GUIDE 60

Conformity assessment — Code of good practice

Second edition 2004

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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.

ISO/IEC Guide 60 was prepared by the ISO *Committee on conformity assessment* (CASCO).

This second edition cancels and replaces the first edition (ISO/IEC Guide 60:1994), which has been technically revised.

Introduction

Conformity assessment involves activities to demonstrate the fulfilment of specified requirements by products, processes, systems, persons or bodies. Conformity assessment includes activities that provide various types of assurance that products, processes, systems, persons or bodies fulfil requirements set out in specifications such as international, regional, or national standards, guides or other normative documents.

Rapid technological development, integration of economic and production systems, and increased levels of international trade have emphasized the need for commonality among conformity assessment procedures and systems. Harmonized international standards are increasingly accepted as one effective vehicle to improve competition and eliminate technical barriers to trade. However, the use of harmonized international practices is less advanced in the area of conformity assessment, where different practices and approaches continue to persist. This environment may result in additional costs for manufacturers, exporters and consumers, and poses challenges for regulatory authorities and industry in all countries including developing countries.

The evolution of international, regional and private-sector conformity assessment systems and schemes is also noteworthy. These systems continue to expand, building confidence for the users of conformity assessment services (including industry, regulators and consumers) and promoting global acceptance through a variety of methods. In addition, the use of declarations of conformity (DoCs) has continued to increase in many product areas.

Different conformity assessment procedures and requirements, and the lack of recognition of conformity assessment results, can constrain the exchange of goods and services. Efforts are required to ensure that all conformity assessment systems and procedures attempt to involve all interested parties, are non-discriminatory, transparent and avoid unnecessary obstacles to trade. Members of the conformity assessment community are encouraged to participate in the development of international standards and guides, to utilize them as the basis for their respective conformity assessment activities and systems, and to engage in information exchange and confidence building to increase knowledge and acceptance of other systems and approaches.

This Guide is presented in a form suitable for use by conformity assessment bodies, accreditation bodies and other interested parties, whether governmental or non-governmental, at international, regional, national or sub-national levels. This Guide is intended to be used in conjunction with, or when preparing, ISO/IEC International Standards or Guides relating to conformity assessment, and may also be used in conjunction with the World Trade Organization’s (WTO's) Technical Barriers to Trade (TBT) Agreement.

Adoption of this Guide is voluntary and is intended to promote conformity assessment practices that are characterized by openness, transparency, impartiality, confidentiality, coherence and effectiveness.

Conformity assessment — Code of good practice

1 Scope

This Guide recommends good practices for all elements of conformity assessment, including normative documents, bodies, systems, schemes and results.

It is intended for use by individuals and bodies who wish to provide, promote or use ethical and reliable conformity assessment services. These include, as appropriate, regulators, trade officials, calibration laboratories, testing laboratories, inspection bodies, product certification bodies, management system certification/registration bodies, personnel certification bodies, accreditation bodies, organizations providing declarations of conformity, and designers and administrators of conformity assessment systems and schemes, and users of conformity assessment.

This Guide is designed to facilitate trade at the international, regional, national and sub-national level.

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

NOTE Additional ISO/IEC International Standards, Guides and other reference documents are listed in the Bibliography.

3 Terms and definitions

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

4 Principles related to good practices in conformity assessment

4.1 General

This clause contains general principles related to good practices in conformity assessment under four main headings: 1) conformity assessment normative documents, 2) conformity assessment activities, 3) conformity assessment systems and schemes, and 4) conformity assessment results.

4.2 Conformity assessment normative documents

Conformity assessment normative documents (e.g. standards, guides and procedures) used by conformity assessment bodies and accreditation bodies to carry out their work and activities should

a) be prepared in a transparent, open, impartial and coherent manner,

b) respond appropriately to regulatory and market needs,

c) be technically relevant,

d) address, where appropriate, the technical competence of relevant bodies,

e) avoid unnecessary obstacles to trade and reflect the principles of non-discrimination and national treatment,

f) where appropriate, be written to be used directly in first-party, second-party and third-party conformity assessment, and

g) take into account issues related to the participation of, and use by, developing countries.

