An American National Standard

Standard Practice for Dosimetry for a Self-Contained Dry-Storage Gamma Irradiator[1]

This standard is issued under the fixed designation ISO/ASTM 52116; 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 practice outlines dosimetric procedures to be followed with self-contained dry-storage gamma irradiators. For irradiators used for routine processing, procedures are given to ensure that product processed will receive absorbed doses within prescribed limits.

1.2 This practice covers dosimetry in the use of dry-storage gamma irradiators, namely self-contained dry-storage ^{137}Cs or ^{60}Co irradiators (shielded freestanding irradiators). It does not cover underwater pool sources, panoramic gamma sources, nor does it cover self-contained bremsstrahlung X-ray units.

1.3 The absorbed-dose range for the use of the dry-storage self-contained gamma irradiators covered by this practice is typically 1 to 10^5 Gy, depending on the application. The absorbed-dose rate range typically is from 10^{-2} to 10^3 Gy/min.

1.4 For irradiators supplied for specific applications, specific ISO/ASTM or ASTM practices and guides provide dosimetric procedures for the application. For procedures specific to dosimetry in blood irradiation, see ISO/ASTM Practice 51939. For procedures specific to dosimetry in radiation research on food and agricultural products, see ISO/ASTM Practice 51900. For procedures specific to radiation hardness testing, see ASTM Practice E1249. For procedures specific to the dosimetry in the irradiation of insects for sterile release programs, see ISO/ASTM Guide 51940. In those cases covered by ISO/ASTM 51939, 51900, 51940, or ASTM E1249, those standards take precedence.

1.5 This document is one of a set of standards that provides recommendations for properly implementing and utilizing dosimetry in radiation processing. It is intended to be read in conjunction with ASTM E2628, "Practice for Dosimetry in Radiation Processing".

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]

E170 Terminology Relating to Radiation Measurements and Dosimetry

E1249 Practice for Minimizing Dosimetry Errors in Radiation Hardness Testing of Silicon Electronic Devices Using Co-60 Sources

E2628 Practice for Dosimetry in Radiation Processing

E2701 Guide for Performance Characterization of Dosimeters and Dosimetry Systems for Use in Radiation Processing

2.2 *ISO/ASTM Standards:*[2]

51261 Practice for Calibration of Routine Dosimetry Systems for Radiation Processing

51539 Guide for Use of Radiation-Sensitive Indicators

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing

51900 Guide for Dosimetry in Radiation Research on Food and Agricultural Products

51939 Practice for Blood Irradiation Dosimetry

51940 Guide for Dosimetry for Sterile Insects Release Programs

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

ICRU 85a Fundamental Quantities and Units for Ionizing Radiation

2.4 *ANSI Standards:*[4]

ANSI/HPS N43.7 Safe Design and Use of Self-Contained, Dry Source Storage Gamma Irradiators (Category I)

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 Measurement[5]

---

[1] This practice 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.

Current edition approved by Aug. 16, 2012. Published April 2013. Originally published as ASTM E 2116–00. Last previous edition ASTM E 2116–00. The present International Standard ISO/ASTM 52116:2013(E) replaces E 2116-00 and is a major revision of the last previous edition ISO/ASTM 52116:2002:(E).

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

[3] International Commission on Radiation Units and Measurements (ICRU), 7910 Woodmont Ave., Suite 800, Bethesda, MD 20810, U.S.A.

[4] Available from the Health Physics Society, http://hps.org.

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

JCGM 100:2008, VIM International vocabulary of metrology – Basis and general concepts and associated terms[6]

3. Terminology

3.1 *Definitions:*

3.1.1 *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.

3.1.2 *calibration*—[VIM, 6.11] set of operations under specified conditions, which establishes the relationship between values indicated by a measuring instrument or measuring system, and the corresponding values realised by standards traceable to a nationally or internationally recognised laboratory.

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

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

3.1.4 *measurement management system*—set of interrelated or interacting elements necessary to achieve metrological confirmation and continual control of measurement processes.

3.1.5 *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.

3.2 Definitions of other terms used in this standard that pertain to radiation measurement and dosimetry may be found in ASTM Terminology E170. Definitions in ASTM Terminology E170 are compatible with ICRU 85a; that document, therefore, may be used as an alternative reference.

4. Significance and use

4.1 The design and operation of a self-contained irradiator should ensure that reproducible absorbed doses are obtained when the same irradiation parameters are used. Dosimetry is performed to determine the relationship between the irradiation parameters and the absorbed dose.

4.1.1 For most applications, the absorbed dose is expressed as absorbed dose to water (see ISO/ASTM Practice 51261). For conversion of absorbed dose to water to that to other materials, for example, silicon, see Annex A1 of ISO/ASTM Practice 51261.

4.2 Self-contained dry-storage gamma irradiators contain properly shielded radioactive sources, namely ^{137}Cs or ^{60}Co, that emit ionizing electromagnetic radiation (gamma radiation). These irradiators have an enclosed, accessible irradiator sample chamber connected with a sample positioning system, for example, irradiator drawer, rotor, or irradiator turntable, as part of the irradiation device.

