ISO/ASTM 51940:2013(E)



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-induced reproductive sterilization of live insects for use in pest management programs. The primary use of such insects is in the Sterile Insect Technique, where large numbers of reproductively 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 assurance program to ensure that irradiated insects are adequately sterilized and fully competitive or otherwise suitable for their intended purpose.

1.2 This guide provides information on dosimetry for the irradiation of insects for these types of irradiators: self-contained dry-storage ¹³⁷Cs or ⁶⁰Co irradiators, self-contained low-energy X-ray irradiators (maximum processing energies from 150 to 300 keV), large-scale gamma irradiators, and electron accelerators (electron and X-ray modes).

NOTE 2—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 processing at energies over 300 keV), 51649 (electron beam facilities), 51702 (large-scale gamma facilities), and 52116 (self-contained dry-storage gamma facilities), and in Ref (1)² (self-contained X-ray facilities).

1.3 The absorbed dose for insect sterilization is typically within the range of 20 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 document is one of a set of standards that provides recommendations for properly implementing and utilizing dosimetry in radiation processing and describes a means of achieving compliance with the requirements of ASTM Practice E2628. It is intended to be read in conjunction with ASTM E2628.

1.7 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:³

- E170 Terminology Relating to Radiation Measurements and Dosimetry
- E2303 Guide for Absorbed-Dose Mapping in Radiation Processing Facilities
- E2628 Practice for Dosimetry in Radiation Processing
- E2701 Guide for Performance Characterization of Dosimeters and Dosimetry Systems for Use in Radiation Processing
- 2.2 ISO/ASTM Standards:³
- 51261 Practice for Calibration of Routine Dosimetry Systems for Radiation Processing
- 51275 Practice for Use of a Radiochromic Film Dosimetry System
- 51310 Practice for Use of a Radiochromic Optical Waveguide Dosimetry System
- 51539 Guide for the Use of Radiation-Sensitive Indicators
- 51607 Practice for Use of an 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

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² The boldface numbers in parentheses refer to the bibliography at the end of this standard.

³ 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 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
- 52116 Practice for Dosimetry for a Self-Contained Dry-Storage Gamma-Ray Irradiator

2.3 International Commission on Radiation Units and Measurements (ICRU) Reports:⁴

ICRU 85a Fundamental Units and Quantities for Ionizing Radiation

2.4 ISO Standards:⁵

ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories

2.5 Joint Committee for Guides in Metrology (JCGM) Reports:

- JCGM 100:2008, GUM, with minor corrections, Evaluation of measurement data – Guide to the Expression of Uncertainty in Measurement⁶
- JCGM 100:2008, VIM International vocabulary of metrology – Basis and general concepts and associated terms⁷

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 85a).

$D = \mathrm{d}\bar{\varepsilon}/\mathrm{d}m$

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.

3.1.2 *absorbed-dose mapping*—measurement of absorbeddose within an irradiated product 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. Also see ASTM E170. The SI unit is Gy·s⁻¹

 $\dot{D} = dD/dt$

3.1.3.1 *Discussion*—The absorbed-dose rate can be specified in terms of its average value over long-time intervals, for example in units of $\text{Gy}\cdot\text{min}^{-1}$ or $\text{Gy}\cdot\text{h}^{-1}$

3.1.4 *approved laboratory*—laboratory that is a recognized national metrology institute, or has been formally accredited to ISO/IEC 17025, or has a quality system consistent with the requirements of ISO/IEC 17025.

3.1.4.1 *Discussion*—A recognized national metrology institute or other calibration laboratory accredited to ISO/IEC 17025 should be used in order to ensure traceability to a national or international standard. A calibration certificate provided by a laboratory not having formal recognition or accreditation will not necessarily be proof of traceability to a national or international standard.

3.1.5 *calibration [VIM*, 6.11]—set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

3.1.5.1 *Discussion*—Calibration conditions include environmental and irradiation conditions present during irradiation, storage and measurement of the dosimeters that are used for the generation of a calibration curve. To achieve stable environmental conditions, it may be necessary to condition the dosimeters before performing the calibration procedure.

3.1.6 *dose uniformity ratio*—ratio of maximum to minimum absorbed dose within the irradiated product.

3.1.6.1 *Discussion*—The concept is also referred to as the max/min dose ratio.

3.1.7 *dosimeter*—device that, when irradiated, exhibits a quantifiable change that can be related to absorbed dose in a given material using appropriate measurement instruments and procedures.

3.1.8 *dosimeter batch*—quantity of dosimeters made from a specific mass of material with uniform composition, fabricated in a single production run under controlled, consistent conditions and having a unique identification code.

3.1.9 *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.

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

3.1.11 *influence quantity*—quantity that is not the measurand but that affects the result of the measurement.

