
**Practice for dosimetry in an electron-beam
facility for radiation processing at energies
between 300 keV and 25 MeV**

*Pratique de la dosimétrie utilisant des faisceaux d'énergie comprise entre
300 keV et 25 MeV*



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.

International Standard ISO 15569 was prepared by the American Society for Testing and Materials (ASTM) Subcommittee E10.01 (as E 1649-94) and was adopted, under a special "fast-track procedure", by Technical Committee ISO/TC 85, *Nuclear energy*, in parallel with its approval by the ISO member bodies.

A new ISO/TC 85 Working Group WG 3, *High-level dosimetry for radiation processing*, was formed to review the voting comments from the ISO "Fast-track procedure" and to maintain these standards. The USA holds the convenership of this working group.

International Standard ISO 15569 is one of 20 standards developed and published by ASTM. The 20 fast-tracked standards and their associated ASTM designations are listed below:

ISO Designation	ASTM Designation	Title
15554	E 1204-93	<i>Practice for dosimetry in gamma irradiation facilities for food processing</i>
15555	E 1205-93	<i>Practice for use of a ceric-cerous sulfate dosimetry system</i>
15556	E 1261-94	<i>Guide for selection and calibration of dosimetry systems for radiation processing</i>
15557	E 1275-93	<i>Practice for use of a radiochromic film dosimetry system</i>
15558	E 1276-96	<i>Practice for use of a polymethylmethacrylate dosimetry system</i>
15559	E 1310-94	<i>Practice for use of a radiochromic optical waveguide dosimetry system</i>
15560	E 1400-95a	<i>Practice for characterization and performance of a high-dose radiation dosimetry calibration laboratory</i>
15561	E 1401-96	<i>Practice for use of a dichromate dosimetry system</i>

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15562	E 1431-91	<i>Practice for dosimetry in electron and bremsstrahlung irradiation facilities for food processing</i>
15563	E 1538-93	<i>Practice for use of the ethanol-chlorobenzene dosimetry system</i>
15564	E 1539-93	<i>Guide for use of radiation-sensitive indicators</i>
15565	E 1540-93	<i>Practice for use of a radiochromic liquid dosimetry system</i>
15566	E 1607-94	<i>Practice for use of the alanine-EPR dosimetry system</i>
15567	E 1608-94	<i>Practice for dosimetry in an X-ray (bremsstrahlung) facility for radiation processing</i>
15568	E 1631-96	<i>Practice for use of calorimetric dosimetry systems for electron beam dose measurements and dosimeter calibrations</i>
15569	E 1649-94	<i>Practice for dosimetry in an electron-beam facility for radiation processing at energies between 300 keV and 25 MeV</i>
15570	E 1650-94	<i>Practice for use of cellulose acetate dosimetry system</i>
15571	E 1702-95	<i>Practice for dosimetry in a gamma irradiation facility for radiation processing</i>
15572	E 1707-95	<i>Guide for estimating uncertainties in dosimetry for radiation processing</i>
15573	E 1818-96	<i>Practice for dosimetry in an electron-beam facility for radiation processing at energies between 80 keV and 300 keV</i>

For the purposes of this International Standard, the following amendments to the ASTM text apply.

Page 1, subclause 1.2, note 2, and subclause 1.3

Replace note 2 and subclause 1.3 by the following.

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

1.4 For the irradiation of food and the radiation sterilization of health care products, other specific ISO standards exist. For food irradiation, see ISO 15562:1998, *Practice for dosimetry in electron and bremsstrahlung irradiation facilities for food processing* (ASTM Practice E 1431). For the radiation sterilization of health care products, see ISO 11137:1995, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization*. In those areas covered by ISO 11137, that standard takes precedence.

Page 1, subclause 1.4

Renumber this subclause as 1.5.



