ISO/ASTM 51608:2015 (Reapproved 2022)(E)

Standard Practice for Dosimetry in an X-Ray (Bremsstrahlung) Facility for Radiation Processing at Energies between 50 keV and 7.5 MeV[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 dosimetric procedures to be followed during installation qualification, operational qualification, performance qualification and routine processing at an X-ray (bremsstrahlung) irradiator. Other procedures related to operational qualification, performance qualification and routine processing that may influence absorbed dose in the product are also discussed.

NOTE 1—Dosimetry is only one component of a total quality assurance program for adherence to good manufacturing practices used in radiation processing applications.

NOTE 2—ISO/ASTM Practices 51649, 51818 and 51702 describe dosimetric procedures for electron beam and gamma facilities for radiation processing.

1.2 For radiation sterilization of health care products, see ISO 11137-1, *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*. In those areas covered by ISO 11137-1, that standard takes precedence.

1.3 For irradiation of food, see ISO 14470, *Food irradiation – Requirements for development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food*. In those areas covered by ISO 14470, that standard takes precedence.

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

1.5 In contrast to monoenergetic gamma radiation, the X-ray 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).

1.6 Information about effective or regulatory dose limits and energy limits for X-ray applications is not within the scope of this practice.

1.7 *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]

E170 Terminology Relating to Radiation Measurements and Dosimetry

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

E2303 Guide for Absorbed-Dose Mapping in Radiation Processing Facilities

2.2 *ISO/ASTM Standards:*[2]

51261 Practice for Calibration of Routine Dosimetry Systems for Radiation Processing

51539 Guide for Use of Radiation-Sensitive Indicators

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

51702 Practice for Dosimetry in a Gamma Facility for Radiation Processing

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing

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

52628 Practice for Dosimetry in Radiation Processing

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

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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.

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

2.3 *ISO Standards:*[3]

ISO 11137-1 Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

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

2.4 *International Commission on Radiation Units and Measurements (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 80 Dosimetry Systems for Use in Radiation Processing

ICRU Report 85a Fundamental Quantities and Units for Ionizing Radiation

2.5 *Joint Committee for Guides in Metrology (JCGM) Report:*

JCGM 100:2008, GUM 1995, with minor corrections, Evaluation of measurement data–Guide to the expression of uncertainty in measurement[5]

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 dm, where dε is the mean incremental energy imparted by ionizing radiation to matter of incremental mass dm (see ICRU Report 85a).

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

3.1.2 *beam length*—dimension of the irradiation zone along the direction of product movement, at a specified distance from the accelerator window.

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

3.1.3 *beam width*—dimension of the irradiation zone perpendicular to the direction of product movement, at a specified distance from the accelerator window.

3.1.3.1 *Discussion*—For graphic illustration, see ISO/ASTM Practice 51649. This term usually applies to electron irradiation.

3.1.4 *bremsstrahlung*—broad-spectrum electromagnetic radiation emitted when an energetic charged particle is influenced by a strong electric or magnetic field, such as that in the vicinity of an atomic nucleus.

3.1.4.1 *Discussion*—In radiation processing, bremsstrahlung photons with sufficient energy to cause ionization are generated by the deceleration or deflection of energetic electrons in a target material. When an electron passes close to an atomic nucleus, the strong coulomb field causes the electron to deviate from its original motion. This interaction results in a loss of kinetic energy by the emission of electromagnetic radiation. Such encounters are uncontrolled and they produce a continuous photon energy distribution that extends up to the maximum kinetic energy of the incident electron. The bremsstrahlung energy spectrum depends on the electron energy, the composition and thickness of the X-ray target, and the emission direction of photon angle of emission with respect to the incident electron.

3.1.5 *charged-particle equilibrium* (referred to as electron equilibrium in the case of electrons set in motion by photon-beam irradiation of a material)—condition in which the kinetic energy of charged particles (or electrons), excluding rest mass, entering an infinitesimal volume of the irradiated material equals the kinetic energy of charge particles (or electrons) emerging from it.

