An American National Standard

Standard Practice for Dosimetry in Radiation Processing[1]

This standard is issued under the fixed designation ISO/ASTM 52628; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision.

INTRODUCTION

The use of ionizing radiation for the treatment of commercial products such as the sterilization of medical devices, the reduction of microbial contamination in food or the modification of polymers is referred to as radiation processing. The types of radiation used may be gamma radiation (typically from cobalt-60 sources), X-radiation or accelerated electrons.

It is necessary to ensure that the specified absorbed dose is applied in each of the radiation processing applications. The absorbed dose must be measured, and measurement systems have been developed for this purpose. Much of the development of these systems rests on the early development of dosimetry systems for personnel radiation protection and for medical treatment. However, the absorbed doses used in radiation processing are generally higher, ranging from ~10 Gy up to 100 kGy or more and new dosimetry systems have been developed for measurements of these doses.

Note that the terms “dose” and “absorbed dose” are used interchangeably in this standard (see 3.1.1).

The dose measurements required in radiation processing concern characterization of radiation facilities in installation qualification (IQ) and operational qualification (OQ), measurement of dose distribution in irradiated products in performance qualification (PQ) and routine monitoring of the irradiation process.

The literature is abundant with articles on dosimeters for radiation processing, and guidelines and standards have been written by several organizations (the International Atomic Energy Agency (IAEA) and the International Commission on Radiation Units and Measurements (ICRU), for example) for the operation of the dosimetry systems and for their use in the characterization and validation of the radiation processing applications. In particular, ICRU Report 80 provides information on the scientific basis and historical development of many of the systems in current use.

ASTM Subcommittee E10.01 on Radiation Processing: Dosimetry and Applications was formed in 1984 initially with the scope of developing standards for food irradiation, but its scope was widened to include all radiation processing applications. The subcommittee, now Committee E61, has under its jurisdiction approximately 30 standard practices and standard guides, collectively known as the E61 standards on radiation processing. A number of these standards have been published as ISO/ASTM standards, thereby ensuring a wider international acceptance. These practices and guides describe the dosimetry systems most commonly used in radiation processing, and the dose measurements that are required in the validation and routine monitoring of the radiation processes. A current list of the E61 standards on radiation processing is given in 2.1 and 2.2.

The development, validation and routine control of a radiation process comprises a number of activities, most of which rely on the ability to measure the delivered dose accurately. It is therefore necessary that dose is measured with traceability to national, or international, standards, and the uncertainty is known, including the effect of influence quantities. The E61 standards on radiation processing dosimetry serve to fulfill these requirements.

The practices describing dosimetry systems have several common attributes, and there is a need to have one general standard that can act as a common reference and that can be used as a basis for the selection of dosimetry systems for defined tasks. ISO/ASTM Practice 52628 serves this purpose. It outlines general requirements for the calibration and use of dosimetry systems and for the estimation of measurement uncertainties. Details relating to each dosimetry system are found in the respective standards and each of these refer to ISO/ASTM Practice 52628 for the general requirements.

1. Scope

1.1 This practice describes the basic requirements that apply when making absorbed dose measurements in accordance with the ASTM E61 series of dosimetry standards. In addition, it provides guidance on the selection of dosimetry systems and directs the user to other standards that provide specific information on individual dosimetry systems, calibration methods, uncertainty estimation and radiation processing applications.

1.2 This practice applies to dosimetry for radiation processing applications using electrons or photons (gamma- or X-radiation).

1.3 This practice addresses the minimum requirements of a *measurement management system*, but does not include general quality system requirements.

1.4 This practice does not address personnel dosimetry or medical dosimetry.

1.5 This practice does not apply to *primary standard dosimetry systems*.

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

2. Reference documents

2.1 *ASTM Standards:*[2]

E170 Terminology Relating to Radiation Measurements and Dosimetry

E1026 Practice for Using the Fricke Dosimetry System

E2232 Guide for Selection and Use of Mathematical Methods for Calculating Absorbed Dose in Radiation Processing Applications

E2303 Guide for Absorbed-Dose Mapping in Radiation Processing Facilities

E2304 Practice for Use of a LiF Photo-Fluorescent Film Dosimetry System

E2381 Guide for Dosimetry In Radiation Processing of Fluidized Beds and Fluid Streams

E2449 Guide for Irradiation of Pre-packaged Processed Meat and Poultry Products to Control Pathogens and Other Microorganisms

F1355 Guide for Irradiation of Fresh Agricultural Produce as a Phytosanitary Treatment

F1356 Practice for Irradiation of Fresh and Frozen Red Meat and Poultry to Control Pathogens and Other Microorganisms

F1736 Guide for Irradiation of Finfish and Aquatic Invertebrates Used as Food to Control Pathogens and Spoilage Microorganisms

F1885 Guide for Irradiation of Dried Spices, Herbs, and Vegetable Seasonings to Control Pathogens and Other Microorganisms

2.2 *ISO/ASTM Standards:*[2]

