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Practice for dosimetry for a self-contained dry-storage gamma-ray irradiator

Pratique de la dosimétrie appliquée à un irradiateur gamma renfermant une source auto-protégée entreposée à sec

Reference number
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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 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 52116 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 Practice for Dosimetry for a Self-Contained Dry-Storage Gamma-Ray 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-ray irradiators. If followed, these procedures will help to ensure that calibration and testing will be carried out with acceptable precision and accuracy and that the samples processed with ionizing radiation from gamma rays in a self-contained dry-storage irradiator receive absorbed doses within a predetermined range.

1.2 This practice covers dosimetry in the use of dry-storage gamma-ray irradiators, namely self-contained dry-storage ^{137}Cs or ^{60}Co irradiators (shielded freestanding irradiators). It does not cover underwater pool sources, panoramic gamma-ray sources such as those raised mechanically or pneumatically to irradiate isotropically into a room or through a collimator, 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-ray 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 This practice describes general procedures applicable to all self-contained dry-storage gamma-ray irradiators. 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 E 1249. 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 Practices 51939, 51900, 51940, or ASTM E 1249, those standards take precedence. In addition, this practice does not cover absorbed-dose rate calibrations of radiation protection instrumentation.

1.5 *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 Statistics[3]

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

E 1249 Practice for Minimizing Dosimetry Errors in Radiation Hardness Testing of Silicon Electronic Devices Using Co-60 Sources[2]

2.2 *ISO/ASTM Standards:*

51204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing[2]

51205 Practice for Use of a Ceric-Cerous Sulfate Dosimetry System[2]

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

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

51276 Practice for Use of a Polymethylmethacrylate Dosimetry System[2]

51310 Practice for Use of a Radiochromic Optical Waveguide Dosimetry System[2]

51400 Practice for Characterization and Performance of a High-Dose Gamma Radiation Dosimetry Calibration Laboratory[2]

51401 Practice for Use of a Dichromate Dosimetry System[2]

51431 Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing[2]

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

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

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

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

51650 Practice for Use of the Cellulose Acetate Dosimetry System[2]

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

[1] This practice 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.

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing[2]
51900 Guide for Dosimetry in Radiation Research on Food and Agricultural Products[2]
51939 Practice for Blood Irradiation Dosimetry[2]
51940 Guide for Irradiation of Insects for Sterile Release Programs[2]

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 44 Tissue Substitutes in Radiation Dosimetry and Measurement
ICRU 51 Quantities and Units in Radiation Protection Dosimetry
ICRU 60 Fundamental Quantities and Units for Ionizing Radiation Metrology

2.4 *ANSI Standards*:[5]

ANSI N323, Radiation Protection Instrumentation Test and Calibration
ANSI Report N433.1, Safe Design and Use of Self-Contained, Dry-Source Storage Gamma Irradiators (Category I)

2.5 *NCRP Publications:*[6]

NCRP Report No. 58, Handbook of Radioactivity Measurements
NCRP Report No. 69, Dosimetry of X-Ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV

2.6 *ISO Publications:*[7]

ISO/IEC 17025, General Requirements for the Competence of Calibration and Testing Laboratories
ISO 11137 Sterilization of Health Care Products—Requirements for Validation and Routine Control-Radiation Sterilization

2.7 *IAEA Publication:*[8]

IAEA TECDOC-619 X-Ray and Gamma-Ray Standards for Detector Calibration

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 J/kg 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 51).

$$D = \frac{d\bar{\epsilon}}{dm} \quad (1)$$

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:

$$D = \Phi \cdot E \cdot \frac{\mu_{en}}{\rho} \quad (2)$$

where:

Φ = particle fluence (particles/m^2),
E = energy of the ionizing radiation (J/particle), 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 a 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 ($\dot{D}$)*—the absorbed dose in a material per incremental time interval, that is, the quotient of dD by dt.

$$\dot{D} = \frac{dD}{dt} \quad (3)$$

SI unit: Gy · s^{-1}.

3.1.3.1 *Discussion*—The absorbed-dose rate often is specified in terms of total value of D as a function of longer time intervals, for example, in units of Gy·min^{-1} or Gy·h^{-1}.

3.1.4 *activity (A)*—of an amount of radioactive nuclide in a particular energy state at a given time, the quotient of dN by dt, where dN is the expectation value of the number of spontaneous nuclear transformations from that energy state in the time interval dt (ICRU 60).

$$A = \frac{dN}{dt} \quad \text{Unit: s}^{-1} \quad (4)$$

The unit of activity, A, is the becquerel (Bq).

3.1.4.1 *Discussion*—The former special unit of activity was the curie (Ci).

$$1\ \text{Ci} = 3.7 \times 10^{10}\ s^{-1} = 3.7 \times 10^{10}\ \text{Bq (exactly)} \quad (5)$$

The particular energy state is the ground state of the nuclide unless otherwise specified. The activity of an amount of radioactive nuclide in a particular energy state is equal to the product of the decay constant, λ, for that state and the number of nuclei in the state (that is, $A = N\lambda$) (see decay constant).

