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Guide for dosimetry for sterile insect release programs

Guide de la dosimétrie pour des programmes de lâchers
d'insectes stériles

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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 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 51940 was developed by ASTM Committee E10, Nuclear Technology and Applications, through Subcommittee E10.01, and by Technical Committee ISO/TC 85, Nuclear energy.



Standard Guide for Dosimetry for Sterile Insect Release Programs¹

This standard is issued under the fixed designation ISO/ASTM 51940; 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 guide outlines dosimetric procedures to be followed for the radiation sterilization of live insects for use in pest management programs. The primary use of irradiated, reproductively sterile insects is in the Sterile Insect Technique, where large numbers of sterile insects are released into the field to mate with and thus control pest populations of the same species. A secondary use of sterile insects is as benign hosts for rearing insect parasitoids. The procedures outlined in this guide will help ensure that insects processed with ionizing radiation from gamma, electron, or X-ray sources receive absorbed doses within a predetermined range. Information on effective dose ranges for specific applications of insect sterilization, or on methodology for determining effective dose ranges, is not within the scope of this guide.

NOTE 1—Dosimetry is only one component of a total quality control program to ensure that irradiated insects are adequately sterilized and sufficiently competitive or otherwise suitable for their intended purpose.

1.2 This guide covers dosimetry in the irradiation of insects for these types of irradiators: self-contained dry-storage ¹³⁷Cs or ⁶⁰Co irradiators, large-scale gamma irradiators, and electron accelerators. Additional, detailed information on dosimetric procedures to be followed in installation qualification, operational qualification, performance qualification, and routine product processing can be found in ISO/ASTM Practices 51608 (X-ray [bremsstrahlung] facilities), 51649 (electron beam facilities), 51702 (large-scale gamma facilities), and ASTM Practice E 2116 (self-contained dry-storage gamma facilities).

1.3 The absorbed dose for insect sterilization is typically within the range of 20 Gy to 600 Gy.

1.4 This guide refers, throughout the text, specifically to reproductive sterilization of insects. It is equally applicable to radiation sterilization of invertebrates from other taxa (for example, Acarina, Gastropoda) and to irradiation of live insects or other invertebrates for other purposes (for example, inducing mutations), provided the absorbed dose is within the range specified in 1.3.

1.5 This guide also covers the use of radiation-sensitive indicators for the visual and qualitative indication that the insects have been irradiated.

1.6 *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 668 Practice for Application of Thermoluminescence-Dosimetry (TLD) Systems for Determining Absorbed Dose in Radiation-Hardness Testing of Electronic Devices

E 1026 Practice for Using the Fricke Reference Standard Dosimetry System

E 2116 Practice for Dosimetry for a Self-Contained Gamma-Ray Irradiator

E 2303 Guide for Absorbed-Dose Mapping in Radiation Processing Facilities

E 2304 Practice for Use of a LiF Photo-Fluorescent Film Dosimetry System

2.2 ISO/ASTM Standards:²

51261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing

51275 Practice for Use of a Radiochromic Film Dosimetry System

51400 Practice for Characterization and Performance of a High-Dose Radiation Dosimetry Calibration Laboratory

51538 Practice for Use of the Ethanol-Chlorobenzene Dosimetry System

51539 Guide for the 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

51608 Practice for Dosimetry in an X-Ray (Bremsstrahlung) Facility for Radiation Processing

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

¹ This guide 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.

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² For referenced ASTM and 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

51956 Practice for Use of Thermoluminescence-Dosimetry (TLD) Systems for Radiation Processing

2.3 International Commission on Radiation Units and Measurements (ICRU) Reports:³

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

ICRU 17 Radiation Dosimetry: X-rays Generated at Potentials of 5 to 150 kV

ICRU 34 The Dosimetry of Pulsed Radiation

ICRU 35 Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV

ICRU 60 Fundamental Quantities and Units for Ionizing Radiation

2.4 NCRP Publications:⁴

NCRP Report No. 69, Dosimetry of X-Ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV, December 1981

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 $d\bar{\epsilon}$ by dm , where $d\bar{\epsilon}$ is the mean incremental energy imparted by ionizing radiation to matter of incremental mass dm (see ICRU 60).

$$D = d\bar{\epsilon}/dm$$

3.1.1.1 *Discussion*—The discontinued unit for absorbed dose is the rad (1 rad = 100 erg/g = 0.01 Gy). Absorbed dose is sometimes referred to simply as dose. For a photon source under conditions of charged particle equilibrium, the absorbed dose, D , may be expressed as follows:

$$D = \Phi E \mu_{en}/\rho$$

where:

Φ = particle fluence (particles/m²),

E = energy of the ionizing radiation (J), and

μ_{en}/ρ = mass energy absorption coefficient (m²/kg).

If bremsstrahlung production within the specified material is negligible, the mass energy absorption coefficient (μ_{en}/ρ) is equal to the mass energy transfer coefficient (μ_{tr}/ρ), and absorbed dose is equal to kerma if, in addition, charged particle equilibrium exists.

³ Available from the International Commission on Radiation Units and Measurements, 7910 Woodmont Ave., Suite 800, Bethesda, MD 20814, USA.

⁴ Available from the National Council on Radiation Protection and Measurements, 7910 Woodmont Ave., Bethesda, MD 20814, USA.

3.1.2 *absorbed-dose mapping*—measurement of absorbed dose within process load using dosimeters placed at specified locations to produce a one-, two- or three-dimensional distribution of absorbed dose, thus rendering a map of absorbed-dose values.

