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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000, ISO/IEC 17000 and the following apply.

3.1
assessor
〈certification〉 competent person assigned by a product certification body to perform, alone or as part of an assessment team, an assessment of an organization

4 Steps in the scheme

4.1 Deciding on the scheme

In order to achieve the needed assurance within the product certification scheme, the scheme criteria should incorporate quality management system requirements, as established in ISO 9001 or a similar quality management system standard.

NOTE The quality management system requirements can be based on ISO 9001, one of its sector applications (e.g. ISO/TS 16949 and ISO/TS 29001), or a similar quality management system standard.

The product certification body should give consideration to the risks and cost involved in the application of a product certification scheme when it decides the extent of the requirements of the quality management system to be incorporated into the scheme criteria.

If the level of risks is high, the certification body should consider incorporating a greater number of quality management system requirements into the scheme criteria.

4.2 Functions in the implementation of a product certification scheme

All forms of product certification schemes within the scope of this Guide include the following functions:

a) selection;

b) determination;

c) review and attestation;

d) surveillance.

NOTE These functions are consistent with the requirements established in ISO/IEC Guide 65. The product certification schemes that certification bodies develop by using this Guide are given in ISO/IEC Guide 67. A description of the functions described above appears in ISO/IEC 17000.

Clauses 5 to 8 describe activities, for each of the above functions, related to utilizing an organization's quality management system as part of the product certification scheme.

5 Selection

5.1 During this function, the certification body should gather information to determine the extent of conformity with requirements (see Clause 6).

5.2 When the organization has implemented a quality management system, the certification body should conduct a document review in order to establish the readiness and capability of the organization, and the degree to which the system has been established.

5.3 To facilitate the assessment, the applicant may need to provide pertinent information in a scheme data form. Two examples of such forms, one fairly simple and one more complex with regard to the number of quality management system requirements involved in the scheme, are shown in Annexes A and B.

5.4 Depending on the nature of the scheme and the degree to which the scheme utilizes an organization's quality management system, the certification body should ensure that the organization has a minimum level of experience in the application of its quality management system before the organization submits an application for product certification.

5.5 The certification body may take into account the organization's current quality management system certification provided that the certification covers

a) the scope of products being considered, and

b) the sites where the activities take place.

NOTE Consideration could also be given to the extent that the quality management certification is mutually recognised, through it originating from a certification body that is accredited and/or peer assessed in accordance with relevant International Standards (e.g. ISO/IEC 17021 and/or ISO/IEC 17040).

5.6 The certification body should evaluate the information provided, request additional information as needed, and determine whether the application can proceed to the determination function.

5.7 The certification body should arrange a date for a visit to the applicant's organization and should form an assessment team that includes persons competent in

a) the applicable product requirements,

b) appropriate test and/or inspection procedures and techniques,

c) conformity assessment procedures,

d) the quality management system requirements included in the scheme, and

e) audit methodologies as recommended in ISO 19011.

NOTE For additional information on audit activities and personal attributes, and knowledge and skills of auditors, reference can be made to ISO 19011.

6 Determination

6.1 The matters to be investigated by the assessment team at the organization's facilities will vary widely depending upon the specific quality management system requirements that have been included within the relevant product certification scheme. Normally, however, the assessment team should take the following actions:

a) determine that all information provided in the application is correct and complete;

b) check to ensure that the organization has the necessary equipment, staff and facilities for carrying out the tasks assigned to it for its participation in the product certification scheme;

c) ask the organization to demonstrate its capability to monitor and measure the product so as to assure conformity with the specific product requirements used in the scheme; this may involve verification of test results or inspection reports by the certification body;

d) ensure that the organization performs those quality management system processes that are to be carried out by the organization as part of the product certification scheme, and that the organization has the necessary planned arrangements to ensure that the quality management system processes will continue to be effectively implemented and maintained.

