

GUIDE 60

ISO/IEC Code of good practice for conformity assessment

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for world-wide 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.

ISO/IEC Guide 60 was prepared by ISO/CASCO/AHG, ISO/IEC Code of good practice for conformity assessment. A draft was circulated to CASCO members and IEC National Committees for comments. A final draft has subsequently been approved by ISO/CASCO and by IEC Council for publication as an ISO/IEC Guide.

This Guide cancels and replaces ISO/IEC Guide 16:1978. DARD PREVIEW (standards.iteh.ai)

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Printed in Switzerland



Introduction

Conformity assessment involves evaluating products, processes, or services to determine the extent to which assurance may be given that they fulfil specified requirements. Conformity assessment includes activities which may result in first-party, second-party or third-party assurance that products, processes or services conform to requirements set out in specifications such as international, regional, or national standards. Conformity assessment also includes the recognition of the competence of conformity assessment bodies.

Adoption of this Code is voluntary and intended to ensure openness and transparency, together with an optimum degree of order, coherence and effectiveness in worldwide conformity assessment processes. Provisions which are intended to be of a binding nature are in this Code preceded by "shall" and the particular requirements are given in other guides or standards.

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ISO/IEC Code of good practice for conformity assessment

1 General provisions

- 1.1 For the purposes of this Code, the definitions given in annex A shall apply.
- 1.2 This Code, which is intended to promote equal rights of access to conformity assessment services worldwide, is presented in a form suitable for use by conformity assessment bodies, whether governmental or non-governmental, at international, regional, national or sub-national level.
- 1.3 This Code is intended to be used in conjunction with, or when preparing, ISO/IEC standards or guides relating to conformity assessment activities.
- 1.4 Although this Code has been prepared primarily with third-party conformity assessment in mind, its provisions may be used as appropriate for first-party or second-party activities.

- 3.2 Conformity assessment activities shall be conducted confidentially and in an ethical and non-discriminatory manner.
- 3.3 All applications for conformity assessment and any subsequent validations or appeals (where applicable) shall be handled in a prompt manner without undue delay.
- 3.4 Proper records of conformity assessment activities shall be prepared and maintained for a period consistent with the conformity assessment body's contractual and legal obligations. These records shall include adequate documentation for any determination of denial, suspension or termination of the authorization to use evidence of conformity.
- 3.5 Information on all conformity assessment services offered and related fees shall be maintained and made readily available.

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2 Promotion of trade

2.1 Conformity assessment activities should meet the needs of the market-place and should contribute to promoting free trade in the broadest possible geographic and economic context. Conformity assessment activities shall be so conducted as not to impede or inhibit trade.

- 2.2 Conformity assessment activities should, as far as possible, be based on ISO and IEC standards and guides. The specifications and/or standards used for the conformity assessment of products, processes and services should be developed in accordance with ISO/IEC Guide 7:1994, Guidelines for drafting of standards suitable for use for conformity assessment and ISO/IEC Guide 59:1994, Code of Good Practice for Standardization.
- 2.3 Accreditation systems for conformity assessment bodies shall not be used to impede or inhibit trade.

3 Responsibilities of a conformity assessment body

3.1 Conformity assessment activities shall be so designed, administered and operated as to give assurance in a cost-effective way of conformity of products, processes and services with the designated standards.

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4.1 Written rules of procedure shall govern the oper-

ation for conformity assessment systems.

- **4.2** Such rules of procedure shall specify, or explain the absence of, among others:
- the criteria and process for access to any scheme which forms part of the system;
- the specifications and/or standards upon which the scheme is based;
- how verification of conformity is to be achieved;
- how evidence of conformity is to be documented;
- how documentation is to be authorized including its extension, suspension or termination;
- how integrity, impartiality and competence is to be maintained.
- **4.3** Such rules of procedure shall contain an identifiable, realistic and readily available appeals mechanism for the impartial handling of any substantive and procedural complaints that arise at any time under a scheme.
- **4.4** Such rules of procedure shall be available to interested parties in a reasonable and timely manner upon request.

Annex A

Terms and definitions

For the purposes of this Code, the definitions given in ISO/IEC Guide 2:1991, General terms and their definitions concerning standardization and related activities, shall apply.

The expression "product, process or service" has been adopted throughout this Code to encompass the subjects of conformity assessment in a broad sense and shall be understood to cover, for example, any material, component, equipment, system (including quality system), interface, protocol, procedure, function, method, activity of bodies or persons.

In addition, for the purposes of this Code, the definitions given below shall apply. With regard to definition A.2, it is recognized that a conformity assessment body may operate at first-party, second-party or third-party level (see ISO/IEC Guide 2:1991, subclause 13.2).

A.1 conformity assessment [GATT, adapted]: Any activity concerned with determining directly or indirectly that relevant requirements are fulfilled.

NOTE 1 Typical examples of conformity assessment activities are sampling, testing and inspection; evaluation, verification and assurance of conformity (supplier's declaration, certification); registration, accreditation and approval as well as their combinations.

- **A.2** conformity assessment body [14.3 extended]: Body that performs conformity assessment.
- A.3 conformity assessment system [14.1 extended]: System that has its own rules of procedure and management for carrying out conformity assessment.

NOTES

- 2 Conformity assessment systems may be administered, for example, at the national, regional or international level.
- 3 Typical examples of conformity assessment systems are test systems, inspection systems and certification systems.

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International Organization for Standardization Case postale 56 • CH-1211 GENEVA 20 • Switzerland

International Electrotechnical Commission Case postale 131 • CH-1211 GENEVA 20 • Switzerland

Ref. No. ISO/IEC GUIDE 60:1994 (E)

ICS 03.120.20

Descriptors: certification, conformity, quality control, general conditions.

Price based on 2 pages