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Guide for dosimetry for irradiation of insects for sterile release programs

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

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75% of the member bodies casting a vote.

ASTM International is one of the world's largest voluntary standards development organizations with global participation from affected stakeholders. ASTM technical committees follow rigorous due process balloting procedures.

A pilot project between ISO and ASTM International has been formed to develop and maintain a group of ISO/ASTM radiation processing dosimetry standards. Under this pilot project, ASTM Subcommittee E10.01, Dosimetry for Radiation Processing, is responsible for the development and maintenance of these dosimetry standards with unrestricted participation and input from appropriate ISO member bodies.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. Neither ISO nor ASTM International shall be held responsible for identifying any or all such patent rights.

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

Annexes A1 and A2 of this International Standard are for information only.

Standard Guide for Irradiation of Insects for Sterile Release Programs[1]

This standard is issued under the fixed designation ISO/ASTM 51940; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision.

1. Scope

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

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

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

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

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

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

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

E 170 Terminology Relating to Radiation Measurements and Dosimetry[2]

E 177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods[3]

E 456 Terminology Relating to Quality and Statistics[3]

E 668 Practice for Application of Thermoluminescence-Dosimetry (TLD) Systems for Determining Absorbed Dose in Radiation-Hardness Testing of Electronic Devices[2]

E 1026 Practice for Using the Fricke Reference Standard Dosimetry System[2]

2.2 *ISO/ASTM Standards:*

51261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing[2]

51275 Practice for Use of a Radiochromic Film Dosimetry System[2]

51538 Practice for Use of the Ethanol-Chlorobenzene Dosimetry System[2]

51539 Guide for the Use of Radiation-Sensitive Indicators[2]

51540 Practice for Use of a Radiochromic Liquid Dosimetry System[2]

51607 Practice for Use of the Alanine-EPR Dosimetry System[2]

51608 Practice for Dosimetry in an X-Ray (Bremsstrahlung) Facility for Radiation Processing[2]

51649 Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 300 keV and 25 MeV[2]

51702 Practice for Dosimetry in a Gamma Irradiation Facility for Radiation Processing[2]

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing[2]

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

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

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

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

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[1] This guide is under the jurisdiction of ASTM Committee E10 on Nuclear Technology and Applications and is the direct responsibility of Subcommittee E10.01 on Dosimetry for Radiation Processing, and is also under the jurisdiction of ISO/TC 85/WG 3..

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

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

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

ICRU 34 The Dosimetry of Pulsed Radiation
ICRU 35 Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV
ICRU 60 Radiation Quantities and Units

2.4 *NCRP Publications:*[5]

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

3. Terminology

3.1 *Definitions:*

3.1.1 *absorbed dose (D)*—quantity of ionizing radiation energy imparted per unit mass of a specified material. The SI unit of absorbed dose is the gray (Gy), where 1 gray is equivalent to the absorption of 1 joule per kilogram of the specified material (1 Gy = 1 J · kg^{-1}, which is equivalent to 100 rad). The mathematical relationship is the quotient of $d\bar{\epsilon}$ by dm, where $d\bar{\epsilon}$ is the mean incremental energy imparted by ionizing radiation to matter of incremental mass dm (see ICRU 60).

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

3.1.1.1 *Discussion*—The discontinued unit for absorbed dose is the rad (1 rad = 1 cGy = 100 erg per gram). Absorbed dose is sometimes referred to simply as dose.

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

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

$$\dot{D} = dD/dt \text{ (SI unit: Gy} \cdot \text{s}^{-1}\text{)}$$

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

3.1.4 *calibration*—the comparison of a measurement system or device of known accuracy that is traceable to national standards to detect, correlate, report, or eliminate by adjustment any variation from the required performance limits of the unverified measurement system or device.

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

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

3.1.6 *dose uniformity ratio*—ratio of maximum to minimum absorbed dose within the irradiated factory-reared insects. This concept is also referred to as the "max/min ratio."

3.1.6.1 *Discussion*—The central plane/minimum dose ratio is not used in this guide.

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

3.1.7.1 *Discussion*—A dosimeter shall exhibit the reproducible and quantifiable properties that allow it to be calibrated and compared to national standards.

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

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

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

3.1.10.1 *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.

3.1.11 *measurement quality assurance plan*—a documented program for the measurement process that ensures on a continuing basis that the overall uncertainty meets the requirements of the specified application. This plan requires traceability to, and consistency with, nationally or internationally recognized standards.