Designation: E 1649 – 94

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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 E 1649; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

1. Scope

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

NOTE 1—For guidance in the selection and calibration of dosimeters, see Guide E 1261. For further guidance in the selection, calibration, and use of specific dosimeters, and interpretation of absorbed dose in the product from dosimetry, also see Practices E 668, E 1275, E 1276, E 1431, E 1607, E 1631, and E 1650. For use with electron energies above 5 MeV, see Practices E 1026, E 1205, E 1401, E 1538, and E 1540 for discussions of specific large volume dosimeters. For discussion of radiation dosimetry for pulsed radiation, see ICRU Report 34. When considering a dosimeter type, be cautious of influences from dose rates and accelerator pulse rates and widths (if applicable).

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

NOTE 2—For application of dosimetry in the characterization and operation of electron beam and X-ray (bremsstrahlung) irradiation facilities for food processing, see Practice E 1431. For application of dosimetry in the characterization and operation of irradiation facilities using X-ray radiation (bremsstrahlung), see Practice E 1608.

1.3 Dosimetry is one component of a total quality assurance program for adherence to good manufacturing practices. Specific applications of electron beam radiation processing may require additional controls.

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

2. Referenced Documents

2.1 ASTM Standards:

E 170 Terminology Relating to Radiation Measurements and Dosimetry²

E 668 Practice for the Application of Thermoluminescence-Dosimetry (TLD) Systems for Determining

Absorbed Dose in Radiation-Hardness Testing of Electronic Devices²

E 1026 Practice for Using the Fricke Reference Standard Dosimetry System²

E 1205 Practice for Use of a Ceric-Cerous Sulfate Dosimetry System²

E 1261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing²

E 1275 Practice for Use of a Radiochromic Film Dosimetry System²

E 1276 Practice for Use of a Polymethylmethacrylate Dosimetry System²

E 1401 Practice for Use of a Dichromate Dosimetry System²

E 1431 Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing²

E 1538 Practice for Use of an Ethanol-Chlorobenzene Dosimetry System²

E 1539 Guide for the Use of Radiation-Sensitive Indicators²

E 1540 Practice for Use of a Radiochromic Liquid Solution Dosimetry System²

E 1607 Practice for Use of the Alanine-EPR Dosimetry System²

E 1608 Practice for Dosimetry in an X-Ray (Bremsstrahlung) Irradiation Facility for Radiation Processing²

E 1631 Practice for Use of Calorimetric Dosimetry Systems for Electron Beam Measurements and Dosimeter Calibrations²

E 1650 Practice for Use of a Cellulose Acetate Dosimetry System²

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

ICRU Report 33 Radiation Quantities and Units³

ICRU Report 34 The Dosimetry of Pulsed Radiation³

ICRU Report 35 Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV³

ICRU Report 37 Stopping Powers for Electrons and Positrons³

3. Terminology

3.1 *Definitions*—Other terms used in this practice may be found in Terminology E 170 and ICRU Report 33.

3.2 Descriptions of Terms Specific to This Standard:

3.2.1 *absorbed dose, D*—the quotient of $d\bar{e}$ by dm , where $d\bar{e}$ is the mean energy imparted by ionizing radiation to the

¹ This practice is under the jurisdiction of ASTM Committee E-10 on Nuclear Technology and Applications and is the direct responsibility of Subcommittee E10.01 on Dosimetry for Radiation Processing.

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² Annual Book of ASTM Standards, Vol 12.02.

³ Available from International Commission on Radiation Units and Measurements, 7910 Woodmont Ave., Suite 800, Bethesda, MD 20814.

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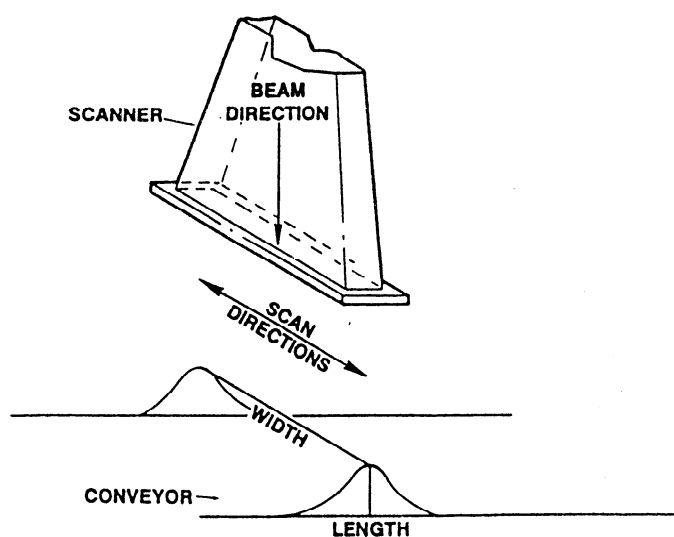


FIG. 1 Diagram Showing Beam Length and Width for a Scanned Beam Using a Conveyor Material Handling System

matter of mass dm (see ICRU Report 33).

