
**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*

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Foreword

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

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

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

A project between ISO and ASTM International has been formed to develop and maintain a group of ISO/ASTM radiation processing dosimetry standards. Under this project, ASTM Committee E61, Radiation Processing, is responsible for the development and maintenance of these dosimetry standards with unrestricted participation and input from appropriate ISO member bodies.

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

International Standard ISO/ASTM 51649 was developed by ASTM Committee E61, Radiation Processing, through Subcommittee E61.03, Dosimetry Application, and by Technical Committee ISO/TC 85, Nuclear energy, nuclear technologies and radiological protection.

This third edition cancels and replaces the second edition (ISO/ASTM 51649:2005), which has been technically revised.

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Standard Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 300 keV and 25 MeV¹

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

1. Scope

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

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

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

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

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

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

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate*

safety and health practices and determine the applicability of regulatory requirements prior to use.

2. Referenced documents

2.1 ASTM Standards:²

[E170](#) Terminology Relating to Radiation Measurements and Dosimetry

[E2232](#) Guide for Selection and Use of Mathematical Methods for Calculating Absorbed Dose in Radiation Processing Applications

[E2303](#) Guide for Absorbed-Dose Mapping in Radiation Processing Facilities

[F1355](#) Guide for Irradiation of Fresh Agricultural Produce as a Phytosanitary Treatment

[F1356](#) Practice for Irradiation of Fresh and Frozen Red Meat and Poultry to Control Pathogens and Other Microorganisms

[F1736](#) Guide for Irradiation of Finfish and Aquatic Invertebrates Used as Food to Control Pathogens and Spoilage Microorganisms

[F1885](#) Guide for Irradiation of Dried Spices, Herbs, and Vegetable Seasonings to Control Pathogens and Other Microorganisms

2.2 ISO/ASTM Standards:²

[51261](#) Practice for Calibration of Routine Dosimetry Systems for Radiation Processing

[51275](#) Practice for Use of a Radiochromic Film Dosimetry System

[51539](#) Guide for the Use of Radiation-Sensitive Indicators

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

[51702](#) Practice for Dosimetry in a Gamma Facility for Radiation Processing

[51707](#) Guide for Estimating Uncertainties in Dosimetry for Radiation Processing

[51818](#) Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 80 and 300 keV

[52628](#) Practice for Dosimetry in Radiation Processing

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

Current edition approved Sept. 8, 2014. Published February 2015. Originally published as E 1649–94. Last previous ASTM edition E 1649–00. ASTM E 1649–94¹ was adopted by ISO in 1998 with the intermediate designation ISO 15569:1998(E). The present International Standard ISO/ASTM 51649:2015(E) is a major revision of the last previous edition ISO/ASTM 51649:2005(E), which replaced ISO/ASTM 51649:2002(E).

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

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

2.3 ISO Standards:³

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

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

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

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

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

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

ICRU Report 34 The Dosimetry of Pulsed Radiation

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

ICRU Report 37 Stopping Powers for Electrons and Positrons

ICRU Report 80 Dosimetry for Use in Radiation Processing

ICRU Report 85a Fundamental Quantities and Units for Ionizing Radiation

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

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

3. Terminology

3.1 Definitions:

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

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

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

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

3.1.2 *approved laboratory*—laboratory that is a recognized national metrology institute; or has been formally accredited to

ISO/IEC 17025, or has a quality system consistent with the requirements of ISO/IEC 17025.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

⁵ Document produced by Working Group 1 of the Joint Committee for Guides in Metrology (JCGM/WG 1). Available free of charge at the BIPM website (<http://www.bipm.org>).