3.1.5 *calibration*—the process whereby the response of a measuring system or measuring instrument is characterized through comparison with an appropriate standard that is traceable to a nationally or internationally recognized standard.

3.1.6 *calibration curve*—graphical representation of the

[4] International Commission on Radiation Units and Measurements (ICRU), 7910 Woodmont Ave., Suite 800, Bethesda, MD 20810, U.S.A.
[5] American National Standards Institute, 25 West 43rd St., New York, NY 10036, U.S.A.
[6] National Council on Radiation Protection (NCRP), 7910 Woodmont Ave., Suite 800, Bethesda MD 20814, U.S.A.
[7] International Organization for Standardization (ISO), 1 rue de Varembé, Case Postale 56, CH-1211 Geneva 20, Switzerland.
[8] International Atomic Energy Agency (IAEA), Wagrammerstrasse 5, P.O. Box 100, A-1400 Vienna, Austria.

dosimetry system's response function.

3.1.7 *calibration facility*—combination of an ionizing radiation source and its associated instrumentation that provides a uniform and reproducible absorbed dose, or absorbed dose rate, traceable to national or international standards at a specific location and within a specified material, and that may be used to derive the dosimetry system's response function or calibration curve.

3.1.7.1 *Discussion*—Some manufacturers calibrate instruments in units of exposure (see 3.1.15).

3.1.8 *canister*—a container, usually an aluminum or steel cylinder, used to house the sample, or simulated product, during the radiation process.

3.1.9 *charged particle equilibrium*—the condition that exists in an incremental volume within a material under irradiation if the kinetic energies and number of charged particles (of each type) entering that volume are equal to those leaving that volume.

3.1.9.1 *Discussion*—When electrons are the predominant charged particle, the term "electron equilibrium" is often used to describe charged particle equilibrium. See also the discussions attached to the definitions of kerma and absorbed dose in ASTM E 170.

3.1.10 *decay constant (λ)*—of a radioactive nuclide in a particular energy state, the quotient of *dP* by *dt*, where *dP* is the probability of a given nucleus undergoing spontaneous nuclear transition from that energy state in the time interval dt (ICRU 60).

$$\lambda = \frac{dP}{dt} \quad \text{Unit: } s^{-1} \tag{6}$$

3.1.10.1 *Discussion*—The quantity (ln 2)/λ is commonly called half life, $t_{1/2}$, of the radioactive nuclide, that is, the time taken for the activity of an amount of radioactive nuclide to become half its initial value.

3.1.11 *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.

3.1.12 *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 measurement instrumentation and techniques.

3.1.13 *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.

3.1.14 *electron equilibrium*—charged particle equilibrium for electrons.

3.1.15 *exposure (X)*—the quotient of *dQ* by *dm*, where the value of *dQ* is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in air of mass *dm* are completely stopped in air (ICRU 60).

$$X = \frac{dQ}{dm} \tag{7}$$

Unit: C kg^{-1}

3.1.15.1 *Discussion*—Formerly, the special unit of exposure was the roentgen (R): 1 R = 2.58 × 10^{-4} C · kg^{-1} (exactly).

3.1.16 *exposure rate ($\dot{X}$)*—the quotient of *dX* by *dt*, where *dX* is the increment of exposure in the time interval, *dt*.

$$\dot{X} = \frac{dX}{dt} \tag{8}$$

Unit: C kg^{-1} s^{-1}

3.1.17 *half life ($t_{1/2}$)*—see *decay constant.*

3.1.18 *irradiator drawer*—the cylindrical chamber in which the sample to be irradiated is transported by the sample positioning system back and forth between the loading/unloading and the irradiation positions.

3.1.19 *irradiator rotor*—the sample positioning system used to load the sample or sample holder, to rotate it to the stationary shielded irradiation position and when the irradiation is completed, to move it to the unloading position.

3.1.20 *irradiator sample chamber*—the accessible enclosed volume in which a sample or sample holder may be placed in the loading/unloading position of the irradiator (typically a gamma cell) prior to irradiation, and which can be transported by the sample positioning system to the irradiation position.

3.1.21 *irradiator turntable*—device used to rotate the irradiated samples during the irradiation to improve (decrease) the dose uniformity ratio.

3.1.21.1 *Discussion*—Some irradiator geometries, for example, with an annular array of radiation sources surrounding the sample, may not need a turntable.

3.1.22 *isodose curve*—lines or surfaces of constant absorbed dose through a specified medium.

3.1.23 *measurement intercomparison*—a process by which an on-site measurement system is evaluated against a measurement of a standard reference device or material that is traceable to a nationally or internationally recognized standard.

3.1.23.1 *Discussion*—In radiation processing, reference standard or transfer standard dosimeters are irradiated at one irradiation facility, and sent to another for analysis. For example, an issuing laboratory may send dosimeters to an irradiation facility and the irradiated dosimeters are sent back to the issuing laboratory for analysis.

3.1.24 *kerma (K)*—the quotient of dE_{tr} by *dm*, where dE_{tr} is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass *dm* of material.

$$K = \frac{dE_{tr}}{dm} \quad \text{Unit: J } kg^{-1} \tag{9}$$

The special name for the unit of kerma is gray (Gy).