3.1.12 *measurement traceability*—the ability to demonstrate by means of an unbroken chain of comparisons that a measurement is in agreement within acceptable limits of uncertainty with comparable nationally or internationally recognized standards.

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

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

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

3.1.15.1 *Discussion*—Radiation-sensitive indicators are often referred to as "indicators." Radiation-sensitive indicators cannot be classified as a "label" under certain trade association guidelines. 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.

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

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

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

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

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

3.1.19 *traceability*—see *measurement traceability*.

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

3.1.21 *transit dose*—absorbed dose delivered to product while the product moves from the load position to the irradiate position, and immediately back to the unload position.

3.2 Definitions of other terms used in this standard that pertain to radiation measurement and dosimetry may be found in ASTM Terminology E 170. Definitions in ASTM Terminology E 170 are compatible with ICRU 60; that document, therefore, may be used as an alternative reference.

4. Significance and Use

4.1 The major use of factory-reared insects is in sterile release programs (for example, Sterile Insect Technique, or SIT) for suppressing or eradicating pest populations **(1)**[6]. 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 irradiation dose absorbed by the factory-reared insects should be with a range that induces the desired level of sterility without substantially reducing the ability of factory-reared males to compete with wild males for mates. Species targeted by SIT programs are typically major pests affecting agriculture or human health, so the assurance by standardized dosimetry that insects have been properly irradiated is of crucial importance to agriculture growers, agricultural regulators, public health officials, the public or a combination of these **(1, 2, 3,** and **4)**. The irradiator operator must demonstrate by means of accurate absorbed-dose measurements within the volume of irradiated insects, or in simulated product, that all insects will receive an absorbed dose that produces an acceptable level of sterility.

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

4.3 Factory-reared insects may be treated with ionizing radiation, such as gamma rays from ^{137}Cs or ^{60}Co sources, X-rays, and in electron accelerators. Gamma irradiation of insects is usually carried out in small, fixed-geometry, dry-storage irradiators **(6, 7,** and **8)**. Dosimetry methods for gamma irradiation of insects have been demonstrated and include useful procedures for mapping the absorbed dose throughout the volume of the insect canister in these small irradiators **(9)** as well as larger gamma units **(10)**.

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

4.5 For each irradiator, and absorbed-dose rate at a reference dose position within the irradiated volume of insects or simulated product is measured using a reference-standard dosimetry system. That reference-standard measurement must be used to calculate the timer setting, conveyor speed, or other parameter required to deliver the specified absorbed dose to the center of the irradiated sample or other reference position within the sample. Either relative or absolute absorbed-dose measurements are performed within the irradiated sample of insects or insect-equivalent material for determining the absorbed-dose distribution **(9)**. Accurate radiation dosimetry at a reference position which could be the position of the minimum absorbed dose (D_{min}) or maximum absorbed dose (D_{max}) offers a quantitative, independent method of process control.

4.6 Dosimetry is part of a measurement quality assurance plan that is applied to ensure that the radiation process meets predetermined specifications **(11, 12)**.

4.7 Absorbed-dose mapping for establishing locations of D_{min} and D_{max}, is often performed using simulated product **(9)**.

5. Types of Facilities and Modes of Operation

5.1 *Self-Contained Dry-Source Irradiators* (see Ref **(13)**)—Most insect sterilization is accomplished by using gamma rays from either ^{137}Cs or ^{60}Co self-contained irradiators. These devices house the radiation source in a protective lead shield (or other appropriate high atomic number material), and usually have a mechanism to rotate or lower the canister from the load position to the irradiation position.

5.1.1 A common method of use is to distribute the source in an annular array. The factory-reared insects are located at the center of the array, resulting in a relatively uniform absorbed-dose distribution. In this design, irradiator turntables would not normally be necessary.

5.1.2 A second method is to rotate the canister holding the insects on an irradiator turntable in front of the source such that the only points that remain a fixed distance from the source are along an axis of rotation.

5.2 *Large-Scale Gamma Irradiators*—Gamma irradiation

[6] The boldface numbers in parentheses refer to the bibliography at the end of this standard.

of insects is also carried out in pool-type irradiators, and larger-scale dry-storage irradiators could also be used. In these facilities, the source typically consists of a series of rods (pencils) containing ^{60}Co or ^{137}Cs which can be raised or lowered into a large irradiation chamber. When retracted from the chamber, the source is shielded by water (pool-type) or lead, or both, or other appropriate high atomic number material.