3.1.3 *absorbed-dose rate, \dot{D}* —absorbed dose in a material per incremental time interval, that is, the quotient of dD by dt (see ICRU 60).

$$\dot{D} = dD/dt$$

SI Unit: Gy·s⁻¹

3.1.3.1 *Discussion*—The absorbed-dose rate can be specified in terms of average value of \dot{D} over long-time intervals, for example, in units of Gy·min⁻¹ or Gy·h⁻¹.

3.1.4 *calibration*—process whereby the response of a measuring system or measuring instrument is characterized through comparison with an appropriate standard that is traceable to, and consistent with, a national standard.

3.1.5 *canister*—durable, reusable container, usually an aluminum or steel cylinder, used to house a product (for example, factory-reared insects in packaging containers) during the radiation process.

3.1.5.1 *Discussion*—Canisters are not used in some applications in which the packaging container is sufficiently rigid and the design of the irradiator is appropriate.

3.1.6 *dose uniformity ratio*—ratio of maximum to minimum absorbed dose within the process load. The concept is also referred to as the max/min dose ratio.

3.1.7 *dosimeter*—device that, when irradiated, exhibits a quantifiable change in some property of the device which can be related to absorbed dose in a given material using appropriate analytical instrumentation and techniques.

3.1.8 *dosimeter set*—one or more dosimeters used to measure the absorbed dose at a location and whose average reading is used to determine absorbed dose at that location.

3.1.9 *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.

3.1.10 *factory-reared insects*—insects that are reared in large quantity in a laboratory or factory setting for use, following reproductive sterilization through irradiation, as live animals in pest management programs.

3.1.11 *installation qualification*—obtaining and documenting evidence that the irradiator, with all its associated equipment and instrumentation, has been provided and installed in accordance with specifications.

3.1.12 *irradiator turntable*—device used to rotate the canister during the radiation process so as to improve dose uniformity.

3.1.12.1 *Discussion*—An irradiator turntable is often referred to as a turntable. Some irradiator geometries, for example, with an annular array of radiation sources surrounding the product, may not need a turntable.



3.1.13 *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.

3.1.14 *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.

3.1.15 *operational qualification*—obtaining and documenting evidence that installed equipment and instrumentation operate within predetermined limits when used in accordance with operational procedures.

3.1.16 *packaging container*—container such as a paper cup with lid, plastic bag, or plastic bottle that is used to hold factory-reared insects during irradiation and, typically, during subsequent shipment from the irradiation facility to the release site.

3.1.17 *performance qualification*—obtaining and documenting evidence that the equipment and instrumentation, as installed and operated in accordance with operation procedures, consistently perform according to predetermined criteria and thereby yield product that meets specifications.

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

3.1.19 *radiation-sensitive indicator*—material such as a coated or impregnated adhesive-back (or adhesive-front) substrate, ink, or coating which may be affixed to or printed on the irradiated sample and which undergoes a visual change when exposed to ionizing radiation (see ISO/ASTM Guide 51539).

3.1.19.1 *Discussion*—Radiation-sensitive indicators are often referred to as “indicators.” Indicators may be used to show that products have been exposed to ionizing radiation. They can be used to provide a visual and qualitative indication of radiation exposure and can be used to distinguish between irradiated and unirradiated samples. Indicators cannot be used as a substitute for proper dosimetry.

3.1.20 *reference-standard dosimeter*—dosimeter of high metrological quality, used as a standard to provide measurements traceable to and consistent with measurements made with primary-standard dosimeters (see ISO/ASTM Guide 51261).

3.1.21 *routine dosimeter*—dosimeter calibrated against a primary-, reference-, or transfer-standard dosimeter and used for routine absorbed-dose measurement (see ISO/ASTM Guide 51261).

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

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

3.1.23 *traceability*—see *measurement traceability*.

3.1.24 *transfer-standard dosimeter*—dosimeter, often a reference-standard dosimeter, suitable for transport between different locations, used to compare absorbed-dose measurements (see ISO/ASTM Guide 51261).

3.1.25 *transit dose*—absorbed dose delivered to irradiated samples while the item to be irradiated in a fixed or turntable position moves into and out of that position or while the movable source moves into and out of its irradiation position.

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 60; that document, therefore, may be used as an alternative reference.

4. Significance and use

4.1 The major use of factory-reared insects is in sterile release programs (for example, Sterile Insect Technique, or SIT) for suppressing or eradicating pest populations (1)⁵. Large numbers of reproductively sterile (irradiated) insects are released into an area where a wild “target population” of the same species exists. The wild population is reduced to the extent that the sterile males are successful in mating with wild females. The radiation dose to the factory-reared insects should be within a range that induces the desired level of sterility without substantially reducing the ability of factory-reared males to compete with wild males for mates. Species targeted by SIT programs are typically major pests affecting agriculture or human health, so the assurance by standardized dosimetry that insects have been properly irradiated is of crucial importance to agriculture growers, agricultural regulators, public health officials, and the public (1-4). The irradiator operator must demonstrate by means of accurate absorbed-dose measurements that all insects will receive absorbed dose within the specified range.

4.2 Another use of factory-reared insects is in the production of parasitoids for release against populations of insect pests (5). Parasitoids are insects that spend the larval stage feeding within the body of a “host” species, typically killing the host. In some parasitoid programs, factory-reared host insects are irradiated before being offered to parasitoids. This eliminates the need to separate unparasitized hosts from parasitoids so that fertile, unparasitized host insects are not inadvertently released into the field.

4.3 Factory-reared insects may be treated with ionizing radiation, such as gamma radiation from ¹³⁷Cs or ⁶⁰Co sources, or X-rays or electrons from accelerators. Gamma irradiation of insects is usually carried out in small, fixed-geometry, dry-storage irradiators (6-8). Dosimetry methods for gamma irradiation of insects have been demonstrated and include useful procedures for mapping the absorbed dose throughout the volume of the insect canister in these small irradiators (ASTM Practice E 2116 and Ref (9)) as well as large-scale gamma irradiators (ISO/ASTM Practice 51702 and Ref (10)).

