INTERNATIONAL STANDARD

ISO/ASTM 51608

Second edition
2005-05-15

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)

Reference number
ISO/ASTM 51608:2005(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. Neither the ISO Central Secretariat nor ASTM International accepts any liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies and ASTM members. In the unlikely event that a problem relating to it is found, please inform the ISO Central Secretariat or ASTM International at the addresses given below.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

ASTM International, 100 Barr Harbor Drive, PO Box C700,
West Conshohocken, PA 19428-2959, USA
Tel. +610 832 9634
Fax +610 832 9635
E-mail khooper@astm.org
Web www.astm.org

Published in the United States

Contents

Page

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.

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.

Current edition approved by ASTM June 1, 2004. Published May 15, 2005. Originally published as ASTM E 1608–94. Last previous ASTM edition E 1608–00. ASTM E 1608–94 was adopted by ISO in 1998 with the intermediate designation ISO 15567:1998(E). The present International Standard ISO/ASTM 51608:2005(E) is a major revision of the last previous edition ISO/ASTM 51608:2002(E), which replaced ISO 15567.

[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 $d\epsilon$ by dm, where $d\epsilon$ is the mean incremental energy imparted by ionizing radiation to matter of incremental mass dm (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*:

11.4.1 When dose mapping a specific product loading configuration, consideration should be given to possible variations in the absorbed doses measured at similar locations in different process loads.

11.4.2 To evaluate the extent of this dose variability, place dosimeter sets in the expected regions of the minimum and maximum absorbed doses in several process loads and irradiate them under the same conditions. The measured variations in the absorbed-dose values reflect, for example, variations in product loading configuration (due to shifts in the contents of the process load during its movement through the irradiator), small differences in bulk density of the process loads, fluctuations in operating parameter values, and the uncertainty in the routine dosimetry system.

11.4.3 *Target Dose Values*—Because of the statistical nature of the absorbed-dose measurement and the inherent variations in the radiation process, it is advisable to set the operating parameters to deliver an absorbed dose greater than any prescribed minimum dose and smaller than any prescribed maximum dose **(21, 22)**. This requirement in effect modifies the process dose limits. These modified dose limits may be referred to as "target dose values." Generally, these target dose values should be chosen so that there is a low probability of irradiating the product or part of the product with doses lower than the required minimum or higher than the allowed maximum, and that this probability is known and documented. For further discussion on determination of the target dose values, see Refs **(23, 24)**.

NOTE 16—It is usually necessary to conduct testing of the product materials to ensure compatibility with the maximum absorbed dose received during the X-ray treatment.

11.5 *Unacceptable Dose Uniformity Ratio*:

11.5.1 If the dose mapping procedure of 11.3 reveals that the measured dose uniformity ratio is too large, for example, larger than the ratio between the modified values of the maximum and minimum absorbed-dose limits (such as target dose values), change the process parameters (operating parameters, process load characteristics or irradiation conditions) to reduce the ratio to an acceptable level.

11.5.1.1 *Operating Parameters*—Changing the beam characteristics can reduce the dose uniformity ratio. Other means to reduce the dose uniformity ratio may be employed, such as the use of attenuators, scatterers, reflectors and collimators **(9, 25, 26)**.

11.5.1.2 *Irradiation Conditions*—Depending on the bulk density, thickness, and heterogeneity of a process load, some processes may require a double-sided irradiation to achieve an acceptable dose uniformity ratio **(27)**. For double-sided irradiation, the regions of maximum and minimum dose may be quite different from those for single-sided irradiation. In the case of bulk-flow irradiators, absorbed-dose uniformity can be improved by arranging baffles to control product flow through the irradiation zone.

11.5.1.3 *Process Load Characteristics*—For some cases, a redesign of the process load may be needed to achieve an acceptable dose uniformity ratio.

11.5.2 If any process parameter that affects the magnitudes or locations of maximum and minimum absorbed dose is changed (for example, for the purpose of improving the dose uniformity ratio), repeat the dose mapping to the extent necessary to establish the effects. The information gathered during operational qualification (Section 10) should serve as a guide in determining the extent of these absorbed-dose mapping studies.

11.6 The procedures described above should yield the appropriate values of all process parameters (namely, all key operating parameters, process load characteristics and irradiation conditions) that would satisfy the dose requirements for all process loads. Document these values for future use.

