ISO/ASTM 51649:2015(E)

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

This standard is issued under the fixed designation ISO/ASTM 51649; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision.

1. Scope

1.1 This practice outlines dosimetric procedures to be followed in installation qualification (IQ), operational qualification (OQ) and performance qualifications (PQ), and routine processing at electron beam facilities.

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

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

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

1.5 This document is one of a set of standards that provides recommendations for properly implementing and utilizing dosimetry in radiation processing. It is intended to be read in conjunction with ISO/ASTM 52628, "Practice for Dosimetry in Radiation Processing".

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

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

2. Referenced documents

2.1 *ASTM Standards:*[2]

E170 Terminology Relating to Radiation Measurements and Dosimetry

E2232 Guide for Selection and Use of Mathematical Methods for Calculating Absorbed Dose in Radiation Processing Applications

E2303 Guide for Absorbed-Dose Mapping in Radiation Processing Facilities

F1355 Guide for Irradiation of Fresh Agricultural Produce as a Phytosanitary Treatment

F1356 Guide for Irradiation of Fresh, Frozen or Processed Meat and Poultry to Control Pathogens and Other Microorganisms

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

F1885 Guide for Irradiation of Dried Spices, Herbs, and Vegetable Seasonings to Control Pathogens and Other Microorganisms

2.2 *ISO/ASTM Standards:*[2]

51261 Practice for Calibration of Routine Dosimetry Systems for Radiation Processing

51275 Practice for Use of a Radiochromic Film Dosimetry System

51539 Guide for the Use of Radiation-Sensitive Indicators

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

51702 Practice for Dosimetry in a Gamma Facility for Radiation Processing

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing

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

[1] This practice is under the jurisdiction of ASTM Committee E61 on Radiation Processing and is the direct responsibility of Subcommittee E61.03 on Dosimetry Application, and is also under the jurisdiction of ISO/TC 85/WG 3.

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[2] For referenced ASTM and ISO/ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

52628 Practice for Dosimetry in Radiation Processing
52701 Guide for Performance Characterization of Dosimeters and Dosimetry Systems for Use in Radiation Processing

2.3 *ISO Standards:*[3]
ISO 11137-1 Sterilization of Health Care Products–Radiation – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
ISO 11137-3 Sterilization of Health Care Products–Radiation – Part 3: Guidance on dosimetric aspects
ISO 14470 Food Irradiation – Requirements for the development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food
ISO 10012 Measurement Management Systems – Requirements for Measurement Processes and Measuring Equipment
ISO/IEC 17025 General Requirements for the Competence of Calibration and Testing Laboratories

2.4 *International Commission on Radiation Units and Measurements (ICRU) Reports:*[4]
ICRU Report 34 The Dosimetry of Pulsed Radiation
ICRU Report 35 Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV
ICRU Report 37 Stopping Powers for Electrons and Positrons
ICRU Report 80 Dosimetry for Use in Radiation Processing
ICRU Report 85a Fundamental Quantities and Units for Ionizing Radiation

2.5 *Joint Committee for Guides in Metrology (JCGM) Reports:*[5]
JCGM 100:2008, GUM 1995 , with minor corrections, Evaluation of measurement data – Guide to the expression of uncertainty in measurement

3. Terminology

3.1 *Definitions:*

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

3.1.1.1 *Discussion—(1)* The SI unit of absorbed dose is the gray (Gy), where 1 gray is equivalent to the absorption of 1 joule per kilogram in the specified material (1 Gy = 1 J/kg). The mathematical relationship is the quotient of $d\bar{\varepsilon}$ by dm, where $d\bar{\varepsilon}$ is the mean incremental energy imparted by ionizing radiation to matter of incremental mass dm. (See ICRU Report 85a.)

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

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

3.1.2 *approved laboratory*—laboratory that is a recognized national metrology institute; or has been formally accredited to ISO/IEC 17025, or has a quality system consistent with the requirements of ISO/IEC 17025.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[3] Available from International Organization for Standardization, 1 Rue de Varembé, Case Postale 56, CH-1211 Geneva 20, Switzerland.
[4] Available from the International Commission on Radiation Units and Measurements, 7910 Woodmont Ave., Suite 800, Bethesda MD 20814, U.S.A.
[5] Document produced by Working Group 1 of the Joint Committee for Guides in Metrology (JCGM/WG 1). Available free of charge at the BIPM website (http://www.bipm.org).

