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Guide for selection and calibration of dosimetry systems for radiation processing

Guide de choix et d'étalonnage des appareils de mesure dosimétrique pour le traitement par irradiation

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Foreword

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

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

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

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

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

International Standard ISO/ASTM 51261 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, A2, A3, A4 and A5 of this International Standard are for information only.

ISO/ASTM 51261:2002(E)

Standard Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing[1]

This standard is issued under the fixed designation ISO/ASTM 51261; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision.

1. Scope

1.1 This guide covers the basis for selecting and calibrating dosimetry systems used to measure absorbed dose in gamma-ray or X-ray fields and in electron beams used for radiation processing. It discusses the types of dosimetry systems that may be employed during calibration or on a routine basis as part of quality assurance in commercial radiation processing of products. This guide also discusses interpretation of absorbed dose and briefly outlines measurements of the uncertainties associated with the dosimetry. The details of the calibration of the analytical instrumentation are addressed in individual dosimetry system standard practices.

1.2 The absorbed-dose range covered is up to 1 MGy (100 Mrad). Source energies covered are from 0.1 to 50 MeV photons and electrons.

1.3 This guide should be used along with standard practices and guides for specific dosimetry systems and applications covered in other standards.

1.4 Dosimetry for radiation processing with neutrons or heavy charged particles is not covered in this guide.

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 178 Practice for Dealing with Outlying Observations[3]

E 456 Terminology Relating to Quality and Statistics[3]

E 666 Practice for Calculating Absorbed Dose from Gamma or X Radiation[2]

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

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

2.2 *ISO/ASTM Standards:*

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

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

51631 Practice for Use of Calorimetric Dosimetry Systems for Electron Beam Dose Measurements and Dosimeter Calibrations[2]

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

51650 Practice for Use of Cellulose Acetate Dosimetry Systems[2]

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

51707 Guide for Estimating Uncertainties in Dosimetry[2]

51956 Practice for the Use of Thermoluminescence-Dosimetry (TLD) Systems for Radiation Processing[2]

2.3 *International Commission on Radiation Units and Measurements Reports:*

ICRU Report 14 Radiation Dosimetry: X-rays and Gamma rays with Maximum Photon Energies Between 0.6 and 50 MeV[4]

ICRU Report 17 Radiation Dosimetry: X-rays Generated at Potentials of 5 to 150 kV[4]

ICRU Report 34 The Dosimetry of Pulsed Radiation[4]

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

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

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

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

ICRU Report 35 Radiation Dosimetry: Electron Beams with Energies between 1 and 50 MeV[4]
ICRU Report 37 Stopping Powers for Electrons and Positrons[4]
ICRU Report 60 Radiation Quantities and Units[4]

3. Terminology

3.1 *Definitions:*

3.1.1 *accredited dosimetry calibration laboratory*—a laboratory that meets specific performance criteria and has been tested and approved by a recognized accrediting organization.

3.1.2 *calibration curve*—graphical representation of the dosimetry system's response function.

3.1.3 *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 specified location and within a specific material, and that may be used to derive the dosimetry system's response function or calibration curve.

3.1.4 *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 the volume are equal to those leaving that volume.

3.1.4.1 *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 E 170.

3.1.5 *dosimeter batch*—quantity of dosimeters made from a specific mass of material with uniform composition, fabricated in a single production run under controlled, consistent conditions, and having a unique identification code.

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

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

3.1.8 *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.

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

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

3.1.10 *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.

3.1.11 *primary–standard dosimeter*—dosimeter, of the highest metrological quality, established and maintained as an absorbed dose standard by a national or international standards organization.

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

3.1.13 *quality assurance*—all systematic actions necessary to provide adequate confidence that a calibration, measurement, or process is performed to a predefined level of quality.

3.1.14 *reference–standard dosimeter*—dosimeter of high metrological quality used as a standard to provide measurements traceable to, and consistent with, measurements made using primary–standard dosimeters.