3.1.25 *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 specific applications. This plan requires traceability to, and consistency with, nationally or internationally recognized standards.

3.1.26 *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.

3.1.27 *radioactive–source decay*—spontaneous nuclear transformation of an unstable nucleus, with emission of a particle or photon or both; rate of decay usually is expressed in terms of radionuclide decay constant or half-life.

3.1.28 *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.

3.1.29 *reset timer*—an electronic timer, usually digital, that is equipped as part of the irradiator to time the period for which the sample is to be irradiated. Besides the timer, it contains reset buttons or switches for rezeroing the timer clock, and it is usually connected to the sample positioning system, irradiator drawer, or irradiator rotor.

3.1.30 *routine dosimeter*—dosimeter used for routine absorbed-dose measurement, calibrated against a primary-, reference-, or transfer-standard dosimeter.

3.1.31 *sample holder*—a relatively small container that fits at a fixed or repeatable position in the enclosed chamber of the irradiation device that serves to hold the sample in a reproducible way, and, in the case of dosimeters being calibrated, serves to provide standardized electronic equilibrium conditions during irradiation. The sample holder often is referred to as the product holder.

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

3.1.32.1 *Discussion*—Simulated product often 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.

3.1.33 *transfer–standard dosimeter*—a dosimeter, often a reference–standard dosimeter, suitable for transport between different locations, used to compare absorbed-dose measurements.

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

3.1.34.1 *Discussion*—See ISO/ASTM Guide 51261 for details.

3.1.35 *validation*—establishment of documented evidence which provides a high degree of assurance that a specified process will consistently produce a product meeting its predetermined specifications and quality attributes.

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 Self-contained dry-storage gamma-ray irradiators contain radioactive sources, namely ^{137}Cs or ^{60}Co, that emit ionizing electromagnetic radiation (gamma rays), under properly shielded conditions. 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.

4.2 Self-contained dry-storage gamma-ray irradiators can be used for many radiation processing applications, including the following: calibration of dosimeters; dosimeter studies for research; irradiations of relatively small samples for inducing desired radiation effects or for radiation process validation purposes; 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 relatively small containers of samples, such as blood products, insect canisters, prosthetic devices, and pharmaceuticals.

NOTE 1—In the case of irradiated health care products, pharmaceuticals, foodstuffs, animals and plants, the assurance that they are properly irradiated is of crucial importance. The irradiator operator must demonstrate by means of accurate absorbed dose measurements in sample, or in simulated product, that the specified absorbed dose is achieved (see ISO/ASTM Guide 51261, ISO/ASTM Practices 51204, 51400, 51702, and ISO 11137). For most applications, the absorbed dose is expressed as absorbed dose in water (see ISO/ASTM Guide 51261). For conversion of absorbed dose in water to that in other materials, for example, silicon, solid-state devices, polymers, see Annex A1 of ISO/ASTM Guide 51261.

4.3 Self-contained dry-storage gamma-ray irradiators contain a sealed source, or an array of sealed sources completely held in a dry container constructed of solid materials. The sealed sources are shielded at all times, and human access to the chamber undergoing irradiation is not physically possible due to design configuration (see ANSI N433.1).

4.4 For each irradiator, an absorbed–dose rate at a reference position within the sample or sample holder is measured. That measurement is used to calculate the timer setting required to deliver the specified absorbed dose. The irradiator manufacturer may perform reference-standard measurements and dose-mapping measurements within the irradiation chamber.

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 in air, water or tissue (gray). 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.

4.5 Dosimetry carried out with such sources may be part of a measurement quality assurance program that is applied to ensure that the radiation process, test or calibration meets predetermined specifications **(1)**.[9]

4.6 Absorbed-dose mapping for establishing the locations of minimum (D_{min}) and maximum (D_{max}) doses usually is performed using the sample or simulated product (see 9.3).

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

5. Types of facilities and modes of operation

5.1 *Self-Contained Gamma Irradiators*—Typical self-contained dry-storage gamma-ray irradiators are illustrated in Annex A1. These irradiators house the radiation source(s) in a protective lead shield (or other appropriate solid high atomic-number 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. Details on the calibration of dosimeters **(2)** and dose mapping in such irradiators may be found, respectively in ISO/ASTM Guide 51261 and in this practice (7.3 and 9.3). Details on the designs of such irradiators may be found in Refs **(1)** and **(3)**. Details on safety considerations in the use of such irradiators may be found in ANSI Report N433.1. Four common modes of operation are described. This does not purport to include all modes of operation.

5.1.1 One method of use is to rotate the sample holder or canister 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 **(1** and **3)**.

5.1.2 A second method is to move the sample holder closer to, or away from, the radiation source using a transport mechanism. In this case, a sample is moved to a predetermined distance from the source to achieve a desired dose. A turntable may be used to achieve a uniform dose **(1)**.

5.1.3 A third 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 **(1)**.

5.1.4 A fourth method is to use opposed sources with appropriate beam flattening to obtain a uniform dose throughout the sample holder **(1)**.

