

**GENERAL AGREEMENT
ON TARIFFS AND TRADE**

RESTRICTED

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Committee on Technical Barriers to Trade

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COMMUNICATION FROM THE ISO/IEC

A draft version of ISO/IEC Code of Good Practice for Conformity Assessment and, attached to it, a letter dated 28 January 1994 have been received from the ISO, indicating that the draft code has recently been circulated to ISO and IEC member bodies for approval. It was suggested that the draft ISO/IEC Code of Good Practice for Conformity Assessment could be circulated to members of the Committee so that they may be informed and allowed to comment on the document as they see fit.

DRAFT - ISO/IEC CODE OF GOOD PRACTICE FOR CONFORMITY ASSESSMENT

[Secretariat notes (not part of the draft)]

1. *An initial draft of this document was prepared in January 1992 in accordance with the decision taken by IEC Council 1991-10-11 that a Code similar to the one already being prepared for standardization should be prepared by IEC and ISO for the field of conformity assessment. At its meeting 1992-05-26 the IEC PCA edited the initial draft and agreed that, after having been shown to the IEC GPC at its meeting 1992-05-02/03, the edited draft should be further processed by ISO/CASCO. Thereafter the resulting document should be circulated to IEC National Committees and as appropriate in ISO for national comments. This was agreed by ISO Council in its resolution 18/1992, asking CASCO "to prepare, with the usual participation of IEC, a draft ISO/IEC Code of Good practice for Conformity Assessment in connection with the revision of ISO/IEC Guide 16, with the view to its submission to the ISO and IEC Councils as soon as possible for approval, taking account of existing relevant provisions within GATT in order to avoid any contradiction or overlapping". In response to that resolution, CASCO set up an ad hoc group, with the usual participation of IEC. The ad hoc group met in Geneva on 27 April 1993 and again on 29-30 June 1993. The first draft was submitted to ISO and IEC national member bodies for their comments. The working group has reviewed these comments and prepared a revised draft for approval by CASCO members.*

2. *In the final document, the clauses will be numbered in the same manner as other ISO/IEC Guides.]*

INTRODUCTORY COMMENTARY

Conformity assessment is an activity involving the evaluation of 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 document preceded by "shall" and the particular requirements are given in other guides or standards.

**ARTICLE ONE
GENERAL PROVISIONS**

- A. For the purpose of this code, the definitions included in the annex shall apply.
- B. 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.
- C. This Code is intended to be used in conjunction with relevant ISO/IEC standards or guides containing requirements to be met by conformity assessment bodies.
- D. Although this Code has been prepared, having primarily third-party conformity assessment in mind, its provisions may be used as appropriate for first-party or second-party activities.

ARTICLE TWO ADVANCEMENT OF TRADE

- A.** Conformity assessment activities should meet the needs of the market place and should contribute to advancing free trade in the broadest possible geographic and economic context. Conformity assessment activities shall be so conducted as not to impede or inhibit trade.
- B.** 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 the ISO/IEC Guide 59: Code of Good Practice for Standardization.
- C.** Accreditation systems for conformity assessment bodies shall not be used to impede or inhibit trade.

ARTICLE THREE RESPONSIBILITIES OF A CONFORMITY ASSESSMENT BODY

- A.** 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.
- B.** Conformity assessment activities shall be conducted with confidentiality and in an ethical and non-discriminatory manner.
- C.** All applications for conformity assessment and any subsequent validations or appeals (where applicable) shall be handled in a prompt manner without undue delay.
- D.** 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.
- E.** Information on all conformity assessment services offered and related fees shall be maintained and made readily available.

ARTICLE FOUR PROCEDURES FOR CONFORMITY ASSESSMENT

- A.** Written procedures shall govern the operation for conformity assessment systems and shall be available to interested parties in a reasonable and timely manner upon request.
- B.** Such written procedures shall prescribe, or explain the absence of, among others:
- the criteria and process for the 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.

C. Such written procedures 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.

ANNEX A

TERMS AND DEFINITIONS

When used in this code, the terms presented in ISO/IEC Guide 2:1991, *General terms and their definitions concerning standardization and related activities*, shall have the same meaning as given in the definitions in Guide 2.

The expression "product, process or service" has been adopted through out this document 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 purpose of this Code, the definitions below shall apply. With regard to definition 1.2, it is recognized that a conformity assessment body may operate at first-party, second-party or third-party level (see ISO/IEC Guide 2, sub-clause 13.2).

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

NOTE - 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.

1.2 conformity assessment body [14.3 ext]: Body that performs conformity assessment.

1.3 conformity assessment system [14.1 ext]: System that has its own rules of procedure and management for carrying out conformity assessment.