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Practice for dosimetry in an X-ray (bremsstrahlung) facility for radiation processing

Pratique de la dosimétrie dans une installation de traitement par des rayons X (bremsstrahlung)

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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 51608 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 51608:2002), which has been technically revised.

ISO/ASTM 51608:2005(E)

Standard Practice for Dosimetry in an X-Ray (Bremsstrahlung) Facility for Radiation Processing[1]

This standard is issued under the fixed designation ISO/ASTM 51608; 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 the installation qualification program for an X-ray (bremsstrahlung) irradiator and the dosimetric procedures to be followed during operational qualification, performance qualification and routine processing to ensure that the entire product has been treated within a predetermined range of absorbed dose. Other procedures related to operational qualification, performance qualification and routine processing that may influence absorbed dose in the product are also discussed. Information about effective or regulatory dose limits and energy limits for X-radiation is not within the scope of this practice.

1.2 In contrast to monoenergetic gamma radiation, the bremsstrahlung energy spectrum extends from low values (about 35 keV) up to the maximum energy of the electrons incident on the X-ray target (see Section 5 and Annex A1).

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

1.4 For the irradiation of food and the radiation sterilization of health care products, other specific ISO standards exist. For food irradiation, see ISO/ASTM Practice 51431. For the radiation sterilization of health care products, see ISO 11137. In those areas covered by ISO/ASTM Practice 51431 or ISO 11137, those standards take precedence.

NOTE 1—For guidance in the selection, calibration, and use of specific dosimeters and interpretation of absorbed dose in the product from dose measurements, see the documents listed in Section 2.

NOTE 2—Bremsstrahlung characteristics are similar to those of gamma radiation from radioactive nuclides. See ISO/ASTM Practices 51204 and 51702 for the applications of dosimetry in the characterization and operation of gamma irradiation facilities. For information concerning electron beam irradiation technology and dosimetry, see ISO/ASTM Practices 51431 and 51649.

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

2. Referenced documents

2.1 *ASTM Standards:* [2]

E 170 Terminology Relating to Radiation Measurements and Dosimetry

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

E 2303 Guide for Absorbed Dose-Mapping in Radiation Processing Facilities

2.2 *ISO/ASTM Standards:*[2]

51204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing

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

51310 Practice for Use of a Radiochromic Optical Waveguide 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 Beam and X-ray (Bremsstrahlung) Irradiation Facilities for Food Processing

51538 Practice for Use of the Ethanol-Chlorobenzene Dosimetry System

51539 Guide for Use of Radiation-Sensitive Indicators

51540 Practice for Use of a Radiochromic Liquid Dosimetry System

51607 Practice for Use of the Alanine-EPR Dosimetry System

51649 Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 300 keV and 25 MeV

51650 Practice for Use of a Cellulose Triacetate Dosimetry System

[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.

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[2] For referenced ASTM or 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.

51702 Practice for Dosimetry in a Gamma Irradiation Facility for Radiation Processing
51707 Guide for Estimating Uncertainties in Dosimetry 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 *ICRU Reports:*[4]

ICRU Report 14 Radiation Dosimetry: X Rays and Gamma Rays with Maximum Photon Energies Between 0.6 and 50 MeV
ICRU Report 34 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 of the specified material (1 Gy = 1 J/kg). The mathematical relationship is the quotient of dϵ by d*m*, where dϵ is the mean incremental energy imparted by ionizing radiation to matter of incremental mass d*m* (see ICRU Report 60).

$$D = d\epsilon / dm \quad (1)$$

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

3.1.2 *absorbed dose enhancement*—increase or decrease in the absorbed dose, as compared to the equilibrium dose, at a point in the material of interest. This will occur near an interface between materials with different atomic numbers.

3.1.3 *bremsstrahlung*—broad-spectrum electromagnetic radiation emitted when an energetic electron is influenced by a strong electric or magnetic field, such as that in the vicinity of an atomic nucleus (see 3.1.14).