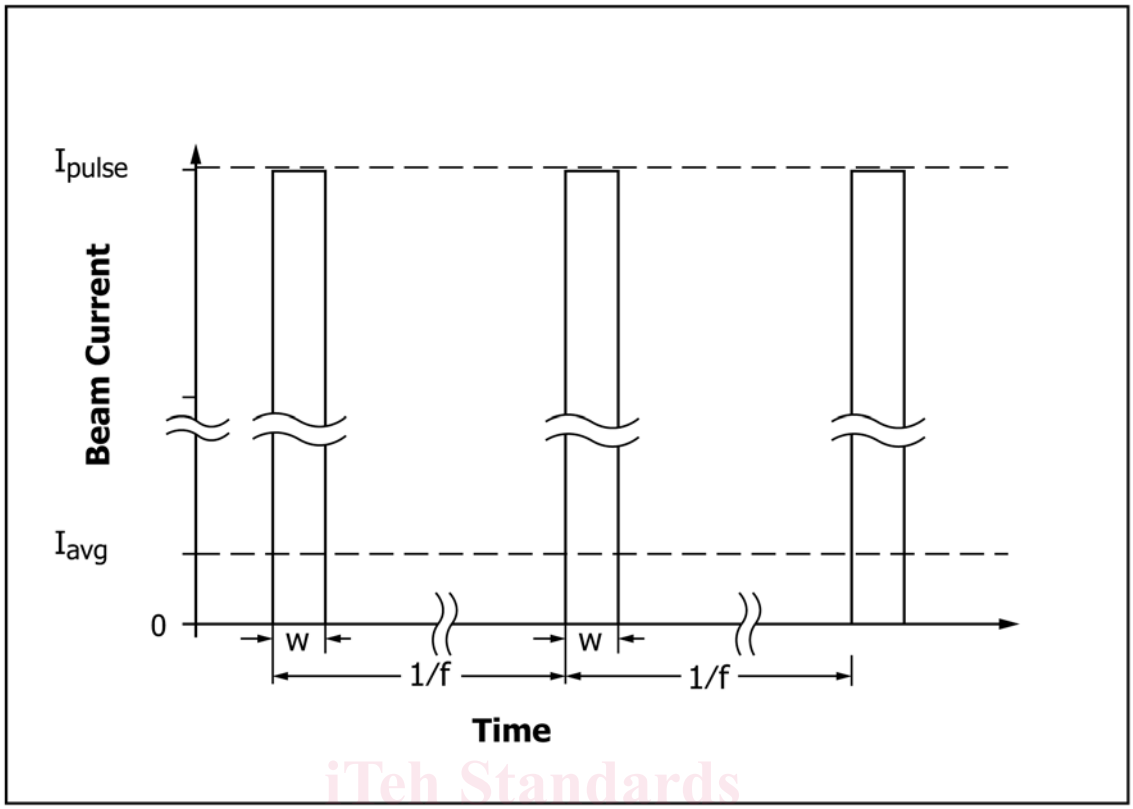


FIG. 1 Example showing pulse beam current (I_{pulse}), average beam current (I_{avg}), (pulse width (W) and repetition rate (f) for a pulsed accelerator

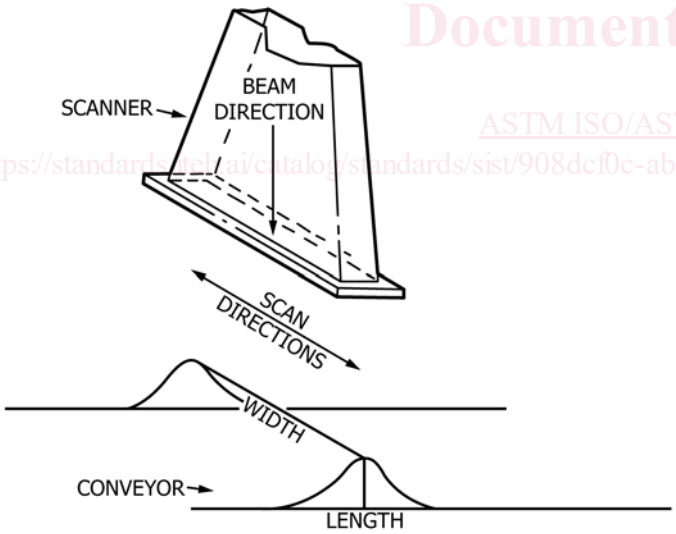


FIG. 2 Diagram showing beam length and beam width for a scanned beam using a conveyor system

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 (see Fig. 4 and Annex A4).