4.3 Self-contained dry-storage gamma irradiators can be used for many radiation processing applications, including the calibration irradiation of dosimeters; studies of dosimeter influence quantities; radiation effects studies, and irradiation of materials or biological samples for process compatibility studies; batch irradiations of microbiological, botanical, or in-vitro samples; irradiation of small animals; radiation "hardness" testing of electronics components and other materials; and batch radiation processing of containers of samples.

NOTE 1—Self-contained dry-storage gamma irradiators contain a sealed radiation source, or an array of sealed radiation sources securely held in a dry container constructed of solid materials. The sealed radiation sources are shielded at all times, and human access to the chamber undergoing irradiation is not physically possible due to the irradiator's design configuration (see ANSI/HPS N43.7).

NOTE 2—For reference–standard dosimetry, the absorbed dose and absorbed-dose rate can be expressed in water or other material which has similar radiation absorption properties to that of the samples or dosimeters being irradiated. In some cases, the reference-standard dosimetry may be performed using ionization chambers, and may be calibrated in terms of exposure (C kg^{-1}), or absorbed dose to air, water or tissue (Gy). Measurements performed in terms of exposure apply to ionization in air, and care should be taken to apply that measurement to the sample being irradiated.

5. Types of facilities and modes of operation

5.1 *Facility Types*—Typical self-contained dry-storage gamma irradiators are illustrated in Annex A1. These irradiators house the radiation source(s) in a protective lead shield (or other appropriate material), and usually have a sample positioning mechanism tied to an accurate calibrated reset timer to lower or rotate the sample holder from the load/unload position to the irradiation position and back to the load/unload position. Details on the calibration of dosimetry systems and dose mapping in such irradiators may be found, respectively in ISO/ASTM Guide 51261 and in this practice. Details on the designs of such irradiators and on safety considerations in the use of such irradiators may be found in ANSI/HPS N43.7.

5.2 *Modes of Operation*—Three common modes of operation are described. This does not purport to include all modes of operation.

5.2.1 One method of use is to rotate the sample holder 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 (ANSI/HPS N43.7).

5.2.2 A second method is to distribute the source in an annular array, resulting in a relatively uniform absorbed-dose distribution. In this design, the irradiator turntable normally would not be necessary.

5.2.3 A third method is to use opposed sources with appropriate beam flattening to obtain a uniform dose throughout the sample.

6. Radiation source characteristics

6.1 The radiation sources used in the irradiation devices considered in this practice consist of sealed elements of ^{60}Co

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

or ^{137}Cs, which are typically linear rods or pencils arranged singly or in a planar array or cylindrical array.

6.2 Cobalt-60 emits photons with energies of approximately 1.17 and 1.33 MeV in nearly equal proportions; cesium-137 emits photons with energies of approximately 0.662 MeV.

6.3 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[7] gave values of 1925.20 (± 0.25) days for ^{60}Co and 11018.3 (± 9.5) days for ^{137}Cs. In addition, the ^{137}Cs radiation source may contain radioimpurities which should be qualified by the source manufacturer.

6.4 For pure ^{60}Co and ^{137}Cs gamma sources, the only variation in the source strength 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 to deliver the same dose may be calculated or obtained from tables provided by the irradiator manufacturer.

7. Dosimetry systems

7.1 The basic requirements that apply when making absorbed dose measurements are given in ASTM E2628. ASTM E2628 also provides guidance on the selection of dosimetry systems and describes the classification of dosimeters based on two criteria. Users are directed to other standards that provide specific information on individual dosimetry systems, calibration methods, and uncertainty estimation.

NOTE 3—The operation of a self-contained dry-storage irradiator, absorbed-dose measurements made in the sample under controlled environmental and geometrical conditions of calibration, testing, or processing provide an independent quality control record.

8. Installation qualification (IQ)

8.1 *Objective*—The purpose of an installation qualification (IQ) program is to obtain and document evidence that the irradiator and measurement instruments have been delivered and installed in accordance with their specifications. IQ 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 4—Table A2.1 gives some recommended steps in the following areas: installation qualification, operational qualification, performance qualification, and routine product processing.

8.2 *Equipment Documentation*—Establish and document an IQ program that includes descriptions of the instrumentation and equipment 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,

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

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

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

8.2.6 Operating procedures and calibration procedures for associated measurement instruments or systems.

8.3 *Equipment Testing and Calibration*—Test all processing equipment and instrumentation that may influence absorbed dose in order to verify satisfactory operation of the irradiator within the design specifications.

8.3.1 Implement a documented calibration program to ensure that all processing equipment and instrumentation that may influence absorbed-dose delivery are calibrated periodically.

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

8.4 For self-contained irradiators, some IQ may begin prior to the shipment of the irradiator to the customer's site.

9. Operational qualification (OQ)

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

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

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

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

[7] Unterweger, M. P., Hoppes, D. D., Schima, F. J., and Coursey, J. S., "Radionuclide Half-Life Measurements," National Institute of Standards and Technology, available online at http://physics.nist.gov/Halflife (updated October 5, 2010).

9.3.1 *Absorbed-Dose Rate*—A reference- or transfer-standard dosimetry system, traceable to nationally or internationally recognized standards, shall be used to measure the absorbed-dose rate within product or simulated product at a reference position (such as the center of the product or simulated product volume). For a defined irradiation geometry, the absorbed-dose rate at the reference position should have a reproducible and documented relationship to the absorbed-dose rate at locations of maximum (D_{max}) and minimum (D_{min}) dose rate.