3.1.11.1 *Discussion*—In radiation processing dosimetry, this term includes temperature, relative humidity, time intervals, light, radiation energy, absorbed-dose rate, and other factors that might affect dosimeter response, as well as quantities associated with the measurement instrument.

3.1.12 *in-situ/in-plant calibration*—calibration where the dosimeter irradiation is performed in the place of use of the routine dosimeters.

3.1.12.1 *Discussion*—In-situ/in-plant calibration of dosimetry systems refers to irradiation of dosimeters along with

⁴ Available from the International Commission on Radiation Units and Measurements, 7910 Woodmont Ave., Suite 800, Bethesda, MD 20814, USA.

⁵ Available from International Organization for Standardization (ISO), 1 Rue de Varembé, Case Postale 56, CH-1211, Geneva 20, Switzerland.

⁶ Document produced by Working Group 1 of the Joint Committee for Guides in Metrology (JCGM/WG 1). Available free of charge at the BIPM website (http://www.bipm.org).

⁷ Document produced by Working Group 2 of the Joint Committee for Guides in Metrology (JCGM/WG 2). Available free of charge at the BIPM website (http://www.bipm.org).

reference or transfer dosimeters, under operating conditions that are representative of the routine processing environment, for the purpose of developing a calibration curve for the routine dosimetry systems.

3.1.13 installation qualification-process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification.

3.1.14 irradiation container-holder in which product is placed during the irradiation process.

3.1.14.1 Discussion-For insect irradiation, the configuration of irradiation containers varies widely with such factors as type and energy of radiation, irradiator design, insect species, insect stage being irradiated, and other process specifications (for example, some insects are irradiated in reduced-oxygen atmospheres, requiring air-tight containers). Irradiation containers for insects range from single-use items such as paper cylinders or plastic bags to reusable canisters of stainless steel or other durable material. When canisters are used, insects are often held secondarily within the canister in a plastic bag or other disposable container.

3.1.15 irradiator turntable-device used to rotate the sample during the irradiation process so as to improve dose uniformity.

3.1.15.1 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.

3.1.16 operational qualification (OQ)-process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

3.1.17 performance qualification (PQ)-process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operation procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification.

3.1.18 radiation-sensitive indicator-material such as a coated or impregnated adhesive-backed substrate, ink, coating or other materials which may be affixed to or printed on the product or irradiation container and which undergoes a visual change when exposed to ionizing radiation (see ISO/ASTM Guide 51539).

3.1.18.1 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.

3.1.19 reference standard dosimetry system-dosimetry system, generally having the highest metrological quality available at a given location or in a given organization, from which measurements made there are derived.

3.1.20 routine dosimetry system-dosimetry system calibrated against a reference standard dosimetry system and used for routine absorbed-dose measurements, including dose mapping and process monitoring.

3.1.21 simulated product-mass of material with absorption and scattering properties similar to those of the product, material or substance to be irradiated.

3.1.21.1 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 in order to compensate for the absence of product, it is sometimes referred to as compensating dummy. When used for absorbed-dose mapping, simulated product is sometimes referred to as a phantom material.

3.1.22 *traceability*—property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

3.1.22.1 Discussion—The unbroken chain of comparisons is called a "traceability chain."

3.1.23 transfer standard dosimetry system-dosimetry system used as an intermediary to calibrate other dosimetry systems.

3.1.24 transit dose-absorbed dose delivered to a product (or a dosimeter) while it travels between the non-irradiation position and the irradiation position, or in the case of a movable source while the source moves into and out of its irradiation position.

3.1.25 type I dosimeter-dosimeter of high metrological quality, the response of which is affected by individual influence quantities in a well-defined way that can be expressed in terms of independent correction factors.

3.1.26 type II dosimeter—dosimeter, the response of which is affected by influence quantities in a complex way that cannot practically be expressed in terms of independent correction factors.

3.2 Definitions of Terms Specific to This Standard:

3.2.1 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.

3.3 Definitions of other terms used in this standard that pertain to radiation measurement and dosimetry may be found in ASTM Terminology E170. Definitions in E170 are compatible with ICRU 85a; 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 insect release programs (for example, Sterile Insect Technique, or SIT) for suppressing or eradicating pest populations (2,3). 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 absorbed by the factory-reared insects should be within a range that induces the desired level of sterility without substantially reducing the ability of factoryreared 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

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dosimetry that insects have been properly irradiated is of crucial importance to agriculture growers, agricultural regulators, public health officials, and the public (3). The irradiator operator must demonstrate by means of accurate absorbed-dose measurements that all insects have received 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 (4). Parasitoids are insects that spend the larval stage feeding within or on 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 137 Cs or 60 Co sources, or X-radiation or electrons from accelerators. Gamma irradiation of insects is often carried out in small, fixed-geometry, dry-storage irradiators (5). Dosimetry methods for gamma and X-ray irradiation of insects have been demonstrated and include useful procedures for measuring the absorbed dose distribution throughout the volume of the irradiation container(s) in these small irradiators (ASTM Practice 52116 and Refs (1,6)) as well as large-scale gamma irradiators (ISO/ASTM Practice 51702 and Ref (7)).