3.1.15 *response function*—mathematical representation of the relationship between dosimeter response and absorbed dose for a given dosimetry system.

3.1.16 *routine dosimeter*—dosimeter calibrated against a primary, reference, or transfer–standard dosimeter and used for routine absorbed dose measurement.

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

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

3.1.18 *dosimeter stock*—part of a dosimeter batch held by the user.

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

3.1.20 *verification*—confirmation by examination of objective evidence that specified requirements have been met.

3.1.20.1 *Discussion*—In the case of measuring equipment, the result of verification leads to a decision to restore to service or to perform adjustments, repair, downgrade, or declare obsolete. In all cases it is required that a written trace of the verification performed be kept on the instrument's individual record.

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 Ionizing radiation is used to produce various desired effects in products. Examples include the sterilization of medical products, processing of food, modification of polymers, irradiation of electronic devices, and curing of inks, coatings, and adhesives **(1, 2)**[5]. The absorbed doses employed in these applications range from about 10 Gy to more than 100 kGy.

4.2 Regulations for sterilization of medical products and radiation processing of food exist in many countries. These regulations may require that the response of the dosimetry system be calibrated and traceable to national standards **(3, 4, 5)**. Adequate dosimetry, with proper statistical controls and documentation, is necessary to ensure that the products are properly processed.

4.3 Proper dosimetric measurements must be employed to ensure that the product receives the desired absorbed dose. The dosimeters must be calibrated. Calibration of a routine dosimetry system can be carried out directly in a national or accredited standards laboratory by standardized irradiation of routine dosimeters. Alternatively, it may be carried out through the use of a local (in-house) calibration facility **(6)** or in a production irradiator. All possible factors that may affect the response of dosimeters, including environmental conditions and variations of such conditions within a processing facility, should be known and taken into account. The associated analytical instrumentation must also be calibrated.

5. Dosimeter Classes and Applications

5.1 Dosimeters may be divided into four basic classes in accordance with their relative quality and areas of applications as follows:

5.1.1 *Primary–Standard Dosimeter*—Primary–standard dosimeters are established and maintained by national standards laboratories for calibration of radiation environments (fields). Primary–standard dosimeters are typically used to calibrate or intercompare radiation environments in dosimetry calibration laboratories, and are not normally used as routine dosimeters. Discussions about the selection and calibration of primary–standard dosimeters are provided in 6.1 and 8.2.1, respectively. The two most commonly used primary–standard dosimeters are ionization chambers and calorimeters (for details, see ICRU Reports 14, 17, 34, and 35).

5.1.2 *Reference–Standard Dosimeter*—Reference–standard dosimeters are used to calibrate radiation environments and to calibrate routine dosimeters. Reference–standard dosimeters may also be used in routine dosimetry applications for radiation processing where higher quality dosimetry measurements are desired. Widely used reference dosimeters include the ferrous sulfate (Fricke) aqueous solution (see ASTM Practice E 1026) and the alanine-EPR dosimetry system (see ISO/ASTM Practice 51607). Discussions about the selection and calibration of reference–standard dosimeters are provided in 6.2 and 8.2.2, respectively. Devices used as primary–standard dosimeters may also be used as reference–standard dosimeters, in which case they shall be calibrated (see 8.2.2). Examples of reference dosimeters are listed in Table 1; more details of the characteristics of several systems may be found in Annex A4.

5.1.3 *Routine Dosimeters*—Routine dosimeters are used in radiation processing facilities for absorbed dose mapping and process monitoring. Discussions about the selection and calibration of routine dosimeters are provided in 6.2 and 8.4, respectively. Examples of routine dosimeters are listed in Table 2; more details of the characteristics of several of these systems may be found in Annex A4.

