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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

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Foreword

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

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

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

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

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

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

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

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

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

1. Scope

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

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

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

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

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

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

2. Referenced documents

2.1 *ASTM Standards:* [2]

E 170 Terminology Relating to Radiation Measurements and Dosimetry

E 1026 Practice for Using the Fricke Reference Standard Dosimetry System

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

E 2303 Guide to Dose Mapping in Radiation Processing Facilities

2.2 *ISO/ASTM Standards:*[2]

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

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

51275 Practice for Use of a Radiochromic Film Dosimetry System

51276 Practice for Use of a Polymethylmethacrylate Dosimetry System

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

51401 Practice for Use of a Dichromate Dosimetry System

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

51538 Practice for Use of an Ethanol-Chlorobenzene Dosimetry System

51539 Guide for the Use of Radiation-Sensitive Indicators

51540 Practice for Use of a Radiochromic Liquid Solution Dosimetry System

51607 Practice for Use of the Alanine–EPR Dosimetry System

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

51650 Practice for Use of a Cellulose Triacetate Dosimetry System

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing

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

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

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

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

2.3 *ISO Standard:*[3]

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

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

ICRU Report 34 The Dosimetry of Pulsed Radiation

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

ICRU Report 37 Stopping Powers for Electrons and Positrons

ICRU Report 60 Fundamental Quantities and Units for Ionizing Radiation

3. Terminology

3.1 *Definitions:*

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

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

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

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

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

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

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

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

3.1.6.1 *Discussion*—For a radiation processing facility with a conveyor system, the beam width is usually perpendicular to the flow of motion of the conveyor (see Fig. 2). Beam width is the distance between two points along the dose profile, which

