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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 51649:2002(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 pilot project between ISO and ASTM International has been formed to develop and maintain a group of ISO/ASTM radiation processing dosimetry standards. Under this pilot 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 International Standard 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.

Annexes A1, A2, A3 and A4 of this International Standard are for information only.

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

NOTE 1—For guidance in the selection and calibration of dosimeters, see ISO/ASTM Guide 51261. For further guidance in the selection, calibration, and use of specific dosimeters, and interpretation of absorbed dose in the product from dosimetry, also see ASTM Practice E 668 and ISO/ASTM Practices 51275, 51276, 51431, 51607, 51631, and 51650. For use with electron energies above 5 MeV, see ASTM 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. When considering a dosimeter type, be cautious of influences from dose rates and accelerator pulse rates and widths (if applicable).

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

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

1.4 For the irradiation of food and the radiation sterilization of health care products, other specific ISO standards exist. For food irradiation, see ISO/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 limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

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

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

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

2.2 *ISO/ASTM Standards:*

51205 Practice for Use of a Ceric-Cerous Sulfate Dosimetry System[2]

51261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing[2]

51275 Practice for Use of a Radiochromic Film Dosimetry System[2]

51276 Practice for Use of a Polymethylmethacrylate Dosimetry System[2]

51401 Practice for Use of a Dichromate Dosimetry System[2]

51431 Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing[2]

51538 Practice for Use of an Ethanol-Chlorobenzene Dosimetry System[2]

51539 Guide for the Use of Radiation-Sensitive Indicators[2]

51540 Practice for Use of a Radiochromic Liquid Solution Dosimetry System[2]

51607 Practice for Use of the Alanine–EPR Dosimetry System[2]

51608 Practice for Dosimetry in an X-Ray (Bremsstrahlung) Irradiation Facility for Radiation Processing[2]

51631 Practice for Use of Calorimetric Dosimetry Systems for Electron Beam Measurements and Dosimeter Calibrations[2]

51650 Practice for Use of a Cellulose Acetate Dosimetry System[2]

2.3 *ISO Standard:*

ISO 11137 Sterilization of Health Care Products–Requirements for Validation and Routine Control–Radiation Sterilization[3]

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

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[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 Jan. 22, 2002. Published March 15, 2002. 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 51649:2002(E) is a revision of ISO 15569.

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

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

ICRU Report 34 The Dosimetry of Pulsed Radiation[4]
ICRU Report 35 Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV[4]
ICRU Report 37 Stopping Powers for Electrons and Positrons[4]
ICRU Report 60 Radiation Quantities and Units[4]

3. Terminology

3.1 *Definitions*—Other terms used in this practice may be found in ASTM Terminology E 170 and ICRU Report 60.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *absorbed dose, D*—the quotient of $d\bar{e}$ by dm, where $d\bar{e}$ is the mean energy imparted by ionizing radiation to the matter of mass dm (see ICRU Report 60).

$$D = \frac{d\bar{e}}{dm} \tag{1}$$

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

$$1\ Gy = 1\ J \cdot \mathrm{kg}^{-1} \tag{2}$$

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

$$1\ \mathrm{rad} = 10^{-2}\ J \cdot \mathrm{kg}^{-1} = 10^{-2}\ Gy \tag{3}$$

and:

$$1\ \mathrm{Mrad} = 10\ \mathrm{kGy} \tag{4}$$

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

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

3.2.3.1 *Discussion*—See Fig. 1.

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

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

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

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

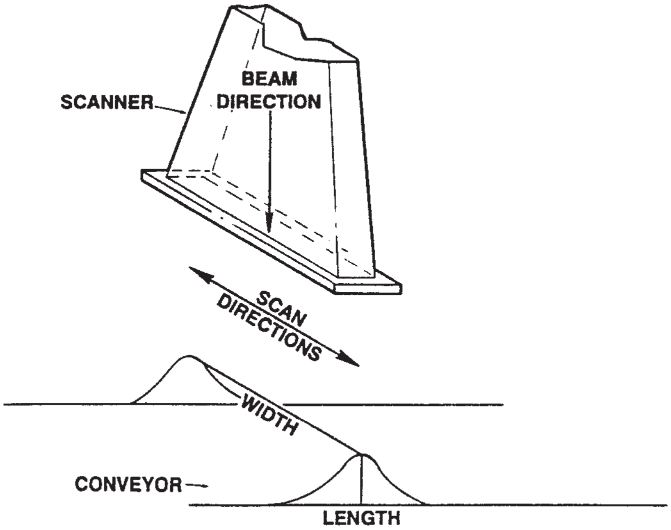

FIG. 1 Diagram Showing Beam Length and Width for a Scanned Beam Using a Conveyor Material Handling System

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

3.2.7.1 *Discussion*—A typical distribution in homogeneous material produced by an electron beam along the beam axis is shown in Fig. 3. See Annex A1.

