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Practice for dosimetry in radiation processing

Pratique standard pour dosimétrie au 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 Committee E61, Radiation Processing, is responsible for the development and maintenance of these dosimetry standards with unrestricted participation and input from appropriate ISO member bodies.

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

International Standard ISO/ASTM 52628 was developed by ASTM Committee E61, Radiation Processing, through Subcommittee E61.01, on Dosimetry, and by Technical Committee ISO/TC 85, Nuclear energy, nuclear technologies and radiological protection.

This first edition of ISO/ASTM 52628 cancels and replaces ASTM E2628-09ε1.

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.

Current edition approved July 20, 2013. Published November 2013. Originally published as ASTM E2628–09. Last previous ASTM edition E2628–09$^{\varepsilon 1}$. The present International Standard ISO/ASTM 52628–2013(E) replaces ASTM E2628–09$^{\varepsilon 1}$.

[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