3.1.6 *dose uniformity ratio*—ratio of the maximum to the minimum absorbed dose within the irradiated product.

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

3.1.7 *dosimeter*—device that, when irradiated, exhibits a quantifiable change that can be related to absorbed dose in a given material using appropriate measurement instrument(s) and procedures.

3.1.8 *dosimeter response*—reproducible, quantifiable effect produced in the dosimeter by ionizing radiation.

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

3.1.10 *electron energy*—kinetic energy of an electron.

3.1.10.1 *Discussion*—Unit is usually electron volt (eV), kiloelectron volt (keV), or megaelectron volt (MeV). 1 eV is the kinetic energy acquired by a single electron accelerated through a potential difference of 1 V. 1 eV is equal to energy of 1.602×10^{-19} joules.

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

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

[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.

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

3.1.13 *irradiation container*—holder in which product is placed during the irradiation process.

3.1.13.1 *Discussion*—"Irradiation container" is often referred to simply as "*container*" and can be a carrier, cart, tray, product carton, pallet, product package or other holder.

3.1.14 *measurement management system*—set of interrelated or interacting elements necessary to achieve metrological confirmation and continual control of measurement processes.

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

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

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

3.1.18 *processing category*—group of different product that can be processed together.

3.1.18.1 *Discussion*—Processing categories can be based on, for instance, composition, density or dose requirements.

3.1.19 *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.

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

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

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *X-radiation*—ionizing electromagnetic radiation, which includes both bremsstrahlung and the characteristic radiation emitted when atomic electrons make transitions to more tightly bound states. See *bremsstrahlung*.

3.2.1.1 *Discussion*—In radiation processing applications, the principal X-radiation is bremsstrahlung.

3.2.2 *X-ray*—of or relating to X-radiation.

3.2.2.1 *Discussion*—X-ray is used as an adjective while X-radiation is used as a noun.

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

3.2.4 *X-ray target*—component of the X-ray converter that is struck by the electron beam and which produces X-radiation.

3.2.4.1 *Discussion*—The X-ray target is usually made of metal with a high atomic number (such as tantalum), high melting temperature, and high thermal conductivity.

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

4. Significance and use

4.1 A variety of products and materials are irradiated with X-radiation to modify their characteristics and improve the economic value or to reduce their microbial population for health-related purposes. Dosimetry requirements might vary depending on the type and end use of the product. Some examples of irradiation applications where dosimetry may be used are:

4.1.1 Sterilization of health care products;

4.1.2 Treatment of food for the purpose of parasite and pathogen control, insect disinfestation, and shelf life extension;

4.1.3 Disinfection of consumer products;

4.1.4 Cross-linking or degradation of polymers and elastomers;

4.1.5 Curing composite material;

4.1.6 Polymerization of monomers and oligomer and grafting of monomers onto polymers;

4.1.7 Enhancement of color in gemstones and other materials;

4.1.8 Modification of characteristics of semiconductor devices; and

4.1.9 Research on materials effects of irradiation.

NOTE 3—Dosimetry with measurement traceability and with known measurement uncertainty is required for regulated irradiation processes, such as the sterilization of health care products and treatment of food. Dosimetry may be 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 radiation process.

4.2 Radiation processing specifications usually include a pair of absorbed-dose limits: a minimum value to ensure the intended beneficial effect and a maximum value that the product can tolerate while still meeting its functional or regulatory specifications. 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 help meet these requirements. Dosimetry is essential to the radiation process since it is used to determine both of these limits and to confirm that the product is routinely irradiated within these limits.

4.3 Several critical parameters must be controlled to obtain reproducible dose distributions in the process load. The absorbed-dose distribution within the product depends on the overall product dimensions and mass and irradiation geometry. The processing rate and dose distribution depend on the X-ray intensity, photon energy spectrum, and spatial distribution of the radiation field and conveyor speed.

