This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

Designation: 51261 – 26

Standard Practice for Calibration of Routine Dosimetry Systems for Radiation Processing[1]

This standard is issued under the fixed designation 51261; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This practice specifies the requirements for calibrating routine dosimetry systems for use in radiation processing, including establishing measurement traceability and estimating uncertainty in the measured dose using the calibrated dosimetry system.

NOTE 1—Regulations or other directives exist in many countries that govern certain radiation processing applications such as sterilization of healthcare products and radiation processing of food requiring that absorbed-dose measurements be traceable to national or international standards (ISO 11137-1, Refs (**1-3**)).[2]

1.2 The absorbed-dose range covered is up to 1000 kGy.

1.3 The radiation types covered are photons and electrons with energies from 80 keV to 25 MeV.

1.4 This document is one of a set of standards that provides requirements for implementing dosimetry in radiation processing and provides guidance for achieving compliance with the requirements of ISO 11137-1 (radiation sterilization of health care products), ISO 14470 (treatment of food), and ASTM 52628 (Standard Practice for Dosimetry in Radiation Processing). It relates to the evaluation and documentation of the dosimetry system calibration in conjunction with ASTM 52628 (Standard Practice for Dosimetry in Radiation Processing), and ASTM 51707 (Standard Guide for Estimation of Measurement Uncertainty in Dosimetry for Radiation Processing).

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

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced documents

2.1 *ASTM Standards:*[3]

E178 Practice for Dealing With Outlying Observations

E3083 Terminology Relating to Radiation Processing: Dosimetry and Applications

51275 Practice for Use of a Radiochromic Film Dosimetry System

51607 Practice for Use of an Alanine-EPR Dosimetry System

51707 Guide for Estimation of Measurement Uncertainty in Dosimetry for Radiation Processing

52628 Practice for Dosimetry in Radiation Processing

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

2.2 *International Commission on Radiation Units and Measurements Reports:*[4]

ICRU Report 80 Dosimetry Systems for Use in Radiation Processing

ICRU Report 85a Fundamental Quantities and Units for Ionizing Radiation

2.3 *ISO Standards:*[5]

ISO 11137-1 Sterilization of Health Care Products — Radiation — Requirements for the 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 Development, Validation and Routine Control

[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. Originally developed as a joint ISO/ASTM standard in conjunction with ISO/TC 85/WG 3.

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[2] The boldface numbers in parentheses refer to a list of references at the end of this standard.

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

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

[5] 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.

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ISO 11137-4 Sterilization of health care products — Radiation — Part 4: Guidance on process control. General information

ISO 11139 Sterilization of Health Care Products — Vocabulary of Terms Used in Sterilization and Related Equipment and Process Standards

ISO 12749-4 Nuclear Energy, Nuclear Technologies, and Radiological Protection — Vocabulary — Part 4: Dosimetry for Radiation Processing

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 *Joint Committee for Guides in Metrology (JCGM) Reports:*[6]

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

JCGM 200:2008 International Vocabulary of Metrology – Basis and General Concepts and Associated Terms

3. Terminology

3.1 *Definitions:* (unless otherwise stated, definitions are from ASTM E3083):

3.1.1 *approved calibration laboratory*—calibration laboratory that is a recognized national metrology institute; or has been formally accredited to ISO/IEC 17025.

3.1.1.1 *Discussion*—A recognized national metrology institute or other calibration laboratory accredited to ISO/IEC 17025 should be used for irradiation of dosimeters or dose measurements for calibration in order to ensure traceability to a national or international standard.

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 the corresponding measured quantity value. **VIM**

3.1.4 *calibration phantom*—a fixture or item used for positioning dosimeter samples in a documented geometry during irradiations which are performed in the process of calibrating dosimetry systems.

3.1.4.1 *Discussion*—Its purpose is to ensure that multiple dosimeters placed on or in the fixture receive doses with a known relationship and associated uncertainty during irradiation. A specific reproducible package may also be used.

3.1.5 *charged-particle equilibrium*—condition in which the kinetic energy of charged particles (or electrons), excluding rest mass, entering an infinitesimal volume of the irradiated material equals the kinetic energy of charged particles (or electrons) emerging from it.

3.1.5.1 *Discussion*—It is also referred to as electron equilibrium in the case of electrons set in motion by photon irradiation of a material.

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

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

3.1.8 *dosimetry system*—interrelated elements 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 *electron equilibrium*—charged particle equilibrium for electrons. (See *charged-particle equilibrium*.)

3.1.10 *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**

3.1.11 *in situ / in-plant calibration*—calibration where the dosimeter irradiation is performed in the place of use of the routine dosimeters.

3.1.12 *measurand*—quantity intended to be measured. **VIM**

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

3.1.14 *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.

3.1.15 *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.

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

3.1.17 *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**

3.1.17.1 *Discussion*—Measurement traceability is a requirement of any measurement management system (see Annex A4).

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

[6] 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).