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Guidance for dosimetry for sterile insects release programs

Lignes directrices de la dosimétrie pour des programmes de lâchers d'insectes stériles

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Foreword

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This document was prepared by ASTM Committee E61 Radiation Processing and by Technical Committee ISO/TC 85, nuclear energy, nuclear technologies and radiological protection.

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ISO/ASTM 51940:2022(E)



Standard Guidance 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.

INTRODUCTION

The purpose of this document is to present information on the use of ionizing energy (radiation) for the radiation-induced reproductive sterilization of live insects for use in pest management programs.

This document is intended to serve as a recommendation to be followed when using irradiation technology where approved by an appropriate regulatory authority. It is not to be construed as a requirement for the use of irradiation nor as a required code of practice. While the use of irradiation involves certain essential requirements to attain the objective of the treatment, some parameters can be varied in optimizing the process.

1. Scope

1.1 This document 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. A third use is for testing detection traps for fruit flies and moths, and testing mating disruption products for moths. The procedures outlined in this document 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 document.

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 document 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 keV 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, perfor-

mance 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 values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard except for the non-SI units of minute (min) hour (h) and day (d). These non-SI units are accepted for use within the SI system.

1.4 This document is one of a set of standards that provides recommendations for properly implementing and utilizing radiation processing. It is intended to be read in conjunction with ISO/ASTM Practice 52628.

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

1.6 This document 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 1.5.

1.7 This document also covers the use of radiation-sensitive indicators for the visual and qualitative indication that the insects have been irradiated (see ISO/ASTM Guide 51539).

1.8 *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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

¹ This document is under the jurisdiction of ASTM Committee E61 on Radiation Processing and is the direct responsibility of Subcommittee E61.04 on Specialty Application, and is also under the jurisdiction of ISO/TC 85/WG 3.

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



1.9 This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

2. Referenced documents

2.1 ASTM Standards:³

E3083 Terminology Relating to Radiation Processing: Dosimetry and Applications

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 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 at Energies Between 50 keV and 7.5 MeV

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

51702 Practice for Dosimetry in a Gamma Facility for Radiation Processing

51707 Guide for Estimation of Measurement Uncertainty in Dosimetry for Radiation Processing

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

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

52303 Guide for Absorbed-Dose Mapping in Radiation Processing Facilities

52628 Practice for Dosimetry in Radiation Processing

52701 Guide for Performance Characterization of Dosimeters and Dosimetry Systems for Use in Radiation Processing

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

ICRU Report 80 Dosimetry Systems for Use in Radiation Processing

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

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.

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 Varembe, Case Postale 56, CH-1211, Geneva 20, Switzerland.

ISO 12749-4 Nuclear energy – Vocabulary – Part 4: Dosimetry for radiation processing

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

JCGM 100:2008, GUM 1995, with minor corrections, Evaluation of measurement data – Guide to the Expression of Uncertainty in Measurement⁶

JCGM 200:2012, VIM International Vocabulary of Metrology – Basic and General Concepts and Associated Terms⁷

3. Terminology

3.1 Definitions:

3.1.1 *absorbed dose (D)*—quotient of $d\bar{\epsilon}$ by dm , where $d\bar{\epsilon}$ is the mean energy imparted by ionizing radiation to matter of mass dm thus

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

3.1.1.1 *Discussion*—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).

3.1.2 *absorbed-dose mapping*—measurement of absorbed dose 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 Terminology **E3083**. The SI unit is $\text{Gy}\cdot\text{s}^{-1}$.

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

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

⁶ Document produced by Working Group 1 of the Joint Committee for 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 Metrology (JCGM/WG 2). Available free of charge at the BIPM website (<http://www.bipm.org>).



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 or DUR.

3.1.7 *dosimeter*—device that, when irradiated, exhibits a quantifiable change that can be related to a dosimetric quantity 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*—interrelated elements used for measuring a dosimetric quantity, including dosimeters, instruments and their associated reference standards, and procedures for their use.

3.1.11 *influence quantity*—quantity that, in a direct measurement, does not affect the quantity that is actually measured, but affects the relation between the indication and the measurement result.