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 To demonstrate control of the radiation process, the absorbed dose must be measured using a calibrated dosimetry system. Regulations or policies under which the facility operates may require the calibration to be traceable to appropriate national or international standards. The radiation-induced change in the dosimeter is evaluated and related to absorbed dose through calibration (ISO/ASTM Practice 51261).

4.6 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 provides a basis for calculating the duration of irradiation, conveyor speed, or other parameter required to deliver the specified absorbed dose to the insects.

4.7 Absorbed-dose mapping for establishing magnitudes and locations of minimum dose (D_{\min}) and maximum dose (D_{\max}) is performed using actual product or simulated product (5).

5. Types of facilities and modes of operation

5.1 *Self-Contained Irradiators* —These devices house the radiation source in a protective shield of lead (or other appropriate high atomic number material), and require no additional or external shielding against radiation. The radiation source could be either a radionuclide or an X-ray tube.

5.1.1 Gamma Irradiators (IAEA Category I, Ref (8,9)— Currently, most reproductive sterilization of insects is accomplished by using gamma radiation from either ¹³⁷Cs or ⁶⁰Co in dry-storage, self-contained irradiators. These irradiators often have a mechanism to move the irradiation container from the load/unload position to the irradiation position and back, or to rotate the irradiation container from a load position to the irradiation position and then to a separate unload position.

5.1.1.1 In a typical configuration, the radionuclide is housed in rods or "pencils" (see 6.1.1) that are distributed in an annular array around the irradiation chamber. For processing, the irradiation container is located at the center of the array, where the absorbed-dose rate is relatively uniform.

5.1.1.2 In an alternative configuration, the radionuclide is contained in a single rod. In this case, the irradiation container is rotated on an irradiator turntable within the irradiation chamber to achieve an acceptably uniform dose. The axis of rotation is parallel to the source rod, which is vertical.

5.1.2 Low-energy X-ray irradiators—Low-energy X-ray irradiators utilize X-ray tubes that consist of an electron source (generally a heated wire, a filament which emits electrons), an electrostatic field to accelerate these electrons and a converter to generate X-radiation. In the currently available irradiators, the converter is present throughout the curved surface of the tube, and hence the X-radiation is emitted in all directions.

5.1.2.1 One method is to operate the irradiator in a batch mode where several canisters of insects are placed around and parallel to the X-ray tube, and revolve around the tube during irradiation while maintaining their orientation (much like chairs on a Ferris wheel), achieving acceptable dose uniformity.

5.1.2.2 An alternate method is to continuously pass trays with insects between two X-ray tubes, providing irradiation from two sides.

5.2 Large-Scale Panoramic Gamma Irradiators—Gamma irradiation of insects is also carried out in large-scale irradiators, either wet-storage or dry-storage. In these facilities, the source typically consists of either a single rod or a series of rods (pencils) that contain ⁶⁰Co and can be raised or lowered into a large irradiation room. When retracted from the irradiation room, the source is shielded by water (wet-storage; IAEA Category IV (10), or lead or other appropriate high atomic number material (dry-storage; IAEA Category II (10), or both.

5.2.1 *Continuous Operation*—A common method of use is for irradiation containers to be carried on a conveyor in one or more revolutions around a central source, resulting in a relatively uniform absorbed dose. 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 irradiation container(s) of insects into the irradiation room while the source is shielded, and then raise or lower the source into the irradiation room for the length of time required to achieve the desired absorbed dose. For this mode of operation, each irradiation container is typically rotated around its own axis to improve dose uniformity.

5.3 *Electron Accelerator*—Accelerator-generated high energy (3-10 MeV) electrons can also be used for insect irradiation. Such irradiators are housed in heavily shielded rooms.

5.3.1 Typically, accelerators produce a narrow electron beam that is scanned to cover the length and width of the insect container, generally a tray.

5.3.2 X-radiation (bremsstrahlung) produced by striking an X-ray target with an electron beam can also be used for this purpose. The target is made of tungsten, tantalum, or other metal with a high atomic number, high melting temperature, and high thermal conductivity.

5.3.3 For processing, insects 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 and X-ray facilities and their modes of operation may be found in ISO/ASTM Practices 51649 (electrons) and 51608 (X-radiation).

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 ⁶⁰Co or ¹³⁷Cs 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. Cesium-137 emits photons with energies of approximately 0.662 MeV (**11**).