3.1.3.1 *Discussion*—When an electron passes close to a nucleus, the strong coulomb field causes the electron to deviate sharply from its original path. The change in direction is due to radial acceleration, and in accordance with classical theory, the electron loses energy by electromagnetic radiation at a rate proportional to the square of the acceleration. This means that the bremsstrahlung photons have a continuous energy distribution that ranges downward from a theoretical maximum equal to the kinetic energy of the incident electron. Bremsstrahlung is produced when an electron beam strikes any material (converter). The bremsstrahlung spectrum depends on the electron energy, the composition and thickness of the converter, and the angle of emission with respect to the incident electron.

3.1.4 *calibration facility*—combination of an ionizing radiation source and its associated instrumentation that provides, at a specified location and within a specified material, a uniform and reproducible absorbed dose, or absorbed dose rate, traceable to national or international standards, and that may be used to derive the dosimetry system's response function or calibration curve.

3.1.5 *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.

3.1.6 *dosimeter*—device that, when irradiated, exhibits a quantifiable change in some property of the device, which can be related to the absorbed dose in a given material using appropriate analytical instrumentation and techniques.

3.1.7 *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.

3.1.8 *electron energy*—kinetic energy of an electron that is usually given in units of electron volts (eV), kiloelectron volts (keV), or megaelectron volts (MeV).

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

3.1.10 *equilibrium absorbed dose*—absorbed dose in a finite volume within the material in which the condition of approximate electron equilibrium exists.

3.1.11 *measurement quality assurance plan*—documented program for the measurement process that ensures on a continuing basis that the overall uncertainty meets the requirements of the specific application. This plan requires traceability to, and consistency with, nationally or internationally recognized standards.

3.1.12 *measurement traceability*—ability to demonstrate by means of an unbroken chain of comparisons that a measurement is in agreement within acceptable limits of uncertainty with comparable nationally or internationally recognized standards.

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

3.1.14 *X-radiation*—short wave-length electromagnetic radiation emitted by high-energy electrons when they are accelerated, decelerated or deflected by strong electric or magnetic fields. The term includes both bremsstrahlung from nuclear interactions and the characteristic monoenergetic radiation emitted when atomic electrons make transitions to more tightly bound states (see 3.1.3).

3.1.15 *X-ray*—common term used for X-radiation.

3.1.16 *X-ray converter*—device for generating X-rays (bremsstrahlung) from an electron beam, consisting of a target, means for cooling the target, and a supporting structure.

3.1.17 *X-ray target*—component of the X-ray converter that is struck by the electron beam. It is usually made of metal with a high atomic number, high melting temperature, and high thermal conductivity.

[3] Available from the 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.

3.2 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 Report 60, which may be used as an alternative reference.

4. Significance and use

4.1 A variety of products and materials may be irradiated with X-radiation to modify their characteristics and improve the economic value or for health-related purposes. Examples are single-use medical devices (sterilization), agricultural commodities (preservation), and various polymeric products (material modification). Dosimetry requirements for X-ray processing may vary depending on the type and end use of the product.

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

NOTE 3—Dosimetry is required for regulated irradiation processes, such as the sterilization of medical devices and the preservation of food, because the results may affect the health of the consumer. It is less important for other industrial processes, such as polymer modification, which can be evaluated by changes in the physical properties of the irradiated materials. Nevertheless, routine dosimetry may be used to monitor the reproducibility of the treatment process.

NOTE 4—It is necessary to specify the material in which radiation is absorbed. Frequently, water is selected as the reference material for this purpose. Water is a convenient medium to use because its radiation absorption and scattering properties are close to those of tissue and it is universally available and understood. The requirement of tissue-equivalency historically originated from radiation therapy applications. Absorbed dose in materials other than water may be determined by applying conversion factors in accordance with ISO/ASTM Guide 51261.

4.3 Radiation processing specifications usually include a pair of absorbed-dose limits: a minimum value to ensure the intended beneficial effect and a maximum value to avoid product degradation. For a given application, one or both of these values may be prescribed by process specifications or regulations. Knowledge of the dose distribution within irradiated material is essential to meet these requirements.

4.4 Several critical parameters must be controlled to obtain reproducible dose distributions in the processed materials. The processing rate and dose distribution depend on the X-ray intensity, photon energy spectrum, spatial distribution of the radiation field, conveyor speed, and product configuration (see Sections 5, 8, and Annex A1).