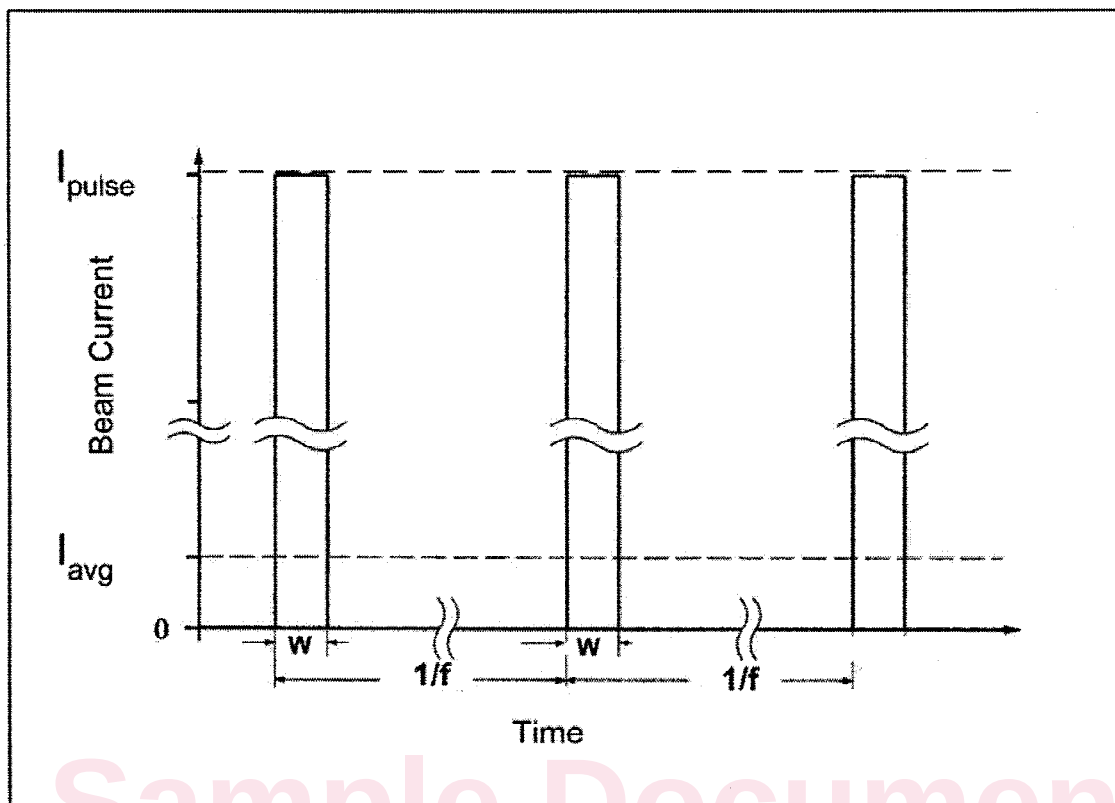


FIG. 1 Example showing pulse beam current (I_{pulse}), average beam current (I_{avg}), (pulse width (W) and repetition rate (f) for a pulsed accelerator

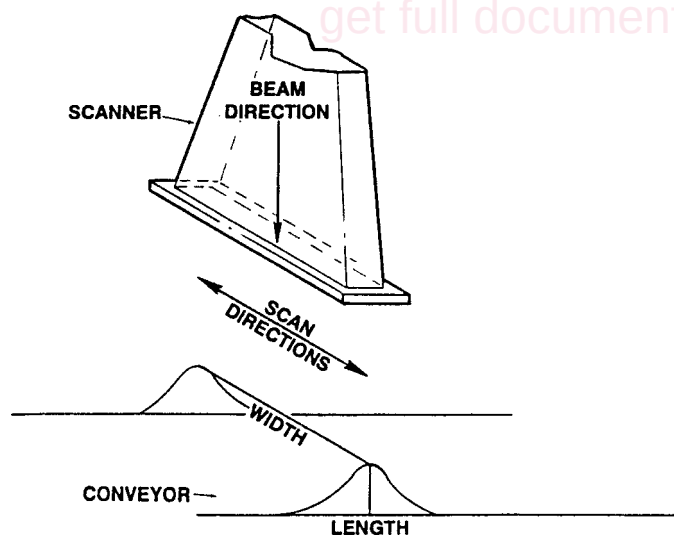


FIG. 2 Diagram showing beam length and beam width for a scanned beam using a conveyor system

