



Standard Guide for Surveillance of Accredited Laboratories¹

This standard is issued under the fixed designation E 1580; 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 covers a number of procedures that may be used by a laboratory accrediting body, either singly or as complementary activities, to provide assurance 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 Competence²

E 994 Guide for Calibration and Testing Laboratory Accreditation Systems General Requirements for Operation and Recognition²

E 1187 Terminology Relating to Conformity Assessment²

E 1224 Guide for Categorizing Fields of Capability for Laboratory Accreditation Purposes²

E 1301 Guide for the Proficiency Testing by Interlaboratory Comparisons²

E 1323 Guide for Evaluating Laboratory Measurement Practices and the Statistical Analysis of the Resulting Data²

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 assurance 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.

¹ This guide is under the jurisdiction of ASTM Committee E36 on Laboratory and Inspection Agency Evaluation and Accreditation and is the direct responsibility of Subcommittee E36.50 on Directories of Accredited Laboratories and Scopes of Accreditation.

Current edition approved Nov. 15, 1993. Published April 1994.

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