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

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

Reference number
ISO 15560:1998(E)

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.

International Standard ISO 15560 was prepared by the American Society for Testing and Materials (ASTM) Subcommittee E10.01 (as E 1400-95a) and was adopted, under a special "fast-track procedure", by Technical Committee ISO/TC 85, *Nuclear energy*, in parallel with its approval by the ISO member bodies.

A new ISO/TC 85 Working Group WG 3, *High-level dosimetry for radiation processing*, was formed to review the voting comments from the ISO "Fast-track procedure" and to maintain these standards. The USA holds the convenership of this working group.

International Standard ISO 15560 is one of 20 standards developed and published by ASTM. The 20 fast-tracked standards and their associated ASTM designations are listed below:

ISO Designation	ASTM Designation	Title
15554	E 1204-93	*Practice for dosimetry in gamma irradiation facilities for food processing*
15555	E 1205-93	*Practice for use of a ceric-cerous sulfate dosimetry system*
15556	E 1261-94	*Guide for selection and calibration of dosimetry systems for radiation processing*
15557	E 1275-93	*Practice for use of a radiochromic film dosimetry system*
15558	E 1276-96	*Practice for use of a polymethylmethacrylate dosimetry system*
15559	E 1310-94	*Practice for use of a radiochromic optical waveguide dosimetry system*
15560	E 1400-95a	*Practice for characterization and performance of a high-dose radiation dosimetry calibration laboratory*
15561	E 1401-96	*Practice for use of a dichromate dosimetry system*

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15562	E 1431-91	*Practice for dosimetry in electron and bremsstrahlung irradiation facilities for food processing*
15563	E 1538-93	*Practice for use of the ethanol-chlorobenzene dosimetry system*
15564	E 1539-93	*Guide for use of radiation-sensitive indicators*
15565	E 1540-93	*Practice for use of a radiochromic liquid dosimetry system*
15566	E 1607-94	*Practice for use of the alanine-EPR dosimetry system*
15567	E 1608-94	*Practice for dosimetry in an X-ray (bremsstrahlung) facility for radiation processing*
15568	E 1631-96	*Practice for use of calorimetric dosimetry systems for electron beam dose measurements and dosimeter calibrations*
15569	E 1649-94	*Practice for dosimetry in an electron-beam facility for radiation processing at energies between 300 keV and 25 MeV*
15570	E 1650-94	*Practice for use of cellulose acetate dosimetry system*
15571	E 1702-95	*Practice for dosimetry in a gamma irradiation facility for radiation processing*
15572	E 1707-95	*Guide for estimating uncertainties in dosimetry for radiation processing*
15573	E 1818-96	*Practice for dosimetry in an electron-beam facility for radiation processing at energies between 80 keV and 300 keV*

Designation: E 1400 – 95a

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

This standard is issued under the fixed designation E 1400; 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 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]

E 1261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing[2]

E 1707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing[2]

2.2 *International Organization for Standardization Documents:*

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

3.1.3 *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.

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.

3.1.4 *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.

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

[1] This practice is under the jurisdiction of ASTM Committee E-10 on Nuclear Technology and Applications and is the direct responsibility of Subcommittee E10.01 on Dosimetry for Radiation Processing.

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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.

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.

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) 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,

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

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,

5.12.2.9 Any deviations from, additions to, or exclusions from the calibration method, and any other information relevant to a specific calibration, such as environmental conditions,

5.12.2.10 Measurements, examinations, and derived results, supported by tables, graphs, sketches, and photographs as appropriate, and any failures identified,

5.12.2.11 A statement of the estimated overall uncertainty of the calibration result (where relevant),

5.12.2.12 A signature and title, or an equivalent identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue,

5.12.2.13 Where relevant, a statement to the effect that the results relate only to the dosimeters calibrated, and

5.12.2.14 A statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory.

5.12.3 Where the certificate or report contains results of calibrations performed by sub-contractors, these results shall be clearly identified.

