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**INTERNATIONAL ELECTROTECHNICAL COMMISSION**

**IEC SCHEME FOR CERTIFICATION TO STANDARDS FOR SAFETY OF  
ELECTRICAL EQUIPMENT FOR EXPLOSIVE ATMOSPHERES (IECEX  
SCHEME)**

**Ex Management Committee, ExMC, ExTAG and WG1**

**Title: C/1258/DC Draft ISO/IEC Guide 67: Fundamentals of product  
certification**

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**Introductory Note**

Doc C/1258/DC Draft ISO/IEC Guide 67: Fundamentals of product  
certification has been issued to IEC National Committees for comment.

The IECEX Secretariat is circulating this document to members of ExMC,  
ExTAG and WG1 for useful information and for consideration in the revision  
of the IECEX Scheme Rules and Procedures.

Should you wish to submit any comments you may do so through your  
National Committee of the IEC

As this document may be discussed within CAB the Secretary would also be  
pleased to receive any comment that might be considered relevant to the  
Scheme.

Address: IECEX Secretariat c/o QAS GPO Box 5420 Sydney NSW 2000 Australia	Visiting Address: 286 Sussex Street Sydney NSW 2140 Australia	Tel: +61 2 8206 6000 Fax: +61 2 8206 6032 Email: <a href="mailto:chris.agius@gas.com.au">chris.agius@gas.com.au</a> Internet address: <a href="http://www.iecex.com">www.iecex.com</a>
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C/1258/DC

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

### COUNCIL

### SUBJECT

Draft ISO/IEC Guide 67: Fundamentals of product certification

### BACKGROUND

This draft has been prepared by ISO/CASCO WG 14: Product certification and is circulated to CASCO member bodies and IEC National Committees for comment as a second CD, in accordance with the ISO/IEC Directives, Part 1 Annex A.

This draft supersedes document C/1211/CD, circulated 2001-01-26.

### ACTION

IEC National Committees are invited to submit comments to [gb@iec.ch](mailto:gb@iec.ch) before 2002-05-05

## **Fundamentals of product certification**

*Éléments fondamentaux de la certification des produits*

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards and Guides 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 national bodies for voting. Publication as a Guide requires approval by at least 75 % of the national bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this Guide may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/IEC Guide 67 was prepared by the ISO Committee on Conformity Assessment (ISO/CASCO).

## Introduction

As products are designed, produced, distributed, used and ultimately disposed of, societal concerns can arise regarding them. A very frequent concern is simply whether a product is what it appears to be. Concerns can involve such product attributes as safety, quality, durability, size, and suitability for intended purpose and similar considerations. Addressing these concerns serves a dual purpose: 1) society is able to make better decisions about products in the marketplace, and 2) suppliers have more efficient markets in which to sell their goods.

The type of activity undertaken to demonstrate compliance with requirements is often determined by the consequences of non-compliance. When consequences are insignificant or not severe, society may require little or no demonstration of compliance since the problems generated can be easily addressed and solved after they occur. The supplier's claims may be sufficient. However, when the consequences of non-compliance are significant, society may demand completion of compliance demonstration activities prior to allowing the product on the market, concurrent with the product appearing on the market, or both. One means to provide for such assurance is through product certification.

Product certification is a means by which a third party provides assurance that a product complies with specified standards and other normative documents. This Guide deals specifically with third party product certification. Product certification is carried out in many ways and by many different parties. 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 scheme.

ISO has recognized that various individuals 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 serve as a declaration that each of the elements should be present, but rather to address the way(s) in which each of the elements can be practiced. This Guide shows various ways of combining these elements to design a product certification scheme.

While this Guide deals specifically with product certification carried out by third parties, there are other types of product conformity assessment, including first- and second-party product conformity assessment. In many cases, product conformity assessment is a matter strictly between the supplier and the purchaser without any third party involvement whatsoever. Such direct relationships between a supplier and a purchaser can range from implicit expression of conformity, that occurs for example when the purchaser recognizes the supplier's brand name, all the way through to more rigorous expressions of conformity, including a supplier's declaration of conformity of products to specific standards or requirements, and declarations relative to a supplier's own quality assessment and product production controls.

