Designation: E 1702 – 00

An American National Standard

Standard Practice for Dosimetry in a Gamma Irradiation Facility for Radiation Processing[1]

This standard is issued under the fixed designation E 1702; 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 outlines dosimetric procedures to be followed in irradiator characterization, process qualification, and routine processing in a gamma irradiation facility. These procedures ensure that all product processed with ionizing radiation from isotopic gamma sources receive absorbed doses within a predetermined range. Other procedures related to irradiator characterization, process qualification, and routine processing that may influence absorbed dose in the product are also discussed. Information about effective or regulatory dose limits is not within the scope of this document.

1.2 Dosimetry is 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.

1.3 For the irradiation of food and the radiation sterilization of health care products, other specific ISO standards exist. For food irradiation, see ISO 15554:1998, *Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing* (ASTM Practice E 1204). 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* **(1)** [2]. In those areas covered by ISO 11137, that standard takes precedence.

1.4 For guidance in the selection, calibration, and use of specific dosimeters, and interpretation of absorbed dose in the product from dosimetry measurements, see Guide E 1261 and Practices E 666, E 668, E 1026, E 1205, E 1275, E 1276, E 1310, E 1400, E 1401, E 1538, E 1540, E 1607, and E 1650. For discussion of radiation dosimetry for gamma rays, see ICRU Report 14.

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[3]

E 177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods[4]

E 456 Terminology Relating to Quality and Statistics[4]

E 666 Practice for Calculating Absorbed Dose from Gamma or X Radiation[3]

E 668 Practice for Application of Thermoluminescence-Dosimetry (TLD) Systems for Determining Absorbed Dose in Radiation Hardness Testing of Electronic Devices[3]

E 1026 Practice for Using the Fricke Reference Standard Dosimetry System[3]

E 1204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing[3]

E 1205 Practice for Use of a Ceric-Cerous Sulfate Dosimetry System[3]

E 1261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing[3]

E 1275 Practice for Use of a Radiochromic Film Dosimetry System[3]

E 1276 Practice for Use of a Polymethylmethacrylate Dosimetry System[3]

E 1310 Practice for Use of a Radiochromic Optical Waveguide Dosimetry System[3]

E 1400 Practice for Characterization and Performance of a High-Dose Radiation Dosimetry Calibration Laboratory[3]

E 1401 Practice for Use of a Dichromate Dosimetry System[3]

E 1431 Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing[3]

E 1538 Practice for Use of the Ethanol-Chlorobenzene Dosimetry System[3]

E 1539 Guide for Use of Radiation-Sensitive Indicators[3]

E 1540 Practice for Use of a Radiochromic Liquid Dosimetry System[3]

E 1607 Practice for Use of the Alanine-EPR Dosimetry System[3]

[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.

Current edition, which is the same as the last previous edition E 1702-95ε1 except for some changes to the Scope and References sections, was approved Jan. 10, 2000. Published February 2000. Originally published as E 1702-95. Except for removal of three references, International Standard ISO 15571:1998(E) is identical to this practice.

[2] The boldface numbers in parentheses refer to a list of references at the end of this practice.

[3] *Annual Book of ASTM Standards*, Vol 12.02.

[4] *Annual Book of ASTM Standards*, Vol 14.02.

E 1650 Practice for Use of a Cellulose Acetate Dosimetry System[3]

E 1707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing[3]

2.2 *ICRU Reports:*

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

3. Terminology

3.1 *Definitions*—Other terms used in this practice are defined in Terminology E 170 and ICRU Report 33.

3.1.1 *absorbed dose*—quantity of radiation energy imparted per unit mass of a specified material. The unit of absorbed dose is the gray (Gy), where 1 Gy is equivalent to the absorption of 1 J per kg (= 100 rad). The mathematical relationship is the quotient of $d\bar{\epsilon}$ by dm, where $d\bar{\epsilon}$ is the mean energy imparted by ionizing radiation to matter of mass dm (see ICRU 33).

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

3.1.2 *absorbed-dose mapping*—measurement of the absorbed-dose distribution within an irradiation unit through the use of dosimeters placed at specified locations.

3.1.3 *compensating dummy*—simulated product used during routine production runs with irradiation units containing less product than specified in the product loading configuration or used at the beginning or end of a production run to compensate for the absence of product.

