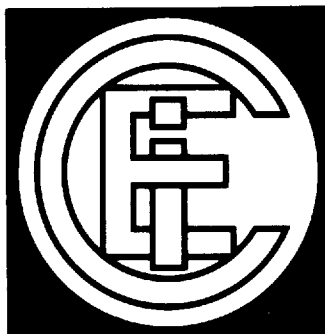




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General rules for ISO or IEC international third-party certification schemes for products

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Foreword

This Guide was drawn up by the ISO Committee on conformity assessment, ISO/CASCO. It was approved by the IEC Council in May 1985 and by the ISO Council in August 1985.

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GUIDE 44-1985 (E)

General rules for ISO or IEC international third-party certification schemes for products

0 Introduction

0.1 International certification schemes have an inherent possibility of reducing time and expense as opposed to complete retesting and reappraisal in each country.

0.2 Although this Guide addresses ISO or IEC certification schemes, it may also serve as a model for other international certification schemes.

0.3 An ISO or IEC certification scheme (hereafter called "the scheme") can take different forms depending on

- the product in question;
- the practical needs for certification;
- the existing legal, financial, trade or other conditions in the countries interested in the scheme in question.

0.4 The question of whether the establishment of a scheme or whether a solution based on bi- or multilateral arrangements is more suitable should also be considered. (See ISO/IEC Guide 42.)

0.5 It is up to those considering the establishment of a scheme to judge the merits of establishing such a scheme.

0.6 The following elements form the basis of the certification schemes for products :

- a) use of suitable standards, approved by ISO or IEC;
- b) operation of such schemes through the national member bodies of ISO or IEC, or the bodies they have designated to act on their behalf;
- c) a degree of co-ordination and monitoring of the certification activities under the authority of the ISO Council or IEC Council.

0.7 For each scheme a set of Specific Rules, which can vary from scheme to scheme, must be prepared. ISO/IEC Guide 28 gives general rules for a model system. In addition, further elements must be added to the rules of ISO/IEC Guide 28 if the scheme is to be suitable for international purposes.

0.8 There are essential principles which have to be followed if a scheme is to be established. These are outlined in clause 4.

0.9 In establishing a scheme, there are certain procedures which should be followed and these are outlined in clause 5.

1 Scope and field of application

This Guide applies to international certification schemes for determining conformity with product standards through initial testing and assessment of a manufacturer's quality system and its acceptance followed by surveillance that takes into account the manufacturer's quality system and the testing of samples from the factory and the open market¹⁾. They are operated in accordance with ISO/IEC Guide 28 and placed under the authority of ISO or IEC. This Guide outlines general rules which parties interested in establishing an ISO or IEC certification scheme should use in developing such schemes.

1) The certification system described in clause 1 is identified in ISO/IEC booklet, *Certification — Principles and practice*, as System No. 5. This type of certification system was chosen because it is the most comprehensive and includes information on elements that may be found in other systems. This Guide may thus serve as a basis for the development of other systems.

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2 References

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

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

ISO/IEC Guide 16, *Code of principles on third party certification systems and related standards.*

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

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

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

ISO/IEC Guide 38, *General requirements for the acceptance of testing laboratories.*

ISO/IEC Guide 39, *General requirements for the acceptance of inspection bodies.*

ISO/IEC Guide 40, *General requirements for the acceptance of certification bodies.*

ISO/IEC Guide 42, *Guidelines for a step-by-step approach to an international certification system.*

ISO/IEC Guide 43, *Development and operation of laboratory proficiency testing.*

3 Definitions

The relevant definitions of ISO Guide 2 are applicable. In addition, for the purpose of the present Guide, the following definition applies :

member organization : National member of ISO or IEC which has been admitted into the relevant certification scheme through having met the membership requirements.

NOTE — This term includes all categories of membership in an ISO or IEC certification scheme, with or without national certification activity, by the ISO or IEC member body or the body it has designated to act on its behalf.

4 Essential principles¹⁾ for the establishment of ISO or IEC certification schemes

4.0 A scheme may be established only after authorization by the ISO Council or IEC Council.

4.1 The rules of the scheme shall adhere to the general principles and rules for ISO or IEC certification schemes developed by ISO/CASCO and approved by the ISO Council or IEC Council.

4.2 The creation of the rules for the scheme shall be the responsibility of a Provisional Certification Committee (PCC) — see 5.4.

4.3 The administration of the scheme shall be the responsibility of a Certification Committee (see 5.5) and the certification activity including granting, revoking and withdrawal of licences in accordance with the rules of the scheme shall be the responsibility of the designated national body performing the certification function.

4.4 Only certification schemes based on approval or validation and surveillance by third parties can form the basis of the scheme.

4.5 ISO or IEC standards suitable for certification purposes complying with ISO/IEC Guide 7 shall be used, except that in the absence of such standards other standards complying with ISO/IEC Guide 7 may be considered for provisional use, in consultation with any relevant ISO or IEC technical committee, subject to prior approval by the Certification Committee (see 5.5) and by the ISO Council or IEC Council.

1) See also document ISO/CERTICO 283 (Rev.) "CERTICO statement on general approach to ISO international certification systems", available on request from the ISO Central Secretariat.

4.6 The rules of the scheme shall require provisions for addressing liability issues. This is normally accomplished through signed agreements between member organizations themselves and between member organizations and ISO or IEC as appropriate.

4.7 Each scheme shall be financially self-supporting.

4.8 The opportunity to obtain certification under the rules of the scheme shall be open to all interested parties, regardless of whether or not there is a national member of ISO or IEC in their countries.

4.9 The rules of the scheme shall require *inter alia* that evaluation be conducted to determine that all member organizations, testing laboratories, inspection bodies and certification bodies in the scheme meet the requirements in ISO/IEC Guides 25, 38, 39 and 40, as appropriate.

4.10 Membership in the scheme presupposes a degree of reciprocity¹⁾. The nature of the reciprocity shall be addressed when the detailed procedures of each scheme are developed.

4.11 The specific rules of the scheme shall not detract from the basic responsibility of the manufacturer that only products complying with the requirements of the relevant standard and applicable rules are indicated as being covered by conformity certification.

4.12 There shall not be more than one scheme for a given product standard.

4.13 The rules of the scheme shall require that each member organization shall make available to its licensees a procedure for appealing against the decisions of the organization. The appeal procedure shall include as a minimum, provisions which adequately address each of the following :

- a) Confidentiality — Matters of a proprietary nature shall be so identified and, if agreed to by the body responsible for administering the appeal procedure (see annex A), shall be so handled.
- b) Due notice — Adequate notice of any and all hearings held in connection with an appeal shall be given to all concerned parties.
- c) Right to be heard — The procedures shall not deny any of the involved parties the right to be fully heard and shall offer each side equal opportunity to make its case, such as by time allotted or by number of representatives present and participating.
- d) Published procedures — Procedures under which an appeal is heard shall be in writing and available to parties having a primary interest in the subject of the appeal.
- e) Judgement — Judgement on the appeal shall be rendered by impartial and non-involved parties.
- f) Records — A full and complete record of any appeal shall be made and shall be made available to the involved parties.
- g) Time restraints — For each step in the processing of an appeal, appropriate time limits shall be established in the rules.

4.14 The rules of the scheme shall, in addition to the elements addressed in 4.13 as appropriate, include provisions for settling disputes between member organizations. Annex A illustrates an example of an Appeal Procedure that is judged to incorporate the provisions of 4.13 except item g, which may vary from scheme to scheme. This example does not necessarily include all the required details of an Appeal Procedure.

4.15 The rules of the scheme shall specify the methods for achieving, on a continuous basis, technical coordination among all certification bodies, testing laboratories and inspection bodies in the scheme.

5 Procedures for setting up an ISO or IEC certification scheme

5.1 Initiation

Proposals to establish a scheme may emanate in the ISO or IEC Technical Committee (TC) which establishes a working group to investigate the proposal and proceed in accordance with this Guide.

¹⁾ A reference paper on this subject, document ISO/CERTICO 107 (Rev. 3), is available on request from the ISO Central Secretariat.