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

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

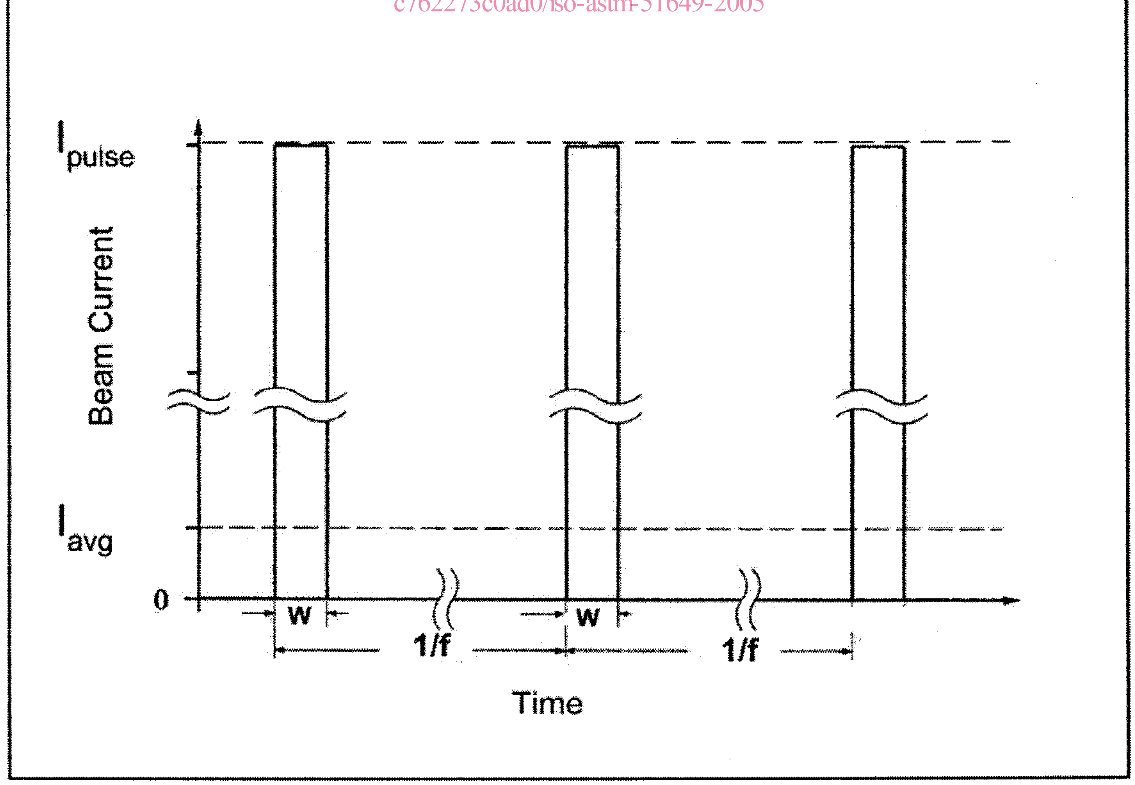


FIG. 1 Example pulse current (I_{pulse}), average beam current (I_{avg}), pulse width (*W*) and repetition rate (*f*) for a pulsed accelerator

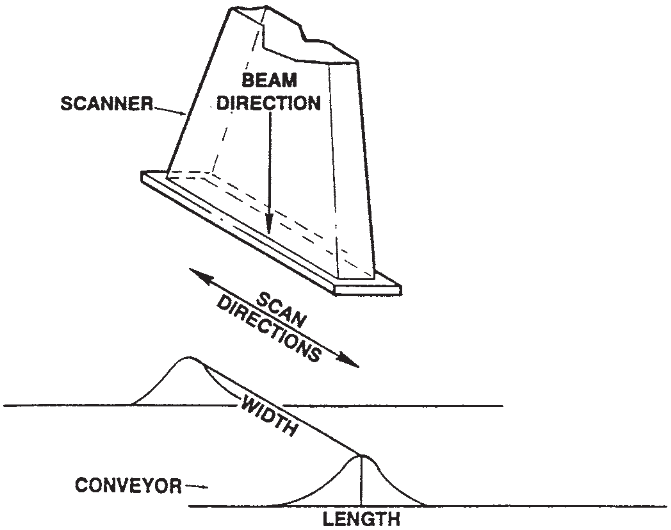


FIG. 2 Diagram showing beam length and width for a scanned beam using a conveyor system

are at a defined level from the maximum dose region in the profile (see Fig. 3). Various techniques may be employed to produce an electron beam width adequate to cover the processing zone, for example, use of electromagnetic scanning of a pencil beam (in which case beam width is also referred to as scan width), defocussing elements, and scattering foils.

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

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

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

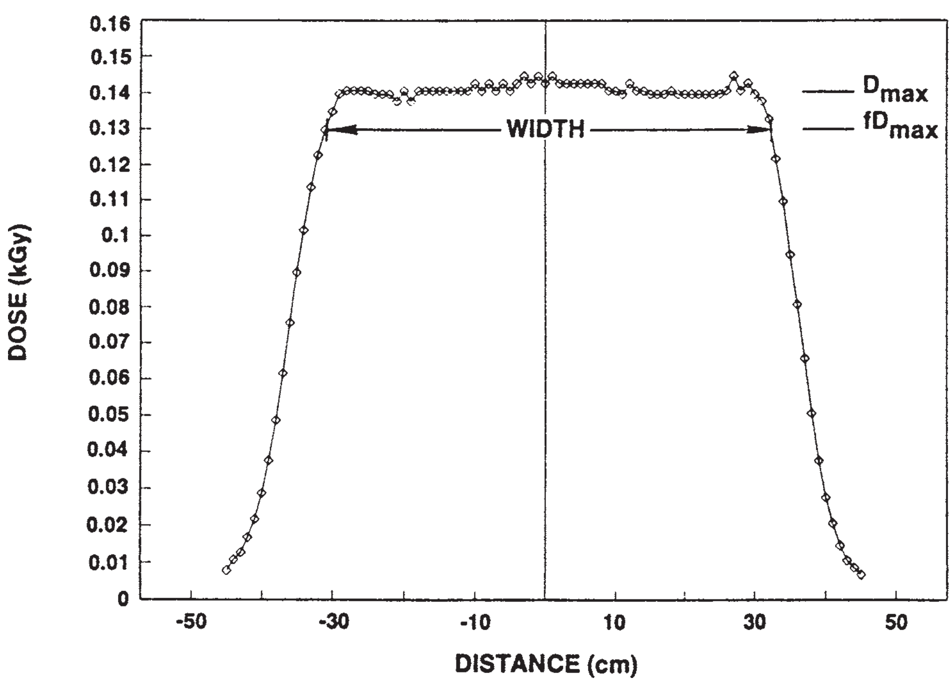
3.1.8.1 *Discussion*—In this approximation, the rate of energy loss at every point along the track is assumed to be equal to the total stopping power. Energy-loss fluctuations are neglected. The CSDA range is obtained by integrating the reciprocal of the total stopping power with respect to energy. Values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