3.1.4 *dosimeter set*—one or more dosimeters used to measure the absorbed dose at a location to a desired confidence level and whose average reading is used as the absorbed dose measurement at that location.

3.1.5 *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.

3.1.6 *irradiation unit*—a volume of material with a specified loading configuration irradiated as a single entity.

3.1.7 *production run (continuous-flow irradiation)*—a series of irradiation units consisting of materials or products having similar radiation-absorption characteristics that are irradiated sequentially to a specified range of absorbed dose.

3.1.8 *simulated product*—a mass of material with attenuation and scattering properties similar to those of a particular material or combination of materials. This term is sometimes referred to as dummy product.

3.1.9 *timer setting*—parameter varied to control the time during which an irradiation unit is exposed to radiation.

4. Significance and Use

4.1 Various products and materials routinely are irradiated at predetermined doses at gamma irradiation facilities to reduce their microbial population or to modify their characteristics. Dosimetry requirements may vary depending upon the irradiation application and end use of the product. Some examples of irradiation applications where dosimetry may be used are:

4.1.1 Sterilization of medical devices;

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

4.1.3 Disinfection of consumer products;

4.1.4 Cross-linking or degradation of polymers and elastomers;

4.1.5 Polymerization of monomers and grafting of monomers onto polymers;

4.1.6 Control of pathogens in liquid or solid waste;

4.1.7 Enhancement of color in gemstones and other materials;

4.1.8 Modification of characteristics of semiconductor devices; and

4.1.9 Research on materials effects.

NOTE 1—Dosimetry is required for regulated irradiation processes such as the sterilization of medical devices and the treatment of food. It may be less important for other industrial processes, for example, polymer modification, which can be evaluated by changes in the physical and chemical properties of the irradiated materials.

4.2 Dosimeters are used as a means of quality control of the process by relating the measured response of the dosimeter to radiation to the absorbed dose in the product or in a specified material such as water.

4.3 An irradiation process usually requires a minimum absorbed dose to achieve the desired effect. There also may be a maximum absorbed dose that the product can tolerate and still meet its functional specifications. Dosimetry is essential to the irradiation process since it is used both to determine these limits and to confirm that the product is irradiated within these limits.

4.4 The absorbed-dose distribution within the product depends on the overall product dimensions and weight, irradiation geometry, and source activity distribution. The operating parameter that determines the absorbed dose is the timer setting. The timer setting must be controlled to obtain reproducible results.

4.5 Before an irradiation process can be used, the irradiator must be qualified to determine its effectiveness in reproducibly delivering known, controllable absorbed doses. This involves testing the process equipment, calibrating the equipment and dosimetry system, and characterizing the magnitude, distribution, and reproducibility of the absorbed dose delivered by the irradiator to a reference material.

4.6 To ensure consistent and reproducible dose delivery in a qualified process, routine process control requires documented product handling procedures before and after the irradiation, consistent product loading configurations, monitoring of critical processing parameters, routine product dosimetry, and documentation of the required activities and functions.

5. Radiation Source Characteristics

5.1 The radiation source used in a facility considered in this practice consists of sealed linear elements (rods or "pencils") of cobalt-60 or cesium-137 arranged in one or more planar or cylindrical arrays. Cobalt-60 and cesium-137 sources decay at known rates, emitting photons with known energies. Between source additions, removals, or redistributions, the only variation in the source output is the steady reduction in the activity due to the radioactive decay.

6. Types of Facilities and Modes of Operation

6.1 Radiation processing facilities may be categorized by

irradiator type (for example, container or bulk flow), conveyor system (for example, shuffle-dwell or continuous), and operating mode (for example, batch or continuous). Product may be moved to the location in the facility where the irradiation will take place either while the source is shielded (batch operation), or while the source is exposed (continuous operation). Product may be transported in irradiation containers past the source at a uniform controlled speed (continuous conveyance), or instead may undergo a series of discrete controlled movements separated by controlled time periods during which the irradiation container is stationary (shuffle-dwell). The source may extend above and below the product (overlapping source) or the product may extend above and below the source (overlapping product). For the overlapping product configuration, the irradiation unit is moved past the source at two or more different levels. For irradiators with rectangular source arrays, the irradiation container generally makes one or more passes on each side of the source. In bulk-flow irradiators, products such as grain or flour flow in loose form past the source.

