ISO IEC

GUIDE 67

Conformity assessment — Fundamentals of product certification

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work. In the field of conformity assessment, the ISO Committee on conformity assessment (CASCO) is responsible for the development of International Standards and Guides.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

Draft Guides adopted by the responsible Committee or Group are circulated to the member bodies for voting. Publication as a Guide requires approval by at least 75 % of the member bodies casting a vote.

ISO/IEC Guide 67 was prepared by the ISO *Committee on conformity assessment* (CASCO).

Introduction

As products are designed, produced, distributed, used and ultimately disposed of, they may give rise to societal concerns. A very frequent concern is simply whether a product is what it appears to be. Concerns can involve such product attributes as safety, health or environmental impacts, durability, compatibility, suitability for intended purposes or for stated conditions, and similar considerations. Addressing these concerns through product certification serves a dual purpose:

a) users and consumers are able to make better decisions about products in the marketplace;

b) by demonstrating conformity, suppliers may more effectively achieve market acceptance.

The type of activity undertaken to demonstrate conformity of product with requirements is often determined by the consequences of nonconformity. When consequences are insignificant or not severe, society may (require) expect little or no demonstration of conformity of product since the problems generated can be easily addressed and solved after they occur. In these cases the supplier's claims may be sufficient but they may be complemented by third-party product certification on a voluntary basis. However, where the consequences of nonconformity are significant, society may demand completion of activities that demonstrate conformity to requirements prior to allowing the product on the market, concurrent with the product appearing on the market, or both. One method of providing such assurance is through product certification.

Product conformity assessment is carried out in many ways and by many different parties (first party, second party and third party). Product certification is a means by which a third party provides assurance that a product conforms to specified standards and other normative documents. This Guide was developed to respond to the need to provide better understanding of the diverse functions and types of product certification.

This Guide describes some of the activities of product certification, identifies basic elements and types of product certification, and shows some of the ways of combining these elements to design a product certification system.

Various parties who have involvement in product certification tend to view product certification only in terms of the manner in which it is carried out in their own particular circumstances. Therefore, this Guide emphasizes that there are many approaches to product certification, each having legitimacy for its own particular application.

Furthermore, this Guide identifies the various activities that can be included within the general context of product certification. The consideration of each of these elements is not intended to imply that each of the elements should be present, but rather to address the way(s) in which each of the elements can be practised. This Guide shows various ways of combining these elements to design a product certification system.

This Guide is intended to foster understanding of the wide range of possibilities that fall within the context of product certification, and thereby assist those wishing to develop product certification for a particular purpose, and those with responsibility for evaluating such systems.

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1 Scope

This Guide gives guidance on product certification systems by identifying their various elements based on current practices.

It is intended for use by product certification bodies and other interested parties wishing to understand, develop, establish or compare third-party product certification systems.

This Guide is not intended to describe all existing forms of product certification. It does not address first- and second-party product conformity assessment.

NOTE 1   The term "product" is used in this Guide in its widest sense and includes processes and services; the term "standard" is used to include other normative documents such as specifications or technical regulations (see, for example, ISO/IEC Guide 65).

NOTE 2   Product certification is a third-party conformity assessment activity (see ISO/IEC 17000).

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17000:2004, *Conformity assessment — Vocabulary and general principles*

3 Terms and definitions

For the purposes of this document, the terms and definitions in ISO/IEC 17000 and the following apply.

3.1
product certification system
rules, procedures and management for carrying out third-party product conformity assessment

NOTE   Adapted from ISO/IEC 17000:2004, definition 2.7.

3.2
product certification scheme
product certification system related to specific products to which the same specified requirements, specific rules and procedures apply

NOTE 1   Adapted from ISO/IEC 17000:2004, definition 2.8.

NOTE 2   A distinction between "product certification scheme" and "product certification system" is not always made at the national level.