4.4 Before an irradiator can be used, it must be qualified (IQ, OQ) to determine its effectiveness in reproducibly delivering known, controllable absorbed doses. This involves testing the process equipment, calibrating the equipment and dosimetry system, and characterizing the magnitude, distribution and reproducibility of the absorbed dose delivered by the irradiator for a range of product densities.

4.5 To ensure consistent dose delivery in a qualified irradiation process, routine process control requires procedures for routine product dosimetry and for product handling before and after the treatment, consistent product loading configuration, control and monitoring of critical process parameters, and documentation of the required activities and functions.

5. Radiation source characteristics

5.1 X-radiation (bremsstrahlung) is a form of electromagnetic radiation, which is analogous to gamma radiation. Although its effects on irradiated materials are generally similar, it differs in energy spectrum, angular distribution, and dose rate.

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 X-radiation and its suitability for radiation processing are reviewed in more detail in Annex A1.

6. Types of facilities

6.1 The design of an irradiator affects the delivery of absorbed dose to a product. Therefore, the irradiator design should be considered when performing the absorbed-dose measurements described in Sections 9 – 11.

6.2 The electron beam energy range used to produce X-radiation covered in this practice is between 50 keV and 7.5 MeV. The upper limit is determined to avoid the induction of activity in a tantalum target and or product (**1**, **2**).[6]

6.3 *Irradiator Components*—An X-ray irradiator typically includes an electron accelerator with X-ray converter, product conveyor system, radiation shield with personnel safety system, products loading and storage areas, auxiliary equipment for power, cooling, ventilation, etc., equipment room, laboratory for dosimetry and product testing, and personnel offices. The irradiator design shall conform to applicable regulations and guidelines. For information on some industrial facilities, see Refs (**3-7**).

6.3.1 *Discussion*—The configuration of the X-ray converter, the electron beam distribution on the X-ray target, the penetrating characteristic of the radiation, and the size, shape, and density of the process load affect the dose uniformity ratio (see Refs **3**, **4**, **8-10**). In some cases, the dose uniformity ratio may be improved by the use of collimators between the X-ray converter and the product (**11**), or by the use of a magnet before the X-ray converter to control the divergence of the beam.

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

6.4 *Product Handling System*—The process load size for optimum photon power utilization and dose uniformity depends on the maximum photon energy and product density. The narrow width of X-Ray field favors the use of continuously moving product rather than shuffle-dwell systems to improve dose uniformity.

7. Selection and calibration of dosimetry system

7.1 *Selection of Dosimetry Systems*—Dosimetry systems suitable for the expected radiation processing applications at the irradiator shall be selected in accordance with the selection criteria listed in ISO/ASTM 52628. During the selection process, for each dosimetry system, the performance behavior with respect to relevant influence quantities and the dose measurement uncertainty associated with it shall be taken into account.

NOTE 4—Most dosimetry systems suitable for gamma radiation (such as those from ^{60}Co) may also be suitable for X-radiation (**3**, **12**, **13**).

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

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

8. Process parameters

8.1 Absorbed dose in a product is determined and controlled by several characteristics of the irradiator as well as of the product. Thus, all parameters characterizing the irradiator components, process load and the irradiation conditions that affect absorbed dose 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 X-ray facilities, process parameters include:

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

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

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, multiple passes, rotation, source or product overlap.

8.3 The parameters in 8.2.1, 8.2.2 and 8.2.3 characterize the irradiator 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 obtain and document evidence that the irradiator with its associated processing equipment and measurement instruments has 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.

9.2 *Equipment Documentation*—Document descriptions of the irradiator and the associated processing equipment and measurement instruments installed at the irradiator. This documentation shall be retained for the life of the irradiator. 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 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,

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

9.2.8 Description of X-ray converter characteristics (dimension, materials and nature of construction).

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

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 is required to be traceable to a national or international standard.