4.5 The irradiation process must be qualified to determine its effectiveness in delivering known, controllable doses. This involves testing the process equipment, calibrating the measuring instruments and dosimetry system, and demonstrating the ability of the process to deliver dose distributions in a reliable and reproducible manner (see Sections 9 and 10).

4.6 To ensure consistent dose delivery in a qualified irradiation process, routine process control requires procedures for routine product dosimetry, product handling before and after the treatment, prescribed orientation of the products during irradiation, monitoring of critical process parameters, and documentation of the required activities and functions (see Sections 11 and 12).

5. Radiation source characteristics

5.1 A high-energy X-ray (bremsstrahlung) generator emits short-wavelength electromagnetic radiation, which is analogous to nuclear gamma radiation. Although their effects on irradiated materials are generally similar, these kinds of radiation differ in their energy spectra, angular distributions, and dose rates.

5.2 The physical characteristics of the X-ray field depend on the design of the X-ray converter and the parameters of the electron beam striking the target, that is, the electron energy spectrum, average electron beam current, and beam current distribution on the target.

5.3 These aspects of an X-ray source and its suitability for radiation processing are reviewed in more detail in Annex A1.

6. Irradiation facilities

6.1 *Facility Components*—An X-ray irradiation facility typically includes a high-energy electron accelerator with X-ray converter, product conveyor, radiation shield with personnel safety system, product staging, loading and storage areas, auxiliary equipment for power, cooling, ventilation, etc., an equipment room, laboratory for dosimetry and product testing, and personnel offices. The design shall conform to applicable regulations and guidelines. For information on some industrial facilities, see Refs **(1-5)**.[5]

6.2 *Product Handling System*—The penetrating quality of high-energy X-radiation permits the treatment of large containers or full pallet loads of products. The container size for optimum photon power utilization and dose uniformity depends on the maximum energy and product density. The narrow angular distribution of the radiation favors the use of continuously moving conveyors rather than shuffle-dwell systems to enhance dose uniformity.

6.3 *Irradiation System*—The configuration of the X-ray converter, the beam current distribution on the X-ray target, and the penetrating quality of the radiation, and the size, shape, and density of the process load affect the dose uniformity ratio (see Refs **1, 2, 6-8**). In some cases, the dose uniformity ratio may be improved by the use of collimators between the X-ray target and the product **(9)**.

7. Dosimetry systems

7.1 Dosimetry systems are used to measure absorbed dose. They consist of dosimeters, measurement instruments and their associated reference standards, and procedures for the system's use.

NOTE 5—For a comprehensive discussion of various dosimetry methods applicable to the radiation types and energies discussed in this practice, see ICRU Reports 14, 34 and 35, and Ref **(10)**.

7.2 *Description of Dosimeter Classes*—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/

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

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.

7.2.1 *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.

7.2.2 *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 absorbed-dose ranges, are given in ISO/ASTM Guide 51261.

7.2.3 *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.

7.2.4 *Routine Dosimeters*—Routine dosimeters may be used for radiation process quality control, absorbed-dose monitoring, and absorbed-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 absorbed-dose ranges, are given in ISO/ASTM Guide 51261.

7.3 *Selection of Dosimetry Systems*—Select dosimetry systems suitable for the expected radiation processing applications at the facility using the selection criteria listed in ISO/ASTM Guide 51261. During the selection process, for each dosimetry system, take into consideration its performance behavior with respect to relevant influence quantities and the uncertainty associated with it. For accelerator applications, it is also essential to consider the influences of dose rate (average and peak absorbed dose rate for pulsed accelerators), pulse rate and pulse width (if applicable) on dosimeter performance. Some of the dosimetry systems that are suitable for gamma radiation from radionuclides (such as those from ^{60}Co) may also be suitable for X-rays **(1, 11)**.

NOTE 6—Dosimeters consisting mainly of water or hydrocarbon materials are suitable for both gamma radiation from radionuclides and X-radiation. Some exceptions are dosimeters containing substantial amounts of material with high atomic numbers, which are highly sensitive to the low-energy photons in the X-ray spectrum.

NOTE 7—X-ray dose rate may be higher than that for gamma radiation used for radiation processing, especially in products passing near the converter. The dose-rate dependence of the dosimeters should be considered in their calibration procedure **(11, 12)**.