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 or ^{137}Cs, which are typically linear rods or pencils arranged singly or in one or more planar or cylindrical arrays.

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 (see NCRP 58 for the detailed radioactive decay components).

6.3 The half-lives for ^{60}Co and ^{137}Cs are approximately 5.2708 (±0.0013) years **(4)** and 30.07 (±0.03) years **(5)**, respectively. In addition, the ^{137}Cs radiation source may contain ^{134}Cs as an impurity that may affect the dose rate produced by the radiation source over time.

6.4 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 for the same dose (see Note 8) may be calculated **(1)** or obtained from tables provided by the irradiator manufacturer.

7. Dosimetry systems

7.1 Dosimetry systems used to determine 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 measure absorbed dose. They consist of the dosimeters, measurement instruments and their associated reference standards, and the 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.

7.2.2.2 *Reference–Standard Dosimeters*—Reference–standard dosimeters are used to calibrate radiation environments and routine dosimeters. Reference–standard dosimeters also may 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 the application in this practice, the following reference–standard dosimeters may be suitable: alanine, ferrous sulfate solution, ceric-cerous sulfate solution, potassium/silver dichromate solution, ethanol chlorobenzene solution, calorimeter, and ionization chamber.

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 measurement traceability for that facility. These dosimeters should be used under carefully controlled conditions as per the protocol of the issuing laboratory. Transfer–standard dosimeters may be selected from either reference–standard or routine dosimeters and shall have performance characteristics that meet the requirements listed in ISO/ASTM Guide 51261.

NOTE 3—In the routine 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 the operator and regulatory authorities with an independent quality control record for the documentation procedure **(1)**.

7.2.2.4 *Routine Dosimeters*—Routine dosimeters may be used for quality control and routine monitoring. 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.

7.2.3 *Dosimetry System Selection*—It is important that the dosimetry system be evaluated for those parameters associated with self-contained dry-storage irradiators that may influence the dosimeter response, for example, differences in gamma–ray energy, absorbed-dose rate, and environmental conditions, such as temperature, relative humidity, and light. Guidance as to desirable characteristics and selection criteria can be found in

ISO/ASTM Guide 51261. Details for individual dosimetry systems are given in ASTM Practice E 1026, ISO/ASTM Practices 51205, 51275, 51276, 51310, 51401, 51538, 51540, 51607, and 51650.

7.3 *Calibration of Dosimetry Systems*:

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

7.3.3 *Calibration Irradiation of Routine Dosimeters*—Calibration irradiations may be performed in several ways, including irradiating the routine dosimeters using a calibration facility that provides an absorbed dose or an absorbed-dose rate having measurement traceability to nationally or internationally recognized standards; or an in-house calibration facility that provides an absorbed dose or an absorbed-dose rate having measurement traceability to nationally or internationally recognized standards.

NOTE 4—The self-contained dry-storage gamma-ray irradiators covered in this practice are the most typical irradiation devices used for dosimeter calibrations as cited here. Calibration laboratories also may use panoramic irradiation devices.

7.3.4 *Measurement 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.

7.4 *Factors that Affect the Response of Dosimeters*—Factors that affect the response of dosimeters, including environmental conditions and variations of such conditions within the processing facility, shall be known or taken into account (see ISO/ASTM Guide 51261).

8. Pre- and post-installation qualification

8.1 Pre- and post-installation qualification involves using dosimetry at integral stages prior to or after the installation procedure as part of the manufacturer's release for shipment criteria, and it usually includes absorbed-dose mapping and measuring the absorbed-dose rate at one position within the sample chamber.

8.2 *Objective*—When self-contained dry-storage irradiators are used to irradiate samples in situations requiring validation of the process and qualification of the facility, the purpose of pre- and post-installation dosimetry is to establish baseline data for evaluating the facility effectiveness, predictability, and reproducibility for the range of operating conditions. For example, dosimetry can be used *(1)* to establish relationships between the absorbed dose for a reproducible geometry and the operating parameters of the irradiator, *(2)* to characterize absorbed-dose variations when facility and processing parameters fluctuate statistically through normal operations, and *(3)* to measure absorbed-dose distributions in simulated product material and other reference materials.

8.3 *Equipment Documentation*—Establish and document an irradiator qualification program to demonstrate that the irradiator is operating within specified limits and will consistently produce an absorbed-dose distribution in simulated product to predetermined specification. Document for the life of the irradiator the descriptions of instrumentation and equipment for ensuring the reproducibility in absorbed-dose delivery, within specified limits.

8.4 *Equipment Testing and Calibration*:

8.4.1 *Processing Equipment*—The absorbed dose in sample or simulated product depends on the operating parameters of the irradiator.

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

8.4.1.2 Implement a documented calibration program to assure that all processing equipment and instrumentation that may influence absorbed-dose delivery are calibrated periodically, for example, the irradiator reset timer mechanism on an annual basis.

8.4.2 *Measurement Equipment*—The accuracy of the absorbed-dose measurement depends on the correct operation and calibration of the analytical equipment used in the analysis of the dosimeters.