⁵ The boldface numbers in parentheses refer to the bibliography at the end of this standard.



4.4 Specifications for irradiation of factory-reared insects include a lower limit of absorbed dose and may include a central target dose and an upper limit. These values are based on program requirements and on scientific data on effects of absorbed dose on the sterility, viability, and competitiveness of the factory-reared insects.

4.5 For each irradiator, absorbed-dose rate at a reference position within the irradiated volume of insects or simulated product is measured using a transfer- or reference-standard dosimetry system. That measurement may be used to calculate the timer setting, conveyor speed, or other parameter required to deliver the specified absorbed dose to the insects.

4.6 Absorbed-dose mapping for establishing magnitudes and locations of D_{\min} and D_{\max} is performed using actual product or simulated product (9).

4.7 Dosimetry is part of a measurement quality assurance plan that is applied to ensure that the radiation process meets predetermined specifications (11).

5. Types of facilities and modes of operation

5.1 *Self-Contained Dry-Source Irradiators* (see Ref (12))—Most insect sterilization is accomplished by using gamma radiation from either ^{137}Cs or ^{60}Co self-contained irradiators. These devices house the radiation source in a protective shield of lead (or other appropriate high atomic number material), and usually have a mechanism to rotate or lower the canister from the load position to the irradiation position.

5.1.1 A common method is to distribute the source in an annular array. During irradiation, the sample of factory-reared insects is located at the center of the array, where the absorbed-dose distribution is relatively uniform. In this design, an irradiator turntable would not normally be necessary.

5.1.2 A second method is to rotate the canister holding the insects on an irradiator turntable within the radiation field to achieve a more uniform dose distribution within the process load. The axis of rotation should be parallel to the source pencils (see 6.1.1), which are generally vertical.

5.2 *Large-Scale Gamma Irradiators*—Gamma irradiation of insects is also carried out in large-scale irradiators, either pool-type or dry-storage. In these facilities, the source typically consists of a series of rods (pencils) that contain ^{60}Co and can be raised or lowered into a large irradiation room. When retracted from the irradiation room, the source is shielded by water (pool-type), or lead or other appropriate high atomic number material (dry-storage), or both.

5.2.1 *Continuous Operation*—A common method of use is for samples of insects to be carried on a conveyor in one or more revolutions around a central source, resulting in a relatively uniform absorbed-dose distribution. The source is retracted from the irradiation room only when the irradiator is not in use.

5.2.2 *Batch Operation*—An alternative method of use is to place canister(s) of insects into the irradiation room while the source is shielded, and then raise or lower the source into the chamber for the length of time required to achieve the desired absorbed dose.

5.3 *Electron Accelerator*—Accelerator-generated radiation is in the form of electrons or X-rays (bremsstrahlung).

5.3.1 Typically, accelerators produce a narrow electron beam that is diffused to cover the length and width of a target area, which may be the location where samples are irradiated (see 5.3.3) or an X-ray target (see 5.3.2). Diffusion may be accomplished using a magnetic scanner (to sweep the beam back and forth rapidly), magnetic defocusing lens, or scattering foils.

5.3.2 X-rays (bremsstrahlung) are produced by striking an X-ray target with an electron beam. The target is made of tungsten, tantalum, or other metal with a high atomic number, high melting temperature, and high thermal conductivity.

NOTE 2—Insects could be irradiated using a self-contained portable X-ray irradiator. The X-rays (bremsstrahlung) are produced in a conventional manner, but the unit is totally self-contained (requiring no additional shielding).

5.3.3 For processing, samples are typically carried on a moving conveyor through the electron or X-ray beam. Because of the narrow angular distribution of the radiation, use of continuously moving conveyors (rather than static-irradiation or shuffle-dwell systems) enhances dose uniformity.

5.3.4 Additional information on electron accelerator facilities and modes of operation may be found in ISO/ASTM Practices 51649 (electron beam) and 51608 (X-ray).

6. Radiation source characteristics

6.1 Gamma Irradiators:

6.1.1 The radiation source used in the gamma facilities considered in this guide consists of sealed elements of ^{60}Co or ^{137}Cs which are typically linear rods or “pencils” arranged in one or more planar or cylindrical arrays.

6.1.2 Cobalt-60 emits photons with energies of approximately 1.17 and 1.33 MeV in nearly equal proportions (13). Cesium-137 emits photons with energies of approximately 0.662 MeV (13).

6.1.3 The half-lives for ^{60}Co and ^{137}Cs are 5.2708 years (14) and 30.07 years (15), respectively.

6.1.4 For gamma-radiation sources, the only variation in the source output is the known reduction in the activity caused by radioactive decay. The reduction in the source strength, and the required increase in the irradiation time, may be calculated (see 9.3.4) or obtained from tables provided by the irradiator manufacturer.

6.2 Electron Accelerator (Electron and X-ray Modes):

6.2.1 For an electron accelerator, the two principal beam characteristics are the energy spectrum and the average beam current. The electron energy spectrum affects the variation of absorbed dose with depth in a given material, and the average beam current affects the absorbed-dose rate.

6.2.1.1 Direct-action electron accelerators employ dc or pulsed high-voltage generators typically produce electron energies up to 5 MeV.

6.2.1.2 Indirect-action electron accelerators use microwave or very high frequency (VHF) ac power to produce electron energies typically from 5 MeV to 15 MeV.