5.1.4 *Transfer–Standard Dosimeters*—Transfer–standard dosimeters are specially selected dosimeters used for transferring dose information from an accredited or national standards laboratory to an irradiation facility in order to establish traceability for that calibration facility. Transfer–standard dosimeters should be used under conditions specified by the issuing laboratory. They may be either reference–standard dosimeters (Table 1) or routine dosimeters (Table 2) that have characteristics meeting the requirements of the particular application. In addition to the references given in Tables 1 and 2, relevant information on some other types of dosimeters may be found in ASTM Practice E 668 and in ISO/ASTM Practices 51275 and 51276,.

NOTE 1—None of the reference–standard dosimeters or routine dosimeters listed have all of the desirable characteristics given in Section 6 for

TABLE 1 Examples of Reference–Standard Dosimeters

Dosimeter	Readout System	Useful Absorbed Dose, Gy	References[A]
Ionization chamber	Electrometer	10^{-4} to 10	**(11,12)**
Calorimeter	Thermometer	10^2 to 10^5	**(13)**
Alanine	EPR spectrometer	1 to 10^5	**(14)**
Ceric cerous sulfate solution	UV spectrophotometer or electrochemical potentiometer	10^3 to 10^5	**(15,16)**
Ethanol chlorobenzene solution	Spectrophotometer, color titration, high frequency conductivity	10 to 2×10^6	**(17, 18)**
Ferrous sulfate solution	UV spectrophotometer	20 to 4×10^2	**(19)**
Potassium/silver dichromate	UV/visible spectrophotometer	10^3 to 10^5	**(20)**

[A] These references are not exhaustive; others may be found in the literature.

TABLE 2 Examples of Routine Dosimeters

Dosimeter	Readout System	Useful Absorbed Dose, Gy	References[A]
Alanine	EPR spectrometer	1 to 10^5	**(14)**
Dyed polymethyl-methacrylate	Visible spectrophotometer	10^2 to 10^5	**(21,22,23)**
Clear polymethyl-methacrylate	UV spectrophotometer	10^3 to 10^5	**(21,24)**
Cellulose acetate	Spectrophotometer	10^4 to 4×10^5	**(25)**
Lithium borate, lithium fluoride	Thermoluminescence reader	10^{-4} to 10^3	**(26)**
Lithium fluoride (optical grade)	UV/Visible spectrophotometer	10^2 to 10^6	**(27)**
Radiochromic dye films, solutions, optical wave guide	Visible spectrophotometer	1 to 10^5	**(6,8,28)**
Ceric cerous sulfate solution	Potentiometer or UV spectrophotometer	10^3 to 10^5	**(15)**
Ferrous cupric sulfate solution	UV spectrophotometer	10^3 to 5×10^3	**(29)**
Ethanol chlorobenzene solution	Spectophotometer, color titration, high-frequency conductivity	10 to 2×10^6	**(18)**
Amino acids	Lyoluminescence reader	10^{-5} to 10^4	**(30)**
MOSFET	Voltmeter	1 to 2×10^2	**(31)**

[A] These references are not exhaustive; others may be found in the literature.

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

an "ideal" transfer–standard dosimeter. However, such dosimeters may be used as transfer–standard dosimeters if the absence of one or more desirable characteristics has negligible effect on the response of the dosimeter, or if correction factors can be applied to bring the dosimeter's response into conformity within the necessary limits of uncertainty for the application.

6. Selection of Dosimetry Systems

6.1 *Primary Standard Dosimetry System*—The criterion for the selection of a specific primary–standard dosimeter by a national laboratory depends on the specific measurement application requirement.

6.2 *Reference Standard, Transfer Standard and Routine Dosimetry Systems*

6.2.1 *General Criteria*:

6.2.1.1 Suitability of the dosimeter for the absorbed-dose range of interest and for use with a specific product,

6.2.1.2 Stability and reproducibility of the system,

6.2.1.3 Ease of system calibration,

6.2.1.4 Ability to control or correct system response for systematic error, such as those caused by temperature and humidity (for example, see Ref **(6)**),

6.2.1.5 Overall initial and operational cost of the system, including dosimeters, readout equipment, and labor,

6.2.1.6 Variance (that is, correlation coefficient) of the dosimetry system response data within established limits about a fitted calibration curve over the absorbed-dose range of interest,

6.2.1.7 Dependence of dosimeter response on environmental conditions (such as temperature, humidity, and light) before, during, and after calibration and production irradiation. Effects of environmental conditions on the dosimeter readout equipment shall also be considered.

