



GUIDE 28

First edition — 1982-12-15

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UDC 006.063

Ref. No. : ISO/IEC GUIDE 28-1982 (E)

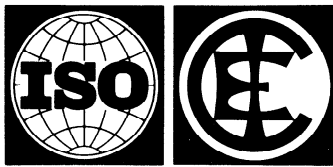
Descriptors : certification, rules (instruction).

Foreword

This document was drawn up by the ISO Committee on certification, ISO/CERTICO. It was approved by the IEC Council in June 1982 and by the ISO Council in November 1982.

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International Electrotechnical Commission

Printed in Switzerland



GUIDE 28-1982 (E)

General rules for a model third-party certification system for products

0 Introduction

These model general rules are valid for the following type of certification system :

A third party certification system of determining conformity with product standards through initial testing and assessment of a factory quality management system and its acceptance followed by surveillance that takes into account the factory quality management system and the testing of samples from the factory and the open market.

NOTE — This model system corresponds to system No. 5 as described in ISO/ITC Publication, *Certification — Principles and practice*. This system was chosen because it was the most comprehensive and could thus offer the best basis for the eventual development of other systems.

The identification of conformity may be in the form of a certificate of conformity or a mark of conformity. (See ISO/IEC Guide 23.)

A certification body operating the system at national level shall as a minimum have a suitable organizational structure¹⁾ and utilize personnel, equipment, and operating procedures that comply with the criteria given in ISO Guide 24 and ISO/IEC Guide 25 (latest edition).

Any certification scheme under the system requires as a prerequisite a standard that is suitable for certification purposes. (See ISO/IEC Guide 7.)

1 References

ISO Guide 2, *General terms and their definitions concerning standardization and certification*.

ISO/IEC Guide 7, *Requirements for standards suitable for product certification*.

ISO/IEC Guide 23, *Methods of indicating conformity with standards for third-party certification systems*.

ISO Guide 24, *Guidelines for the acceptance of testing and inspection agencies by certification bodies*.

ISO/IEC Guide 25, *General requirements for the technical competence of testing laboratories*.

2 Definitions

The relevant definitions of ISO Guide 2-1980 and its Addendum 1-1981 are applicable.

3 Basic conditions

The basic conditions for obtaining and retaining the licence²⁾ to issue a certificate of conformity or to use a mark of conformity are that the applicant/licensee follows these General Rules and the Specific Rules³⁾ of the relevant scheme and that he applies the identification of conformity only to products that are within the scope of his licence and are in conformity with the relevant standard(s).

4 Application for licence

The application shall be made on a special form obtainable from the certification body. An example of such a form is given in annex B.

The application relates to the specific product or group of products determined by the certification scheme and specified in the Specific Rules. It should normally cover products coming from one factory only.

1) Guidelines on this subject are in preparation within ISO/CERTICO.

2) For the purpose of this document the words "licence" and "licensee" are used although the granting of a licence is only one of several means of indicating that the applicant concerned has been accepted by the certification body.

3) For Specific Rules, see annex A.

A certification body on acceptance of a completed application form and receipt of the deposit, if required, will confirm this to the applicant and provide him with any further information necessary for the processing of the application.

5 Initial inspection of factory and quality management system¹⁾, and initial testing

5.1 General

After confirmation of the acceptance of the application, the certification body shall make the necessary arrangements with the applicant for the initial inspection in accordance with the rules of the scheme.

The certification body is responsible for all actions of certification, from initial testing and inspection, assessment of the factory quality management system through surveillance of the product produced.

The certification body shall inform the applicant of the results of the initial inspection and testing.

If the certification body is not satisfied that all the requirements for licensing are being met, it will inform the applicant of those aspects in which his application has failed.

If the applicant can show that remedial action has been taken by him to meet all the requirements within a specified time limit, the certification body will repeat only the necessary parts of the initial inspection procedure and testing. Otherwise the application will be cancelled.

Where a cost limit is specified by a certification body as part of its application procedure, the filing of a new application or an extension of the cost limit may be required.

Reinspection may not be needed for subsequent submittals of the same product.

5.2 Assessment of factory quality management system

Assessment of the applicant's system of factory quality management forms part of the initial inspection. This may be done according to requirements specified in the Specific Rules of the scheme.

All records produced from implementation of the quality management system related to certification shall be readily available for certification body inspection.

The applicant shall ensure that the question of responsibility to the certification body for the quality management system is clearly defined, e.g. by appointing a designated person who is independent from production management as far as the technical performance of his function is concerned and who is qualified to maintain the contact with the certification body, to ensure that the above provisions have been observed.

5.3 Initial testing²⁾

5.3.1 Selection of samples

The selection of samples for tests and examination shall be based on the rules of the scheme.

Samples should be representative of the entire line or group of production to be certified, and be made from production tools and assembled using methods established for the production run.

Where testing is based on prototype samples, confirmation tests or examination, as appropriate, should be made on production samples.

5.3.2 Conduct of initial testing

The initial testing is carried out in accordance with the applicable standard(s) and the Specific Rules of the scheme.

1) This term is still under consideration by ISO/TC 176, *Quality assurance*.

2) As used herein, "initial testing" refers to the process by which the certification body before granting or extending a licence, determines that a product complies with the requirements of the applicable standard(s). It is often called "type testing".

5.3.3 Use of test data produced by other than the certification body

Where the certification body chooses to use test data produced by others, the body, or its designated test agency, shall ensure that the party conducting the testing complies with at least the criteria of ISO Guide 24 and ISO/IEC Guide 25.

6 Licensing

The certification body, when complete fulfilment of the requirements has been established, informs the applicant accordingly, submits a licensing agreement¹⁾ for his signature (unless already done) and, on conclusion, issues a licence. (An example of such an agreement and a licence is included in annex C.)

7 Extending a licence

A licensee wishing to extend his licence to allow the application of identification of conformity to additional types or models of products, made in the same factory to the same standard as the products for which a licence is already held, shall apply to the certification body, using the usual application form (annex B). The certification body in such cases may decide not to carry out a factory inspection but to require test samples of the additional types of products to determine that they comply with the standard. If the tests are successful, additional licences will be granted.

If the licensee wishes to apply the certification to additional types of products made at the same factory, but to different standards, or if the licensee wishes to apply for certification to be used in an additional factory that is not covered by the earlier licence, those parts of the original application procedure which do not cover the new circumstances will have to be carried out.

8 Surveillance

The certification body exercises the surveillance of the products on the basis of the requirements of the relevant standard and of the quality management system on the basis of the Specific Rules of the scheme.²⁾

The certification body may appoint an agent to carry out the surveillance under its authority and responsibility, exercised under agreed conditions. Any agent appointed by the certification body shall have all the facilities and qualified staff necessary for adequate surveillance.

The licensee shall be informed about the results of the surveillance.

The licensee shall inform the certification body about any intended modification in the product, manufacturing process or quality management system which may affect the compliance of the product, and it is up to the certification body to determine whether the announced changes require another initial testing and inspection or other further investigations. In such cases the licensee will not be allowed to release certified products resulting from such changes until the certification body has notified the licensee accordingly.

The licensee should keep a record of all complaints relative to the products covered by the licence and make these available to the certification body on request.

9 Use of a mark of conformity and marking

9.1 Mark of conformity

In cases where the system utilizes a mark of conformity, the principles of ISO/IEC Guide 23 should be followed. Such a mark of conformity shall be distinctive and shall, *inter alia*.

- be proprietary in nature — with legal protection as regards composition, control of use;
- be so coded or otherwise designed as to aid in detection of counterfeiting or other forms of misuse;

1) If a certification scheme falls under a law that specifies in detail the scheme in question and if such a scheme is administered by a governmental body or body acting on its behalf, such an agreement may not be necessary.

2) In some cases it may be unnecessary to base surveillance on a repetition of all the elements of initial testing; this could be the case with custom-built products and be applied to cases where the initial testing is very complicated or where the samples are very expensive. In such cases the surveillance may be based on examination only or combined with more simple identification tests which ensure that the product is in conformity with the tested sample. Such identification tests should be described in the Specific Rules of the scheme.

- be non-transferable from one product to another;
- be directly applied to each unit of production except where the physical size of the unit or the type of product does not permit, in which case the mark may be applied to the smallest package in which the unit is marketed.

9.2 Marking

In certain circumstances it may be appropriate to use other marking in association with the mark of conformity, such as :

- name or trademark of certification body where such cannot be determined from the mark of conformity used;
- name of product classification where such is not completely obvious;
- identification of the relevant standard(s).

Such marking shall be in accordance with the Specific Rules of the scheme.

In the event of revision of a standard on which a certification scheme has been based it is important that the marking clearly indicates the appropriate edition of the standard in question or a date code marking where applicable, so that the user is informed correctly of the requirements laid down for the product.

10 Publicity by licensees

A licensee has the right to publish that he has been authorized to issue a certificate of conformity or apply a mark of conformity for products to which the license applies.

In every case the licensee shall take sufficient care of his publications and advertizing that no confusion arises between certified and non-certified products.

If the manufacturer wishes to publish parts of a test report which relates to the certification of his products he shall have a written agreement of the certification body.

The licensee shall not specify function, claim or the like in user information, that could mislead purchasers to believe that performances of the product or its use are covered by the certification when in fact they are not. Instruction books or other user information accompanying the product and related to the certification scheme shall be approved by the certification body if so required by the Specific Rules of the scheme.

11 Confidentiality

The certification body is responsible for ensuring that secrecy is maintained by its employees and those of its agent (see clause 8, second paragraph) concerning all confidential information with which they become acquainted as a result of their contacts with the licensee.

12 Misuse of a certificate or mark of conformity

The certification body shall operate a checking programme as a part of its programme of proper control on the use of its certificates or mark of conformity.

Incorrect references to the certification system or misleading use of certificates or the mark found in advertisements, catalogues, etc., should be dealt with by suitable actions which could include legal or corrective action or publication of the transgression.

In cases of misuse of certificates or the mark of conformity by licensees corrective action shall be taken.

13 Suspension of a licence for a product

The licence applicable to a specific product may be suspended for a limited period, for example in the following cases :

- if the surveillance shows non-compliance with the requirements of such a nature that immediate withdrawal is not necessary;
- if a case of improper use of the certificate or the mark, e.g. misleading prints or advertisement is not solved by suitable retractions and appropriate remedial measures by the licensee;