



Standard Practice for Characterization and Performance of a High-Dose Radiation Dosimetry Calibration Laboratory¹

This standard is issued under the fixed designation ISO/ASTM 51400; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision.

1. Scope

1.1 This practice addresses the specific requirements for laboratories engaged in dosimetry calibrations involving ionizing radiation, namely, gamma-radiation, electron beams or X-radiation (bremsstrahlung) beams. It specifically describes the requirements for the characterization and performance criteria to be met by a high-dose radiation dosimetry calibration laboratory.

1.2 The absorbed-dose range is typically between 10 and 10⁵ Gy.

1.3 This practice addresses criteria for laboratories seeking accreditation for performing high-dose dosimetry calibrations, and is a supplement to the general requirements described in ISO/IEC 17025.

1.3.1 By meeting these criteria and those in ISO/IEC 17025, the laboratory may be accredited by a recognized accreditation organization.

1.3.2 Adherence to these criteria will help to ensure high standards of performance and instill confidence regarding the competency of the accredited laboratory with respect to the services it offers.

1.4 *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. Referenced documents

2.1 ASTM Standards:

E 170 Terminology Relating to Radiation Measurements and Dosimetry²

E 1249 Practice for Minimizing Dosimetry Errors in Radiation Hardness Testing of Silicon Electronic Devices Using Co-60 Sources²

E 1250 Test Method for Application of Ionization Chambers to Assess the Low Energy Gamma Component of Cobalt-60 Irradiators Used in Radiation-Hardness Testing of Silicon Electronic Devices²

¹ This practice is under the jurisdiction of ASTM Committee E10 on Nuclear Technology and Applications and is the direct responsibility of Subcommittee E10.01 on Dosimetry for Radiation Processing, and is also under the jurisdiction of ISO/TC 85/WG 3.

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² *Annual Book of ASTM Standards*, Vol 12.02.

E 2116 Practice for Dosimetry for a Self-Contained Dry-Storage Gamma-Ray Irradiator²

2.2 ISO/ASTM Standards:

51261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing²

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing²

2.3 International Organization for Standardization Documents:

ISO/IEC 17025 (1999) General Requirements for the Competence of Calibration and Testing Laboratories³

2.4 International Commission on Radiation Units and Measurements (ICRU) Reports:

ICRU Report 60, Fundamental Quantities and Units for Ionizing Radiation⁴

3. Terminology

3.1 Definitions:

3.1.1 *accredited dosimetry calibration laboratory*—a dosimetry laboratory that has formal recognition that it is competent to carry out specific calibrations in accordance with documented requirements of a recognized accreditation organization.

3.1.2 *calibration*—the process whereby the response of a dosimeter or measuring instrument is characterized through comparison with an appropriate standard that is traceable to, and consistent with, a nationally or internationally recognized standard.

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

3.1.4 *measurement quality assurance plan*—a documented program for the measurement process that ensures, on a continuing basis, that the overall uncertainty meets the requirements of the specific application. This plan requires traceability to, and consistency with, nationally or internationally recognized standards.

3.1.5 *measurement traceability*—the ability to demonstrate by means of an unbroken chain of comparisons that a measurement is in agreement within acceptable limits of uncertainty with comparable nationally or internationally recognized standards.

³ Available from International Organization for Standardization (ISO), 1 Rue de Varembe, Case Postale 56, CH-1211, Geneva 20, Switzerland.

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



3.1.6 *primary-standard dosimeter*—a dosimeter of the highest metrological quality, established and maintained as an absorbed-dose standard by a national or international standards organization.

3.1.7 *proficiency testing*—evaluation of the measurement capability of a calibration laboratory and demonstration of consistency with appropriate national standards.

3.1.8 *quality assurance*—all systematic actions necessary to provide adequate confidence that a calibration, measurement or process is performed to a predefined level of quality.

3.1.9 *quality control*—the operational techniques and procedures that are employed routinely to achieve and sustain a predefined level of quality.

3.1.10 *quality manual*—document stating the quality policy, quality system, and quality practices of an organization.