6.2.2 For an X-ray (bremsstrahlung) facility, besides beam characteristics noted in 6.2.1, X-ray target design is a critical



parameter. X-rays are similar to gamma radiation from radioactive isotopic sources. Although their effects on materials are generally similar, these kinds of radiation differ in their energy spectra, angular distributions, and absorbed-dose rates. The continuous energy spectrum of the X-rays (bremsstrahlung) varies from approximately 35 keV up to the maximum energy of the electrons incident on the X-ray target (see ISO/ASTM Practice 51608). In some X-ray facilities, spectrum filtration is used to reduce the low energy component of the radiation, thus improving dose uniformity.

7. Dosimetry systems

7.1 Description of Dosimeter Classes:

7.1.1 Dosimeters may be divided into four basic classes according to their accuracy and areas of application: primary standard, reference standard, transfer standard, and routine dosimeters. ISO/ASTM Guide 51261 provides information about the selection of dosimetry systems for different applications. All classes of dosimeters, except primary standard, require calibration before their use.

7.1.1.1 *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 (see ISO/ASTM Guide 51261, ICRU Reports 14, 17, 34, and 35 and NCRP Report 69).

7.1.1.2 *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. For insect irradiators, the following reference-standard dosimeters may be suitable: ferrous sulfate (Fricke) aqueous solution (ASTM Practice E 1026), alanine dosimeters (ISO/ASTM Practice 51607), radiochromic solutions (ISO/ASTM Practice 51540 and Ref (16)), and ethanol-chlorobenzene solution (ISO/ASTM Practice 51538).

7.1.1.3 *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 the facility. These dosimeters should be 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.

7.1.1.4 *Routine Dosimeters*—Routine dosimeters may be used for radiation process quality control, dose monitoring, and 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 dose ranges, are given in ISO/ASTM Guide 51261. Examples of dosimeters that may be useful in routine processing or absorbed-dose mapping for insect irradiation facilities are listed in Annex A1.

7.2 Calibration of Dosimetry Systems:

7.2.1 Prior to use, the dosimetry system (consisting of a specific batch of dosimeters and specific measurement instruments) 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. Calibration methods are described in ISO/ASTM Guide 51261.

7.2.2 Irradiation is a critical component of the calibration of the dosimetry system.

7.2.3 *Calibration of Reference or Transfer Dosimeters*—Calibration irradiations shall be performed at an accredited calibration laboratory, or in-house calibration facility meeting the requirements of ISO/ASTM Practice 51400, that provides an absorbed dose (or absorbed-dose rate) having measurement traceability to nationally or internationally recognized standards.

7.2.4 *Calibration of Routine Dosimeters*—Calibration irradiations may be performed per 7.2.3, or at 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 *Measurement Instrument Calibration and Performance Verification*—For the calibration of instruments, and for the verification of instrument performance 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. Installation qualification

8.1 *Objective*—The purpose of an installation qualification program is to obtain and document evidence that the irradiator and measurement instruments have been delivered and installed in accordance with their specifications. Installation qualification includes documentation of the irradiator equipment and measurement instruments; establishment of testing, operation and calibration procedures for their use; and verification that the installed irradiator equipment and measurement instruments operate according to specification.

NOTE 3—Table A2.1 gives some recommended steps in the following areas: installation qualification, operational qualification, performance qualification, and routine product processing. The recommended steps in Table A2.1 are not meant to be exhaustive.

8.2 *Equipment Documentation*—Establish and document an installation qualification program that includes descriptions of the instrumentation and 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:

8.2.1 A description of the irradiator's specifications, characteristics and parameters, including any modifications made during or after installation,

8.2.2 A description of the location of the irradiator within the operator's premises, including its relation to any means provided for segregating unirradiated from irradiated products,



8.2.3 Operating instructions and standard operating procedures for the irradiator and associated measurement instruments,

8.2.4 Description of the construction and operation of the product handling system,

8.2.5 Licensing and safety documents and procedures, including those required by regulatory and occupational health and safety agencies,

8.2.6 A description of a calibration program to ensure that all processing equipment that may influence absorbed-dose delivery is calibrated periodically (for example, the reset timer mechanism on a gamma irradiator), and

8.2.7 Descriptions, operating procedures, and calibration procedures for associated measurement instruments or systems (such as those used for dosimetry).

8.3 *Equipment Testing and Calibration*—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 Implement a documented calibration program (8.2.6) to ensure that all processing equipment and instrumentation that may influence absorbed-dose delivery are calibrated periodically.

8.3.2 If any modification or change is made to the irradiator equipment or measurement instruments during the installation qualification phase, they shall be re-tested.

8.4 Specific information on installation qualification for various types of facilities can be found in ASTM Practice E 2116 (self-contained dry-storage gamma irradiators) and in ISO/ASTM Practices 51608 (X-ray [bremsstrahlung]), 51649 (electron beam), and 51702 (large-scale gamma facilities).

8.4.1 For self-contained irradiators, installation qualification may begin prior to the shipment of the irradiator to the customer's site.

9. Operational qualification

9.1 *Objective*—The purpose of operational qualification of an irradiation facility is to establish baseline data for evaluating irradiator effectiveness, predictability, and reproducibility for the range of conditions of operation for key processing parameters that affect absorbed dose in the product. As part of this process, dosimetry may, for example, be performed to: (1) establish relationships between the absorbed dose for a reproducible geometry and the operating parameters of the irradiator, (2) measure absorbed-dose distributions in insect-equivalent material and other reference materials, (3) characterize absorbed-dose variations when irradiator and processing parameters fluctuate statistically through normal operations, and (4) measure the absorbed-dose rate at a reference position within the canister filled with insects or simulated product.

