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An American National Standard

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

This standard is issued under the fixed designation E 1608; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This practice covers dosimetric procedures to be followed in facility characterization, process qualification, and routine processing using 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 the Appendix).

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

1.4 For the irradiation of food and the radiation sterilization of health care products, other specific ISO standards exist. For food irradiation, see ISO 15562:1998, *Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing* (ASTM Practice E 1431). For the radiation sterilization of health care products, see ISO 11137:1995, *Sterilization of Health Care Products- Requirements for Validation and Routine Control-Radiation Sterilization*. In those areas covered by ISO 11137, that standard takes precedence.

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, 2.2 and 2.3.

NOTE 2—Bremsstrahlung characteristics are similar to gamma rays from radioactive isotopes. See Practices E 1204 and E 1702 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 Practices E 1431 and E 1649.

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:*

E 170 Terminology Relating to Radiation Measurements and Dosimetry[2]
E 177 Recommended Practice for Use of the Terms Precision and Accuracy as Applied to Measurement of a Property of a Material[3]
E 275 Practice for Describing and Measuring Performance of Ultraviolet, Visible, and Near Infrared Spectrophotometers[4]
E 456 Terminology Relating to Quality and Statistics[3]
E 925 Practice for the Periodic Calibration of Narrow Band-Pass Spectrophotometers[4]
E 958 Practice for Measuring Practical Spectral Bandwidth of Ultraviolet-Visible Spectrophotometers[4]
E 1026 Practice for Using the Fricke Reference Standard Dosimetry System[2]
E 1204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing[2]
E 1205 Practice for Use of a Ceric-Cerous Sulfate Dosimetry System[2]
E 1261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing[2]
E 1275 Practice for Use of a Radiochromic Film Dosimetry System[2]
E 1276 Practice for Use of a Polymethylmethacrylate Dosimetry System[2]
E 1310 Practice for Use of a Radiochromic Optical Waveguide Dosimetry System[2]
E 1400 Practice for Characterization and Performance of a High-Dose Radiation Dosimetry Calibration Laboratory[2]
E 1401 Practice for Use of a Dichromate Dosimetry System[2]
E 1431 Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing[2]

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

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[2] *Annual Book of ASTM Standards*, Vol 12.02.
[3] *Annual Book of ASTM Standards*, Vol 14.02.
[4] *Annual Book of ASTM Standards*, Vol 14.01.

E 1538 Practice for Use of the Ethanol-Chlorobenzene Dosimetry System[2]
E 1539 Guide for Use of Radiation-Sensitive Indicators[2]
E 1540 Practice for Use of a Radiochromic Liquid Dosimetry System[2]
E 1607 Practice for Use of the Alanine-EPR Dosimetry System[2]
E 1649 Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 300 keV and 25 MeV[2]
E 1650 Practice for Use of Cellulose-Acetate Dosimetry Systems[2]
E 1702 Practice for Dosimetry in a Gamma Irradiation Facility for Radiation Processing[2]
E 1707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing[2]

2.2 *ICRU Reports:*[5]

ICRU Report 14—Radiation Dosimetry: X Rays and Gamma Rays with Maximum Photon Energies Between 0.6 and 50 MeV
ICRU Report 33—Radiation Quantities and Units
ICRU Report 35—Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV
ICRU Report 37—Stopping Powers for Electrons and Positrons

2.3 *ISO Standards:*[6]

ISO 11137 Sterilization of Health Care Products - Requirements for Validation and Routine Control - Radiation Sterilization
ISO 15562 Practice for Dosimetry in Electron Beam and Bremsstrahlung Irradiation Facilities for Food Processing

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 33).

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

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*—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 *bremsstrahlung*—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 bremsstrahlung 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

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

[6] Available from the International Organization for Standardization, 1 Rue de Varembé, Case Postale 56, CH–1211, Geneva 20, Switzerland.

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 Terminology Standard E 170. Definitions in E 170 are compatible with ICRU Report 33. 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 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 the Appendix).

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 the Appendix.

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 (see Refs **(1)** and **(2)**[7]).

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. Guide E 1261 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] The boldface numbers in parentheses refer to the list of references at the end of this practice.