

7.1.1.2 *Reference-Standard Dosimeters*—Reference-standard dosimeters are used to calibrate radiation environments and routine dosimeters. Reference-standard dosimeters may also be used as routine dosimeters. Examples of reference-standard dosimeters, along with their useful dose ranges, are given in ISO/ASTM Guide 51261.

7.1.1.3 *Transfer-Standard Dosimeters*—Transfer-standard dosimeters are specially selected dosimeters used for transferring absorbed-dose information from an accredited or national standards laboratory to an irradiation facility in order to establish traceability for that facility. These dosimeters should be carefully used under conditions that are specified by the issuing laboratory. Transfer-standard dosimeters may be selected from either reference-standard dosimeters or routine dosimeters taking into consideration the criteria listed in ISO/ASTM Guide 51261.

7.1.1.4 *Routine Dosimeters*—Routine dosimeters may be used for radiation process quality control, dose monitoring and dose mapping. Proper dosimetric techniques, including calibration, shall be employed to ensure that measurements are reliable and accurate. Examples of routine dosimeters, along with their useful dose ranges, are given in ISO/ASTM Guide 51261.

7.2 It is important that the dosimeter be evaluated for those parameters which may influence the dosimeter's response; for example, average and peak absorbed dose rate (particularly for pulsed accelerators), environmental conditions (for example, temperature, humidity, and light) and electron energy. Guidance as to desirable characteristics and selection criteria for dosimetry systems can be found in ISO/ASTM Guide 51261, Practice E 1026, and ISO/ASTM Practices 51205, 51275, 51276, 51401, 51538, 51540, 51607, 51631, and 51650.

7.3 *Calibration of Dosimetry Systems*:

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

7.3.2 *Calibration Irradiation*—Irradiation is a critical component of the calibration of the dosimetry system. Acceptable ways of performing the calibration irradiation depend on whether the dosimeter is used as a reference-standard, transfer-standard or routine dosimeter.

7.3.2.1 *Reference- or Transfer-Standard Dosimeters*—Calibration irradiation shall be performed at a national or accredited laboratory using criteria specified in ISO/ASTM Practice 51400.

7.3.2.2 *Routine Dosimeters*—The calibration irradiation may be performed by irradiating the dosimeters at *(a)* a national or accredited laboratory using criteria specified in ISO/ASTM Practice 51400, *(b)* an in-house calibration facility that provides an absorbed dose (or an absorbed-dose rate) having measurement traceability to nationally or internationally recognized standards, or *(c)* a production irradiator under actual production irradiation conditions, together with reference- or transfer-standard dosimeters that have measurement traceability to nationally or internationally recognized standards. In case of option *(a)* or *(b)*, the resulting calibration curve shall be verified for the actual conditions of use.

7.3.3 *Measurement Instrument Calibration and Performance Verification*—For the calibration of the instruments, and for the verification of instrument performance between calibrations, see ISO/ASTM Guide 51261, the corresponding ISO/ASTM or ASTM standard for the dosimetry system, and/or instrument-specific operating manuals.

NOTE 4—For some dosimetry systems, the dosimeter response at different absorbed-dose rates for the same given absorbed dose may differ over portions of the system's working range. Accelerator systems are available which operate from about 1 kW to many hundred kW average beam power. Some are DC, others are pulsed with low duty cycles. So, dose rates (average and peak) can be very different from one system to the next. Because of this, it may be difficult to match the dose rate characteristics of the processing plant to that of the calibration facility. For this reason, calibration irradiation using the production irradiator (in-situ calibration) should be strongly considered (see ISO/ASTM Guide 51261).

8. Process parameters

8.1 There are various processing parameters that play essential roles in determining and controlling the absorbed dose in radiation processing. They should, therefore, be considered when performing the absorbed-dose measurements required in Sections 8 to 11.

8.2 Processing parameters include process load 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.

8.2.1 Operating parameters include beam characteristics (for example, energy, average beam current, and pulse rate), performance characteristics of material handling (see 6.2), and beam dispersion parameters (for example, beam width and frequency at which the beam is scanned across product). Operating parameters are measurable and should be monitored. During irradiation facility qualification (see Sections 9 and 10), absorbed dose characteristics over the expected range of the operating parameters are established for a reference material.

8.2.2 Processing parameters for a radiation process are established during performance qualification (see Section 11) to achieve the absorbed dose within the specified limits.

8.2.3 During routine product processing (see Section 12), the facility operating parameters are controlled and monitored to maintain values that were set during performance qualification.

8.2.4 Different product types may require different values of operating and processing parameters.

9. Installation qualification

9.1 *Objective*—The purpose of the electron beam facility installation qualification is to obtain and document evidence that equipment has been provided and installed in accordance with its specifications.

9.2 *Equipment Documentation*—Documentation of an installation qualification program shall be retained for the life of the irradiator, and shall include:

9.2.1 The accelerator specifications and characteristics,

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

9.2.3 A description of the process control system and personnel safety system,

9.2.4 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,

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

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

9.2.7 Any modifications made during and after installation. Such documentation is necessary to ensure the reproducibility of absorbed dose in the reference material within specified limits.

9.3 *Testing, Operation and Calibration Procedures*—Establish and implement standard operating procedures for the testing, operation and calibration (if necessary) of the installed irradiator and its associated processing equipment and measurement instruments.

9.3.1 *Testing Procedures*—These procedures describe the testing methods used to ensure that the installed irradiator and its associated processing equipment and measurement instruments operate according to specification.

9.3.2 *Operation Procedures*—These procedures describe how to operate the irradiator and its associated processing equipment and measurement instruments during routine operation.

9.3.3 *Calibration Procedures*—These procedures describe periodic calibration and verification methods that ensure that the installed processing equipment and measurement instruments continue to operate within specifications. The frequency of calibration for some equipment and instruments might be specified by a regulatory authority. Calibration of some equipment and instruments might be required to be traceable to a national or other accredited standards laboratory.

9.4 *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.

9.4.1 *Beam Characteristics*:

9.4.1.1 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 A1). The average beam current, in addition to several other operating parameters, affects the average dose rate.

9.4.1.2 Beam characteristic measurements of importance include:

(1) Electron beam energy,
(2) Average beam current,
(3) Peak beam current (for pulsed machines),
(4) Average beam power,
(5) Peak beam power (for pulsed machines),
(6) Duty cycle (for pulsed machines),
(7) Pulse (or Repetition or rep) Rate,
(8) Pulse width (for pulsed machines), and
(9) Beam cross-section.

NOTE 5—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.

9.4.2 *Beam Dispersion*:

9.4.2.1 Dispersion of the electron beam to obtain 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.

9.4.2.2 Beam dispersion measurements of importance include:

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

NOTE 6—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 (see Annex A2).

9.4.3 *Material Handling*:

9.4.3.1 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 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 so that a variation in one causes a corresponding change in the other to maintain a constant value of the absorbed dose.

9.4.3.2 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.

9.4.4 *Measurement Instruments*—The accuracy of the absorbed-dose measurements depends on the correct operation and calibration of the measurement instruments used in the analysis of the dosimeters.

9.4.4.1 Check the performance of the measurement instruments to ensure that the instruments are functioning according to performance specifications. Repeat this check following any modification or servicing of the instruments and prior to their use for a dosimetry system calibration. This check can be accomplished by using standards, such as calibrated optical density filters, wavelength standards, or calibrated thickness gauges, supplied by the equipment manufacturer or by national or accredited standards laboratories.

10. Operational qualification

10.1 *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 **(2, 3)**. Dosimetry can be used *(1)* to establish relationships between measured absorbed dose distributions in reference material under reference irradiation geometries and operating parameters of the facility, and *(2)* to characterize dose variations when these conditions fluctuate statistically through normal operations **(4)**.

10.2 *Dosimetry Systems*—Calibrate the dosimetry systems to be used at the facility as discussed in Section 7.

10.3 *Dose Mapping*:

10.3.1 Map the absorbed-dose distribution by a three-dimensional placement of dosimeter sets in a process load containing homogeneous material as discussed in ASTM Guide E 2303. The amount of homogeneous material in this process load should be the amount expected during typical production runs or should be the maximum design volume for the process load.

10.3.2 Using appropriate dosimetry, establish the depth-dose distribution within a reference material under reference irradiation geometry (see Annex A1 and Annex A3). 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.

10.4 *Absorbed Dose and Operating Parameters*:

10.4.1 *Objective*—The dose in the product depends on several operating parameters (such as, conveyor speed, beam current, electron energy, scan width). Over the expected range of these parameters, establish the absorbed-dose characteristics in a reference material using appropriate dosimetry.

10.4.1.1 The depth-dose distribution depends on electron beam energy and the reference material characteristics.

10.4.1.2 Surface dose and its uniformity depend on conveyor speed, beam characteristics and beam dispersion.

10.4.2 *Depth-dose Distribution*—Establish depth-dose distributions for the expected ranges of electron beam energy and the reference material bulk density, for 1-sided and 2-sided irradiation.