8.4.2.1 Check the performance of the analytical equipment periodically to ensure that the equipment is functioning according to performance specifications. Repeat this check following any equipment modification or servicing and prior to the use of the equipment for a dosimetry system calibration. This check can be accomplished by using standards such as calibrated optical density filters, wavelength standards, or calibrated thickness gages supplied by the manufacturer or national or accredited standards laboratories.

8.4.2.2 Implement a documented calibration program to assure that all analytical equipment used in the analysis of dosimeters is calibrated periodically.

8.4.3 Typical testing steps and testing frequencies are given in Annex A2.

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

8.5.1 In order to facilitate reproducible absorbed-dose delivery to the sample, the transit dose should be small relative to the total dose received by the sample. The effect on transit dose caused by movement of the sample or source to and from the irradiation position should be considered and quantified. Procedures for measuring and correcting for transit dose in terms

of transit times are given in ISO/ASTM Guide 51261.

NOTE 5—If the transit dose is well characterized and reproducible, it can be applied as a correction factor to the dose as calculated from the calibrated irradiator absorbed-dose rate.

8.5.2 The irradiator characterization process includes mapping the absorbed-dose distributions on irradiated sample or simulated product (see 9.3). Dosimetry data from previously characterized irradiators of the same design or theoretical calculations may provide useful information for determining the number and location of dosimeters needed for this characterization process or test.

8.5.3 Ideally, the irradiation procedure is designed to irradiate the sample uniformly; in reality, a certain variation in absorbed dose through the sample will exist. Absorbed-dose mapping is used to determine the magnitude and locations of D_{max} and D_{min} for a given set of operating parameters, for example, timer setting, sample loading configuration. In most self-contained dry-storage irradiator applications the sample is close to the centerline axis where the dose-rate distribution is relatively uniform; however, when the sample chamber is full or nearly full, the sample may extend radially close to the sources, resulting in pronounced absorbed-dose gradients near the periphery of the sample. It is important, therefore, to choose a dosimeter, that is able to detect these gradients.

8.5.4 Map the absorbed-dose distribution by placing dosimeters throughout the sample or simulated product. Select placement patterns that can identify the locations of D_{max} and D_{min}.

NOTE 6—In the case of static irradiations, such as when the sample is located at the center of an annular source array of the self-contained dry-storage irradiator, the dose mapping should be done in three dimensions. When a uniform and symmetrically placed sample is irradiated on a turntable, the dose mapping can be done in two dimensions, such as an arbitrary vertical plane through the axis of rotation or a horizontal plane at a level where the dose distribution is relatively uniform. In this case, the result is a three-dimensional mapping due to the uniform rotation during irradiation.

8.5.5 Changes in any component of the irradiation system that impacts the current characterization may require a recharacterization of the irradiator.

8.5.6 Most dry-storage irradiator manufacturers use a reference–standard dosimetry system to measure the absorbed-dose rate at a reference location (such as the center of the sample chamber. That absorbed-dose rate also may be measured with routine dosimeters, which have been calibrated using a calibration facility (see ISO/ASTM Guide 51261). The measurement may be used to calculate the reset timer setting necessary to deliver the specified absorbed dose to the sample. The continued usage of this timer setting, adjusted for source decay, will help to ensure that samples will be irradiated, tested, or processed to the specified minimum absorbed dose. If the sample volume occupies much less than the available irradiation volume, care must be taken to ensure that the D_{max} delivered to the sample is still within specification (see 10.2.1.1). The frequency of testing depends on the manufacturer's recommendations and user requirements.

NOTE 7—Procedures and typical frequencies for testing of self-contained dry-storage gamma-ray irradiators for different applications are tabulated in Annex A2.

8.5.7 An important calculation in the use of gamma-ray 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_o (at time = 0 which is usually specified as the date of the last calibration), the activity at some later time, t, is given by:

$$\frac{A_t}{A_o} = e^{-\lambda t} \tag{10}$$

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

$$\lambda = \frac{\ln(2)}{t_{1/2}} \tag{11}$$

where:

$t_{1/2}$ is the half-life for a given radionuclide. The half-lives for gamma-ray emission by ^{60}Co and ^{137}Cs are 5.2708 (±0.0013) years **(4)** and 30.07 (±0.03) years **(5)**, respectively. Using 365.2422 days per year, the values for λ in Eq 11 for ^{60}Co and ^{137}Cs are as follows:

$$\text{For } ^{60}\text{Co}, \lambda = 3.60054 \times 10^{-4}\ \text{day}^{-1} \tag{12}$$

$$\text{For } ^{137}\text{Cs}, \lambda = 6.31119 \times 10^{-5}\ \text{day}^{-1} \tag{13}$$

The decay factor is defined as follows:

$$\text{Decay Factor} = \frac{A_t}{A_0} = e^{-\lambda t} \tag{14}$$

NOTE 8—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 12 and 13, Eq 14 gives decay factors for ^{60}Co and ^{137}Cs of 0.835248 and 0.968934, respectively.