12. Routine product processing

12.1 *Routine Procedure*:

12.1.1 Before commencing routine product processing, set all process parameters as established during performance qualification to ensure that the product in each process load will be processed within specifications (see 11.6).

NOTE 17—The average beam current I and the conveyor speed v may be set in such a way that the quotient I/v has the same value in performance qualification and in routine product processing. For example, if the beam current is lowered by 20 %, the conveyor speed should be decreased by the same percentage to deliver the same absorbed dose.

12.1.2 Ensure that product loading configuration remains the same for all process loads, and constant for the bulk-flow irradiation.

12.1.3 *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. As determined during performance qualification (see 11.3.1.2), it may be necessary to place compensating dummies adjacent to these units so as to make their dose distributions acceptable.

12.1.4 *Partial Loading*—For partially-loaded process loads, ensure that the product loading configuration conforms to that established during performance qualification (see 11.3.1.3).

12.2 *Process Control*—It is essential to demonstrate that the irradiation process is continuously under control. This is accomplished through these process control elements: *(1)* continuously controlling and monitoring during product processing all operating parameters that affect dose (12.3), and *(2)* use of routine production dosimetry (12.4). Additionally, the application of radiation-sensitive indicators to process loads or product packages may be a convenient means to show that they have been irradiated and to assist in inventory control (12.5).

12.3 *Operating Parameters*:

12.3.1 Control, monitor and document the relevant operating parameters as evidence to show the continuity of the process, and thus to ensure that each process load is processed in accordance with specifications.

12.3.2 If these parameters deviate outside the tolerance limits prescribed during performance qualification, take appropriate actions. For example, immediately interrupt the process to evaluate and correct the cause of the deviations.

NOTE 18—Monitoring of operating parameters alone may not be sufficient for some irradiation processes (for example, sterilization of

medical products and preservation of food). Dosimetry is required during routine processing for these applications.

12.4 *Routine Production Dosimetry*—Ensure that the product receives the required absorbed dose by employing proper dosimetric procedures with appropriate statistical controls and documentation. These procedures involve the use of routine in-plant dosimetry performed as described below.

NOTE 19—Dosimeters used for routine dosimetry need not be of the same type as those used for the absorbed-dose mapping procedure.

12.4.1 *Dosimeter Location*—Place dosimeter sets either in or on the selected process loads at predetermined locations of the maximum or minimum absorbed dose (see 11.3), or alternatively, at the reference dose locations discussed in 11.3.4.

12.4.2 *Placement Frequency*—It is not necessary to have routine dosimeters on every process load. Select a sufficient number of process loads on which to place dosimeter sets at the locations described in 12.4.1 in order to verify that the absorbed doses for the entire production run fall within specified limits. Always place dosimeter sets at the start of the run. For long production runs, place dosimeter sets at other intervals as appropriate. Available dosimetry data may be useful in determining this.

NOTE 20—The absorbed-dose distribution in the process load is already known from the dose mapping effort described in Section 11. However, the use of a sufficient number of strategically placed dosimeter sets serves to confirm that the absorbed doses have been achieved within the specified range. More frequent (than suggested in 12.4.2) placement of dosimeters during the production run will provide more dosimetry information that could result in less product rejection if some operational uncertainty or failure arises (such as malfunction of the conveyor speed measurement equipment).

12.4.3 *Bulk-flow*—For some types of bulk-flow irradiators (for example, where fluids or grains continuously flow during irradiation), it may not be feasible during routine production to place dosimeters at the locations of minimum and maximum absorbed dose. In this case, add several dosimeters mixed randomly with and carried by the product through the irradiation zone at the beginning of the production run. For a long irradiation run, also add dosimeters at the middle, and near the end of the production run or as required by regulations. Each set of absorbed dose measurements requires several dosimeters to ensure, at a specified level of confidence that the minimum and maximum absorbed doses are known. This procedure requires that the total irradiation time and rate of flow of the dosimeters are the same as those of product **(20, 27)**.

