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Standard Guide for Estimation of Measurement Uncertainty in Dosimetry for Radiation Processing[1]

This standard is issued under the fixed designation 51707; 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 standard provides guidance on the use of concepts described in the JCGM (*Joint Committee for Guides in Metrology*) Evaluation of Measurement Data – Guide to the Expression of Uncertainty in Measurement (GUM) to estimate the uncertainties in the measurement of absorbed dose in radiation processing.

1.2 Methods are given for identifying, evaluating, and estimating the components of measurement uncertainty associated with the use of dosimetry systems, and for calculating combined standard measurement uncertainty and expanded uncertainty of dose measurements based on the GUM methodology.

1.3 Examples are given on how to develop a measurement uncertainty budget and a statement of uncertainty.

1.3.1 Key components of uncertainty are derived as part of the derivation of the uncertainty budget. This standard identifies which components of uncertainty are carried forward as part of other analyses (e.g., assessment of process capability and process targets, and process variability), and which components from other standards are brought forward into this standard (e.g., precision of the dose measurement, calibration curve fit, and indirect measurement of dose).

1.4 This document is one of a set of standards that provides recommendations for properly 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 ISO/ASTM 52628 related to the evaluation and documentation of the uncertainties associated with measurements made with a dosimetry system. It is intended to be read in conjunction with ISO/ASTM 52628 (Standard Practice for Dosimetry in Radiation Processing), and ISO/ASTM 51261 (Practice for Calibration of Routine Dosimetry Systems for Radiation Processing).

1.5 To achieve compliance with the requirements of ISO 11137-1 (radiation sterilization of health care products), ISO 14470 (treatment of food), and other applications, a measurement is accompanied by a statement of the uncertainty.

1.6 This guide does not address the establishment of process specifications or conformity assessment.

1.7 *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.*

1.8 *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:*[2]

E178 Practice for Dealing With Outlying Observations

E456 Terminology Relating to Quality and Statistics

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

2.2 *ISO/ASTM Standards:*[2]

51261 Practice for Calibration of Routine Dosimetry Systems for Radiation Processing

51608 Practice for dosimetry in an X-ray (bremsstrahlung) facility for radiation processing at energies between 50 keV and 7.5 MeV

51649 Practice for Dosimetry in an Electron Beam Facility

[1] This guide 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 ASTM/ISO standard in conjunction with 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.

for Radiation Processing at Energies Between 300 keV and 25 MeV

51702 Practice for Dosimetry in a Gamma Facility for Radiation Processing

52628 Practice for Dosimetry in Radiation Processing

2.3 *ISO Documents:*

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[3]

ISO 11137-3 Sterilization of Health Care Products — Radiation — Part 3: Guidance on Dosimetric Aspects of Development, Validation and Routine Control[3]

ISO 11137-4 Sterilization of health care products — Radiation — Part 4: Guidance on process control. General information[3]

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[4]

ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories[4]

2.4 *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 200:2008, VIM, International vocabulary of metrology — Basis and general concepts and associated terms[6]

2.5 *ICRU Reports:*[7]

ICRU Report 80 Dosimetry Systems for Use in Radiation Processing

ICRU Report 85a Fundamental Quantities and Units for Ionizing Radiation

3. Terminology

3.1 *VIM Definitions:*

3.1.1 For definitions quoted here from the VIM, only selected NOTES and EXAMPLES are included in 3.2. See VIM for further information.

3.2 *Definitions:*

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

3.2.1.1 *Discussion*—A recognized national metrology institute or other calibration laboratory accredited by 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.

3.2.2 *arithmetic mean, average* [GUM, C.2.19]—sum of values divided by the number of values:

$$\bar{x} = \frac{1}{n}\sum_i x_i,\ i = 1, 2, 3 \ldots n \tag{1}$$

where:

x_i = individual values of parameters with $i = 1, 2, 3 \ldots n$.

3.2.2.1 *Discussion*—The term ‘mean’ is used generally when referring to a population parameter and the term ‘average’ when referring to the result of a calculation on the data obtained in a sample.

3.2.3 *calibration curve* [VIM, 4.31]—expression of the relation between indication and corresponding measured quantity value.

3.2.3.1 *Discussion*—In radiation processing standards, the term “dosimeter response” is generally used for “indication.”

3.2.4 *coefficient of variation (CV)*—sample standard deviation expressed as a percentage of sample average value:

$$CV = \frac{S}{\bar{x}} \times 100\ \% \tag{2}$$

3.2.5 *combined standard measurement uncertainty* [VIM, 2.31]—standard measurement uncertainty that is obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model.

3.2.5.1 *Discussion*—

(1) It is also referred to as ‘combined standard uncertainty.’

(2) In case of correlations of input quantities in a measurement model, covariances must also be taken into account when calculating the combined standard measurement uncertainty. A description of covariances may be found in the GUM reference, Annex C.

3.2.6 *coverage factor (k)* [VIM, 2.38]—number larger than one by which a combined standard measurement uncertainty is multiplied to obtain an expanded measurement uncertainty.

3.2.7 *expanded uncertainty* [GUM, 2.3.5]—quantity defining the interval about the result of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the measurand.

3.2.7.1 *Discussion*—Expanded uncertainty is obtained by multiplying the combined standard uncertainty by a coverage factor, the value of which determines the magnitude of the ‘fraction.’ Expanded uncertainty is also referred to as ‘overall uncertainty.’

3.2.8 *influence quantity* [VIM, 2.52]—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.

3.2.8.1 *Discussion*—In radiation processing dosimetry, this

[3] Available from Association for the Advancement of Medical Instrumentation (AAMI), 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633, http://www.aami.org.

[4] Available from International Organization for Standardization (ISO), ISO Central Secretariat, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, https://www.iso.org.

[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).

[7] Available from International Commission on Radiation Units and Measurements (ICRU), 7910 Woodmont Ave., Suite 400, Bethesda, MD 20841-3095, http://www.icru.org.