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

**iTeh STANDARD PREVIEW**  
Pratique de la dosimétrie dans une installation de traitement par  
des rayons X (bremsstrahlung)  
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## Foreword

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

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

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

A pilot project between ISO and ASTM International has been formed to develop and maintain a group of ISO/ASTM radiation processing dosimetry standards. Under this pilot 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 International Standard 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.

Annex A1 of this International Standard is for information only.



## Standard Practice for Dosimetry in an X-Ray (Bremsstrahlung) Facility for Radiation Processing<sup>1</sup>

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 covers dosimetric procedures to be followed in facility characterization, process qualification, and routine processing using X rays (bremsstrahlung) to ensure that the entire product has been treated within an acceptable range of absorbed doses. Other procedures related to facility characterization, process qualification, and routine processing that may influence absorbed dose in the product are also discussed. The establishment of effective or regulatory dose and X-ray energy limits are not within the scope of this practice.

1.2 In contrast to monoenergetic gamma rays, the bremsstrahlung energy spectrum extends from low values 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 11137:1995. In those areas covered by ISO 11137, that standard takes 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 2.1, 2.3 and 2.4.

NOTE 2—Bremsstrahlung characteristics are similar to gamma rays from radioactive isotopes. See ISO/ASTM Practices 51204 and 51702 for the applications of dosimetry in the characterization and operation of gamma-ray 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.*

<sup>1</sup> 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 Jan. 22, 2002. Published March 15, 2002. 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 51608:2002(E) is a revision of ISO 15567.

### 2. Referenced Documents

#### 2.1 ASTM Standards:

- E 170 Terminology Relating to Radiation Measurements and Dosimetry<sup>2</sup>
- E 177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods<sup>3</sup>
- E 275 Practice for Describing and Measuring Performance of Ultraviolet, Visible, and Near Infrared Spectrophotometers<sup>4</sup>
- E 456 Terminology Relating to Quality and Statistics<sup>3</sup>
- E 925 Practice for the Periodic Calibration of Narrow Band-Pass Spectrophotometers<sup>4</sup>
- E 958 Practice for Measuring Practical Spectral Bandwidth of Ultraviolet-Visible Spectrophotometers<sup>4</sup>
- E 1026 Practice for Using the Fricke Reference Standard Dosimetry System<sup>2</sup>

#### 2.2 ISO/ASTM Standards:

- 51204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing<sup>2</sup>
- 51205 Practice for Use of a Ceric-Cerous Sulfate Dosimetry System<sup>2</sup>
- 51261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing<sup>2</sup>
- 51275 Practice for Use of a Radiochromic Film Dosimetry System<sup>2</sup>
- 51276 Practice for Use of a Polymethylmethacrylate Dosimetry System<sup>2</sup>
- 51310 Practice for Use of a Radiochromic Optical Waveguide Dosimetry System<sup>2</sup>
- 51400 Practice for Characterization and Performance of a High-Dose Radiation Dosimetry Calibration Laboratory<sup>2</sup>
- 51401 Practice for Use of a Dichromate Dosimetry System<sup>2</sup>
- 51431 Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing<sup>2</sup>
- 51538 Practice for Use of the Ethanol-Chlorobenzene Dosimetry System<sup>2</sup>
- 51539 Guide for Use of Radiation-Sensitive Indicators<sup>2</sup>
- 51540 Practice for Use of a Radiochromic Liquid Dosimetry System<sup>2</sup>
- 51607 Practice for Use of the Alanine-EPR Dosimetry System<sup>2</sup>
- 51649 Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 300 keV and 25 MeV<sup>2</sup>

<sup>2</sup> Annual Book of ASTM Standards, Vol 12.02.

<sup>3</sup> Annual Book of ASTM Standards, Vol 14.02.

<sup>4</sup> Annual Book of ASTM Standards, Vol 03.06.



51650 Practice for Use of Cellulose-Acetate Dosimetry Systems<sup>2</sup>

51702 Practice for Dosimetry in a Gamma Irradiation Facility for Radiation Processing<sup>2</sup>

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing<sup>2</sup>

2.3 ICRU Reports:<sup>5</sup>

ICRU Report 14 Radiation Dosimetry: X Rays and Gamma Rays with Maximum Photon Energies Between 0.6 and 50 MeV

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 Radiation Quantities and Units

2.4 ISO Standards:<sup>6</sup>

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

### 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).

$$D = d\epsilon / dm$$

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

3.1.3.1 *Discussion*—When a beta particle (electron) passes close to a nucleus, the strong attractive coulomb force causes the beta particle to deviate sharply from its original path. The change in direction is due to radial acceleration, and in accordance with classical theory the beta particle 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 beta particle. Practically, bremsstrahlung is produced when an electron beam strikes any material (converter). The

bremstrahlung spectrum depends on the electron energy, converter material, and its thickness.

3.1.4 *calibration curve*—graphical representation of the dosimetry system's response function.

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

3.1.8 *electron energy*—the 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*—the 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*—a 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*—the 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*—a volume of material with a specified loading configuration irradiated as a single entity.

3.1.14 *X rays*—the common name for the short wavelength electromagnetic radiation emitted by high-energy electrons when they are accelerated, decelerated or deflected by strong electric and magnetic fields. The term includes both bremsstrahlung from nuclear collisions and the characteristic monoenergetic radiation emitted when atomic electrons make transitions to more tightly bound states.

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

3.1.16 *X-ray target*—that 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.

3.2 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 ASTM E 170 are compatible with ICRU Report 60. That document, therefore, may be used as an alternative reference.

### 4. Significance and Use

4.1 A variety of products and materials may be irradiated

<sup>5</sup> Available from the International Commission on Radiation Units and Measurements, 7910 Woodmont Ave., Suite 800, Bethesda, MD 20814, U.S.A.

<sup>6</sup> Available from the International Organization for Standardization, 1 Rue de Varembe, Case Postale 56, CH-1211, Geneva 20, Switzerland.





with X rays 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.

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.

4.2 As a means of (quality) control of an irradiation process, dosimeters are used to relate their calibrated response to radiation exposure to the absorbed dose in the material or product being irradiated (see Section 7).

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 and 10 and Annex A1).

4.5 Before an irradiation process can be used, it 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 8 and 9).

4.6 To ensure consistent dose delivery in a qualified irradiation process, routine process control requires procedures for product handling before and after the treatment, prescribed orientation of the products during irradiation, monitoring of critical process parameters, routine product dosimetry, and documentation of the required activities and functions (see Sections 10 and 11).

## 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 includes a high-energy, high-power 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 existing industrial facilities, see Refs (1) and (2)<sup>7</sup>.

6.2 *Product Handling System*—The penetrating quality of high-energy X rays 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 target, and the penetrating quality of the radiation, and the size, shape, and density of the product load affect the dose uniformity ratio (see Refs (3-5)).

## 7. Dosimetry Systems

7.1 *Description of Dosimeter Classes:*

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

7.1.2 Dosimeters may be divided into four basic classes according to the accuracy of the dosimetry systems and areas of application: primary standard, reference standard, transfer standard, and routine dosimeters. ISO/ASTM Guide 51261 provides detailed information about the selection of dosimetry systems for different applications.

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

7.1.2.2 *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 dose ranges are given in a table in ISO/ASTM Guide 51261.

7.1.2.3 *Transfer-Standard Dosimeters*—Transfer-standard dosimeters are specially selected dosimeters used for transferring absorbed-dose information from an accredited or national

<sup>7</sup> The boldface numbers in parentheses refer to the bibliography at the end of this practice.



standards laboratory to an irradiation facility in order to establish traceability for that facility. These dosimeters should be used under conditions that are carefully controlled by the issuing laboratory. Transfer–standard dosimeters may be selected from either reference–standard dosimeters or routine dosimeters and shall have performance characteristics that meet the requirements listed in a table in ISO/ASTM Guide 51261.

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

**7.2 Dosimeter Selection**—The ASTM, ISO/ASTM and ICRU documents listed in 2.1 to 2.3 provide detailed information on the selection and use of high-dose dosimeter systems for gamma-ray (photon) and electron-beam irradiation facilities. Many of these dosimetry systems are also applicable for high-energy X rays, since their radiation responses are relatively insensitive to the photon or electron energies (see ASTM Practice E 1026 and ISO/ASTM Practices 51204, 51205, 51275, 51276, 51310, 51400, 51401, 51431, 51538, and 51540, 51607, 51649, and 51702, ISO/ASTM Guides 51261 and 51539, and ICRU Reports 14, 35, 37, and 60).

**NOTE 4**—Dosimeters consisting mainly of water or hydrocarbon materials are suitable for both gamma rays and high-energy X rays. Some exceptions are dosimeters containing substantial amounts of materials with high atomic numbers. These may be especially sensitive to the low-energy photons in the bremsstrahlung spectrum.

**NOTE 5**—The X-ray dose rate may be higher than that of gamma rays used for radiation processing, especially in products passing near the X-ray converter. The dose-rate dependence of the dosimeters should be considered in their calibration procedure (see Refs (6) and (7)).

### 7.3 Calibration of Dosimetry Systems:

**7.3.1** Prior to use, dosimetry systems shall be calibrated in accordance with the user's documented procedure that specifies details of the calibration process and quality assurance requirements. This calibration procedure shall be repeated at regular intervals to ensure that the accuracy of the absorbed dose measurement is maintained within required limits. Irradiation is a critical component of the calibration of the dosimetry system. Detailed calibration procedures are provided in ISO/ASTM Guide 51261.

**7.3.2 Calibration Irradiation of Reference or Transfer Dosimeters**—Calibration irradiations shall be performed by irradiating the reference or transfer–standard dosimeters using a calibration facility that provides an absorbed dose or an absorbed-dose rate having measurement traceability to nationally or internationally recognized standards.

**7.3.3 Calibration Irradiation of Routine Dosimeters**—Calibration irradiations may be performed in several ways, including irradiating the routine dosimeters using:

**7.3.3.1** a calibration facility that provides an absorbed dose or an absorbed-dose rate having measurement traceability to nationally or internationally recognized standards, or

**7.3.3.2** 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

**7.3.3.3** a production or research irradiation facility together with reference or transfer–standard dosimeters that have measurement traceability to nationally or internationally recognized standards.

**7.3.4** When a reference of transfer–standard dosimeter is to be used as a routine dosimeter, calibration may also be performed as stated in 7.3.3.2 or 7.3.3.3.

**7.3.5 Analytical Instrument Calibration and Performance Verification**—For the calibration of the individual instruments used in the analysis of the dosimeters, and for the verification of instrument performance between calibrations, see ISO/ASTM Guide 51261.

## 8. Installation Qualification

**8.1** The purpose of dosimetry in qualifying an X-ray facility is to establish baseline data for monitoring the effectiveness, predictability, and reproducibility of the irradiation process throughout a typical range of operating parameters. Dosimetry shall be used for the following purposes:

**8.1.1** To establish relationships between absorbed dose in a reproducible geometry and operating parameters.

**8.1.2** To characterize the stability of dose when these parameters fluctuate statistically and through normal operations.

**8.1.3** To measure absorbed dose distributions in reference materials.

**8.2 Equipment Documentation**—Documentation shall exist describing the equipment, any modifications, and its operation. This information shall be retained for the life of the facility. It shall include the following:

**8.2.1** The layout of the facility showing the locations of the major components.

**8.2.2** The descriptions, specifications, and characteristics of the electron accelerator, the X-ray converter, the product conveyor, the control system, and all other auxiliary equipment and instrumentation.

**8.2.3** The testing, calibrating, and operating procedures for all of the equipment and instrumentation, including the dosimetry system.

**8.2.4** Identification of the instrumentation used to control, monitor, and record the critical process parameters that affect the absorbed dose in the irradiated products.

**8.3 Equipment Testing and Calibration**—The first phase of qualifying an irradiation facility is to determine that the processing equipment performs according to its specifications. This includes the accelerator and X-ray converter, product conveyor, control system and its software, and other auxiliary equipment and instrumentation. Calibration of the equipment, instrumentation, and dosimetry system is also essential. Special emphasis must be given to the critical parameters that affect the dose distribution in the irradiated products. These include the electron energy, electron beam current, beam scanning amplitude, and conveyor speed.

**8.4 Irradiator Characterization**—The second phase is to show that the irradiation process can be accomplished within the specified tolerances under prescribed operating conditions





and that the results are reproducible. Reference material or product can be used for this purpose. The dose distribution within the reference material or product should be determined by detailed dose mapping. The effects of small variations in the critical process parameters should be assessed and recorded.

8.5 *Measurement Quality Assurance Plan*—Proper measurement procedures, with appropriate statistical controls and documentation, shall be used to ensure that the equipment works properly and that the treatment process delivers the required dose according to specifications.

## 9. Process Qualification

9.1 *Process Parameters*—For each product to be treated in the irradiation facility, there will usually be a minimum dose to obtain the desired effect and a maximum dose that the product can tolerate without degradation in quality. These dose limits may have to be determined experimentally. The equipment parameters to achieve the required doses must also be determined.

9.2 *Absorbed Dose Mapping*—The dose distribution within the process load must be measured to find the locations of the minimum and maximum doses. The relationship of these doses to that obtained at a conveniently accessible point on the outside of the process load may also be determined for use in routine process monitoring. The reproducibility of these doses at the minimum, maximum and monitoring points should be evaluated. The effects of variations in the critical process parameters must also be evaluated.

NOTE 6—Monitoring of operating parameters alone may not be adequate for some irradiation processes (for example, sterilization of medical products and preservation of food). Dosimetry is required during routine processing for these situations.

NOTE 7—In conjunction with dose distribution measurements, it is usually necessary to conduct testing of the product materials to ensure compatibility with the X-ray treatment. It is recommended that this testing be performed at doses larger than the maximum absorbed dose attained during routine processing.

## 10. Routine Processing

10.1 *Process Monitoring*—All critical process parameters that can affect the absorbed dose distribution must be controlled and monitored during all routine processing. The tolerance limits on these parameters must be determined and the treatment process aborted if excessive variations occur. Measurements of these critical parameters should be made and also recorded at regular intervals to prove the continuity of the process (see 4.4).

10.2 *Routine Dosimetry*—It is not necessary to have dosimeters on every process load, but they should be placed at the beginning and the end of a production run to confirm the validity of the irradiation process. For long runs, dosimeters should also be placed near the middle of the run and at other intervals as appropriate.

## 11. Certification

11.1 *Process Control*—All equipment functions and personnel activities that ensure the effectiveness of the irradiation

process are components of the process control program. These include product handling procedures before and after irradiation, proper loading of the product conveyor, monitoring of the critical process parameters, and routine dosimetry.

11.2 *Documentation*—All aspects of the irradiation process that can affect its validity should be covered by written procedures. Installation qualification and process qualification should be accomplished according to plan and all of the results recorded. Routine operations and dosimetry data should be recorded and correlated with product records.

11.3 Documentation should be reviewed by authorized personnel and maintained for inspection.

## 12. Measurement Uncertainty

12.1 To be meaningful, a measurement of absorbed dose shall be accompanied by an estimate of uncertainty. Components of uncertainty shall be identified as belonging to one of two groups:

- (A) those which are evaluated by statistical methods, or
- (B) those which are evaluated by other means.

Additional information is given in ISO/ASTM Guide 51707 and Refs (72) and (73), where these components are referred to as Type A and Type B, respectively. In reporting uncertainty, other classifications such as *precision* and *bias* may be useful.

NOTE 8—The identification of Type A and Type B uncertainties is based on the methodology adopted in 1993 by the International Organization for Standardization (ISO) for estimating uncertainty. This is different from the way uncertainty has been traditionally expressed in terms of *precision* and *bias*, where *precision* is a measure of the extent to which replicated measurements made under specified conditions are in agreement, and *bias* is a systematic error (see ASTM Terminologies E 170 and E 456, and ASTM Practice E 177). The purpose of using the method of expressing uncertainties as Type A and Type B recommended in the ISO Guide to the Expression of Uncertainty in Measurement (Ref (73)) is to promote an understanding of how uncertainty statements are arrived at and to provide a basis for the international comparison of measurement results.

NOTE 9—ISO/ASTM Guide 51707 defines possible sources of error in dosimetry performed in radiation processing facilities and offers procedures for estimating the resulting magnitude of the uncertainties in the measurement results. Basic concepts of measurement, estimate of the measured value of a quantity, “true” value, error and uncertainty are defined and discussed. Components of uncertainty are discussed and methods are given for evaluating and estimating their values. Their contributions to the standard uncertainty in the reported values of absorbed dose are considered and methods are given for calculating the combined standard uncertainty and an estimate of overall (expanded) uncertainty.

NOTE 10—Additional information on regulations and guidelines for radiation processing can be found in Refs (8-20) and ISO 11137.

## 13. Keywords

13.1 absorbed dose; bremsstrahlung; dose distribution; dose mapping; dosimeter; dosimetric procedures; dosimetry; electron accelerator; electron beam; facility characterization; ionizing radiation; irradiator characterization; photon; radiation; radiation dosimetry; radiation facility; radiation processing; X-ray processing; X-ray target; X-ray utilization; X ray; ICS 17.240