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

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

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

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

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

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

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

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

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

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

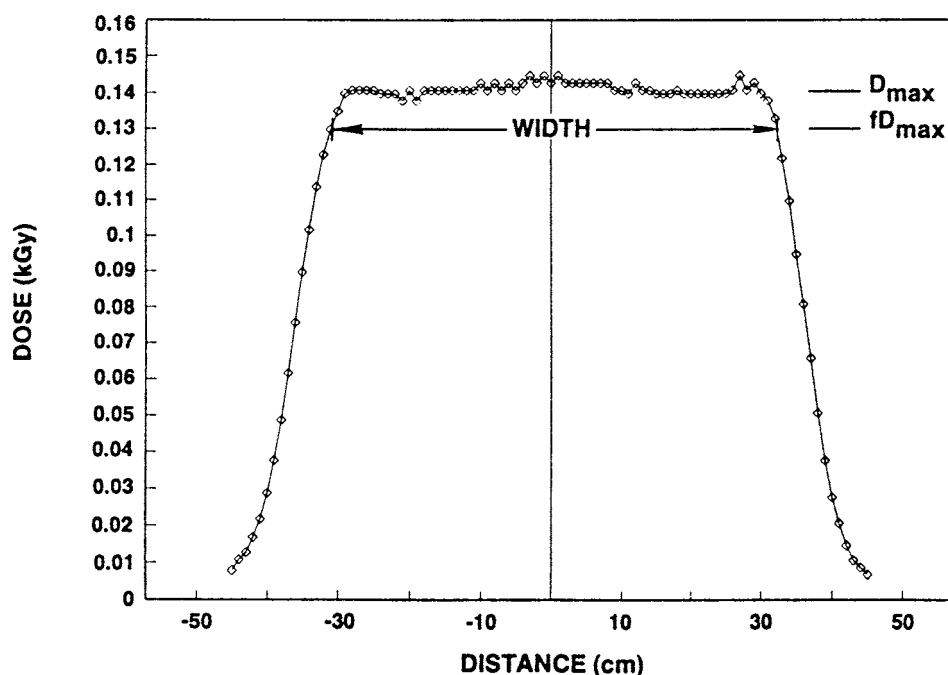
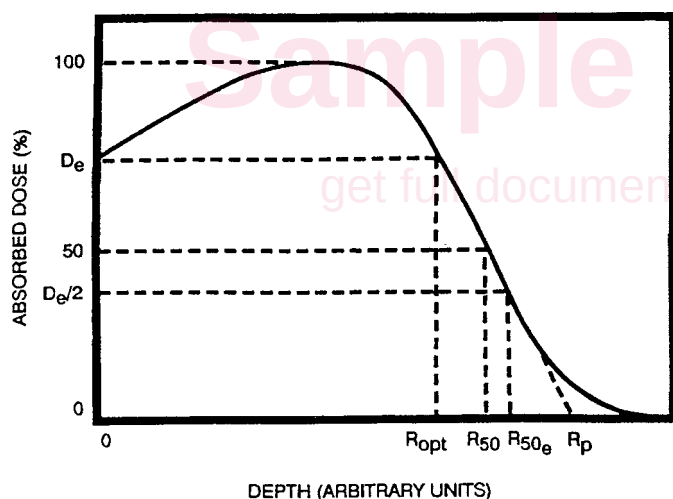


FIG. 3 Example of electron-beam dose distribution along the scan direction, where the beam width is specified at a defined fractional level f of the average maximum dose $D_{\max}$



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

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

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

3.1.20.1 *Discussion*—This position may be a location of minimum or maximum dose in the process load or it may be an alternate convenient location in, on or near the process load

where the relationship of the dose at this position with the minimum and maximum dose has been established.

