ISO/ASTM 51400:2003(E)

Standard Practice for Characterization and Performance of a High-Dose Radiation Dosimetry Calibration Laboratory[1]

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 10^5 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 Dosimetry[2]

E 1249 Practice for Minimizing Dosimetry Errors in Radiation Hardness Testing of Silicon Electronic Devices Using Co-60 Sources[2]

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 Devices[2]

E 2116 Practice for Dosimetry for a Self-Contained Dry-Storage Gamma-Ray Irradiator[2]

2.2 *ISO/ASTM Standards:*

51261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing[2]

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing[2]

2.3 *International Organization for Standardization Documents:*

ISO/IEC 17025 (1999) General Requirements for the Competence of Calibration and Testing Laboratories[3]

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

ICRU Report 60, Fundamental Quantities and Units for Ionizing Radiation[4]

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.

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[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.

[3] Available from International Organization for Standardization (ISO), 1 Rue de Varembé, 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.

5.5.1 It is recommended that the laboratory's technical manager have a post-secondary degree awarded by a recognized educational institution, preferably in physical science, as well as experience in radiation metrology or a closely related scientific field.

5.5.2 It is recommended that the supervisor of the calibration laboratory has experience in radiation metrology or a closely related scientific field.

5.6 *Facilities and Environment*:

5.6.1 Suitable storage facilities shall be provided for reference standards, equipment, documented instructions, manuals, and calibration certificates and reports.

5.6.2 Environmental monitoring equipment shall be provided for recording temperature and relative humidity within the laboratory. If interpretation of the response of a particular type of dosimeter requires a history of the environmental conditions, the temperature and humidity shall be recorded.

5.6.3 Although strict temperature control is not essential, it is recommended that the laboratory be kept at a reasonably uniform temperature so that the accuracy of equipment is not adversely affected, and so that an adequate stability is achieved before the start of calibration measurements. It is recommended that the laboratory temperature be maintained within the range of 15 to 25°C. The degree of environmental control may have to be more stringent for some applications.

5.6.4 It is recommended that the relative humidity be maintained within the range of 15 to 65 % for laboratory operation unless the calibration of specific dosimeter types requires a different range.

5.6.5 A closely controlled environment is not normally necessary in a storage area, but wide temperature and humidity fluctuations should be avoided so as to protect instruments and physical standards temporarily held there, and to minimize the time required for an instrument to reach equilibrium when brought to the operational area from the storage area. Any area used for storage of dosimeters shall have its temperature and relative humidity controlled as required for the specific dosimetry system employed.

5.6.6 Fluorescent lamps, sunlight, and other sources of ultraviolet light shall be filtered if the dosimeters are adversely affected by ultraviolet radiation.

5.6.7 The electrical power shall be appropriate to the equipment used, suitably stable, and free of switching surges and significant line noise. When necessary, local auxiliary voltage stabilizers and filters shall be used.

5.6.8 The laboratory shall be provided with an adequate electrical grounding system. Where there is a possibility of interference arising from equipment connected to a single grounding system, use separate grounding systems taking adequate precautions to avoid interference from interconnections between systems.

5.6.9 If compressed air is used, a pressure regulator and means for removing moisture, dust, and oil from the compressed air shall be provided.

5.7 *Equipment*:

5.7.1 *Radiation Source(s)*—For a laboratory that utilizes gamma (^{60}Co or ^{137}Cs), electron beam and/or X-radiation (bremsstrahlung) radiation sources, the fluence rate should be sufficient to deliver an absorbed dose within the range of 10 to 10^5 Gy within a reasonable time interval.

5.7.2 *Characterization of the Radiation Field*:

5.7.2.1 Determine the absorbed-dose rate using a reference-standard dosimetry system in each location in which dosimeters are irradiated. Ensure that dosimeters are irradiated in the locations where the dose rate is determined. At the time of accreditation and at intervals not to exceed those specified by the accreditation organization (generally, one year or less), demonstrate that the dose-rate measurements are traceable to appropriate national standards by direct measurement intercomparisons.

5.7.2.2 Ensure that the uniformity of the absorbed-dose rate over the irradiation volume at each irradiation position has been quantified. Typically, the absorbed-dose rate should not vary more than ± 1 %.

5.7.2.3 Monitor and control the temperature of the dosimeter during irradiation to the accuracy required by the characteristics of the dosimeter. Measure this temperature during a simulated irradiation of dosimeters or in a manner that will not perturb the radiation field during the irradiation of dosimeters.

5.7.2.4 If required, the photon or electron energy spectrum should be known at the dosimeter location.

5.7.3 *Reference Standards*:

5.7.3.1 The laboratory shall have reference standards and/or transfer standards that cover the range of calibrations performed.

5.8 *Measurement Traceability and Calibration*:

5.8.1 The reference standards used by the laboratory shall be traceable to a national or international standards laboratory.

5.8.2 The standards or equipment originally calibrated by comparison with a higher-level standard shall be recalibrated when the need is demonstrated by the results of proficiency testing or routine quality control.

5.9 *Records*:

5.9.1 The laboratory's permanent records shall include:

5.9.1.1 The date, customer name, description of the dosimeters calibrated, the batch number or serial number, details of the service provided, and calibration report or certificate number,

5.9.1.2 Documentation of routine quality control actions and any resultant control charts, and

5.9.1.3 The results of all proficiency testing.

5.10 *Certificates and Reports*:

5.10.1 Calibration certificates or reports shall include an appropriate statement clearly specifying the conditions under which the calibrations or measurements were performed, including the type of radiation (gamma-radiation, X-radiation, or electron beam), the dose rate(s), temperature, and for electron beams, the electron energy, pulse width, dose rate within the pulse, and pulse repetition rate.

5.10.2 Certificates or reports should state that application of the calibration results to an individual measurement is the responsibility of the user, and that care must be exercised in interpolation of the calibration results.

5.10.3 The laboratory shall indicate whether the calibration was performed using either an accredited or non-accredited procedure. The use of non-accredited procedures shall be justified and those procedures completely explained and documented.

5.10.4 If the calibration laboratory discovers a discrepancy in a calibration report, the person or institution that received the report shall be immediately notified. The discrepancy shall be corrected as soon as possible, either by sending a corrected report to the client or by recalibrating a new group of dosimeters, as applicable. The laboratory shall determine the reason for the discrepancy and take action necessary to prevent recurrences. The severity of the discrepancy in a calibration may require notification to the accreditation organization in accordance with the policies of the accreditation organization.

6. Measurement uncertainty

6.1 To be meaningful, a measurement of absorbed dose shall be accompanied by an estimate of uncertainty.

6.2 Components of uncertainty shall be identified as belonging to one of two categories:

6.2.1 Type A—those evaluated by statistical methods, or

6.2.2 Type B—those evaluated by other means.

6.3 Other ways of categorizing uncertainty have been widely used and may be useful for reporting uncertainty. For example, the terms *precision* and *bias* or *random* and *systematic* (non-random) are used to describe different categories of uncertainty.

NOTE 1—The identification of Type A and Type B uncertainties is based on methodology for estimating uncertainties published in 1993 by the International Organization for Standardization (ISO) in the Guide to the Expression of Uncertainty in Measurement.[6] The purpose of using this type of characterization is to promote an understanding of how uncertainty statements are arrived at and to provide a basis for the international comparison of measurement results.

[6] *Guide to the Expression of Uncertainty in Measurement*, International Organization for Standardization, 1993, ISBN 92-67-10188-9.

NOTE 2—ISO/ASTM Guide 51707 defines possible sources of uncertainty in dosimetry performed in radiation processing facilities, and offers procedures for estimating the magnitude of the resulting uncertainties in the measurement of absorbed dose using a dosimetry system. The document defines and discusses basic concepts of measurement, including estimation of the measured value of a quantity, "true" value, error and uncertainty. Components of uncertainty are discussed and methods are provided for estimating their values. Methods are also provided for calculating the combined standard uncertainty and estimating expanded (overall) uncertainty.

6.4 The components of uncertainty involved in a measurement shall be estimated or determined. The overall uncertainty in the measurement may be estimated from a combination of these components, and the procedure for combining these components shall be specifically stated or referenced in all results.

6.5 The laboratory shall be capable of providing a service within the following indicated expanded uncertainty for a coverage factor k = 2 (which corresponds approximately to a 95 % level of confidence). These values include an assumed uncertainty of ±2 % (coverage factor k = 2) associated with the national standard.

6.5.1 Irradiation of dosimeters to a specified absorbed dose: ±4 %.

6.5.2 Evaluation of transfer-standard dosimeters supplied by the laboratory to customer for irradiation: ±6 %.

6.6 The uncertainty value provided for the national standard may change and hence require an adjustment of the other two associated uncertainty values of 6.5.1 and 6.5.2. It shall be the responsibility of the calibration laboratory to notify each affected customer of any such changes, and the corrected values of all affected quantities previously reported to that customer.

7. Keywords

7.1 absorbed dose; accreditation; calibration laboratory; dosimeter; dosimetry system; electron beam; gamma-radiation; ionizing radiation; radiation processing; reference-standard dosimeter; transfer-standard dosimeter; X-radiation

ANNEX

(informative)

A1. EXAMPLES OF ACCREDITATION ORGANIZATIONS

A1.1 At the international level, recognized accreditation organizations are signatories to the International Laboratory Accreditation Cooperation (ILAC). With approximately 37 members, ILAC includes accreditation organizations in Europe, the European Cooperation for Accreditation (EA), and in the Asian Pacific Rim, Asian Pacific Laboratory Accreditation Cooperation (APLAC).

A1.2 In the United States of America, a recognized accreditation organization is one that is a signatory to the National Cooperation for Laboratory Accreditation (NACLA). The National Voluntary Laboratory Accreditation Program (NVLAP), operated by the U.S. National Institute of Standards and Technology (NIST), is a signatory to NACLA. NVLAP accredits calibration laboratories in many fields including ionizing radiation. It provides the administrative organization for the accreditation process, arranges for proficiency testing by NIST technical groups, and provides technical experts for on-site assessment of the competence of the calibration laboratory requesting accreditation.