4.3 Conformity assessment activities

All organizations involved in conformity assessment activities, including conformity assessment bodies and accreditation bodies, should

a) base their activities as far as possible on international standards and guides developed by consensus, such as ISO/IEC International Standards and Guides,

b) be managed and operated to give the sufficient level of assurance of the conformity of products, processes, systems, persons or bodies with specified requirements,

c) protect all confidential information,

d) conduct their activities with professional integrity, in an ethical and non-discriminatory manner and avoid conflicts of interests,

e) process applications and assessments in a prompt, impartial and efficient manner and ensure that anticipated timeframes are communicated to the client,

f) process complaints or appeals (where applicable) in a prompt, impartial and efficient manner, and take corrective action when justified,

g) prepare proper records of conformity assessment activities and maintain these records for a period consistent with the body's contractual and legal obligations; these records should include adequate documentation for any determination of denial, withdrawal, suspension or termination of the authorization to use evidence of conformity,

h) maintain and make readily available information on all services offered and related fees, as well as information on certificates held or granted, scopes of accreditation, etc.,

i) be subject to monitoring procedures (as appropriate),

j) demonstrate their competence by a suitable mechanism (e.g. accreditation, peer assessment),

k) provide an adequate written report of a conformity assessment procedure which highlights, where applicable, any nonconformities or necessary corrective actions,

l) ensure, where a mark is utilized, that the rules or conditions related to the use of the mark are applied to guard against any misuse, and

m) take into account issues related to the participation of, and use by, developing countries.

NOTE Item b) implies the maintenance of adequate technical competence in order to facilitate acceptance of conformity assessment results.

4.4 Conformity assessment systems and schemes

Conformity assessment systems and schemes should

a) be operated by a body or bodies adhering to the principles outlined in 4.3,

b) be designed and administered in a transparent, open, non-discriminatory and reliable manner,

c) be designed and administered in such a way as to not create unnecessary obstacles to trade,

d) be appropriate to the particular situation or industry sector in order to facilitate acceptance of the conformity assessment results,

e) be governed by rules and procedures that are documented and available to interested parties in a reasonable and timely manner upon request, and that specify elements including

- criteria and processes for access to the system or scheme,
- how documentation is to be controlled,
- specifications and/or standards upon which the system or scheme is based,
- how demonstration of conformity is to be achieved and maintained,
- how evidence of conformity is to be documented,
- how integrity, impartiality and competence is to be maintained,
- identifiable, realistic and readily available mechanisms for the impartial handling of any substantive and procedural appeal or complaint, and

f) take into account issues related to the participation of, and use by, developing countries.

4.5 Conformity assessment results

Conformity assessment results (assessment reports, test reports, declarations, certificates, marks, etc.) should

a) be clear, unambiguous, easily understood and not designed to mislead in any way,

b) identify the specified requirements (e.g. standards, guides, regulations or technical specifications) against which the conformity assessment activity has been made, the applicable scope of the assessment and how the results are assured (e.g. through accreditation, formal recognition and peer assessment),

c) be accurately maintained by the conformity assessment body, system or scheme and, while maintaining the confidentiality of the information, be made available upon request, and

d) be comparable to facilitate recognition or acceptance.

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[12] ISO/IEC 17021:— [1)], *Conformity assessment — Requirements for bodies providing audit and certification of management systems*

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[14] ISO/IEC 17025:— [2)], *General requirements for the competence of testing and calibration laboratories*

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[16] ISO/IEC 17050-1:2004, *Conformity assessment — Supplier's declaration of conformity — Part 1: General requirements*

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2) To be published. (Revision of ISO/IEC 17025:1999)

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[20] World Trade Organization (WTO): Second Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade, 2000 (G/TBT/9)

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