6.1.3 The radioactive decay half-lives for 60 Co and 137 Cs are regularly reviewed and updated. The most recent publication by the National Institute of Standards and Technology (**12**) gave values of 1925.20 (±0.25) days for 60 Co and 11018.3 (±9.5) days for 137 Cs. In addition, the 137 Cs radiation source may contain radioimpurities which should be quantified by the source manufacturer.

6.1.4 For gamma sources, the only variation in the source output is the known reduction in the activity caused by radioactive decay. The reduction in the activity (source strength), and the corresponding required increase in the irradiation time, may be calculated (see 8.2.3) or obtained from tables provided by the irradiator manufacturer.

6.2 *Self-Contained Low-Energy X-ray Irradiators*—The electrons that generate X-radiation (bremsstrahlung) are electrostatically accelerated through a small potential difference to energies in the range of a few hundred keV (**13,14**).

6.2.1 Currently, available low-energy X-ray irradiators use tubes that generate X-radiation with a maximum energy of 150 keV. The continuous energy spectrum of the X-radiation extends from approximately 35 keV up to the energy of the electrons (1).

NOTE 3—Because of the low photon energy, some dosimetry systems that are commonly used with gamma irradiators and accelerators are not applicable to low-energy X-ray irradiators (see Annex A1 and Refs (1,13)). For example, Farmer-type ionization chambers are appropriate as reference standard dosimetry systems for low-energy X-ray irradiators (1,13,15).



6.2.2 Energy of the X-radiation influences the size and shape of the irradiation container needed to achieve the desired level of dose uniformity. The tube current influences the absorbed-dose rate and thus time of irradiation.

6.3 *Electron Accelerator (Electron and X-ray Modes)*:

6.3.1 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. Because of low penetration of electrons, electron energy of at least 3 MeV is necessary to achieve useful dose uniformity.

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

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

6.3.2 For an X-ray (bremsstrahlung) facility, besides beam characteristics noted in 6.3.1, X-ray target design is a critical parameter. X-radiation is 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-radiation (bremsstrahlung) extends 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 Dosimeters and Dosimetry Systems— Classification of dosimeters and dosimetry systems is based on the inherent metrological dosimeter properties and the field of application of the dosimetry system (see ASTM Practice E2628). These classifications influence both the selection and calibration of dosimetry systems.

7.1.1 *Classification of Dosimeters*—Classification of dosimeters is based on their inherent metrological properties. The method of measurement may be important in the classification (see below), but the classification does not include consideration of the actual instrumentation used, or the quality of preparation (manufacture) of the dosimeter.

7.1.1.1 *Type I Dosimeters*—In order for a dosimeter to be classified as a type I dosimeter, it must be possible to apply accurate, independent corrections to its response to account for the effects of influence quantities, such as temperature and dose rate. In classifying a dosimeter as a type I dosimeter, it may be necessary to specify the method of measurement. For example, free radicals produced in irradiated alanine can, in principle, be measured by a number of different techniques; however, only the EPR technique has been shown to provide the high metrological quality necessary to classify alanine as a type I dosimeter. Refer to ASTM Practice E2628 for a list of type I dosimeters.

7.1.1.2 *Type II Dosimeters*—The classification of a dosimeter as a type II dosimeter is based on the complexity of

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interaction between influence quantities, such as temperature and dose rate, which makes it impractical to apply independent correction factors to the dosimeter response. Refer to ASTM Practice E2628 for a list of type II dosimeters.

7.1.2 Classification of Dosimetry Systems:

7.1.2.1 Reference Standard Dosimetry Systems:

(1) The classification of a dosimetry system as a reference standard dosimetry system is based on its application. Reference standard dosimetry systems are used as standards to calibrate other dosimetry systems that are used for routine measurements. In addition, the reference standard dosimetry systems are used to certify the absorbed-dose rate at a reference position within the irradiator. The uncertainty of the reference standard dosimetry system will affect the uncertainty of the system being calibrated and thus the uncertainty in the absorbed dose value for the product being irradiated.

(2) Reference standard dosimetry systems may take the form of systems held at a given location or they may take the form of transfer standard dosimetry systems operated by a national standards laboratory or an accredited dosimetry calibration laboratory. In the case of transfer standard dosimetry systems, dosimeters are sent to a facility for irradiation and then returned to the issuing laboratory for measurement. The requirement that dosimeters be transported without unduly increasing the measurement uncertainty restricts the type of dosimeter that can be used. Alanine/EPR, dichromate and Ceric-Cerous dosimetry systems are commonly used in this way.

(3) The dosimeter used in a reference standard dosimetry system is generally a type I dosimeter. The expanded uncertainty achievable with measurements made using a reference standard dosimetry system is typically of the order of $\pm 3\%$ (at the 95 % confidence level).