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

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

9.3.2 *Dose Mapping*—Ideally, the irradiation process is designed to irradiate product uniformly throughout the irradiated volume; in reality, a certain variation in absorbed-dose through the product will exist. The OQ process includes mapping the absorbed-dose distributions for product (or simulated product), and identifying the magnitudes and locations D_{max} and D_{min} within the product.

9.3.2.1 Map the absorbed-dose distribution by placing dosimeters throughout the actual or simulated product. Select placement patterns that can identify the locations of D_{max} and D_{min}. Dosimetry data from previously characterized irradiators of the same design or theoretical calculations may provide useful information for determining the number and locations of dosimeter sets needed for this characterization process.

NOTE 5—In the case of static irradiations (such as when the product is located at the center of an annular source array), the dose mapping should be performed in three dimensions; otherwise, two-dimensional dose mapping usually suffices. A common method for presenting the dose mapping results is to use isodose curves (lines or surfaces of constant absorbed dose through the actual or simulated product).

9.3.2.2 Changes in the product handling system (for example, irradiator turntable) requires a new absorbed-dose mapping.

9.3.3 *Transit Dose*—The transit dose and its relation to total absorbed dose should be quantified.

9.3.3.1 Dosimetry performed at the same dose level as used for product irradiation includes the transit dose contribution. Therefore, it is usually unnecessary to measure the transit dose separately.

9.3.3.2 Procedures for measuring and correcting for transit dose in terms of transit time are given in Annex A3.

9.3.3.3 In self-contained gamma irradiators, the transit dose should be small relative to the total dose delivered (for example, less than 1 %).

9.3.3.4 The absorbed-dose range of the dosimetry system used for mapping the dose distribution may not be suitable for measuring the transit dose. Thus, it may be necessary to utilize a different dosimetry system for measuring the transit dose.

9.3.4 *Timer Setting Calculation*—An important calculation in the use of gamma sources is the correction for radioactive decay. For a pure radionuclide source, the reduction in activity with time is exponential. For an initial activity of A_0(at time = 0 which is usually specified as the date of the last reference dose-rate measurement), the activity at some later time, t, is given by:

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

where A_t is the source activity at time t, and the decay constant, λ, for a given radionuclide, is defined as:

$$\lambda = \frac{\ln(2)}{t_{1/2}} \tag{2}$$

where:

$t_{1/2}$ is the half-life for a given radionuclide. The half-lives used in these examples for gamma emission by ^{60}Co and ^{137}Cs are 1925.20 (±0.25) days and 11018.3 (±9.5) days, respectively (see 6.3). The values for λ in Eq 2 for ^{60}Co and ^{137}Cs are as follows:

$$\text{For } ^{60}\text{Co}, \lambda = 3.60076 \times 10^{-4} \text{ day}^{-1} \tag{3}$$

$$\text{For } ^{137}\text{Cs}, \lambda = 6.29087 \times 10^{-5} \text{ day}^{-1} \tag{4}$$

where no round-off occurs until the final answer. The decay factor is defined as follows:

$$\text{Decay Factor} = \frac{A_t}{A_0} = e^{-\lambda t} \tag{5}$$

NOTE 6—Examples of using these equations to obtain decay factors are given as follows: for an elapsed time period of 500 days and using the decay constants according to Eq 3 and Eq 4, Eq 5 gives decay factors for ^{60}Co and ^{137}Cs of 0.835238 and 0.969035, respectively. The decay factor can be used to correct a known dose rate or source activity for time. Refer to http://physics.nist.gov/Halflife for up-to-date radionuclide half lives.

Since the absorbed-dose rate due to a radionuclide source also varies exponentially with the decay time, t, the dose rate, dR, is given by:

$$DR_t = DR_0 \cdot e^{-\lambda t} \tag{6}$$

where: DR_t is the dose rate at time t; D_0 is the dose rate at some earlier time (t = 0). The timer setting, TS, necessary to deliver the targeted central dose varies inversely with the dose rate or source activity, and is given by:

$$(TS)_t = (TS)_0 \cdot e^{-\lambda t} \tag{7}$$

where: $(TS)t$ is the timer setting necessary to deliver the required target dose, for example, D_{min}, at a time t; $(TS)_0$ is the timer setting at some earlier time, t = 0, to deliver the same target dose. Typically for free-standing irradiators with a ^{137}Cs radionuclide source, the timer setting is adjusted (increased) by ~1.1 % every six months. Typically, for free-standing irradiators with a ^{60}Co radionuclide source, the timer setting is adjusted (increased) by ~1.1 % every month.

NOTE 7—Calculations of source decay, and therefore adjustments of timers, always should be done as referenced to the date of last dose-rate measurement (t = 0), to avoid compounding error.