6.2 For low absorbed-dose applications that may require particularly high mechanical speed, various techniques are used to reduce the absorbed-dose rates. These may include use of only a portion of the source, use of attenuators, and irradiation at greater distances from the source.

6.3 The details of a particular irradiator design and the mode of operation affect the delivery of absorbed dose to a product. They therefore should be considered when performing the absorbed-dose measurements required in Sections 8, 9, and 10.

7. Dosimetry Systems

7.1 Dosimetry systems used to determine absorbed dose shall cover the absorbed dose range of interest and shall be calibrated before use.

7.2 *Dosimetry System Selection*—It is important that the dosimetry system be evaluated for those parameters associated with gamma irradiation facilities that may influence the dosimeter response, for example, gamma-ray energy, absorbed-dose rate, and environmental conditions such as temperature, humidity, and light. Guidance as to desirable characteristics and selection criteria can be found in Guide E 1261. Details for individual dosimetry systems are given in Practices E 1026, E 1205, E 1275, E 1276, E 1310, E 1401, E 1538, E 1540, E 1607, and E 1650.

7.3 *Dosimetry System Calibration*—It is important that the dosimetry system used is properly calibrated with calibration traceable to a recognized national or international standard. Guidance for calibration can be found in Guide E 1261.

8. Installation Qualification

8.1 *Objective*:

8.1.1 The purpose of dosimetry in qualifying a gamma irradiation facility is to establish baseline data for evaluating the effectiveness, predictability, and reproducibility of the system under the range of conditions over which the facility will operate. For example, dosimetry shall be used (*1*) to establish relationships between absorbed dose in a reproducible geometry and the operating parameters of the facility, (*2*) to characterize dose variations when these conditions fluctuate statistically and through normal operations, and (*3*) to measure absorbed dose distributions in reference materials.

8.2 *Equipment Documentation*:

8.2.1 Establish and document the irradiator qualification program that demonstrates that the irradiator, operating within specified limits, will consistently produce an absorbed-dose distribution in a given product to predetermined specification. Such documentation shall be retained for the life of the irradiator, and shall include:

8.2.1.1 A description of the instrumentation and equipment for ensuring the reproducibility, within specified limits, of the source-to-product geometry and of the time the product spends at different locations in the irradiation zone.

8.3 *Equipment Testing and Calibration*:

8.3.1 *Processing Equipment*—The absorbed dose in the product in an irradiation container depends on the operating parameters of the irradiation facility, which are controlled by the processing equipment and instrumentation.

8.3.1.1 Test all processing equipment and instrumentation that may influence absorbed dose in order to verify satisfactory operation of the irradiator within the design specifications.

8.3.1.2 Implement a documented calibration program to ensure that all processing equipment and instrumentation that may influence absorbed dose are calibrated periodically.

8.3.2 *Analytical Equipment*—The accuracy of the absorbed-dose measurement depends on the correct operation and calibration of the analytical equipment used in the analysis of the dosimeters.

8.3.2.1 Check the performance of the analytical equipment periodically to ensure that the equipment is functioning in accordance with performance specifications. Repeat this check following equipment modification or servicing and prior to the use of the equipment for a dosimetry system calibration. This check can be accomplished by using standards such as calibrated optical density filters, wavelength standards, or calibrated thickness gages supplied by the manufacturer or national or accredited standards laboratories. The correct performance of dosimetry analysis equipment also can be demonstrated by showing that the analysis results from dosimeters, given known absorbed doses, are in agreement with the expected results within the limits of the dosimetry system uncertainty. However, this method is only applicable to reference standard dosimetry systems where the long-term stability of the response has been demonstrated and documented.

8.3.2.2 Implement a documented calibration program to ensure that all analytical equipment used in the analysis of dosimeters is calibrated periodically.

8.3.2.3 Prior to each use of an analytical instrument, check the zero setting and, if applicable, the full scale reading.

8.4 *Irradiator Characterization*:

8.4.1 The absorbed dose received by any portion of product in an irradiation unit depends on facility parameters such as the activity and geometry of the source, the source-to-product distance, and the irradiation geometry, and on processing parameters such as the irradiation time, the product composition and density, and the product loading configuration.

8.4.2 The absorbed-dose rate and absorbed-dose distribution in the product will change during movement of the irradiation unit. Therefore, changing from one absorbed dose to