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Guide for dosimetry for sterile insect release programs

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

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Foreword

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

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

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

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

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

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

Standard Guide for
Dosimetry for Sterile Insect Release 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 sterile insects is as benign hosts for rearing insect parasitoids. The procedures outlined in this guide will help ensure that insects processed with ionizing radiation from gamma, electron, or X-ray sources receive absorbed doses within a predetermined range. Information on effective dose ranges for specific applications of insect sterilization, or on methodology for determining effective dose ranges, is not within the scope of this guide.

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

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

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

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

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

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

2. Referenced documents

2.1 *ASTM Standards:* [2]

- E 170 Terminology Relating to Radiation Measurements and Dosimetry
- E 668 Practice for Application of Thermoluminescence-Dosimetry (TLD) Systems for Determining Absorbed Dose in Radiation-Hardness Testing of Electronic Devices
- E 1026 Practice for Using the Fricke Reference Standard Dosimetry System
- E 2116 Practice for Dosimetry for a Self-Contained Gamma-Ray Irradiator
- E 2303 Guide for Absorbed-Dose Mapping in Radiation Processing Facilities
- E 2304 Practice for Use of a LiF Photo-Fluorescent Film Dosimetry System

2.2 *ISO/ASTM Standards:*[2]

- 51261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing
- 51275 Practice for Use of a Radiochromic Film Dosimetry System
- 51400 Practice for Characterization and Performance of a High-Dose Radiation Dosimetry Calibration Laboratory
- 51538 Practice for Use of the Ethanol-Chlorobenzene Dosimetry System
- 51539 Guide for the Use of Radiation-Sensitive Indicators
- 51540 Practice for Use of a Radiochromic Liquid Dosimetry System
- 51607 Practice for Use of the Alanine-EPR Dosimetry System
- 51608 Practice for Dosimetry in an X-Ray (Bremsstrahlung) Facility for Radiation Processing
- 51649 Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 300 keV and 25 MeV

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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] For referenced ASTMand ISO/ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard’s Document Summary page on the ASTM website.

51702 Practice for Dosimetry in a Gamma Irradiation Facility for Radiation Processing

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing

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

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

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

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

ICRU 34 The Dosimetry of Pulsed Radiation

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

ICRU 60 Fundamental Quantities and Units for Ionizing Radiation

2.4 *NCRP Publications:*[4]

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

3. Terminology

3.1 *Definitions:*

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

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

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

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

where:

Φ = particle fluence (particles/m^2),
E = energy of the ionizing radiation (J), and
μ_{en}/ρ = mass energy absorption coefficient (m^2/kg).

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

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

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

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

SI Unit: $Gy \cdot s^{-1}$

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3.1.23 *traceability*—see *measurement traceability*.

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

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

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

4. Significance and use

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

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

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

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

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

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

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

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

5. Types of facilities and modes of operation

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

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

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

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

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

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

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

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

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

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

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

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

6. Radiation source characteristics

6.1 *Gamma Irradiators*:

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

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

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

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

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

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

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

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

6.2.2 For an X-ray (bremsstrahlung) facility, besides beam characteristics noted in 6.2.1, X-ray target design is a critical parameter. X-rays are similar to gamma radiation from radioactive isotopic sources. Although their effects on materials are generally similar, these kinds of radiation differ in their energy spectra, angular distributions, and absorbed-dose rates. The continuous energy spectrum of the X-rays (bremsstrahlung) varies from approximately 35 keV up to the maximum energy of the electrons incident on the X-ray target (see ISO/ASTM Practice 51608). In some X-ray facilities, spectrum filtration is used to reduce the low energy component of the radiation, thus improving dose uniformity.

7. Dosimetry systems

7.1 *Description of Dosimeter Classes*:

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

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

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

7.1.1.3 *Transfer-Standard Dosimeters*—Transfer-standard dosimeters are specially selected dosimeters used for transferring absorbed-dose information from an accredited or national standards laboratory to an irradiation facility in order to establish traceability for the facility. These dosimeters should be used under conditions that are specified by the issuing laboratory. Transfer-standard dosimeters may be selected from either reference-standard dosimeters or routine dosimeters taking into consideration the criteria listed in ISO/ASTM Guide 51261.

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

7.2 *Calibration of Dosimetry Systems*:

7.2.1 Prior to use, the dosimetry system (consisting of a specific batch of dosimeters and specific measurement instruments) shall be calibrated in accordance with the user's documented procedure that specifies details of the calibration process and quality assurance requirements. This calibration procedure shall be repeated at regular intervals to ensure that the accuracy of the absorbed dose measurement is maintained within required limits. Calibration methods are described in ISO/ASTM Guide 51261.

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

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

7.2.4 *Calibration of Routine Dosimeters*—Calibration irradiations may be performed per 7.2.3, or at a production or research irradiation facility together with reference- or transfer-standard dosimeters that have measurement traceability to nationally or internationally recognized standards.

7.3 *Measurement Instrument Calibration and Performance Verification*—For the calibration of instruments, and for the verification of instrument performance between calibrations, see ISO/ASTM Guide 51261, the corresponding ISO/ASTM or ASTM standard for the dosimetry system, and/or instrument-specific operating manuals.

8. Installation qualification

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

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

8.2 *Equipment Documentation*—Establish and document an installation qualification program that includes descriptions of the instrumentation and equipment and measurement instruments installed at the facility. This documentation shall be retained for the life of the facility. At a minimum, it shall include:

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

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