10.4.3 *Surface Dose*—Establish the relationships between surface dose (or dose in a reference plane) and conveyor speed, beam characteristics and beam dispersion parameters over the expected range of operation.

10.4.3.1 Establish the range of uniform surface dose that can be delivered to reference material. This will set the range of operation for the conveyor speed, pulse rate and scan frequency.

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 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 pulse rate. Improper coordination of these parameters can cause unacceptable dose variation in the reference plane.

NOTE 9—Indirect-action accelerators may deliver higher dose rates during the pulse compared to direct-action accelerators with the same average beam current. Also, scanning of a small-diameter beam can produce dose pulses at points along the beam width. This can influence the dosimeters' performance if they are sensitive to dose rate.

10.4.3.2 Establish the relationship between surface dose and conveyor speed, where all other operating parameters are held constant. Generally, surface dose should be inversely proportional to the conveyor speed.

NOTE 10—The conveyor speed and the beam current may be linked during routine product processing so that a variation in one causes a corresponding change in the other to maintain a constant value of the surface (or reference plane) dose.

10.5 *Dose Variability*:

10.5.1 Establish the capability of the facility to deliver a reproducible dose in a reference material 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.

10.5.2 Following the procedure of 10.3, map a sufficient number of nominally identical process loads containing reference material to allow the estimation of the variability of the magnitude and distribution of the absorbed dose. Dosimetry data from previously qualified irradiators of the same design may provide useful information for determining the number of process loads for this qualification.

10.6 *Process Interruption/Restart*:

10.6.1 In the event of a process interruption, for example stoppage of the conveyor system due to power failure, the implication of a restart on the process (for example, uniformity of dose in a reference plane) shall be investigated.

10.6.1.1 Expose an array of dosimeters or a strip of dosimeter film in a reference plane through a stop/start sequence of the conveyor system.

10.6.1.2 The delivery of dose within specifications through the stop/start sequence would suggest that the conveyor could be restarted after the failure to continue the process. The effect of the process interruption (for example, time delay) on the product itself is discussed in 12.4.

10.6.1.3 If the dose is found to be significantly non-uniform through the stop/start sequence, the subsequent impact on the process shall be evaluated.

10.6.2 The procedure described in 10.6.1.1-10.6.1.3 should be conducted for the extremes of the operating parameters.

10.7 *Documentation and Maintenance of OQ*—The baseline data collected during the procedures described in 10.2-10.6 shall be documented. These procedures shall be repeated periodically as specified in the quality assurance program to update the baseline data from the previous operational qualification.

10.8 *Facility Changes*—If changes that could affect the magnitudes or locations of the absorbed-dose extremes are made to the facility (for example, beam characteristics, beam dispersion parameters, material handling, etc.) or its mode of operation, repeat the operational qualification procedures to the extent necessary to establish the effects.

11. Performance qualification

11.1 *Objective*—Absorbed dose requirements vary depending on 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 limit. For a given process, one or both of these limits may

be prescribed by regulations. Therefore, the objective of performance qualification is to establish all processing parameters so that absorbed dose requirements are satisfied. This is accomplished by mapping the dose distribution throughout the process load for a specific product loading pattern. Such processing parameters include electron energy, beam current, material handling parameters (conveyor speed or irradiation time), beam width, process load characteristics and irradiation conditions (see, for example, Refs **2, 4, 7, 8**).

11.2 *Product Loading Configuration*—A loading pattern for irradiation shall be established for each product type. The specification for this loading pattern shall document the following:

11.2.1 Product 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

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

11.3 *Process load Absorbed-Dose Mapping*:

11.3.1 Determine the locations and values of absorbed dose extremes for the selected product loading pattern. This can be accomplished by placing dosimeters throughout the volume of interest for several process loads (see ASTM Guide E 2303). 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 **(9, 10)**. Measured values of dose extremes will vary between process loads because of variations in packaging geometry or product distribution, uncertainty in dosimetry system performance and minor fluctuations in the values of the operating parameters. Thus, dosimeters placed in similar locations in several process loads may produce a range of absorbed dose measurements. Select a sufficient number of process loads for mapping to determine the variability in the extreme dose values among process loads.

NOTE 11—The irradiation of tubing, wire, cable, continuous web, and other 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 in the product.

11.3.2 Results from the dose mapping measurements will determine the values of the processing parameters 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 there is a low probability of irradiating the product or part of the product with doses lower than the required minimum or higher than the allowed maximum and this probability is known and documented **(4, 7)**.

11.3.3 *Partial Loading*—For partially-loaded process loads, follow the same process qualification requirements as for fully-loaded process loads. Perform the dose mapping procedures of 11.3 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 process load.

11.3.4 *Bulk-Flow Irradiators*—For irradiators used in a bulk flow mode, absorbed-dose mapping as described in 11.3.1 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 **(8, 10)**. Calculation of the absorbed dose extremes may be an appropriate alternative **(8)**.

11.3.5 *Reference Dose Locations*—If the locations of absorbed dose extremes identified during the dose mapping procedure of 11.3.1 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 absorbed dose extremes shall be established, shown to be reproducible, and documented.

11.4 *Dose Variability*:

11.4.1 When dose mapping a specific product loading configuration, consideration should be given to possible variations in the absorbed doses measured at similar locations in different process loads.

11.4.2 To evaluate the extent of this dose variability, place dosimeter sets in the expected regions of the minimum and maximum absorbed doses in several process loads and irradiate them under the same conditions. The measured variations in the absorbed-dose values reflect, for example, variations in product loading configuration (due to shifts in the contents of the process load during its movement through the irradiator), small differences in bulk density of the process loads, fluctuations in operating parameter values, and the uncertainty in the routine dosimetry system.

11.5 *Unacceptable Dose Uniformity Ratio*:

11.5.1 If the dose mapping procedure of 11.3.1 or 11.3.4 reveals that the measured dose extremes are unacceptable, it may be possible to change the processing parameters to improve 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.

11.5.2 *Operating Parameters*—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.

11.5.3 *Irradiation Conditions*—Depending upon the density, thickness, and inhomogeneity of a process load and electron 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 process load or fluctuations in electron beam energy may cause more pronounced changes in absorbed dose within the product for double-sided irradiation as compared to single-sided irradiation.

11.5.4 *Process Load Characteristics*—For some cases, a redesign of the process load may be needed to achieve an acceptable dose uniformity ratio.

11.5.5 If any process parameter that affects the magnitudes or locations of maximum and minimum absorbed dose is changed (for example, for the purpose of improving the dose uniformity ratio), repeat the dose mapping to the extent necessary to establish the effects. The information gathered during operational qualification (Section 10) should serve as a guide in determining the extent of these absorbed-dose mapping studies.

11.6 The procedures described above should yield the appropriate values of all process parameters (namely, all key operating parameters, process load characteristics and irradiation conditions) that would satisfy the dose requirements for all types of process loads that have been mapped. Document these values for future use.

12. Routine product processing

12.1 *Processing Parameters*:

12.1.1 For routine product processing, set the processing parameters 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. This means that if, for example, the beam current is lowered by 20 % the process speed has to be decreased by the same percentage to deliver the same absorbed dose.

12.1.2 Control, monitor and document the operating parameters to ensure that each process load that passes through the irradiator is processed in accordance with specifications.

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

12.2 *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 dosimetry performed as follows:

NOTE 12—Monitoring of operating parameters alone may not be adequate for some radiation processes (for example, sterilization of health care products and food irradiation). For these situations, dosimetry is required during routine product processing.

NOTE 13—Some processes, such as the modification of material properties, may not require routine dosimetry (see Note 2 and Note 11).

12.2.1 *Dosimeter Location*—Place dosimeters either within or on the selected process load at predetermined locations of the minimum (and maximum, if a prescribed limit) absorbed dose (see 11.3.1), or at the reference positions determined in 10.3.2.

12.2.2 *Placement Frequency*—Always place dosimeters at the start of the run. For long production runs, place dosimeters at other intervals as appropriate.

NOTE 14—More frequent placement of dosimeters during the production run could result in less product quarantine should some operational uncertainty or failure arise.

12.2.3 *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 15—In case it is not feasible to utilize dosimeters during the routine processing of bulk materials, it may be acceptable to rely on processing 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 processing parameters and by repeating the performance qualification procedure at appropriate intervals.

12.2.4 *Environmental Changes*—A change in the environment (for example, temperature or humidity) of a dosimeter during the irradiation process may affect its response. In such a case, correct the dosimeter response for any such effect (see ISO/ASTM Guide 51261).

12.3 *Radiation-Sensitive Indicators*—For some dose levels, radiation-sensitive indicators may be available that can be used for quality control and for inventory purposes. A radiation-sensitive indicator may be affixed on each process load to help ensure that the unit has passed through the irradiation zone. For multiple irradiations, 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 process load has traversed. However, the use of radiation-sensitive indicators is not a substitute for the dosimetry procedures described in 12.2. For information on use of Radiation-Sensitive Indicators see ISO/ASTM Guide 51539.

12.4 *Process Interruption*—If there is a process failure, 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 before re-starting the process.

12.4.1 Based on the data collected during operational qualification (see 10.6), determine if the dose when the process is re-started would be adequately uniform for the process under consideration. If not, it may be necessary to discard those process loads affected by the process interruption.

13. Measurement uncertainty

13.1 To be meaningful, a measurement of absorbed dose shall be accompanied by an estimate of uncertainty.

13.2 Components of uncertainty shall be identified as belonging to one of two categories:

13.2.1 *Type A*—Those evaluated by statistical methods, or

13.2.2 *Type B*—Those evaluated by other means.

13.3 Other ways of categorizing uncertainty have been widely used and may be useful for reporting uncertainty. For example, the terms *precision* and *bias* or *random* and *systematic* (non-random) are used to describe different categories of uncertainty.

NOTE 16—The identification of Type A and Type B uncertainties is based on methodology for estimating uncertainties published in 1995 by the International Organization for Standardization (ISO) in the Guide to the Expression of Uncertainty in Measurement **(11)**. The purpose of using this type of characterization is to promote an understanding of how uncertainty statements are developed and to provide a basis for the international comparison of measurement results.

NOTE 17—ISO/ASTM Guide 51707 defines possible sources of uncertainty in dosimetry performed in radiation processing facilities, and offers procedures for estimating the magnitude of the resulting uncertainties in the measurement of absorbed dose using a dosimetry system. The document defines and discusses basic concepts of measurement, including estimation of the measured value of a quantity, "true" value, error and uncertainty. Components of uncertainty are discussed and methods are provided for estimating their values. Methods are also provided for calculating the combined standard uncertainty and estimating expanded (overall) uncertainty.

14. Certification

14.1 *Documentation Accumulation*:

14.1.1 *Equipment Documentation*—Record or reference the calibration and maintenance of equipment and instrumentation used to control or measure the absorbed doses delivered to the product (see ISO/ASTM Guide 51261).

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

14.1.3 *Dosimetry Data*—Record and document all dosimetry data for operational qualification, performance qualification, and routine production processing. Include date, time, product type, loading diagrams, and absorbed doses for all products processed (see ISO/ASTM Guide 51261).

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

14.1.5 *Facility Log*—Record the date the lot 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.

14.1.6 *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.

14.2 *Review and Certification*:

14.2.1 Prior to release of product, review dosimetry results and recorded values of the processing parameters to verify compliance with specifications.

14.2.2 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.

14.2.3 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.

14.3 *Retention of Records*:

14.3.1 File all information pertaining to each production run (for example, copies of the shipping document, certificates of irradiation, and the irradiation control record (see 14.1.1-14.1.5)). Retain the files for the period of time specified in the quality assurance program and have the files available for inspection as needed.

15. Keywords

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

ANNEXES

(informative)

A1. ELECTRON BEAM DEPTH-DOSE DISTRIBUTIONS, MATERIAL PROCESSING RATES, AND TEMPERATURE RISE DURING RADIATION TREATMENT

A1.1 Scope

A1.1.1 This annex 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.

A1.2 Depth-dose distribution

A1.2.1 Depth-dose distribution curves presented in this section, except where noted, are theoretically calculated for monoenergetic electron beams and may exhibit varying levels of accuracy. Practical measurements of these curves may deviate from these theoretical curves because the electron

beam is usually not monoenergetic. Additionally, scanned electron beams may exhibit changing energy spectra along the direction of the scanned beam.

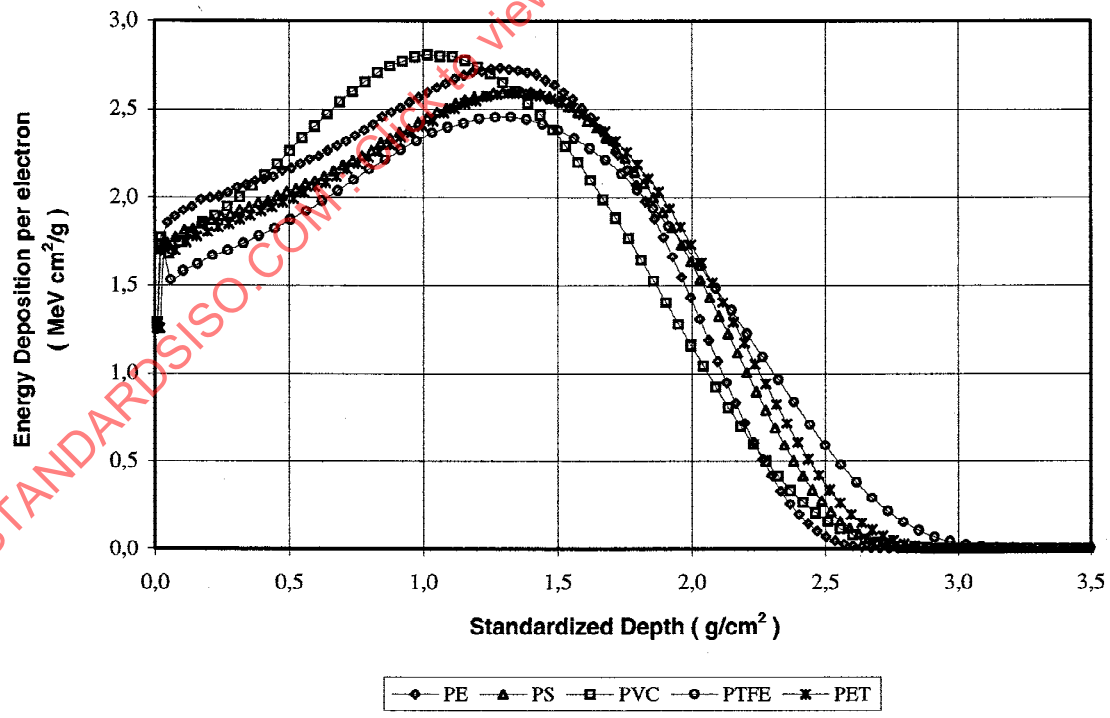
A1.2.2 Electron beam irradiation of homogeneous materials produces absorbed dose distributions that tend to rise with increasing depth within the material to about the midpoint of the electron range and then rapidly fall to low values. The shape of the depth-dose distribution curve is determined by collisions 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 **(12-15)**. This is illustrated in Figs. A1.1 and A1.2 which present theoretically calculated depth-dose curves 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 **(13, 15)**.

A1.2.3 The depth of penetration (electron range) is nearly proportional to the incident electron energy. This is shown in Figs. A1.3-A1.5 which present the Monte Carlo calculated depth-dose distribution curves for polystyrene with monoenergetic electrons from 300 keV to 12 MeV. The vertical axis in Figs. A1.1-A1.6, and also in Figs. A1.7 and A1.8, 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 **(13)**. 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 by using Eq A1.2 in Section A1.3. 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 A1.1—The depth-dose distribution curves in Figs. A1.1-A1.6 have been calculated for normal incidence of monoenergetic electrons on flat sheets of homogeneous materials using the ITS 3 Monte Carlo Transport Code **(13)**. Other simpler programs can also be used for this purpose **(16, 17)**. The use and selection of mathematical models for calculating absorbed dose in radiation processing applications is discussed in Guide E 2232.

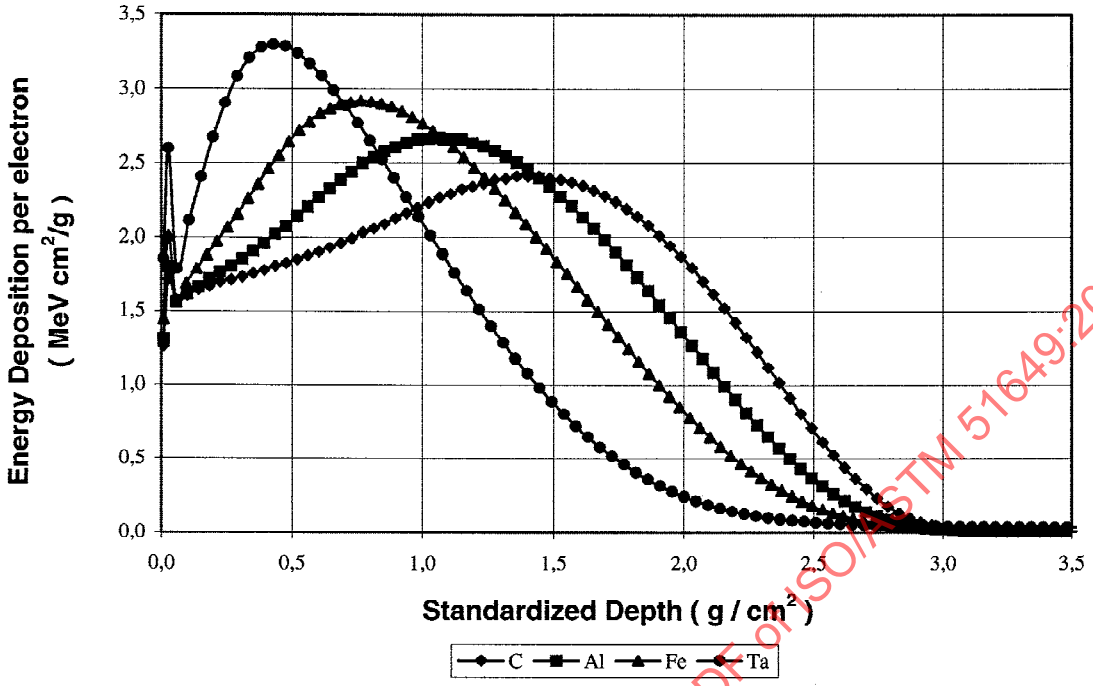
A1.2.4 X-rays (bremsstrahlung) are created when electrons are decelerated in material. This radiation contributes to the depth dose distribution. Fig. A1.6 illustrates the X-ray contribution in the tail of the Monte Carlo calculated curve **(18)**. For electrons with energies below 10 MeV which are incident 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.

A1.2.5 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 electron treatment from one side of the



NOTE—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. A1.1 Calculated depth-dose distribution curves in various homogeneous polymers for normally incident monoenergetic electrons at 5.0 MeV using the Program ITS3 (13, 15)



NOTE—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 represent the energy deposition in the air space. The third data points correspond to the energy deposition at the surface of the irradiated material.

FIG. A1.2 Calculated depth-dose distribution curves in various homogeneous metals for normally incident monoenergetic electrons at 5.0 MeV using the Program ITS3 (13, 15)

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 A1.2.8). For treatment from 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 figures in pages 62 and 64 of Ref (**5**) for additional information).

NOTE A1.2—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. A1.9).

NOTE A1.3—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. A1.9).

NOTE A1.4—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. A1.9). For thicknesses greater than two times R_{50e}, the dose uniformity ratio will dramatically increase with increasing thickness.

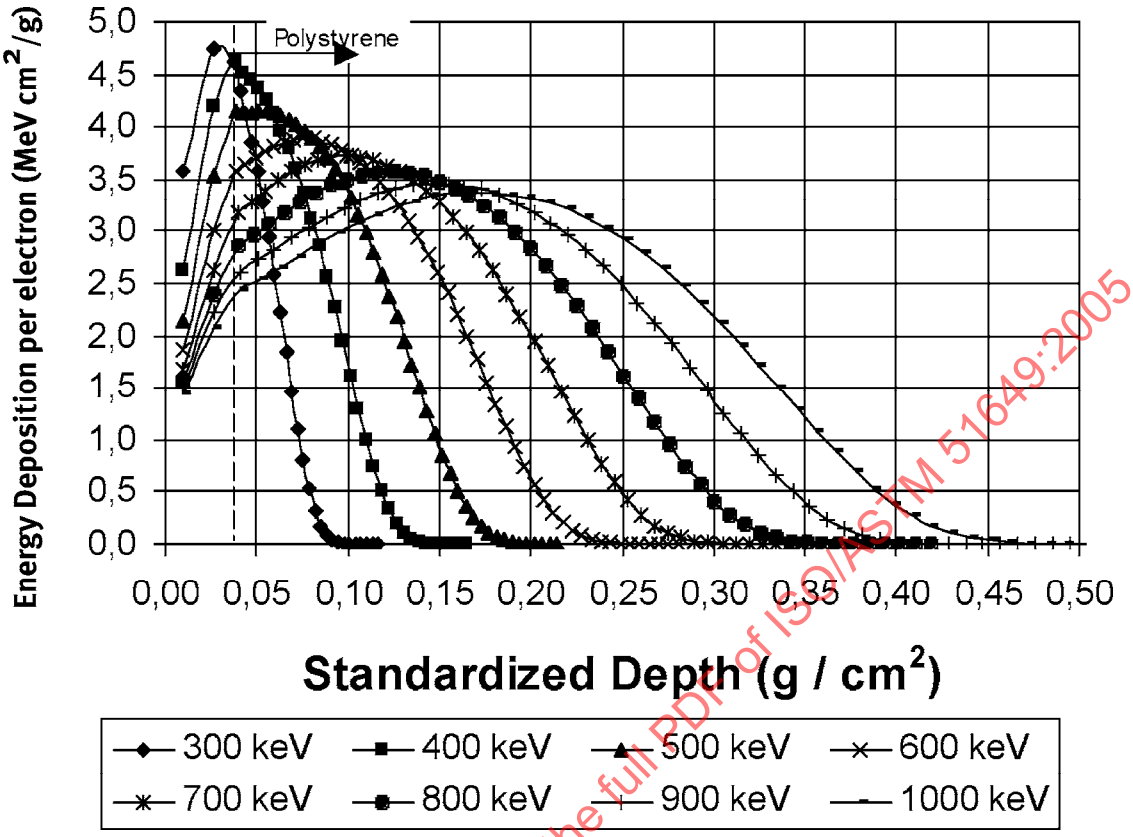
A1.2.6 The correlations between optimum thickness R_{opt}, half-value depth R_{50}, half-entrance depth R_{50e}, and the practical range R_p, and the incident electron energy are shown in Figs. A1.10 and A1.11 (**14**). These values have been obtained from the calculated depth-dose distribution curves for polystyrene shown in Figs. A1.3-A1.5. The energy dependence of these thickness parameters are nearly linear from 1 to 12 MeV.

A1.2.7 Fig. A1.12 presents measured depth-dose distribution curves for nominal 10 MeV electron beams incident on homogeneous polystyrene.[6,7] These curves are provided by accelerator manufacturers and electron beam facilities. Important parameters influencing the curves are presented in Table A1.1. There are noticeable differences between these measured curves and the theoretical 10 MeV curve presented in Fig. A1.5. 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 broader 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.

A1.2.8 If the material thickness is less than the maximum range of the electrons, then the dose near the exit surface will be affected by the composition of the backing material. This is

[6] Morrisseau, D., Ross, A., and Sadat, T., MeV Industrie, S.A., private communication, 1993. Example of a depth-dose distribution curve for nominal 10 MeV electrons incident on polystyrene using a CIRCE linear accelerator at Societe des Proteines Industrielles (SPI), Berric, France.

[7] McKeown, J., AECL Accelerators, private communication. Example of a depth-dose distribution curve using a 10 MeV IMPELA linear accelerator.



NOTE—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 represent the energy deposition in the air space. The third data points correspond to the energy deposition at the surface of the irradiated material.

FIG. A1.3 Calculated depth-dose distribution curves in polystyrene for normally incident electrons at monoenergetic energies from 300 to 1000 keV using the Program ITS3 (13, 14)

caused by backscattering of electrons from the backing material. This effect can be estimated with the EDMULT program **(16, 17)** or Monte Carlo programs **(13, 19, 20)**.

A1.2.8.1 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. A1.13 which presents measured depth-dose distributions with 400 keV electrons in stacks of cellulose acetate films backed with wood, aluminum, and iron **(21)**. The effective atomic numbers of wood (cellulose), aluminum and iron are 6.7, 13, and 26, respectively.

A1.2.8.2 With backing materials of lower effective atomic number than the irradiated material, the exit dose will be lower than indicated by the depth-dose distribution curves for thick absorbers **(22)**.

NOTE A1.5—This effect decreases as the electron energy increases.

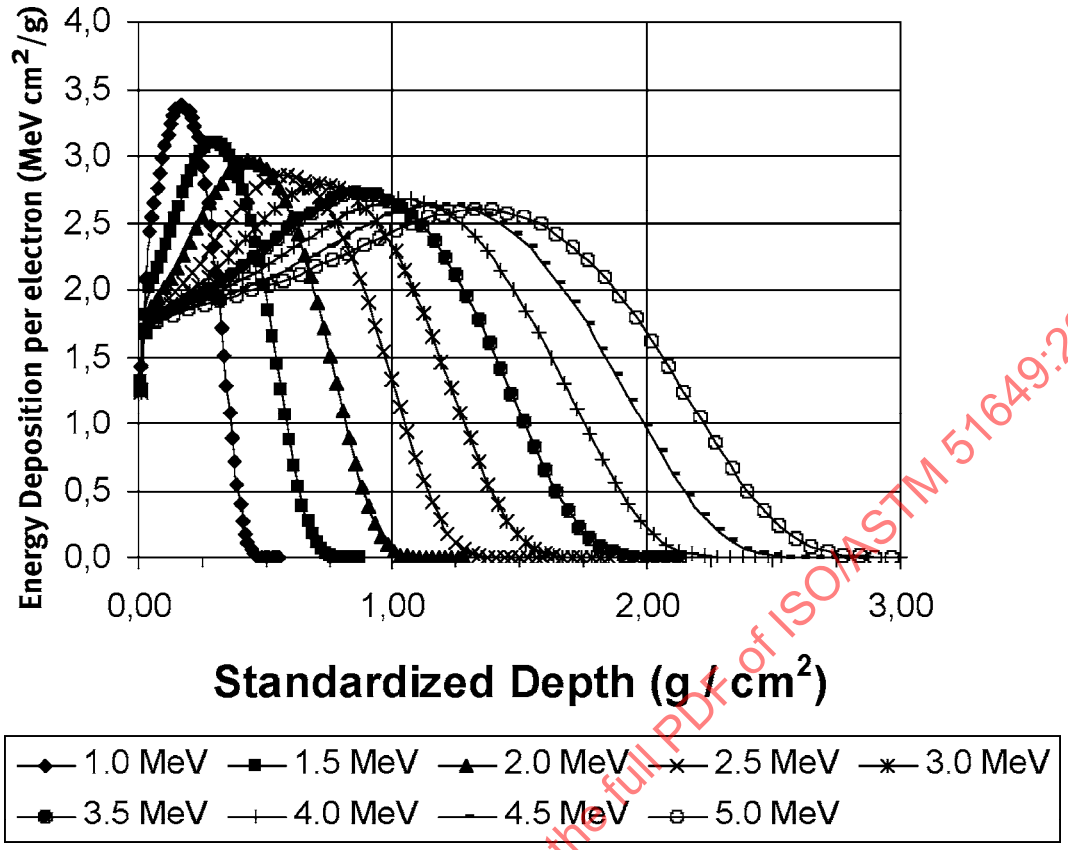
A1.2.9 If the incident angle of the electron beam is not normal (perpendicular) to the surface of the material, then the shape of the depth-dose distribution curve will be modified. This is shown in Fig. A1.14 which presents measured depth-dose distribution curves with 2 MeV electrons incident on polystyrene 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 **(22)**.

A1.2.10 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 10.3.

A1.3 Area processing rate

A1.3.1 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.

A1.3.2 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:



NOTE—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 represent the energy deposition in the air space. The third data points correspond to the energy desposition at the surface of the irradiated material.

FIG. A1.4 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 ITS3 (13, 14)

$$A/T = K(z)IF_i/D(z) \quad \text{(A1.1)}$$

where A/T is the area processing rate, I is the electron beam current, F_i is the fraction of the current in the radiation zone, and $D(z)$ is the absorbed dose at a specified depth z in the treated material. The quantities A/T and F_i can be evaluated for the radiation zone rather than the individual objects in the zone. The factor $K(z)$ may be called the area processing coefficient. $K(z)$ must be evaluated at the depth z where the dose $D(z)$ is specified **(23, 24)**.

A1.3.3 The area processing coefficient $K(z)$ is proportional to the energy deposition per electron per unit area density $D_e(z)$. Values of $D_e(z)$ for flat sheets of homogeneous material can be calculated with the EDMULT program **(16, 17)** or Monte Carlo programs **(13, 20)**. For complex product shapes and compositions, 3-dimensional Monte Carlo programs are more appropriate **(13)**. Surface values of the quantity $D_e(z)$ for polystyrene are given in Table A1.2.

A1.3.4 The quantities $K(z)$ and $D(z)$ are usually specified at the product surface which is facing the incident electron beam. This is where the minimum value of the absorbed dose usually occurs. These surface values are nearly independent of the electron energy above 2 MeV. However, they increase substantially below 2 MeV. These trends are shown for polystyrene in Figs. A1.7 and A1.8.

NOTE A1.6—In Eq A1.1, $K(z)$ is numerically equal to the energy deposition per electron per unit area density $D_e(z)$ when this quantity is given in units of eV·m^2/kg, the area processing rate is in m^2/s, the beam current is in A and the dose is in Gy. Then $K(z)$ is given in SI units of Gy·m^2/(A·s).

NOTE A1.7—Some other units are often used in Eq A1.1 (see Table A1.3) .

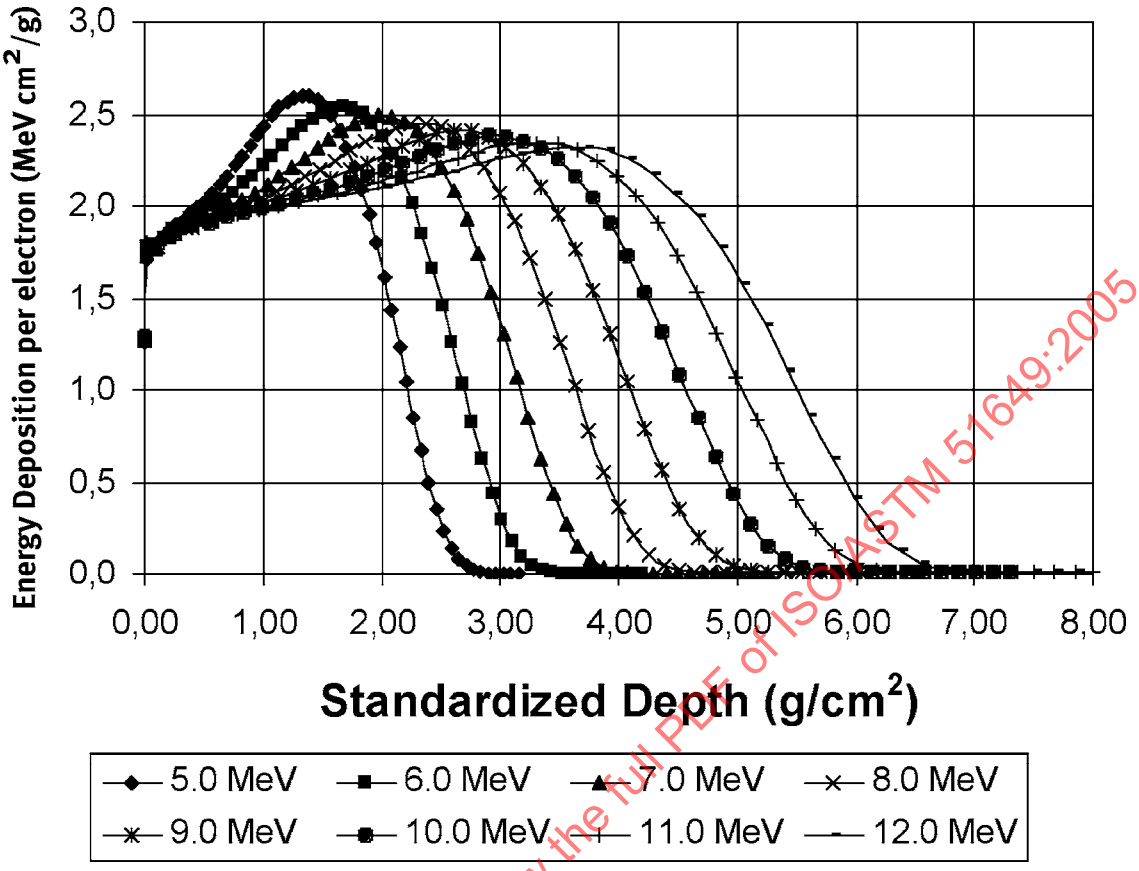
NOTE A1.8—Surface values of $D_e(z)$ are nearly independent of the electron energy above 2 MeV. For example, with polystyrene and other hydrocarbon materials of similar atomic composition, the surface value is about 0.17 MeV·m^2/kg or 1.7 MeV cm^2/g. Therefore, the surface value of K is about 170 kGy·m^2/(A·s) or 10 kGy·m^2/(mA·min). The latter value means that the surface dose will be about 10 kGy (1 Mrad) for a beam current of 1 mA and an area throughput rate of 1 m^2/min. This relationship is sometimes called the "unity rule."

A1.3.5 Eq A1.1 can be rearranged as follows to show how the absorbed dose $D(z)$ depends on the other process parameters.

$$D(z) = K(z)IF_i/(A/T) \quad \text{(A1.2)}$$

$$D(z) = K(z)IF_iT/A \quad \text{(A1.3)}$$

A1.3.5.1 Eq A1.2 shows that the absorbed dose is proportional to the beam current I and inversely proportional to the area throughput rate A/T. Eq A1.3 shows that the dose is also proportional to the electron fluence (electrons injected per unit area), which is proportional to the quantity IF_iT/A (beam



NOTE—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 represent the energy deposition in the air space. The third data points correspond to the energy desposition at the surface of the irradiated material.

FIG. A1.5 Calculated depth-dose distribution curves in polystyrene for normally incident, plane parallel incident electrons at monoenergetic energies from 5.0 to 12.0 MeV using the program ITS3 (13, 14)

current multiplied by the treatment time and divided by the area of the treated material).