3.1.11 *quality system*—documented organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

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

3.1.13 *recognized accreditation organization*—an organization, operating in conformance with national regulations or requirements, that conducts and administers a laboratory accreditation program and grants accreditation to calibration laboratories.

3.1.14 *reference-standard dosimeter*—a dosimeter of high metrological quality used as a standard to provide measurements traceable to, and consistent with, measurements made using primary-standard dosimeters.

3.1.15 *transfer-standard dosimeter*—a dosimeter, often a reference-standard dosimeter suitable for transport between different locations, used to compare absorbed-dose measurements.

3.2 Definitions of other terms used in this standard that pertain to radiation measurement and dosimetry may be found in ASTM Terminology E 170. Definitions in E 170 are compatible with ICRU 60; that document, therefore, may be used as an alternative reference.

4. Significance and use

4.1 The radiation industry needs reliable, prompt dosimetry calibration services to support accurate measurements of absorbed dose. These measurements should be consistent with, and traceable to, the physical measurement standards maintained by an appropriate national or international standards laboratory. Organizations that provide calibration services, and thereby serve as a link to national standards, include universities, government-owned laboratories, and private companies.

4.2 To ensure the provision of adequate services, a calibration laboratory should be operating with a full measurement quality assurance (MQA) plan. The fundamental requirements for such a program include:

4.2.1 compliance with operational requirements of this practice and those of ISO/IEC 17025,

4.2.2 documented procedures and in-house quality assurance (QA) program specific to the calibration services provided, and

4.2.3 periodic performance evaluations, including proficiency tests and on-site expert assessments.⁵

4.3 When a calibration laboratory applies for accreditation, the accreditation organization (see Annex A1) determines whether the laboratory's quality documentation is satisfactory, performs proficiency tests for each calibration category for which accreditation is requested, and provides technical experts for on-site assessments to determine whether the laboratory meets the criteria of this practice, the accreditation organization and those of ISO/IEC 17025.

4.4 Section 5 sets forth specific criteria for laboratories engaged in dosimetry calibrations involving ionizing radiation, that is, gamma-radiation, electron beams and X-radiation (bremsstrahlung) beams. This section amplifies and interprets the general requirements of ISO/IEC 17025.

5. Specific criteria for ionizing radiation

5.1 This section sets specific requirements to which a laboratory shall adhere if it is to be accredited for dosimetry calibrations involving ionizing radiation, specifically gamma-radiation, electron beams and X-radiation (bremsstrahlung) beams. This section amplifies and interprets certain general requirements set forth in ISO/IEC 17025.

5.2 This section is to be used in conjunction with ISO/IEC 17025 to assess ionizing radiation dosimetry calibration laboratories for the purpose of accreditation by an appropriate accreditation organization.

5.3 This section may also be used with ISO/IEC 17025 as a guide by ionizing radiation dosimetry calibration laboratories in the development and implementation of their quality systems.

5.4 *Quality System, Assessment and Review:*

5.4.1 The quality manual and related quality documentation shall contain:

5.4.1.1 A statement of the scope of the laboratory's work for which accreditation is sought, including the radiation types, energies, and dose rates, and

5.4.1.2 Documentation of the model and serial numbers of each critical piece of equipment used in a particular calibration.

5.4.2 The laboratory's proficiency shall be tested at a frequency specified by the accreditation organization.

5.4.2.1 The proficiency tests of the calibration laboratory shall be performed by a nationally or internationally recognized standards laboratory.

5.4.2.2 The acceptable level of performance in the proficiency test shall be determined by the accreditation organization. Typically, the absorbed-dose rate (or absorbed dose) measured in the calibration laboratory is within 4 %, at the 95 % level of confidence, of the value defined by comparison with the appropriate national or international standard.

5.5 *Personnel:*

⁵ Inn, K. G. W., Coursey, B. M., Eisenhower, E. H., Walker, M. D., Humphreys, J. C., Heaton, H. T., and Duvall, K. C., "The Role of the Office of Radiation Measurement in Quality Assurance," *The Science of the Total Environment*, 130/131 Elsevier Science Publishers B. V., Amsterdam, 1993, pp. 497–507.