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Standard Guide for Evaluation and Assessment of Analytical Chemistry Laboratories[1]

This standard is issued under the fixed designation E 1691; 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 guide sets the minimum requirements which an analytical chemistry laboratory should meet to be recognized as competent to carry out specific analytical procedures.

1.2 Additional requirements and information which have to be disclosed for assessing competence or for determining compliance with other criteria may be specified by the organization or authority granting the accreditation, depending upon the specific character of the task of the laboratory.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

E 50 Practices for Apparatus, Reagents, and Safety Considerations for Chemical Analysis of Metals, Ores, and Related Materials[2]

E 416 Practice for Planning and Safe Operation of a Spectrochemical Laboratory[2]

E 548 Guide for Generic Criteria for Evaluating Laboratory Competence[3]

E 876 Practice for Use of Statistics in the Evaluation of Spectrometric Data[2]

E 882 Guide for Accountability and Quality Control in the Chemical Analysis Laboratory[2]

E 994 Guide for Calibration and Testing Laboratory Accreditation Systems General Requirements for Operation and Recognition[3]

E 1187 Terminology Relating to Conformaity Assessment[3]

E 1329 Practice for Verification and the Use of Control Charts in Spectrochemical Analysis[2]

E 1581 Practice for Using Pre-Control in the Instrumental Analysis Laboratory[4]

2.2 *Other Documents:*

ANSI/ASQCQ90 Quality Management and Quality Assurance Standards—Guidelines for Selection and Use[5]

ISO/IECGuide 25 General Requirements for the Competence of Calibration and Testing Laboratories[5]

3. Terminology

3.1 *Definitions*—For definitions of terms used in this guide, refer to Terminology E 1187.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *audit*—an examination of a laboratory's operation and quality control to ascertain that it is able to obtain valid analyses.

3.2.2 *authority*—an organization that evaluates the performance of a laboratory; the authority may be a company that maintains the laboratory for its own analytical requirements.

3.2.3 *client*—an organization that requires a laboratory's service.

3.2.4 *protocol*—a set of procedures which must be followed to obtain acceptable analytical results.

3.2.5 *traceability*—the property of a result of a measurement where it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.

3.2.6 *valid analysis*—analytical results obtained when a procedure follows proper protocol and statistical control is verified.

4. Significance and Use

4.1 This guide provides a mechanism for promoting confidence in analytical chemistry laboratories by demonstrating that they operate in accordance with the guide's requirements.

4.2 This guide is for use by analytical chemistry laboratories in the development and implementation of their quality systems. It may also be used by accreditation bodies, certification bodies, and others concerned with the competence of laboratories.

4.3 It is intended that analytical chemistry laboratories meeting the requirements of this guide will be in conformity with the relevant requirements of the ISO 9000 series of

[1] This guide is under the jurisdiction of ASTM Committee E01 on Analytical Chemistry for Metals, Ores, and Related Materials and is the direct responsibility of Subcommittee E01.22 on Statistics and Quality Control .

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[2] *Annual Book of ASTM Standards*, Vol 03.05.

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

[4] Discontinued 1998; see *1997 Annual Book of ASTM Standards*, Vol 03.06.

[5] Available from American National Standards Institute, 11 W. 42nd Street, 13th Floor, New York, NY 10036.

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standards, including those of the model described in ISO 9002 when they are acting as suppliers producing test results. The ISO 9000 and ISO 9002 standards are identical to the standards appearing in the ANSI/ASQC Q90 Series.

4.4 This guide follows criteria of ISO/IEC Guide 25-1990, and Guides E 548 and E 994. It is intended as a generic guide for analytical chemistry laboratories. Specific analytical techniques or instruments, or both, may require additional specific criteria.

5. Organization and Management

5.1 The laboratory shall be legally identifiable, and organized and operated in such a way that its facilities meet the requirements of this guide, as follows:

5.1.1 Have managerial staff with the proper authority and resources to discharge their duties;

5.1.2 Permit no pressure on personnel to obtain "favorable" test results;

5.1.3 Specify and document the responsibility, authority, and interrelation of all personnel who manage, perform, or verify work affecting the quality of analysis;

5.1.4 Provide supervision by persons familiar with the analytical methods, the objective of the methods, and the assessment of the results. The ratio of supervisory to nonsupervisory personnel shall ensure adequate supervision;

5.1.5 Have a technical manager (however named) who has overall responsibility for the technical operations;

5.1.6 Have a quality manager (however named) who has responsibility for the system and its implementation. The quality manager shall have access to the technical manager and to the highest level of management at which decisions are taken on laboratory policy and resources;

5.1.7 Nominate deputies in case of absence of the technical or quality manager;

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

5.1.9 Participate in interlaboratory comparisons and proficiency testing programs. See 6.2.14.

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 analytical services it provides. The elements of this system shall be documented. The quality documentation shall be available to all laboratory personnel.

6.1.1 The laboratory shall define and document its policies and objectives for and its commitment to proper laboratory practice and analytical services.

6.1.2 The laboratory management shall ensure that their policies and objectives are documented in a quality manual and communicated to, understood by, and implemented by all laboratory personnel concerned.

6.1.3 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, established operational procedures, and shall also contain:

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

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 maintenace 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 analytical services;

6.2.9 Arrangements for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources;

6.2.10 Reference to the calibration, verification, or test procedures, or combination thereof, used;

6.2.11 Procedures for handling samples;

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 Procedures may be used by laboratory management to permit departures from documented policies and procedures or from standard specifications under exceptional circumstances;

6.2.17 Procedures for dealing with complaints;

6.2.18 Procedures for protecting confidentiality and proprietary rights; and

6.2.19 Procedures for audit and review.

6.3 The laboratory shall arrange for audits of its activities annually or at some other appropriate interval 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 analytical 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 guide 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 time schedule.

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