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CABPUB/187A/CD

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

DRAFT ISO/IEC CONFORMITY ASSESSMENT PUBLICATIONS THROUGH THE IEC CONFORMITY ASSESSMENT BOARD (CAB)

SUBJECT

ISO/IEC CD 17060 Conformity assessment – Code of good practice

BACKGROUND

This document replaces the document CABPUB/187A/CD that was circulated on the 2nd of October 2020. The closing date has been corrected.

ISO/CASCO WG 56, *Conformity Assessment - Code of good practice*, has opened the ballot for the DTR (IEC CD stage ballot). The document is attached.

This document 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

The ballot period set by ISO started on 2020-09-30 with a closing date on 2020-11-27.

ACTION

National Committees are invited to comment on CABPUB/187/CD no later than 2020-11-27, using the IEC form and stating whether their comments are identical to the ones made sent to ISO/CASCO.

National Committees are strongly encouraged to consult the IECEE, IECQ, IECEx and IECRE communities in their country when developing their national position on this draft.

ISO/IEC CD1 17060-:20XX(E)

ISO CASCO/WG56

Secretariat: ISO CS

Conformity assessment — Code of good practice

CD1

Warning for WDs and CDs

This document is not an ISO International Standard. It is distributed for review and comment. It is subject to change without notice and may not be referred to as an International Standard.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO and IEC shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents) or the IEC list of patent declarations received (see <http://patents.iec.ch>).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by the ISO Committee on Conformity Assessment (CASCO). This second edition cancels and replaces the first edition (ISO/IEC Guide 60: 2004, Conformity assessment, Code of good practice) which has been technically revised.

The main changes compared to the previous edition are as follows:

- replacement in the title of ISO/IEC Guide 60 with ISO/IEC 17060,
- new clause on good practice related to 'object of conformity',
- inclusion of language on risk-based thinking,
- clause 4 renumbered in separate clauses;
- terminology and text updated to be consistent with other ISO/CASCO standards.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Conformity assessment involves activities to demonstrate the fulfilment of specified requirements by products, processes, services, systems, installations, projects, data, designs, materials, claims, persons, bodies or organizations, or any combination thereof. Conformity assessment includes activities that provide various types of assurance that requirements set out in specifications such as international, regional, or national standards, guides or other normative documents are fulfilled.

Rapid technological development, integration of economic and production systems, and increased levels of international trade have emphasized the need for convergence among conformity assessment practices 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 in the area of conformity assessment needs continuous attention, where different practices and approaches continue to persist. This environment may result in additional costs for manufacturers, service providers, exporters and consumers, and poses challenges for regulatory authorities and industry.

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.

Different conformity assessment practices 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 practices attempt to involve all interested parties, are non-discriminatory, transparent, impartial 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 document is designed to facilitate trade and support the development of societal benefits and/or needs at the international, regional, national and sub-national level.

Adoption of this document is voluntary and is intended to establish and promote conformity assessment policies and practices that are characterized by openness, transparency, impartiality, confidentiality, coherence and effectiveness, thereby supporting credibility of conformity assessment.

This document 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 document is intended to be used in conjunction with, or when preparing, ISO/IEC International Standards 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.

1 Scope

This document 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, proficiency testing providers, reference material providers, inspection bodies, validation and/or verification bodies, product certification bodies, management system certification 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.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 17000:2020, *Conformity assessment — Vocabulary and general principles*

3 Terms and definitions

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at <https://www.iso.org/obp>

— IEC Electropedia: available at <http://www.electropedia.org/>

3.1

conformity assessment system

set of rules and *procedures* (5.2) for the management of similar or related *conformity assessment schemes* (4.9)

Note 1 to entry: A conformity assessment system can be operated at an international, regional, national, sub-national, or industry sector level.

3.2

conformity assessment scheme

conformity assessment programme

set of rules and *procedures* (5.2) that describes the *objects of conformity assessment* (4.2), identifies the *specified requirements* (5.1) and provides the methodology for performing *conformity assessment* (4.1)

Note 1 to entry: A conformity assessment scheme can be managed within a *conformity assessment system* (4.8).

Note 2 to entry: A conformity assessment scheme can be operated at an international, regional, national sub-national, or industry sector level.

Note 3 to entry: A scheme can cover all or part of the conformity assessment functions explained in [Annex A of ISO/IEC 17000](#).

4 Principles related to good practices in conformity assessment

This document contains general principles related to good practices in conformity assessment under five main headings:

- object of conformity (5),
- conformity assessment normative documents (6),
- conformity assessment activities (7),
- conformity assessment systems and schemes (8), and
- conformity assessment results (9).

5 Object of conformity assessment

Objects of conformity assessment such as for products, processes, services, systems, installations, projects, data, design, material, claims, persons, bodies or organizations should:

- a) have its characteristics clearly defined,
- b) be capable of having their conformity assessed,
- c) have defined boundaries of the object of conformity,
- d) have its requirements separate from requirements for conformity assessment activities.

6 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, market or societal needs,
- c) define the relevant product, process, service, system, installation, project, data, design, material, claim, person, body or organization, or any combination thereof,
- d) be technically relevant,
- e) address, where appropriate, the competence of relevant bodies,
- f) avoid unnecessary obstacles to trade and reflect the principles of non-discrimination and national treatment,
- g) where appropriate, be written to be used directly in first-party, second-party and third-party conformity assessment activities, and
- h) apply risk-based thinking.

NOTE Further details related to all conformity assessment normative documents can be found in ISO/IEC 17007.

7 Conformity assessment activities

Conformity assessment activities include, but are not limited to testing, inspection, validation, verification, certification and accreditation. 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
- b) be managed and operated to give the sufficient level of assurance of the conformity of products, processes, services, systems, installations, projects, data, designs, materials, claims, persons, bodies or organizations, or any combination thereof, with specified requirements,
- c) provide conformity assessment activities in a risk-based manner,
- d) protect all confidential information,
- e) conduct their activities with impartiality, professional integrity, in an ethical and non-discriminatory manner and avoid conflicts of interests,
- f) have a process (s) to manage the risks to impartiality arising from their activities,
- g) process applications and assessments in a prompt, impartial and efficient manner and ensure that anticipated timeframes are communicated to the client,
- h) process complaints or appeals (where applicable) in a prompt, impartial and efficient manner, and take corrective action when justified,
- i) 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,
- j) 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.,
- k) be subject to monitoring (as appropriate),
- l) demonstrate their competence by a suitable mechanism (e.g. accreditation, peer assessment),
- m) provide an adequate report of a conformity assessment procedure which highlights, where applicable, any nonconformities or necessary corrective actions,
- n) 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
- o) take into account issues related to the participation of, and use by, developing countries.

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

8 Conformity assessment systems, schemes (programmes)

Conformity assessment systems, schemes (programmes) should:

- a) be designed and administered in a transparent, open, non-discriminatory and reliable manner,
- b) be designed and administered in such a way as to not create unnecessary obstacles to trade,

- c) be appropriate to the needs of interested parties (e.g. consumer groups, NGOs, regulators, industry groups, voluntary organizations, developing countries) in order to facilitate acceptance of the conformity assessment results,
- d) 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
- e) take into account issues related to the participation of, and use by, developing countries.

9 Conformity assessment results

Conformity assessment results (reports, declarations, certificates, attestations, statements, 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 conformity assessment and how the results are assured (e.g. through accreditation, formal recognition and peer assessment),
- c) be accurately maintained and, while safeguarding the confidentiality of the information, be made available upon request, and
- d) be comparable to facilitate recognition or acceptance.

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