6.2 Following the assessment of the quality management system by the certification body's assessment team, a report on the team's observations should be prepared. This report should be submitted, together with

the completed application, to the responsible persons or group in the certification body who will decide whether and under what conditions the applicant may be approved. Such conditions may relate to establishing confidence that the applicant's quality management system can result in products being consistently produced or supplied to specified requirements.

6.3 An organization should only be approved for additional product categories when the certification body has confirmed that the product complies with specified requirements and when it has completed another assessment of the quality management systems directed to the new product category(s), as applicable.

6.4 If required by the relevant product certification scheme, all the organization's facilities involved in the product design process, whether part of the organization or not, should be covered in the determination function by the certification body.

6.5 The certification body should give consideration to the amount of assessment time when the organization’s quality management system is certified by an accredited or peer assessed quality management system certification body.

NOTE Consideration could also be given to the extent to which the quality management certification is mutually recognised. This can be through it originating from a certification body that is accredited and/or peer assessed in accordance with relevant International Standards (e.g. ISO/IEC 17021 and/or ISO 17040).

7 Review and attestation

7.1 The specific way in which the accepted quality management system is utilized will depend upon the specific requirements in the relevant product certification scheme.

The certification process should be completed as described in the scheme and the acceptability of the organization's quality management system at all sites covered by the product certification should be included in the certification documents.

7.2 As a first example, a simple procedure may be based only upon acceptance of test data generated by the organization’s laboratory; i.e. only those requirements related to the organization's testing facilities and practices are involved in the assessment (see Annex A). In such a case, an assessor of the certification body should visit the laboratory in order

a) to witness all types of tests or inspections, including sampling, or

b) to witness some types of tests or inspections, or

c) to review the organization's test results or inspection reports and, if found to be in order, to accept them.

NOTE For testing and calibration laboratories, ISO/IEC 17025 contains both management systems requirements and the requirements for technical competence. In operating a product certification scheme in accordance with this Guide, it is only the assessment of the quality management system requirements that are relevant. ISO/IEC 17025 is not intended to be used as the basis for certification of quality management of laboratories.

7.3 As a second example (see Annex B), following a determination function which involves assessment of a large number of processes of an organization’s quality management system and of all other requirements of the product certification scheme, the organization is permitted to apply the certification body’s mark to certain categories of products under an ongoing surveillance function.

7.4 The examples given in Annexes A and B are illustrative of schemes that utilize very few requirements (Annex A) and many requirements (Annex B) of a quality management system. In addition to these examples, there are many different combinations of possible requirements that a certification body may decide to employ in order to meet different needs.

NOTE Providing a product certification within a product certification scheme that is based on this Guide does not mean that the relevant quality management system is also certified.

8 Surveillance

This function is to provide assurance that a certified product continues to meet specified requirements for an ongoing period of time.

Details of the surveillance may vary depending on the needs of the type of scheme. However, the following general principles always apply.

a) In carrying out surveillance at the organization's facility, an assessor of the certification body should ensure that all quality management system requirements prescribed in the scheme are being fulfilled, and that the product covered by the scheme continues to comply with the specified requirements. Normally this should also include witnessing some selected tests or inspections, verification of records and examination of products to determine conformity with requirements.

b) During surveillance, consideration should be given to the scheme criteria as they relate to new or modified products within the approved product category. When it has been determined that changes have occurred that could affect the application of the mark to new or modified products, the assessor should refer to the person or group of persons who have overall responsibility for the certification decision at the certification body.

c) The minimum frequency of surveillance visits should be stated in the scheme. Surveillance should take place at all locations covered by the scheme. For example, if products are manufactured at or supplied from different locations from that at which the products are designed, tested and inspected, and all these activities are part of the scheme, surveillance should cover all relevant locations (see also 6.4).

9 Mark of conformity

Requirements for the issuing and use of third-party marks of conformity are contained in ISO/IEC 17030. Further guidance can be found in ISO/IEC Guide 23 and ISO Guide 27.