9.3.4.1 Although the output of gamma sources is expected to be constant (except for radioactive decay), errors may be introduced by the existence of radioactive impurities. For example, ^{134}Cs may be an impurity in ^{137}Cs sources. This could lead to an error in the manufacturer's measurement of source activity. In addition, the dose measurements cannot differentiate the dose contributions from ^{134}Cs and ^{137}Cs. Although the original dosimetry measurements take this into account, ^{134}Cs and ^{137}Cs decay at different rates, which may lead to an error in the timer setting calculations. If the contribution to the central dose rate from the radioimpurity is greater than 1 %, the irradiator manufacturer should provide a timer setting methodology to accurately account for source decay. Periodic re-measurement of the central dose rate using a reference-standard dosimetry system may help to minimize the uncertainty introduced by the presence of radio-impurities.

10. Performance qualification (PQ)

10.1 *Objective*—For irradiators to be used for routine processing, performance qualification (PQ) dosimetry shall be performed to ensure that all products processed within specified parameters receive the required absorbed dose.

10.1.1 Minimum and maximum absorbed-dose limits are often associated with the irradiation application. In addition, for many applications, one or both of these limits may be prescribed by government regulations. Dosimetry is used in performance qualification (PQ) to determine the appropriate process parameters (including timer setting and product loading configuration) to help ensure that the absorbed-dose requirements for a particular product can be satisfied. This is accomplished by absorbed-dose mapping of specific product. The purpose of the mapping is to determine the magnitudes and locations of the minimum and maximum absorbed doses and their relationships to the absorbed doses at locations used for monitoring during routine product processing.

10.2 *Product Loading Configuration*—A loading configuration for the irradiation should be established for each product type. The documentation for this loading configuration shall include specifications for parameters that influence the absorbed-dose distribution. These parameters typically include volume of the product and packaging. The product holder shall not be loaded beyond its designed maximum volume.

10.3 *Product or Simulated Product Absorbed-dose Mapping*—For each type of irradiated product, there is a minimum dose to achieve the desired effect and a maximum dose that the product can tolerate without unacceptable degradation in quality. Both these limits are usually defined by the facility. Establish the locations of the regions of D_{max} and D_{min} for each selected product-loading configuration by placing dosimeter sets throughout the product volume or simulated product. Concentrate the dosimeters in expected regions of D_{max} and D_{min} with fewer dosimeters placed in areas likely to receive intermediate absorbed dose. In many applications, the product is relatively close to the radiation sources, resulting in pronounced absorbed-dose gradients near the periphery of the volume of the sample. It is important, therefore, to choose a dosimeter that is small enough to detect these gradients. Dosimeter film in strips or sheets may be employed to obtain useful information.

NOTE 8—One of the primary design intents for dry-storage gamma irradiators is a highly reproducible dose distribution. As such, it is often straight-forward for the user to demonstrate that one dose mapping is adequate for OQ and PQ and to determine the locations for D_{max} and D_{min}.

10.3.1 Results of absorbed-dose mapping will be used to determine the degree of dose uniformity. In the case when the measured dose uniformity is close to the acceptable dose uniformity, irradiator or processing parameters can be adjusted to improve dose uniformity (for example, installing an irradiator turntable or reducing the product volume to exclude product from areas with low or high dose rates).

10.3.2 If any changes are made to the irradiator or mode of operation that could affect the magnitude or location of the absorbed-dose extremes, repeat the absorbed-dose mapping to the extent necessary to establish the effect. In addition, the established dose rate should be re-verified.

10.3.3 *Reference Position*—Identify a reference position for each loading configuration. This may be, for example, the location of D_{min} or D_{max}, or a location in or on the product holder. The absorbed dose at this location shall have a reproducible and documented relationship to the absorbed dose at the locations of D_{min} and D_{max}.

10.4 *Establishing Process Parameters*—Values of process parameters that yield absorbed dose within specified limits should be established for each product and loading configuration. Value(s) of all parameters that affect absorbed dose are established based on results of the absorbed-dose mapping in

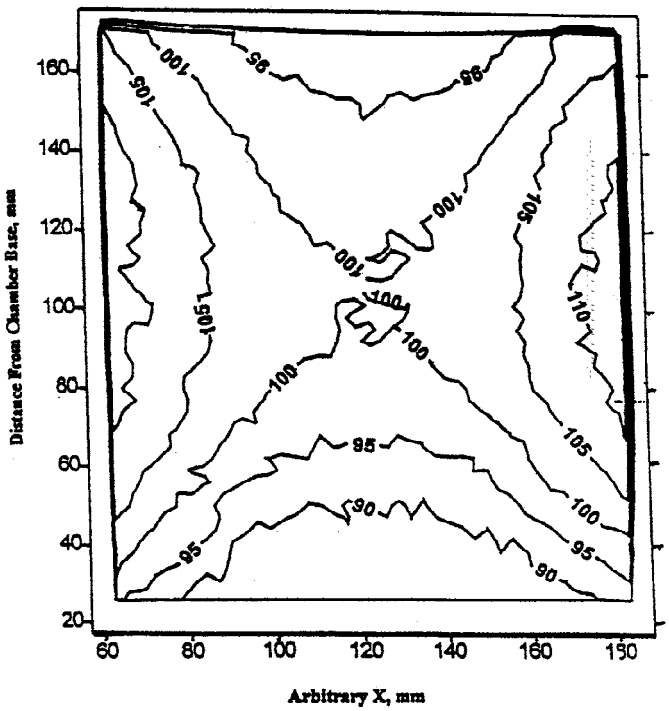

FIG. 1 Example of two-dimensional dose mapping results normalized to a central dose of 100 %

conjunction with results of reference- or transfer-standard measurements of absorbed-dose rate at a reference position. For most irradiation facilities, the absorbed dose is controlled by adjusting a single process parameter such as timer setting. The value that is established for that parameter shall result in an absorbed-dose distribution that is within specified limits throughout the product.