9.4 *Testing of Processing Equipment and Measurement Instruments*—It must be verified that the installed processing equipment and measurement instruments operate within their design specifications by following the testing procedures noted in 9.3.1. The equipment and instruments shall be calibrated according to the calibration procedures.

9.4.1 All equipment associated with operating the irradiator shall be tested to verify that the irradiator is operating in accordance with design and performance specifications. All test results shall be recorded.

9.4.2 The performance of measurement instruments shall be verified or calibrated (if required) to ensure that the instruments are operating in accordance with design and performance specifications. All test results shall be recorded.

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.

9.4.4 The characteristics of the electron beam (such as average beam current, energy) and X-ray field (such as dimension and uniformity) shall be determined and recorded. They typically include the following:

9.4.4.1 *Electron beam energy estimation with direct measurement* (also see ISO/ASTM 51649)—When the electron beam is accessible, the depth-dose distribution is measured by irradiating dosimeters in a stack of plates of homogeneous material or by placing dosimeters or a dosimeter strip at an angle through a homogeneous absorber. Electron beam energy can be determined from depth-dose distribution parameters based on established relationships.

9.4.4.2 *Electron beam energy estimation with indirect measurement*—When the electron beam is not readily accessible, for example when the X-ray converter is attached to the end of the scanner and the electron beam is not transmitted into the air before striking the X-ray target, then the attenuation of X-radiation in a suitable reference material might be used to indirectly estimate the electron beam energy.

NOTE 5—A procedure suitable for typical industrial irradiation processes, which is based on common practice in the field of therapeutic X-ray treatment, has been published (**14**). Additionally, measurements of induced radioactivity in certain elements with threshold values below 8 MeV might be used for energy determination (**15, 16**).

9.4.4.3 *X-ray field characterization (width, length and depth)*—The target cooling system and target geometry have a significant effect on X-ray field, and therefore the X-ray field shall be characterized before OQ is started (See Figs. A1.1-A1.3). The electron beam width and length are measured by placing dosimeter strips or discrete dosimeters at selected intervals over the full beam width and length range without the converter in place, or if not possible, directly on the converter. Whenever possible, dosimeters shall also be placed beyond the expected beam dimension to identify the limits of the full beam dimensions. X-ray field may be characterized by placing dosimeter strips or discrete dosimeter at selected intervals over the full X-ray beam width and length range at varying intervals and distances from the X-ray target.

10. Operational qualification

10.1 *Objective*—The objective of the operational qualification (OQ) of an X-ray irradiator is to obtain and document evidence that installed equipment and instrumentation operate within predetermined limits when used in accordance with operational procedures. The purpose of dosimetry during operational qualification is to establish baseline operational limits and performance expectations for routine processing and in turn evaluate the following characteristics:

10.1.1 Ability to predict the delivered dose for the range of conditions of operation for the key operating parameters that affect absorbed dose in the product.

10.1.2 Ability of the irradiator to deliver reproducible dose for the range of conditions of operation for the key operating parameters that affect absorbed dose in the product (**17**).

10.1.3 Absorbed-dose distribution in process loads.

NOTE 6—The absorbed dose received by any portion of product in a process load depends on the conveyor design, the converter design, the X-ray field geometry and characteristics, the process load characteristic and configuration, the treatment geometry.

10.1.4 Dosimetry tests carried out during IQ (see 9.4.4) should be repeated as part of irradiator OQ.

10.2 *Absorbed-dose Mapping*—Absorbed-dose mapping is performed to characterize the irradiator with respect to the dose distribution and reproducibility of absorbed-dose delivery. Mapping the absorbed-dose distribution is carried out by placing sets of dosimeters in a three-dimensional array within a process load containing reference material. For guidance on performing absorbed-dose mapping see ASTM Guide E2303.

10.2.1 The amount of reference material in each irradiation container should be the amount expected during typical production runs or should be the maximum design volume for the irradiation container.