7.4 *Calibration of Dosimetry Systems*:

7.4.1 A dosimetry system shall be calibrated prior to use and at intervals thereafter in accordance with the user's documented procedure that specifies details of the calibration process and quality assurance requirements. Calibration requirements are given in ISO/ASTM Guide 51261.

7.4.2 *Calibration Irradiation*—Irradiation is a critical component of the calibration of the dosimetry system. Acceptable ways of performing the calibration irradiation depend on whether the dosimeter is used as a reference-standard, transfer-standard or routine dosimeter.

7.4.2.1 *Reference- or Transfer-Standard Dosimeters*—Calibration irradiation shall be performed at a national or accredited laboratory using criteria specified in ISO/ASTM Practice 51400.

7.4.2.2 *Routine Dosimeters*—The calibration irradiation may be performed by irradiating the dosimeters at *(a)* a national or accredited laboratory using criteria specified in ISO/ASTM Practice 51400, *(b)* an in-house calibration facility that provides an absorbed dose (or an absorbed-dose rate) having measurement traceability to nationally or internationally recognized standards, or *(c)* a production irradiator under actual production irradiation conditions, together with reference- or transfer-standard dosimeters that have measurement traceability to nationally or internationally recognized standards. In case of option *(a)* or *(b)*, the resulting calibration curve shall be verified for the actual conditions of use.

7.4.3 *Measurement Instrument Calibration and Performance Verification*—For the calibration of the instruments, and for the verification of instrument performances between calibrations, see ISO/ASTM Guide 51261, the corresponding ISO/ASTM or ASTM standard for the dosimetry system, and/or instrument-specific operating manuals.

8. Process parameters

8.1 Absorbed dose in a product is determined and controlled by several components of the irradiation facility as well as the product. Thus, all parameters characterizing the facility components, process load and the irradiation conditions are referred to as 'process parameters'. They should, therefore, be considered when performing the absorbed-dose measurements required in Sections 10-12.

8.2 For accelerator-generated radiation (electrons and X-radiation) facilities, process parameters include:

8.2.1 Beam characteristics (for example, electron beam energy, beam current, pulse frequency, bremsstrahlung converter design),

8.2.2 Beam dispersion (for example, scan width, scan frequency, collimator aperture),

8.2.3 Product handling characteristics (for example, conveyor speed),

8.2.4 Product loading characteristics (for example, size of the process load, bulk density, orientation of product), and

8.2.5 Irradiation geometry (for example, 1- or 2-sided irradiation, multiple passes, reflectors).

8.3 The first three sets of parameters (8.2.1, 8.2.2 and 8.2.3) characterise the irradiation facility without reference to the product or the process. These subsets of parameters are referred to as "operating parameters."

8.4 Procedures during operational qualification (OQ) deal with operating parameters.

8.5 The objective of performance qualification (PQ) is to establish the values of all process parameters for the radiation process under consideration.

8.6 During routine product processing, operating parameters are continuously controlled and monitored for process control.

9. Installation qualification

9.1 *Objective*—The purpose of an installation qualification program is to demonstrate that the irradiator with its associated processing equipment and measurement instruments have been delivered and installed in accordance with their specifications. Installation qualification includes documentation of the irradiator and the associated processing equipment and measurement instruments, establishment of the testing, operation and calibration procedures for their use, and verification that they operate according to specifications. An effective installation qualification program will help ensure correct operation of the irradiator.

9.2 *Equipment Documentation*—Document descriptions of the irradiator and the associated processing equipment and measurement instruments installed at the facility. This documentation shall be retained for the life of the facility. At a minimum, it shall include:

9.2.1 Description of the location of the irradiator (accelerator) within the operator's premises in relation to the areas assigned and the means established for ensuring the segregation of un-irradiated products from irradiated products,

9.2.2 Accelerator specifications and characteristics,

9.2.3 Description of the operating procedure of the irradiator,

9.2.4 Description of the construction and operation of the product handling equipment,

9.2.5 Description of the materials and construction of any containers used to hold products during irradiation,

9.2.6 Description of the process control system, and

9.2.7 Description of any modifications made during and after the irradiator installation.

9.3 *Testing, Operation and Calibration Procedures*—Establish and implement standard operating procedures for the testing, operation and calibration (if necessary) of the installed irradiator and its associated processing equipment and measurement instruments.