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

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

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

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

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

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

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

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

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

3.2.15.1 *Discussion*—See Fig. 3.

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

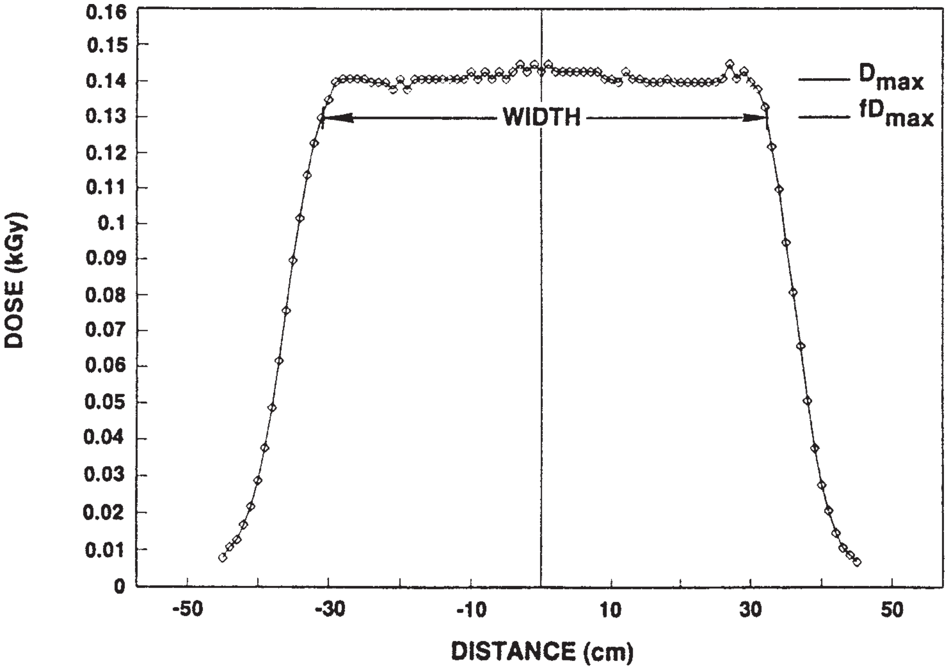

FIG. 2 Example of Electron-beam Dose Distribution Along the Beam Width[4] with the Width Noted at Some Defined Fractional Level *f* of the Average Maximum Dose D_{max}

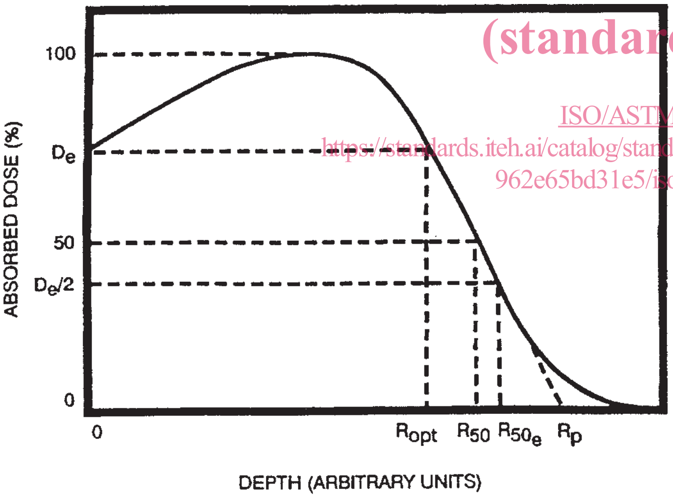

FIG. 3 A Typical Depth-Dose Distribution for an Electron Beam

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

3.2.16.1 *Discussion*—See Fig. 3.

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

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

3.2.18.1 *Discussion*—See Fig. 3.

3.2.19 *practical range* (R_p)—distance from the surface of homogeneous material where the electron beam enters to the point where the tangent at the steepest point (the inflection point) on the almost straight descending portion of the depth-dose distribution curve meets the depth axis.

3.2.19.1 *Discussion*—See Fig. 3.

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

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

3.2.21.1 *Discussion*—See Fig. 4.