6.2.1.8 Dependence of dosimeter response on absorbed-dose rate or incremental delivery of absorbed dose, or both,

6.2.1.9 Stability of dosimeter response both before and after irradiation,

6.2.1.10 Agreement of dosimeter response within a batch and between batches,

6.2.1.11 Effects of size, location, orientation, and composition of the dosimeter on the radiation field or the interpretation of the absorbed-dose measurement. In cases where it is desirable to measure absorbed dose at the interface of different materials (for example, at a bone-tissue interface or the surface of a product), dosimeters should be used that are thin compared to distances over which the absorbed-dose gradient is significant, and

6.2.1.12 Effects of differences in radiation energy spectra between calibration and product irradiation fields.

NOTE 2—Availability of adequate information on the performance characteristics of the dosimetry systems should be considered in selecting a dosimetry system.

6.2.2 *Additional Criteria Specific to Routine Dosimetry Systems*:

6.2.2.1 Ease and simplicity of use

6.2.2.2 Availability of dosimeters in reasonably large quantities

6.2.2.3 Time required for dosimeter response development, and labor required for dosimeter readout and interpretation, and

6.2.2.4 Ruggedness of the system (resistance to damage during routine handling and use in a processing environment).

6.2.3 *Additional Criteria Specific to Transfer Standard Dosimetry Systems*:

6.2.3.1 Long pre-irradiation shelf life,

6.2.3.2 Post-irradiation response stability (ability to be archived), and

6.2.3.3 Portability, that is ability to withstand shipping to an irradiation facility and insensitivity to extremes of environmental conditions during transport.

7. Analytical Instrument Calibration and Performance Verification

7.1 Before the overall system is calibrated, and at periodic intervals between calibrations, the individual component instruments of the dosimetry system shall be calibrated or shall have their performance verified. These periodic checks should verify the stability of the components of the system, and should demonstrate that the components are performing as they were when the overall system was calibrated.

7.1.1 If appropriate standards exist, calibrate the individual instruments in accordance with documented procedures so that the instruments' measurements are traceable to nationally or internationally recognized standards.

7.1.1.1 For optical absorbance measurements using a spectrophotometer, check and document that the wavelength and absorbance scales are within the documented specifications at or near the analysis wavelength using optical absorbance filters and wavelength standards traceable to national or international standards.

7.1.1.2 For thickness measurements using a thickness gauge, check and document that the instrument is within documented specifications using gauge blocks traceable to national or international standards.

7.1.2 For dosimetry system instruments where nationally or internationally recognized standards do not exist, verify correct instrument performance using documented industry or manufacturer's procedures to demonstrate that the instrument is functioning in accordance with its own performance specifications.

NOTE 3—For example, the alanine dosimetry system employs electron paramagnetic resonance (EPR) spectroscopy for analysis. The proper operation of the EPR spectrometer instrumentation is verified with appropriate EPR spin standards such as irradiated alanine dosimeters, pitch sample, or Mn(II) in CaO (see ISO/ASTM Practice 51607 for details).

7.1.3 Repeat instrument calibration or instrument performance verification at periodic intervals between the overall system calibrations in accordance with documented procedures, and again if any maintenance or modification of the instrument occurs that may affect its performance.

NOTE 4—For some analytical instrumentation, correct performance can be demonstrated by showing that the readings of dosimeters given known absorbed doses are in agreement with the expected readings within the limits of the dosimetry system uncertainty. This method is only applicable for reference standard dosimetry systems where the long term stability of the response has been demonstrated and documented.

7.1.4 Instrument calibrations and instrument performance verifications shall be conducted by qualified individuals in accordance with documented quality procedures.

