



GUIDE 65

General requirements for bodies operating product certification systems

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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.

Draft Guides adopted by the responsible Committee or Group are circulated to national bodies for voting. Publication as a Guide requires approval by at least 75 % of the national bodies casting a vote.

ISO/IEC Guide 65 was prepared by the ISO Committee on Conformity Assessment (CASCO).

This first edition cancels and replaces ISO/IEC Guide 40:1983.

Introduction

Certification of a product (a term used to include a process or service) is a means of providing assurance that it complies with specified standards and other normative documents. Some product certification systems may include initial testing of a product and assessment of its suppliers' quality systems, followed by surveillance that takes into account the factory quality system and the testing of samples from the factory and the open market. Other systems rely on initial testing and surveillance testing, while still others comprise type testing only.

This Guide specifies requirements, the observance of which is intended to ensure that certification bodies operate third-party certification systems in a consistent and reliable manner, thereby facilitating their acceptance on a national and international basis and so furthering international trade.

The requirements contained in this Guide are written, above all, to be considered as general criteria for organizations operating product certification systems; they may have to be amplified when specific industrial or other sectors make use of them, or when particular requirements such as health and safety have to be taken into account.

Assertion of conformity to the appropriate standards or other normative documents will be in the form of certificates or marks of conformity. Systems for certifying particular products or product groups to specified standards or other normative documents will, in many cases, require their own explanatory documentation.

While this Guide is concerned with third-parties providing product certification, many of its provisions may also be useful in first- and second-party product conformity assessment procedures.

The diversity in certification systems may at first seem unnecessary and even confuse newcomers in the field, clients and operators alike. The ISO/IEC publication *Certification and related activities* is available for background reading and will help to answer questions regarding the practices of the worldwide conformity assessment community.

General requirements for bodies operating product certification systems

1 Scope

1.1 This Guide specifies general requirements that a third-party operating a product certification system shall meet if it is to be recognized as competent and reliable.

In this Guide the term "certification body" is used to cover any body operating a product certification system. The word "product" is used in its widest sense and includes processes and services; the word "standard" is used to include other normative documents such as specifications or technical regulations.

1.2 The certification system used by the certification body may include one or more of the following, which could be coupled with production surveillance or assessment and surveillance of the supplier's quality system or both, as described in ISO/IEC Guide 53:

- a) type testing or examination;
- b) testing or inspection of samples taken from the market or from supplier's stock or from a combination of both;
- c) testing or inspection of every product or of a particular product, whether new or already in use;
- d) batch testing or inspection;
- e) design appraisal.

NOTE 1 ISO/IEC Guide 28 may be consulted for a model of one form of a third-party product certification system.

2 References

ISO 8402:1994, *Quality management and quality assurance — Vocabulary*.

ISO 10011-1:1990, *Guidelines for auditing quality systems — Part 1: Auditing*.

ISO/IEC Guide 2:1996, *Standardization and related activities — General vocabulary*.

ISO/IEC Guide 7:1994, *Guidelines for drafting of standards suitable for use for conformity assessment*.

ISO/IEC Guide 23:1982, *Methods of indicating conformity with standards for third-party certification systems*.

ISO/IEC Guide 25:1990, *General requirements for the competence of calibration and testing laboratories*.

ISO/IEC Guide 27:1983, *Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity*.

ISO/IEC Guide 28:1982, *General rules for a model third-party certification system for products*.

ISO/IEC Guide 39:1988, *General requirements for the acceptance of inspection bodies*.

ISO/IEC Guide 53:1988, *An approach to the utilization of a supplier's quality system in third-party product certification*.

ISO/IEC Guide 62:1996, *General requirements for bodies operating assessment and certification/registration of quality systems*.

3 Definitions

For the purposes of this Guide, the relevant definitions given in ISO/IEC Guide 2 and ISO 8402 apply, together with the following definition.

3.1 supplier: The party that is responsible for ensuring that products meet and, if applicable, continue to meet, the requirements on which the certification is based.