



Standard Guide for General Requirements for Bodies Operating Product Certification Systems¹

This standard is issued under the fixed designation E 1906; 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.

INTRODUCTION

Certification of a product, a term used to include a process or service, is a means of providing assurance that it complies with specified standards and other normative documents. Some product certification systems may include initial testing of a product and assessment of its suppliers' quality systems, followed by surveillance that takes into account the factory quality system and the testing of samples from the factory and the open market. Other systems rely on initial testing and surveillance testing while still others comprise type testing only.

This guide specifies requirements, the observance of which is intended to ensure that certification bodies operate third-party certification systems in a consistent and reliable manner, thereby facilitating their acceptance on a national and international basis and so furthering international trade.

The requirements contained in this guide are written, above all, to be considered as general criteria for organizations operating product certification systems; they may have to be amplified when specific industrial or other sectors make use of them, or when particular requirements such as health and safety have to be taken into account.

Assertion of conformity to the appropriate standards or other normative documents will be in the form of certificates or marks of conformity. Systems for certifying particular products or product groups to specified standards or other normative documents, in many cases, will require their own explanatory documentation.

While this guide is concerned with third-parties providing product certification, many of its provisions also may be useful in first- and second-party product conformity assessment procedures.

The diversity in certification systems may at first seem unnecessary and even confuse newcomers in the field, clients, and operators alike. The ISO/IEC publication "Certification and Related Activities" is available for background reading and will help to answer questions regarding the practices of the worldwide conformity assessment community. This standard replaces **ANSI Z34.1** Third Party Certification Programs for Products, Processes, and Services.

NOTE 1—The introduction does not form an integral part of this guide.

1. Scope

1.1 This guide specifies general requirements that a third-party operating a product certification system shall meet if it is to be recognized as competent and reliable.

1.2 In this guide the term *certification body* is used to cover any body operating a product certification system. The word *product* is used in its widest sense and includes processes and

services. The word *standard* is used to include other normative documents such as specifications or technical regulations.

1.3 The certification system used by the certification body may include one or more of the following, which could be coupled with production surveillance or assessment and surveillance of the supplier's quality system or both, as described in **ISO/IEC Guide 53**:

Type testing or examination;

Testing or inspection of samples taken from the market or from supplier's stock or from a combination of both;

Testing or inspection of every product or of a particular product, whether new or already in use;

Batch testing or inspection; and,

Design appraisal.

¹ This guide is under the jurisdiction of ASTM Committee E-36 on Conformity Assessment and is the direct responsibility of Subcommittee E36.20 on Certification/Registration Bodies.

Current edition approved Oct. 10, 1999. Published November 1999. Originally published as E 1906–97. Last previous edition E1906–97.

NOTE 1—**ISO/IPC Guide 28** may be consulted for a model of one form of a third-party product certification system.

2. Referenced Documents

2.1 *ASTM Standards:*

E 548 Guide for General Criteria Used for Evaluating Laboratory Competence²

2.2 *ISO Standards:*

ISO 8402:1994, Quality Management and Quality Assurance—Vocabulary³

ISO 10011–1:1990, Guidelines for Auditing Quality Systems—Part 1: Auditing³

2.3 *ISO/IEC Standards:*

ISO/IEC Guide 2:1996, Standardization and Related Activities—General Vocabulary³

ISO/IEC Guide 7:1994, Guidelines for Drafting of Standards Suitable for Use for Conformity Assessment³

ISO/IEC Guide 23:1982, Methods of Indicating Conformity with Standards for Third-Party Certification Systems³

ISO/IEC Guide 25:1990, General Requirements for the Competence of Calibration and Testing Laboratories³

ISO/IEC Guide 27:1983, Guidelines for Corrective Action to Be Taken by a Certification Body in the Event of Misuse of Its Mark of Conformity³

ISO/IEC Guide 39:1988, General Requirements for the Acceptance of Inspection Bodies³

ISO/IEC Guide 53:1988, An Approach to the Utilization of a Supplier's Quality System in Third-Party Product Certification³

ISO/IEC Guide 62:1996, General Requirements for Bodies Operating Assessment and Certification/Registration of Quality Systems³

ISO/IEC Guide 65, General Requirements for Bodies Operating Product Certification Systems³

2.4 *ISO/IPC Standard:*

ISO/IPC Guide 28:1982, General Rules for a Model Third-Party Certification System for Products^{3,2}

2.5 *ANSI Standard:*

ANSI Z34.1 Third Party Certification Programs for Products, Processes, and Services³

3. Terminology

3.1 *Definitions*—For the purposes of this guide, the relevant definitions given in **ISO/IEC Guide 2** and ISO 8402 apply, together with the following definition:

3.1.1 *supplier, n*—the party that is responsible for ensuring that products meet, and if applicable, continue to meet, the requirements on which the certification is based.

4. Certification Body

4.1 *General Provisions:*

4.1.1 The policies and procedures under which the certification body operates and their administration shall be nondiscriminatory and shall be administered in a nondiscriminatory manner.

Procedures shall not be used to impede or inhibit access by applicants, other than as provided for in this guide.

4.1.2 The certification body shall make its services accessible to all applicants whose activities fall within its declared field of operation. There shall not be undue financial or other conditions. Access shall not be conditional upon the size of the supplier or membership of any association or group, nor shall certification be conditional upon the number of certificates already issued.

4.1.3 The criteria against which the products of a supplier are evaluated shall be those outlined in specified standards. Requirements for standards suitable for this purpose are contained in **ISO/IEC Guide 7**. If explanation is required as to the application of these documents for a specific certification system, it shall be formulated by relevant and impartial committees or persons possessing the necessary technical competence, and published by the certification body.

4.1.4 The certification body shall confine its requirements, evaluation, and decision on certification to those matters specifically related to the scope of the certification being considered.

4.2 *Organization*—The structure of the certification body shall be such as to foster confidence in its certifications. In particular, the certification body shall do the following:

4.2.1 Be impartial;

4.2.2 Be responsible for decisions relating to its granting, maintaining, extending, suspending and withdrawing of certification;

4.2.3 Identify the management (committee, group, or person), which shall have overall responsibility for all of the following:

4.2.3.1 Performance of testing, inspection, evaluation, and certification as defined in this guide;

4.2.3.2 Formulation of policy matters relating to the operation of the certification body;

4.2.3.3 Decisions on certification;

4.2.3.4 Supervision of the implementation of its policies;

4.2.3.5 Supervision of the finances of the body;

4.2.3.6 Delegation of authority to committees or individuals as required to undertake defined activities on its behalf; and

4.2.3.7 Technical basis for granting certification;

4.2.3.8 Have documents which demonstrate it is a legal entity;

4.2.3.9 Have a documented structure which safeguards impartiality including provisions to ensure the impartiality of the operations of the certification body; this structure shall enable the participation of all parties significantly concerned in the development of policies and principles regarding the content and functioning of the certification system;

4.2.3.10 Ensure that each decision on certification is taken by a person(s) different from those who carried out the evaluation;

4.2.3.11 Have rights and responsibilities relevant to its certification activities;

4.2.3.12 Have adequate arrangements to cover liabilities arising from its operations or activities, or both.

² Annual Book of ASTM Standards, Vol 14.02.

³ Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

4.2.3.13 Have the financial stability and resources required for the operation of a certification system;

4.2.3.14 Employ a sufficient number of personnel having the necessary education, training, technical knowledge, and experience for performing certification functions relating to the type, range, and volume of work performed, under a responsible senior executive;

4.2.3.15 Have a quality system giving confidence in its ability to operate a certification system for products;

4.2.3.16 Have policies and procedures that distinguish between product certification and any other activities in which the certification body is engaged;

4.2.3.17 Together with its senior executive and staff, be free from any commercial, financial, and other pressures, which might influence the results of the certification process;

4.2.3.18 Have formal rules and structures for the appointment and operation of any committees which are involved in the certification process; such committees shall be free from any commercial, financial, and other pressures that might influence decisions; a structure where members are chosen to provide a balance of interests where no single interest predominates will be deemed to satisfy this provision;

4.2.3.19 Ensure that activities of related bodies do not affect the confidentiality, objectivity, and impartiality of its certifications, and it shall not supply or design products of the type it certifies; give advice or provide consulting services to the applicant as to guides of dealing with matters which are barriers to the certification requested; provide any other products or services which could compromise the confidentiality, objectivity or impartiality of its certification process and decisions; and,

4.2.3.20 Have policies and procedures for the resolution of complaints, appeals and disputes received from suppliers or other parties about the handling of certification or any other related matters.

4.3 Operations:

4.3.1 The certification body shall take all steps necessary to evaluate conformance with the relevant product standards according to the requirements of specific product certification system. The certification body shall specify the relevant standards or parts thereof and any other requirements, such as sampling, testing, and inspection requirements, which form the basis for the applicable certification system.

4.3.2 In conducting its certification operations, the certification body shall observe, as appropriate, the requirements for the suitability and competence of body(ies) or person(s) carrying out testing, inspection, and certification/registration as specified in **ISO/IEC Guides 25, 39, and 62**.

4.4 *Subcontracting*— When a certification body decides to subcontract work related to certification, for example, testing or inspection, to an external body or person, a properly documented agreement covering the arrangements including confidentiality and conflict of interest shall be drawn up. The certification body shall take full responsibility for such subcontracted work and maintain its responsibility for granting, maintaining, extending, suspending or withdrawing certification; and shall ensure that the subcontracted body or person is competent and complies with the applicable provisions of this

guide and other methods, standards, and guides relevant to testing, inspection, or other technical activities, and is not involved either directly or through the person's employer with the design or production of the product in such a way that impartiality would be compromised. The certification body also shall obtain the applicant's consent.

NOTE 2—Where the certification body subcontracts certain specialized activities, it shall have access to a qualified and experienced person who is able to form an independent assessment of the results of these subcontracted activities. The responsibility for the determination of conformity with the requirements rests with the certification body.

NOTE 3—Where work related to certification has been undertaken prior to the application for certification, the body may take account of it, provided it can take responsibility and satisfy itself as detailed in 4.4.

NOTE 4—The requirements given in 4.4 also are relevant, by extension, when a certification body uses, for granting its own certification, work performed by another certification body with which it has signed an agreement.

4.5 Quality System:

4.5.1 The management of the certification body having executive responsibility for quality shall define and document its policy for quality and its objectives for and commitment to quality. The management shall ensure that this policy is understood, implemented, and maintained at all levels of the organization.

4.5.2 The certification body shall operate an effective quality system in accordance with the relevant elements of this guide and appropriate for the type, range, and volume of work performed. This quality system shall be documented and the documentation shall be available for use by the certification body staff. The certification body shall ensure effective implementation of the documented quality system, procedures, and instructions. The certification body shall designate a person having direct access to its highest executive level who, irrespective of other responsibilities, shall have defined authority for ensuring that a quality system is established, implemented, and maintained in accordance with this guide, and reporting on the performance of the quality system to the body's management for review and as a basis for improvement of the quality system.

4.5.3 The quality system shall be documented in a quality manual and associated quality procedures, and the manual shall contain or refer to at least the following:

4.5.3.1 A quality policy statement;

4.5.3.2 A brief description of the legal status of the certification body, including the names of its owners and, if different, names of the persons who control it;

4.5.3.3 The names, qualifications, experience, and terms of reference of the senior executive and other certification personnel, both internal and external;

4.5.3.4 An organization chart showing lines of authority, responsibility, and allocation of functions stemming from the senior executive;

4.5.3.5 A description of the organization of the certification body, including details of the management (committee, group, or person) identified in 4.2.3, its constitution, terms of reference and rules of procedure;

4.5.3.6 The policy and procedures for conducting management reviews;