INTERNATIONAL STANDARD

ISO/IEC 17050-2

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Conformity assessment — Supplier's declaration of conformity —

Part 2: Supporting documentation

Évaluation de la conformité — Déclaration de conformité du fournisseur —

Partie 2: Documentation d'appui

Reference number
ISO/IEC 17050-2:2004(E)

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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 International Standards are circulated to the national bodies for voting. Publication as an International Standard requires approval by at least 75 % of the national 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 17050-2 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 first edition of ISO/IEC 17050-2, together with ISO/IEC 17050-1, cancels and replaces the second edition of ISO/IEC Guide 22:1996, *General criteria for supplier's declaration of conformity.*

ISO/IEC 17050 consists of the following parts, under the general title *Conformity assessment — Supplier's declaration of conformity*:

— *Part 1: General requirements*

— *Part 2: Supporting documentation*

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Introduction

A supplier’s declaration of conformity is a form of attestation of conformity to meet demands from the market and regulators for confidence. The acceptance of a supplier’s declaration of conformity could be enhanced by retaining documented information on which the supplier bases the declaration and making this documentation available upon request.

This part of ISO/IEC 17050 specifies requirements for the documentation to support a supplier’s declaration of conformity. Besides enhancing confidence in the supplier's declaration of conformity, such documentation may assist relevant authorities in their surveillance activities.

Conformity of a product (including service), process, management system, person or body to specified requirements, which can include normative documents such as standards, guides, technical specifications, laws and regulations, may need to be rigorously substantiated under the responsibility of the supplier, irrespective of the industry sector involved.

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Conformity assessment — Supplier's declaration of conformity —

Part 2: Supporting documentation

1 Scope

This part of ISO/IEC 17050 specifies general requirements for supporting documentation to substantiate a supplier's declaration of conformity, as described in ISO/IEC 17050-1.

For the purposes of this part of ISO/IEC 17050, the object of a declaration of conformity can be a product, process, management system, person or body.

Instead of "supplier's declaration of conformity", the term "declaration of conformity" can be used when appropriate.

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*

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

3 Terms and definitions

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

NOTE 1 "Supplier's declaration of conformity" is a "declaration" as defined in ISO/IEC 17000, i.e. first-party attestation.

NOTE 2 To avoid any confusion with attestation by certification bodies, the term "self-certification" is deprecated and should not be used.

4 General requirements

4.1 Traceability

Supporting documentation shall be developed, kept, controlled and maintained in a way that allows traceability from a supplier's declaration of conformity.

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4.2 Availability

The issuer (issuing organization or person) of the declaration of conformity shall make supporting documentation available, as requested, to the relevant regulatory authority to the extent necessary to satisfy regulatory requirements. The issuer may make supporting documentation available to any other requesting person or body.

4.3 Retention period

The retention of supporting documentation shall be for a period in accordance with applicable laws and regulations, but may be longer at the discretion of the issuer. Specific needs of customers and other interested parties shall be considered.

5 Contents of the supporting documentation

5.1 The supporting documentation shall include, as applicable, the following information to demonstrate conformity with the declared requirements (see ISO/IEC 17050-1:2004, Clause 6 and Annex A):

a) description of the object of the declaration (product, process, management system, person or body);

b) design documentation (e.g. descriptions, diagrams, drawings, identification of the area of expertise and competence, specifications);

c) conformity assessment results, such as

   — description of methods used (e.g. auditing; audit procedures; batch testing; design review, verification and validation; inspection; sampling plan; serial testing; test methods; type testing) and reasons for their selection,

   — results (e.g. audit report, test report), and

   — evaluation of results, including deviations and concessions;

d) identification and relevant qualifications and technical competence of the first-, second- or third-party conformity assessment bodies involved, and details of their accreditation status (e.g. scope, name of the accreditation body).

5.2 Where necessary to demonstrate conformity to declared requirements, the following should also be included:

a) description of the management system relevant to the object of the declaration;

b) other relevant information (e.g. risk analysis, re-assessment procedures and schedules).

5.3 Any change in the supporting documentation described in 5.1 and 5.2 which affects the validity of the declaration of conformity shall be documented.

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