11. Routine sample processing

11.1 *Process Parameters and Control*—For sample batch processing, set the process parameters as established during performance qualification, taking into account source decay. All critical process parameters that can affect the absorbed-dose distribution should be controlled and monitored during routine processing. These parameters include sample geometry and timer setting. Control, monitor and document the process parameters to help ensure that the product is processed in accordance with specifications. If these parameters deviate from prescribed processing limits, take appropriate actions.

11.2 *Routine Monitoring of the Radiation Process*—Routine measurements of absorbed dose to the product at the reference position will help ensure that the product has been treated within the dose limits prescribed by the process. Radiation-sensitive indicators may be used to monitor the radiation process (see ISO/ASTM Guide 51539). In order to detect any anomalies during the course of the irradiation, more than one reference position may be necessary.

11.2.1 *Process Monitoring Using Dosimeters*—Routine process monitoring may be performed using routine dosimetry. Routine dosimetry can be part of the verification process for establishing that the irradiation process is under control.

11.2.1.1 *Dosimeter Location(s)*—When used, place one or more dosimeters on the product at predetermined locations of the $D_{\max}$ and $D_{\min}$ or at a reference dose position. Under predefined conditions of operation, the absorbed dose at the reference-dose position has a quantitative and reproducible relationship with D_{max} and D_{min}.

11.2.1.2 *Dosimeter Placement Frequency*—Placement frequency should always be done according to the measurement management system. Irradiation using a self-contained dry-storage gamma irradiator has the inherent advantage that for a defined product geometry, the only process parameter is often the timer setting. The relative dose distribution is not expected to change from irradiation to irradiation.

11.3 *Environmental Effects*—If there is a change in the environment (for example, temperature, humidity) of a dosimeter or radiation-sensitive indicator during the irradiation process or pre- or post-irradiation storage, the response of the dosimeter and indicator may be affected. If this occurs, correct the dosimeter response for any such effect. A radiation-sensitive indicator's response cannot be corrected for such conditions, and therefore, care should be taken when using the indicators in those conditions. Care must also be taken in handling and storage of dosimeters and indicators before and after irradiation (see ISO/ASTM Guides 51261 and ASTM E2701).

11.4 *Chilled or Frozen Product*—Absorbed dose is not a function of the product temperature. The response of the dosimeter and radiation-sensitive indicator, however, may be a function of temperature. The dose-mapping information for simulated product (representing the actual product geometry) at ambient temperature can be applied to the chilled or frozen product. Determine the temperature of the dosimeter during irradiation of product and apply the appropriate temperature correction. Dosimeters and radiation-sensitive indicators that exhibit a highly temperature-dependent response should not be placed in locations with large temperature gradients. (See ISO/ASTM Practice 51261 and ASTM E2701.)

11.5 *Partially Loaded Product Holders*—Irradiations may be performed using less product than that used for the initial dose mapping. For partially loaded holders, the D_{max} received by the product may be greater than the D_{max} measured in the product. Care must be taken, therefore, to ensure that the D_{max} allowed for the process is not exceeded during routine use. Changes to the absorbed-dose distribution arising from partially loaded product holders may be minimized by the use of simulated product placed at the appropriate locations in the irradiation volume, and by center-loading the product.

11.6 *Radiation-Sensitive Indicators*—In some applications, radiation-sensitive indicators (sometimes known as "go/no go" indicators) may be used to show that product has been exposed to a radiation source. However, these indicators provide only a qualitative indication of radiation exposure. In addition, the color change of radiation-sensitive indicators is not always stable and may be affected by, for example, light or heat. Thus, their use is neither a substitute for nor a complement to dosimetry. Also, while radiation-sensitive indicators can conveniently be used to assist in production inventory control, they shall not be used to replace other administrative inventory control procedures.

12. Measurement uncertainty

12.1 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).

12.1.1 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.

13. Keywords

13.1 caesium-137; cesium-137; cobalt-60; dosimetry; dry-storage irradiator; gamma cell; gamma radiation; self-contained irradiator

ANNEXES

(informative)

A1. TYPICAL SELF-CONTAINED DRY-STORAGE IRRADIATORS

A1.1 Typical self-contained dry-storage irradiators (see ANSI/HPS N43.7) include the GammaCell 220, the JL Shepherd Mark I (see A1.3), the Husman Model 521A and the Gamma Chamber 5000.

A1.1.1 The BRIT Gamma Chamber 5000 is compact self-shielded cobalt-60 gamma irradiator providing an irradiation volume of approximately 5 L. The product is placed in an irradiation chamber located in the vertical drawer which moves into the radiation field. The chamber can be temperature controlled via the use of access ports.

A1.1.2 The JL Shepherd Mark I irradiator (Fig. A1.1) contains ^{137}Cs sources. After the sample is loaded into the sample cavity and the door is closed securely, the radiation source moves into the irradiation position for a predetermined period of time.