7.1.2.2 Routine Dosimetry Systems—The classification of a dosimetry system as a routine dosimetry system is based on its application, i.e. routine absorbed-dose measurements, including dose mapping and process monitoring. The dosimeter used in a routine dosimetry system is generally a type II dosimeter, although there may be exceptions, for example the use of type I alanine dosimeters. The expanded uncertainty achievable with measurements made using a routine dosimetry system is typically of the order of ± 6 % (at the 95 % confidence level).

7.2 Dosimetry System Calibration:

7.2.1 Dosimetry systems consist of dosimeters, measurement instruments and their associated reference standards, and procedures for the system's use. Prior to use, routine dosimetry systems shall be calibrated in accordance with documented procedures that specify details of the calibration process and be in compliance with ISO/ASTM 51261. Calibration shall be repeated at regular intervals to ensure that the accuracy of the absorbed-dose measurement is maintained within required limits. Detailed calibration procedures are provided in ISO/ASTM 51261. All dosimetry equipment requires either calibration traceable to appropriate standards or performance checks to verify its operation. Similarly, each dosimeter batch that a facility uses requires calibration. If required by regula-

tion or policy, it is necessary to demonstrate that dose measurements are traceable to recognized national or international standards.

7.2.2 Irradiation is a critical component of the calibration of the dosimetry system. There are two methods for irradiating dosimeters for calibration:

7.2.2.1 Calibration irradiations performed at an approved laboratory followed by a calibration verification exercise for the actual conditions of use (see ISO/ASTM 51261), and

7.2.2.2 In-situ/in-plant calibration irradiations of routine dosimeters along with transfer standard dosimeters issued and analyzed by an approved laboratory.

7.2.3 Calibration of a dosimetry system is most commonly made in terms of absorbed dose to water, but absorbed dose to other materials might be used.

8. Installation and operational qualification

8.1 Installation qualification is performed 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. Specific information on installation qualification for various types of facilities can be found in ISO/ASTM Practices 52116 (self-contained dry-storage gamma facilities), 51608 (X-ray [bremsstrahlung] facilities), 51649 (electron beam facilities), and 51702 (large-scale gamma facilities).

NOTE 4—Table A2.1 gives some recommended steps in the following areas for insect irradiation: 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 Operational qualification of an irradiation facility is performed to establish baseline data for characterizing facility effectiveness, predictability, and reproducibility for the range of conditions of operation for key process 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 reference geometry and the operating parameters of the irradiator, (2) measure absorbed-dose distributions in irradiation containers containing homogeneous simulated product (dose mapping), (3) characterize absorbed-dose variations when a facility and process parameters fluctuate statistically during normal operations, and (4) measure the absorbed-dose rate at a reference position within the irradiation container filled with insects or simulated product.

NOTE 5—Specific information on operational qualification can be found in ISO/ASTM Practices 52116 (for self-contained dry-storage gamma facilities), 51608 (for X-ray facilities), 51649 (for electron beam facilities), and 51702 (for large-scale gamma facilities), and in Ref (1) (for self-contained low-energy X-ray facilities).

8.2.1 *Irradiator Characterization*—The absorbed dose received by insects depends on the operating parameters (such as

the source activity or power at the time of irradiation, the geometry of the source, the source-to-product distance, the irradiation geometry) and other process parameters (such as the irradiation time, the product composition and density, and the loading configuration).

8.2.1.1 *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 at a reference position, such as the center of the irradiation container filled with insects or simulated product. This measurement of absorbed-dose rate at a reference position provides a basis for calculating the value of parameter(s) (e.g., duration of irradiation or conveyor speed) necessary to deliver the specified absorbed dose to the insects (see 9.4). The measurement should be repeated periodically (for example, every three years for a gamma facility) and following any changes to the source, geometry, or other irradiator parameters that could affect dose rate.

NOTE 6—When the irradiator absorbed-dose rate is measured per 8.2.1.1, it is convenient to calibrate the facility's routine dosimetry system concurrently per 7.2.2.2. ISO/ASTM 51261 provides guidelines on calibration procedures.

8.2.1.2 Dose Mapping—Ideally, the irradiation process should be designed to irradiate insects uniformly throughout the irradiated volume; in reality, a certain variation in absorbed dose through the irradiation container will exist. Irradiator characterization includes mapping the absorbed-dose distribution for the irradiation container filled with homogeneous simulated product, and identifying the magnitudes and locations of maximum dose (D_{max}) and minimum dose (D_{min}) within the irradiation container (see ASTM E2303 for details regarding dose mapping procedures). Changes in the product handling system (for example, irradiator turntable) or radiation source characteristics require a new absorbed-dose mapping.

8.2.2 *Transit Dose*—In gamma 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 Practice 52116.

