# GUIDE 53

# Conformity assessment — Guidance on the use of an organization's quality management system in product certification



Second edition 2005

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# 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.

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

ISO/IEC Guide 53 was prepared by the ISO *Committee on conformity assessment* (CASCO). It was circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

This second edition cancels and replaces the first edition (ISO/IEC Guide 53:1988), which has been technically revised.

# Introduction

Product certification schemes incorporating an organization's quality management system can be beneficial for both the organization and the certification body in determining the conformity of products to specified requirements and in assuring that products continue to conform to those requirements.

In these types of schemes, product certification is based on both the assessment of conformity of an organization's quality management system to specified requirements, and the assessment of conformity of the product to specified product requirements. Certification bodies can conduct both types of assessment for product certification schemes that are covered by this Guide.

Product certification schemes can take many forms, including those that do not utilize an organization's quality management system. There is no inference in this Guide that one form of product certification scheme is superior to another. Furthermore, when a certification body has several forms of product certification schemes available for a class of product, the organization has the right to choose the scheme under which it wishes to apply for certification.

NOTE In some countries, technical regulations predetermine the available type(s) of product certification scheme to be used.

This Guide is based on the understanding that interested parties using it to develop product certification schemes are familiar with

— the principles and practices covered by the ISO 9000 family of International Standards,

— the more general certification and surveillance provisions established for product certification systems in ISO/IEC Guide 67, and

— the specific product requirements.

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## 1 Scope

**1.1** This Guide outlines a general approach by which certification bodies can develop and apply product certification schemes utilizing requirements of an organization's quality management system. The provisions given in this Guide are not requirements for the accreditation of a product certification body and do not substitute the requirements of ISO/IEC Guide 65.

**1.2** The schemes contained in this Guide are for product certification only and in all cases involve the following principles:

a) assessment of an organization's quality management system and its capability to consistently supply products conforming to specified requirements;

b) testing, inspection or comparable verification of the product's conformity to scheme criteria and specified requirements;

c) application of a suitable surveillance scheme to ensure continual conformity to specified requirements of products supplied by the organization;

d) control of the mark of conformity and/or logo of the certification body.

**1.3** Within product certification schemes, it is possible for certification bodies to verify conformity with the specified requirements through a variety of ways, including the assessment of an applicant's quality management system. Whatever the form of scheme that is developed, the certification body retains the authority to certify or not. A certification body can at its discretion specify scheme criteria in addition to those described in this Guide.

## 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 9000:2000, *Quality management systems — Fundamentals and vocabulary*

ISO/IEC 17000:2004, *Conformity assessment — Vocabulary and general principles*