3.1.11.1 *Discussion*—(1) In dosimetry for radiation processing, typical examples of influence quantities include radiation type and energy, irradiation temperature, dose rate and the time interval between irradiation and determination of the indication of the dosimeter. (2) The dosimeter's response (e.g. color change) is measured and related to dose via the calibration curve. The dosimeter's signal may be susceptible to the influence quantity, and therefore the interpretation of dose, not the actual dose.

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 routine dosimeters along with 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 way that is well-defined and capable of expression 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 raised in large quantities 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 ISO/ASTM Practice 52628. Other terms that pertain to radiation measurement and dosimetry may be found in ASTM Terminology E3083 and ISO Terminology ISO 12749-4. Where appropriate, definitions used in these standards have been derived from, and are consistent with definitions in ICRU Report 85a, and general metrological definitions given in the VIM.

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, or sterile insects are released into an area as a preventative measure to protect against the wild pest establishing. 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 factory-reared males to compete with wild males for mates. In some cases, sterile females may also be released as part of an SIT program. 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 (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 An additional use of factory-reared insects is for testing detection traps for fruit flies and moths, and testing mating disruption products for moths.

4.4 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)).

4.5 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.

4.6 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).

4.7 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.

4.8 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*—Self-contained irradiators expose samples to gamma irradiation produced by isotopes of either ^{137}Cs or ^{60}Co (8, 9) (ISO/ASTM Practice 52116), or to low energy X-radiation (bremsstrahlung) produced by an X-ray tube. These irradiators house their radiation source in a protective lead shield or other appropriate high atomic number material in accordance with the safety requirements. Currently



available units using low energy X-radiation (bremsstrahlung) require less shielding than units containing gamma-emitting radioactive isotopes. Such units containing radionuclides usually have a mechanism to move the canister from the load/unload position to the irradiation position.

5.1.1 Some common methods used for improving absorbed dose uniformity in the insect canister are to either rotate the canister holding the insects in front of the radiation source or to have multiple sources irradiating the product from different directions.

5.2 *Large-Scale Panoramic Gamma Irradiators* (see ISO/ASTM Practice 51702)—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 ^{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 (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 source of gamma radiation used in the irradiators considered in this practice consists of sealed ^{137}Cs or ^{60}Co radionuclides that are typically linear rods arranged in one or more planar or annular arrays.

6.1.2 Cobalt-60 emits photons with energies of approximately 1.17 MeV 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 d (± 0.25 d) for ^{60}Co and 11018.3 d (± 9.5 d) 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. This reduction in the source output and the required increase in the irradiation time to deliver the same dose may be calculated (see Eq 1 and Eq 2 or Eq 3 from 8.2.3) or obtained from tables provided by the irradiator manufacturer.

6.2 *X-ray Irradiators:*

6.2.1 Low energy X-ray irradiators use 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 (13, 14).

6.2.2 An X-ray (bremsstrahlung) irradiator emits short wavelength electromagnetic radiation, which is analogous to gamma radiation from radioactive sources. Although their effects on irradiated materials are generally similar, these kinds of radiation differ in their energy spectra (see 6.2.3), angular distribution, and dose rates. The physical characteristics of the X-radiation (bremsstrahlung) field depend on the design of the X-ray tube.

6.2.3 Currently available low-energy X-ray irradiators generate X-radiation with a maximum energy of a few hundred keV. The spectrum of the X-ray energy extends from the maximum energy to approximately 30 keV. Effective energy or other energy spectrum characteristics are needed for characterization of dosimeter response (see Ref 15).

NOTE 3—With lower photon energy, some dosimetry systems that are commonly used with gamma irradiators and accelerators are not applicable to low-energy X-ray irradiators (see Table 1 and Table 2, and Refs (1, 13, 15, 16). For example, Farmer-type ionization chambers are appropriate as reference standard dosimetry systems for low-energy X-ray irradiators (1, 13, 17).

6.2.4 The energy of the X-radiation influences the size and shape of the canister needed to achieve the desired level of dose uniformity in the insect canister. Filters are used to reduce the low-energy components to improve dose uniformity in the canister. These filters may form part of the X-ray tube or may be material added to the irradiator or canister. Reflectors may also be used to improve the dose uniformity.

6.2.5 The absorbed-dose rate and thus time of irradiation is determined by the tube current.

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 MeV 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 ISO/ASTM Practice 52628). 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, but the classification does not include consideration of the actual instrumentation used, or the quality of preparation (manufacturer) of the dosimeter. See ISO/ASTM Practice 52628 for a list of type I and 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 approved 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).