5.2.1 For pool irradiators, a common method of use is for samples of insects to be carried on a conveyor in one or more revolutions around a central source, resulting in a relatively uniform absorbed-dose distribution. The source is lowered into the pool only when the irradiator is not in use or the conveyors require service.

5.2.2 An alternative method of use is to distribute the source in an annular array. After the irradiated sample is placed in the center of the irradiation chamber, the source is raised or lowered around it for the length of time required to achieve the desired absorbed dose.

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

5.3.1 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.

5.3.2 A bremsstrahlung X-ray accelerator emits short-wavelength electromagnetic radiation, similar in energy to nuclear gamma radiation. Although their effects on materials are generally similar, these kinds of radiation differ in their energy spectra, angular distributions, and absorbed-dose rates.

5.3.3 Insects could be irradiated using a self-contained portable bremsstrahlung X-ray irradiator. The bremsstrahlung X-rays are produced in a conventional manner, but the unit is totally self-contained (free standing). Spectrum filtration would be used to reduce the low energy component of the radiation, thus improving the dose uniformity ratio.

6. Radiation Source Characteristics

6.1 *Self-Contained Dry-Storage and Large-Scale Gamma Irradiators*:

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

6.1.2 Cobalt-60 emits photons with energies of approximately 1.17 and 1.33 MeV in nearly equal proportions. Cesium-137 produces photons with energies of approximately 0.662 MeV **(11)**.

6.1.3 The half-lives for ^{60}Co and ^{137}Cs are approximately 5.27 years **(14)** and 30.1 years, respectively **(15)**.

6.1.4 For gamma-ray sources, the only variation in the source output is the known reduction in the activity caused by radioactive decay. The reduction in the source strength, and the required increase in the irradiation time, may be calculated (see 9.4.7) or obtained from tables provided by the irradiator manufacturer.

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

6.2.1 Direct-action electron accelerators that employ dc or pulsed high-voltage generators typically produce electron energies up to 5 MeV. Indirect-action electron accelerators use microwave or very high frequency (VHF) ac power to produce electron energies typically from 5 MeV to 15 MeV.

6.2.2 The continuous energy spectrum of the X-rays (bremsstrahlung) varies from approximately 35 keV up to the maximum energy of the electrons incident on the X-ray target (see ISO/ASTM Practice 51608).

7. Dosimetry Systems

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

7.2 *Description of Dosimeter Classes*:

7.2.1 Dosimetry systems are used to determine absorbed dose. They consist of dosimeters, measurements instruments, and their associated reference standards, and procedures for the system's use.

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

7.2.2.1 *Primary–Standard Dosimeters*—Primary–standard dosimeters are established and maintained by national standards laboratories for calibration of radiation environments (fields) and other dosimeters. The two most commonly used primary standard dosimeters are ionization chambers and calorimeters (see ISO/ASTM Guide 51261, ICRU Reports 14, 17, 34 and 35 and NCRP Report 69).

7.2.2.2 *Reference–Standard Dosimeters*—Reference–standard dosimeters are used to calibrate radiation environments and routine dosimeters. Reference–standard dosimeters may also be used as routine dosimeters. Examples of reference–standard dosimeters along with their useful dose ranges are given in a table in ISO/ASTM Guide 51261. For insect irradiators, the following reference–standard dosimeters may be suitable; ferrous sulfate (Fricke) aqueous solution (ASTM Practice E 1026), alanine dosimeters (ISO/ASTM Practice 51607), radiochromic solutions (ISO/ASTM Practice 51540 and Refs **(11)** and **(16)**), and ethanol-chlorobenzene solution (ISO/ASTM Practice 51538).

7.2.2.3 *Transfer–Standard Dosimeters*—Transfer–standard dosimeters are specially selected dosimeters used for transferring absorbed-dose information from an accredited or national standards laboratory to an irradiation facility in order to establish traceability for the facility. These dosimeters should be used under conditions that are carefully controlled by the issuing laboratory. Transfer–standard dosimeters may be selected from either reference–standard dosimeters or routine dosimeters and shall have performance characteristics that meet the requirements listed in a table in ISO/ASTM Guide 51261.

7.2.2.4 *Routine Dosimeters*—Routine dosimeters may be used for quality control and process monitoring. Proper dosimetric techniques, including calibration, shall be employed to ensure that the measurements are reliable and accurate. Examples of routine dosimeters along with their useful dose ranges are given in a table in ISO/ASTM Guide 51261. Examples of dosimeters that may be useful in routine processing or absorbed-dose mapping for insect irradiation facilities are listed in Annex A1.