10.2.2 Dosimeter placement patterns should be selected to identify the locations of the absorbed-dose maxima and minima. It may be necessary to place more dosimeter sets in these locations and fewer dosimeter sets in locations likely to receive intermediate absorbed doses to adequately identify the absorbed-dose maxima and minima. Dosimetry data from previously qualified irradiators of the same design or calculations using mathematical models (see ASTM Guide E2232) may provide useful information for determining the number and location of dosimeters for this qualification process.

NOTE 7—Dosimeter strips or sheets may be used to increase spatial resolution of the absorbed-dose map, if the use of individual dosimeters is inadequate.

10.2.3 A sufficient number of process loads (minimum 3) of homogenous density should be dose mapped to estimate the variability of the magnitude and distribution of the absorbed dose within the process load. Dosimetry data from previously qualified irradiators of the same design may provide useful information for determining the number of process loads for this qualification.

10.2.4 The number of process loads preceding and following the dose-mapped process load shall be sufficient to effectively simulate an irradiator filled with the product.

10.2.5 Absorbed-dose mapping shall be carried out at and between the density range for products expected to be irradiated routinely.

10.2.6 Absorbed-dose mapping shall be carried out for each different irradiator pathway to be used for routine product processing.

10.2.7 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 product through the irradiation zone. A statistical model should be used to estimate the number of dosimeters required. Calculations of minimum and maximum absorbed doses may be an appropriate alternative.

NOTE 8—Theoretical calculations may be performed using the Monte Carlo methods (**18**), and applied to industrial radiation processing (**19**). The use of the point-kernel method can be considered for X-ray facilities (**20**). Both of these methods require that accurate radiation interaction cross-sections for all materials between and surrounding the source point and dose point are known. General-purpose software packages are available for these types of calculations (see ASTM Guide E2232). 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 irradiator.

NOTE 9—For an X-ray irradiator, the depth-dose distribution in a homogeneous material of 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).

10.3 *Absorbed Dose and Operating Parameters:*

10.3.1 *Objective*—The absorbed 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 an appropriate calibrated dosimetry system.

10.3.1.1 The dose distribution within a process load depends on photon energy spectrum, photon field geometry, the distance to the X-ray target and the reference material characteristics.

NOTE 10—For X-ray irradiators, photon energy spectrum and angular distribution depend on the design and composition of the X-ray converter and on the electron beam energy spectrum. Higher energy electrons will increase forward concentration of the photon distribution and therefore improve penetration in the product (**9**, **21**, **22**).

10.3.2 The relationships between the minimum and maximum doses for an irradiation container filled with a reference material of known density, and product speed (or irradiation time), beam characteristics and parameters controlling the photon field over the expected range of these parameters should be established. These relationships should be established for each density (10.2.5) and irradiator pathway (10.2.6).

10.3.2.1 Establish the range of absorbed dose that can be delivered, the range of densities that can be processed and the number of irradiator pathways that can be used during routine processing. This will set the operational limits for the irradiator.

NOTE 11—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 delivery of the dose.

10.4 *Dose Variability:*

10.4.1 The magnitude of the dose variations in a reference material should be estimated by, for example, 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.

NOTE 12—It is often difficult to separate the effect of operating parameter variability and dosimetry system uncertainty; thus, the measured variability will often be a combination of the two.

10.4.2 *Routine Monitoring Positions*—If the locations of absorbed dose extremes identified during the dose mapping procedure are not readily accessible during production runs, alternative locations (external or internal to the process load) may be used for routine product processing dosimetry. These positions could be located on the irradiation container or on the process load. Dose variability in routine monitoring position shall be evaluated.

10.5 *Effect of adjacent process loads with different product densities*—For a production run with process loads of different densities close to each other, dose distribution within adjacent process loads may be different. These effects may be due to scattering of X-radiation from the process load which is front of the target, and they can be determined by dose mapping of the process load in front of the source as well as the adjacent process loads for these geometries to verify that the maximum and minimum dose values are acceptable. Multiple combinations of different densities adjacent to each should be evaluated to determine the magnitude of the effect, if any, and to establish acceptable operational limits for this effect.

