



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

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^{ε1} NOTE—Footnote 1 was editorially altered in June 1999.

1. Scope

1.1 This practice contains the characterization and performance criteria to be met by a high-dose radiation dosimetry calibration laboratory. By meeting these criteria, the laboratory may be accredited by a recognized accreditation organization. Adherence to these criteria will ensure high standards of performance and instill confidence that the accredited laboratory is competent to provide reliable, accurate services.

2. Referenced Documents

2.1 ASTM Standards:

E 170 Terminology Relating to Radiation Measurements and Dosimetry²

E 177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods³

E 456 Terminology Relating to Quality and Statistics³

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

E 1261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing²

E 1707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing²

2.2 International Organization for Standardization Documents:

ISO/IEC Guide 25 (1990) General Requirements for the Competence of Calibration and Testing Laboratories⁴

3. Terminology

3.1 Descriptions of Terms Specific to This Standard:

3.1.1 *accuracy goals*—the maximum acceptable deviation from the accepted reference value of a measured quantity, where the accepted reference value is defined by the appropriate national standard.

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 national standard.

3.1.2.1 *Discussion*—The types of dosimeters include *reference standard dosimeters*, *transfer standard dosimeters*, and *routine dosimeters*. See Guide E 1261 for guidance on the selection and calibration of the various dosimetry systems.

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 *laboratory*—high-dose calibration laboratory that includes pertinent radiation calibration facilities, services, personnel, and equipment.

3.1.5 *laboratory accreditation*—formal recognition that a laboratory is competent to carry out specific calibrations in accordance with documented requirements of a recognized accrediting organization.

3.1.6 *measurement quality assurance plan*—a documented program for the measurement process that quantifies, on a continuing basis, the overall uncertainty of the measurements. This plan requires traceability to and consistency with national or international standards, and shall ensure that the overall uncertainty meets the requirements of the specific application.

3.1.7 *measurement traceability*—the ability to demonstrate and document periodically that the measurement results from a particular measurement system are in agreement with comparable measurement results obtained with a national standard (or some identifiable and accepted standard) to a specified uncertainty.

3.1.8 *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.

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

³ *Annual Book of ASTM Standards*, Vol 14.02.

⁴ Available from International Organization for Standardization, 1 Rue de Varembe, Case Postale 56, CH-1211 Geneva 20, Switzerland.

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

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

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

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

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

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

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

3.1.16 *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.

3.1.17 *routine dosimeter*—a dosimeter calibrated against a primary-, reference-, or transfer-standard dosimeter and used for routine absorbed dose measurement.

3.1.18 *transfer standard dosimeter*—a dosimeter, often a reference standard dosimeter, suitable for transport between different locations for use as an intermediary to compare absorbed dose measurements.

3.1.19 *verification*—confirmation by examination of objective evidence that specified requirements have been met.

3.1.19.1 *Discussion*—In the case of measuring equipment, the result of verification leads to a decision either to restore to service or to perform adjustments, or to repair, or to downgrade, or to declare obsolete. In all cases it is required that a written trace of the verification performed be kept on the instrument's individual record.

3.1.20 *working standard*—a standard, usually calibrated against a reference standard, used routinely to calibrate or check measuring instruments or devices.

3.2 Also see Terminology E 170.

4. Significance and Use

4.1 The radiation industry needs a source of reliable, prompt dosimeter calibration services to support accurate measurements of absorbed dose during radiation processing. Those measurements, made routinely in industrial facilities, should be consistent with and traceable to the physical measurement standards maintained by an appropriate national or international standards laboratory. Organizations that might 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) program. The fundamental requirements for such a program include: (1) compliance with operational requirements of this practice; (2) documented procedures and in-house quality assurance (QA) program specific to the calibration services provided; and (3) periodic performance evaluations, including proficiency tests and on-site expert assessments. **(1,2)**⁵

4.3 When a potential calibration laboratory applies for accreditation, the accrediting organization (see Appendix X1) 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.

4.4 Section 5 sets forth general criteria that shall be satisfied by each laboratory seeking accreditation. These general criteria are completely consistent with ISO/IEC Guide 25. Laboratories that meet these general requirements comply, for calibration activities, with Guide 25 and the relevant requirements of the ISO 9000 series of standards, including those of the model described in ISO 9002 when they are acting as suppliers producing calibration results.

4.5 For laboratories engaged in specific fields of calibration, the general requirements of ISO/IEC Guide 25 need amplification and interpretation. Section 6 of this practice contains specific criteria which provide that amplification and interpretation for ionizing radiation. Section 7 contains specific criteria for particular types of ionizing radiation, that is, gamma rays, electron beams and X-ray (bremsstrahlung) beams.

4.6 For ease of use, all sections of this document after Section 5 employ the format established in Section 5. It is therefore readily apparent how the subsequent sections amplify and interpret the general requirements contained in Section 5.

5. General Criteria

5.1 This section sets forth the general requirements that shall be satisfied by each laboratory seeking accreditation. In addition to satisfying the general criteria of this section, a laboratory shall also satisfy the specific criteria contained in Section 6 and in those parts of Section 7 relevant to each calibration service for which accreditation is sought (see 4.4 and 4.5).

5.2 This section may also be used by calibration laboratories in the development and implementation of their quality systems, and by others concerned with evaluating the competence of laboratories.

5.3 Organization and Management:

5.3.1 The laboratory shall be organized and shall operate in such a way that its facilities meet the requirements of this section.

5.3.2 The laboratory shall:

5.3.2.1 Have managerial staff with the authority and resources needed to discharge their duties,

5.3.2.2 Have arrangements to ensure that its personnel are free from any commercial, financial, and other conflicts which might adversely affect the quality of their work,

⁵ The boldface numbers in parentheses refer to a list of references at the end of this practice.

5.3.2.3 Be organized in such a way that confidence in its independence of judgement and integrity is maintained at all times,

5.3.2.4 Specify and document the responsibility, authority, and interrelation of all personnel who manage, perform, or verify work affecting the quality of calibrations,

5.3.2.5 Provide adequate supervision by persons familiar with the calibration methods and procedures, the objective of the calibration, and the assessment of the results,

5.3.2.6 Have a technical manager (however named) who has overall responsibility for the technical operations,

5.3.2.7 Have a quality manager (however named) who has responsibility for the quality system and its implementation. The quality manager shall have direct access to the highest level of management at which decisions are made on calibration laboratory policy or resources, and to the technical manager. In some laboratories, the quality manager may also be the technical manager or deputy technical manager of the calibration laboratory,

5.3.2.8 Nominate deputies in case of absence of the technical or quality manager,

5.3.2.9 Where relevant, have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights, and

5.3.2.10 Where appropriate, participate in interlaboratory comparisons and proficiency testing programs.

5.4 *Quality System, Audit, and Review:*

5.4.1 The laboratory shall establish and maintain a quality system appropriate to the type, range, and volume of calibration activities it undertakes. The elements of this system shall be documented. The quality documentation shall be available for use by the laboratory personnel. The laboratory shall define and document its policies and objectives for, and its commitment to, good laboratory practice and quality of calibration services. The laboratory management shall ensure that these policies and objectives are documented in a quality manual and communicated to, understood, and implemented by all laboratory personnel concerned. The quality manual shall be maintained current under the responsibility of the quality manager.

5.4.2 The quality manual, and related quality documentation, shall state the laboratory's policies and operational procedures established in order to meet the requirements of this section. The quality manual and related quality documentation shall also contain:

5.4.2.1 A quality policy statement, including objectives and commitments, by top management,

5.4.2.2 The organization and management structure of the laboratory, its place in any parent organization, and relevant organizational charts,

5.4.2.3 The relations between management, technical operations, support services, and the quality system,

5.4.2.4 Procedures for control and maintenance of documentation,

5.4.2.5 Job descriptions of key staff and reference to the job descriptions of other staff,

5.4.2.6 Identification of the laboratory's approved signatories,

5.4.2.7 The laboratory's procedures for achieving traceability of measurements,

5.4.2.8 The laboratory's scope of calibrations,

5.4.2.9 Arrangements for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work,

5.4.2.10 Reference to the calibration and verification procedures used,

5.4.2.11 Procedures for handling calibration and test items,

5.4.2.12 Reference to the major equipment and reference measurement standards used,

5.4.2.13 Reference to procedures for calibration, verification, and maintenance of equipment,

5.4.2.14 Reference to verification practices including interlaboratory comparisons, proficiency testing programs, use of reference materials, and internal quality control schemes,

5.4.2.15 Procedures to be followed for consultation and corrective action whenever discrepancies in proficiency testing are detected or departures from documented policies and procedures occur,

5.4.2.16 The laboratory management arrangements for exceptionally permitted departures from documented policies and procedures or from standard specifications,

5.4.2.17 Procedures for dealing with complaints,

5.4.2.18 Procedures for protecting confidentiality and proprietary rights, and

5.4.2.19 Procedures for audit and review.

5.4.3 The laboratory shall arrange for audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system. Such audits shall be carried out by trained and qualified staff who are, wherever possible, independent of the activity to be audited. Where the audit findings cast doubt on the correctness or validity of the laboratory's calibration results, the laboratory shall take corrective action and shall notify, in writing, as soon as practically possible, any client whose work may have been affected.

5.4.4 The quality system adopted to satisfy the requirements of this section shall be reviewed at least once a year by the management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements. Any changes in the quality system shall be approved by the accrediting organization prior to implementation.

5.4.5 All audit and review findings and any corrective actions that arise from them shall be documented. The person responsible for quality shall ensure that these actions are discharged within the agreed time scale.

5.4.6 In addition to periodic audits the laboratory shall ensure the quality of results provided to clients by implementing and documenting checks. These checks shall be reviewed by management and shall include, as appropriate, but not be limited to:

5.4.6.1 Internal quality control schemes using, whenever practical, statistical techniques,

5.4.6.2 Participation in proficiency testing or other interlaboratory comparisons,

5.4.6.3 Replicate calibrations using the same or different methods, and