NOTE 21—In case it is not feasible to measure dose during the routine processing of bulk materials, it may be acceptable to rely on operating parameter control. For some processes, it may be sufficient to determine the average dose and the maximum and minimum doses in process experiments using samples of product to be irradiated or simulated products. Calculation of dose extremes may also be acceptable (ASTM Guide E 2232). The consistency of the dose distribution can be ensured by monitoring all of the critical operating parameters and by repeating the performance qualification procedure at appropriate intervals.

12.4.4 *Heated or Cooled Products*—Use a dosimetry system that is characterised at the processing temperature, or that has insignificant temperature dependence. If a dosimetry system is used that is significantly temperature dependent, place the dosimeters at reference dose locations that are isolated from the temperature gradient (see 11.3.2). See ISO/ASTM Guide 51261 and practices for individual dosimetry systems listed in 2.1 and 2.2.

12.4.5 *Environmental Effects*—A change in the environment (for example, temperature, humidity) of a dosimeter during the irradiation process may affect its response. If required, adjust the measured value of the dosimeter response for any such effect. Care must also be taken in handling and storage of dosimeters before and after irradiation. (See ISO/ASTM Guide 51261 and practices for individual dosimetry systems listed in 2.1 and 2.2.)

12.5 *Radiation-sensitive Indicators*:

12.5.1 In some applications, radiation-sensitive indicators (sometimes known as "go/no go" indicators) may be used to visually confirm that product packages or process loads have been exposed to a radiation source (see ISO/ASTM Guide 51539). These indicators provide only a qualitative indication of radiation exposure.

12.5.2 The color change of radiation-sensitive indicators is not always stable and may be affected by, for example, light or heat. Thus they are useful only within the irradiation facility where these conditions are controlled.

12.5.3 For multiple irradiations, one indicator may be affixed before each pass on the side facing the radiation beam to give visual evidence of the number of passes the process load has traversed.

12.5.4 Their use is not a substitute for the dosimetry procedures described in 12.4.

12.6 *Process Interruption*:

12.6.1 If there is a process failure, for example due to power loss, its implication on the process and the product shall be evaluated before re-starting the process. Generally in radiation processing, the radiation-induced effect is additive and the process can be restarted from where it was interrupted. In some processes, the product characteristics may change during the delay.

12.6.2 If the product is irradiated under controlled temperature, care should be taken to maintain those conditions throughout the interruption or return them prior to restarting the process if appropriate.

12.6.3 Product dose uniformity during a process interruption is typically characterized during the Operational Qualification (see 10.6).

13. Measurement uncertainty

13.1 To be meaningful, a measurement of absorbed dose shall be accompanied by an estimate of uncertainty.

13.2 Components of uncertainty shall be identified as belonging to one of two categories:

13.2.1 *Type A*—Those evaluated by statistical methods, or

13.2.2 *Type B*—Those evaluated by other means.

13.3 Other ways of categorizing uncertainty have been widely used and may be useful for reporting uncertainty. For example, the terms *precision* and *bias* or *random* and *systematic* (non-random) are used to describe different categories of uncertainty **(28)**.

13.4 The level of uncertainty in the absorbed-dose measurement that is acceptable should take into account both regulatory and commercial requirements pertaining to the specific product being irradiated.

NOTE 22—The identification of Type A and Type B uncertainties is based on the methodology for estimating uncertainties published in 1995 by the International Organization for Standardization (ISO) in the Guide for Expression of Uncertainty in Measurement **(29)**. The purpose of using this type of characterization is to promote an understanding of how uncertainty statements are developed and to provide a basis for the international comparison of measurement results.

NOTE 23—ISO/ASTM Guide 51707 defines possible sources of uncertainty in dosimetry performed in radiation processing facilities, and offers procedures for estimating the magnitude of the resulting uncertainties in the measurement of absorbed dose using a dosimetry system. The document defines and discusses basic concepts of measurement, including estimation of the measured value of a quantity, "true" value, error and uncertainty. Components of uncertainty are discussed and methods are provided for estimating their values. Methods are also provided for calculating the combined standard uncertainty and estimating expanded (overall) uncertainty.

NOTE 24—Additional information on regulations and guidelines for radiation processing can be found in Refs **(23, 30-42)** and ISO 11137.

14. Certification

14.1 *Documentation Accumulation*:

14.1.1 *Equipment Documentation*—Record or reference the calibration and maintenance of equipment and instrumentation used to control or measure the absorbed doses delivered to the product (see ISO/ASTM Guide 51261).