10.6 *Partially Filled Irradiation Containers*—The absorbed dose distributions and the magnitudes of the minimum and maximum absorbed dose in partially filled irradiation containers in a given production run may be affected by or affect adjacent irradiation containers in the production run or in adjacent product runs. These effects will be due to any differences between the radiation scattering characteristics and empty voids in the irradiation container of the given production run and those of the products in the adjacent production runs. Absorbed dose distribution studies should be conducted with partially filled irradiation containers of different fill levels to evaluate the magnitude of this effect, if any, and to establish acceptable operational limits for this effect.

10.7 *Process Interruption/Restart*—In the case of a process interruption, the implication of a restart on dose delivery (for example, uniformity of dose in a reference plane) shall be investigated.

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

10.7.2 Influence of process interruption/restart should be evaluated for the extremes of the operating parameters.

10.7.3 If there is any effect on dose delivery to product of a process interruption, its magnitude shall be determined to establish acceptable operational limits for this effect.

10.8 *Documentation and Maintenance of OQ*—Operational qualification procedures shall be repeated at a defined time interval. The interval shall be justified and the rationale documented to provide assurance that the irradiator is consistently operating within specifications.

10.9 *Irradiator Changes*—If changes that could affect the dose distribution are made to the irradiator (for example, beam characteristics, X-ray converter, conveyor) or its mode of operation, the operational qualification should be repeated to the extent necessary to determine the effect on the process. Examples of such changes include:

10.9.1 Changes to the conveyor,

10.9.2 Changes to the irradiation container,

10.9.3 Repair or replacement of scanning magnet,

10.9.4 Repair or replacement of beam bending magnet,

10.9.5 Changes in the element of the irradiator creating scattering effects, and

10.9.6 Changes to the X-ray Target (including cooling system).

11. Performance qualification

11.1 *Objective*—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, can consistently process product within the specified absorbed-dose limits. Dosimetry is used to obtain this evidence and to determine the appropriate values of all key process parameters. Minimum and maximum absorbed-dose limits are almost always associated with irradiation applications. For a given application, one or both of these limits may be prescribed by government regulations. Dosimetry is used in performance qualification to determine the appropriate process parameters, including treatment time, beam current, conveyor speed, and product loading configuration to ensure that the absorbed-dose requirements for a particular process can be satisfied. This is accomplished by absorbed-dose mapping of irradiation containers with specific product and product loading configurations. The purpose of the mapping is to determine the magnitudes and locations of the minimum and maximum absorbed doses and their relationships to the absorbed doses at locations used for monitoring during routine product processing.

11.2 *Product Loading Configuration*—A process load configuration shall be established for each product. The documentation for this loading configuration shall include specifications for parameters that influence the absorbed-dose distribution. Examples of such parameters include product size, product mass, material composition, product density/bulk density, and product orientation.

11.3 *Processing category*—If the concept of a processing category is to be used for the purpose of routine processing, product shall be assessed against documented criteria as to whether it is to be included in a processing category. Assessment shall include consideration of product-related variables that affect dose to product and process specification. The outcome of the assessment shall be evaluated and documented.

11.3.1 A processing category limit shall be defined and the performance qualification shall be carried out at the extreme limits of the processing category.

11.4 *Absorbed-Dose Mapping* (See ASTM Guide E2303)

11.4.1 *Minimum and Maximum Dose Locations:*

11.4.1.1 The locations of the regions of minimum and maximum absorbed dose for the selected product loading configuration shall be established. This is accomplished by placing dosimeters throughout the volume of interest for three or more process loads. The placement patterns shall be selected to identify the locations of the absorbed-dose extremes, using data obtained from the absorbed-dose mapping studies during