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

51261 Practice for Calibration of Routine Dosimetry Systems for Radiation Processing

51275 Practice for Use of a Radiochromic Film Dosimetry System

51276 Practice for Use of a Polymethylmethacrylate Dosimetry System

51310 Practice for Use of a Radiochromic Optical Waveguide Dosimetry System

51401 Practice for Use of a Dichromatic Dosimetry System

51431 Practice for Dosimetry in Electron Beam and X-Ray (Bremsstrahlung) Irradiation Facilities for Food Processing

51538 Practice for Use of the Ethanol-Chlorobenzene Dosimetry System

51540 Practice for Use of a Radiochromic Liquid Dosimetry System

51607 Practice for Use of the Alanine-EPR Dosimetry System

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

51631 Practice for Use of Calorimetric Dosimetry Systems for Electron Beam Dose Measurements and Routine Dosimeter Calibration

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

51650 Practice for Use of a Cellulose Triacetate Dosimetry System

51702 Practice for Dosimetry in a Gamma Facility for Radiation Processing

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing

51818 Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 80 and 300 keV

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

51939 Practice for Blood Irradiation Dosimetry

51940 Guide for Dosimetry for Sterile Insect Release Programs

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

52116 Practice for Dosimetry for a Self-Contained Dry-Storage Gamma Irradiator

52701 Guide for Performance Characterization of Dosimeters and Dosimetry Systems for Use in Radiation Processing

[1] This practice is under the jurisdiction of ASTM Committee E61 on Radiation Processing and is the direct responsibility of Subcommittee E61.01 on Dosimetry, and is also under the jurisdiction of ISO/TC 85/WG 3.

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

2.3 *ISO Standards:*[3]

ISO 11137-1 Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

ISO 11137-3 Sterilization of health care products – Radiation – Part 3: Guidance on dosimetric aspects

ISO 10012 Measurement managements systems – Requirements for measurement processes and measuring equipment

ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

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

ICRU Report 80 Dosimetry Systems for Use in Radiation Processing

ICRU Report 85a Fundamental Quantities and Units for Ionizing Radiation

2.5 *Joint Committee for Guides in Metrology (JCGM) Reports:*

JCGM 100:2008, GUM , 1995, with minor corrections, Evaluation of measurement data – Guide to the Expression of Uncertainty in Measurement[5]

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

3. Terminology

3.1 *Definitions:*

3.1.1 *absorbed dose (D)*—quotient of $d\bar{\varepsilon}$ by dm, where $d\bar{\varepsilon}$ is the mean energy imparted by ionizing radiation to matter of mass dm, thus

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

ICRU 85a

3.1.1.1 *Discussion*—The SI unit of absorbed dose is the gray (Gy), where 1 gray is equivalent to the absorption of 1 joule per kilogram of the specified material (1 Gy = 1 J/kg).

3.1.2 *accredited dosimetry calibration laboratory*—dosimetry laboratory with formal recognition by an accrediting organization that the dosimetry laboratory is competent to carry out specific activities which lead to the calibration or calibration verification of dosimetry systems in accordance with documented requirements of the accrediting organization.

3.1.3 *calibration*—set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

3.1.4 *dosimeter*—device that, when irradiated, exhibits a quantifiable change that can be related to absorbed dose in a given material using appropriate measurement instruments and procedures.

3.1.5 *dosimeter/dosimetry system characterization*—determination of performance characteristics, such as dose range, reproducibility and the effect of influence quantities, for a dosimeter/dosimetry system under defined test conditions.

3.1.6 *dosimeter response*—reproducible, quantifiable effect produced in the dosimeter by ionizing radiation.

3.1.6.1 *Discussion*—The dosimeter response value, obtained from one or more measurements, is used in the estimation of the derived absorbed dose. The response value may be obtained from such measurements as optical absorbance, thickness, mass peak-to-peak distance in EPR spectra, or electropotential between solutions.

3.1.7 *dosimetry*—measurement of absorbed dose by the use of a dosimetry system.

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

3.1.9 *influence quantity*—quantity that, in a direct measurement, does not affect the quantity that is actually measured, but affects the relation between the indication and the measurement result. **VIM**

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

3.1.11 *primary standard dosimetry system*—dosimetry system that is designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same quantity.

3.1.12 *radiation processing*—intentional irradiation of products or materials to preserve, modify or improve their characteristics.

3.1.13 *reference standard dosimetry system*—dosimetry system, generally having the highest metrological quality available at a given location or in a given organization, from which measurements made there are derived.

3.1.14 *reference standard radiation field*—calibrated radiation field, generally having the highest metrological quality available at a given location or in a given organization, from which measurements made there are derived.

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 dosimetry system*—dosimetry system calibrated against a reference standard dosimetry system and used for routine absorbed dose measurements, including dose mapping and process monitoring.

3.1.17 *traceability*—property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

[3] Available from International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, Case postale 56, CH-1211, Geneva 20, Switzerland, http://www.iso.ch.

[4] Available from the International Commission on Radiation Units and Measurements, 7910 Woodmont Ave, Suite 800, Bethesda, MD 20815, USA.

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

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

3.1.18 *transfer standard dosimetry system*—dosimetry system used as an intermediary to calibrate other dosimetry systems.

