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

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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

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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.

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.

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 statistical techniques, such as those presented in Practice E 876, Guide E 882, and Practice E 1329, whenever possible;

6.6.2 Participation in proficiency testing or other interlaboratory comparisons;

6.6.3 Regular use of certified reference materials or secondary reference materials, or both;

6.6.4 Replicate testings using the same or different methods; and

6.6.5 Retesting of retained samples;

7. Personnel

7.1 The laboratory shall have sufficient personnel who have 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.

NOTE 1—Confidential records on an employee are not part of the technical qualifications that are to be maintained by the laboratory for the purpose of the evaluation and assessment of a laboratory.

8. Facilities and Environment

8.1 Laboratory facilities, including work areas, energy sources, lighting, heating, and ventilation shall be such as to facilitate proper performance of the analytical procedures. See Practices E 50 and E 416.

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. This may include dust, electromagnetic interference, humidity, line voltage, temperature, and sound and vibration levels.

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 2—It is the laboratory's responsibility to comply with the relevant health and safety requirements. Refer to Practices E 50 and E 416.

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 the analytical procedures. In those cases where the laboratory needs to use equipment outside its permanent control, the laboratory shall ensure that the relevant requirements of this guide are met.

9.2 All equipment shall be properly maintained. Maintenance procedures shall be documented. Any item of the equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective, shall be taken out of service. Withdrawn equipment shall be 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 and determine if defective equipment affected previous analyses.

9.3 Records shall be maintained of each major item of equipment and all reference materials significant to the analyses performed. The records shall include the following:

9.3.1 The name of the item of equipment;

9.3.2 The manufacturer's name, type identification, serial number, or other unique identification;

9.3.3 Date received and placed in service;

9.3.4 Current location, where appropriate;

9.3.5 Condition when received (for example, new, used, reconditioned);

9.3.6 Copy of the manufacturer's instruction, where available;

9.3.7 Dates and results of calibrations or verifications, or both, and date of the next calibration or verification, or both;

9.3.8 Details of maintenance carried out to date and planned for the future; and

9.3.9 History of any damage, malfunction, modification or repair.

10. Measurement Traceability

10.1 All measuring and testing equipment that affect the accuracy or validity of analyses 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 analytical instrumentation.

10.2 The overall program of calibration or verification, or both, and validation of equipment shall be designed and operated in a manner that will ensure that measurements made by the laboratory are traceable to certified reference materials, if they are available.

10.3 Where traceability to certified reference materials 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).

11. Analytical Methods

11.1 The laboratory shall have documented instruction on the use and operation of all relevant analytical instrumentation and related equipment, on the handling, and preparation of analytical samples. 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 analyses and related activities within its responsibility, including sampling, handling, transport and

storage, preparation of samples, estimation of uncertainty of measurement, and analysis of data.

11.3 Where methods are not specified, the laboratory shall wherever possible, select methods that have been published in international or national standards, published by reputable technical organizations, or appear 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 representative samples.

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

11.7 Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage, or retrieval of analytical data, the laboratory shall ensure the following:

11.7.1 All requirements of this guide are complied with.

11.7.2 Computer software is documented and adequate for use.

NOTE 3—For documenting commercial software programs, record name and version. For specially written programs, keep at least two copies as backup. Include a manual on how to use the special program, and when appropriate, hold a printout of the program. Before accepting any program, test it with observed data of known reference material.

11.7.3 *Software Quality Control*—Up-to-date records of all changes in the software program are maintained to ensure that if a program has to be reentered, the latest calibration parameters and reference material data will be used.

NOTE 4—Software records may be kept on diskettes or in other independent memories. Three copies are recommended, with one copy held by either the technical or quality manager.

11.7.4 Procedures are established and implemented for protecting the integrity of data, including but not limited to, integrity of data entry or capture, data storage, data transmission, and data processing.

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

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

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

12. Handling of Samples

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

12.2 Upon receipt, the condition of the sample, including any abnormalities or departures from standard condition as prescribed in the relevant analytical method, shall be recorded. Where there is any doubt as to the sample's suitability for analysis, where the sample does not confirm to the description provided, or where the analysis required is not fully specified, the laboratory shall consult the client for further instruction before proceeding. The laboratory shall establish whether the sample has received all necessary preparation or whether the client requires preparation to be undertaken or arranged by the laboratory.

12.3 The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or unnecessary damage to the samples during storage, handling, preparation, and analysis, or test. Any relevant instructions provided with the sample shall be followed. Where samples have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored, and recorded where necessary. Where a sample or portion of a sample is to be held secure (for example, for reasons of record, safety or value, or to enable check analyses to be performed later) the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured samples.

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

13. Records

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

13.2 All records and reports, including those pertaining to analytical instrumentation shall be safely stored, held secure, and in confidence to the client.

14. Analytical Reports

14.1 The results of each analysis, or series of analyses carried out by the laboratory shall be reported accurately, clearly, unambiguously, and objectively, in accordance with any instructions in the analytical methods. The results should normally be reported in an analytical report and should include all the information necessary for the interpretation of the analytical results and all information required by the method used.

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

14.2.1 A title, for example, "Analytical Report";

14.2.2 Name and address of laboratory and location where the analysis was carried out, if different from the address of the laboratory;

14.2.3 Unique identification of the analytical report (such as serial number) and of each page, and the total number of pages;

14.2.4 Name and address of client, where appropriate;

14.2.5 Description and unambiguous identification of the sample analyzed;

14.2.6 Characterization and condition of the sample;

14.2.7 Date of receipt of the sample and date(s) of performance of analysis, where appropriate;

14.2.8 Identification of the analytical method used or unambiguous description of any non-standard method used;

14.2.9 Reference to sampling procedure, where relevant;

14.2.10 Any deviations from, additions to, or exclusions from the analytical method, and any other information relevant to a specific analysis, such as environmental condition, where appropriate;

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

14.2.12 A statement of the estimated uncertainty of the analytical result, where relevant;

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

14.2.14 Where relevant, a statement to the effect that the results relate only to the sample(s) analyzed;

14.2.15 A statement that the analytical report shall not be reproduced except in full, without the written approval of the laboratory.

14.3 Where the certificate or report contains results of analyses performed by subcontractors, these results shall be clearly identified.

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

14.5 Material amendments to an analytical report after issue shall be made only in the form of a further document or data transfer including the statement "Supplement to Analytical Report", serial number (or as otherwise identified), or equivalent form of wording. Such amendments shall meet all the relevant requirements of 14.2.

14.6 The laboratory shall notify clients promptly in writing of any event, such as the identification of a defective analytical instrument that casts doubt on the validity of results given in any analytical report or amendment to a report or certificate.

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

15. Subcontracting of Analysis

15.1 Where a laboratory subcontracts any part of the analytical work, this work shall be placed with a laboratory complying with these requirements. The laboratory shall ensure and be able to demonstrate that its subcontractor 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 subcontract any portion of the testing to another party.

15.2 The laboratory shall record and retain details of its investigation of the competence and compliance of its subcontractors and maintain a register of all subcontracting.

16. Outside Support and Supplies

16.1 In support of analytical work, where the laboratory procures outside services and supplies, other than those referred to in this guide, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's analytical work.

16.2 Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall 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 analysis concerned.

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

17. Complaints

17.1 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.

17.2 Where a complaint or any other circumstance raises doubt about the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this guide, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with 6.3.

18. Keywords

18.1 accreditation; ISO Guide 25; laboratory assessment