7.1.5 Calibration or performance verification of each instrument shall demonstrate that the measurements are within specified limits over the full range of utilization.

8. Dosimetry System Calibration

8.1 *General*:

8.1.1 The calibration of a dosimetry system consists of the irradiation of dosimeters to a number of known absorbed doses over the range of use, analysis of the dosimeters using calibrated analytical equipment, and the generation of a calibration curve or response function. Calibration verification is performed periodically to confirm the continued validity of the calibration curve or response function. Calibration facilities shall meet the requirements specified in ISO/ASTM Practice 51400 and therefore shall have an absorbed-dose rate that has measurement traceability to nationally or internationally recognized standards.

NOTE 5—In several countries, the national standard is realized indirectly through a calibrated radiation field. For example, the absorbed-dose rate in the center of a ^{60}Co source array at the U.S. National Institute of Standards and Technology (NIST) has been well characterized by calorimetry and is one of the national standards used by NIST to irradiate reference standard, transfer standard, and routine dosimeters to known absorbed-dose levels.

8.1.2 Procedures, protocols, and training of personnel shall be provided to ensure that the correct absorbed dose is given to dosimeters.

8.2 *Calibration of Dosimetry Classes*:

8.2.1 *Primary–Standard Dosimeters*—These devices do not require calibration against other standards because their measurements are based on fundamental physical principles.

8.2.2 *Reference–Standard Dosimeters*—Calibration of reference–standard dosimeters is carried out by national or accredited laboratories using criteria specified in ISO/ASTM Practice 51400.

8.2.3 *Transfer–Standard Dosimeters*—Transfer–standard dosimeters may be selected from either reference–standard dosimeters or routine dosimeters (see 5.1.4). Transfer–standard dosimeters shall be calibrated by the class distinction requirements of the dosimeter type selected for dose measurement intercomparison transfer (see 8.2.2 and 8.2.4).

8.2.4 *Routine Dosimeters*—Calibration of routine dosimeters is performed by irradiation of the dosimeters in a calibration facility or in a production irradiator followed by analysis at the production irradiator.

8.3 *Calibration Procedure*:

8.3.1 The number of sets of dosimeters required to determine the calibration curve or response function of the dosimetry system depends on the absorbed-dose range of utilization. Use at least five sets for each factor of ten span of absorbed dose, or at least four sets if the range of utilization is less than a factor of ten.

NOTE 6—To determine mathematically the minimum number of sets to be used, divide the maximum dose in the range of utilization (D_{max}) by the minimum dose (D_{min}), then, calculate log(base 10) of this ratio: $Q = \log(D_{max}/D_{min})$. If Q is equal to or greater than 1, calculate the product of $5 \times Q$, and round this up to the nearest integer value. This value represents the minimum number of sets to be used.

8.3.2 For each absorbed dose point, use the number of dosimeters required to achieve the desired confidence level (see ASTM Practice E 668).

8.3.3 Position the dosimeters in the calibration radiation field in a defined, reproducible location. The variation in absorbed-dose rate within the volume occupied by the dosimeters should be as low as practically possible.

8.3.4 When using a gamma-ray source or X-ray beam for calibration, surround the dosimeter with a sufficient amount of material to achieve approximate electron equilibrium conditions **(7)**.

NOTE 7—The appropriate thickness of such material depends on the energy of the radiation (see ASTM Practices E 666 and E 668). For measurement of absorbed dose in water, use materials that have radiation-absorption properties essentially equivalent to water. For example, for a ^{60}Co source, 3 to 5 mm of solid polystyrene (or equivalent polymeric material) should surround the dosimeter in all directions.

8.3.5 Monitor and, if required, control the temperature of the dosimeters during irradiation.

NOTE 8—To minimize temperature extremes and to aid in the measurement of dosimeter temperature it is important that there be good thermal contact between the dosimeters and a heat sink especially for electron beam or x-ray irradiation.

8.3.6 If the response of the dosimeters is affected by humidity and they are not in a sealed container, monitor, and if required, control the relative humidity during irradiation.