Since the absorbed-dose rate, $\dot{D}$, due to gamma-ray emission by a radionuclide source also varies exponentially with the decay time, t, the dose rate, $\dot{D}_t$, at a given time, t, is given by:

$$\dot{D}_t = \dot{D}_0 \cdot e^{-\lambda t} \tag{15}$$

where:

$\dot{D}_t$ is the dose rate at time t; $\dot{D}_0$ 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:

$$(TS)_t = (TS)_0 \cdot e^{\lambda t} \tag{16}$$

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.

NOTE 9—Calculations of source decay, and therefore adjustments of timers, always should be done as referenced to the date of last calibration (t = 0), to avoid compounding errors.

9. Process qualification

9.1 *Objective*—The purpose of dosimetry in process qualification is to ensure that the absorbed-dose requirements for a particular sample can be satisfied. This is accomplished by absorbed-dose mapping (see 9.3) of specific samples and sample loading configurations or in simulated product representing the near-worst case geometry to determine the magnitude and location of D_{max} and D_{min}, and the irradiator timer

setting necessary to achieve the absorbed doses within the set requirements.

9.2 *Sample Loading Configuration*—A loading configuration for the irradiation should be established for each sample type. The documentation for this loading configuration shall include specifications for parameters such as sample size, sample mass or sample density, which influence the absorbed-dose distribution.

NOTE 10—The sample holder or canister should not be loaded beyond the designed maximum volume.

9.3 *Sample or Simulated Product Absorbed-Dose Mapping*—For each sample treated in the self-contained dry-storage irradiator there is a minimum dose to achieve the desired effect and a maximum dose that the sample can tolerate without degradation in quality. Often, the process is defined by targeting a known dose to the center of the sample while achieving the required minimum dose everywhere else. Establish the locations of the regions of D_{max} and D_{min} for the selected sample and sample loading pattern by placing dosimeters throughout the volume of interest for one or more sample or simulated product. Concentrate the dosimeters in regions of D_{max} and D_{min} with fewer dosimeters placed in areas likely to receive intermediate absorbed dose. Dosimeter film in strips or sheets may be employed to obtain useful information **(1, 6, 7)** as illustrated in Fig. 1 **(8)**.

9.3.1 If any changes that could affect the magnitude or location of the absorbed dose extremes are made to the irradiator or mode of operation, repeat the absorbed-dose mapping to the extent necessary to establish the effect. Examples are the insertions of accessories, such as field-flattening attenuators, temperature control devices, or bulky fixtures inside the irradiator chamber.

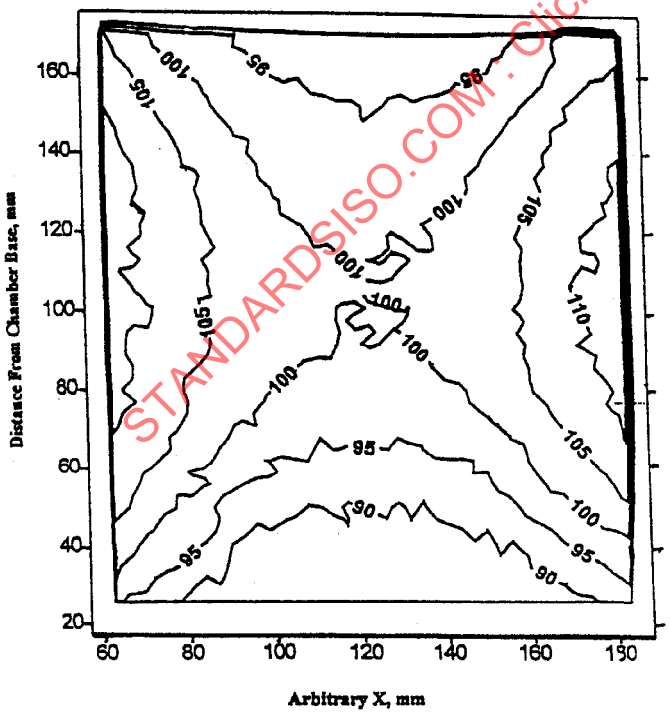

FIG. 1 Example of dose mapping results normalized to a central dose of 100 %

9.3.2 If the locations of absorbed-dose extremes identified during the mapping procedure of 9.3 are not readily accessible during routine source operation, alternative positions may be used for routine dosimetry. The relationships between the absorbed dose at these alternative positions and the absorbed-dose extremes should be established, shown to be reproducible, and documented.

9.3.3 Results from the absorbed-dose mapping will be used to determine the degree of dose uniformity, and to show that the irradiation was within specification for that application.

9.3.4 When a single radioisotope source is being used, such as ^{60}Co and ^{137}Cs, source decay does not change the relative absorbed-dose distribution. Any change in the relative dose distribution usually is attributed to a change in the sample or irradiation geometry.

10. Routine sample batch processing

10.1 *Process Parameters and Control*—For sample batch processing, set the operating parameters as established during process qualification, taking into account source decay. All the critical parameters that can affect the absorbed-dose distribution should be controlled and monitored during routine processing, including, sample loading, timer setting, and turntable rotation. Document the process parameters to help ensure that the sample is processed in accordance with specifications. If these parameters deviate from prescribed processing limits, take appropriate actions.

