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Standard Guide for Surveillance of Accredited Laboratories[1]

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1. Scope

1.1 This guide covers a number of procedures that may be used by a laboratory accrediting body, either singly or as complementary activities, to provide ensurance that accredited laboratories continue to satisfy criteria and conditions for accreditation required by the accrediting body.

1.2 *This standard does not purport to address all of the safety problems, 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 548 Guide for General Criteria Used for Evaluating Laboratory Competence[2]

E 994 Guide for Calibration and Testing Laboratory Accreditation Systems General Requirements for Operation and Recognition[2]

E 1187 Terminology Relating to Conformity Assessment[2]

E 1224 Guide for Categorizing Fields of Capability for Laboratory Accreditation Purposes[2]

E 1301 Guide for the Proficiency Testing by Interlaboratory Comparisons[2]

E 1323 Guide for Evaluating Laboratory Measurement Practices and the Statistical Analysis of the Resulting Data[2]

3. Terminology

3.1 *Definitions*—The terms and definitions used in this guide are based on those in Terminology E 1187.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *assessment, n—of a laboratory*, the activity of evaluating a laboratory's compliance with accreditation criteria.

3.2.2 *surveillance, n— of a laboratory*, a set of activities (for example, on-site assessment, proficiency testing, questionnaire, quality audit) performed or reviewed by an accrediting body to ensure that accredited laboratories demonstrate ongoing compliance with accreditation requirements.

4. Significance and Use

4.1 This guide is intended to be used by laboratory accrediting bodies to apply a variety of surveillance procedures that are appropriate in the maintenance of accreditation. It supplements and expands on the information related to surveillance provided in Guide E 994.

4.2 None of the surveillance procedures used alone provide ensurance on all elements of laboratory competence, but taken together, they can provide confidence for the accrediting body as to the continuing compliance of a laboratory with accreditation criteria.

4.3 Surveillance procedures establish documentary evidence as to the continuing competence of an accredited laboratory.

4.4 Confidentiality shall be maintained by the accrediting body, its staff, and its contractors for all confidential and proprietary laboratory information.

5. Surveillance Elements

5.1 *Scope of Accreditation*—A laboratory may be accredited for less than the full range of work it undertakes (see Guide E 1224). Accordingly, surveillance procedures usually address only laboratory work performed within the formally defined scope of accreditation, unless other activities of the laboratory can affect the work covered by the accreditation or are considered likely to bring the accrediting body into disrepute.

5.2 *Criteria*—An accrediting body shall ensure that any changes to its accreditation criteria (see Guide E 548) are understood and implemented by accredited laboratories.

6. Surveillance Procedures

6.1 *Information Updating*:

6.1.1 An accredited laboratory should provide information to the accrediting body on matters affecting its accreditation.

6.1.2 Questionnaires may be used to solicit updated information between routine assessments and usually just prior to an assessment. Significant changes in personnel, facilities, equipment, or management may precipitate an assessment, more frequent proficiency tests, or other surveillance activity by the accrediting body.

6.2 *Routine Assessment*:

6.2.1 Regularly scheduled routine on-site assessments are one of the means of surveillance of accredited laboratories.

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

6.2.2 Such visits to each laboratory should normally follow the procedures adopted for initial assessments, but may emphasize particular attention to new testing techniques or methods, changes in the scope of accreditation, changes in personnel, adherence to an agreed quality system, performance in proficiency testing programs, previous observations and analysis of complaints received concerning the laboratory.

6.2.3 Frequency of routine assessments may vary depending on factors such as the totality of other surveillance procedures used by the accrediting body, demonstrated longterm stability and competence of the laboratory, adequacy of the laboratory's quality system, and documented program/procedures of the accrediting body.

6.3 *Supplemental Assessments*:

6.3.1 In addition to routine assessments, use supplemental assessments as needed to ensure a laboratory's continued compliance with accreditation criteria.

6.3.2 Supplemental assessments may be used to enable a laboratory to extend its scope of accreditation, to address some significant change to the original conditions under which accreditation was granted or renewed, to investigate unsatisfactory performance in proficiency testing, or to consider a complaint against the laboratory.

6.3.3 Such assessments may consider the total accreditation or may focus on a specific area of work.

6.3.4 A supplemental assessment would normally be made at a time mutually agreeable to the laboratory and the accrediting body.

6.4 *Proficiency Testing Programs*:

6.4.1 Accrediting bodies should have well-defined policies on participation in proficiency testing programs, their frequency, reporting outcomes of programs and action to be taken depending on that outcome, and on recognition of programs managed by bodies other than the accrediting body (see Guide E 1301 on proficiency testing programs).

6.4.2 Where proficiency testing is feasible, it is usual to require participation by laboratories at regular intervals for at least a representative selection of the tests for which each laboratory is accredited.

6.4.3 In some instances, the frequency or intensity of proficiency testing may be changed by an individual laboratory based upon past performance.

6.5 *Other Quality Audits*:

6.5.1 An accrediting body should consider the potential usefulness of information provided from quality audits performed by other parties or internal quality audits performed by the laboratory itself. Documented results from such audits describing identified problems and subsequent corrective/preventative action taken by the laboratory, demonstrate one key aspect of a functioning quality system (see Guide E 1323). Disclosure of quality audits performed by other parties and submittal of internal quality audits should not be a requirement. However, the laboratory should expect to show assessors of an accrediting body during an on-site assessment all evidence (for example, internal audit reports) demonstrating compliance with relevant accreditation criteria.

6.5.2 Where an accredited laboratory is audited by other parties or has a well-developed internal audit procedure involving appropriately trained staff, the accrediting body should consider using the results of such audits to reduce or increase the frequency of its own surveillance activities as appropriate.

6.5.3 The decision of a laboratory not to submit results of internal audits to the accrediting body should not be considered negatively, but treated as a decision to protect confidential information.

6.6 *Electronic Assessment*:

6.6.1 Some computer-based laboratory information management systems (LIMS) make it possible for accrediting bodies to monitor the performance of a laboratory's quality system by telephone.

6.6.2 Electronic "read-only" access to a LIMS system may allow an accrediting body to review a laboratory's implementation of required quality-control procedures and the resulting data (see Guide E 1323) without the need for an on-site visit. Information from electronic assessment may allow an accrediting body to reduce the frequency of more expensive surveillance procedures such as on-site assessment and proficiency testing.

6.6.3 Electronic assessment should be considered only an option and not a requirement by an accrediting body. Before implementation of electronic assessment procedures, an accrediting body should obtain written permission from the laboratory.

7. Outcome of Surveillance

7.1 Surveillance procedures may reveal problems such as: nonconformance to criteria by laboratories, information on previously imposed conditions and agreements; unsatisfactory performance by laboratories in proficiency testing programs; failures in communication between laboratories and the accrediting body; and variations in the effectiveness of previous assessments.

7.2 Surveillance procedures may reveal that a laboratory is in compliance with all accreditation criteria.

7.3 The information obtained from surveillance procedures should be used by the accrediting body to determine continued accreditation of its accredited laboratories.

8. Frequency of Surveillance

8.1 In order to provide confidence to the users of the services of accredited laboratories, some form of surveillance should be performed as warranted but some form should occur at least yearly.

8.2 This surveillance should include one or more of the following:

8.2.1 On-site assessment;

8.2.2 Review of proficiency testing results;

8.2.3 Review of a completed questionnaire submitted by the laboratory; or

8.2.4 Quality audit information.

9. Report

9.1 An accrediting body should provide an accredited laboratory with an appropriate report of each surveillance conducted on that laboratory.

10. Keywords

10.1 accreditation; accrediting body; assessment; criteria; laboratory; surveillance; testing