8.3.7 Specify the calibration dose in terms of the material of interest. The calibration dose is usually specified in terms of absorbed dose in water. See Annex A1 for conversion factors for calculating the absorbed dose in different materials.

8.4 *Absorbed Dose Rate Effects*:

8.4.1 For some routine dosimetry systems, the dosimeter response at different absorbed-dose rates for the same given absorbed dose may differ over portions of the system's working range. This divergence may be dependent on several factors, such as the magnitude of the absorbed dose and type of radiation (gamma, electron beam, or X ray). If the absorbed dose rate effects are not known, divergence tests shall be performed. In these tests, other factors that could influence dosimeter response, for example irradiation temperature, should be either fixed or kept within a narrow range. The divergence may be checked by several methods. Two such methods are described in Annex A5.

8.5 *Transit Dose Effects*:

8.5.1 Transit dose effects occur when the timing of a calibration irradiation does not take into account the dose received during the movement of the dosimeters or the source into and out of the irradiation position. For example, the timer on a Gammacell-type irradiator does not start until the sample drawer reaches the fully-down (irradiate) position. Some dose is received as the drawer goes down and after the irradiation as the drawer goes up that is not accounted for in the timer setting. This transit dose can be significant for low-dose irradiations and should be determined experimentally and taken into account when calculating timer settings. Two methods of determining transit dose correction are given in Annex A2.

8.6 *Frequency of Calibration and Verification*:

8.6.1 Calibrate the dosimetry system for each new batch of reference standard, transfer standard, or routine dosimeters prior to use.

8.6.2 At an interval not exceeding one year, re-calibrate the dosimetry system for each batch of reference standard, transfer standard, or routine dosimeters unless the dosimetry system is more frequently validated by measurement intercomparison. This re-calibration shall include the analytical instrumentation (see Section 7). Depending on seasonal variations in ambient conditions (for example, temperature and relative humidity) the interval between re-calibrations may be decreased (see Note 4).

8.6.3 Verify the calibration of the dosimetry system for each new stock of reference standard, transfer standard, and routine dosimeters using at least three absorbed doses over the range of application in order to confirm that their responses are the same as for the current stock.

8.7 *Calibration and Dose Measurement Uncertainties*:

8.7.1 The uncertainties in the calibration and absorbed dose measurement of a dosimetry system depend on the specific dosimetry system employed. Refer to ISO/ASTM Guide 51707 and the appropriate standard for a given dosimetry system for uncertainty statements. See 2.1 and Annex A4 for references to the appropriate dosimetry system standards.

8.8 *Irradiation of Dosimeters*—The irradiation of routine dosimeters may be performed by one of three different methods. One method (described in 8.8.1) calls for routine dosimeters to be irradiated in a gamma, electron beam, or X-ray (bremsstrahlung) calibration facility. The second method (described in 8.8.2) calls for routine dosimeters to be irradiated in an in-house calibration facility that has an absorbed-dose rate measured by reference or transfer–standard dosimeters. The third method (described in 8.8.3) calls for routine dosimeters to be irradiated together with reference or transfer–standard dosimeters in the production irradiator.

NOTE 9—The response of some routine dosimeters may be affected by the combined effect of several environmental factors such as absorbed dose rate, energy spectrum, temperature, or relative humidity (including seasonal variations in temperature or relative humidity). For these cases, it may not be possible to take these combined effects into account by applying a correction factor. Therefore, the calibration of routine dosimeters should be performed using irradiation conditions similar to those in the actual production irradiator.

NOTE 10—The response of reference and transfer–standard dosimeters to environmental effects such as temperature and relative humidity, absorbed-dose rate, and energy spectrum, should be documented. Differences in the dosimeter response between calibration and use conditions should be taken into account using known correction factors.