NOTE 11—It is the responsibility of the user to determine the absorbed-dose distribution associated with different types of samples, and the necessary process parameters.

10.2 *Routine Dosimetry in Full or Partially Full Sample Chambers*—Routine measurements of absorbed dose to the sample will help ensure that it has been treated with the minimum dose prescribed by the process. Often, however, the minimum absorbed dose is not measured. The measured absorbed dose at the reference dose position should have a known and reproducible relationship with the minimum dose.

10.2.1 *Routine Process Monitoring Using Dosimeters*—Routine processing monitoring may be performed using routine dosimeters. It can be part of the verification process for establishing that the radiation process is under control.

10.2.1.1 *Dosimeter Location*—Place one or more dosimeters on the sample at predetermined locations of the D_{max} and D_{min} or at a reference dose position (see 9.3.2). The absorbed dose at the reference dose position has a quantitative and reproducible relationship with D_{max} and D_{min}. Any accurate dosimetry at a reference position, which could be either a center-line dose-rate position where the dose-rate distribution is relatively uniform or the established positions of the maximum absorbed dose (D_{max}) and the minimum absorbed dose (D_{min}), offers a quantitative, independent method of achieving and maintaining standard measurement quality assurance and radiation process or test control.

10.2.1.2 *Dosimeter Placement*—The placement for monitoring shall be sufficient to ensure that the absorbed dose

received by the sample falls within specified limits.

NOTE 12—The absorbed-dose distribution in the sample or simulated product should already be known from the pre- or post-installation dosimetry and dose mapping described in Sections 8 and 9.

10.2.1.3 *Environmental Effects*—If there is a change in the environment (for example, temperature or relative humidity) of a dosimeter during the radiation process or pre- or post-irradiation storage, the response of the dosimeter may be affected **(1)**. If required, correct the dosimeter response for any such effect. Care also must be taken in handling and storage of dosimeters before and after irradiation (see ISO/ASTM Guide 51261 and practices for individual dosimetry systems).

10.2.1.4 *Chilled or Frozen Samples*—Absorbed dose is not a function of the temperature of the irradiated sample; however, the response of the dosimeter may be a function of the sample temperature. The dose-mapping information for simulated product (representing the actual sample geometry or near-worst case geometry) at ambient temperature can be applied to the chilled or frozen sample. Exercise care when determining the temperature of the dosimeter during irradiation of chilled or frozen samples and when applying the appropriate temperature correction. Dosimeters that exhibit a highly temperature-dependent response should not be placed in locations with large temperature gradients (see ISO/ASTM Guide 51261 and practices for individual dosimetry systems).

11. Measurement uncertainty

11.1 To be meaningful, a measurement of absorbed dose shall be accompanied by an estimate of uncertainty. Components of uncertainty shall be identified as belonging to one of two groups:

11.1.1 Those that are identified by statistical methods, or

11.1.2 Those that are evaluated by other means.

11.1.3 Additional information is given in ISO/ASTM Guide 51707 and Refs **(9 and 10)**, where these components are referred to as Type A and Type B, respectively. In reporting uncertainty, other classifications, such as precision and bias may be useful.

11.2 If this practice is followed, the estimate of the expanded uncertainty of an absorbed dose determined by a specified dosimetry system should be within specified uncertainty limits.

NOTE 13—The identification of Type A and Type B uncertainties is based on the methodology adopted in 1993 by the International Organization for Standardization (ISO) for estimating uncertainty. This is different from the way uncertainty has traditionally been expressed in terms of precision and bias, where precision is a measure of the extent to which replicate measurements made under specified conditions are in agreement, and bias is a systematic error (see ASTM Terminologies E 170 and E 456, and ASTM Practice E 177). The purpose of using the method of expressing uncertainties as Type A and Type B recommended in the ISO Guide to the Expression of Uncertainty in Measurement **(10)** is to promote an understanding of how uncertainty statements are arrived at and to provide a basis for the international comparison of measurement results.

NOTE 14—ISO/ASTM Guide 51707 defines possible sources of error in dosimetry performed in radiation processing facilities and offers procedures for estimating the resulting magnitude of the uncertainties in the measurement results. Basic concepts of measurement, estimate of the measured value of a quantity, "true" value, error and uncertainty are defined and discussed. Components of uncertainty are discussed and methods are given for evaluating and estimating their values. Their contributions to the standard uncertainty in the reported values of absorbed dose are considered, and methods are given for calculating the combined standard uncertainty and an estimate of overall (expanded) uncertainty.

11.3 The components of uncertainty involved in a measurement shall be estimated or determined. The overall uncertainty in the measurement may be estimated from a combination of these components, and the procedure for combining these components shall be stated or referenced specifically in all results.