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

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

$$1 \text{ Gy} = 1 \text{ J} \cdot \text{kg}^{-1}$$

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

$$1 \text{ rad} = 10^{-2} \text{ J} \cdot \text{kg}^{-1} = 10^{-2} \text{ Gy}$$

and:

$$1 \text{ Mrad} = 10 \text{ kGy}$$

3.2.2 average beam current—time-averaged electron

beam current; for a pulsed machine, the averaging shall be done over a large number of pulses.

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

DISCUSSION—See Fig. 1.

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

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

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

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

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

DISCUSSION—A typical distribution in homogeneous material produced by an electron beam along the beam axis is shown in Fig. 3. See

⁴ McKeown, J., AECL Accelerators, private communication, 1993. Example of a beam width profile of an AECL Impela accelerator.

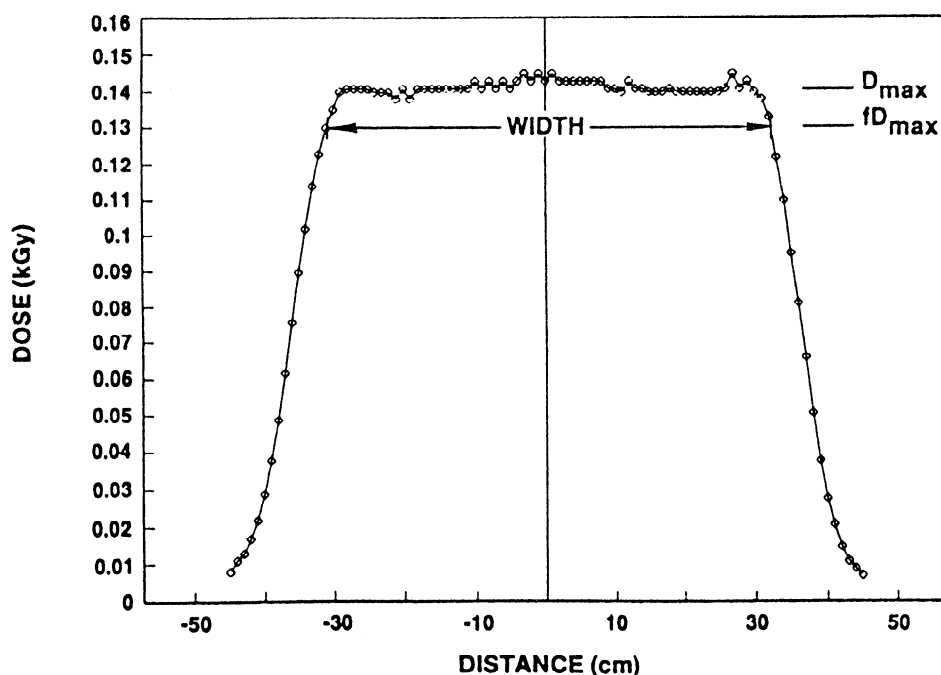


FIG. 2 Example of Electron-beam Dose Distribution Along the Beam Width⁴ with the Width Noted at Some Defined Fractional Level f of the Average Maximum Dose D_{max}