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

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

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

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

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

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

3.2 Definitions of Terms Specific to This Standard:

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

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

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

as it slows down to rest, calculated in the continuous-slowng-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).

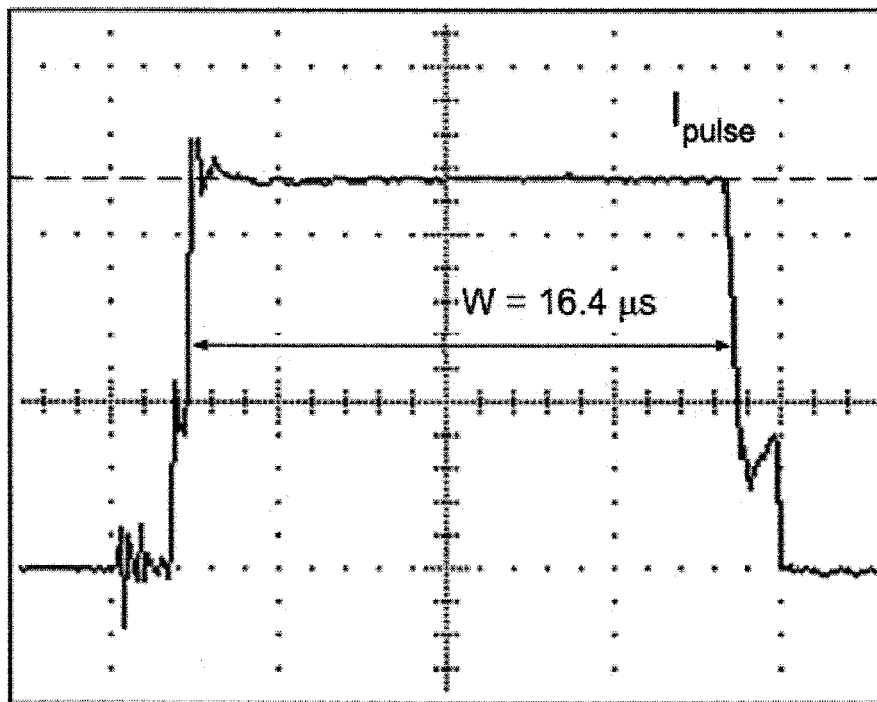
3.2.10.1 *Discussion*—Penetration can be measured from experimental depth-dose distributions in a given material. Other forms of electron range are found in the dosimetry literature, for example, extrapolated range derived from depth-dose data and the continuous-slowng-down-approximation range. Electron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

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

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

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

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



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

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

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

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

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

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

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

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

4. Significance and use

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

- 4.1.1 Polymerization of monomers and grafting of monomers onto polymers,
- 4.1.2 Cross-linking or degradation of polymers,
- 4.1.3 Curing of composite materials,
- 4.1.4 Sterilization of health care products,
- 4.1.5 Disinfection of consumer products,
- 4.1.6 Food irradiation (parasite and pathogen control, insect disinfestation, and shelf-life extension),
- 4.1.7 Control of pathogens and toxins in drinking water,
- 4.1.8 Control of pathogens and toxins in liquid or solid waste,
- 4.1.9 Modification of characteristics of semiconductor devices,
- 4.1.10 Color enhancement of gemstones and other materials, and
- 4.1.11 Research on radiation effects on materials.

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

NOTE 2—Dosimetry with measurement traceability and known uncertainty is required for regulated radiation processes such as sterilization of health care products (see ISO 11137-1 and Refs (1-3⁶)) and preservation of food (see ISO 14470 and Ref (4)). It may be less important for other processes, such as polymer modification, which may be evaluated by changes in the physical and chemical properties of the irradiated materials. Nevertheless, routine dosimetry may be used to monitor the reproducibility of the treatment process.

NOTE 3—Measured dose is often characterized as absorbed dose in

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

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

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

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

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

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

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

5. Radiation source characteristics

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

6. Documentation

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

7. Dosimetry system selection and calibration

7.1 Selection of dosimetry systems:

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

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