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

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

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

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



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

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

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

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

3.1.13.1 *Discussion*—Electron volt (eV) is often used as the unit for electron beam energy where 1 eV = $1.602{\cdot}10^{-19}$ J (approximately). In radiation processing, where beams with a broad electron energy spectrum are frequently used, the terms *most probable energy* (E_p) and *average energy* (E_a) are common. They are linked to the *practical electron range* R_p and *half-value depth* R_{50} by empirical equations.

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

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

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

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

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

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

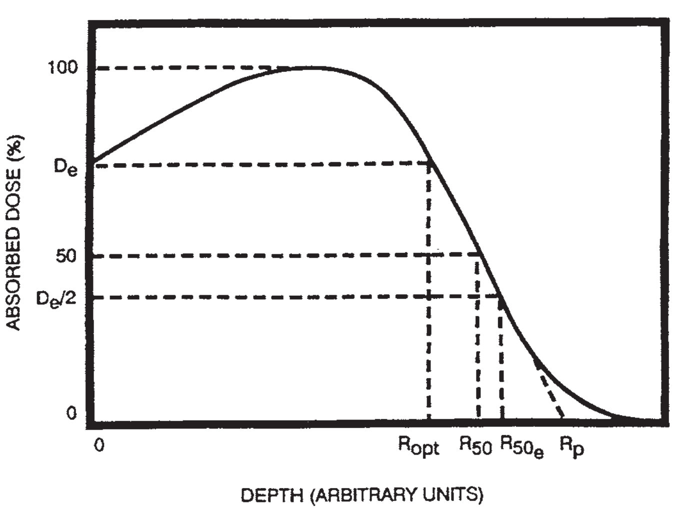


FIG. 4 A typical depth-dose distribution for an electron beam in a homogeneous material

3.1.19 *optimum thickness* (R_{opt})—depth in homogeneous material at which the absorbed dose equals the absorbed dose at the surface where the electron beam enters (see Fig. 4).

3.1.20 *practical electron range* (R_p)—depth in homogeneous material to the point where the tangent at the steepest point (the inflection point) on the almost straight descending portion of the depth-dose distribution curve meets the extrapolated X-ray background (see Fig. 4 and Fig. A1.6 in Annex A1).

3.1.21 *extrapolated electron range* (R_{ex})—depth in homogeneous material to the point where the tangent at the steepest point (the inflection point) on the almost straight descending portion of the depth-dose distribution curve meets the depth axis (see Fig. A1.6 in Annex A1).

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

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

3.1.24 *pulse beam current, for a pulsed accelerator*—beam current averaged over the top ripples (aberrations) of the pulse current waveform; this is equal to I_{avg}/wf, where I_{avg} is the average beam current, *w* is the pulse width, and *f* is the pulse rate (see Fig. 5).

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

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

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

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

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

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

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

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

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

3.1.32.1 *Discussion*—Simulated product is used during irradiator characterization as a substitute for the actual product, material or substance to be irradiated. When used in routine production runs, it is sometimes referred to as compensating

