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Assessment For The Suitability Of Scheme, Standards And Normative Documents For Use In The ANSI Accreditation Programs For Product Certification Bodies

- References
- ISO 9000:2005, Quality management systems - Fundamentals and vocabulary*
 - ISO/IEC 17000:2004, Conformity assessment - Vocabulary and general principles*
 - ISO/IEC 17007: 2009, Guidance for drafting normative documents suitable for use for conformity assessment*
 - ISO/IEC 17065:2012 Conformity Assessment, Requirements for bodies certifying products, processes and service*
 - ISO/IEC Directives, Part 1: 2004 – Procedures for the technical work*
 - ISO/IEC Directives, Part 2: 2004, Rules for the structure and drafting of International Standards*
 - ISO/IEC Guide 65:1996, General requirements for bodies operating product certification systems*
 - ISO/IEC Supplement – Procedures specific to ISO (the ISO Supplement)*

1 Objective

1.1 ISO/IEC Guide 65 references ISO/IEC Guide 7 as “requirements suitable for . . . criteria against which the products of a supplier are evaluated” which has been superseded by ISO/IEC 17007 Section 5. However, through formal consensus or informal processes, markets/regulators have been known to specifically endorse product requirements for product certification that do not meet ISO/IEC 17007 Section 5.

This document is for use by ANSI staff as it considers applications for accreditation of product certification bodies and complaints/appeals about accredited product certification bodies. During those activities, ANSI staff may encounter situations in which the product requirements in standards or other normative documents used in product certification deviate from ISO/IEC 17007 Section 5. If ANSI staff can not confirm that those deviations are the consensus (formal or informal) of the parties affected by product certification it shall:

- a) apply the requirements of ISO/IEC 17007 Section 5:2009 to the product requirements being used;
- b) identify deviations from those requirements of ISO/IEC 17007 Section 5; and
- c) report these deviations for consideration and resolution by the ANSI Accreditation Committee.

1.2 ISO/IEC 17007 Section 6 is not applicable of product certification bodies since it applies to the entity responsible for the development and maintenance of the certification program (or "scheme"). No accreditation requirements apply to such entities. However, ANSI staff may find Section 6 useful when considering involvement with new product certification program/schemes.

2 Definitions

2.1 For the purposes of this procedure the relevant definitions given in ISO/IEC 17000:2004 and the following definitions apply:

2.2 CONFORMITY ASSESSMENT: Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled.

NOTE: The subject field of conformity assessment includes activities defined elsewhere in this International Standard, such as testing, inspection and certification as well as the accreditation of conformity assessment bodies.

2.3 Object of Conformity Assessment: particular material, product (including services), installation, process, system, person or body to which conformity assessment is applied.

2.4 Specified Requirement: need or expectation that is stated.

NOTE: Specified requirement may be stated in normative documents such as regulations, standards and technical specifications.

[ISO/IEC 17000:2004, 3.1]

2.5 PRODUCT: Result of a process [ISO 9000:2005, 3.4.2].

NOTE 1: Four generic product categories are noted in ISO 9000:2000: services (e.g. transport); software (e.g. computer program, dictionary); hardware (e.g. engine, mechanical part); processed materials (e.g. lubricant). Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element.

NOTE 2: Pertinent references are ISO Guide 7:1994, Clauses 4, 5, and 6.

2.6 Certification Scheme: See ISO/IEC 17065:2012 Section 3, Item 3.9.

3 Analysis of Scheme taking in consideration the ISO/IEC 17065

3.1 ANSI staff and Assessor conduct an analysis of the schemes that will be used by applicant's certification bodies. If contradictions to ISO/IEC 17065 are found through this analysis, scheme owners shall provide evidence that a consensus rationale was achieved among all significantly interested parties to intentionally include these contradictions in the scheme*.

NOTE 1: * - in some situations, the number of significantly interested parties may be very limited. For example, when the scheme owner is a regulatory body carrying out its regulatory mission within the constraints of legislation, the interested parties may be limited to the legislature and the regulatory body; or when there is only one or a very limited number of users who will rely on the scheme for assurance that specified requirements are fulfilled.

3.2 ANSI staff will submit the following to the ANSI Accreditation Committee:

- a) Name of the Scheme owner;
- b) Information on the certification scheme's purpose;
- c) Result of schemes analysis;
- d) Response of the scheme owner; and
- e) Information on the number of applicants and accredited certification bodies.

3.3 The ANSI Accreditation Committee will develop and provide feedback (as a Committee, not as individual members) to ANSI management about the merits of the certification scheme's explanation of the situation and, if possible, about a consensus recommendation for a course of action going forward. A final decision will be taken by ANSI.

3.4 If ANSI provides accreditation related to a certification scheme that imposes requirements that contradict ISO/IEC 17065, ANSI shall:

- a) Include a summary of those contradictions as part of the Directory of Accredited Bodies related to that certification scheme; and
- b) Include a reference to this summary on accreditation certificates issued to bodies whose accreditation relates to such schemes.