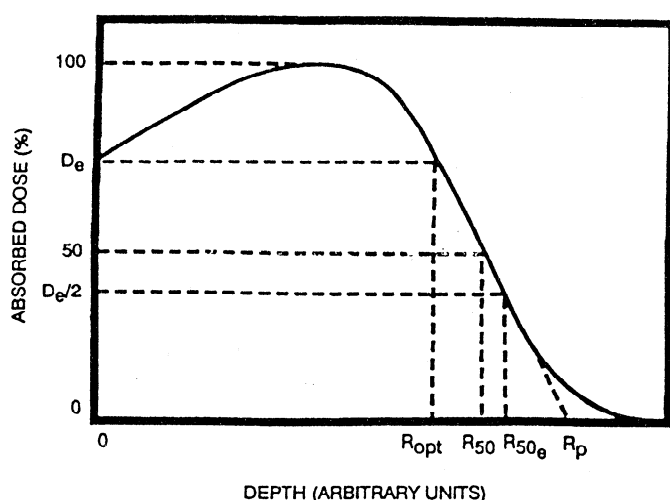


FIG. 3 A Typical Depth-Dose Distribution for an Electron Beam

Appendix X1.

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

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

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

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

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

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

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

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

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

DISCUSSION—See Fig. 3.

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

DISCUSSION—See Fig. 3.

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

3.2.18 *optimum thickness* (R_{opt})—depth in homogeneous material at which the absorbed dose equals the absorbed dose

at the surface where the electron beam enters.

DISCUSSION—See Fig. 3.

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

DISCUSSION—See Fig. 3.

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

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

DISCUSSION—See Fig. 4.

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

3.2.23 *pulse width*—for a pulsed accelerator, the time interval between the half peak beam current amplitude points on the leading and falling edges of the pulse beam current waveform.

DISCUSSION—See Fig. 4.

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

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

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

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.

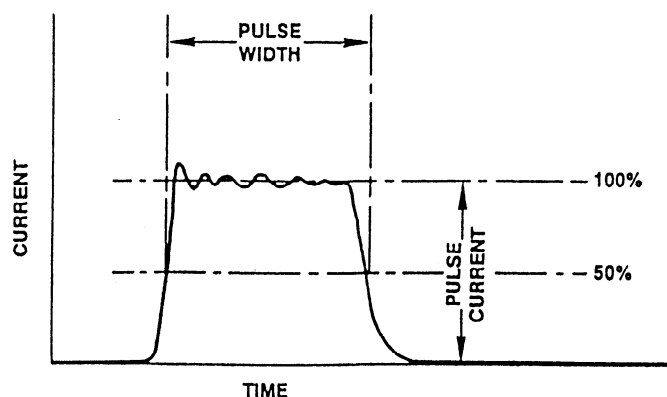


FIG. 4 Typical Pulse Current Waveform with Pulse Current and Pulse Width Noted

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

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

4. Significance and Use

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

4.1.1 Cross-linking or degradation of polymers and elastomers,

4.1.2 Polymerization of monomers and grafting of monomers onto polymers,

4.1.3 Sterilization of medical devices,

4.1.4 Disinfection of consumer products,

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

4.1.6 Control of pathogens in liquid or solid waste,

4.1.7 Modification of characteristics of semiconductor devices,

4.1.8 Color enhancement of gemstones and other materials, and

4.1.9 Research on materials effects.

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

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

NOTE 4—Measured dose is often characterized as absorbed dose in water because materials commonly found in disposable medical devices and food are approximately equivalent to water in the absorption of ionizing radiation. Absorbed dose in materials other than water may be determined by applying conversion factors in accordance with Guide E 1261.

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

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

⁵ The boldface numbers in parentheses refer to a list of references at the end of this practice.

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

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

5. Radiation Source Characteristics

5.1 Radiation sources for electrons with energies greater than 300 keV considered in this practice are either direct-action (potential-drop) or indirect-action (microwave-powered) accelerators. These are further discussed in Appendix X2.

6. Types of Irradiation Facility

6.1 An electron beam facility includes the electron beam accelerator system; material handling systems; a radiation shield with personnel safety system; product staging, loading, and storage areas; auxiliary equipment for power, cooling, ventilation, etc.; equipment control room; a laboratory for dosimetry and product testing; and personnel offices. The electron beam accelerator system consists of the radiation source (see Appendix X2), equipment to disperse the beam on product, and associated equipment (4).

6.2 Process Parameters:

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

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

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

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

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