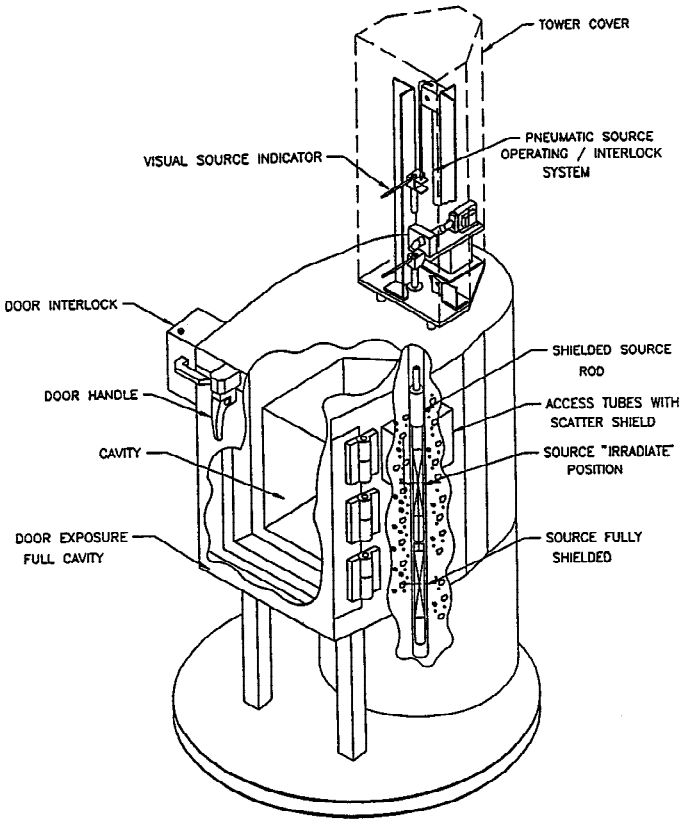

FIG. A1.1 Basic construction of J.L. Shepherd Mark I irradiator

A1.1.3 The Best Theratronics GC40, GC1000 and GC3000 irradiators contain shielded ^{137}Cs sources. For the GC1000/3000 irradiators, the sample is loaded into a holder and placed on the turntable within the sample cavity. The door is closed securely, the sample cavity rotates 180° into the irradiate position for a predetermined period of time. For the GC40 irradiator, the sample is loaded into the sample cavity. The door is closed securely and the radiation source moves into the irradiate position for a predetermined period of time.

A1.1.4 The Husman 521A irradiator contains sealed ^{137}Cs source sources in an annular array around the irradiation chamber (Fig. A1.2).

A1.1.5 The GammaCell Model 220 irradiator contains sealed ^{60}Co sources in an annular array around the irradiation chamber (Fig. A1.3).

A1.2 These irradiation devices house the gamma source(s) in a protective shield, or other appropriate high atomic-number material, and usually have a sample positioning mechanism interlocked with a calibrated timer. After securing the door, either the product moves into the radiation field or the radiation source(s) moves into the irradiation position. For details on the operations and precautions in the use of these irradiators, see the appropriate manufacturers' instruction manuals as well as the references cited.

A1.3 Manufacturers of self-contained dry-storage irradiators include:

Irradiator Model	Contact
Gamma Chamber 1200 Gamma Chamber 5000	Board of Radiation and Isotope Technology (BRIT) V.N. Purav Marg, Mumbai 400 094, India www.britatom.gov.in
Blood Irradiatior BI-2000	
JL Shepherd Mark I	J.L. Shepherd & Associates 1010 Arroyo Avenue San Fernando, CA 91340-1822 USA www.jlshepherd.com
GC40, GC1000, GC3000	Best Theratronics (part of Best Medical, Inc.) 413 March Rd., Ottawa, Ontario K2K 0E4 Canada www.theratronics.ca
Husman 521A	This unit is no longer being manufactured but is still in use.
GammaCell 220	This unit is no longer being manufactured but is still in use.

