



## GUIDE 44

First edition **4 1985-10-01** 

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

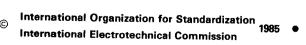
150/1EC GUIDE 44-1985 (E)

UDC 006.063

Ref. No.: ISO/IEC GUIDE 44-1985 (E)

### **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.



# 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.
- D.6 The following elements form the basis of the certification schemes for products:
  - a) use of suitable standards, approved by ISO or VEC;
  - 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 market<sup>1)</sup>. 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.

<sup>1)</sup> The certification system described in clause 1 is identified in ISO/ITC 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.

#### ISO/IEC GUIDE 44-1985 (E)

#### 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.