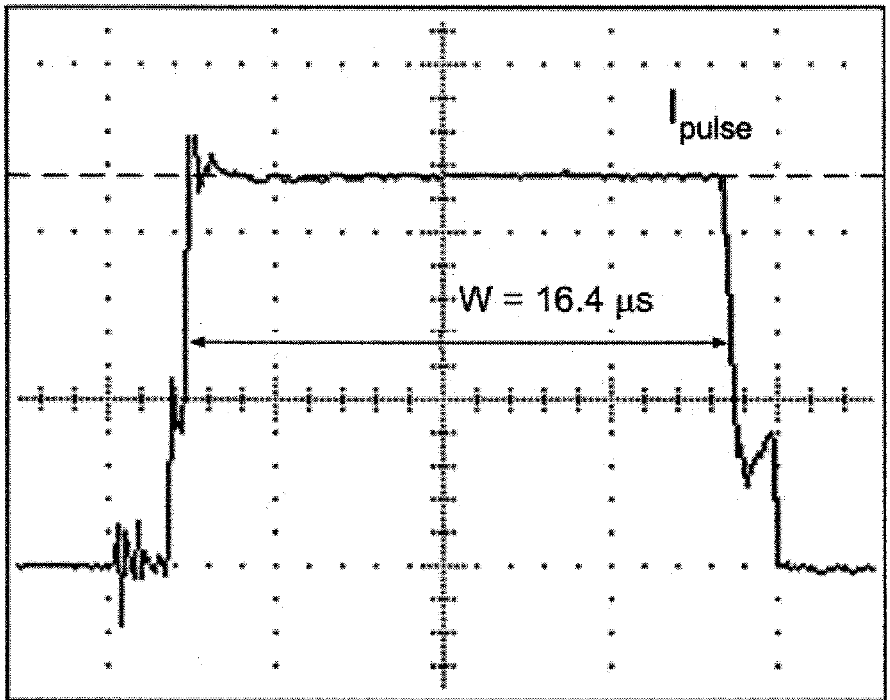


FIG. 5 Typical pulse current waveform from an S-Band linear accelerator

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

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

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

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

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

3.2 *Definitions*—Definitions of other terms used in this standard that pertain to radiation measurement and dosimetry may be found in ASTM Terminology E 170. Definitions in E 170 are compatible with ICRU 60; that document, therefore, may be used as an alternative reference.

4. Significance and use

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

4.1.1 Polymerization of monomers and grafting of monomers onto polymers,

4.1.2 Cross-linking or degradation of polymers,

4.1.3 Curing of composite materials,

4.1.4 Sterilization of medical devices,

4.1.5 Disinfection of consumer products,

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

4.1.7 Control of pathogens and toxins in drinking water,

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

4.1.9 Modification of characteristics of semiconductor devices,

4.1.10 Color enhancement of gemstones and other materials, and

4.1.11 Research on radiation effects on materials.

NOTE 2—Dosimetry is required for regulated radiation processes such as sterilization of medical devices (see ISO 11137 and Refs **(1-4)**[5] and preservation of food (see ISO/ASTM 51431 and Ref **(5)**). It may be less important for other processes, such as polymer modification, which may be evaluated by changes in the physical and chemical properties of the irradiated materials. Nevertheless, routine dosimetry may be used to monitor the reproducibility of the treatment process.

4.2 Dosimeters are used as a means of monitoring the radiation process.

NOTE 3—Measured dose is often characterized as absorbed dose in water to have a traceable standard reference. Moreover, materials commonly found in disposable medical devices and food are approximately equivalent to water in the absorption of ionizing radiation. Absorbed dose in materials other than water may be determined by applying conversion

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

factors in accordance with ISO/ASTM Guide 51261.

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

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

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

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

5. Radiation source characteristics

5.1 Electron radiation sources considered in this practice are either direct-action (potential-drop) or indirect-action (RF- or microwave-powered) accelerators. These are discussed in Annex A4.

6. Types of irradiation facilities

6.1 *Irradiation Facility Design*:

6.1.1 The design of an irradiation facility affects the delivery of absorbed dose to a product. Therefore, the facility design should be considered when performing the absorbed-dose measurements required in Sections 8 to 11.

6.1.2 An electron beam facility includes the electron beam accelerator system; material handling systems, a radiation shield with personnel safety system, product staging, loading and storage areas; auxiliary equipment for power, cooling, ventilation, etc.; equipment control room; laboratories for dosimetry and product testing; and personnel offices. The electron beam accelerator system consists of the radiation source (see Annex A4), equipment to disperse the beam on product, control system, and associated equipment **(2)**.

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

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

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

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

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

7. Dosimetry systems

7.1 *Description of Dosimeter Classes*:

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

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

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

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

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