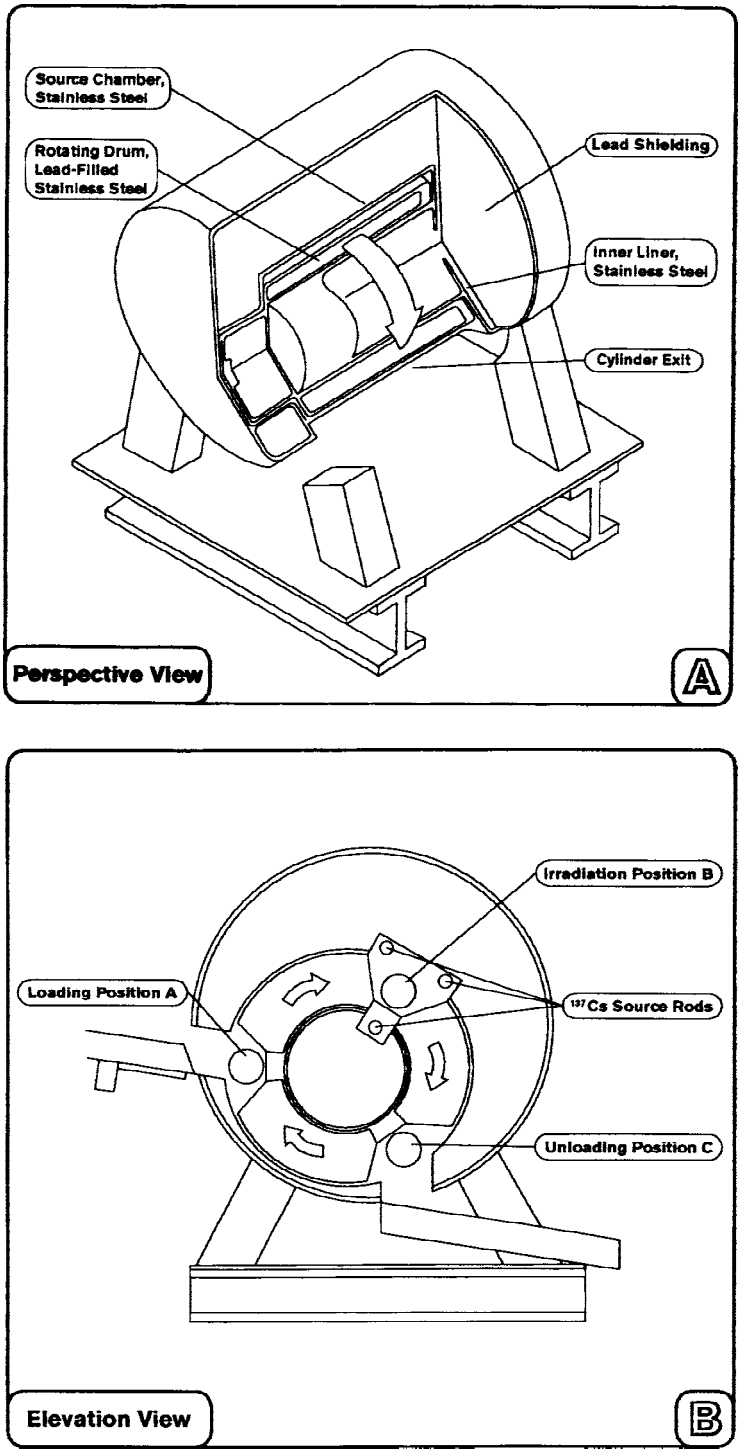

FIG. A1.2 Basic construction of the Husman ^{137}Cs irradiator

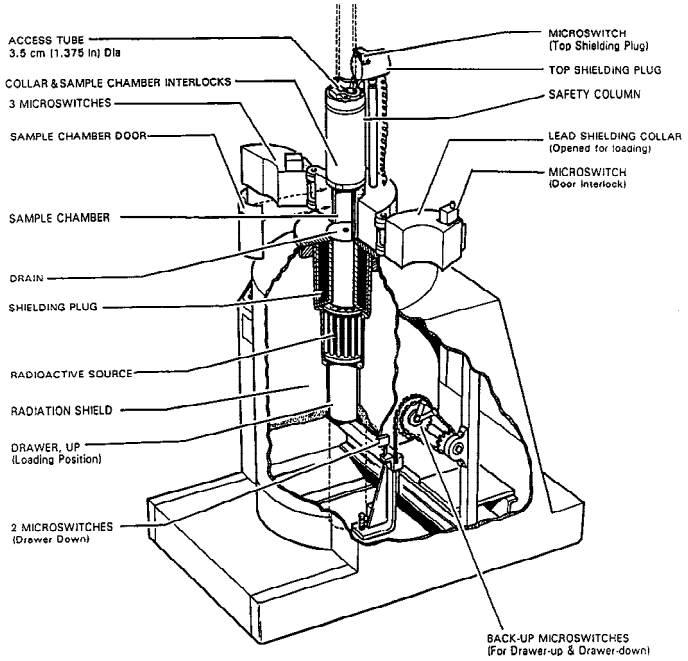

FIG. A1.3 Basic construction of the GammaCell 220 ^{60}Co irradiator

A2. PROCEDURES FOR TESTING OF SELF-CONTAINED DRY-STORAGE IRRADIATORS

A3. DETERMINATION OF TRANSIT DOSE

A3.1 Two methods for the determination of transit dose are as follows:

A3.1.1 In the first method, select a series of incremental irradiation times that start as close to zero as is possible with the dosimetry system employed. It may be necessary to utilize a dosimetry system with a higher sensitivity (lower dose capability such as Alanine or Fricke) than the system normally employed for routine use. Use at least five different irradiation times. Analyze the results using linear regression analysis. A graph of the results should look similar to Fig. A3.1. Note that the intercept with the *Y* axis gives the value of the transit dose.

A3.1.2 In the second method, select a high sensitivity dosimeter such as the Fricke. Set the irradiator timer at zero and perform ten irradiation cycles. The dosimeter receives ten times the transit dose; hence divide the total dose by ten to obtain the transit dose. Repeat this process three times, and calculate the average of the three measurements to obtain the transit dose.

