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An American National Standard

Standard Guide for General Criteria Used for Evaluating Laboratory Competence

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ε[1] NOTE—The scope was corrected editorially in June 1995.

1. Scope

1.1 This standard sets forth general criteria (harmonized with ISO/IEC Guide 25-1990) for evaluating the competence of calibration laboratories or testing laboratories.[1]

2. Referenced Documents

2.1 *ASTM Standards:*

E 994 Guide for Laboratory Accreditation Systems[2]

E 1187 Terminology Relating to Laboratory Accreditation[2]

2.2 *ISO Standards:*[3]

8402 Quality-Vocabulary

9000 Quality Management and Quality Assurance Standards, Guidelines for Selection and Use

9001 Quality Systems—Model for Quality Assurance In Design/Development, Production, Installation and Servicing

9002 Quality Systems—Model for Quality Assurance In Production and Installation

9003 Quality Systems—Model for Quality Assurance In Final Inspection and Test

9004 Quality Management and Quality System Elements—Guidelines

Guide 2—General Terms and their Definitions Concerning Standardization and Related Activities

Guide 25—General Requirements for the Competence of Calibration and Testing Laboratories

Guide 30 Terms and Definitions Used in Connection with Reference Materials

3. Terminology

3.1 *Definitions*—The following definitions of terms are applicable to this standard. When the terms are taken from other documents such as ISO/IEC Guide 2, Guide 30, 8402 or the *International vocabulary of basic and general terms in metrology (VIM)* appropriate reference is made.

3.1.1 *laboratory*—body that calibrates and/or tests.

3.1.1.1 *Discussion*—In cases where a laboratory forms part of an organization that carries out other activities besides calibration and testing, the term" laboratory" refers only to those parts of that organization that are involved in the calibration and testing process.

3.1.1.2 As used herein, the term "laboratory" refers to a body that carries out calibration or testing—at or from a permanent location,—at or from a temporary facility, or—in or from a mobile facility.

3.1.2 *testing laboratory*—laboratory that performs tests. [ISO/IEC Guide 2—12.4]

3.1.3 *calibration laboratory*—laboratory that performs calibration.

3.1.4 *calibration*—the set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a measurand.

3.1.4.1 *Discussion*—The results of a calibration permits the estimation of errors of indication of the measuring instrument, measuring system or material measure, or the assignment of values to marks on arbitrary scales.

3.1.4.2 A calibration may also determine other metrological properties.

3.1.4.3 The result of a calibration may be recorded in a document, sometimes called a calibration certificate or calibration report.

3.1.4.4 The result of a calibration is sometimes expressed as a calibration factor, or as a series of calibration factors in the form of a calibration curve. [VIM—6.13]

[1] This practice is under the jurisdiction of ASTM Committee E-36 on Laboratory and Inspection Agency Evaluation and Accreditation and is the direct responsibility of Subcommittee E36.10 on Generic Criteria.

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

[3] Available from ISO, 1 Rue de Varembe, Case Postale 56, Crt 1221, Geneva 20, Switzerland.

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3.1.5 *test*—a technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure.

3.1.5.1 *Discussion*—The result of a test is normally recorded in a document sometimes called a test report or a test certificate. [ISO/IEC Guide 2—12.1, amended]

3.1.6 *calibration method*—defined technical procedure for performing a calibration.

3.1.7 *test method*—defined technical procedure for performing a test.

3.1.8 *verification*—confirmation by examination and provision of evidence that specified requirements have been met.

3.1.8.1 *Discussion*—In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment.

3.1.8.2 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 measuring instrument's individual record.

3.1.9 *quality system*—the organizational structure, responsibilities, procedures, processes and resources for implementing quality management. [ISO 8402—3.8 without the notes]

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

3.1.10.1 *Discussion*—The quality manual may call up other documentation relating to the laboratory's quality arrangements.

3.1.11 *reference standard*—A standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived. [VIM—6.08]

3.1.12 *reference material*—A material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement, or for assigning values to materials. [ISO Guide 30—2.1]

4. Significance and Use

4.1 Laboratories meeting the requirements of this standard comply, for calibration and testing activities, with 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 or test results.

4.2 Since laboratories provide services in many diverse technical areas, the generic statements contained in this document will need to be interpreted for the specific technical areas or type of testing which will require evaluation. Each individual test, class of tests, or technical field will generally have unique requirements that must be satisfied in order to properly conduct the test(s).

4.2.1 The interpretations and specific requirements should be developed by persons technically knowledgeable in the specific technical field. The requirements developed should provide the specificity in each subject area describing in detail what a laboratory in that specific technical field must have to perform, have on hand, be aware of, or is otherwise essential to conduct testing on a specific product, class of products or material.

4.3 This guide should be particularly useful as a guide to ASTM technical committees which are developing standard test methods, and need to include specific information that can be used to evaluate a laboratory's ability to conduct the test.

4.4 This guide should also be a useful guide to accreditation, or other types of evaluation bodies, in developing specific technical evaluation requirements.

4.5 Using this guide should promote the development of documents that are more uniform in content and style, and therefore should be much more universally useful to bodies who perform evaluations of many different types of laboratories in different technical fields.

4.6 An accrediting body may also impose other nontechnical requirements such as payment of fees or submittal of quality documentation for review.

5. Organization and Management

5.1 The laboratory shall be legally identifiable. It shall be organized and shall operate in such a way that its permanent, temporary and mobile facilities meet the requirements of this standard.

5.2 The laboratory shall:

5.2.1 have managerial staff with the authority and resources needed to discharge their duties;

5.2.2 have arrangements to ensure that its personnel are free from any commercial, financial and other pressures which might adversely affect the quality of their work;

5.2.3 be organized in such a way that confidence in its independence of judgment and integrity is maintained at all times;

5.2.4 specify and document the responsibility, authority, and interrelation of all personnel who manage, perform or verify work affecting the quality of calibrations and tests;

5.2.5 provide supervision by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test and the assessment of the results. The ratio of supervisory to non-supervisory personnel shall be such as to ensure adequate supervision;

5.2.6 have a technical manager (however named) who has overall responsibility for the technical operations;

5.2.7 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 taken on 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;

5.2.8 nominate deputies in case of absence of the technical or quality manager;

5.2.9 where relevant, have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights;

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5.2.10 where appropriate, participate in interlaboratory comparisons and proficiency testing programs.

6. Quality System, Audit and Review

6.1 The laboratory shall establish and maintain a quality system appropriate to the type, range and volume of calibration and testing 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 or testing 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.

6.2 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 standard. The quality manual and related quality documentation shall also contain:

6.2.1 a quality policy statement, including objectives and commitments, by top management;

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

6.2.3 the relations between management, technical operations, support services and the quality system;

6.2.4 procedures for control and maintenance of documentation;

6.2.5 job descriptions of key staff and reference to the job descriptions of other staff;

6.2.6 identification of the laboratory's approved signatories (where this concept is appropriate);

6.2.7 the laboratory's procedures for achieving traceability of measurements;

6.2.8 the laboratory's scope of calibrations and/or tests;

6.2.9 arrangements for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;

6.2.10 reference to the calibration, verification and/or test procedures used;

6.2.11 procedures for handling calibrations and test items;

6.2.12 reference to the major equipment and reference measurement standards used;

6.2.13 reference to procedures for calibration, verification and maintenance of equipment;

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

6.2.15 procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur;

6.2.16 the laboratory management arrangements for exceptionally permitting departures from documented policies and procedures or from standard specifications;

6.2.17 procedures for dealing with complaints;

6.2.18 procedures for protecting confidentiality and proprietary rights;

6.2.19 procedures for audit and review.

6.3 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 calibrations or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.

6.4 The quality system adopted to satisfy the requirements of this standard 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.

6.5 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 timescale.

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

6.6.1 internal quality control schemes using whenever possible statistical techniques;

6.6.2 participation in proficiency testing or other interlaboratory comparisons;

6.6.3 regular use of certified reference materials and/or in-house quality control using secondary reference materials;

6.6.4 replicate testings using the same or different methods;

6.6.5 re-testing of retained items;

6.6.6 correlation of results for different characteristics of an item.

7. Personnel

7.1 The laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions.

7.2 The laboratory shall ensure that the training of its personnel is kept up-to-date.

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

8. Accommodation and Environment

8.1 Laboratory accommodation, calibration and test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of calibrations or tests.

8.2 The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.

8.3 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

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biological sterility, dust, electromagnetic interference, humidity, mains voltage, temperature, and sound and vibration levels, as appropriate to the calibrations or tests concerned.

8.4 There shall be effective separation between neighboring areas when the activities therein are incompatible.

8.5 Access to and use of all areas affecting the quality of these activities shall be defined and controlled.

8.6 Adequate measures shall be taken to ensure good housekeeping in the laboratory.

NOTE 1—It is the laboratory's responsibility to comply with the relevant health and safety requirements. This aspect, however, is outside the scope of this standard.

9. Equipment and Reference Materials

9.1 The laboratory shall be furnished all items of equipment (including reference materials) required for the correct performance of calibrations and tests. In those cases where the laboratory needs to use equipment outside its permanent control it shall ensure that the relevant requirements of this standard are met.

9.2 All equipment shall be properly maintained. Maintenance procedures shall be documented. Any item of the equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise 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 or tests.

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

9.4 Records shall be maintained of each major item of equipment and all reference materials significant to the calibrations or tests performed. The records shall include:

9.4.1 the name of the item of equipment;

9.4.2 the manufacturer's name, type identification, and serial number or other unique identification;

9.4.3 date received and date placed in service;

9.4.4 current location, where appropriate;

9.4.5 condition when received (for example, new, used, reconditioned);

9.4.6 copy of the manufacturer's instructions, where available;

9.4.7 dates and results of calibrations and/or verifications and date of the next calibration and/or verification;

9.4.8 details of maintenance carried out to date and planned for the future;

9.4.9 history of any damage, malfunction, modification or repair.

10. Measurement Traceability and Calibration

10.1 All measuring and testing equipment having an effect on the accuracy or validity of calibrations or tests shall be calibrated and/or verified before being put into service. The laboratory shall have an established program for the calibration and verification of its measuring and test equipment.

10.2 The overall program of calibration and/or verification 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 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 and/or a statement of compliance with an identified metrological specification.

10.3 Where traceability to national standards of measurement is 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.

10.4 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 their performance as reference standards has not been invalidated.

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

10.6 Where relevant, reference standards and measuring and testing equipment shall be subjected to in-service checks between calibrations and verifications.

10.7 Reference materials shall, where possible, be traceable to national or international standards of measurement, or to national or international standard reference materials.

11. Calibration and Test Methods

11.1 The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of items and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests. 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.

11.2 The laboratory shall use appropriate methods and procedures for all calibrations and tests and related activities within its responsibility (including sampling, handling, transport and storage, preparation of items, estimation of uncertainty of measurement and analysis of calibration and/or test data). They shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations or tests concerned.

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

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

11.5 Where sampling is carried out as part of the test method, the laboratory shall use documented procedures and appropriate statistical techniques to select samples.

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