8.8.1 *Irradiation Using a Calibration Facility*—The calibration of routine dosimeters using a gamma, electron beam, or X-ray calibration facility meeting the requirements of ISO/ASTM Practice 51400 has the advantage that the dosimeters are irradiated to accurately known absorbed doses under well-controlled and documented conditions. However, use of these routine dosimeters under different environmental conditions in a production irradiator may introduce uncertainties that are difficult to quantify. Transporting of the dosimeters to and from the calibration facility may also introduce uncertainties from pre- and post-irradiation storage effects.

8.8.1.1 Irradiate routine dosimeters to known absorbed doses in a calibration facility.

8.8.1.2 Specify to the calibration facility that the irradiation conditions should be as similar as possible to those in the actual production irradiator. These conditions, including the energy spectrum, absorbed-dose rate, and irradiation temperature, should be as close as practical to those encountered during routine use. The variation of these conditions should be documented and incorporated into the uncertainty analysis.

NOTE 11—The temperature and absorbed dose rate experienced by dosimeters may vary during a production run. However, it is usually not practical to perform the calibration of the dosimeters under the same varying conditions. To approximate production irradiator conditions, the calibration should be performed at a fixed temperature somewhere between the average and the maximum temperatures encountered during routine production; and, if a calibration facility with the desired dose rate is available, at a fixed dose rate somewhere between the average and the maximum dose rates experienced during routine production. The possible effects of differences in temperature and dose rate between the calibration facility and production irradiator can be minimized by performing the calibration using the method described in 8.8.3.

8.8.1.3 Adverse environmental conditions (such as high or low temperature and humidity) during transport of the dosimeters to and from the calibration facility may affect the dosimeter response.

8.8.1.4 Package dosimeters to minimize the effects of environmental conditions during transport.

8.8.1.5 Include maximum temperature indicators in the dosimeter package during transport to determine if the calibration has been compromised and is therefore invalid.

8.8.1.6 Confirm that the environmental conditions during transport have not changed the response of the dosimeter. This may be achieved by sending a set of dosimeters irradiated to known absorbed doses along with the set of dosimeters sent for calibration. The readings of the two sets of dosimeters should be compared when they are returned with readings from additional dosimeters given the same absorbed dose and stored under controlled conditions.

8.8.1.7 Calibration curves for routine dosimetry systems obtained by irradiating dosimeters in a calibration facility irradiator shall be verified for the actual conditions of use in the production irradiator (see 8.8.1.8).

8.8.1.8 Calibration verification may be performed by irradiating the routine dosimeters together with reference standard or transfer–standard dosimeters to a minimum of three different absorbed doses in the production irradiator. The reference–standard or transfer–standard dosimeters should be of a different type than the routine dosimeters to reduce the probability that both types of dosimeters are influenced by the same combined environmental effects. Ensure that the routine and reference standard or transfer dosimeters receive the same absorbed dose (see 8.7 and 8.8.3.5 for guidance). Corrective action will be required if the differences in dose readings between the routine dosimeters and the reference standard or transfer dosimeters are significant in comparison to the accuracy required for the application. Appropriate corrective action may include: repeating the calibration using more appropriate environmental conditions, carrying out a full calibration in a production irradiator (see 8.8.3), or applying a correction factor in cases where a single factor is applicable over the entire dose range of interest.

8.8.2 *Irradiation Using an In-House Calibration Facility*—The calibration of routine dosimeters using an in-house calibration facility has the advantage that the pre- and post-irradiation storage conditions of the dosimeters can be controlled so that they are similar to those encountered during routine production. However, it may not be possible for the in-house calibration facility to meet all the irradiation requirements of ISO/ASTM Practice 51400.

8.8.2.1 Irradiate routine dosimetry systems to known absorbed doses in an in-house calibration facility.

8.8.2.2 The absorbed-dose rate of the in-house calibration facility shall be demonstrated to be traceable to nationally or internationally recognized standards by direct measurement intercomparisons or calibrations using transfer–standard dosimeters supplied by a nationally recognized radiation dosimetry calibration laboratory.

8.8.2.3 Measurement intercomparisons or calibrations of absorbed-dose rates of the in-house calibration facility shall be performed at least once every three years and after any change in source activity or geometry.