A1.3.5.2 According to section A1.3.4, the area processing coefficient $K(z)$ is proportional to the energy deposition per electron per unit area density $D_e(z)$, so the absorbed dose $D(z)$ is also proportional to this quantity. See section A1.3.4, Note A1.6, Note A1.7, and Table A1.3. Surface values of $D_e(z)$ for polystyrene absorbers are given in Table A1.2 and are also shown in Figs. A1.7 and A1.8.

A1.3.5.3 The quantity $D_e(z)$ is an inherent property of an energetic electron, while the absorbed dose also depends on the other processing parameters. Therefore, values of $D_e(z)$ are shown in Figs. A1.1-A1.6 instead of values for absorbed dose, which would have to be calculated for specific values of the beam current and the area throughput rate. Even so, the vertical scales of these figures are proportional to the absorbed dose according to Eq A1.2 and A1.3.

A1.4 Mass processing rate

A1.4.1 The mass processing rate is the mass of material that can be processed per unit time. The definition of absorbed dose (3.1.1) is the basis of the relationship between mass processing rate and beam power, which can be expressed as follows:

$$M/T = PF_p/D_a \quad \text{(A1.4)}$$

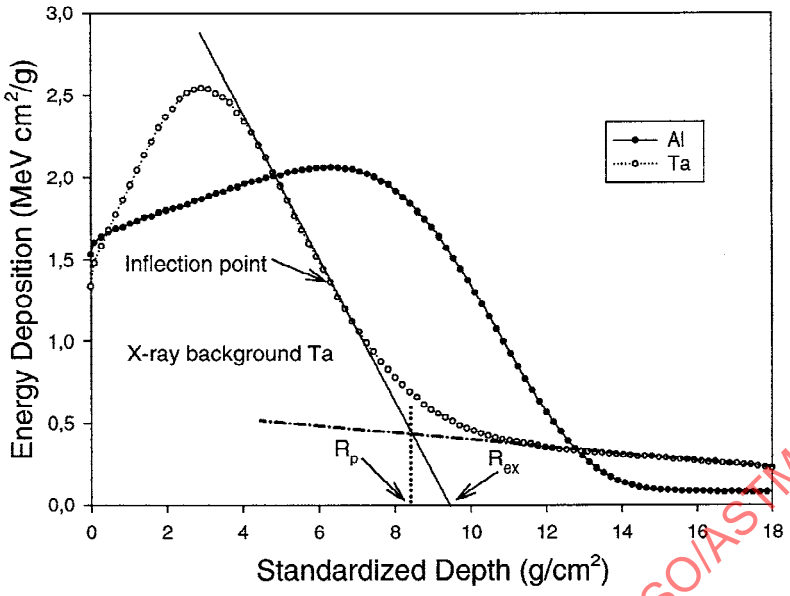
where M/T is the mass processing rate in kg/s, P is the electron beam power in W, F_p is the fraction of the beam power absorbed by the treated material, and D_a is the dose in Gy. D_a is the average dose throughout the treated material in contrast to the dose $D(z)$ in Eq A1.1 which must be measured at a specified depth z. The average dose is usually different from the surface dose **(23-25)**.

A1.4.2 Eq A1.4 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.

A1.4.2.1 With heterogeneous materials like medical devices or molded parts, it is difficult to calculate accurate values for F_p, so Eq A1.4 is not very useful for such processes.

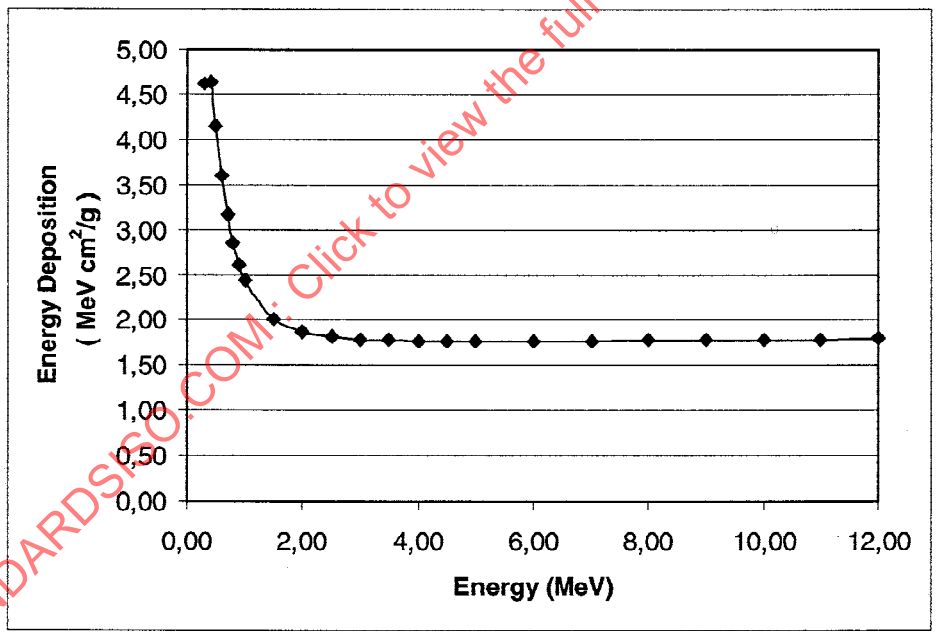
A1.5 Temperature rise

A1.5.1 Irradiation causes the temperature of the treated material to increase. This is the basis of the calorimetric method of dose measurement (see ISO/ASTM Practice 51631).



NOTE—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. A1.6 Calculated depth-dose distribution curves in Al and Ta for normally incident, plane parallel incident electrons at a monoenergetic energy of 25 MeV using the program ITS3 (13, 18)



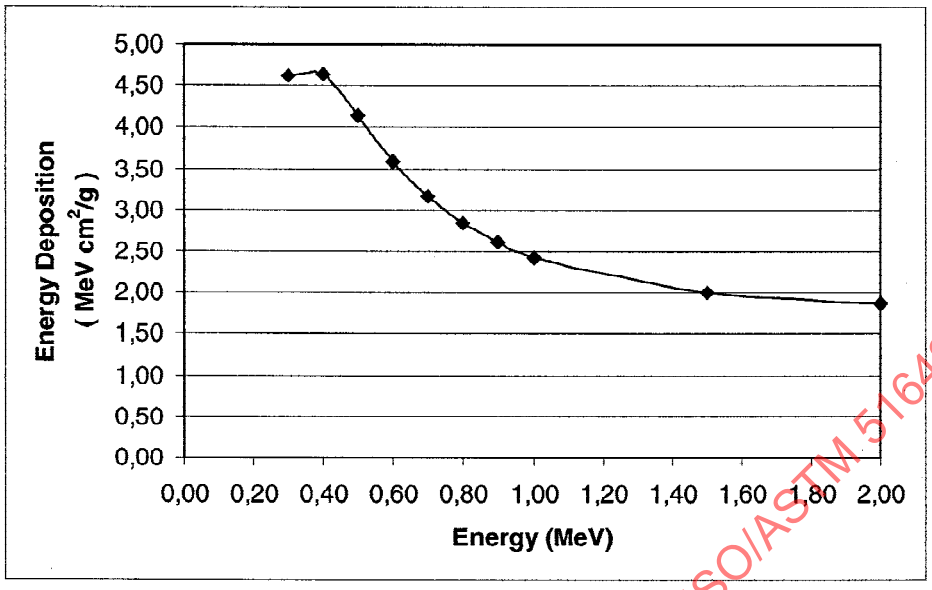
NOTE—The electron beam window is assumed to be 4×10^{-5} m titanium (0.018 g/cm^2) followed by 0.15 m of air (0.018 g/cm^2).

FIG. A1.7 Electron energy deposition $D_e(0)$ 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. A1.3-A1.5

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.

A1.5.2 Neglecting energy transformations from chemical reactions and any convective, conductive, or radiant cooling, the adiabatic temperature increase ΔT is given by:

$$\Delta T = D_a/c \quad \text{(A1.5)}$$



NOTE—The electron 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. A1.8 Electron energy deposition $D_e(0)$ 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. A1.3 and Fig. A1.4

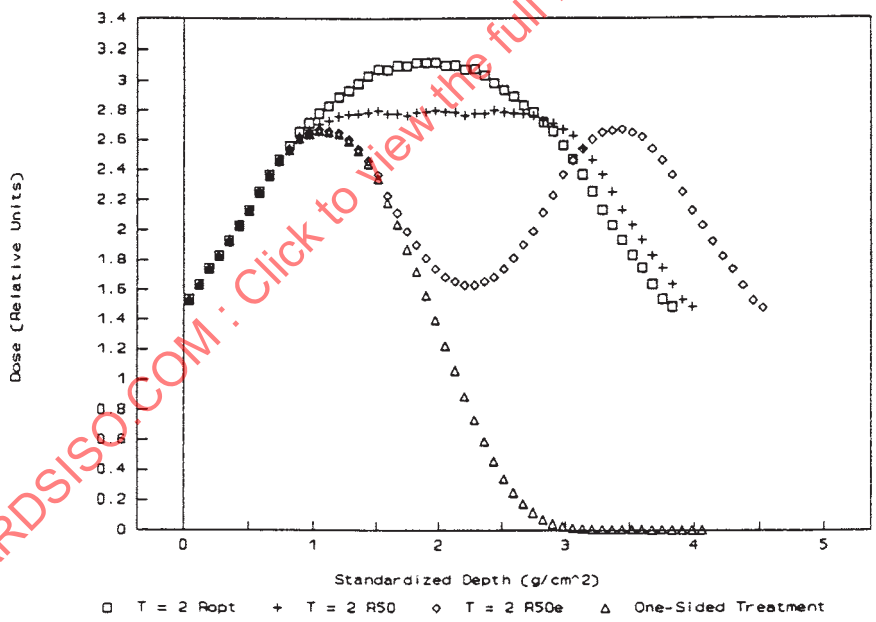
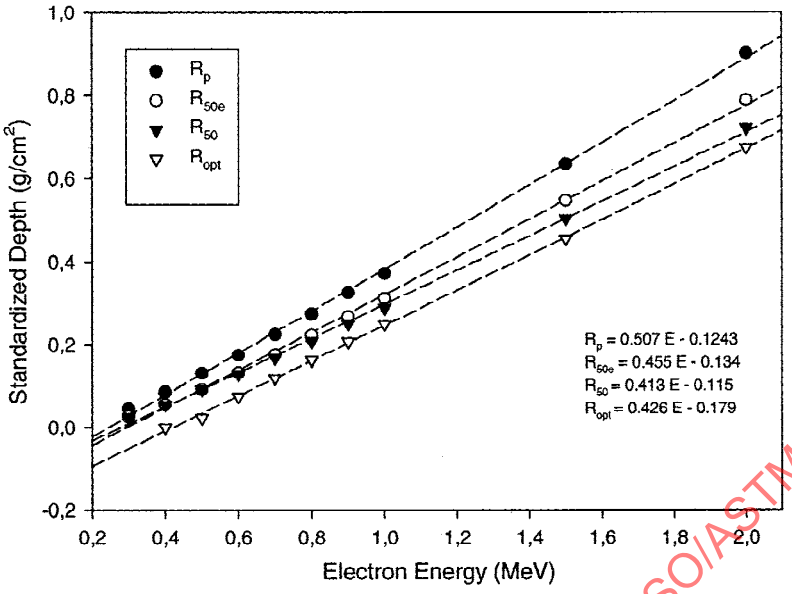


FIG. A1.9 Superposition of theoretically calculated depth-dose distribution curves for aluminum irradiated with 5 MeV monoenergetic electrons from both sides with different thicknesses (*T*) and from one side using experimental data presented in Refs (12 and 25) (see Notes A1.2-A1.4)

where D_a is the average dose in Gy for the specific irradiated material, 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 for the same dose.

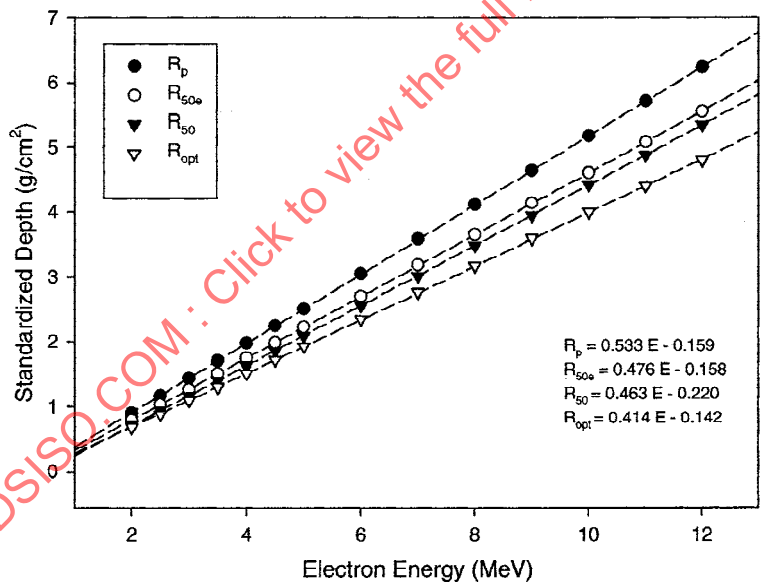
A1.5.3 For accurate calculations of temperature increase, it may be necessary to apply a conversion factor to the dosimetric values (see ISO/ASTM 51261, Annex A1, Interpretation of Absorbed Dose). Since most dosimeters are calibrated to measure water-equivalent dose quantities, the dose absorbed in the material may be significantly different from the dose measured by the dosimeter, especially for material that is very different from water.

NOTE A1.9—Temperature increases due to absorbed dose may affect the response of dosimeters placed on or within the material.



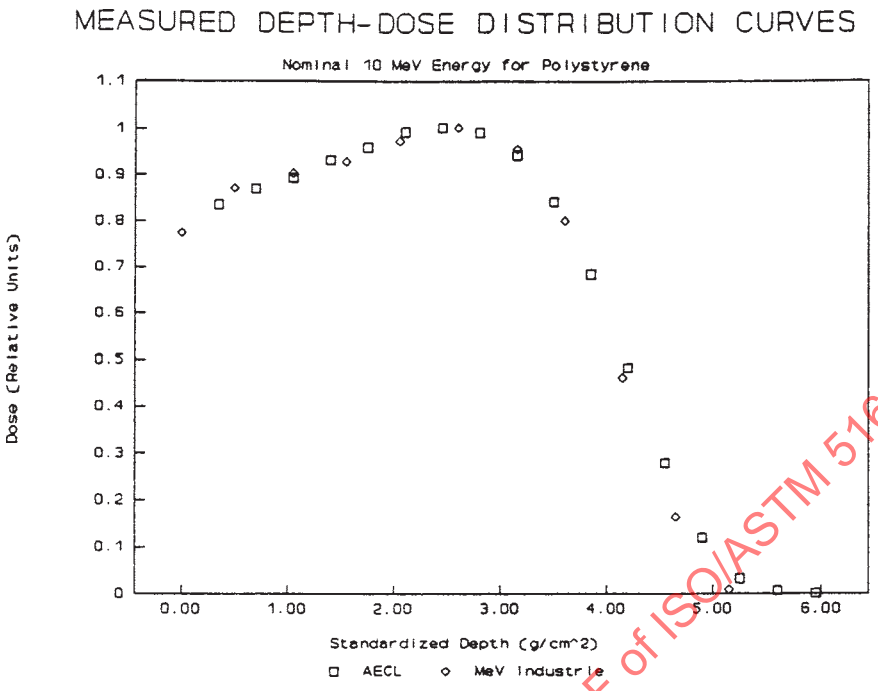
NOTE—Nearly equivalent values may be expected for water.

FIG. A1.10 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 Fig. A1.3 and Fig. A1.4 (see Table A3.2)



NOTE—Nearly equivalent values may be expected for water.

FIG. A1.11 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. A1.4 and A1.5 (see Table A3.2)



NOTE—See Table A1.1 for key parameters.

FIG. A1.12 Measured depth-dose distribution curves for nominal 10 MeV electron beams incident on polystyrene for two electron beam facilities[6,7]

TABLE A1.1 Key parameters for measured depth-dose distribution curves presented in Fig. A1.12

	MeV industrie CIRCE[A]	AECL Impela[B]
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.[6]
[B] Installed at E-Beam Services, Cranbury, NJ.[7]

TABLE A1.2 Electron energy deposition $D_e(0)$ 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. A1.3-A1.5

Energy in MeV	$D_e(0)$ in MeV cm^2/g	Energy in MeV	$D_e(0)$ in MeV cm^2/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		

TABLE A1.3 Compatible units for the quantities used in Eq A1.1

A/T	I	D(z)	$D_e(z)$	K(z)
m^2/s	A	Gy	eV m^2/kg	1 $D_e(z)$
m^2/s	A	Gy	MeV m^2/kg	10^6 $D_e(z)$
m^2/s	A	kGy	MeV m^2/kg	10^3 $D_e(z)$
m^2/s	A	kGy	MeV cm^2/g	10^2 $D_e(z)$
m^2/s	mA	kGy	MeV cm^2/g	10^{-1} $D_e(z)$
m^2/min	mA	kGy	MeV cm^2/g	6 $D_e(z)$

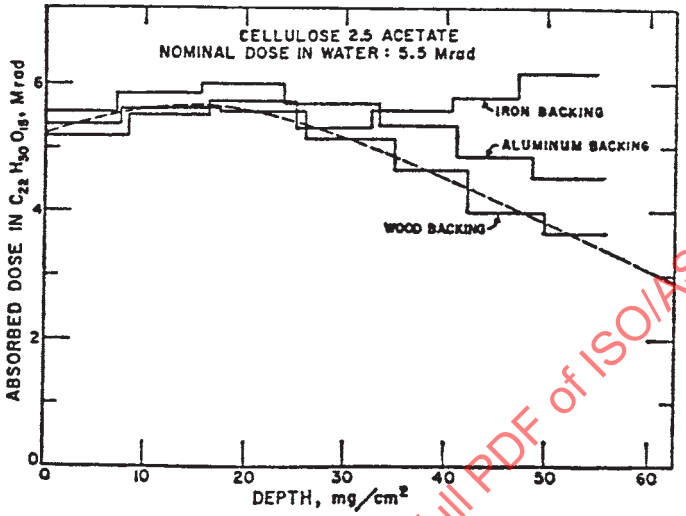


FIG. A1.13 Depth-dose distribution curves in stacks of cellulose acetate films backed with wood, aluminum, and iron for incident electrons with 400 keV energy (21)

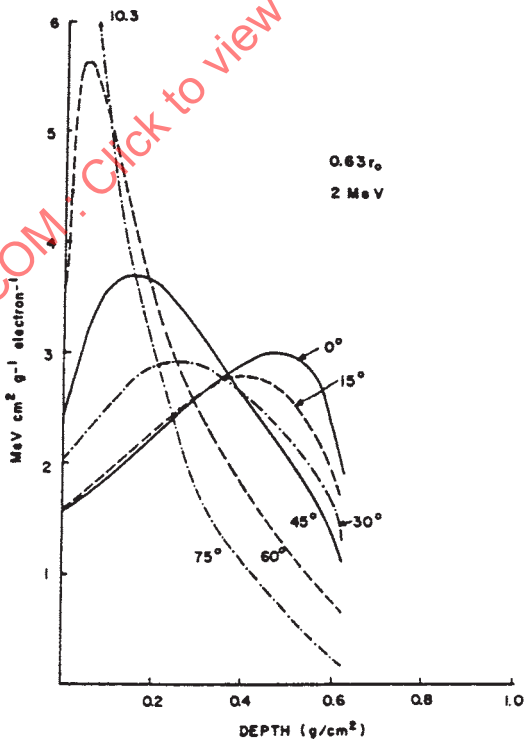


FIG. A1.14 Depth-dose distributions with 2 MeV electrons incident on polystyrene absorbers at various angles from the normal direction (22)

A2. MEASUREMENT OF BEAM WIDTH AND DOSE UNIFORMITY ALONG BEAM WIDTH

A2.1 Scope

A2.1.1 There are various methods for determining the beam width and dose uniformity along the scan direction. This annex describes methods that use dosimetry to measure the dispersion and uniformity for facilities using conveyors or carrier systems. Fig. 3 is an example dose distribution along the scan direction.

A2.2 Procedure

A2.2.1 An array or long strips of dosimeter film are mounted on a fixture with homogeneous backing material. Either individual dosimeters or a dosimeter strip may be used. The use of individual dosimeters will limit the spatial resolution of the measurement.

A2.2.2 The length of the array should be longer than the anticipated beam width. The fixture should be reproducibly mounted to the conveyor or carrier at a set distance from the beam exit window.

A2.2.3 The fixed backing material can be plastics such as polystyrene or polyethylene. Metals with low specific heat should not be used because of excessive heat generation.

A2.2.4 Irradiate the dosimeter fixture 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 can be influenced by interactions between the following parameters:

A2.2.4.1 Beam width,

A2.2.4.2 Scan frequency,

A2.2.4.3 Beam spot shape,

A2.2.4.4 Pulse width (for pulsed accelerators),

A2.2.4.5 Pulse repetition rate (for pulsed accelerators),

A2.2.4.6 Conveyor speed, and

A2.2.4.7 Distance of the dosimeter fixture from the beam exit window and from the conveyor or carrier.

A2.2.5 Determine the dose values and plot them 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.

A2.2.6 Determine the beam width and the variation of the measured dose along the scan direction. Beam width is the distance between the points along the dose profile which are some defined fractional level from the maximum dose region in the profile (see Fig. 3).

A2.2.7 The measured beam width should adequately cover the process load width.

A3. ELECTRON BEAM ENERGY DETERMINATION THROUGH DEPTH-DOSE DISTRIBUTION

A3.1 Scope

A3.1.1 This annex describes methods that use depth-dose distribution measurements in homogeneous materials to determine the electron 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 energy, provided the same equation and technique are consistently used. In this way, the constancy of the energy at the facility can be determined.

A3.1.2 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 electrons.

A3.2 Energy and depth correlations

A3.2.1 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 scan width.

A3.2.2 *Empirically derived Correlations for Water and Aluminum*:

A3.2.2.1 Empirically derived relationships (see ICRU Report 35) of the most probable electron beam energy E_p and the average (mean) electron beam energy E_a at the entrance surface of water to the range and depth parameters R_p and R_{50}(see Fig. 4) are:

$$E_p\,(\text{MeV}) = 0.22 + 1.98\,R_p + 0.0025\,R_p^2 \qquad \text{(A3.1)}$$

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

$$E_a\,(\text{MeV}) = 2.33\,R_{50} \qquad \text{(A3.2)}$$

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

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:

$$R_w = R_m \frac{(r_{0,w} \times \rho_m)}{(r_{0,m} \times \rho_m)} \qquad \text{(A3.3)}$$

where ρ is the density of the material, 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.

TABLE A3.1 Some relevant properties of common reference materials

Reference Material	Density (g/cm³)	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/cm² (ICRU Report 37).

A3.2.2.2 Empirically derived relationships (see ICRU Report 35 and Ref **26**) of the most probable electron energy E_p and the average (mean) energy E_a at the entrance surface of aluminum to the parameters R_p and R_{50} (see Fig. 4) are:

$$E_p\,(\text{MeV}) = 0.20 + 5.09\,R_p \qquad \text{(A3.4)}$$

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

$$E_a = 6.2\,R_{50} \qquad \text{(A3.5)}$$

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

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

A3.2.3 *Monte Carlo-derived Correlations for Polystyrene*:

A3.2.3.1 For electron energies of a few MeV, depth-dose distribution measurements with a stack of thin polystyrene sheets are commonly used to determine the electron energy. For these energies, 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.

A3.2.3.2 If the electron beam is monoenergic, the most probable and the average energies are 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 A1, section A1.2, and are given by the following equations for electron energies between 0.3 MeV and 12 MeV **(14)**:

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

$$E = 2.347\,R_{opt} + 0.420 \qquad \text{(A3.6)}$$

$$E = 2.421\,R_{50} + 0.278 \qquad \text{(A3.7)}$$

$$E = 2.198\,R_{50e} + 0.295 \qquad \text{(A3.8)}$$

$$E = 1.972\,R_p + 0.245 \qquad \text{(A3.9)}$$

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

$$E = 2.415\,R_{opt} + 0.343 \qquad \text{(A3.10)}$$

$$E = 2.160\,R_{50} + 0.475 \qquad \text{(A3.11)}$$

$$E = 2.101\,R_{50e} + 0.332 \qquad \text{(A3.12)}$$

$$E = 1.876\,R_p + 0.298 \qquad \text{(A3.13)}$$

The range values are in g/cm² 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 **(14)**. These values are listed in Table A3.2.

TABLE A3.2 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 (14)

E (MeV)	R_{50}(g/cm²)	R_{50e}(g/cm²)	R_{opt} (g/cm²)	R_p (g/cm²)	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	4,1338	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—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).

A3.2.3.3 Eq A3.6-A3.13 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. A1.3) and their effects on the depth-dose distributions in the irradiated material must be taken into account.

NOTE A3.1—When the practical range values Rp are used, ICRU Eq A3.1 is consistent within 2 percent with Monte Carlo Eq A3.13 for higher energies from 2.0 MeV to 12 MeV, provided that ICRU Eq A3.3 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 A3.1 gives energy values about 4 percent less than Eq A3.13. When the half-value depths R_{50} are used, ICRU Eq A3.2 is consistent within 2 percent with Monte Carlo Eq A3.11 for higher energies from 8.0 MeV to 12 MeV, but the deviation increases as the energy decreases. At 5 MeV, Eq A3.2 gives energy values about 6 percent less than Eq A3.11. Eq A3.1 and A3.2 were empirically determined using measured depth-dose distribution curves in water. The consistency between the ICRU and Monte Carlo equations for the higher energies demonstrates the accuracy of the Monte Carlo calculations and provides assurance that they are reliable for the lower energies as well. The validity of the Monte Carlo method for electron energies below 2.0 MeV has been demonstrated by the data presented in Ref **(12)**. The comparisons between the Monte Carlo equations and ICRU equations indicate that ICRU Eq A3.1 should not be used below 2.0 MeV, and that ICRU Eq A3.2 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 A3.6 through Eq A3.13 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 **(14, 27, 28)**.

A3.2.4 *Monte Carlo-derived Correlations for Aluminum*: