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Practice for characterization and performance of a high-dose radiation dosimetry calibration laboratory

Pratique de caractérisation et d'exploitation d'un laboratoire d'étalonnage de dosimétrie d'irradiations à hautes doses

Reference number
ISO/ASTM 51400:2002(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75% of the member bodies casting a vote.

ASTM International is one of the world's largest voluntary standards development organizations with global participation from affected stakeholders. ASTM technical committees follow rigorous due process balloting procedures.

A pilot project between ISO and ASTM International has been formed to develop and maintain a group of ISO/ASTM radiation processing dosimetry standards. Under this pilot project, ASTM Subcommittee E10.01, Dosimetry for Radiation Processing, is responsible for the development and maintenance of these dosimetry standards with unrestricted participation and input from appropriate ISO member bodies.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. Neither ISO nor ASTM International shall be held responsible for identifying any or all such patent rights.

International Standard ISO/ASTM 51400 was developed by ASTM Committee E10, Nuclear Technology and Applications, through Subcommittee E10.01, and by Technical Committee ISO/TC 85, Nuclear Energy.

Annex A1 of this International Standard is for information only.

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 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 Dosimetry[2]

E 177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods[3]

E 456 Terminology Relating to Quality and Statistics[3]

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]

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 Guide 25 (1990) General Requirements for the Competence of Calibration and Testing Laboratories[4]

ISO 9002 Quality Systems— Model for Quality Assurance in Production, Installation, and Servicing[4]

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 ISO/ASTM Guide 51261 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.

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

[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] *Annual Book of ASTM Standards*, Vol 14.02.

[4] Available from International Organization for Standardization, 1 Rue de Varembé, Case Postale 56, CH–1211 Geneva 20, Switzerland.

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 ASTM 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 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.

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 the bibliography 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

5.4.6.4 Re-calibration of retained instruments and dosimeters.

5.5 *Personnel*:

5.5.1 The laboratory shall have sufficient personnel having the necessary education, training, technical knowledge, and experience to carry out their assigned functions.

5.5.2 The laboratory shall ensure that the training of its personnel is kept up-to-date (see Section 6).

5.5.3 Records on the relevant qualifications, training, skills, and experience of the technical personnel shall be maintained by the laboratory.

5.6 *Facilities and Environment*:

5.6.1 Laboratory facilities including calibration areas, electrical power sources, lighting, heating, and ventilation shall be adequate to facilitate proper performance of calibrations.

5.6.2 The environment in which calibrations and related activities are undertaken shall not invalidate the results or compromise the specified uncertainty of measurement.

5.6.3 The laboratory shall provide facilities for the effective monitoring, control, and recording of environmental conditions as appropriate. Due attention shall be paid, for example, to dust, electromagnetic interference, humidity, electrical power stability, temperature, and sound and vibration levels, as appropriate to the calibrations performed.

5.6.4 The laboratory design shall provide adequate protection between areas where the activities are incompatible.

5.6.5 Access to and use of all areas affecting the quality of calibration and related activities shall be defined and controlled.

5.6.6 Adequate measures shall be taken to ensure good housekeeping.

5.6.7 The laboratory shall comply with all relevant health and safety requirements.

5.7 *Equipment*:

5.7.1 The laboratory shall be furnished with all items of equipment required for the correct performance of calibrations. In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the relevant requirements of this section are met.

5.7.2 All equipment shall be properly maintained. Maintenance procedures shall be documented. Any item of equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or during calibration or use to be defective, shall be taken out of service, clearly identified, and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification, or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations.

5.7.3 Each item of equipment shall, when appropriate, be labelled, marked, or otherwise identified to indicate its calibration status.

5.7.4 Records shall be maintained for each item of equipment significant to the calibrations performed. The records shall include:

5.7.4.1 The name of the item of equipment,

5.7.4.2 The manufacturer's name, type identification, and serial number or other unique identification,

5.7.4.3 The date received and the date placed in service,

5.7.4.4 The current location, where appropriate,

5.7.4.5 The condition when received (for example, new, used, reconditioned),

5.7.4.6 A copy of the manufacturer's instructions, where available,

5.7.4.7 The dates and results of calibrations or verifications, or both, and the date of the next calibration or verification, or both,

5.7.4.8 The name and signature of the person who performed the calibrations or verifications, or both,

5.7.4.9 The details of maintenance carried out to date and planned for the future, and

5.7.4.10 The history of any damage, malfunction, modification, or repair.

5.8 *Measurement Traceability and Calibration*:

5.8.1 All measuring equipment having an effect on the accuracy or validity of calibrations shall be calibrated or verified, or both, before being put into service. The laboratory shall have an established program for the calibration and verification of its measuring equipment. **(3)**

5.8.2 The overall program of calibration or verification, or both, and validation of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national or international standards of measurement where available. Calibration certificates shall, wherever applicable, indicate the traceability to national standards of measurement, and shall provide the measurement results and associated uncertainty of measurement or a statement of compliance, or both, with an identified metrological specification.

5.8.3 Where traceability to national or international standards of measurement is either not available or not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of interlaboratory comparisons or proficiency testing.

5.8.4 Reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be demonstrated that use for other purposes will not invalidate their performance as reference standards.

5.8.5 Reference standards of measurement shall be calibrated by a body that can provide traceability to a national or international standard of measurement. There shall be a program of calibration and verification for reference standards.

5.8.6 Where relevant, reference standards and measuring equipment shall be subjected to in-service checks (constancy checks) between calibrations and verifications.

5.9 *Calibration Methods*:

5.9.1 The laboratory shall have documented instructions for using and operating all relevant equipment, for handling and preparing dosimeters, and for performing calibrations, where the absence of such instructions could jeopardize the calibrations. All instructions, standards, manuals, and reference data

relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

5.9.2 The laboratory shall use appropriate methods and procedures for all calibrations and related activities within its responsibility (including handling, transport, storage, and preparation of dosimeters, estimation of uncertainty of measurement, and analysis of calibration data)**(4,5)**. The methods and procedures shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations concerned.

5.9.3 Where methods and procedures are not specified, the laboratory shall, wherever possible, use those that have been published in international or national standards, published by reputable technical organizations, or published in relevant scientific texts or journals.

5.9.4 Where it is necessary to employ methods and procedures that have not been established as standard, these shall be subject to agreement with the client, be fully validated and documented, and be available to the client and other recipients of the relevant reports.

5.9.5 Calculations and data transfers shall be subject to appropriate checks.

5.9.6 Where computers or automated equipment are used to capture, process, manipulate, record, report, store, or retrieve calibration data, the laboratory shall ensure that:

5.9.6.1 Computer software is validated and documented where the software provides operational control or contributes to a quality management decision process,

5.9.6.2 Procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission, and data processing,

5.9.6.3 Computer and automated equipment is maintained to ensure proper functioning and is provided with the environmental and operating conditions necessary to maintain the integrity of calibration data, and

5.9.6.4 Appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records are established and implemented.

5.9.7 Documented procedures shall exist for the purchase, receipt, and storage of consumable materials used for the technical operations of the laboratory.

5.10 *Handling of Client's Dosimeters*:

5.10.1 The laboratory shall have a documented system for uniquely identifying the dosimeters, to ensure that there can be no confusion regarding the identity of such dosimeters at any time.

5.10.2 Upon receipt, the condition of the dosimeters, including any abnormalities or departures from standard condition as prescribed in the relevant calibration method, shall be recorded. Where there is any doubt as to the dosimeter's suitability for calibration, where the dosimeter does not conform to the description provided, or where the calibration required is not fully specified, the laboratory shall consult the client for further instruction before proceeding. The laboratory shall establish whether the dosimeter has received all necessary preparation, or whether the client requires the laboratory to perform or arrange for such preparations.

5.10.3 The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the dosimeters during storage, handling, preparation, and calibration; any relevant instructions provided with the dosimeter shall be followed. Where dosimeters have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored, and recorded where necessary. Where dosimeters are to be held secure (for example, for reasons of record, safety, or value, or to enable check calibrations to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured dosimeters.

5.10.4 The laboratory shall have documented procedures for the receipt, retention, or safe disposal of dosimeters, including all provisions necessary to protect the integrity of the laboratory.

5.11 *Records*:

5.11.1 The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. It shall retain on record all original observations, calculations and derived data, calibration records, and a copy of the calibration certificate or report, for an appropriate period. The records for each calibration shall contain sufficient information to permit their repetition. The records shall include the identity of personnel involved in calibration.

5.11.2 All records (including those listed in 5.7.4 pertaining to calibration equipment), certificates, and reports shall be safely stored, held secure, and in confidence to the client.

5.12 *Certificates and Reports*:

5.12.1 The results of each calibration or series of calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously, and objectively in accordance with any instructions in the calibration methods or procedures. The results should normally be reported in a calibration certificate or report, and should include all the information necessary for the interpretation of the calibration results and all information required by the method used.

5.12.2 Each certificate or report shall include at least the following information:

5.12.2.1 A title, for example, "Calibration Certificate," or "Calibration Report,"

5.12.2.2 Name and address of the laboratory, and location where the calibration was carried out if different from the address of the laboratory,

5.12.2.3 Unique identification of the certificate or report (such as serial number) and of each page, and the total number of pages,

5.12.2.4 Name and address of client, where appropriate,

5.12.2.5 Description and unambiguous identification of the dosimeters calibrated (supplier, type, and batch number),

5.12.2.6 Characterization and condition of the dosimeters,

5.12.2.7 Date of receipt of dosimeters and date(s) of performance of calibration, where appropriate,

5.12.2.8 Identification of the calibration method used, or unambiguous description of any non-standard method used,