A3.2 To calculate a corrected timer setting for future irradiations, first convert the transit dose into an equivalent irradiation time (transit time, t_t); that is, divide the transit dose by the current dose rate ($\dot{D}$). Subsequent timer settings can be calculated using the formula:

$$t = \frac{D_T}{\dot{D}} - t_t \tag{A3.1}$$

where:

DT = the target dose, and
t = the timer setting required to achieve that dose.

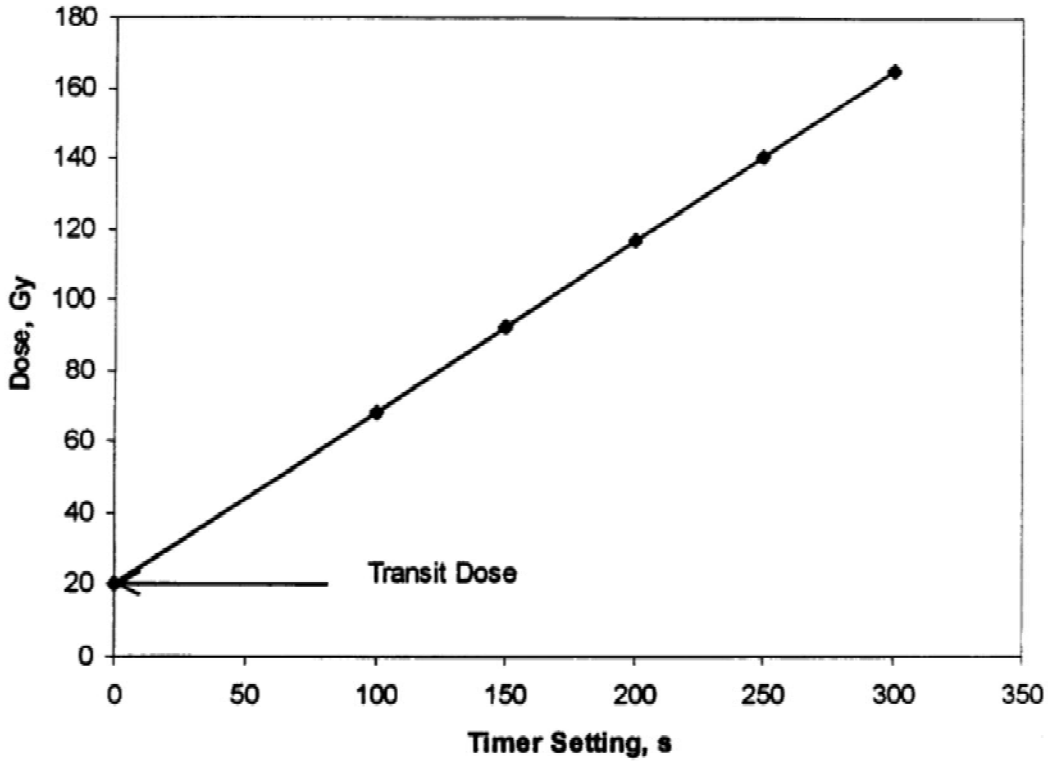

FIG. A3.1 Transit dose determination

TABLE A2.1 Procedures for testing of self-contained dry-storage irradiators

Procedure	Frequency[A]	Relevant Section
Release-for-Shipment Criteria		Section 8
Performed by manufacturer before shipment of the irradiator according to a documented quality assurance program (including mechanical and software testing, absorbed-dose mapping, reference-standard dosimeter measurement)	Performed before shipment of the irradiator from manufacturer to customer	
Installation Qualification		Section 8
Mechanical and software testing	Performed after irradiator installation by manufacturer and facility	
Establish and maintain facility documentation	Ongoing	
Check timer calibration and accuracy		
Check position of holder, if applicable		
Check rotation of holder, if applicable		
Operational Qualification		
Absorbed-dose-rate measurement at a reference position		Section 9
Absorbed-dose mapping of holder filled with simulated product		
Calibrate routine dosimetry system	Upon installation and following any modification	
Standard Process Procedures governing loading configuration, Use of routing dosimetry systems		
Performance Qualification		
Define a loading configuration for each sample type (for example, orientation of sample, maximum number of units to be irradiated at one time)		Section 10
Absorbed-dose mapping with product (or equivalent material) using specific product loading configurations	Before routine processing begins. Reviewed at regular intervals	
Establish operating parameters to achieve specified dose range		
Dose rate verification using transfer-standard dosimeters		
Routine Sample Processing		Section 11
Check timer setting, timer accuracy, turntable rotation, and other processing parameters as applicable	As per the measurement management program	
Use of radiation-sensitive indicators	Per program protocol	
Check holder position and rotation, if applicable	Before and after each irradiation	

[A]The frequency of testing depends on the manufacturer's recommendations and user requirements.

ASTM International takes no position respecting the validity of any patent rights asserted in connection with any item mentioned in this standard. Users of this standard are expressly advised that determination of the validity of any such patent rights, and the risk of infringement of such rights, are entirely their own responsibility.

This standard is subject to revision at any time by the responsible technical committee and must be reviewed every five years and if not revised, either reapproved or withdrawn. Your comments are invited either for revision of this standard or for additional standards and should be addressed to ASTM International Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee, which you may attend. If you feel that your comments have not received a fair hearing you should make your views known to the ASTM Committee on Standards, at the address shown below.