9.1.1 For self-contained irradiators, operational qualification may begin prior to the shipment of the irradiator to the customer's site. As part of release-for-shipment criteria, the irradiator manufacturer may perform absorbed-dose mapping to establish baseline data. After the unit is installed at the user's site, operational qualification is performed as part of the user's quality assurance plan (see ASTM Practice E 2116).

9.1.2 Specific information on operational qualification for facilities other than self-contained dry-storage gamma irradiators can be found in ISO/ASTM Practices 51608 (for X-ray facilities), 51649 (for electron beam facilities), and 51702 (for large-scale gamma facilities).

9.2 *Dosimetry Systems*—Calibrate the routine dosimetry system to be used at the facility as discussed in 7.2.

9.3 *Irradiator Characterization*—The absorbed dose received by any portion of product (in this case, insects) depends on the irradiator parameters (such as the source activity at the time of irradiation, the geometry of the source, the source-to-product distance, the irradiation geometry) and the processing parameters (such as the irradiation time, the product composition and density, and the loading configuration).

9.3.1 *Absorbed Dose Rate*—A reference- or transfer-standard dosimetry system, traceable to nationally or internationally recognized standards, shall be used to measure the absorbed-dose rate within product or simulated product at a reference position (such as the center of the product or simulated product volume) in near worst-case geometry (such as when the product or simulated product nearly completely fills the irradiation volume). The absorbed dose rate at the reference position shall have a reproducible and documented relationship to the absorbed dose rate at locations of maximum (D_{\max}) and minimum (D_{\min}) dose rate (see 9.3.2). This measurement of absorbed dose rate at a reference position may be used when calculating the timer setting necessary to deliver the specified range of absorbed dose to the insects (see 10.4).

9.3.1.1 Most manufacturers of insect irradiators use a reference-standard dosimetry system to measure absorbed dose rate at a reference position within simulated product following installation of (or, in the case of some self-contained units, before shipping) the irradiator.

9.3.1.2 Reference- or transfer-standard measurement of absorbed dose rate at a reference position should be repeated periodically (for example, every three years for a gamma facility) and following any changes to the source, geometry, or other irradiator parameter that could affect absorbed dose rate.

NOTE 4—To the degree possible, subsequent re-calibrations of dose rate should be performed under similar conditions to allow direct comparison among test results. Results obtained when re-calibrating an irradiator should agree with results of previous calibrations, once source decay (if applicable) or other known factors that may affect dose are taken into account. Unexplained discrepancies that are beyond the limit of combined uncertainty for the two procedures should be investigated, as they could indicate problems with the dosimetry or the operation of the irradiator.

NOTE 5—When an irradiator's absorbed dose rate is measured per 9.3.1, it is convenient to calibrate the facility's routine dosimetry system concurrently per 7.2.4. ISO/ASTM Guide 51261 and Ref (17) provide guidelines on procedures and numbers of sets of dosimeters needed.

9.3.2 *Dose Mapping*—Ideally, the irradiation process is designed to irradiate insects uniformly throughout the irradiated volume; in reality, a certain variation in absorbed-dose through the product will exist. The irradiator characterization process includes mapping the absorbed-dose distributions for samples of insects or simulated product, and identifying the magnitudes and locations D_{\max} and D_{\min} within the samples. Dosimetry data from previously characterized irradiators of the



same design or theoretical calculations may provide useful information for determining the number and locations of dosimeter sets needed for this characterization process.

9.3.2.1 Map the absorbed-dose distribution by placing dosimeter sets throughout the volume of actual or simulated product (see ASTM Guide E 2303). Select placement patterns that can identify the locations of D_{\max} and D_{\min} .

NOTE 6—In the case of static irradiations (such as when the product is located at the center of an annular source array of a self-contained dry-storage irradiator), the dose mapping should be done in three dimensions. When product is irradiated on turntables, the dose mapping may be done in two dimensions, such as on an arbitrary vertical plane through the axis of rotation. In this case, the result is a three-dimensional mapping due to the axial symmetry that results from rotation.

9.3.2.2 Changes in the product handling system (for example, irradiator turntable) or radiation source characteristics require a new absorbed-dose mapping.

9.3.3 In gamma-radiation facilities that operate in batch mode, the transit dose should be small relative to the total dose delivered to the insects (for example, <1 %) in order to facilitate reproducible absorbed-dose delivery. The transit dose and its relation to total absorbed dose should be considered and quantified, if necessary. Procedures for measuring and correcting for transit dose in terms of transit time are given in ISO/ASTM Guide 51261.

9.3.4 An important calculation in the use of gamma-radiation sources is the correction for radioactivity decay. For a pure radionuclide source, the exponential loss of activity, A , is given by:

$$A_t = A_0 e^{-\lambda t} \quad (1)$$

Where A_t is the activity at time t , A_0 is the known activity at some earlier time ($t = 0$), and λ is the decay constant for the given radionuclide. Daily decay constants (λ_d) for radionuclides commonly used in gamma-radiation sources are:

$$\text{For } ^{60}\text{Co}, \lambda_d = 3.6005 \times 10^{-4} \text{ day}^{-1} \quad (2)$$

$$\text{For } ^{137}\text{Cs}, \lambda_d = 6.311 \times 10^{-5} \text{ day}^{-1} \quad (3)$$

These constants are based on half lives of 5.2708 years for ^{60}Co (14) and 30.07 years for ^{137}Cs (15). In practice, absorbed dose rate can be substituted for activity in Eq 1. The absorbed-dose rate that was initially established during operational qualification or during a subsequent calibration of the irradiator with reference- or transfer-standard dosimeters (see 9.3.1) provides the value at $t = 0$. The absorbed-dose rate at t days later can then be computed from Eq 1 using λ_d for the appropriate radionuclide from Eq 2 or Eq 3.

10. Performance qualification

10.1 *Objective*—The purpose of dosimetry in performance qualification is to ensure that the absorbed-dose requirements for a particular product can be satisfied. In sterile insect release programs, the end user or a regulatory agency typically specifies the minimum absorbed dose necessary to produce the desired level of reproductive sterility. Although a maximum absorbed dose is not usually specified, the ability of sterile insects to successfully compete for mates will decline with

increased dose. Understanding the dose distribution throughout the process load is critical for ensuring program security and sterile insect quality. This is accomplished by absorbed-dose mapping (see 10.3) of the specific product (or simulated product) and specific product loading configuration to determine the magnitude and location of D_{\max} and D_{\min} , and to establish the appropriate values for the irradiator timer setting, conveyor speed, or other parameter(s) necessary to achieve the absorbed doses within the set requirements.

NOTE 7—In sterile insect programs, tests of absorbed dose versus sterility and viability of irradiated insects are critical (11). Thus, tests to evaluate the sterility and competitiveness of irradiated insects are conducted periodically to provide evidence that the dose limit and other aspects of sterilization processing (for example, induction of hypoxia prior to irradiation) are still valid.

10.2 *Product Loading Configuration*—A loading configuration for the irradiation should be established for each product type. The documentation for this loading configuration shall include specifications for parameters that influence the absorbed dose distribution. For irradiation of insects, these parameters could include species, mass or volume of the insects, size and shape of the packaging container, position of the packaging container(s) within the canister, and position and composition of any plugs of simulated product that are used routinely to improve dose uniformity by excluding insects from portions of the canister.

NOTE 8—The canister shall not be loaded beyond its designed maximum volume.

10.3 *Product or Simulated Product Absorbed-Dose Mapping*—For each type of insect treated in the irradiation facility, there is a minimum dose to achieve the required level of sterility (or other desired effect) and a maximum dose that the animal can tolerate without unacceptable degradation in quality. Establish the locations of the regions of D_{\max} and D_{\min} for each selected product loading configuration by placing dosimeter sets throughout the volume of insects or simulated product within the process load (see ASTM Guide E 2303). Concentrate the dosimeters in regions of D_{\max} and D_{\min} with fewer dosimeters placed in areas likely to receive intermediate absorbed dose. In many insect irradiation applications, the product is relatively close to the radiation sources, resulting in pronounced absorbed-dose gradients near the periphery of the volume of the sample. It is important, therefore, to choose a dosimeter that is small enough to detect these gradients. Dosimeter film in strips or sheets may be employed to obtain useful information (9).

10.3.1 Results of absorbed-dose mapping will be used to determine the degree of dose uniformity. Because the quality and viability of insects tends to decline rapidly as radiation dose is increased, a small dose-uniformity ratio can be critical to ensuring the successful deployment of sterile insects. In some cases, irradiator or processing parameters can be adjusted to improve dose uniformity (for example, installing an irradiator turntable or using plugs of simulated product to exclude insects from areas with low or high dose rates).

10.3.2 If any changes that could affect the magnitude or location of the absorbed dose extremes are made to the



irradiator or mode of operation (for example, those noted in 10.3.1), repeat the absorbed-dose mapping to the extent necessary to establish the effect.

10.3.3 *Reference Dose Location*—Identify a reference dose location for each loading configuration. This may be, for example, the location of D_{\min} or D_{\max} , or an alternate location in or on the canister or packaging container. Dosimeter sets should be placed at the reference dose location during routine dosimetry (see 11.2), so accessibility should be considered. The absorbed dose at this location shall have a reproducible and documented relationship to the absorbed dose at the locations of D_{\min} and D_{\max} within the process load.

10.4 *Establishing Operating Parameters*—To ensure that the absorbed dose received by processed insects is within specified limits, values of operating parameters should be established for each combination of insect species, loading configuration, and dose specification. Value(s) of all parameters that affect absorbed dose are established based on results of the absorbed-dose mapping described in 10.3 in conjunction with results of reference- or transfer-standard measurements of absorbed dose rate at a reference position (see 9.3.1). For most insect irradiation facilities, the absorbed dose delivered to the insects is controlled by adjusting a single operating parameter such as timer setting or conveyor speed. The value that is established for that parameter shall result in an absorbed dose distribution that is within specified limits throughout the volume of irradiated insects.

11. Routine product processing

11.1 *Processing Parameters and Control*—For product processing, set the operating parameters as established during performance qualification, taking into account source decay if applicable. All critical operating parameters that can affect the absorbed-dose distribution shall be controlled, monitored, and documented during routine processing to help ensure that the insects are processed in accordance with specifications. If the values of the operating parameters deviate from prescribed processing limits, take appropriate actions.

11.2 *Routine Dosimetry*—Routine processing monitoring shall be performed using routine dosimetry as part of the verification process for establishing that the radiation process is under control. Routine measurements of absorbed-dose to the product will help ensure that all insects have been treated within the prescribed dose limits for the process. In addition, routine dosimetry may be timed to coincide with other quality control tests such as bioassays of reproductive sterility or sterile insect performance, or may be used to assess effects of partially loaded canisters (see 11.6).

NOTE 9—In the routine operation of an insect irradiator, absorbed-dose measurements made on the product at regular intervals provide the operator and regulatory authorities with an independent quality control record of the process. When D_{\min} has been set by the regulatory authorities, the ability to measure that absorbed dose with proper statistical control is a critical requisite of Good Manufacturing Practices.

11.2.1 *Dosimeter Location*—Place one or more dosimeter sets on the product at the reference dose location (see 10.3.3). The absorbed dose at this location has a quantitative and reproducible relationship with D_{\max} and D_{\min} .

NOTE 10—The absorbed-dose distribution in the product is already known from operational and performance qualification, and from the most recent dose mapping. However, strategic placement of a sufficient number of dosimeter sets as part of routine dosimetry can serve to confirm that the absorbed dose delivered is within specification.

11.2.2 *Dosimeter Placement Frequency*—Select a sufficient number of process loads in which to place dosimeter sets in order to verify that the measurements of absorbed dose are statistically meaningful and absorbed dose received by the insects falls within specified limits.

11.2.2.1 *Gamma-radiation Facilities*—Routine dosimetry should be performed at specified periodic intervals, which may be daily, weekly, or monthly.

NOTE 11—Although source output in a gamma irradiator is affected only by radioactive decay, frequent routine dosimetry can detect otherwise unnoticed processing problems which have, at times, resulted in the release of large numbers of fertile insect pests.

11.2.2.2 *Electron and X-ray (bremsstrahlung) Facilities*—Always place dosimeter sets at the start of a production run. For long runs, in addition to this, place dosimeter sets near the middle of the run, at the end of the run, and at other intervals as appropriate.

NOTE 12—For production runs with contiguous process loads, the first and last process loads may experience dose distributions different from the other units. If prior dosimetry data indicate that an unacceptable dose distribution exists for these two end loads, place compensating dummies adjacent to these units so as to make their dose distributions acceptable.

11.3 Radiation-Sensitive Indicators:

11.3.1 The purpose of radiation-sensitive indicators is to visually determine whether or not a specific container of insects has been exposed to ionizing radiation, rather than to measure different absorbed-dose levels (see ISO/ASTM Guide 51539). The state of each indicator should be checked before and immediately after irradiation, and, if applicable, again at the site where adult insects emerge and are processed for release. Indicators do not give a quantitative value of absorbed dose, and therefore are not a substitute for routine dosimeters used in routine process monitoring.

NOTE 13—This does not preclude the use of calibrated radiochromic film as a dosimeter read with a transmission/reflectance densitometer as listed in Annex A1.

11.3.2 *Radiation-Sensitive Indicator Location*—One or more indicators should be placed in or on the packaging container as required by the program.

NOTE 14—If insects are irradiated in sealed packaging containers that are shipped unopened to a release site, indicators should be placed so that they will be clearly visible, following irradiation, without having to open the packaging container. If portions of the packaging container are transparent, the indicator(s) should, for reasons of security, be placed inside the sealed packaging container in such manner that it can be read without opening the container.

11.3.3 *Radiation-Sensitive Indicator Placement Frequency*—Placement frequency for radiation-sensitive indicators will vary with program requirements and intended use of the irradiated insects. For sterile insect release programs, a common specification is to place an indicator in or on each packaging container of factory-reared insects.



11.4 *Environmental Effects*—The response of a dosimeter or radiation-sensitive indicator may be affected by exposure to such environmental conditions as heat, high humidity, ultraviolet radiation, or gases produced during the radiation process. Dosimeter response should be corrected for any effects that arise from changes in the environment of the dosimeter during the radiation process or pre- or post-irradiation storage. A radiation-sensitive indicator's response cannot be corrected for such conditions, and they should not be used in inappropriate environments. Care should also be taken in handling and storage of dosimeters and indicators before and after irradiation (see ISO/ASTM Guides 51261 and 51539, and practices for individual dosimetry systems listed in Annex A1).

11.5 *Chilled Product*—Absorbed dose is not a function of the temperature of the insects being irradiated. The response of a dosimeter or radiation-sensitive indicator, however, may be a function of their temperature. Dose-mapping information for simulated product (representing the actual product geometry or near-worst case geometry) at ambient temperature can be applied to chilled insects. Determine the temperature of the dosimeter during irradiation of chilled insects and apply the appropriate temperature correction. Dosimeters that exhibit a highly temperature-dependent response should not be placed in locations with large temperature gradients (see ISO/ASTM Guide 51261 and the practices for individual dosimetry systems listed in Annex A1). Radiation-sensitive indicators should not be used on chilled insects unless they have been evaluated and proven to perform adequately at the temperatures used for processing samples.

11.6 *Partially Loaded Canisters*—Irradiations may be performed using less product than was used in dose mapping that was performed with the near-worst case geometry (for example, when the canister is nearly filled with product or simulated product). In that case, the D_{\max} received by the insects may be greater than the D_{\max} measured during dose mapping for operational qualification (10.3). Care should be taken, therefore, to ensure that the specified limits for D_{\max} are not exceeded during routine use. Changes to the absorbed-dose distribution arising from partially loaded canisters may be minimized by the use of simulated product placed at the

appropriate locations in the irradiation volume (so that the near worst-case is approximated), and by placing the sample of insects in the center of the canister.

12. Measurement uncertainty

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

12.2 Components of uncertainty shall be identified as belonging to one of two groups:

12.2.1 *Type A*—Those which are evaluated by statistical methods, or

12.2.2 *Type B*—Those which are evaluated by other means.

12.3 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.

NOTE 15—The identification of Type A and Type B uncertainties is based on methodology for estimating uncertainties published in 1995 by the International Organization for Standardization (ISO) in the Guide to the Expression of Uncertainty in Measurement (18). 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 16—ISO/ASTM Guide 51707 defines possible sources of uncertainty in dosimetry performed in radiation processing facilities, and offers procedures for estimating the resulting magnitude of the uncertainties in the measurement of absorbed dose using a dosimetry system. The document defines and discusses basic concepts of measurement, including the 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.

13. Keywords

13.1 absorbed dose; biological control; cesium-137; cobalt-60; electron accelerator; dosimeter; dosimetry; gamma; insect irradiation; insect rearing; ionizing radiation; irradiation; irradiator characterization; parasitoid rearing; radiation; sterile insect technique; X-ray; ICS 17.240

ANNEXES

(informative)

A1. EXAMPLES OF ROUTINE DOSIMETER CHARACTERISTICS

A1.1 Thermoluminescence dosimeter (TLD)

A1.1.1 *Applicable Dose Range*— 10^{-2} to 10^4 Gy.

A1.1.2 *Applicable Dose Rate*— 10^{-2} to 10^{10} Gy/s.

A1.1.3 *Use*—Electron/gamma radiation/X-ray.

A1.1.4 *Physical Characteristics*—The most commonly used materials for TLD are LiF, CaF₂, CaSO₄ and Li₂B₄O₇. The dosimeter is small, and the material is used in the form of powder, pellets, single crystals, or in sealed glass tubes or bulbs

or suspended in plastics. After irradiation, crystalline material is subjected to a carefully controlled heating cycle, when the freed electrons and hole traps recombine with the emission of characteristic light. This heating cycle erases the dose information in the TLD.

A1.1.5 *Instrumentation Characteristics*—TL reader comprising a heating element, photomultiplier tube measurement system to measure light output and convert to absorbed dose. Reader requires skilled operator.



A1.1.6 Environmental Factors:

A1.1.6.1 *Temperature*— Not generally sensitive.

A1.1.6.2 *Humidity*—Not generally sensitive.

A1.1.6.3 *Ambient Light*— Not generally sensitive.

A1.1.6.4 *Time*—TLDs generally fade after irradiation; read-out time after irradiation must be controlled.

A1.1.7 For more information, see Practice E 668 and ISO/ASTM Practice 51956.

A1.2 Radiochromic film dosimeter

A1.2.1 *Applicable Dose Range*—1 to 10^5 Gy.

A1.2.2 *Applicable Dose Rate*— $<10^{13}$ Gy/s.

A1.2.3 *Use*—Electron/gamma radiation/X-ray

A1.2.4 *Physical Characteristics*—These dosimeters consist of leuco (colorless) dyes that become intensely colored upon irradiation. Film thickness varies from a few μm to about 1 mm.

A1.2.5 *Instrumentation Characteristics*—VIS/UV spectrophotometer (various wavelengths) and visible transmission and reflectance densitometers (various filters).

A1.2.6 Environmental Factors:

A1.2.6.1 *Temperature*—This dosimeter has a positive temperature dependence, depending on the film type, and should be protected from temperature extremes.

A1.2.6.2 *Humidity*—Some films are sensitive to humidity (may be hermetically sealed in water-tight plastic envelopes).

A1.2.6.3 *Ambient Light*—These dosimeters are sensitive to ambient light conditions, especially with wavelengths <370 nm.

A1.2.6.4 *Time*—Dosimeter reading may fade with time after exposure.

A1.2.7 For more information, see ISO/ASTM Practice 51275 and Ref (17).

A1.3 Alanine EPR dosimetry system

A1.3.1 *Applicable Dose Range*—1 to 10^5 Gy.

A1.3.2 *Applicable Dose Rate*— $<10^8$ Gy/s.

A1.3.3 *Use*—Electron/gamma radiation/X-ray.

A1.3.4 *Physical Characteristics*—This dosimeter is used in the form of tablets, small rods, rope of 3-mm to 5-mm diameter and various lengths, or on bar-coded film strips, consisting primarily of α -alanine and a small amount of paraffin or other binder.

A1.3.5 *Instrumentation Characteristics*—EPR spectrometer.

A1.3.6 Environmental Factors:

A1.3.6.1 *Temperature*—Temperature dependence is linear for doses $<10^4$ Gy.

A1.3.6.2 *Humidity*—Somewhat sensitive to humidity (may require preconditioning).

A1.3.6.3 *Ambient Light*—Not generally sensitive to ambient light.

A1.3.6.4 *Time*—Dosimeter reading may change with time after exposure.

A1.3.7 For more information, see ISO/ASTM Practice 51607.

A1.4 Photo-fluorescent film dosimetry system

A1.4.1 *Applicable Dose Range*—20 to 3×10^5 Gy.

A1.4.2 *Applicable Dose Rate*—0.3 to 2×10^4 Gy/s.

A1.4.3 *Use*—Electron/gamma radiation/X-ray.

A1.4.3.1 Radiation energy range for photons of 0.05 to 10 MeV.

A1.4.3.2 Radiation energy range for electrons of 0.1 to 10 MeV.

A1.4.4 *Physical Characteristics*—Alkali-halide based photo-fluorescent film, sufficiently transparent to both the excitation and emission wavelengths.

A1.4.5 *Instrumentation Characteristics*—Fluorimeter; light source and light detector may be on the same or opposite sides of film.

A1.4.6 Environmental Factors:

A1.4.6.1 *Temperature*—Acceptable range of -20 to $+60^\circ\text{C}$; radiation response of unirradiated dosimeters not affected by temperatures within that range.

A1.4.6.2 *Humidity*—Radiation response typically not affected by humidity.

A1.4.6.3 *Ambient Light*—Dosimeters are sensitive to light, especially during the irradiation and stabilization periods.

A1.4.6.4 *Time*—Signal increases with time following irradiation and requires a signal development process, which can be accelerated and stabilized by heat-treating the dosimeters after irradiation and before readout.

A1.4.7 For more information, see ASTM Guide E 2304.