3.1.19 *type I dosimeter*—dosimeter of high metrological quality, the response of which is affected by individual influence quantities in a well-defined way that can be expressed in terms of independent correction factors.

3.1.19.1 *Discussion*—See Section 6 for examples and further details.

3.1.20 *type II dosimeter*—dosimeter, the response of which is affected by influence quantities in a complex way that cannot practically be expressed in terms of independent correction factors.

3.1.20.1 *Discussion*—See Section 6 for examples and further details.

3.1.21 *uncertainty*—parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand or derived quantity.

3.1.22 *uncertainty budget*—quantitative analysis of the component terms contributing to the uncertainty of a measurement, including their statistical distribution, mathematical manipulation and summation.

3.2 Definitions of other terms used in this standard that pertain to radiation measurement and dosimetry may be found in ASTM Terminology E170. Definitions in ASTM E170 are compatible with ICRU Report 85a; that document, therefore, may be used as an alternative reference. Where appropriate, definitions used in this standard have been derived from, and are consistent with, general metrological definitions given in the VIM.

4. Significance and use

4.1 Radiation processing of articles in both commercial and research applications may be carried out for a number of purposes. These include, for example, sterilization of health care products, reduction of the microbial populations in foods and modification of polymers. The radiations used may be accelerated electrons, gamma-radiation from radionuclide sources such as cobalt-60, or X-radiation.

4.2 To demonstrate control of the radiation process, the absorbed dose must be measured using a dosimetry system, the calibration of which, is traceable to appropriate national or international standards. The radiation-induced change in the dosimeter is evaluated and related to absorbed dose through calibration. Dose measurements required for particular processes are described in other standards referenced in this practice.

5. Dosimetry system requirements

5.1 Dosimetry system requirements are a necessary part of a *measurement management system*. The following requirements shall be included as a minimum, but additional requirements may be appropriate depending on the nature of the process. Guidance on these requirements is given in Section 7.

5.1.1 The selection and use of a specific dosimetry system in a given application shall be justified taking into account at least the following:

dose range
radiation type
effect of influence quantities
required level of uncertainty
required spatial resolution

5.1.2 The dosimetry system shall be calibrated in accordance with the requirements of ISO/ASTM Practice 51261.

5.1.3 The uncertainty associated with measurements made with the dosimetry system shall be established and documented. All dose measurements shall be accompanied by an estimate of uncertainty. See ISO/ASTM 51707, GUM and NIST Technical Note 1297[7] for guidance.

5.1.4 Documentation shall be established and maintained to ensure compliance with the minimum requirements specified in the ASTM or ISO/ASTM standard relevant to the specific dosimetry system. The user's quality system might be more detailed than these minimum requirements.

6. Classification

6.1 Classification of dosimeters and dosimetry systems in the ASTM E61 series of dosimetry standards is based on two distinct criteria: *(1)* the inherent metrological properties of the dosimeter (see 3.1.19 and 3.1.20), and *(2)* the field of application of the dosimetry system (see 3.1.13 and 3.1.16). These classifications are important in both the selection and calibration of dosimetry systems.

NOTE 1—*Type I* and *type II* dosimeter classification (see 6.2) and the classification of dosimetry systems (see 6.3) are an extension to the classifications identified in ISO/ASTM Practice 51261. The examples shown in ISO/ASTM 51261 list dosimeters used in reference standard and routine applications but do not distinguish between the dosimeter and the system in which it is used. The classification used in this standard will be incorporated in all subsequent revisions of the ASTM E61 series of dosimetry standards.

6.2 *Classification of Dosimeters Based on Metrological Properties:*

6.2.1 This classification of dosimeters is based on knowledge of their inherent metrological properties. The method of measurement may be important in the classification (see below), but the classification does not include consideration of the actual instrumentation used, or the quality of preparation (manufacture) of the dosimeter. For example, acidic solutions of dichromate ions have certain inherent properties in terms of their response to radiation and the effect of irradiation temperature that mean they are classified as *type I dosimeters*. The actual performance of a given dosimetry system based on dichromate dosimeters will depend, however, on the quality of preparation of the dosimetric solution and the quality of the spectrophotometers used for optical absorbance measurement.

6.2.2 Knowledge of the inherent properties of a dosimeter is important when selecting a dosimeter for a particular application. For example, when selecting a dosimeter to be used to

[7] Taylor, B. N., and Kuyatt, C. E., "Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results," NIST TN-1297, Gaithersburg, MD: NIST 1994.

transfer dose between radiation fields of differing temperatures, it is essential to choose a dosimeter whose response can be corrected for the effect of irradiation temperature, that is, a *type I dosimeter*.

6.2.3 In order for a dosimeter to be classified as a *type I dosimeter*, it must be possible to apply accurate, independent, corrections to its response to account for the effects of relevant influence quantities, such as temperature, dose rate, etc. The magnitude of the correction, the range of values of the influence quantity over which it is applicable and the range of doses over which it is applicable are determined as part of dosimeter characterization (see 7.3). In classifying a dosimeter as a *type I dosimeter*, it may be necessary to specify the method of measurement. For example, free radicals produced in irradiated alanine can, in principle, be measured by a number of different techniques, however, only the EPR technique has been shown to provide the high metrological quality (accuracy) necessary to classify alanine as a *type I dosimeter*. Examples of *type I dosimeters* are given in Table 1.