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

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

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

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

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

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

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

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

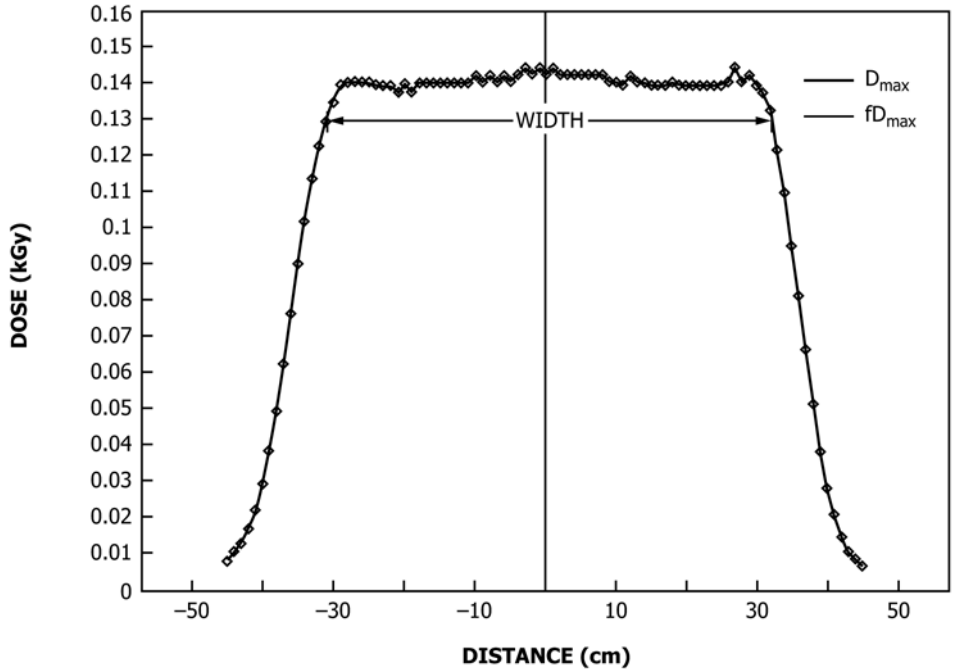
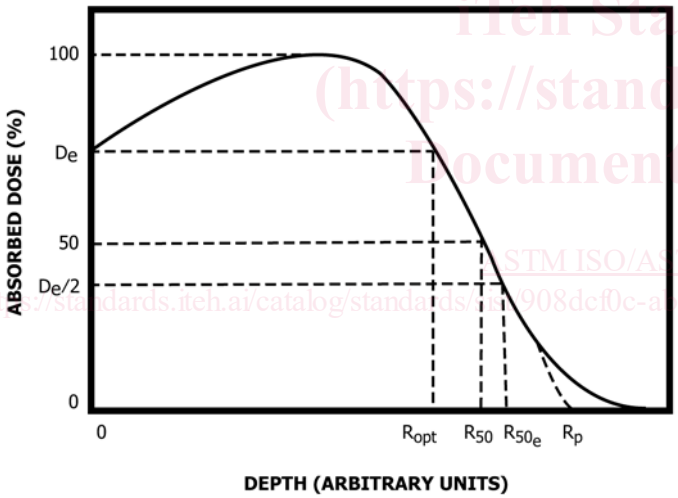


FIG. 3 Example of electron-beam dose distribution along the scan direction, where the beam width is specified at a defined fractional level *f* of the average maximum dose D_{max}



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

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

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

3.1.20 *routine monitoring position*—position where absorbed dose is monitored during routine processing to ensure that the product is receiving the absorbed dose specified for the process.

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

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

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

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

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

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

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

3.2 *Definitions of Terms Specific to This Standard:*

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

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

3.2.3 *continuous-slowing-down-approximation (CSDA) range* (r_0)—average pathlength traveled by a charged particle as it slows down to rest, calculated in the continuous-slowing-down-approximation method.

