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Standard practice for dosimetry in radiation processing

Pratique standard pour dosimétrie au traitement par irradiation

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by ASTM Committee E61, *Radiation processing* (as ASTM E2628-09), and drafted in accordance with its editorial rules. It was assigned to Technical Committee ISO/TC 85, *Nuclear energy, nuclear technologies and radiation protection*, and adopted under the "fast-track procedure".

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

ISO/ASTM 52628:2020(E)

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 healthcare products, 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.

In some applications, it is necessary to ensure that the specified absorbed dose is applied. In these cases, 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 comprise 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 in measured dose 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced documents

2.1 *ASTM Standards:*[2]

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

E3083 Terminology Relating to Radiation Processing: Dosimetry and Applications

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

F1356 Guide for Irradiation of Fresh, Frozen or Processed 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]

51026 Practice for Using the Fricke Dosimetry System

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 Dichromate Dosimetry System

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 an Alanine-EPR Dosimetry System

51608 Practice for Dosimetry in an X-Ray (Bremsstrahlung) Facility for Radiation Processing at Energies between 50 keV and 7.5 MeV

51631 Practice for Use of Calorimetric Dosimetry Systems for Electron Beam Dose Measurements and Dosimetry System 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 Estimation of Measurement Uncertainty 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 Use of a Thermoluminescence-Dosimetry (TLD) System for Radiation Processing

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

52303 Guide for Absorbed Dose Mapping in Radiation Processing Facilities

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

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 of

[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.

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

development, validation and routine control

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

ISO 14470 Food irradiation – Requirements for the development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food

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 200:2012, VIM , International vocabulary of metrology – basic 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 *calibration*—operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication. **VIM**

3.1.3 *calibration curve*—expression of the relation between indication and corresponding measured quantity value. **VIM**

3.1.4 *dosimeter*—device that, when irradiated, exhibits a quantifiable change that can be related to a dosimetric quantity using appropriate measurement instrument(s) and procedures.

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

3.1.6 *dosimeter response (indication)*—reproducible, quantifiable change produced in the dosimeter by ionizing radiation.

3.1.6.1 *Discussion*—The dosimeter response value (indication), obtained from one or more measurements, is used in the estimation of the dosimetric quantity. The response value (indication) may be obtained from such measurements as optical absorbance, intensity of EPR spectra, or electropotential between solutions.

3.1.7 *dosimetry*—measurement of a dosimetric quantity by the use of a dosimetry system.

3.1.8 *dosimetry system*—interrelated elements used for measuring a dosimetric quantity, including dosimeters, instruments and their associated reference standards, and procedures for their use.

3.1.8.1 *Discussion*—As discussed in ICRU-85a, dosimetric quantities provide a physical measure to correlate with actual or potential effects. They are products of radiometric quantities and interaction coefficients. In calculations, the values of these quantities and coefficients must be known, while measurements might not require this information. Dosimetric quantities include air kerma, exposure and absorbed dose to a specified material.

3.1.8.2 *Discussion*—In radiation processing applications the quantity of interest is usually absorbed dose to water. Absorbed dose to silicon might be used in semiconductor irradiations.

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**

3.1.9.1 *Discussion*—In dosimetry for radiation processing, typical examples of influence quantities include radiation type and energy, irradiation temperature, dose rate and the time interval between irradiation and determination of the indication of the dosimeter.

3.1.10 *measurement management system*—set of interrelated or interacting elements necessary to achieve metrological confirmation and continual control of measurement processes. **ISO 10012**

3.1.10.1 *Discussion*—See 7.6 for further details.

3.1.11 *(measurement) uncertainty*—non-negative parameter characterizing characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used. **VIM**

3.1.12 *(metrological) traceability*—property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty. **VIM**

3.1.13 *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.

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

[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).