9.3.1 *Testing Procedures*—These procedures describe the testing methods used to ensure that the installed irradiator and its associated processing equipment and measurement instruments operate according to specification.

9.3.2 *Operation Procedures*—These procedures describe how to operate the irradiator and its associated processing equipment and measurement instruments during routine operation.

9.3.3 *Calibration Procedures*—These procedures describe periodic calibration and verification methods that ensure that the installed processing equipment and measurement instruments continue to operate within specifications. The frequency of calibration for some equipment and instruments might be specified by a regulatory authority. Calibration of some equipment and instruments might be required to be traceable to a national or other accredited standards laboratory.

9.4 *Testing of Processing Equipment and Measurement Instruments*—Verify that the installed processing equipment and measurement instruments operate within their design specifications by following the testing procedures noted in 9.3.1. If necessary, ensure that the equipment and instruments have been calibrated according to the calibration procedures noted in 9.3.3.

9.4.1 Test all processing equipment to verify satisfactory operation of the irradiator within the design specifications. Document all testing results.

9.4.2 Check the performance of the measurement instruments to ensure that they are functioning according to performance specifications. Document all testing results.

9.4.3 If any modification or change is made to the processing equipment or measurement instruments during installation qualification, they shall be re-tested.

10. Operational qualification

10.1 *Objective*—The objective of the operational qualification of an irradiation facility is to obtain and document evidence that installed equipment and instrumentation operate within predetermined limits when used in accordance with operational procedures. This procedure establishes baseline data for evaluating facility effectiveness, predictability, and reproducibility for the range of conditions of operation for the key operating parameters that affect absorbed dose in the product (**13**). This can be accomplished through dosimetry. Thus, dosimetry is used:

10.1.1 To measure absorbed-dose distributions in reference material(s); this process is sometimes referred to as "dose mapping" (see 10.3),

10.1.2 To measure absorbed-dose characteristics over the expected operational range of the operating parameters for reference conditions (see 10.4),

10.1.3 To characterize absorbed-dose variations when operating parameters fluctuate statistically during normal operations (see 10.5), and

10.1.4 To establish the effect of a process interruption/restart (see 10.6).

10.2 *Dosimetry Systems*—Calibrate the dosimetry systems to be used at the facility as discussed in Section 7.

10.3 *Dose Mapping*:

10.3.1 Map the absorbed-dose distribution by a three-dimensional placement of dosimeter sets in the process loads containing homogeneous reference materials (such as grains, cardboard, plywood or sheets of plastics) as discussed in ASTM Guide E 2303 (also see Refs **10, 14**). The amount of material in these process loads should be the amount expected during typical production runs or should be the maximum design volume for the process loads.

NOTE 8—Dosimeter strips or sheets may be used to increase spatial resolution of the absorbed-dose map, if the use of individual dosimeters is inadequate.

10.3.2 The procedures for absorbed-dose mapping outlined in this section may not be feasible for some types of bulk-flow

irradiators. In such cases, minimum and maximum absorbed doses should be estimated by using an appropriate number of dosimeters mixed randomly with and carried by the product through the irradiation zone. Enough dosimeters should be used to obtain statistically significant results (see 11.3.3).

NOTE 9—Theoretical calculations may be performed using the Monte Carlo methods **(15)**, and applied to industrial radiation processing **(16)**. The use of the point-kernel method can be considered for X-ray facilities **(17)**. Both of these methods require accurate radiation interaction cross-sections for all materials between and surrounding the source point and dose point. General-purpose software packages are available for these types of calculations (see ASTM Guide E 2232). Models built using these codes should be validated against dosimetry data for their predictions to be meaningful. Empirically derived models built directly from dosimetry data may be satisfactory but should be confined to the boundaries of experiments at a specific facility.

NOTE 10—For an X-ray facility, the depth-dose distribution in a homogeneous material with low atomic number is approximately exponential, and penetration for 5 MeV X-radiation is slightly greater than that for cobalt-60 gamma radiation (see Fig. A1.7).

10.4 *Absorbed Dose and Operating Parameters*:

10.4.1 *Objective*—The dose in the product depends on several operating parameters. Over the expected range of these parameters, establish the absorbed-dose characteristics in a reference material using appropriate dosimetry.