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 assessing product certification.



## Fundamentals of product certification

### Scope

This Guide gives guidance on product certification systems and schemes, by identifying the various elements of product certification, based on current practices.

This Guide is intended for use by individuals and organizations wishing to understand, establish, assess, or recognize third-party product certification.

The contents of this Guide are not intended to describe all existing forms of third-party product certification. This Guide does not address first and second-party product conformity assessment.

### References

ISO/IEC Guide 2:1996, *Standardization and related activities - General vocabulary*.

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

ISO/IEC Guide 7:1994, *Guidelines for drafting of standards suitable for use for conformity assessment*.

ISO/IEC Guide 28:1982, *General rules for a model third-party certification system for products*.

ISO/IEC Guide 43-1:1997, *Proficiency testing by interlaboratory comparisons – Part 1: Development and operation of proficiency testing schemes*.

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

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

ISO/IEC Guide 62:1996, *General requirements for bodies operating assessment and certification/registration of quality systems*.

ISO/IEC Guide 68: –, *Arrangements for the recognition and acceptance of conformity assessment results*.

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

ISO/IEC 17024: –, *General criteria for certification bodies operating certification of persons*.

ISO/IEC 17025:1999, *General requirements for the competence of testing and calibration laboratories*.

ISO/IEC 17030: –, *Third-party marks of conformity assessment and their use*.

ISO 9000:2000, *Quality management systems – fundamentals and vocabulary*.

### Terms and definitions

For the purposes of this Guide, the terms and definitions in ISO/IEC Guide 2, ISO/IEC Guide 65 and the following terms and definitions apply.

#### 3.1

#### **product certification system**

system that has its own rules of procedure and management for carrying out product certification

NOTE Compare with ISO/IEC Guide 2:1996, 12.4, for "conformity assessment system".

### 3.2

#### product certification scheme

product certification system as related to specified products to which the same particular standards and rules, and the same procedure, apply.

NOTE 1 Compare with ISO/IEC Guide 2:1996, 12.5, for "conformity assessment scheme", and "programme".

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

### 3.3

#### sampling

a defined procedure for taking a representative sample of the whole

## Context of product certification

### Objectives of product certification

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

Compliance with requirements in standards or other normative documents, then, is one technique used to resolve concerns that society has regarding products.

**4.1.2** Using the definition of "certification" from ISO/IEC Guide 2:1996 as a foundation, "product certification" can be defined as a procedure by which a third party gives written assurance that a product process or service conforms to specified requirements. Product is used here to include product, process or service.

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

**4.1.3** Product certification by definition is carried out by a third party. ISO Guide 2:1996 defines "third party" as a body that is recognized as being independent of the parties involved, as concerns the issue in question. Product certification, then, would be expected to apply to those societal concerns whose significance requires an independent certification body for resolution. 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). However, even though products subject to certification cause significant societal concern, such products are in fact desired by society, unlike those that are prohibited from the market.

**4.1.4** From this discussion, two fundamental objectives of product certification become evident:

- product certification should resolve societal concerns by instilling confidence regarding compliance with requirements;
- product certification should not require excessive resources that result in product costs beyond what society in general is willing to bear.

**4.1.5** In general, product certification should instil confidence for those with an interest in compliance with 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.

### Uses of product certification

**4.2.1** 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 technicalities as electrical wiring and construction products are suitable for use in building construction. Retailers of consumer goods rely on certification as evidence that the safety of electrical appliances has 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.

**4.2.2** In each of these various cases, there are different parties involved, each having its own particular interest. For example, national 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 would include electromagnetic radio band allocation and aviation. In such cases,

it is appropriate for governments to negotiate mutual recognition agreements with one another, for such matters as standards and certification.

**4.2.3** Governments are also concerned with matters only within their own borders, such as highway construction or water supply. These are matters for which agreements between countries may be of little relevance. In the area of building construction, regulation may be carried out at a national level in some countries, and in other countries, at the level of province or state, or even by local municipalities. Where such responsibilities are the purview of provincial, state or the local municipality, national governments do not have the prerogative or authority to address mutual recognition.

**4.2.4** At an even more basic level, retailers, and certainly consumers, are free to make their own choices. 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.

**4.2.5** Personal understanding and perception concerning certification is usually determined by an individual's own experiences with and proximity to a particular area or application of certification. It helps to explain why there are various approaches to certification. Such an understanding also helps to explain why a single set of rules cannot be universally applied to every application and circumstance of certification including such as the choice and detail of the system itself or implementation of mutual recognition on a bi-lateral, multi-lateral or universal basis. It is necessary to understand who is involved, in what way and for what purpose.

**4.2.6** Certification by its nature is 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.

## Basics of product certification

Product certification as a technique to resolve societal 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 societal 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.

Product certification incorporate at least the following three functional stages:

- initial evaluation
- evaluation against applicable specified requirements
- review and decision.

Other elements may be added, e.g. factory inspection, sampling from the market, based on the level of product certification system as per table 1 of the present Guide.

### Initial evaluation

The initial evaluation requires selection of characteristics to be assessed, determination of requirements (the specified requirements against which to assess the object of conformity assessment) and the applicable procedural requirements for the assessment.

### Evaluation against applicable specified requirements

The evaluation against the applicable specified requirements may include testing, determination of characteristics, measurements, inspection, and auditing as examples of techniques used to check whether or not the product, service or system 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. Measurement concepts are defined in the *international vocabulary of basic and general terms in metrology (VIM)*.

### Review and decision

Before a decision leading to grant the right to use certificates or marks is taken, the adequacy of the quantitative and qualitative evidence related to the product, service or system will need to be reviewed and documented. If adequate information is available, a decision is made whether a certificate or mark

can be issued. The review and decision stage of assessment is particularly important when the evaluation against the specified requirements and the decision is taken by different people.

## Elements and types of product certification systems

### General considerations on elements

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

For example, how is a suitable standard selected? For that matter, what is it that constitutes or defines a suitable standard? How is a standard to be developed; maintained; interpreted? For the initial conformity assessment of a product, what samples are to be used? How are samples to be obtained? What tests are to be conducted?

**6.1.2** While the issues and alternatives number far more than can be addressed in a 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. Further, 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.

### Matrix on 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 the illustration. The matrix suggests how any these elements may be used in combinations to establish a specific certification system. For reference, each of these combinations can be assigned a type designation. The elements can also be applied in other combinations to create additional systems. Furthermore, additional sub-elements can be added to further refine the matrix for the user's own purposes.

NOTE: the number series for product certification systems which follows is not identical to that appearing in a well-known reference work, *Certification and related activities*, (ISO/IEC, 1992). System 1 in *Certification* corresponds to Systems 1a and 1b, appearing opposite under "types of product certification systems". Furthermore, "n" has been added to show an undefined number of possible systems that it is possible to develop, based on different elements.

**Table 1 — Building a product certification system**

Elements <sup>a</sup> of Product Certification System (see ISO/IEC Guide 65:1996, clause 1.2)	Product certification systems <sup>b c</sup>								Subcontracting possible
	1a	1b	2	3	4	5	-	n	
1) <b>Sampling, as applicable</b>	x	x	x	x	x	x			Yes
2) <b>Determination of characteristics, as applicable, by :</b> a) <b>testing</b> (ISO/IEC 17025) b) <b>inspection</b> (ISO/IEC 17020) c) <b>design appraisal</b> d) <b>assessment of services</b>	x	x	x	x	x	x			Yes (but see <sup>d</sup> )
3) <b>Evaluation</b> (see ISO/IEC Guide 65:1996, clause 10)	x	x	x	x	x	x			No
4) <b>Decision on certification</b> (see ISO/IEC Guide 65:1996, clause 12) (certification: written assurance that a product conforms to specified requirements)  Granting, maintaining, extending, suspending, withdrawing certification	x	x	x	x	x	x			No
5) <b>Licensing</b> (see ISO/IEC Guide 65:1996, clause 14) (granting the right to use certificates or marks)  Granting, maintaining, extending, suspending, withdrawing the right to use certificates or marks		x	x	x	x	x			No
6) <b>Surveillance</b> (see ISO/IEC Guide 65: 1996, clause 13) (evaluation to determine the continued conformity of certified products to specified requirements), as applicable by:									Yes (but not evaluation and decision)

a) testing /inspection of samples in the open market			x		x	x			
b) testing /inspection of samples at the factory				x	x	x			
c) quality system audits combined with random tests/ inspections						x			
d) conformity assessment of the production process				x	x	x			
e) reassessment of services									
NOTE: For certification systems related to specific products, the term "scheme" is used (see clause 3.2).									
<p><sup>a</sup> Where applicable the elements can be coupled with initial conformity assessment and surveillance of the applicant's quality system (an example is given in Guide 53).</p> <p><sup>b</sup> A product certification system should include at least the elements (2), (3) and (4).</p> <p><sup>c</sup> An often used and well-tried model for a product certification system is described in ISO/IEC Guide 28.</p> <p><sup>d</sup> Under certain conditions specified in the relevant systems or schemes</p>									

## Description of types of product certification systems

### 1. General

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

### 2. System 1a

This system includes type testing; samples of the product 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 on request by the certification body;
- b) testing or assessment;
- c) evaluation of the test or assessment report;
- d) decision.

### 3. System 1b

This system includes type 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:

- e) samples on request by the certification body;
- f) testing or assessment;
- g) evaluation of the test or assessment report;
- h) decision;
- i) licence.

### 4. System 2

This system includes type testing and market surveillance. Market surveillance is conducted and samples of the product from the market are assessed for ongoing conformity. While this system may identify the impact of the distribution chain on conformity, the resources it requires may be extensive. Also, when significant non-conformities are found, effective preventative measures may be limited since the product is already distributed to the market.

This certification system includes the following:

- j) samples on request by the certification body;
- k) testing or assessment;
- l) evaluation of the test or assessment report;
- m) initial conformity assessment of the production process;
- n) decision;
- o) licence;
- p) market surveillance.

### 5. System 3

This system includes type testing and factory surveillance. Factory surveillance is conducted and samples of the product, process or service from the point of production are assessed for ongoing conformity. This system does not provide any indication of the impact the distribution channel plays on conformity. When serious non-conformities are found, great opportunity may exist to resolve them before widespread market distribution.

This certification system includes the following:

- q) samples on request by the certification body;
- r) testing;
- s) evaluation of the test report;
- t) initial conformity assessment of the production process;
- u) decision;
- v) licence;
- w) factory surveillance.

### 6. System 4

This system includes type testing and factory, or factory and surveillance on products from the market. Surveillance is conducted and samples of the product may be taken from both the market and the point of production, and are assessed for ongoing conformity. This system can both indicate the impact of the distribution channel on conformity and provide a pre-market mechanism to identify and resolve serious non-conformities. Significant duplication of effort may take place for those products whose conformity is not affected during the distribution process.

This certification system includes the following:

- x) samples on request by the certification body;
- y) testing;
- z) evaluation of the test report;
- aa) initial conformity assessment of the production process;
- bb) decision;
- cc) licence;
- dd) factory surveillance;

ee) market surveillance.

## 7. System 5

This system includes type testing of the involved quality management system. 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 may be assessed for ongoing conformity. The extent to which the three elements of ongoing surveillance are conducted can be adjusted for a given situation. As a result, this system provides significant flexibility for ongoing surveillance.

This certification system includes the following:

- a) samples on request by the certification body;
- b) testing;
- c) evaluation of the test report;
- d) initial conformity assessment of the quality system;
- e) decision;
- f) licence;
- h) surveillance of the quality management system of the organization;
- h) surveillance on products from the market.

## Bibliography

- [1] *Certification and related activities, Assessment and verification of conformity to standard and technical specifications*, International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), Geneva, 1992
- [2] Websites related to product certification:
  - <http://ts.nist.gov/gsp>
  - <http://www.iecee.org/cbscheme>
  - <http://www.wssn.net/WSSN>