8.2.3 An important calculation in the use of gamma sources is the correction for radioactive decay. For a pure radionuclide source, the exponential loss of activity, *A*, is given by:

$$A_t = A_0 e^{-\lambda t} \tag{1}$$

where:

 A_t = the activity at time t,

 A_0 = the known activity at some earlier time (t = 0), and λ = the decay constant for the given radionuclide.

8.2.3.1 Decay constants (λ) for radionuclides commonly used in gamma irradiators are:

For
60
Co. $\lambda = 3.60039 \times 10^{-4} \text{ dav}^{-1}$

For ¹³⁷Cs,
$$\lambda = 6.29087 \times 10^{-5} \text{ day}^{-1}$$
 (3)

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8.2.3.2 These constants are based on half lives of 1925.20 (± 0.25) days for ⁶⁰Co and 11018.3 (± 9.5) days for ¹³⁷Cs (**12**). In practice, absorbed-dose rate can be substituted for activity in Eq 1. The absorbed-dose rate established during operational qualification or during a subsequent calibration of the irradiator with reference or transfer standard dosimetry system (see 8.2.1.1) provides the value at t = 0. The absorbed-dose rate at t days later can then be computed from Eq 1 using λ for the appropriate radionuclide from Eq 2 or Eq 3.

9. Performance qualification

9.1 Objective—The purpose of dosimetry in performance qualification is to ensure that the absorbed-dose requirements for a particular product and process 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. Knowledge of the dose distribution throughout the irradiation container is critical for ensuring program security and sterile insect quality. This is accomplished by absorbed-dose mapping (see 9.3) for the specific product (namely, the insects) and specific loading configuration to determine the magnitude and location of maximum dose (D_{max}) and minimum dose (D_{min}) , and to establish the appropriate values for the duration of irradiation, conveyor speed, or other parameter(s) necessary to achieve the absorbed doses within the set requirements.

NOTE 7—In sterile insect release programs, tests of absorbed dose versus sterility and viability of irradiated insects are critical (16). Thus, tests to evaluate the reproductive sterility and competitiveness of irradiated insects are conducted periodically to provide evidence that the dose limits and other aspects of sterilization processing (for example, induction of hypoxia prior to irradiation) are still valid.

9.2 Product Loading Configuration—A loading configuration for the irradiation should be established for each insect 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 in the irradiation container, size and shape of the irradiation container, and position and composition of simulated product, if used to improve dose uniformity by excluding insects from portions of the canister or irradiation chamber.

NOTE 8-The irradiation container shall not be loaded beyond its designed maximum volume.

9.3 Product Absorbed-Dose Mapping—Establish the locations of the regions of maximum dose (D_{max}) and minimum dose (D_{min}) for each selected insect loading configuration by placing dosimeter sets throughout the volume of insects within the irradiation container (see ASTM E2303). Concentrate the dosimeters in the expected regions of maximum and minimum dose with fewer dosimeters placed in regions likely to receive intermediate absorbed dose. In many irradiators, the product is relatively close to the radiation source, resulting in pronounced absorbed-dose gradients near the periphery of the irradiation

7

(2)



container. 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 (1, 6).

9.3.1 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 value of dose uniformity ratio can be critical to ensuring the successful deployment of sterile insects (16,17). In some cases, irradiator or process parameters can be adjusted to improve dose uniformity (for example, installing an irradiator turntable or using simulated product to exclude insects from regions with low or high dose rates).

9.3.2 If any changes that could affect the magnitude or location of the absorbed-dose extremes are made to the irradiator or mode of operation, repeat the absorbed-dose mapping to the extent necessary to establish the effect.

9.3.3 Routine Monitoring Position—Identify a location for monitoring dose during routine processing for each loading configuration. This may be, for example, the location of the reference position (see 8.2.1.1), minimum dose (D_{\min}) or maximum dose (D_{\max}) , or an alternate location in or on the irradiation container. Dosimeter sets should be placed at this location during routine processing (see 10.2), so accessibility should be considered. The quantitative relationship between the absorbed dose at the routine monitoring position and that at the locations of minimum and maximum dose within the irradiation container shall be established and documented and shown to be reproducible.

9.4 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 the parameter(s) used to control absorbed dose are calculated based on results of the absorbeddose mapping described in 9.3 in conjunction with results of reference standard measurements of absorbed-dose rate at a reference position (see 8.2.1), taking into account the uncertainty in dosimetry and the irradiation process. ISO/ASTM 51707 provides guidelines for estimating uncertainty of absorbed-dose measurements. For most insect irradiation facilities, the absorbed dose delivered to the insects is controlled by adjusting a single operating parameter such as duration of irradiation or conveyor speed. The value that is established for that parameter should result in an absorbed dose distribution that is within specification throughout the volume of irradiated insects.