14.1.2 *Operating Parameters*—Record the values of the operating parameters (see 12.3) affecting absorbed dose together with sufficient information identifying these parameters with specific product lots or production runs.

14.1.3 *Dosimetry*—Record and document all dosimetry data for performance qualification (Section 11) and routine product processing (see 12.4). Include name of the operator, date, time, product type, loading diagrams, and absorbed doses for all product processed. Record the time of dosimeter analysis if the post-irradiation stability of the dosimeters under the conditions of use requires time-dependent corrections to the dosimeter response.

14.1.4 *Dosimetry Uncertainty*—Include estimates of the measurement uncertainty in absorbed dose (Section 13) in records and reports, as appropriate.

14.1.5 *Facility Log*—Record the date the product is processed and the starting and ending times of the irradiation. Record the name of the operator, as well as any special conditions of the irradiator or the facility that could affect the absorbed dose to the product.

14.1.6 *Product Identification*—Ensure that each lot of product that is processed bears an identification that distinguishes it from all other lots in the facility. This identification shall be used on all documents related to that lot.

14.2 *Review and Certification*:

14.2.1 Prior to release of product for use, review dosimetry results and recorded values of the operating parameters to verify compliance with specifications.

14.2.2 Approve and certify the absorbed dose to the product for each production run, in accordance with an established facility quality assurance program. Certification shall be performed by authorized personnel, as documented in the quality assurance program.

14.2.3 Audit all documentation at time intervals specified in the quality assurance program to ensure that records are accurate and complete. If deficiencies are found, ensure that corrective actions are taken.

14.3 *Retention of Records*—File all information pertaining to each production run together (for example, copies of the shipping document, certificates of irradiation, and the irradiation control record (see 14.1.1-14.1.6)). Retain the records for the period of time specified in the quality assurance program and have them available for inspection as needed.

15. Keywords

15.1 absorbed dose; bremsstrahlung; dose distribution; dose mapping; dosimeter; dosimetric procedures; dosimetry; electron accelerator; electron beam; facility characterization; ionizing radiation; irradiation facility; irradiator characterization; photon; radiation; radiation dosimetry; radiation processing; X-radiation; X-ray; X-ray processing; X-ray target; X-ray utilization

ANNEX

(informative)

A1. X-Ray (Bremsstrahlung) Characteristics

A1.1 *X-Ray Processing*—The physical properties of X-rays (bremsstrahlung) are well known and the use of this type of radiation for material processing has been studied extensively **(43)**. Some important characteristics of this technology are described below and more detailed information can be obtained from the selected references listed in the Bibliography following the Annex. Some of this information has been obtained by dosimetry but much is based on theoretical analyses using the Monte Carlo methods listed in Ref **(44)** and the data sources in Refs **(45-49)**.

A1.2 *Electron Accelerators*:

A1.2.1 Since bremsstrahlung is produced by high-energy electrons, an electron accelerator is essential for generating this kind of radiation. Various types of accelerators can be used, including both direct-action and indirect-action machines. High-power, high-energy technologies appropriate for industrial X-ray processing have been reviewed in Refs **(5, 8, 50-70)**.

A1.2.2 *Direct Action Accelerators*—Machines of this type employ dc or pulsed high-voltage generators to create strong electric fields. The electrons are accelerated by these fields through evacuated, single-gap or multiple-gap beam tubes from a thermionic cathode at high negative potential to a grounded anode. The most powerful systems use cascaded rectifier circuits to convert low-voltage ac to high-voltage dc power. Direct action accelerators can now produce electron energies up to 5 MeV and electron beam powers up to 200 kW **(8, 51, 53, 57-59, 65)**.

A1.2.3 *Indirect-Action Accelerators*—Machines of this type use microwave or very high frequency (vhf) ac power to accelerate electrons within evacuated metallic wave-guides or resonant cavities which are at ground potential. The electrons gain energy by moving in phase with the electromagnetic wave. The final energy is determined by the field strength and the length of the beam trajectory. Microwave and vhf accelerators can now produce electron energies in the 5 to 25 MeV range with average beam powers up to 700 kW at 7 MeV **(5, 55, 56, 60-67)**. Linear induction accelerators may be applicable in the future **(50, 52, 68-70)**.

A1.3 *Converter Design*:

A1.3.1 The X-ray conversion efficiency (X-ray power emitted in the forward direction divided by the electron power incident on the target) increases with the electron energy and atomic number of the target material. The heavy metals, tantalum, tungsten, or gold, are suitable materials because of their high atomic numbers and high melting temperatures. Theoretical analyses with Monte Carlo codes have shown that conversion efficiencies of approximately 7 to 8 % at 5 MeV and 14 to 16 % at 10 MeV can be obtained with optimum thicknesses of tantalum or tungsten targets (approximately 40 % of the maximum electron range) backed by a thin copper or stainless steel channel cooled with water **(1, 18, 71-77)**.

A1.3.2 Most of the electron beam power is dissipated as heat in the target assembly and must be removed by a cooling system **(1, 73)**. The total thickness of the target assembly plus the cooling channel should be slightly greater than the maximum electron range in order to avoid irradiating the products with primary electrons.

A1.4 *Converter and Beam Configurations*:

A1.4.1 In contrast to radiographic and therapeutic X-ray machines, which use small-diameter electron beams to make well-collimated X-ray beams, radiation processing equipment must use electron beams with large cross sections and targets with large areas to dissipate the beam power. Electron beams may be dispersed by scanning magnets, defocussing magnetic lenses, or scattering foils.

A1.4.2 For irradiating products on a moving conveyor, it is convenient to use beam scanning to uniformly cover an elongated target that is oriented across the conveyor. This configuration increases the width of the radiation field and facilitates the treatment of large volumes of material (see Fig. A1.1) **(1, 54, 64, 72-74, 78-84)**.

A1.5 *Bremsstrahlung Properties*:

A1.5.1 In the energy range from 5 to 10 MeV, the X-ray power P_x emitted in the forward direction by an optimum converter is proportional to the electron beam current I times the square of the electron energy E **(7, 18, 54, 71, 73, 76, 77, 81, 85)**. With constant electron beam power $P_e = I\,E$, the emitted X-ray power increases linearly with the electron energy.

$$P_x = f\,I\,E^2 = f\,P_e\,E \quad \text{(A1.1)}$$

$$\eta = P_x / P_e = f\,E \quad \text{(A1.2)}$$

where:

f = proportionality factor, and

η = X-ray conversion efficiency.

A1.5.2 Unlike gamma radiation from radionuclides, high-energy X-radiation is not emitted isotropically but is concentrated in the electron beam direction (see Figs. A1.2 and A1.3) **(18, 19, 73, 83-88)**. The angular dispersion decreases as the energy of the electrons increases. For example, the ratios of X-ray intensities in the forward and sideward (slightly backward) directions with small-diameter electron beams on thick, high-density targets are approximately 4/1 at 3 MeV, 10/1 at 5 MeV and 40/1 at 10 MeV (see Fig. A1.4) **(88)**.

A1.5.3 The forward concentration increases the radiation intensity and reduces the size of the radiation field in comparison to a large-area gamma-ray source of equivalent power and throughput capacity. These effects reduce the treatment time and volume of products within the radiation field. This facilitates the transition from one type of product to another in a continuous irradiation process.

A1.5.4 The continuous energy spectrum of bremsstrahlung emitted through the target assembly extends from approximately 35 keV up to the maximum energy of the electrons

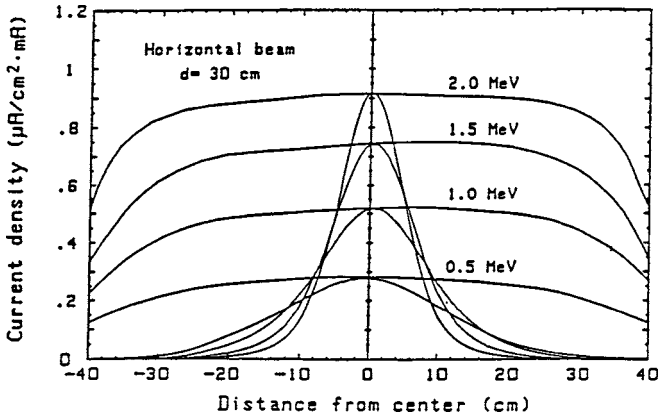


FIG. A1.1 Beam current density distributions along the scan direction (wide curves) and perpendicular to the scan direction (narrow curves) of No. 1 accelerator of JAERI Takasaki (Fig. 2.1 from Ref (73))

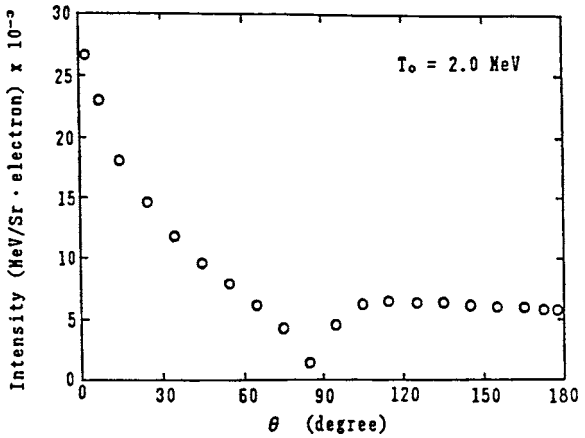


FIG. A1.2 X-ray intensity per 2 MeV electron incident perpendicularly on a tantalum target with thickness of one CSDA electron range as a function of emitting angle calculated by the ETRAN code (Fig. 3.3 from Ref (73))

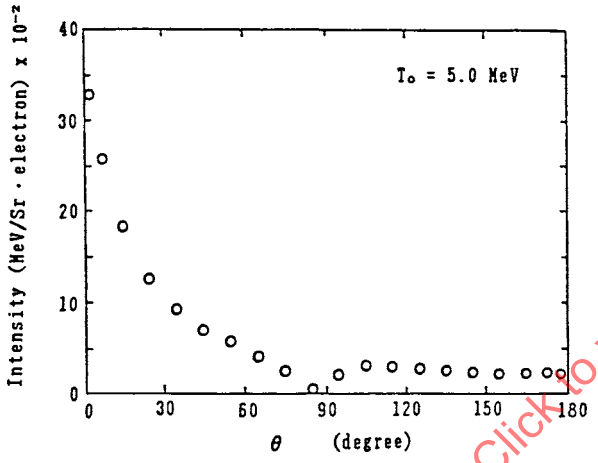
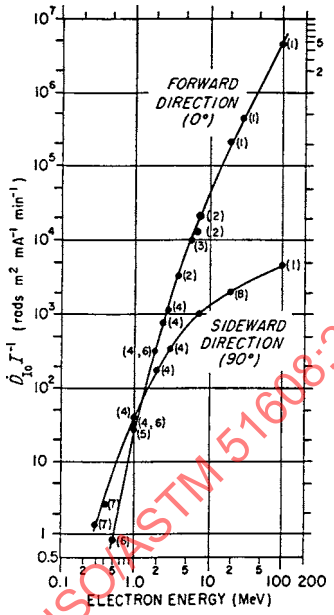


FIG. A1.3 X-ray intensity per 5 MeV electron incident perpendicularly on a tantalum target with thickness of one CSDA electron range as a function of emitting angle calculated by ETRAN code (Fig 3.4 from Ref (73))

incident on the converter. For photon energies greater than 0.3 MeV, the differential energy spectrum (number of photons per unit energy interval) decreases as the photon energy increases (see Figs. A1.5 and A1.6) (**18, 19, 72, 85-87, 89**). For example, the average photon energy produced by 5 MeV electrons in a tantalum or tungsten target with optimum thickness is about 0.75 MeV, and the most probable photon energy is about 0.3 MeV.

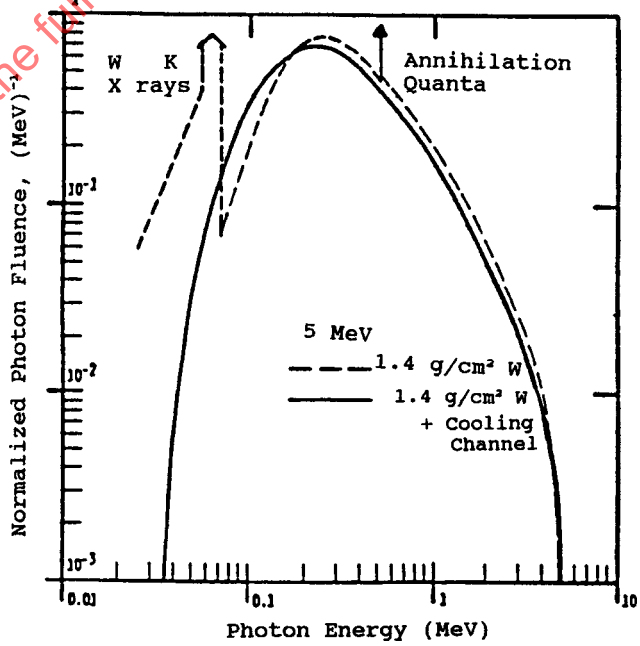
A1.5.5 Even though the average photon energy is low in comparison to the maximum energy, the penetration of broad-beam 5 MeV X radiation in absorbers with low atomic numbers is still greater than that of gamma radiation from Cobalt 60, which have an average photon energy of 1.25 MeV (see Fig. A1.7). This effect is due to the higher energy components and the forward concentration of bremsstrahlung versus the isotropic emission of gamma radiation from large area sources (**1, 7, 50, 69, 74, 76, 77, 83, 84**).

A1.6 *Absorbed Dose Distributions*:



NOTE—The numbers along the curves identify papers cited in Ref (**88**).

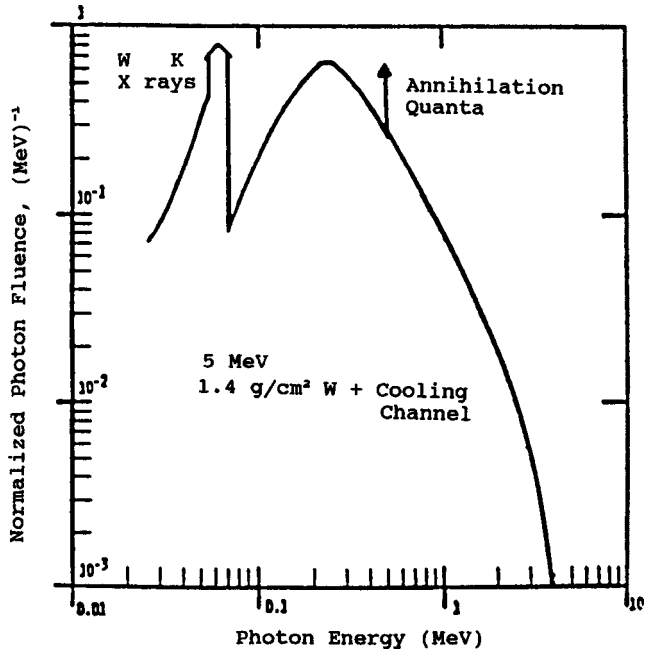
FIG. A1.4 X-ray emission rates from high-Z targets (Fig. E 1 from Ref (88))



NOTE—Results are given for transmission both by the converter plate only and by the converter plate plus cooling channel. The results are for a 5 MeV incident electron beam energy and include all photons regardless of emergent angle.

FIG. A1.5 Spectrum of transmitted photons (Fig 2a from Ref (18))

A1.6.1 With large-volume absorbers and a single-track conveyor, the longitudinal dose distributions (parallel to the direction of conveyor motion) are nearly uniform, except for slight increases on the leading and trailing edges of the



NOTE—Results pertain to reflection by total target. Spectra of photons emergent from target incorporating a 1.4 g/cm^2 W converter. The results are for a 5 MeV incident electron beam energy and include all photons regardless of emergent angle.

FIG. A1.6 Spectrum of reflected photons (Fig. 2b from Ref (18))

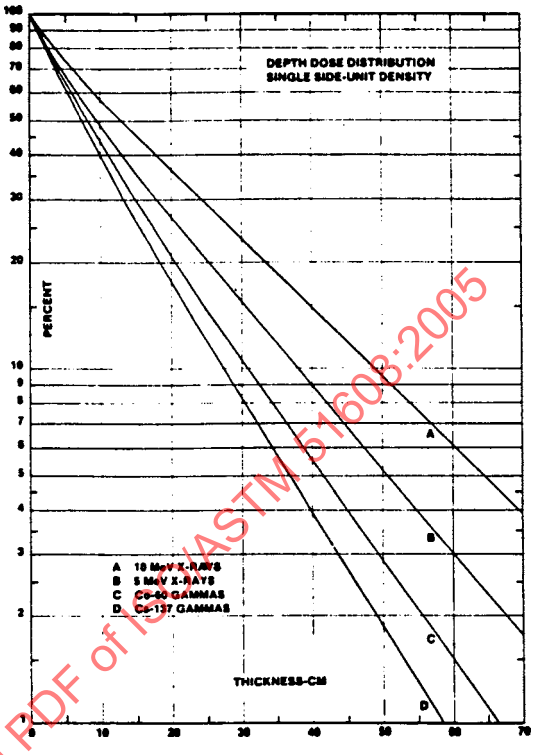
absorber. On the other hand, the latitudinal dose distributions (orthogonal to the conveyor motion) decrease at both sides of the absorber, even if the X-ray source is wider than the absorber (see Fig. A1.8) **(1, 2, 74, 84)**.

A1.6.2 The depth dose distributions (dose attenuation curves) obtained by irradiating low-atomic-number materials (for example, water, plastic, or cardboard) with 5 MeV X rays are essentially exponential. However, the slopes of the curves tend to decrease slightly as the thickness increases, due to hardening of the X-ray spectrum, that is, the greater attenuation of lower-energy photons (see Fig. A1.9) **(1, 2, 18, 74, 83, 84)**.

A1.6.3 With elongated targets, large area absorbers, and a moving product conveyor, the surface dose on the side facing the target is quite near the top of the exponential depth-dose curve (see Fig. A1.10) **(1, 2, 83, 84)**. Thus, the dose buildup effect near the surface, which is seen with collimated beams of high-energy X radiation or gamma radiation and stationary absorbers **(90-92)**, is not significant in a broad-beam X-ray irradiation process.

A1.6.4 The max/min dose ratio and the photon power utilization both depend on the size and density of the irradiated material as well as the method of conveying the material through the radiation field **(1, 71, 80, 81, 84)**. By using dual-track conveyor systems with two-sided irradiation and by rearranging multiple layers of material, it is theoretically possible to achieve low max/min dose ratios (for example, 1.1 to 1.2) and high photon power utilization (for example, 50 to 60 %) in large volumes of absorbing material with low atomic number and low density (for example 0.3 g/cm^3) **(6, 93, 94)**.

A1.7 *Chemical and Biological Effects*:



NOTE—Percentage depth-dose distribution in water or unit-density materials for single-sided irradiation: (*A*) 10 MeV X-rays; (*B*) 5 MeV X-rays; (*C*) ^{60}Co gamma rays; and (*D*) ^{137}Cs gamma rays.

FIG. A1.7 Depth dose distributions (Fig. 1 from Ref (7))

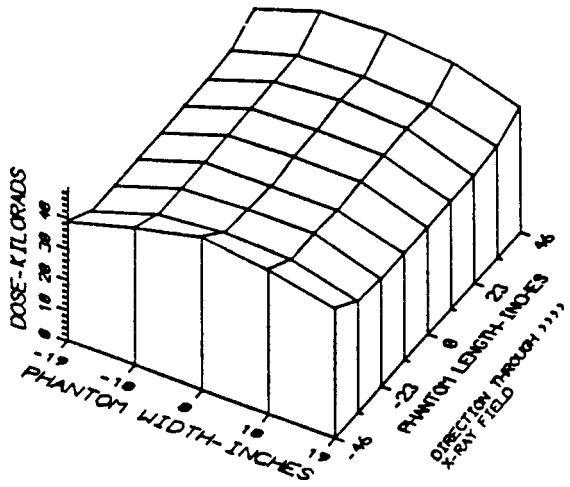


FIG. A1.8 Dose contour map, moving exposure (Fig. 3 from Ref (74))

A1.7.1 Studies on the radiation degradation of polypropylene with gamma rays, X-rays, and electrons have shown that X-ray effects are intermediate between gamma rays and electrons. This is attributed to the differences in dose rates. Higher dose rates deplete the available oxygen in the material faster than it can be replenished by diffusion and reduce the degradation of physical properties accordingly **(95)**.

A1.7.2 The biological effectiveness of gamma rays, X- rays, and electrons is essentially the same for microorganisms