5.12.4 Particular care and attention shall be paid to the arrangement of the certificate or report, especially with regard to presentation of the calibration data and ease of assimilation by the reader. The format shall be carefully and specifically designed for each type of calibration carried out, but the headings shall be standardized as far as possible.

5.12.5 Material amendments to a calibration certificate or report after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Calibration Certificate (or Calibration Report), serial number . . . (or as otherwise identified)," or equivalent form of wording. Such amendments shall meet all the

relevant requirements of 5.12.

5.12.6 The laboratory shall notify clients immediately, orally and in writing, of any event such as the identification of defective measuring equipment that casts doubt on the validity of results given in any calibration certificate or report, or amendment to a report or certificate.

5.12.7 The laboratory shall ensure that, where clients require transmission of calibration results by telephone, telex, facsimile, or other electronic or electromagnetic means, staff will follow documented procedures that ensure the requirements of this section are met and that confidentiality is preserved.

5.13 *Sub-contracting of Calibration:*

5.13.1 Where a laboratory sub-contracts any part of the calibration, this work shall be placed with a laboratory complying with these requirements. The laboratory shall ensure and be able to demonstrate that its sub-contractor is competent to perform the activities in question and complies with the same criteria of competence as the laboratory in respect to the work being subcontracted. The laboratory shall advise the client in writing of its intention to sub-contract any portion of the calibration to another party.

5.13.2 The laboratory shall record and retain details of its investigation of the competence and compliance of its subcontractors and maintain a register of all sub-contracting.

5.14 *Outside Support Services and Supplies:*

5.14.1 Where the laboratory procures outside services and supplies other than those referred to in this section, in support of calibrations, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's calibrations.

5.14.2 Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials, and services comply with specified requirements. The laboratory should, wherever possible, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated, or otherwise verified as complying with any standard specifications relevant to the calibrations concerned.

5.14.3 The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for calibrations.

5.15 *Complaints:*

5.15.1 The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. A record shall be maintained of all complaints and of the actions taken by the laboratory.

5.15.2 Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this section or otherwise concerning the quality of the laboratory's calibrations, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with 5.4.3.

6. Specific Criteria for Ionizing Radiation

6.1 This section sets specific requirements to which a laboratory shall adhere if it is to be accredited for calibrations using ionizing radiation. This section amplifies and interprets the general requirements set forth in Section 5 (see 4.4 and 4.5).

6.2 This section is to be used in conjunction with Section 5 to assess ionizing radiation calibration laboratories for the purpose of accreditation by an appropriate accrediting organization (see Appendix).

6.3 This section may also be used as a guide by ionizing radiation calibration laboratories in the development and implementation of their quality systems.

6.4 *Organization and Management*—The laboratory shall inform the accrediting organization of changes in the organizational structure or management that may have adverse impact on the quality of calibrations performed.

6.5 *Quality System, Audit, and Review:*

6.5.1 The laboratory's proficiency shall be tested at least annually for those types of services covered by accreditation. If the test results indicate that corrective action is required, the laboratory shall take action to achieve the overall uncertainty stated in the appropriate section of this practice.

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

6.5.3 If necessary, the interval between proficiency tests may be increased. Under no circumstances shall more than 15 months pass between proficiency tests.

6.5.4 The quality manual and related quality documentation shall contain:

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

6.5.4.2 A statement of the laboratory's accuracy goals for the calibrations it performs. These accuracies shall be in terms of deviations from the national standard,

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

6.5.4.4 A fully documented generic (or representative specific) procedure for each type of calibration performed (for example, passive radiochromic dosimeters calibrated with gamma radiation). The procedure shall provide the appropriate operational steps to permit a knowledgeable person to reproduce a particular calibration technique with a precision consistent with the goals of the laboratory. Each calibration procedure shall give the following information where relevant;

(*1*) Concise but complete account of the procedure,

(*2*) Range and limitations of the procedure,

(*3*) Equipment and standards to be used,

(*4*) Environmental constraints to be met in addition to those in 6.7,

(*5*) Sequence of the procedure, drawing attention to special precautions,

(*6*) An example of a completed data sheet, and

(*7*) An example of a calibration report or certificate,

6.5.4.5 A tabulated assessment of the various components of uncertainty and their associated confidence levels, the method used in combining the components, and the calculated overall uncertainty associated with determination of the reference field for each generic calibration, and

6.5.4.6 The procedure or reference for auditing calibration data and approving reports.

6.5.5 Each page of the quality manual shall indicate its date of initiation or revision.

6.5.6 A copy of the latest revision of the accredited laboratory's quality manual shall be kept on file with the accrediting organization.

6.6 *Personnel:*

6.6.1 The technical manager (however named) shall understand the quality system and calibration procedures, and ensure that they are being followed.

6.6.2 The technical manager shall have a minimum of a bachelor's degree and should have at least three years of experience in radiological physics or a closely related scientific field.

6.6.3 The supervisor of the calibration laboratory shall have at least three years of experience in radiological physics or a closely related scientific field.

6.6.4 The accrediting organization may consider an alternative organizational structure utilizing existing expertise, provided a clear line of responsibility exists and the organization clearly provides for continuing control.

6.7 *Facilities and Environment:*

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

6.7.2 Environmental monitoring equipment shall be provided for recording temperature and relative humidity within the laboratory.

6.7.3 Although strict temperature control is not essential, it is desirable 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 20°C to 24°C.

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

6.7.5 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 standards temporarily held there, and to minimize the time required for an instrument to reach equilibrium when brought to the calibration laboratory from the storage area.

6.7.6 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 provided.

6.7.7 The laboratory shall be provided with an adequate grounding system. Where there is a possibility of interference arising from equipment connected to a single grounding system, separate grounding systems shall be provided and adequate precautions taken against any possible interconnection between systems.

6.7.8 The radiation room shall be of sufficient size and design such that scattered radiation at the positions where dosimeters or instruments are normally placed for calibration does not compromise the specified accuracy goals. If necessary, appropriate scatter corrections shall be applied. In uncollimated free-air calibration facilities, the radiation room should be used exclusively for calibrations to avoid variable scatter conditions. The contribution to absorbed dose by scattered radiation should be known.

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

6.8 *Equipment*—The laboratory shall have reference standards and transfer standards that cover the range of calibrations performed.

6.9 *Measurement Traceability and Calibration:*

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

6.9.2 The use of a working standard instead of a reference standard is acceptable for calibrations.

6.9.3 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.

6.10 *Calibration Methods*—All new or amended calibration procedures that could have significant impact on the accuracy of a calibration shall receive approval from the accrediting organization before being adopted for routine use.

6.11 *Handling of Dosimeters and Associated Equipment*—All handling, unpacking, and packing of dosimeters, instruments, and reference standards, shall be done by trained staff who are familiar with the equipment.

6.12 *Records:*

6.12.1 The laboratory's permanent records shall include:

6.12.1.1 The date, customer, description of the dosimeters calibrated, the batch number or serial number, details of the service provided, calibration report or certificate number, and invoice or other accounting number,

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

6.12.1.3 The results of all proficiency testing.

6.13 *Certificates and Reports:*

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

6.13.2 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.

6.13.3 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.

6.13.4 If the calibration laboratory discovers a mistake in a calibration report, the person or institution that received the report shall be immediately notified. The mistake 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 mistake and take action necessary to prevent

recurrences. Any such mistake in a calibration shall immediately be reported to the accrediting organization.

6.14 *Sub-contracting of Calibration*—There are no additional requirements beyond the general requirements set forth in Section 5.

6.15 *Outside Support Services and Supplies*—There are no additional requirements beyond the general requirements set forth in Section 5.

6.16 *Complaints*—There are no additional requirements beyond the general requirements set forth in Section 5.

7. Specific Criteria for Calibrations Using Photons and Electrons

7.1 This section sets specific requirements to which a laboratory shall adhere if it is to be accredited for calibrations using gamma rays, electron beams, or X-ray (bremsstrahlung) beams. This section amplifies and interprets the general requirements set forth in Section 5, and expands upon the specific requirements contained in Section 6 (see 4.4 and 4.5).

7.2 The criteria contained in this section apply to calibration of dosimeters at absorbed-dose levels appropriate for radiation processing.

7.3 *Organization and Management*—There are no additional requirements beyond those set forth in Sections 5 and 6.

7.4 *Quality System, Audit, and Review*—The absorbed-dose rate of the calibration facility of the laboratory shall be within ±5 % of the value defined by comparison with the appropriate national standard. This level of agreement with the national standard shall be demonstrated through periodic proficiency tests of the laboratory by a national or international standards laboratory.

7.5 *Personnel*—There are no additional requirements beyond those set forth in Sections 5 and 6.

7.6 *Facilities and Environment:*

7.6.1 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.

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

7.6.3 Any area used for storage of dosimeters shall have its temperature and relative humidity controlled as required for the specific dosimetry system employed.

7.7 *Equipment:*

7.7.1 *Radiation Source(s):*

7.7.1.1 The laboratory shall have access to a source of gamma radiation, either ^{60}Co or ^{137}Cs, with a fluence rate sufficient to deliver an absorbed dose within the range of 10 to 10^5 Gy (10^3 to 10^7 rad) within a reasonable time.

7.7.1.2 In addition, the laboratory may have an electron beam or x-ray beam (bremsstrahlung) radiation source, or both, that can provide dose rates appropriate to radiation processing conditions.

7.7.2 *Characterization of the Radiation Field:*

7.7.2.1 Determine the absorbed-dose rate in each location in which dosimeters are irradiated using reference standard dosimetry systems. 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 one year thereafter, demonstrate that the dose rates are traceable to appropriate national standards by direct measurement intercomparisons.

7.7.2.2 Ensure that the absorbed-dose rate over the volume in which dosimeters are irradiated does not vary more than ±1 % from its average value.

7.7.2.3 If the dosimeters are irradiated in open air (for example, with a beam-port or panoramic irradiator), ensure that the room is of sufficient size and design such that scattered radiation at each position where dosimeters are placed for irradiation does not compromise the specified overall accuracy goals.

7.7.2.4 Monitor and control the temperature of the irradiation volume during irradiation to the degree 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.

7.7.2.5 Maintain information related to the photon or electron energy spectrum at each dosimeter irradiation location.

7.7.2.6 Minimize low-energy components of the photon source spectrum through the use of a filter box when dosimeters used for radiation hardness testing are irradiated. (For additional information see Practice E 1249 and Test Method E 1250).

7.8 *Measurement Traceability and Calibration*—There are no additional requirements beyond those set forth in Sections 5 and 6.

7.9 *Calibration Methods*—There are no additional requirements beyond those set forth in Sections 5 and 6.

7.10 *Handling of Calibration Items*—There are no additional requirements beyond those set forth in Sections 5 and 6.

7.11 *Records*—There are no additional requirements beyond those set forth in Sections 5 and 6.

7.12 *Certificates and Reports*—There are no additional requirements beyond those set forth in Sections 5 and 6.

7.13 *Sub-contracting of Calibration*—There are no additional requirements beyond those set forth in Section 5.

7.14 *Outside Support Services and Supplies*—There are no additional requirements beyond those set forth in Section 5.

7.15 *Complaints*—There are no additional requirements beyond those set forth in Section 5.

8. Measurement Uncertainty

8.1 To be meaningful, a measurement shall be accompanied by an estimate of uncertainty. Components of uncertainty shall be identified as either Type A or Type B according to their method of evaluation. Type A evaluation of standard uncertainty is based on the statistical analysis of a series of observations, and Type B is based on all other methods of analysis. Additional information is given in Guide E 1707 and Refs (6) and (7).

NOTE—This practice uses the methodology adopted in 1993 by the International Organization for Standardization (ISO) for estimating uncertainty. This is different from the way that uncertainty has been traditionally expressed in terms of "precision" and "bias," where