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

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

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

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

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

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

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

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

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

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

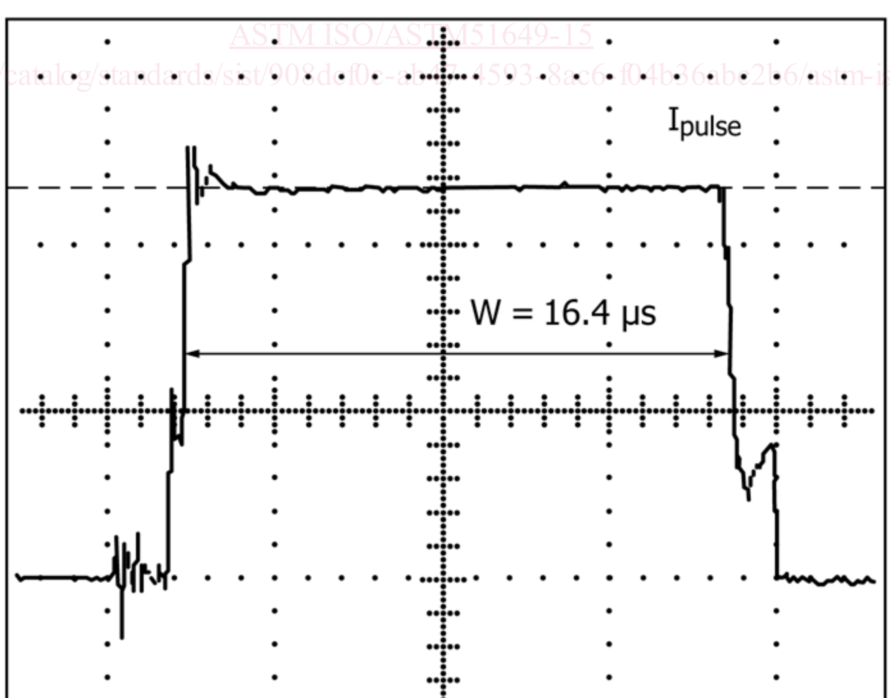
3.2.11 *pulse beam current, for a pulsed accelerator*—beam current averaged over the top ripples (aberrations) of the pulse current waveform.

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

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

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

3.2.13 *pulse width (for a pulsed accelerator)* (w)—time interval between two points on the leading and trailing edges of



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

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

the pulse current waveform where the current is 50 % of its peak value (see Fig. 5).

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

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

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

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

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

4. Significance and use

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

4.1.1 Polymerization of monomers and grafting of monomers onto polymers,

4.1.2 Cross-linking or degradation of polymers,

4.1.3 Curing of composite materials,

4.1.4 Sterilization of health care products,

4.1.5 Disinfection of consumer products,

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

4.1.7 Control of pathogens and toxins in drinking water,

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

4.1.9 Modification of characteristics of semiconductor devices,

4.1.10 Color enhancement of gemstones and other materials, and

4.1.11 Research on radiation effects on materials.

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

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

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

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

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

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

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

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

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

5. Radiation source characteristics

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

6. Documentation

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

7. Dosimetry system selection and calibration

7.1 *Selection of dosimetry systems:*

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

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

7.1.3 Different dosimetry systems may be selected for different dose measurement tasks due to different requirements

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

on, for example, dosimetry systems for dose mapping and dosimetry systems for routine monitoring.

7.2 *Dosimetry system calibration:*

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

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

8. Installation qualification

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

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

8.2.1 Operating procedures for the irradiator and associated conveyor system.

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

8.2.3 Any modifications made to the irradiator during installation.

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

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

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

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

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

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

9. Operational qualification

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

NOTE 6—Dose measurements for OQ may have to be carried out using a dosimetry system calibration curve obtained by irradiation at another facility. This calibration curve should be verified as soon as possible, and corrections applied to the OQ dose measurements as needed.

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

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

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

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

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

where:

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

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

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

9.2.4 *Beam homogeneity:*

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

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

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

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

9.2.6 *Process interruption*—A process interruption can be caused by, for example, failure of beam current delivery or the

conveyor stoppage. The effect of a process interruption shall be determined, so that decisions about possible product disposition can be made. See Annex A9.

