GUIDE 67

Conformity assessment — Fundamentals of product certification

First edition 2004

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

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.

Conformity assessment — Fundamentals of product certification

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.

4 Context of product certification

4.1 General

4.1.1 The first step in addressing concerns regarding products is generally the creation of standards (or other normative documents) for the products involved. The next step concerns the means by which conformity to standards is assured.

Assessment of the fulfilment of requirements in standards, or other normative documents, is one technique used to resolve any concerns that society has regarding products.

4.1.2 Product certification is an activity by which a third party gives written assurance that a product (including process and service) fulfils specified requirements.

Considering the widespread use of product certification throughout the world, several observations can be made that lead to the fundamental objective that product certification should meet.

4.2 Objectives of product certification

4.2.1 Product certification would be expected to apply mainly to those societal concerns whose significance calls for the involvement of an independent body. The use of product certification bears out this observation as it is generally applied only to significant concerns (e.g. safety, health or environmental protection).

Product certification may also be used by suppliers (manufacturers, retailers, warehouses, other service providers, etc.) to improve the acceptability of their products by the market.

4.2.2 Three fundamental purposes of product certification become evident:

— product certification should address concerns of consumers, users and, more generally, all interested parties by instilling confidence regarding fulfilment of requirements;

— product certification may be used by suppliers to show to the market the third-party involvement;

— product certification should not require excessive resources that result in product costs beyond what society in general is willing to bear.

4.2.3 In general, product certification should instil confidence for those with an interest in fulfilment of requirements, and product certification should provide sufficient value so that suppliers can effectively market products. Product certification is most successful when it delivers the required confidence while utilizing the fewest possible resources; i.e. maximizing value.

4.3 Uses of product certification

4.3.1 Product certification is used in various ways. For example, governments may impose certification requirements in connection with such matters as communications, food and drugs. Local governmental authorities rely on certification of products to assure that such technical areas as electrical wiring and construction products are suitable for use in building construction. Retailers of consumer goods rely on certification as evidence that aspects such as the safety of electrical appliances have been addressed by a third party, thus giving confidence that products they place on their shelves for sale to the public are not likely to bring harm to their customers. Manufacturers may require certification of items provided by suppliers.

4.3.2 In each of these various cases, there are different parties involved, each having its own particular interest. For example, governments have assumed responsibility for regulation and control of those matters that concern the broad public interest and welfare. In many cases, the issues concern matters which by their nature extend across national borders. In such cases, it is common for governments to work together to establish basic rules and requirements. Examples include electromagnetic compatibility (EMC), terminal attachment and aviation.

4.3.3 Governments are also concerned with matters only within their own borders, such as highway construction or water supply. In the area of building construction, regulation may be carried out at a national level in some countries, but in other countries at the level of province or state, or even by local municipalities. At an even more basic level, retailers, and certainly consumers, are free to make their own choices.

4.3.4 While these examples illustrate important distinctions in the way certification is used, these brief overviews neither serve to fully explain the details of certification in the respective cases, nor constitute the entire universe of ways in which certification is used.

4.3.5 Personal understanding and perception concerning certification are usually determined by an individual's own experiences with, and proximity to, a particular area or application of certification. Because there may be various approaches to certification, a single set of rules cannot be universally applied to every application and circumstance of certification, such as the choice and detail of the system itself or implementation of mutual recognition on a bilateral, multilateral or universal basis. It is necessary to understand who is involved, in what way, and for what purpose (for further details, see ISO/IEC Guide 68).

4.3.6 Certification is by its nature constraining. If it were not, it would be of no value. Therefore, efforts to address product certification are a challenge. Yet, parties having a common objective can work together to derive the value of certification, without certification imposing undue burden and constraint.

5 Basics of product certification

5.1 General considerations

5.1.1 Product certification as a technique to address concerns related to the design, production, distribution, use and disposal of products has been in use for over 100 years. Many effective forms of product certification can be found all over the world. While all forms of product certification can be highly effective, the specific concerns to be resolved by product certification and the conditions (both voluntary and regulatory) under which product certification will operate will quickly narrow the choices for the optimum set of elements for a specific product certification system.

5.1.2 Product certification incorporates at the least the following three functional stages:

— selection (sampling);

— determination;

— review and attestation (decision).

5.1.3 Various other elements may be included (e.g. assessment of production process, sampling from the market), based on the level of product certification system as per Table 1 and quality management systems.

5.2 Selection (sampling)

Selection (sampling) requires determination of characteristics to be assessed, determination of requirements (the specified requirements against which to assess the conformity of the product), and the applicable procedural requirements for the assessment and sampling.

5.3 Determination

Determination against the applicable specified requirements may include testing, measurements, inspection, design appraisal, assessment of services, and auditing as examples of techniques used to check whether or not the product meets the specified requirements.

Determination of characteristics may combine measurement (in order to determine the value of a quantity or limit) and comparison of the measured value with the required value.

NOTE Measurement concepts are defined in the *International vocabulary of basic and general terms in metrology* (VIM).

5.4 Review and attestation

Before a decision leading to granting the right to use certificates or marks of conformity is taken, the adequacy of the quantitative and qualitative evidence related to the product will need to be reviewed and documented.

If adequate information is available, a decision is made whether a certificate or authorization to use a mark of conformity can be issued.

For a specific product, different people make the decision from those who undertake the determination function.

5.5 Subcontracting

According to the rules of the respective systems, several elements of the product certification system can be subcontracted. The decisions on certification should not be subcontracted.

6 Elements and types of product certification systems

6.1 General considerations on elements

6.1.1 The basic elements of product certification are supported or supplemented by additional elements. These additional elements become identifiable as further, more substantive and concrete consideration is given to the manner in which the basic elements are actually implemented in product certification.

It should be decided, for example, how a suitable standard will be selected. The standard should be suitable for the selected product certification scheme. The determination of the suitability of a standard may consider the method by which a standard is developed, maintained or interpreted.

For the initial assessment of a product, it should be decided how samples are to be obtained, and what tests are to be conducted.

6.1.2 While the issues and alternatives number more than can be addressed in this limited framework, it is instructive to take note of the more general of these elements and to illustrate how they might be used together to constitute a product certification system. Such a structural illustration shows that no single set of elements can be taken as the sole set and arrangement of elements defining product certification. Rather, it demonstrates that circumstances attendant to the perceived need for product certification need to be thoughtfully considered in the course of its design and implementation.

6.2 Matrix of elements and types of product certification systems

A number of the more general and common elements of product certification are shown in the matrix of elements in Table 1. The matrix suggests how any of these elements may be used in combinations to establish a specific certification system. For reference, each of these combinations may be assigned a type designation. The elements may also be applied in other combinations to create additional systems. Furthermore, additional sub-elements may be added to further refine the matrix for the user's own purposes.

NOTE The number series for product certification systems that follows is not identical to that appearing in Reference [16]. System 1 in Reference [16] corresponds to systems 1a and 1b in Table 1. Furthermore, the symbol N has been added to show an undefined number of possible other systems that can be based on different elements.

Table 1 — Building a product certification system

Elements [a] of product certification system		Product certification systems [b, c, d]							
		1a	**1b**	**2**	**3**	**4**	**5**	**6**	N[e]
1)	**Selection**[f] **(sampling), as applicable**	x	x	x	x	x	x		
2)	**Determination**[f,g] **of characteristics, as applicable, by:**	x	x	x	x	x	x	x	
	a) **testing** (ISO/IEC 17025)								
	b) **inspection** (ISO/IEC 17020)								
	c) **design appraisal**								
	d) **assessment of services**								
3)	**Review**[f,g] **(evaluation)**	x	x	x	x	x	x	x	
4)	**Decision on certification**	x	x	x	x	x	x	x	
	Granting, maintaining, extending, suspending, withdrawing certification								
5)	**Licensing (attestation**[f]**)**		x	x	x	x	x	x	
	Granting, maintaining, extending, suspending, withdrawing the right to use certificates or marks								
6)	**Surveillance**, as applicable by:								
	a) testing or inspection of samples from the open market			x		x	x		
	b) testing or inspection of samples from the factory				x	x	x		
	c) quality system audits combined with random tests or inspections						x	x	
	d) assessment of the production process or service				x	x	x	x	

[a] Where applicable, the elements can be coupled with initial assessment and surveillance of the applicant's quality system (an example is given in ISO/IEC Guide 53) or initial assessment of the production process. The order in which the assessments are performed may vary.

[b] A product certification system should include at least the elements 2), 3) and 4).

[c] An often used and well-tried model for a product certification system is described in ISO/IEC Guide 28; it is a product certification system corresponding to system 5.

[d] For product certification systems related to specific products, the term “scheme” is used (see 3.2, Note 2).

[e] Reference [16] mentions system 7 (batch testing) and system 8 (100 % testing). These may be considered product certification systems if at least the elements of system 1a are included.

[f] See ISO/IEC 17000 for definitions.

[g] In some systems, evaluation means determination, and in other systems it means review.

6.3 Description of types of product certification systems

6.3.1 General

The following examples do not necessarily represent all possible forms of product certification systems. They may be used with many types of requirements and may utilize a wide variety of mechanisms for conformity identification.

6.3.2 System 1a

This system includes testing; samples of the product are assessed for conformity. The sampling may or may not be statistically significant of the entire population of product.

This certification system includes the following:

a) samples requested by the certification body;

b) determination of characteristics by testing or assessment;

c) evaluation of the test or assessment report;

d) decision.

6.3.3 System 1b

This system includes testing; samples of the product are assessed for conformity. The sampling covers the entire population of product. A certificate of conformity is given to each product represented by the sample.

This certification system includes the following:

a) samples requested by the certification body;

b) determination of characteristics by testing or assessment;

c) evaluation of the test or assessment report;

d) decision;

e) licence.

6.3.4 System 2

This system includes testing and market surveillance. Market surveillance is conducted and samples of the product from the market are assessed for ongoing conformity.

This certification system includes the following:

a) samples requested by the certification body;

b) determination of characteristics by testing or assessment;

c) initial assessment of the production process or the quality system as applicable;

d) evaluation of the test and assessment reports;

e) decision;

f) licence;

g) surveillance by testing or inspection of samples from the market.

NOTE While this system may identify the impact of the distribution chain on conformity, the resources it requires can be extensive. Also, when significant nonconformities are found, effective preventative measures may be limited since the product has already been distributed to the market.

6.3.5 System 3

This system includes testing and factory surveillance. Factory surveillance is conducted and samples of the product from the point of production are assessed for ongoing conformity.

This certification system includes the following:

a) samples requested by the certification body;

b) determination of characteristics by testing or assessment;

c) initial assessment of the production process or the quality system, as applicable;

d) evaluation of the test and assessment reports;

e) decision;

f) licence;

g) surveillance by testing or inspection of samples from the factory and assessment of the production process.

NOTE This system does not provide any indication of the impact the distribution channel plays on conformity. When serious nonconformities are found, the opportunity may exist to resolve them before widespread market distribution.

6.3.6 System 4

This system includes testing and surveillance of samples from the factory or the open market, or both.

This certification system includes the following:

a) samples requested by the certification body;

b) determination of characteristics by testing or assessment;

c) initial assessment of the production process or the quality system, as applicable;

d) evaluation of the test and assessment reports;

e) decision;

f) licence;

g) surveillance by testing or inspection of samples from the factory and assessment of the production process;

h) surveillance by testing or inspection of samples from the open market.

NOTE This system can both indicate the impact of the distribution channel on conformity and provide a pre-market mechanism to identify and resolve serious nonconformities. Significant duplication of effort may take place for those products whose conformity is not affected during the distribution process.

6.3.7 System 5

This system includes testing and assessment of the quality system involved. Surveillance of the quality system is conducted and samples of the product may be taken from either the market or the point of production, or both, and are assessed for ongoing conformity.

This certification system includes the following:

a) samples requested by the certification body;

b) determination of characteristics by testing or assessment;

c) initial assessment of the production process or the quality system, as applicable;

d) evaluation of the test and assessment reports;

e) decision;

f) licence;

g) surveillance of the production process or quality system or both of the organization;

h) surveillance by testing or inspection of samples from the factory or the open market, or both.

NOTE The extent to which the three elements of ongoing surveillance are conducted may be adjusted for a given situation. As a result, this system provides significant flexibility for ongoing surveillance.

6.3.8 System 6

This system addresses especially certification of processes and services.

The elements of certification include:

a) determination of characteristics by assessment of processes or services;

b) initial assessment of the quality system, as applicable;

c) evaluation;

d) decision;

e) licence;

f) surveillance by audits of the quality system;

g) surveillance by assessment of the processes or services.

Bibliography

[1] ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*

[2] ISO 19011:2002, *Guidelines for quality and/or environmental management systems auditing*

[3] ISO/IEC 17020:1998, *General criteria for the operation of various types of bodies performing inspection*

[4] ISO/IEC 17021:—[1)], *Conformity assessment — Requirements for bodies providing audit and certification of management systems*

[5] ISO/IEC 17024:2003, *Conformity assessment — General requirements for bodies operating certification of persons*

[6] ISO/IEC 17025:—[2)], *General requirements for the competence of testing and calibration laboratories*

[7] ISO/IEC 17030:2003, *Conformity assessment — General requirements for third-party marks of conformity*

[8] ISO/IEC Guide 2:2004, *Standardization and related activities — General vocabulary*

[9] ISO/IEC Guide 23:1982, *Methods of indicating conformity with standards for third-party certification systems*

[10] ISO/IEC Guide 28:2004, *Conformity assessment — Guidance on a third-party certification system for products*

[11] ISO/IEC Guide 43-1:1997, *Proficiency testing by interlaboratory comparisons — Part 1: Development and operation of proficiency testing schemes*

[12] ISO/IEC Guide 43-2:1997, *Proficiency testing by interlaboratory comparisons — Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies*

[13] ISO/IEC Guide 53:1988, *An approach to the utilization of a supplier's quality system in third party product certification*

[14] ISO/IEC Guide 65:1996, *General requirements for bodies operating product certification systems*

[15] ISO/IEC Guide 68:2002, *Guidelines for quality and/or environmental management systems auditing*

[16] *Certification and related activities — Assessment and verification of conformity to standards and technical specifications.* International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), 1992

[17] VIM, *International vocabulary of basic and general terms in metrology.* BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML, 1993

[18] Websites related to product certification:

— http://www.ts.nist.gov

— http://www.iecee.org/cbscheme

— http://www.wssn.net

1) To be published. (Revision of ISO/IEC Guide 62:1996 and ISO/IEC Guide 66:1999)

2) To be published. (Revision of ISO/IEC 17025:1999)

International Organization for Standardization
Case postale 56 • CH-1211 GENEVA 20 • Switzerland

International Electrotechnical Commission
Case postale 131 • CH-1211 GENEVA 20 • Switzerland

Ref. No.: ISO/IEC GUIDE 67:2004(E)

ICS 03.120.20

Price based on 9 pages