NOTE 2—In the routine operation of an insect irradiator, absorbed-dose measurements made on the product at regular intervals provide the operator and regulatory authorities with an independent quality control record of the process. When D_{min} has been set by the regulatory authorities, the ability to measure that absorbed dose with proper statistical control is a critical requisite of Good Manufacturing Practices.

7.3 *Calibration of Dosimetry Systems*:

7.3.1 Prior to use, dosimetry systems shall be calibrated in accordance with the user's documented procedure that specifies details of the calibration process and quality assurance requirements. This calibration procedure shall be repeated at regular intervals to ensure that the accuracy of the absorbed dose measurement is maintained within required limits. Irradiation is a critical component of the calibration of the dosimetry system. Detailed calibration procedures are provided in ISO/ASTM Guide 51261.

7.3.2 *Calibration of Reference or Transfer Dosimeters*—Calibration irradiations shall be performed by irradiating the reference or transfer–standard dosimeters using a calibration facility that provides an absorbed dose or an absorbed-dose rate having measurement traceability to nationally or internationally recognized standards.

7.3.3 *Calibration of Routine Dosimeters*—Calibration irradiations may be performed in several ways, including irradiating the routine dosimeters using:

7.3.3.1 A calibration facility that provides an absorbed dose or an absorbed-dose rate having measurement traceability to nationally or internationally recognized standards, or

7.3.3.2 An in-house calibration facility that provides an absorbed dose or and absorbed-dose rate having measurement traceability to nationally or internationally recognized standards, or

7.3.3.3 A production or research irradiation facility together with reference or transfer–standard dosimeters that have measurement traceability to nationally or internationally recognized standards.

7.3.4 When a reference or transfer–standard dosimeter is to be used as a routine dosimeter, calibration may also be performed as stated in 7.3.3.2 and 7.3.3.3.

7.4 *Analytical Instrument Calibration and Performance Verification*—For the calibration of the individual instruments used in the analysis of the dosimeters, and for the verification of instrument performance between calibrations, see ISO/ASTM Guide 51261.

8. Radiation-Sensitive Indicators

8.1 The purpose of radiation-sensitive indicators is to visually determine whether or not a specific container of insects has been exposed to ionizing radiation, rather than to measure different absorbed-dose levels (see ISO/ASTM Guide 51539 and Ref **(17)**). Indicators do not give a quantitative value of absorbed dose, and therefore are not a substitute for routine dosimeters used in routine process monitoring.

NOTE 3—This does not preclude the use of calibrated radiochromic film as a dosimeter read with a Transmission/Reflectance Densitometer as listed in Annex A1.

9. Installation Qualification

9.1 *Objective*—The purpose of installation qualification is to obtain and document evidence that the irradiation facility has been provided and installed in accordance with its specifications and that it functions within predetermined limits when operated in accordance with the operational instructions. As part of this process, dosimetry may, for example, be performed to: (1) establish relationships between the absorbed dose for a reproducible geometry and the operating parameters of the irradiator, (2) characterize absorbed-dose variations when a facility and processing parameters fluctuate statistically through normal operations, (3) measure absorbed-dose distributions in insect-equivalent material and other reference materials, and (4) measure the absorbed-dose rate at one position (usually the center of the canister volume) within the canister filled with insects or simulated product. Table A2.1 gives some recommended steps in the following areas: installation qualification, process qualification, and routine product processing. The recommended steps in Table A2.1 are not meant to be exhaustive.

9.1.1 For self-contained irradiators, installation qualification may begin prior to the shipment of the irradiator to the customer's site. As part of release-for-shipment criteria, the irradiator manufacturer may perform absorbed-dose mapping to establish baseline data for evaluating facility effectiveness, predictability, and reproducibility for the range of operating conditions. After the unit is installed at the user's site, irradiator qualification is performed as part of the user's quality assurance plan.

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

9.2 *Equipment Documentation*—Establish and document an irradiator qualification program that demonstrates that the irradiator is operating within specified limits, and will consistently produce an absorbed-dose distribution in samples of insects or simulated product to predetermined specifications. Documentation shall be retained for the life of the irradiator and shall include descriptions of instrumentation and equipment for ensuring the reproducibility in absorbed-dose delivery, within specified limits.

9.3 *Equipment Testing and Calibration*:

9.3.1 *Processing Equipment*—The absorbed dose in irradiated insects or simulated product depends on the operating parameters of the irradiator.

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

9.3.1.2 Implement a documented calibration program to