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

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

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

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

9.4 *Requalification*—OQ measurements shall be repeated at intervals specified by the user's documented procedure, and following changes that might affect dose or dose distribution. The intervals shall be chosen to provide assurance that the facility is consistently operating within specifications. Requalification is typically carried out on an annual cycle, with specific parts of requalification at shorter time intervals within this cycle. If requalification measurements show that the irradiator has changed from previous OQ measurements, then PQ might have to be repeated.

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

10. Performance qualification

10.1 Performance Qualification (PQ) uses specific product to demonstrate that the facility consistently operates in accordance with predetermined criteria to deliver specified doses, thereby resulting in product that meets the specified requirements. Therefore, the objective of performance qualification is to establish all process parameters that will satisfy absorbed dose requirements. This is accomplished by establishing the dose distribution throughout the process load for a specific product loading pattern. Key process parameters include electron beam energy, beam current, material handling system parameters (conveyor speed or irradiation time), beam width, process load characteristics and irradiation conditions.

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

NOTE 10—Dose mapping exercises do not have to be carried out at the same dose as used for product irradiations. The use of higher doses, for example, can enable the dosimetry system to be used in a more accurate part of its operating range, thereby improving the overall accuracy of the dose mapping. This may be allowed provided that the linear relationship in 9.2.2 has been demonstrated.

10.3 OQ dose mapping can in some cases be used as PQ dose mapping. For example, this is the case for irradiation treatment of wide webs of infinite length or in the case where no more than a single process load at a given time is processed at the facility. In most other cases, such as medical device sterilization, it is required to carry out specific PQ product dose mapping.

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

10.4.1 dimensions and bulk density of the process load,

10.4.2 composition of product and all levels of packaging,

10.4.3 orientation of the product within its package, and

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

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

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

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

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

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

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

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

10.8 During PQ dose mapping the locations and magnitudes of minimum and maximum doses, as well as the dose at a routine monitoring position, are determined.

10.9 The ratio between maximum and minimum doses (dose uniformity ratio, DUR) should be calculated. If a routine monitoring location is used for process monitoring, then the ratios between the maximum and minimum dose and the dose at the monitoring position should be calculated and documented. This ratio is used during process control (see 11.1.3).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10.15 *Unacceptable Dose Uniformity Ratio:*

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

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

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

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

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

11. Routine process control

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

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

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

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

11.1.2 The dose at the routine monitoring position shall be measured at intervals specified by the operator of the facility. The intervals shall be chosen to verify that the irradiator operates within specifications, and thereby ensuring that the product specifications were achieved.

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

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

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

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

11.3 For some types of bulk-flow irradiators (for example, where fluids or grains continuously flow during irradiation), it is not feasible to place dosimeters at the locations of minimum

or maximum absorbed dose or at defined routine monitoring position during routine processing. In these cases, several dosimeters shall be added to the product stream at the beginning, the middle, and near the end of the production run. Each set of absorbed-dose measurements requires several dosimeters to ensure, within a specified level of confidence, that the minimum (and maximum, if a prescribed limit) absorbed dose has been delivered. This procedure requires that the rate of flow and flow pattern of the dosimeters are the same as those of the product.

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

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

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

12. Certification

12.1 *Documentation:*

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

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

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

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

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

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

12.2 *Review and Certification:*

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

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

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

12.3 *Retention of Records:*

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

13. Measurement uncertainty

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

13.1.1 All components of uncertainty shall be included in the estimate, including those arising from calibration, dosimeter variability, instrument reproducibility, and the effect of influence quantities. A full quantitative analysis of components of uncertainty is referred to as an uncertainty budget, and is often presented in the form of a table. Typically, the uncertainty budget will identify all significant components of uncertainty, together with their methods of estimation, statistical distributions and magnitudes.

14. Keywords

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

ANNEXES

(informative)

A1. TYPES OF ELECTRON BEAM FACILITIES

A1.1 *Electron Beam Facility Design*:

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

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

A1.1.3 *Type of Accelerator:*

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

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

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

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

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

A1.1.4.4 The electron beam is typically pulsed.

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

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

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

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

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

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

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

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

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

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

A1.1.7 *Material Handling:*

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

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

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

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