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

3.2.23 *pulse width*—for a pulsed accelerator, the time interval between the half peak beam current amplitude points on the

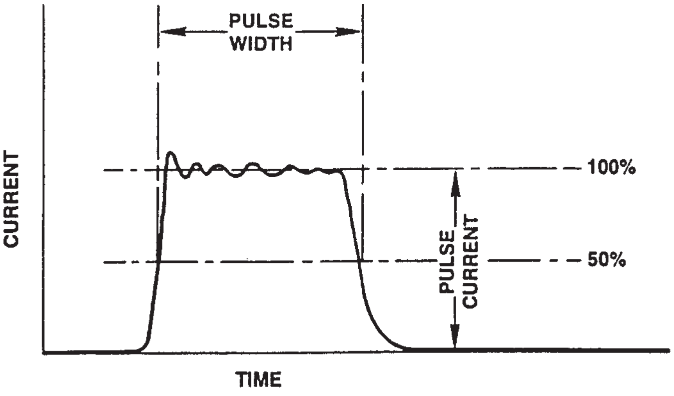

FIG. 4 Typical Pulse Current Waveform with Pulse Current and Pulse Width Noted

leading and falling edges of the pulse beam current waveform.

3.2.23.1 *Discussion*—See Fig. 4.

3.2.24 *reference material*—homogeneous material of known radiation absorption and scattering properties used to establish characteristics of the irradiation process, such as scan uniformity, depth-dose distribution, throughput rate, and reproducibility.

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

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

3.2.26.1 *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.

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

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

4. Significance and Use

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

4.1.1 Cross-linking or degradation of polymers and elastomers,

4.1.2 Polymerization of monomers and grafting of monomers onto polymers,

4.1.3 Sterilization of medical devices,

4.1.4 Disinfection of consumer products,

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

4.1.6 Control of pathogens in liquid or solid waste,

4.1.7 Modification of characteristics of semiconductor devices,

4.1.8 Color enhancement of gemstones and other materials, and

4.1.9 Research on materials effects.

NOTE 2—Dosimetry is required for regulated radiation processes such as the sterilization of medical devices **(1, 2, 3)**[5,6] and the preservation of food. It may be less important for other processes, such as polymer modification, which may be evaluated by changes in the physical and chemical properties of the irradiated materials. Nevertheless, routine dosimetry may be used to monitor the reproducibility of the treatment process.

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

NOTE 3—Measured dose is often characterized as absorbed dose in water because materials commonly found in disposable medical devices and food are approximately equivalent to water in the absorption of ionizing radiation. Absorbed dose in materials other than water may be determined by applying conversion factors in accordance with 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. Since it is used to determine these limits, dosimetry is essential in the evaluation and control of the radiation process.

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

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

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

5. Radiation Source Characteristics

5.1 Radiation sources for electrons with energies greater than 300 keV considered in this practice are either direct-action (potential-drop) or indirect-action (microwave-powered) accelerators. These are further discussed in Annex A2.

6. Types of Irradiation Facility

6.1 An electron beam facility includes the electron beam accelerator system; material handling systems; a radiation shield with personnel safety system; product staging, loading, and storage areas; auxiliary equipment for power, cooling, ventilation, etc.; equipment control room; a laboratory for dosimetry and product testing; and personnel offices. The electron beam accelerator system consists of the radiation source (see Annex A2), equipment to disperse the beam on product, and associated equipment **(4)**.

6.2 *Process Parameters*:

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

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

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

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

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

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

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

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

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

6.3.1 *Conveyors or Carriers*—Material is placed upon carriers or conveyors for passage through the electron beam. The speed of the conveyor or carriers is controlled in conjunction with the electron beam current and beam width so that the required dose is applied.

6.3.2 *Roll-to-Roll Feed System*—Roll-to-roll (also referred to as reel-to-reel) feed systems are used for tubing, wire, cable, and continuous web products. The speed of the system is controlled in conjunction with the electron beam current and beam width so that the required dose is applied.

6.3.3 *Bulk-flow System*—For irradiation of liquids or particulate materials like grain or plastic pellets, bulk-flow transport through the irradiation zone may be used. Because the flow velocity of the individual pieces of the product cannot be controlled, the average velocity of the product in conjunction with the beam characteristics and beam dispersion parameters determines the average absorbed dose.

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

7. Dosimetry Systems

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

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

7.3 The dosimetry system should be properly calibrated using a calibration service traceable to national standards. Guidance for calibration can be found in ISO/ASTM Guide 51261.

8. Irradiation Facility Qualification

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

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

8.2.1 The irradiator specifications and characteristics,

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

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

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

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

8.2.6 Any modifications made during and after installation.

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

8.3.1 *Beam Characteristics*:

8.3.1.1 The three principal beam characteristics that affect dosimetry are the electron energy spectrum, average beam current, and pulse beam current. The electron energy spectrum affects the depth-dose distribution within the product (see Annex A1). The average and pulse beam currents, in addition to several other operating parameters, affect the average and peak dose rates, respectively.

NOTE 4—Indirect-action (microwave-powered) accelerators may deliver higher dose rates while the beam current is actually on compared to direct-action (potential-drop) accelerators with the same average beam current. These higher dose rates in a pulsed mode may affect the dosimeter response.

NOTE 5—The electron energy spectrum of the accelerated electron beam may be characterized by the average electron energy (E_a) and the most probable electron energy (E_p) (see Annex A3). An energy analyzing magnet may be used for more detailed analysis.

8.3.2 *Material Handling*:

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

NOTE 6—The conveyor speed and the beam current may be linked for some types of accelerators so that a variation in one causes a corresponding change in the other to maintain a constant value of the absorbed dose (also see Note 7).

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

8.3.3 *Beam Dispersion Parameters*:

8.3.3.1 Dispersion of the electron beam to produce a beam width adequate to cover the processing zone may be achieved by various techniques. These include electromagnetic scanning of a pencil beam or use of defocussing elements or scattering foils.

8.3.3.2 The beam width, in addition to several other operating parameters, affects the dose rate. Scanning of a pencil beam can produce pulsed dose at points along the beam width. This can influence the dosimeters' performance when they are sensitive to dose rate variations.

8.3.3.3 See Annex A4 for determination of beam width and dose uniformity across the beam width.

8.4 *Irradiator Characterization*:

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

NOTE 7—Electron beam irradiators generally utilize continuously-moving conveyors. Dose uniformity in a reference plane is strongly influenced by the coordination of the beam spot dimensions, conveyor speed, beam width, and scan frequency (for those irradiators that employ beam scanning). For a pulsed-beam accelerator, all these parameters must also be coordinated with the pulse width and repetition rate. Improper coordination of these parameters can cause unacceptable dose variation in the reference plane.

8.4.2 Using appropriate dosimetry, establish the depth-dose distribution within a reference material (see 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. Increasing the electron energy increases the half-value depth (R_{50}), the practical range (R_p), and the optimum thickness (R_{opt}).

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

9. Process Qualification

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

NOTE 8—In conjunction with dose distribution measurements, it is usually necessary to do testing of the product to ensure compatibility with the electron beam treatment. It is recommended that this testing be done at doses higher than the maximum absorbed dose attained during routine processing.

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

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

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

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

NOTE 9—The irradiation of tubing, wire, cable, and continuous web products may not require absorbed dose mapping studies. Desired effects from absorbed dose may be attained through control of the operating parameters and monitoring the desired effects themselves.

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

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

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

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

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

9.3.6 For irradiators being used in a bulk flow mode, absorbed-dose mapping as described in 9.3.1 may not be feasible. In this case, absorbed dose extremes may be estimated by using an appropriate number of dosimeters mixed with and carried by the product through the irradiation zone. Enough dosimeters should be used to obtain statistically significant results **(10, 11)**. Calculation of the absorbed dose extremes may be an appropriate alternative **(8)**.

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

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

9.3.7.2 Depending upon the density, thickness, and inhomogeneity of an irradiation unit and beam energy of the irradiator, many processes require double-sided irradiation to achieve an acceptable dose distribution. For double-sided irradiation, the magnitudes and locations of dose extremes are usually quite different from those for single-sided irradiation. Slight fluctuations in density or thickness of product within the irradiation unit may cause much more pronounced changes in absorbed dose within the product for double-sided irradiation as compared to single-sided irradiation.

10. Routine Product Processing (Ref 4)

10.1 *Process Parameters*:

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

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

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

NOTE 10—Monitoring of operating parameters alone may not be adequate for some radiation processes (for example, sterilization and food irradiation). For these situations, dosimetry is required during routine product processing.

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

NOTE 11—Some processes, such as the modification of material properties, may not require routine dosimetry (see Note 2 and Note 10).

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

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

NOTE 12—More frequent placement of dosimeters during the production run could result in less product rejection should some operational uncertainty or failure arise.