6.2.4 The classification of a dosimeter as a *type II dosimeter* is based on the complexity of interaction between influence quantities, such as temperature and dose rate, which makes it impractical to apply independent correction factors to the dosimeter response. Examples of *type II dosimeters* are given in Table 2.

6.3 *Classification of Dosimetry Systems Based on the Field of Application:*

6.3.1 *Reference Standard Dosimetry Systems:*

6.3.1.1 The classification of a dosimetry system as a *reference standard dosimetry system* is based on its application. *Reference standard dosimetry systems* are used as standards to calibrate the dosimetry systems that are used for routine measurements. The uncertainty of the *reference standard dosimetry system* will affect the uncertainty of the system being calibrated and it is therefore important that the *reference standard dosimetry system* is of high metrological quality. In this context, the concept of high metrological quality implies a system with low uncertainty and with traceability to appropriate national or international standards.

6.3.1.2 *Reference standard dosimetry systems* may take the form of systems held at a given location or they may take the form of *transfer standard dosimetry systems* operated by a national standards laboratory or an accredited dosimetry calibration laboratory. In the case of *transfer standard dosimetry systems*, dosimeters are sent to a facility for irradiation and then returned to the issuing laboratory for measurement. The requirement to transport dosimeters without unduly increasing measurement uncertainty restricts the type of dosimeter that can be used. Alanine/EPR, dichromate or ceric-cerous dosimetry systems are commonly used in this way.

6.3.1.3 A *reference standard dosimetry system* comprises dosimeters and the associated measurement equipment and quality system documentation necessary to ensure traceability to appropriate national and international standards. The dosimeter used in a *reference standard dosimetry system* is generally a *type I dosimeter*, although there may be exceptions (see, for example, ISO/ASTM 51631).

6.3.1.4 The expanded uncertainty achievable with measurements made using a *reference standard dosimetry system* is typically of the order of ±3 % (k=2). In certain specific applications, for example the use of electrons of energy below 1 MeV, practical limitations of the techniques may mean that the *reference standard dosimetry systems* have a larger uncertainty.

NOTE 2—An expanded uncertainty derived by multiplying a combined standard uncertainty by a coverage factor of k=2 provides a level of confidence of approximately 95 %. See ISO/ASTM 51707 and the GUM for further details.

6.3.2 *Routine Dosimetry Systems* —The classification of a dosimetry system as a *routine dosimetry system* is based on its application, i.e. routine absorbed dose measurements, including dose mapping and process monitoring. A *routine dosimetry system* comprises dosimeters and the associated measurement equipment and quality system documentation necessary to ensure traceability to appropriate national or international standards. The dosimeter used in a routine dosimetry system is generally a *type II dosimeter*, although there may be exceptions, for example the use of *type I* alanine dosimeters for routine dose measurements.

6.3.2.1 The classification of a dosimeter as a *type II dosimeter* is based on the complexity of interaction between influence quantities, such as temperature and dose rate, which

TABLE 1 Examples of type I dosimeters

Dosimeter	Description	Reference
Fricke solution	Liquid solution of ferrous and ferric ions in 0.4 mol dm^{-3} sulfuric acid. Measured by spectrophotometry.	ASTM E1026
Alanine/EPR	Pellet or film containing alanine. Measured by EPR spectroscopy of radiation induced radical.	ISO/ASTM 51607
Dichromate	Liquid solution of chromium ions in 0.1 mol dm^{-3} perchloric acid. Measured by spectrophotometry.	ISO/ASTM 51401
Ceric-Cerous Sulphate	Liquid solution of ceric and cerous ions in 0.4 mol dm^{-3} sulphuric acid. Measured by spectrophotometry or potentiometry.	ISO/ASTM 51205
Ethanol Chlorobenzene (Classification dependent on solution composition and method of measurement)	Liquid solutions of various compositions containing chlorobenzene in ethanol. Measured by titration.	ISO/ASTM 51538

TABLE 2 Examples of type II dosimeters

Dosimeter	Description	Reference
Calorimeter	Assembly consisting of calorimetric body (absorber), thermal insulation, and temperature sensor with wiring.	ISO/ASTM 51631
Cellulose Triacetate	Untinted cellulose triacetate (CTA) film. Measured by spectrophotometry.	ISO/ASTM 51650
Ethanol Chlorobenzene (Classification dependent on solution composition and method of measurement)	Liquid solution of various compositions containing chlorobenzene in ethanol. Measured by spectrophotometry or oscillometry.	ISO/ASTM 51538
LiF Photo-Fluorescent	Lithium fluoride based photo-fluorescent film. Mesured by photo-stimulated luminescence.	ASTM E2304
PMMA	Specially developed PMMA materials. Measured by spectrophotometry.	ISO/ASTM 51276
Radiochromic Film	Specially prepared film containing dye precursors. Measured by spectrophotometry.	ISO/ASTM 51275
Radiochromic Liquid	Specially prepared solution containing dye precursors. Measured by spectrophotometry.	ISO/ASTM 51540
Radiochromic Optical Waveguide	Specially prepared optical waveguide containing dye precursors. Measured by spectrophotometry.	ISO/ASTM 51310
TLD	A phosphor, alone, or incorporated in a material. Measured by thermoluminescence.	ISO/ASTM 51956

makes it impractical to apply independent correction factors to the dosimeter response. Examples of *type II dosimeters* are given in Table 2.

6.3.2.2 The expanded uncertainty achievable with measurements made using a *routine dosimetry system* is typically of the order of ±6 % (k=2).

7. Guidance

7.1 *Dosimetry System Components:*

7.1.1 A dosimetry system consists of a number of components used in the measurement of absorbed dose. These include the dosimeter, the instrumentation used and the written procedures necessary for the operation of the system. Instrumentation not only includes the instrument used for measuring the dosimeter response, but also ancillary instruments, such as thickness gauges and reference standard materials for assessing instrument performance. In general, a dosimetry system takes the name of the dosimeter on which it is based.

7.2 *Dosimetry System Selection:*

7.2.1 The selection of a dosimetry system for a particular application is the responsibility of the user.

7.2.2 Section 5.1.1 gives a list of factors that must, as a minimum, be taken into account when selecting a dosimetry system, but careful consideration needs to be given to additional factors that may be relevant to the specific application. Examples include pre- and post-irradiation stability, ease of use and ease of calibration. Safety related aspects, such as toxicity, might also be important, particularly with respect to the irradiation of foods.

7.2.3 Tables 1-6, inclusive, list ISO, ASTM and ISO/ASTM standards that give requirements or guidance, or both, on dosimetry as used in a range of radiation processing applications. There is some overlap in the scopes of a number of these standards, but the requirements in the standards listed in Table 4 always take precedence over those in the general standards listed in Table 3.

TABLE 3 General dosimetry requirements for all radiation applications

Application	Dosimetry Requirements	Radiation Type	Reference
General Industrial Radiation Processing	Dosimetry is required for installation qualification (IQ), operational qualification, (OQ), performance qualifcation (PQ) and routine process monitoring	Gamma	ISO/ASTM 51702
		300 keV to 25 MeV electron beam	ISO/ASTM 51649
		80 to 300 keV electron beam	ISO/ASTM 51818
		X-Ray	ISO/ASTM 51608

TABLE 4 Dosimetry requirements for specific radiation applications

Application	Dosimetry Requirements	Reference
Food Irradiation	Dosimetry is required in process definition, IQ, OQ, PQ and routine process control	ISO/ASTM 51431
Medical Device Sterilization		ISO 11137-1
Blood Irradiation		ISO/ASTM 51939

7.2.4 Summaries of the performance characteristics of dosimeters are given in Annex A1, but for detailed information the relevant ASTM or ISO/ASTM practice should be consulted. Brief guidance on issues that need to be considered when selecting a dosimetry system is given below:

7.2.4.1 *Dose range*—Doses used in radiation processing range from ~10 Gy to ~100 kGy according to the application.

TABLE 5 Guidance for dosimetry in specific radiation applications

Application	Dosimetry Requirements	Reference
Radiation Research on Food and Agricultural Products	Covers the minimum requirements for dosimetry and absorbed-dose validation needed to conduct research on the irradiation of food and agricultural products	ISO/ASTM 51900
Sterile Insect Release Programs	Outlines dosimetric procedures to be followed for the radiation sterilization of live insects for use in pest management programs	ISO/ASTM 51940
Fluidized Beds and Fluid Streams	Describes several dosimetry systems and methods suitable for the documentation of the irradiation of product transported as fluid or in a fluidized bed	ASTM E2381
Irradiation using self-contained dry-storage gamma irradiator	Dosimetry is required for operational qualification (OQ)	ISO/ASTM 52116
Radiation Sterilization	Described guidance for calibration, IQ, OQ, PQ and routine monitoring	ISO 11137-1 and 11137-3
Pre-Packaged Processed Meat and Dairy Products		ASTM E2449
Fresh Agricultural Produce as a Phytosanitary Treatment		ASTM F1355
Fresh and Frozen Red Meat and Poultry Products	These standards outline the minimum requirements for dosimetry and describe absorbed-doses needed for specific effects	ASTM F1356
Finfish and Aquatic Invertebrates Used as Food		ASTM F1736
Dried Spices, Herbs and Vegetable Seasonings		ASTM F1885

TABLE 6 Guidance on absorbed-dose mapping and mathematical methods

Application	Guidance	Reference
Radiation Processing	Measuring absorbed dose distributions in products, materials or substances	ASTM Guide E2303
Selection and Use of Mathematical Methods for Calculating Absorbed Dose	Describes different mathematical methods that may be used to calculate absorbed dose and criteria for their selection	ASTM Guide E2232

The relatively restricted operating range of many dosimeters means that it is often not possible to use the same dosimetry system over the entire dose range of interest. The uncertainty associated with a dosimetry system may increase at both the lower and upper extremes of its quoted dose range.

7.2.4.2 *Radiation type*—Radiation processing applications utilize a wide range of radiation types including X-radiation, gamma radiation and electrons with energies from ~100 keV to ~10 MeV. The suitability of a dosimetry system for a given type of radiation will depend on the physical form and size of the dosimeter and the ability to calibrate the system. The response of some dosimeters is known to vary with both the type of radiation and the dose rate.

7.2.4.3 *Influence quantities*—Influence quantities, such as temperature before, during and after irradiation, dose rate, humidity and radiation type affect the performance of most dosimetry systems to some extent. The classification of dosimeters into *types I and II* is largely on the basis of the nature of the effect of influence quantities. In selecting a dosimeter, it is essential to consider all influence quantities relevant to the application, assess whether their effects are significant and, if so, whether the effects can be satisfactorily accounted for, either by the application of correction factors, or by calibration under the conditions of use.

7.2.4.4 *Stability of dosimeter response*—Pre- and post-irradiation stability of the dosimeter response can be an important consideration. Some dosimeters, such as Fricke solution, exhibit a continuous increase in response before and after irradiation, that requires correction by the use of appropriate control samples, such as unirradiated dosimeters subject to the same environmental conditions as the dosimeters used to measure dose. Other systems show changes in the dosimeter response with time, that may require specification of the interval between irradiation and measurement.

7.2.4.5 *Required level of uncertainty*—A full assessment of both the required and the achievable measurement uncertainty is an essential component of dosimetry system selection (see 7.5).

7.2.4.6 *Required spatial resolution*—Applications such as dose mapping in electron beams and the measurement of doses close to interfaces, place requirements on the spatial resolution of the dosimeter. Large dosimeters, such as liquids contained in ampoules, will only provide information on the mean dose to the volume of solution. If resolution on a small (less than 1 mm) scale is required it may be necessary to use thin film dosimeters. The achievable spatial resolution may be determined by the method of measurement, rather than the size of the dosimeter. For example, large area dosimeters can be scanned by small light beams to give high spatial resolution in two dimensions.

7.3 *Dosimeter/Dosimetry System Characterization:*

7.3.1 Information on the general characteristics of a dosimeter or dosimetry system can be found in the literature and obtained from the manufacturer or supplier. Typically, tests would have been carried out under a range of defined conditions in which potential influence quantities were varied to determine the magnitude of possible effects. ISO/ASTM Guide 52701 describes the influence quantities that need to be considered and sets out experimental techniques that can be used to quantify the effects and their interactions. These tests will also provide information on the useful dose range of the dosimetry system and give an indication of the achievable uncertainty. This activity is generally referred to as dosimeter or dosimetry system characterization (see 3.1.5).

7.3.2 Available information should be reviewed by the user and, if necessary, additional tests carried out to characterize performance under the specific conditions of use.

7.3.3 The classification of a dosimeter as a *type I dosimeter* or a *type II dosimeter* is made in this standard on the basis of characterization experiments and depends on the quantitative nature of the effect of influence quantities and whether or not it is possible to make independent corrections.

7.3.4 It is important to differentiate between characterization and calibration. Characterization provides information on the likely effect of influence quantities and is used in dosimetry system selection and in determining the method of calibration required (see ISO/ASTM Practice 51261). Calibration is the operation used to determine the response function of a given dosimetry system under the conditions of use, and is the responsibility of the user of the dosimetry system.

7.4 *Dosimetry System Calibration:*

7.4.1 All dosimetry equipment requires either calibration traceable to appropriate standards or performance checks to verify its operation. Requirements for calibration of dosimetry systems used in radiation processing are given in ISO/ASTM Practice 51261.

7.4.2 In the majority of radiation processing applications it is necessary to demonstrate that dose measurements are traceable to recognized national or international standards. There are a few applications where only relative dose measurements are carried out, for example, beam width measurements, that may not require traceability.

7.4.3 Many calibration laboratories maintain their absorbed dose standard as a well characterized *reference standard radiation field*, rather than a *reference standard dosimetry system*.

7.4.4 Calibrations of dosimetry systems are most commonly made in terms of absorbed dose to water, but absorbed dose to other materials might be used, for example, absorbed dose to silicon in the case of semiconductor irradiations.

7.5 *Dosimetry Uncertainties:*

7.5.1 All dose measurements need to be accompanied by an estimate of uncertainty.

7.5.2 All components of uncertainty should be included in the estimate, including those arising from calibration, dosimeter reproducibility, instrument stability and the effect of influence quantities. A full quantitative analysis of components of uncertainty is referred to as an *uncertainty budget* and is often presented in the form of a table. Typically, the *uncertainty budget* will identify all significant components of uncertainty together with their methods of estimation, statistical distributions and magnitudes.

NOTE 3—There is a lack of formal definition of *uncertainty budget* in the VIM, GUM and elsewhere, which has led to other uses of this term, for example, as the permissible level of uncertainty in a given application.

7.5.3 An understanding of the components that contribute to uncertainty is essential when assessing the significance of measurements made during radiation processing. For example, in relative dose mapping the only significant component of uncertainty may be dosimeter-to-dosimeter variability, whereas in applications requiring traceable dose measurements, it will be necessary to consider all components of uncertainty.

7.5.4 Specific guidance on estimating uncertainty in radiation processing dosimetry can be found in ISO/ASTM 51707. More general guidance can be found in the GUM and, for example, NIST Technical Note 1297.[7]

7.6 *Measurement Management Systems:*

7.6.1 Many of the aspects discussed previously in this section are essential elements of a wider *measurement management system* that encompasses all of the quality system aspects associated with the measurement process. The more general quality system aspects are outside the scope of the ASTM E61 series of dosimetry standards, but guidance and requirements can be found in documents such as ISO 10012, which can be used to meet the requirements for measurement in ISO 9000 based quality systems. The definition of *measurement management system* (3.1.10) is taken from ISO 10012.

7.6.2 The establishment of a *measurement management system* is an essential component in the demonstration that dose measurements are traceable to recognized national or international standards. The *measurement management system* must include all aspects of the measurement process, including selection of a method, calibration, detailed instructions for use, methods for establishing uncertainty, staff training, record keeping, action to be taken in the event of non-conformities, management responsibilities, etc.

7.6.3 Another standard, ISO 17025 covers requirements to be met by calibration laboratories. The term *accredited dosimetry calibration laboratory* used in the ASTM E61 series of standards generally refers to a laboratory accredited to ISO 17025 by an independent accrediting organisation. Special arrangements exist for national standards laboratories, which may be subject to peer review based on ISO 17025, rather than formal accreditation.

8. Keywords

8.1 absorbed dose; dose measurement; dosimeter; dosimetry; dosimetry system; electron beam; gamma radiation; ionizing radiation; quality control; radiation processing; X-radiation

ANNEX

A1. SUMMARY OF THE CHARACTERISTICS OF DOSIMETERS DESCRIBED IN ASTM AND ISO/ASTM RADIATION PROCESSING STANDARDS

A1.1 See Table A1.1.

TABLE A1.1 Summary of characteristics of dosimeters described in ASTM and ISO/ASTM radiation processing standards

Dosimeter	Description	Radiation Type	Dose Range	Dose Rate	Instrumentation	Effect of Temperature	Effect of Humidity	Effect of Ambient Light
Alanine/EPR see ISO/ASTM Practice 51607	Tablets or small rods of 3 to 5 mm diameter and various lengths, consisting primarily of α-alanine and a small amount of binder. Film dosimeters on a polymer substrate are also available.	Electron, gamma and X-ray	1 to 10^5 Gy	$<10^8$ Gy s^{-1}	EPR spectrometer	Irradiation temperature coefficient in range +0.10 to +0.25 %/°C. Varies with composition and dose. Control may be required during measurement.	Should be kept below 80 % RH. Control may be required during measurement. May require preconditioning	No effect
Calorimeter see ISO/ASTM Practice 51631	Dosimetric absorber and thermal sensor held in thermal insulation. The dimensions depend on the energy of the electron beam.	Electron	10^2 to 10^5 Gy	>~10 Gy s^{-1}	Resistance meter	Possible influence from environmental temperature – dependent on design.	No effect	No effect
Cellulose Acetate see ISO/ASTM Practice 51650	Films, usually as 8 mm wide rolls.	Electron, gamma and X-ray	5 x 10^3 to 10^6 Gy	3 x 10^{-2} to 3 x 10^7 Gy s^{-1}	UV spectrophotometer	Irradiation temperature coefficient approximately +0.5 % / °C	Sensitive to humidity – requires control or water tight packaging	No effect
Ceric-Cerous Sulfate see ISO/ ASTM Practice 51205	Aqueous solution of 1.5 x 10^{-2} mol dm^{-3} $Ce(SO_4)_2$, $Ce_2(SO_4)_3$ and 0.4 mol dm^{-3} H_2SO_4. The dosimeter is usually irradiated in sealed 2-mL glass ampoules of 10-mm inner diameter.	Electron, gamma and X-ray	5 x 10^2 to 10^5 Gy	$<10^6$ Gy s^{-1}	UV spectrophotometer (320 nm) or electrochemical cell (potentiometric readout).	Irradiation temperature coefficient approximately –0.2 % /°C. Varies with Ce^{3+} ion concentration.	Not applicable	No effect
Ethanol Chlorobenzene see ISO/ASTM Practice 51538	Aerated solution of ethanol, chlorobenzene and water, sometimes with a small amount of acetone and benzene added. The dosimeter ampoules are typically 2 to 5 cm^3 in volume and useful dose range depends on the concentration of chlorobenzene.	Electron, gamma and X-ray	10 to 2 x 10^6 Gy	$<10^6$ Gy s^{-1}	Mercurimetric titration, Spectrophotometer or Oscillotitrator.	Between approximately 0.1 and 0.4 % / °C. Varies with composition.	Not applicable	No effect
Fricke Solution see ASTM Practice E1026	Aerated aqueous solution of 10^{-3} mol dm^{-3} ferrous sulfate, and 0.4 mol dm^{-3} sulfuric acid. Sodium chloride, 10^{-3} mol dm^{-3}, is sometimes used to reduce the effect of trace organic impurities, but not in the case of higher dose use.	Electron, gamma and X-ray	20 to 4 x 10^2 Gy (upper limit can be extended to 2 x 10^3 Gy by using a higher concentration of ferrous ions and by solution saturation with oxygen).	$<10^6$ Gy s^{-1}	UV spectrophotometer (usual wavelength 303 nm).	Irradiation temperature coefficient +0.12 % /°C.	Not applicable	No effect

TABLE A1.1 *Continued*

Dosimeter	Description	Radiation Type	Dose Range	Dose Rate	Instrumentation	Effect of Temperature	Effect of Humidity	Effect of Ambient Light
Potassium/Silver dichromate see ISO/ASTM Practice 51401	Aqueous solution of 2×10^{-3} mol dm^{-3} potassium dichromate plus 5×10^{-4} mol dm^{-3} silver dichromate in 0.1 mol dm^{-3} perchloric acid. If 5×10^{-4} mol dm^{-3} silver dichromate only is used, it can be used for a lower dose range from 2 to 10 kGy.	Electron, gamma and X-ray	2×10^3 to 5×10^4 Gy	Pulsed: <600 Gy/pulse (12.5 pps). Continuous: $<7.5 \times 10^3$ Gy s^{-1}	UV spectrophotometer (usual wavelengths: 350 or 440 nm).	Irradiation temperature coefficient approximately –0.2 % / °C. Varies with temperature.	Not applicable	No effect
Polymethylmethacrylate (PMMA) see ISO/ASTM Practice 51276	PMMA strips, with or without radiation sensitive dyes.	Electron, gamma and X-ray	10^2 to 10^5 Gy	10^{-2} to 10^7 Gy s^{-1}(may need correction for dose rate dependence)	Spectrophotometer (various wavelengths depending on dosimeter type).	Complex temperature dependence during irradiation and after irradiation	Sensitive to humidity – requires control or water tight packaging	Effect dependent on formulation
Radiochromic liquid see ISO/ASTM Practice 51540	Organic or aqueous solutions of leuco (colorless) dyes that become intensely colored upon irradiation. Several organic dyes and solvents in a wide range of concentrations are applicable. The solution is usually irradiated in sealed glass ampoules (1, 2, or 5 mL) or in appropriate glass or plastic vials. Open containers may be used for low-energy applications	Electron, gamma and X-ray	5×10^{-1} to 4×10^4 Gy	$<10^{-2}$ to 10^{11}Gy s^{-1}	Spectrophotometer (wavelength dependent on dye and dose range)	Irradiation temperature coefficient approximately – 0.2 % /°C. Varies with composition.	Not applicable	Sensitive to ambient light at wavelengths <370 nm
Radiochromic Film see ISO/ASTM Practice 51275	Polymer films containing leuco (colorless) dyes that become intensely colored upon irradiation. Film thicknesses vary from a few micrometers to about 1 mm.	Electron, gamma and X-ray	10^0 to 10^5 Gy	$<10^{13}$ Gy s^{-1}	Spectrophotometer (wavelength dependent on dye and dose range).	Complex dose dependent interactions between temperature and water content.	Complex dose dependent interactions between temperature and water content - requires control or water tight packaging.	Sensitive to ambient light at wavelengths <370 nm
Radiochromic Optical Waveguide see ISO/ASTM Practice 51310	Organic solutions of leuco (colorless) dyes held in flexible plastic tubes that are sealed at both ends by glass or plastic beads or small rods.		10^0 to 10^4 Gy	10^{-3} to 10^3 Gy s^{-1}	Spectrophotometer (wavelength dependent on dye and dose range).	Irradiation temperature coefficient approximately +0.3 % /°C. Varies with composition.	Not applicable	Sensitive to ambient light at wavelengths <370 nm

TABLE A1.1 *Continued*

Dosimeter	Description	Radiation Type	Dose Range	Dose Rate	Instrumentation	Effect of Temperature	Effect of Humidity	Effect of Ambient Light
Thermoluminescence dosimeters (TLD) see ISO/ASTM Practice 51956	Crystalline material in the form of powder, pellets, single crystals, or in sealed glass tubes or bulbs, or suspended in plastics. When subjected to a carefully controlled heating program, the freed electrons and holes from traps recombine with the emission of characteristic light. Most commonly employed materials for TLD are LiF, CaF_2, $CaSO_4$, and $Li_2Bi_4O_7$.	Electron, gamma and X-ray	10^{-4} to 10^{3} Gy	10^{-2} to 10^{10} Gy s^{-1}	Heat cycling TL reader	Varies with material. Temperature during and after irradiation may need to be controlled.	Varies with material. May require control or water tight packaging.	Varies with material

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