10.4.1.1 The depth-dose distribution depends on beam energy and the reference material characteristics.

10.4.1.2 Surface dose and its uniformity depend on conveyor speed, beam characteristics and beam dispersion.

NOTE 11—For X-ray irradiators, photon energy spectrum and angular distribution depend on the design and composition of the bremsstrahlung converter and on the electron energy spectrum . Higher energy electrons will increase forward concentration of the photon distribution and therefore improve penetration in the product **(7, 18, 19)**.

10.4.2 *Surface Dose*—Establish the relationships between surface dose (or dose in a reference plane) and conveyor speed, beam charactristics and beam dispersion parameters over the expected range of operation.

NOTE 12—Dispersion of the electron beam to obtain an X-ray beam width adequate to cover the processing zone may be achieved by various techniques. These include electromagnetic scanning of a pencil beam or use of defocussing elements or scattering foils.

10.4.2.1 Establish the range of uniform surface dose that can be delivered. This will set the range of operation for the conveyor speed, pulse rate and scan frequency.

NOTE 13—Electron beam and X-ray irradiators generally utilize continuously-moving conveyors. Dose uniformity in a reference plane is strongly influenced by the coordination of the beam spot dimensions, conveyor speed and scan frequency (for those irradiators that employ beam scanning). For a pulsed-beam accelerator, all these parameters must also be coordinated with the pulse width and pulse rate. Improper coordination of these parameters can cause unacceptable dose variation in the reference plane.

NOTE 14—Indirect-action accelerators may deliver higher dose rates during the pulse compared to direct-action accelerators with the same average beam current. Also, scanning of a small diameter beam can produce pulsed dose at points along the beam width. This can influence the dosimeters' performance if they are sensitive to dose rate.

10.4.2.2 Establish relationship between surface dose and conveyor speed, where all other operating parameters are held constant. Generally, surface dose should be inversely proportional to the conveyor speed.

NOTE 15—The conveyor speed and the beam current may be linked during routine product processing so that a variation in one causes a corresponding change in the other to maintain a constant value of the surface (or reference plane) dose.

10.4.2.3 For X-ray irradiators, absorbed dose rate also depends on the incident electron energy spectrum and the design of the X-ray converter.

10.5 *Dose Variability*:

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

10.5.2 Following the procedure of 10.3, map a sufficient number of nominally identical process loads containing reference material to allow the estimation of the variability of the magnitude and distribution of the absorbed dose. Dosimetry data from previously qualified irradiators of the same design may provide useful information for determining the number of process loads for this qualification.

10.6 *Process Interruption/Restart*—In the case of a process interruption, for example stoppage of the conveyor system due to power failure, the implication of a restart on the process (for example, uniformity of dose in a reference plane) shall be investigated.

10.6.1 This can be achieved by exposing a strip of dosimeter film in a reference plane through a stop/start sequence of the conveyor system.

10.6.2 Continuous (seamless) dose through the stop/start sequence would suggest that the conveyor could be restarted after the failure to continue the process. The effect of the process interruption on the product itself is discussed in 12.6.

10.6.3 If the dose is found to be significantly non-uniform through the stop/start sequence, the impact to process load in the radiation zone shall be evaluated.

10.6.4 This procedure should be conducted for the extremes of the operating parameters.

10.7 *Documentation and Maintenance of OQ*—Operational qualification procedures shall be repeated periodically as specified in the quality assurance program to update the baseline data referred to in 10.1.

10.8 *Facility Changes*—If changes that could affect the magnitudes or locations of the absorbed-dose extremes are made to the facility (for example, accelerator, bremsstrahlung

converter, conveyor) or its mode of operation, repeat the operational qualification procedures to the extent necessary to establish the effects.

11. Performance qualification

11.1 *Objective*—Absorbed dose requirements vary depending on the process and type of product being irradiated. Minimum and maximum absorbed-dose limits are almost always associated with medical device sterilization and food irradiation. The objective of performance qualification is to obtain and document evidence that the equipment and instrumentation, as installed and operated in accordance with operational procedures, consistently perform according to predetermined criteria and thereby yield product that meets these absorbed-dose specifications. Dosimetry is used to obtain this evidence and to determine the appropriate values of all key process parameters. This is accomplished by absorbed-dose mapping (see 11.3) of process loads with specific product and product loading configurations using dosimetry procedures described in this section.