10. Routine product processing

10.1 *Process Parameters and Control*—For routine processing, set the operating parameters as established during performance qualification, taking into account source decay if applicable. All critical process 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. Examples of these parameters are given in Table A2.1. If the

values of the operating parameters deviate from prescribed processing limits, take appropriate actions.

10.2 *Routine Dosimetry*—Routine process 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 loading irradiation containers (see 10.6).

NOTE 9—The absorbed-dose distribution in the product is already known from 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.

10.2.1 Dosimeter Location—Place one or more dosimeter sets at the routine monitoring position (see 9.3.3). The absorbed dose at this location has a quantitative and reproducible relationship with maximum dose $(D_{\rm max})$ and minimum dose $(D_{\rm min})$.

10.2.2 Dosimeter Placement Frequency—Select a sufficient number of irradiation containers 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 for the entire production run falls within specified limits.

10.2.2.1 *Gamma and Low-energy X-ray Facilities*— Routine dosimetry should be performed at specified periodic intervals, which may be daily, weekly, or monthly.

NOTE 10—Although source output in a gamma irradiator is affected only by radioactive decay, frequent routine dosimetry can detect otherwise unnoticed process problems which have, at times, resulted in the release of large numbers of fertile insect pests.

10.2.2.2 *Electron Accelerator 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 11—For production runs with contiguous loading of irradiation containers, the product in first and last containers may experience dose distributions different from the other containers. If prior dosimetry data indicate that an unacceptable dose distribution exists within these two end irradiation containers, place compensating dummies adjacent to these units so as to make their dose distributions acceptable.

10.3 Radiation-Sensitive Indicators:

10.3.1 The purpose of radiation-sensitive indicators is to visually determine whether or not a specific irradiation container of insects has been exposed to ionizing radiation, rather than to measure absorbed-dose values (see ISO/ASTM Guide 51539). Indicators do not give a quantitative value of absorbed dose, and therefore are not a substitute for routine dosimeters used in routine process monitoring.

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

ISO/ASTM 51940:2013(E)

NOTE 12—If insects are irradiated in sealed 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 container. If portions of the container are transparent, the indicator(s) may, for reasons of security, be placed inside the sealed container in such manner that it can be seen without opening the container.

10.3.3 *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 irradiation container of factory-reared insects. Check the state of the indicator on each container before and immediately after irradiation, and, if applicable, again at the site where adult insects emerge and are processed for release.

10.4 *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, if possible. 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 Practice 51261 and Guide 51539, ASTM Guide E2701 and practices for individual dosimetry systems listed in Annex A1).

10.5 *Chilled Product*—Sterile insect release programs that irradiate insects in the adult stage often chill the insects to a temperature between 1 and 8°C, depending on the species, to immobilize them during processing. Absorbed dose is not a function of the temperature of the insects being irradiated, but the response of a dosimeter or radiation-sensitive indicator may be a function of its temperature. Dose-mapping information for simulated product (representing the actual product geometry) at ambient temperature can be applied to chilled insects. Alternately, some dosimeters (such as type I) can be used at chilled temperature. In that case, 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 ASTM Practice E2628 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 that temperature.

10.6 Partially Loaded Irradiation Containers—Irradiations in self-contained irradiators may be performed using less product than was used in dose mapping. In that case, the maximum dose $(D_{\rm max})$ received by the insects may be greater than the maximum dose measured during dose mapping. Care should be taken, therefore, to ensure that the specified limits for maximum dose are not exceeded during routine use. Changes to the absorbed-dose distribution arising from partially loaded irradiation containers may be minimized by the use of simulated product placed at the appropriate locations in the irradiation container, and by placing the insects in the center of the irradiation container.

11. Measurement uncertainty

11.1 All dose measurements need to be accompanied by an estimate of uncertainty. Appropriate procedures are recommended in ISO/ASTM Guides 51707 and 51261 (see also GUM).

11.1.1 All components of uncertainty should be included in the estimate, including those arising from calibration, dosimeter variability, instrument reproducibility, and the effect of influence quantities. A full quantitative analysis of components of uncertainty is referred to as an uncertainty budget, and is then often presented in the form of a table. Typically, the uncertainty budget will identify all significant components of uncertainty, together with their methods of estimation, statistical distributions and magnitudes.

12. Keywords

12.1 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; SIT; X-radiation; ICS 17.240

ANNEXES

(informative)

A1. EXAMPLES OF ROUTINE DOSIMETRY SYSTEM CHARACTERISTICS

A1.1 Thermoluminescence dosimetry system (TLD)

A1.1.1 Applicable Dose Range—1 to 10⁵ Gy.

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

A1.1.3 *Use*—Electrons, gamma radiation, X-radiation (accelerator).

A1.1.4 *Physical Characteristics*—The most commonly used materials for TLD are LiF, CaF_2 , $CaSO_4$ and Al_2O_3 . The

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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 Influence Quantities:

A1.1.6.1 Temperature— Not generally sensitive.

A1.1.6.2 *Humidity*—Not generally sensitive.

A1.1.6.3 *Ambient Light*—Dosimeters should be protected from ultraviolet light.

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

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

A1.2 Radiochromic film dosimetry system

A1.2.1 Applicable Dose Range—1 to 10⁵ Gy.

A1.2.2 Applicable Dose Rate—<10¹³ Gy/s.

A1.2.3 *Use*—Electrons, gamma radiation, X-radiation (accelerator, low-energy X-radiation).

A1.2.4 *Physical Characteristics*—The dosimeters consist of leuco (colorless) dyes that become intensely colored upon irradiation. Film thickness varies from a few μ m 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 Influence Quantities:

A1.2.6.1 *Temperature*—The 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 (16,18).

A1.3 Optical wave-guide dosimetry system

A1.3.1 Applicable Dose Range—1 to 10⁴ Gy.

A1.3.2 Applicable Dose Rate Range— 10^{-3} to 10^{3} Gy/s.

A1.3.3 *Use*—Gamma radiation, X-radiation (accelerator). A1.3.4 *Physical Characteristics*—The dosimeters consist of

optical waveguides, which are devices that contain an optical

path at a high index of refraction relative to the material, enclosing the optical path. The waveguides contain ingredients that undergo an ionizing radiation-induced change in photometric absorbance.

A1.3.5 *Instrumentation Characteristics*—Spectrophotometer or modified photometer with holders, optic couplers, and wavelength capabilities appropriate for the dosimeter.

A1.3.6 Influence Quantities:

A1.3.6.1 *Temperature*—These dosimeters may have temperature dependence, depending on the radiation-sensitive material used in their manufacture.

A1.3.6.2 Humidity—not generally sensitive.

A1.3.6.3 *Ambient Light*—These dosimeters may be sensitive to ambient light conditions, especially with wavelengths <370 nm.

A1.3.6.4 *Time*—Dosimeters may require time for full color development after irradiation, and readings may fade slightly with time thereafter. Follow manufacturer's recommendations.

A1.3.7 For more information, see ISO/ASTM Practice 51310.

A1.4 Alanine EPR dosimetry system

NOTE A1.1—This system is generally used as a reference dosimetry system; however, it may be used as a routine dosimetry system also.

A1.4.1 Applicable Dose Range—1 to 10^5 Gy.

A1.4.2 Applicable Dose Rate—up to 10^2 Gy/s for continuous radiation fields and up to 5×10^7 Gy/s for pulsed radiation fields.

A1.4.3 *Use*—Electrons, gamma radiation, X-radiation (accelerator).

A1.4.4 *Physical Characteristics*—The dosimeter is in the form of tablets, small rods, rope of 3 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.

A1.4.5 Instrumentation Characteristics—EPR spectrometer.

A1.4.6 Influence Quantities:

A1.4.6.1 *Temperature*—Temperature dependence is linear for doses $<10^4$ Gy.

A1.4.6.2 Humidity—Somewhat sensitive to humidity.

A1.4.6.3 *Ambient Light*—Not generally sensitive to ambient light.

A1.4.6.4 *Time*—Dosimeter reading may change with time after exposure.

A1.4.7 For more information, see ISO/ASTM Practice 51607.

A2. RECOMMENDED QUALITY ASSURANCE PROCEDURES FOR INSECT IRRADIATION

TABLE A2.1 Recommended Procedures		
Procedure	Frequency	Relevant Section
Installation Qualification:		8.1
Mechanical and software testing	Performed by manufacturer before (self-contained units only) and after installation	
Establish and maintain facility documentation	Ongoing	
Operational Qualification: Reference dose-rate measurements with reference standard dosimetry system Absorbed-dose mapping of irradiation container filled with homogeneous simulated product Calibration of routine dosimetry system	Upon installation and following any modification	8.2
Performance Qualification:	Before routine processing begins. Reviewed at regular intervals.	9
Define a loading configuration for each product (for example, orientation of product, maximum quantity of insects to be irradiated at one time) Absorbed-dose mapping with insects using specific product loading		
configurations Establish process parameters to achieve specified dose range		
Develop standardized procedures governing loading configuration, use of radiation-sensitive indicators, routine dosimetry systems		
Routine Product Processing:		10
Check timer setting, timer accuracy, conveyor speed, mechanical movement of the irradiation container, and other process parameters as applicable	Daily and following each power-up, break in power (for	
Use of radiation-sensitive indicators	Per program protocol; typically, on or in every irradiation container of insects destined for field release	
Use of routine dosimetry system	At specified intervals	
Check irradiation container position and rotation, if applicable	Before and after each irradiation	

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