12. Keywords

12.1 batch radiation processing; calibration of dosimeters; cesium-137; cobalt-60; dosimeter research studies; dosimetry; dry-storage irradiators; gamma cells; gamma radiation; radiation process validation; radiation effects testing; self-contained irradiators

ANNEXES

(informative)

A1. TYPICAL SELF-CONTAINED DRY-STORAGE IRRADIATORS

A1.1 Typical self-contained dry-storage irradiators (see ANSI Report N433.1) include the GammaCell Model 220 **(1,2)**, the JL Shepherd Mark I (see A1.3) and the Husman Model 521A **(3)**.

A1.1.1 The GammaCell Model 220 irradiator, manufactured by MDS Nordion, contains sealed ^{60}Co sources in an annular array around the irradiation chamber (Fig. A1.1).

A1.1.2 The JL Shepherd Mark I irradiator (Fig. A1.2) contains shielded ^{137}Cs sources. After the sample is loaded into the sample cavity and the door is closed securely, the radiation source moves into the irradiate position for a predetermined period of time.

A1.1.3 The Husman 521A irradiator contains sealed ^{137}Cs source rods in an annular array around the irradiation chamber (Fig. A1.3).

A1.2 These irradiation devices house the gamma-ray source(s) in a protective shield, or other appropriate solid high atomic-number 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. 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.

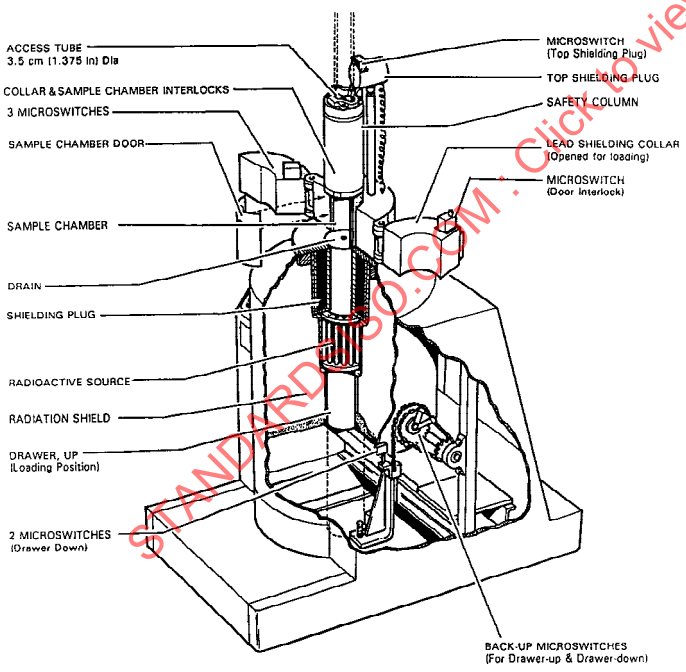

FIG. A1.1 Basic construction of the GammaCell 220 ^{60}Co irradiator

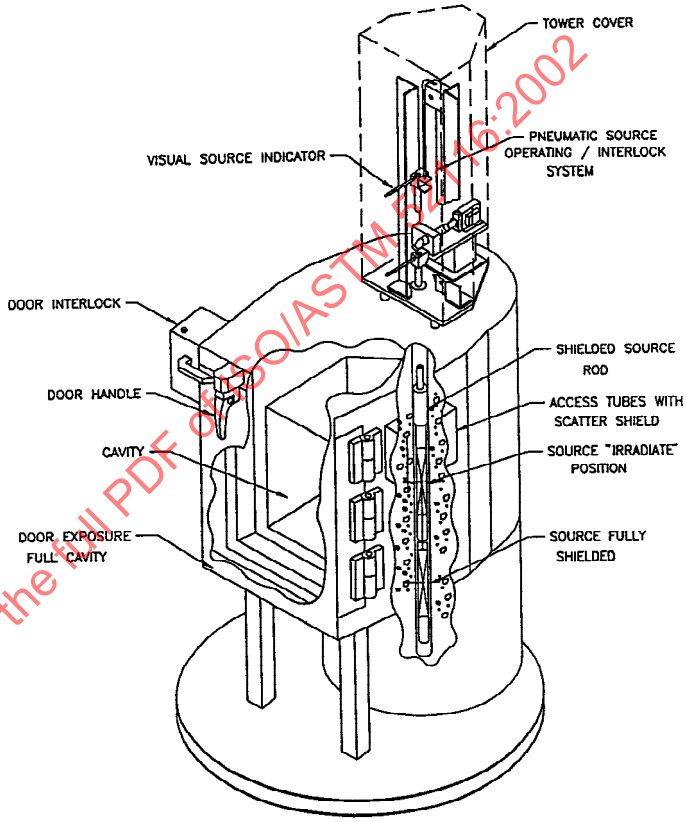

FIG. A1.2 Basic construction of J.L. Shepherd Mark I irradiator

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

Irradiator Model	Contact
GammaCell 220	MDS Nordion International, Inc. 447 March Road Kanata, Ontario K2K 1X8 Canada
JL Shepherd Mark I	J.L. Shepherd & Associates 1010 Arroyo Avenue San Fernando, CA 91340-1822 USA
Husman 521A	This unit is no longer being manufactured but is still in use.