11.2 *Product Loading Configuration*—A loading configuration of product within the process load shall be established for each product type. The specification for this loading pattern shall document the following:

11.2.1 Product, type, size, product density and bulk density of the process load, and if applicable, description of the orientation of the product within its package.

11.2.2 Orientation of the product or its package with respect to the beam axis.

11.3 *Product Absorbed-Dose Mapping*:

11.3.1 The purpose of product dose mapping is to establish the magnitudes and locations of the regions of minimum and maximum absorbed dose for the selected product loading configuration. This is accomplished by placing dosimeter sets throughout the volume of interest for one or more process loads (see ASTM Guide E 2303). Select placement patterns to identify the locations of the absorbed-dose extremes, using data obtained from the absorbed-dose mapping studies during operational qualification (see 10.3) or from theoretical calculations (see ASTM Guide E 2232). Concentrate dosimeter sets in the expected regions of minimum and maximum absorbed dose with fewer dosimeter sets placed in areas likely to receive intermediate absorbed dose.

11.3.1.1 In a process load containing voids or non-uniform product, include dosimeter sets at locations where discontinuities in composition or density may affect the regions of maximum or minimum absorbed dose.

11.3.1.2 *End Process Loads*—For a production run with contiguous process loads, the first and last process loads may experience dose distributions different from the other units. These effects will be due to any differences between the radiation absorption characteristics of the product in the end process loads of the given production run from the products in the adjacent production runs. Perform dose mapping of the end process loads for these geometries to verify that the dose distributions are acceptable. If they are not, compensating dummies will need to be placed adjacent to these end units during routine product processing (see 12.1.3).

11.3.1.3 *Partial Loading*—For partially-loaded process loads, follow the same performance qualification requirements as for fully-loaded process loads. Perform dose mapping procedure of 11.3.1 to ensure that the absorbed-dose distributions are adequately characterized and are acceptable. Variations to the dose distribution from a partial loading may in some cases be minimized by the use of compensating dummy material placed at appropriate locations within the process load.

11.3.1.4 Dosimeters used for dose mapping must be capable of responding to doses and dose gradients likely to occur within irradiated products. Dosimeter films in sheets or strips may be useful for obtaining this information. The dosimeters used for this dose mapping procedure and for routine dose monitoring (12.4) need not be of the same type.

11.3.2 *Processing at High or Low Temperatures*—The response of nearly all dosimeters depend on irradiation temperature, and very often this dependence varies with absorbed dose. Thus, for high or low temperature processing applications, dosimetry may be performed following one of the two methods:

11.3.2.1 Absorbed-dose mapping may be performed with simulated product at room temperature. This requires that there be no change in any parameter that may affect the absorbed dose during processing of the product. Dose mapping at room temperature includes placement of one or more dosimeters at a reference dose location (11.3.4) that would be isolated from temperature gradients in the actual product during routine processing. Routine dosimeters should be placed at this reference dose location during routine processing of the product.

11.3.2.2 Absorbed-dose mapping may be performed at the temperature to which the product will be chilled or frozen during actual product processing, using a dosimetry system that can be characterized at the intended processing temperature or whose response is not significantly affected by temperature. The temperature of the product and the dosimeter during irradiation must be maintained relatively constant (for example, by using insulated totes).

11.3.3 *Bulk-Flow Irradiators*—Absorbed-dose mapping as described in 11.3.1 may not be feasible for products flowing through the irradiation zone in bulk. In this case, minimum and maximum absorbed doses should be estimated by using an appropriate number of dosimeters mixed randomly with and carried by the product through the irradiation zone **(20)**. Enough dosimeters should be used to obtain statistically significant results.

11.3.4 *Reference Dose Locations*—If the locations of absorbed dose extremes identified during the dose mapping procedure of 11.3.1 are not readily accessible during production runs, alternative locations (external or internal to the process load) may be used for routine product processing dosimetry. The relationships between the absorbed doses at these alternative reference dose locations and the absorbed dose extremes shall be established, shown to be reproducible, and documented.

11.4 *Dose Variability*: