



GUIDE 56

**An approach to the review by a
certification body of its own
internal quality system**

First edition 1989



Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) together form a system for worldwide standardization as a whole. 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.

This Guide was drawn up by the ISO Committee on conformity assessment, ISO/CASCO. It was approved by the ISO Council in February 1989 and by the IEC Council in June 1989.

The documents produced by CASCO are issued as Guides and follow the general rules for development and promulgation of ISO and IEC standards except that they are the result of a consensus reached within a Council committee, endorsed by the ISO Council and the IEC Council.

The work of ISO/CASCO in preparing Guides relating to certification, assessment and testing, uses as a basis the principles established in ISO/IEC Guide 16, *Code of principles on third party certification systems and related standards*.

Guide 16 recognizes that third party certification systems should, to the extent possible, be based on internationally agreed standards and procedures. While recognizing the major role of manufacturers' declarations of conformity through normal manufacturer/customer relationship, Council resolutions have emphasized the preparation of guidance documents on third party certification and assessment procedures in order that national systems may be compatible with one another so as to facilitate bilateral and multilateral agreements.

Whilst these documents are intended to provide guidance, it is hoped that any changes from the documents made in introducing systems nationally would be minimal. In recognizing

that some countries may choose to adopt the Guide directly, they are written to enable this to be done by including words such as "shall" to indicate those aspects which desirably would be mandatory. The overriding basis that the document is intended to provide guidance holds good.

While this emphasis on creating the infrastructure for mutual recognition covers most of the work of ISO/CASCO, notice has to be taken that a further objective is to create the basis for an international certification system in due course, if found to be required. Some ISO/CASCO documents relate to the development of rules for such a system.

It is recognized that there are already well established certification systems, e.g. in the electrotechnical field, which have been developed with the aim of facilitating trade and which are functioning satisfactorily in the spirit of relevant ISO/IEC Guides.

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0 Introduction

0.1 One of the most essential elements for the operation of an international certification system or for mutual recognition of national certification systems is confidence in the competence of the certification bodies participating in the system or engaged in mutual recognition.

0.2 Confidence can be built through a progressively expanding set of acceptance arrangements, bilateral or multilateral, in the process of a step-by-step approach to an international certification system, as described in ISO/IEC Guide 42.

0.3 The aim of the procedure recommended in this Guide is to facilitate and accelerate the initiation of such a process, by providing certification bodies with a means of maintaining and improving their competence.¹⁾

0.4 It is recognized that confidence in the conformity certification system operated by a certification body will be based both

- on the organizational structure and documented procedures of the certification body, and
- on the manner in which the procedures are applied and how the organizational structure serves to enhance the effectiveness of the certification body's operation.

0.5 Confidence should be based on identical fundamental elements and criteria to be met by certification bodies, which necessitates the appropriate organization and administrative structure, surveillance facilities and testing facilities (if included), and legal and fees structure — the performance of all functions being specified by the certification system.

0.6 The following factors contribute to increased confidence among certification bodies participating in an international certification system, or involved in mutual certification arrangements:

- 1) use of equivalent standards;

- 2) use of procedures which provide for appropriate organizational and administrative structure, comparable testing equipment and methods, comparable surveillance procedures, comparable legal protection and other features which assure that none of the participants is at undue risk in accepting other participants' work.

0.7 Agreements between parties operating certification systems in different countries will generally include provisions covering a number of items not dealt with in this Guide, including such items as exchanges of personnel, comparison of surveillance, testing and inspection techniques, the legal system to be utilized in case of dispute, etc.

1 Scope

This Guide provides a framework for use by a certification body in assessing itself, its procedures, and its operations. The framework incorporates requirements and recommendations to be found in all relevant ISO/IEC reference documents. Using this framework, a certification body should be able to compile a documentary record of its internal quality system review procedure. It will also be possible to use this documentary record for subsequent distribution to all parties concerned.

Certification bodies may include other specific elements and criteria depending on specific needs.

2 References

ISO/ITC booklet, *Certification — Principles and practice*

ISO/IEC Guide 2, *General terms and their definitions concerning standardization and related activities*

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

¹⁾ Most of the points addressed in this Guide are covered in more detail in other ISO/IEC guides (see clause 2). The purpose of this Guide is only to facilitate the approach to the first steps recommended, for example, in ISO/IEC Guide 42. In no way is it implied, however, that a certification body that has used this Guide to review its internal quality procedures will automatically be recognized by other certification bodies. Agreements between certifying bodies (reciprocity) require some form of assessment of each other's arrangements regarding procedures, experience, organizational structure, legal framework, rules, auditing, testing, etc. A system of assessment involving examination teams may be required for a valid implementation of mutual recognition, as is the case, for example, in the IEC Quality assessment system for electronic components (IECQ).