8.8.2.4 The requirements of 8.8.1.2 are equally applicable to an in-house calibration facility.

8.8.2.5 Calibration of routine dosimeters using an in-house calibration facility reduces the possibility of changes in the response due to adverse storage conditions during transport of dosimeters. After irradiation, the irradiated dosimeters should be stored under similar conditions to those encountered in the production irradiator and read at approximately the same time after irradiation as the dosimeters used in routine production dosimetry.

8.8.2.6 Calibration curves for routine dosimetry systems obtained by irradiating dosimeters using an in-house calibration facility shall be verified (see 8.8.2.7) for the actual conditions of use in the production irradiator.

8.8.2.7 Calibration verification may be performed by irradiating the routine dosimeters together with reference standard or transfer–standard dosimeters to three different absorbed doses in the production irradiator. The reference standard or transfer–standard dosimeters should be of a different type than the routine dosimeters to reduce the probability that both types of dosimeters are influenced by the same combined environmental effects. Ensure that the routine and reference standard or transfer dosimeters receive the same absorbed dose (see 8.7 and 8.8.3.5 for guidance). Corrective action will be required if the differences in dose readings between the routine dosimeters and the reference standard or transfer dosimeters are significant in comparison to the accuracy required for the application. Appropriate corrective action may include: repeating the calibration using more appropriate environmental conditions, carrying out a full calibration in a production irradiator (see 8.8.3), or applying a correction factor in cases where a single factor is applicable over the entire dose range of interest.

8.8.3 *Irradiation Using a Production Irradiator*—The calibration of routine dosimeters by irradiating the dosimeters together with reference or transfer–standard dosimeters in the production irradiator has the advantage that the environmental conditions are similar to those encountered during routine production, reducing the requirement to make corrections to the routine dosimeter response for environmental effects. However, great care must be taken to ensure that the routine and reference or transfer–standard dosimeters irradiated together receive the same absorbed dose **(8)**. For some production irradiators, calibration by this technique may not be practical because of limitations in covering the full range of utilization during irradiator operations.

8.8.3.1 Calibration of routine dosimeters in the production irradiator using reference or transfer–standard dosimeters provides a calibration curve or response function valid for the actual production irradiation conditions existing during the calibration. This method takes combined environmental factors into account to the extent that the reference or transfer dosimeter response can be corrected for differences in environmental factors between the calibration facility and production irradiator.

8.8.3.2 Use reference–standard or transfer–standard dosimeters supplied and analyzed by a nationally recognized radiation dosimetry calibration laboratory to demonstrate traceability to national standards.

8.8.3.3 Reference–standard or transfer–standard dosimeters obtained commercially or prepared in accordance with published standards and analyzed on site may be used provided that the reference standard or transfer standard dosimetry systems have been calibrated in accordance with 8.2 and 8.3.

8.8.3.4 Calibrate routine dosimeters by irradiating them together with reference–standard or transfer–standard dosimeters under actual production irradiation conditions over the entire range of normal use.

8.8.3.5 Design a calibration package that minimizes the difference between the absorbed doses received by the routine and reference standard or transfer dosimeters. The package should hold the two types of dosimeters so that they do not significantly shield each other, that the geometry is appropriate for the radiation source employed, and that they are as close together as possible. See Figs. 1 and 2 for examples of such packages employed for gamma-ray or X-ray sources. See Fig. 3 for an example of a package suitable for electron-beam sources.

NOTE 12—The absorbed dose variation discussed in 8.8.3.5 can be determined by irradiating calibration packages containing transfer or reference–standard dosimeters in all dosimeter positions within the calibration package.

8.8.3.6 When thick and thin dosimeters are irradiated together, surround the thin dosimeters by sufficient polymeric material to ensure that the attenuation characteristics are similar and to ensure that the dosimeters receive the same dose.

8.8.3.7 To calibrate dosimeters under conditions similar to those used for processing, place the calibration packages with