(4) Examples of reference standard dosimetry systems are given in Table 1.

7.1.2.2 *Routine Dosimetry Systems*:

(1) The classification of a dosimetry system as a routine dosimetry system is based on its application, that is, routine absorbed-dose measurements, including dose mapping and process monitoring.

(2) 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).

(3) Examples of routine dosimetry systems are listed in Table 2.

7.2 *Routine 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. 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 (for more information, see the specific ISO/ASTM standard for the dosimetry system being used). Similarly, the dosimetry system shall be calibrated for each dosimeter batch used at the facility. If required by regulation or policy, it is necessary to demonstrate that dose measurements are traceable to recognized national or international standards.

7.2.2 Irradiation of calibration dosimeters 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

TABLE 1 Examples of reference-standard dosimetry systems

Dosimeter	Readout System	Useful Absorbed-dose Range (Gy)	Reference
Alanine ionization chamber	EPR spectrometer Electrometer	1 Gy to 10^5 Gy Can be easily applied to the insect irradiation dose range	ISO/ASTM 51607 (1)



TABLE 2 Examples of routine dosimetry systems

Dosimeter	Readout System	Useful Absorbed-dose Range (Gy)	Reference
Thermoluminescence (TLD)	Thermoluminescence reader	1 Gy to 10 ⁵ Gy	ISO/ASTM 51956
Radiochromic film (Gafchromic film)	UV/visible spectrophotometer, Transmission/Reflectance densitometer	10 Gy to 10 ⁵ Gy	ISO/ASTM 51275 and Ref (18,19)
Alanine	EPR spectrometer	1 Gy to 10 ⁵ Gy	ISO/ASTM 51607
Radiochromic optical waveguide	Photometric means using dual wavelength photometry	1 Gy to 10 ⁴ Gy	ISO/ASTM 51310

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.

7.2.2.3 For gamma irradiators, the most commonly used transfer standard dosimetry system is alanine-EPR. For low-energy X-ray irradiators, ionization chambers or the alanine-EPR dosimetry system may be used as transfer standard dosimetry systems as long as they are calibrated for the appropriate energy (1, 15, 16).

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.

7.2.4 Calibration of the routine dosimetry system shall be repeated at regular intervals to ensure that the accuracy of the absorbed-dose measurement is maintained within required limits.

7.3 Factors That Affect the Response of Dosimeters:

7.3.1 Factors that affect the response of dosimeters (generally referred to as “influence quantities”), including environmental conditions and variations of such conditions within the irradiator, shall be known and their effect taken into account (see ISO/ASTM Practices 52628 and 52701 and the Standard of the specific dosimetry system).

7.3.2 The possible photon energy range for insect irradiation applications is from 40 keV to 1.33 MeV. Since response of many routine dosimeters depends on the photon energy, care must be taken to calibrate the dosimetry system for appropriate energy ranges.

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 A1.1 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 A1.1 are not meant to be exhaustive.

8.2 Operational qualification of an irradiation facility is performed to establish baseline data for evaluating irradiator 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 irradiator 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 the 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, irradiation geometry, or other irradiator parameters that could affect absorbed-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. The irradiator characterization process 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 ISO/ASTM 52303 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:

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

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:

$$\text{For } ^{60}\text{Co}, \lambda = 3.60039 \times 10^{-4} \text{ day}^{-1} \quad (2)$$

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

8.2.3.2 These constants are based on half lives of 5272.9125 d (± 0.25 d) for ^{60}Co and 11018.3 (± 9.5) d for ^{137}Cs (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 performance qualification is to ensure that the absorbed-dose requirements for a particular product and process can be satisfied by the selected irradiation procedure. 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 (18). 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 ISO/ASTM 52303). 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 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 (18, 20). 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 absorbed-dose 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 Operating 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 A1.1. 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 ($D_{\max}$) and minimum dose ($D_{\min}$).

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.

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, ultra-violet 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, ISO/ASTM Guide 52701 and practices for individual dosimetry systems listed in Tables 1 and 2).

10.5 Chilled Product—Sterile insect release programs that irradiate insects in the adult stage often chill the insects to a



temperature between 1 °C 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 ISO/ASTM Practice 52628 and the practices for individual dosimetry systems listed in Tables 1 and 2). 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_{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